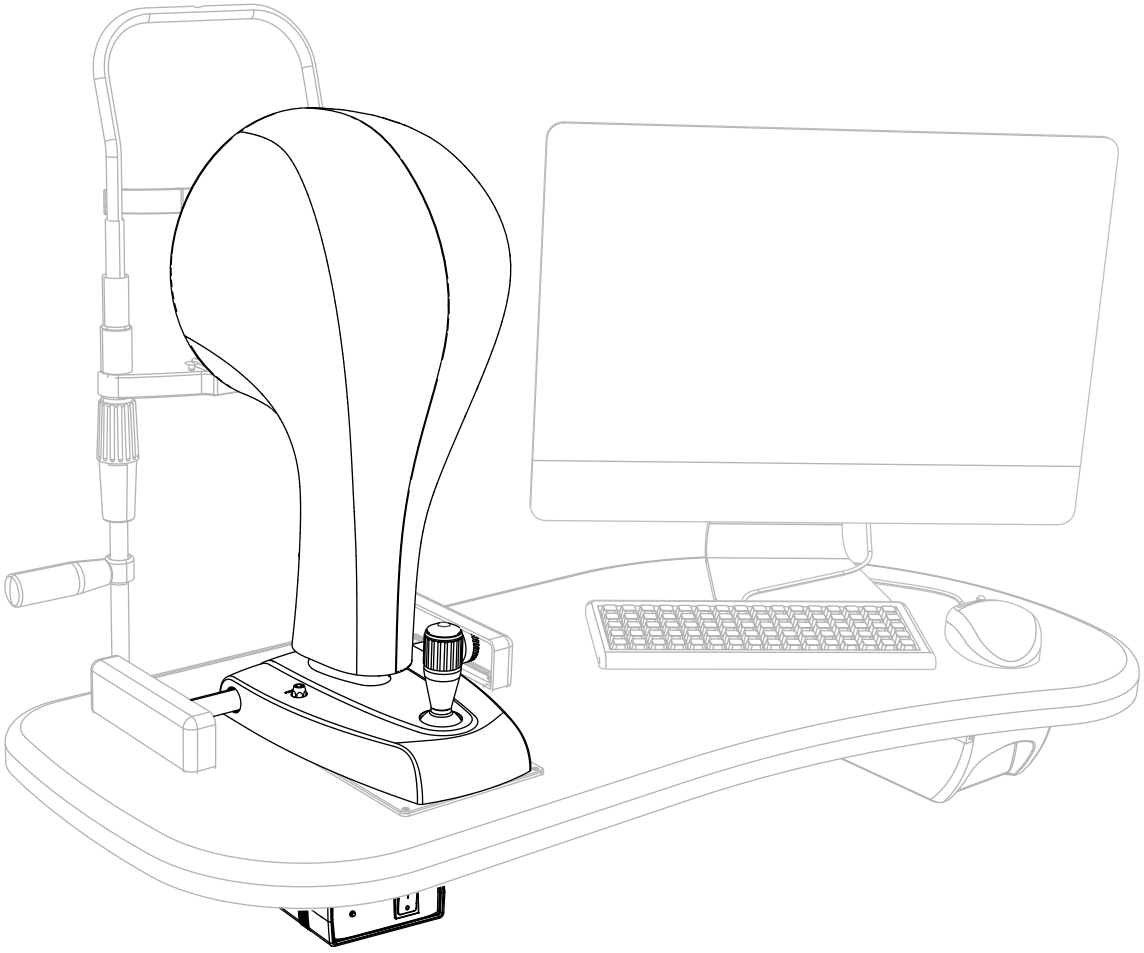
COSTRUZIONE STRUMENTI OFTALMICI



Corneal topographer

SERVICE MANUAL

Antares+

COSTRUZIONE STRUMENTI OFTALMICI

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ANTARES+MTENGCSO0003022025

CE 0051

ENG

TABLE OF CONTENTS

1 INTRODUCTION

The device Antares+ is the result of extensive research, conducted with experts to ensure the product's technical innovation, quality and design.
This manual is intended for technical personnel only, previously trained and authorized by the Manufacturer to carry out ordinary and corrective maintenance technical interventions.
Do not carry out operations not described in this manual.

1.1 SYMBOLS

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

Symbol	Meaning
	Caution
	Danger of electric shock
	Components sensitive to electrostatic discharges (ESD)
	Read the instructions for use
	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)
	Medical device
	Waste disposal in compliance with Directives 2012/19/EU (WEEE) and 2011/65/EU (RoHS II)

1.1.1 DEVICE SYMBOLS

Symbol	Meaning
	Type B applied part

1.2 GENERAL WARNINGS

THE INFORMATION GIVEN IN THESE INSTRUCTIONS FOR THE TECHNICAL ASSISTANCE REFER TO THE ANTARES+ DEVICE ("DEVICE" FROM NOW ON).

THE ORIGINAL TEXT IS IN ENGLISH.

Before carrying out any maintenance on the device, check the concerned model and configuration.

Before carrying out any maintenance on the device, carefully read the instructions for the Technical Assistance. Follow the directions given in the instructions for the Technical Assistance.

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

Keep this manual close by for future consultation.

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

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

1.3 REFERENCE REGULATIONS

1.3.1 EU DIRECTIVES

- Directive 93/42/EEC and subsequent modifications and additions concerning medical devices
- Regulation (EU) 2017/745 of the European Parliament and Council of 5 April 2017 on medical devices (to the extent applicable)
- Directive 2012/19/EU on waste of electric and electronic equipment (WEEE)

1.3.2 TECHNICAL STANDARDS

- IEC 60601-1 - "Medical electrical equipment - Part 1: General requirements for basic safety and essential performance"
- CEI IEC 60601-1-2 - "Medical Electrical Equipment – Collateral Standard: Electromagnetic Compatibility”
- UNI EN ISO 15004-1 - Ophthalmic Instruments. Fundamental requirements and test methods - Part 1: General requirements applicable to all ophthalmic devices
- UNI EN ISO 15004-2 - Ophthalmic Instruments. Fundamental requirements and test methods - Part 2: Light hazard protection.
- UNI CEI EN ISO 14971 - Medical devices. Application of risk management to medical devices
- UNI EN ISO 19980 - Ophthalmic instruments - Corneal topographers

1.3.3 QUALITY MANAGEMENT SYSTEM STANDARDS

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

1.4 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

1.5 MANUFACTURER IDENTIFICATION

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

2 SAFETY

2.1 SAFETY WARNINGS

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

DANGER
Danger of electric shock. Before any maintenance operation, check that the power cables are not damaged. If the cables are damaged, they must be replaced.

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

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

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

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

CAUTION
Danger of tripping and falling. Do not leave loose cables in places where people may walk.

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

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

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

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 cables not authorised by the device Manufacturer.

The device is classified in accordance with technical standard IEC 60601-1 as an electro-medical device, and is therefore suitable for installation in 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.

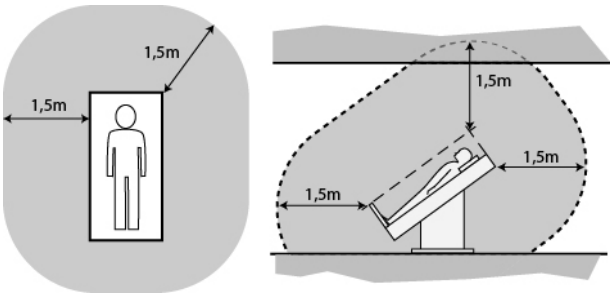


Fig. 1 - Patient area

2.2 DEVICE IDENTIFICATION

2.2.1 REGISTRATION DATA IN THE LIST OF MEDICAL DEVICES

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

2.2.2 DEVICE DATA PLATE

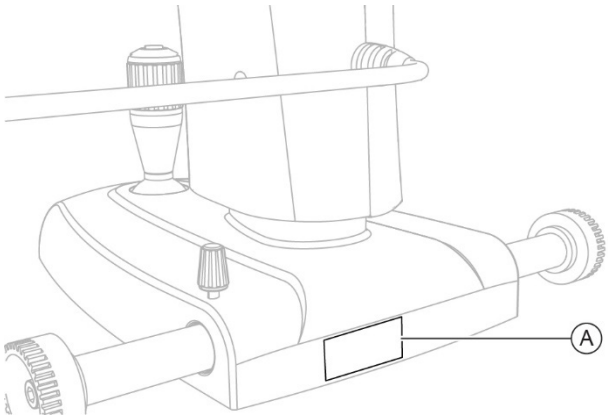


Fig. 2 - Data plate position

Pos	Description
A	Device data plate

Fig. 3 - Device data plate

2.2.3 POWER SUPPLY UNIT DATA PLATE

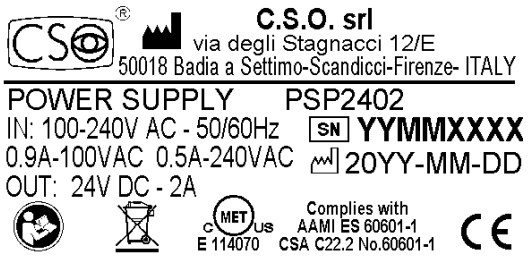


Fig. 4 - Power supply unit data plate

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 in compliance with technical specification IEC 60601-1

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

2.5 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%

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

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

2.6 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 must not be disposed of with urban waste. The device may be delivered to designated separate collection centres set up by the municipal administration or to dealers that offer this service. Separately disposing of an electrical device prevents potential negative consequences for the environment and health caused by improper disposal and allows the materials it is made of to be recycled so as to attain significant savings in energy and resources. The data plate of the device displays the symbol of the crossed-out wheeled bin. The crossed-out wheeled bin symbol indicates the obligation to collect and dispose of electrical and electronic equipment separately at the end of their useful life.

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

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

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

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

3 DEVICE DESCRIPTION

3.1 SUPPLY DESCRIPTION

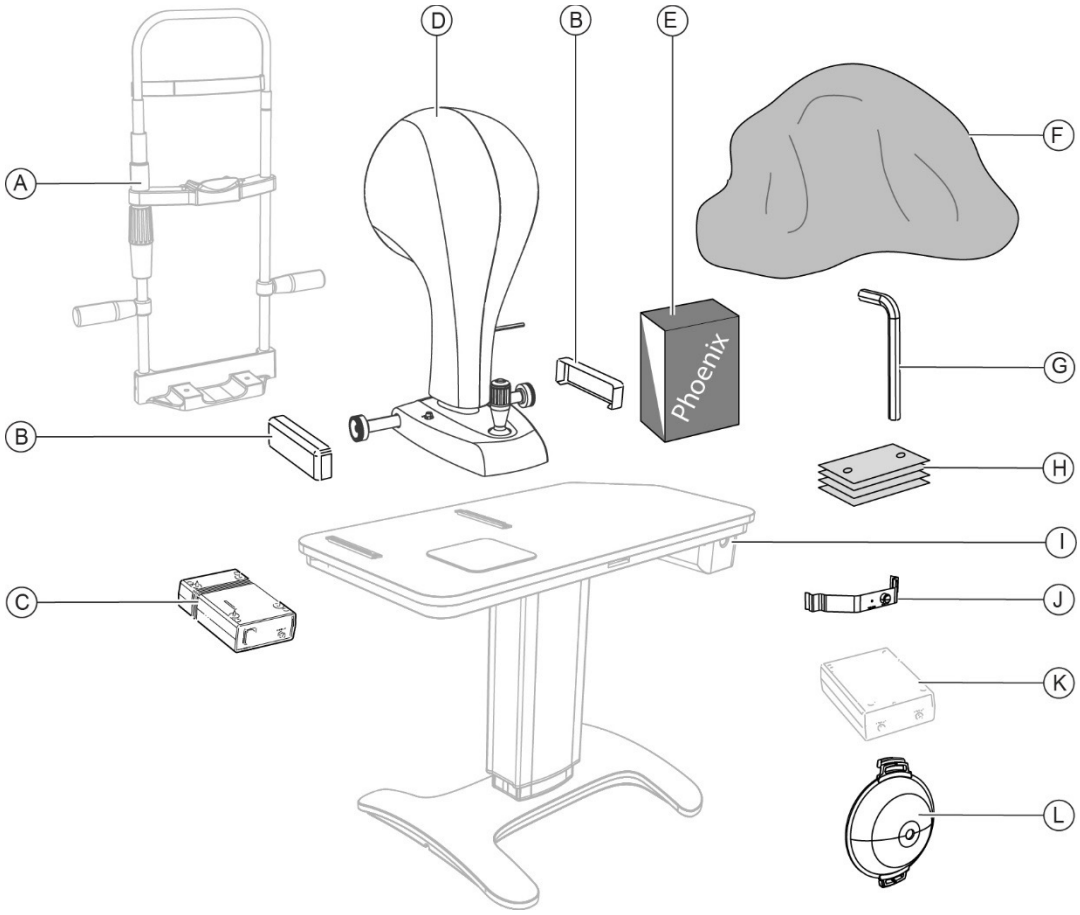


Fig. 5 - Supply composition

Pos	Name		Description
A	Chin rest	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	Device		Consisting of an image acquisition unit, a USB cable for connection to the PC and a connector on the base for connection to the power supply unit.
E	Application software		Application software for image acquisition and device management.
F	Dust cover		Place on the device when not in use to protect it from dust.
G	Hexagon wrench with screws		
H	Chin cup papers		Papers to be placed on the chin cup of the chin rest.
I	Ophthalmic table	Optional	Table top with support base with one or two columns and electric height adjustment. Drawer and auxiliary power sockets with cable guides.
J	Calibration tool		Accessory equipped with sphere (radius 8 mm).
K	Isolation transformer	Optional	230V/230V for the use of non-electromedical devices in the patient area.
L	Diffusion filter		To be magnetically applied to the device for the analysis of the tear lipid layer.

Optional: accessory not provided with the basic supply.

3.1.1 DEVICE

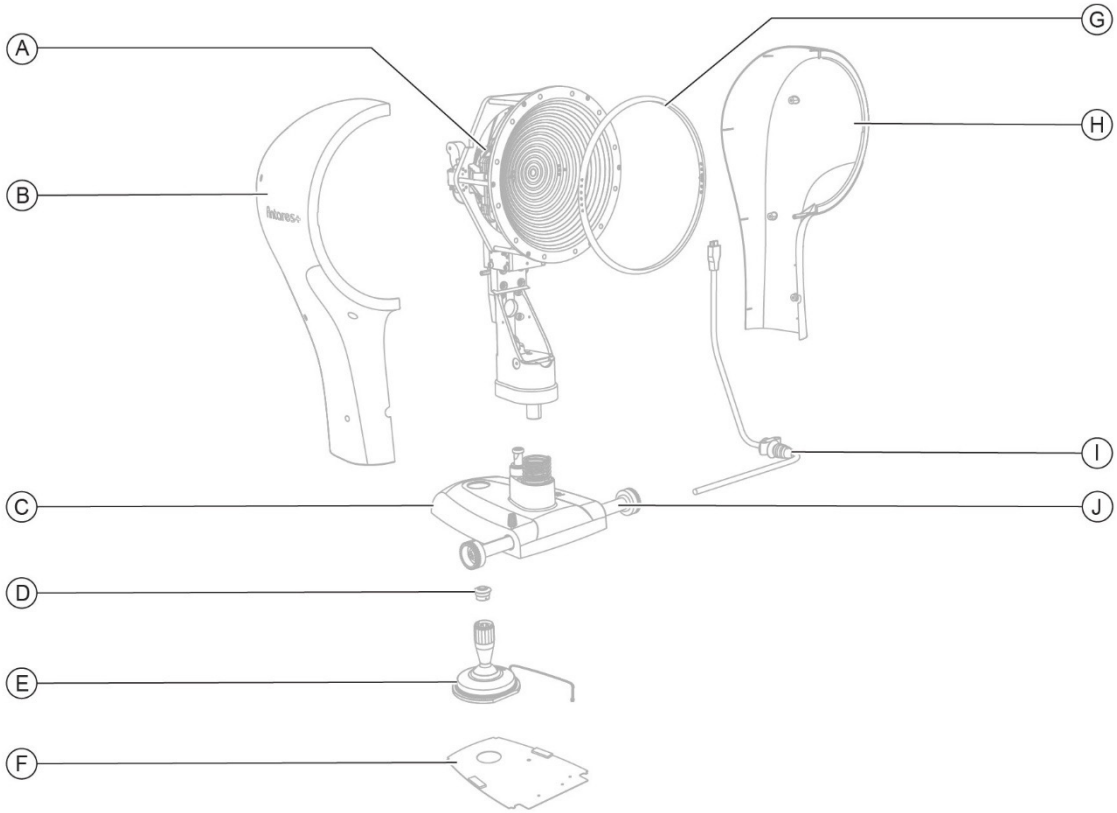


Fig. 6 - Device

Pos	Description
A	Structure assembly
B	Right protective shell
C	Base
D	Joystick button
E	Joystick
F	Plate
G	Ring
H	Left protective shell
I	USB 3.0 cable
J	Sliding rod

For the full list of parts and their features, refer to the **"List of spare parts and accessories" on page 73.**

3.1.2 POWER SUPPLY UNIT

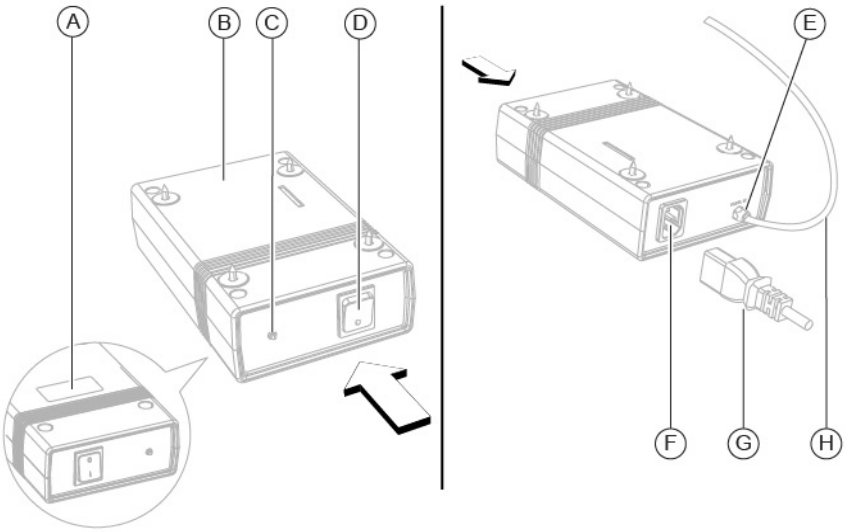


Fig. 7 - Power supply unit

Pos	Description
A	Data plate
B	Power supply unit
C	Power indicator light
D	Power switch
E	Device power supply cable connector
F	Power supply unit power supply cable connector
G	Power supply cable of the power supply unit
H	Device power supply cable

3.1.3 CHIN REST

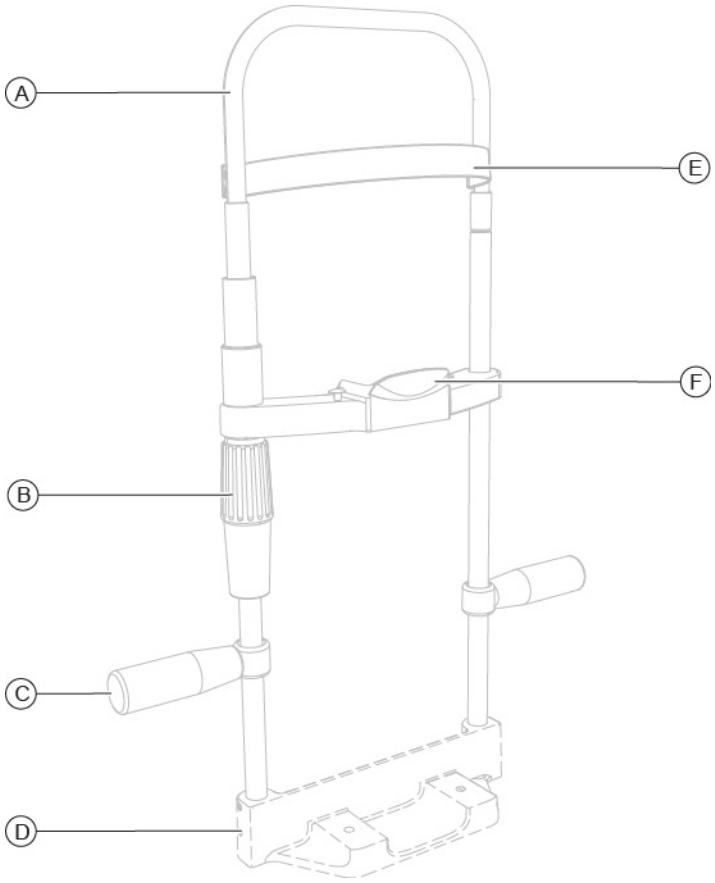


Fig. 8 - Chin rest

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

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

3.1.4 PERSONAL COMPUTER

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

Read the instructions on the Phoenix application software guide.

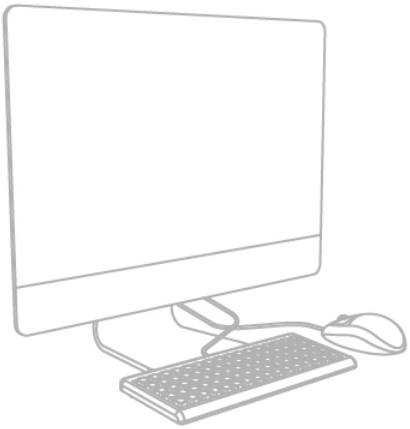


Fig. 9 - Personal Computer

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

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

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

PC technical specifications:

Minimum system requirements:

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

3.2 TECHNICAL DATA

Technical data	Value
Data transfer	USB 3.0
Power supply	External power supply unit 24 VCC In: 100-240 VAC - 50/60 Hz - 0.9-0.5 A Out: 24 VDC 2 A
Network cable	with C14 socket
Dimensions (Height x Length x Depth)	515 x 315 x 255 mm
Weight	6.5 kg
Chin rest 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 millimetres

Light sources

Technical data	Value
Placido Disk	LED @450 - 650 nm
Pupillography and meibography	LED @875 nm
Lighting for Fluorescein examination	LED @470 nm UV-free

Topography

Technical data	Value
Placido Disk	24 rings
Measured points	6144
Topographic covering	ø 10 mm
Measurement accuracy	Class A complying with the UNI EN ISO 19980 standard

Accessories

Technical data	Value
Light diffusion filter for auxiliary illumination, with magnetic lock	Light diffusing filter
Calibration tool	Calibration tool (8 mm radius)

4 INSTALLATION

4.1 ASSEMBLING THE INSTALLATION ACCESSORIES ON THE TABLE TOP

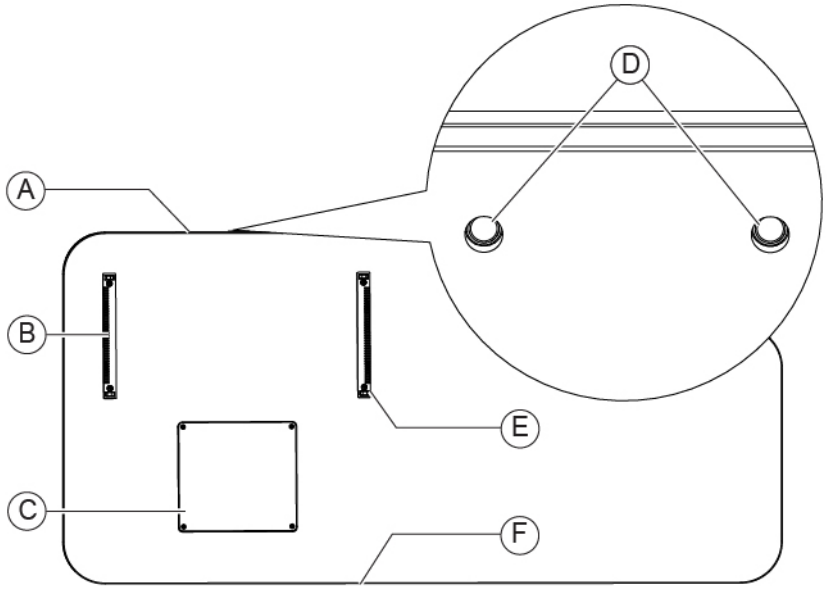


Fig. 10 - Installation accessories on the table top

Pos	Description
A	Table top front edge (Patient side)
B	Left guide rail
C	Sliding plate
D	Inserts for fixing the chin rest on the underside of the table top
E	Right guide rail
F	Table top rear edge (Operator side)

Procedure for assembling the installation accessories on the table top:

1 Install the right and left guide rails on the table top.
Use self-tapping screws Ø 2.9 x 13.

2 Install the sliding plate on the table top.
Use self-tapping screws Ø 2.2 x 2.9. Alternatively, apply the adhesive plate (code 100710831).

The two guides shall be placed equidistant from the central axis, keeping them aligned with the inserts placed on the underside of the table top.

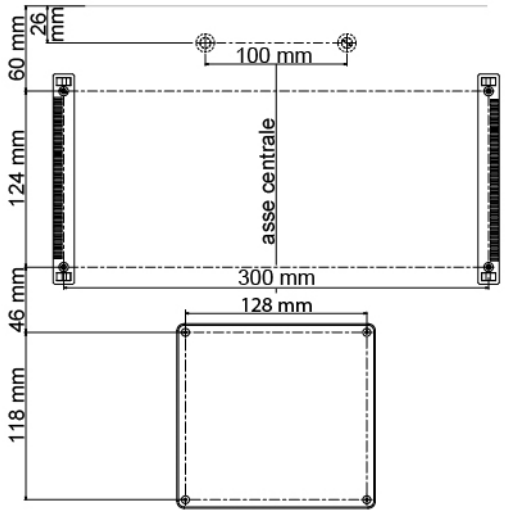


Fig. 11 - Distances for the installation on the table top

3 Carefully clean the surface of the table top.

4.2 INSTALLING THE DEVICE

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

1 Install the guide rails and the sliding plate as described in paragraph **"Assembling the installation accessories on the table top" on page 19.**
2 Place the power supply unit under the table top. Screw the screws into the four holes.

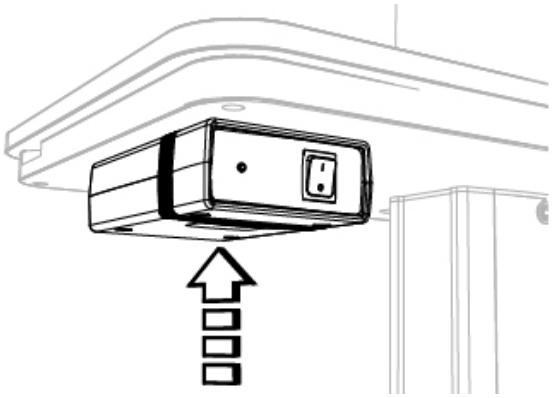


Fig. 12 - Position the power supply unit

3 Position the device on the table top and align the cogwheels on the guide rails.
4 Install the two wheel covers on the guide rails on the table top.

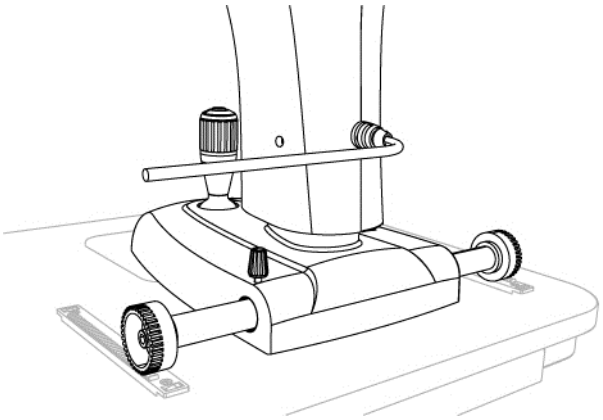


Fig. 13 - Position the device

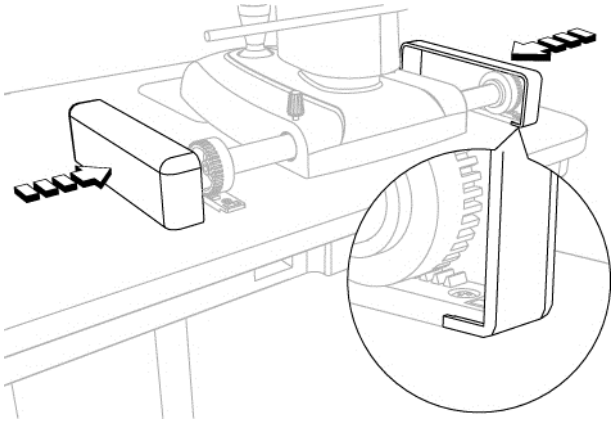


Fig. 14 - Install the wheel covers

5 Install the chin rest. Under the table top there are two inserts to fasten the chin rest support to the table top.

The chin rest must be installed so that the eye level indicator (1) is at a height of 380 mm with respect to the table top.

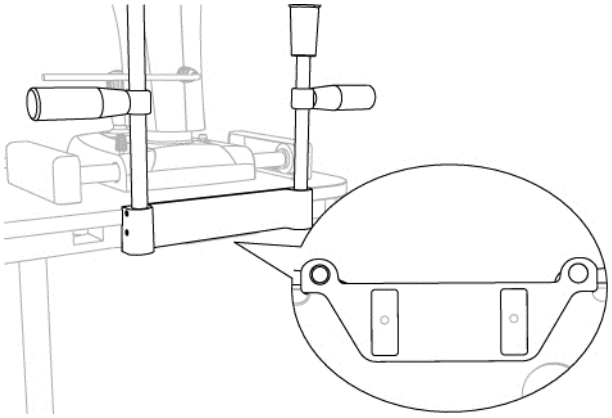


Fig. 15 - Position the chin rest

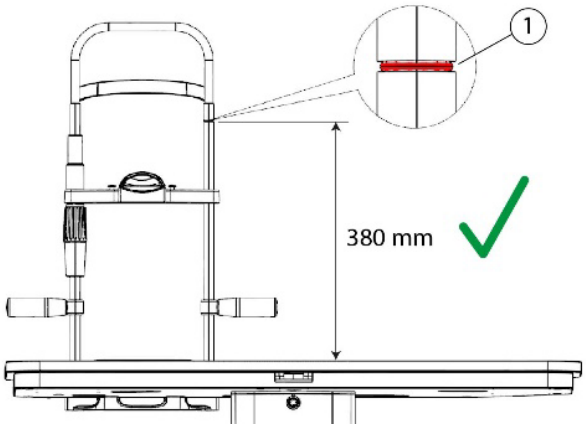


Fig. 16 - Correct height of the eye level indicator

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

The chin rest rods must be adjusted upwards no more than 15 mm.

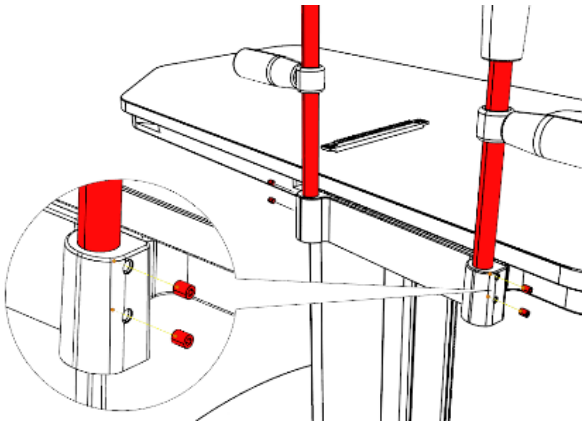


Fig. 17 - Loosen the grub screws of the chin rest

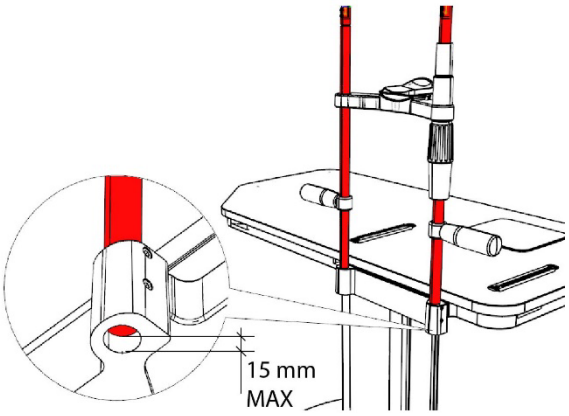


Fig. 18 - Maximum adjustment height of the rods

9 Carry out the electrical connections between the components.

4.3 DEVICE CONNECTIONS

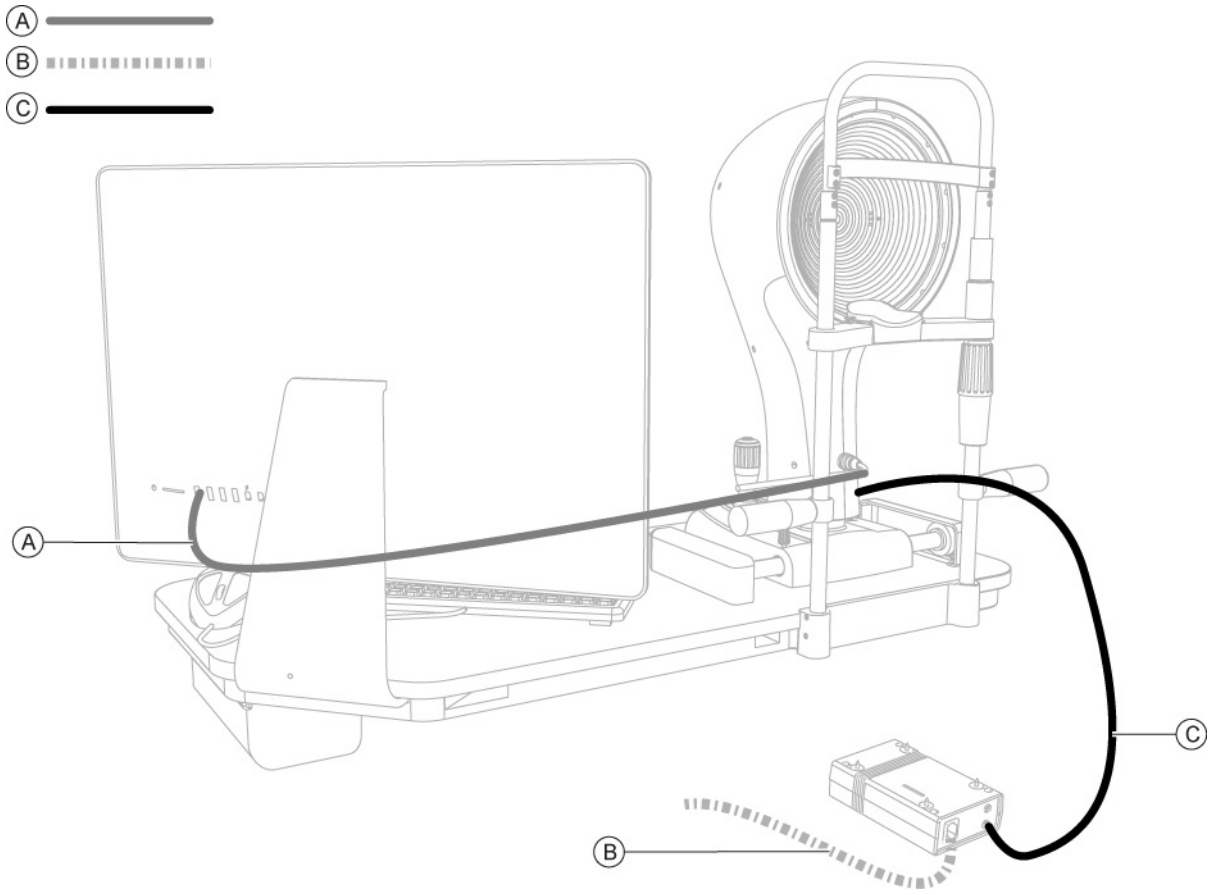


Fig. 19 - Device connections

Pos	Name
A	USB 3.0 connection cable between the device and the PC
B	Power supply cable of the power supply unit
C	Device power supply cable

For the electrical connections of the ophthalmic table, see the instructions for use of the ophthalmic table or the ophthalmic unit.

4.4 POSITIONING OF ELECTRICAL CABLES

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

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

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

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

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

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

4.5 PHOENIX APPLICATION SOFTWARE

4.5.1 INSTALLING THE PHOENIX APPLICATION SOFTWARE

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.

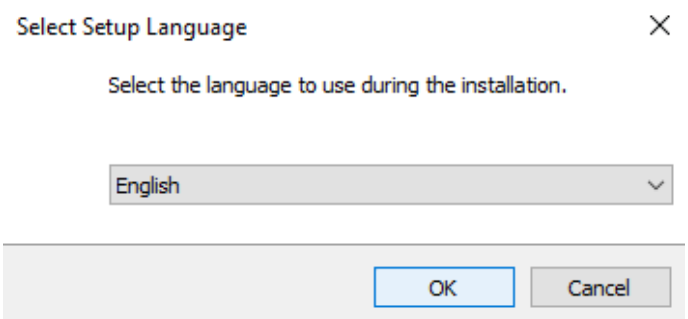


Fig. 20 - Select the language

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.

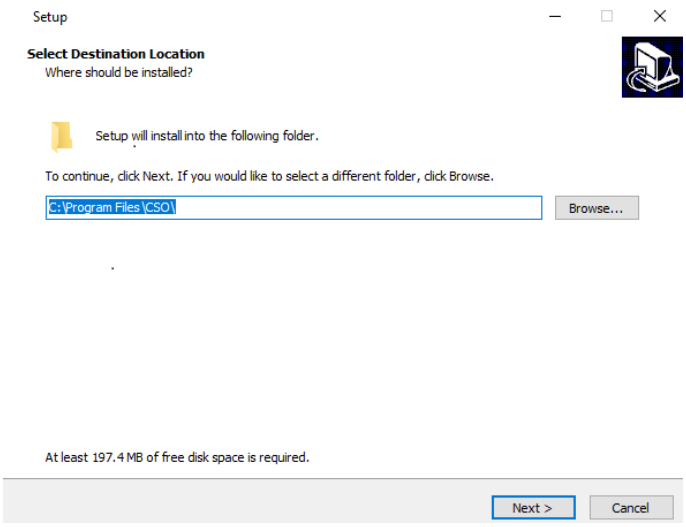


Fig. 21 - Select the destination path

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.

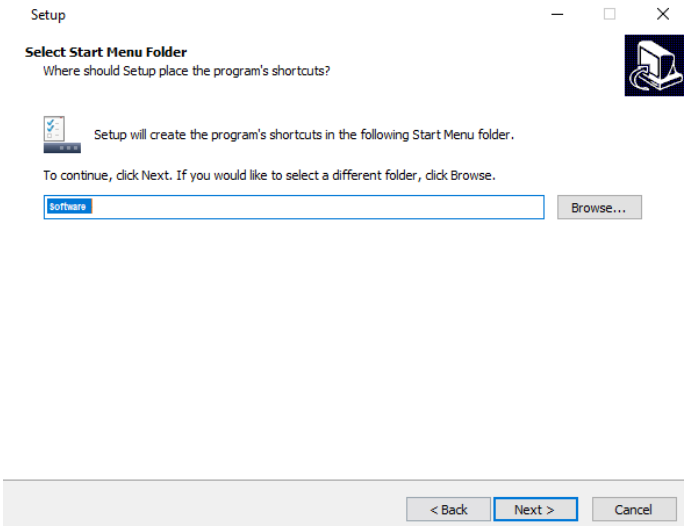


Fig. 22 - Select the destination path

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

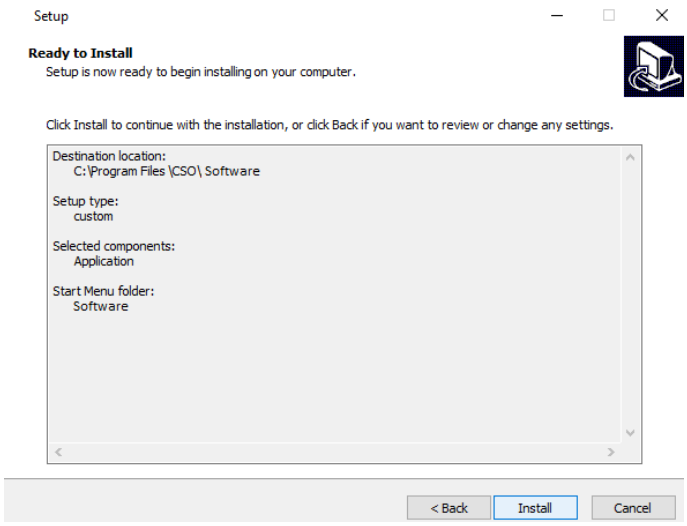


Fig. 23 - Start the installation procedure

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.

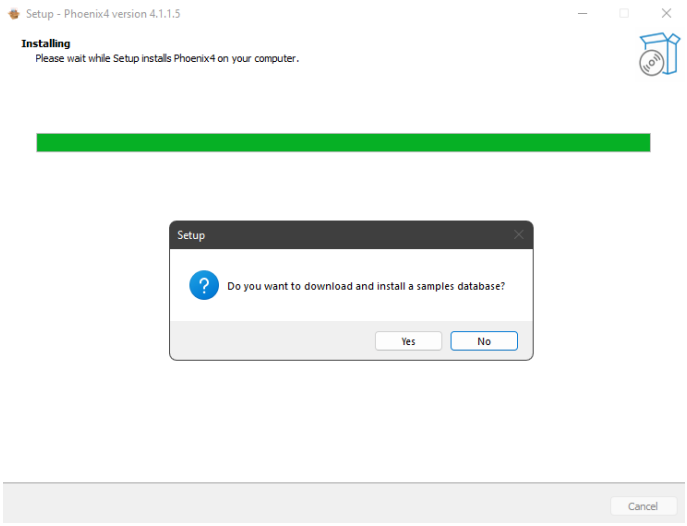


Fig. 24 - Download the demo database

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

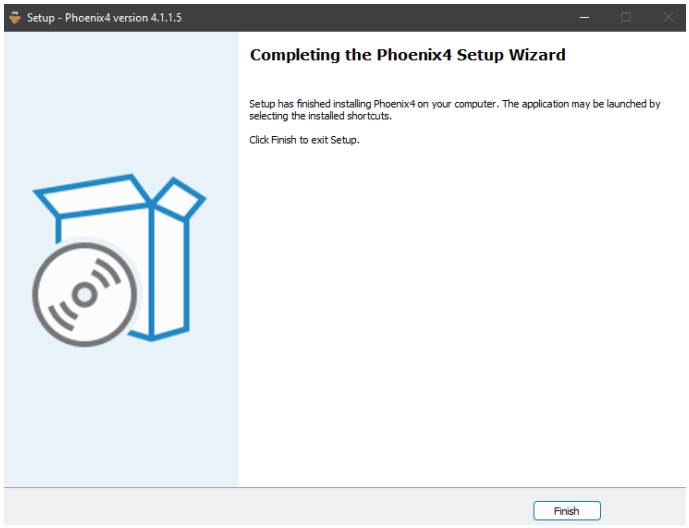


Fig. 25 - Complete the installation

16 Click on the shortcut icon to start 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.

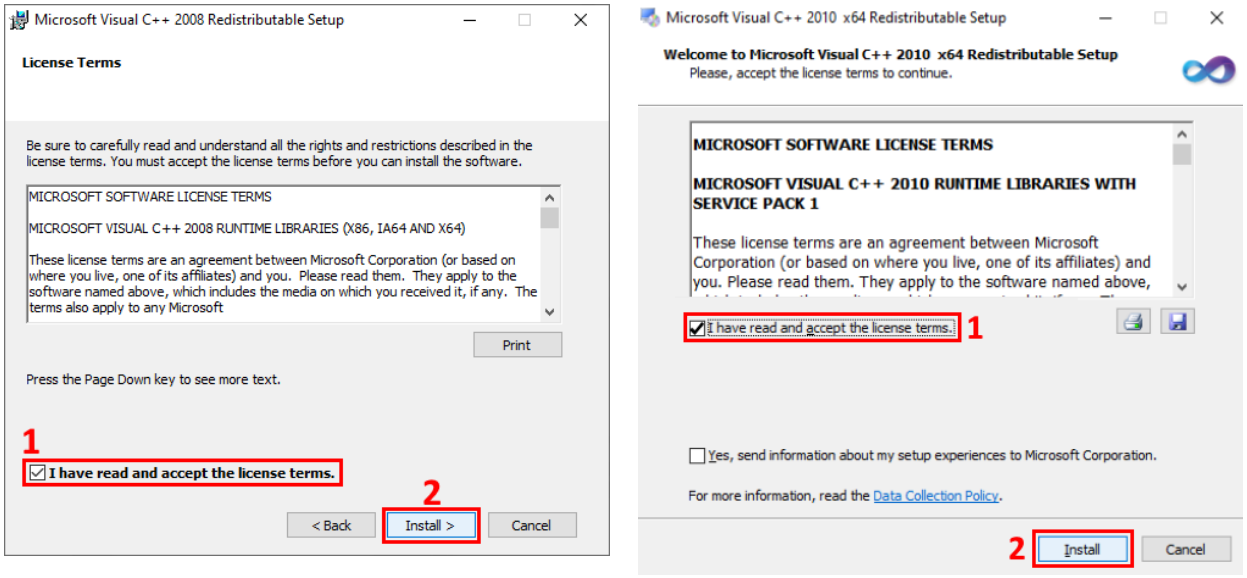


Fig. 26 - Microsoft License Agreement

- 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. 27 - *Windows Security* window

- If *Microsoft .NET Framework 4* 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. 28 - *Setup Wizard* window

- In case of first run, follow the procedure of **"Activation and registration of the Phoenix application software" on page 30.**
- 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.

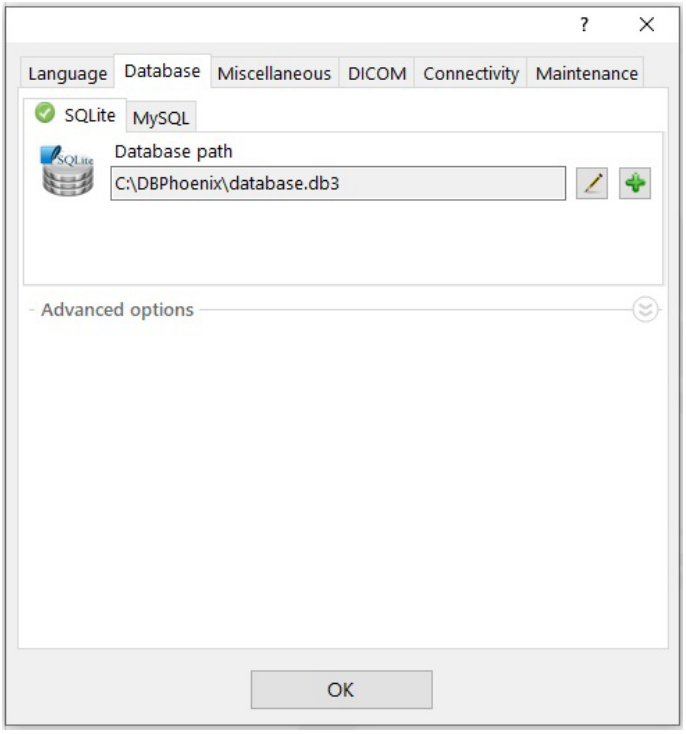


Fig. 29 - Database configuration

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

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/Firewire port. A popup appears on the upper part of the screen, showing the license type, the P-number and the device serial number.

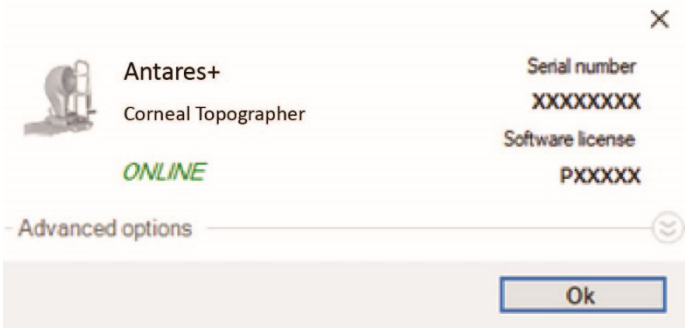


Fig. 30 - Popup window

When the device is disconnected from the USB/Firewire 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 started.

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.

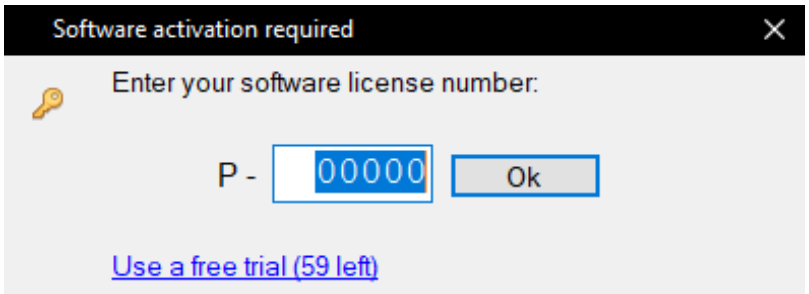


Fig. 31 - Enter the P-number

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.

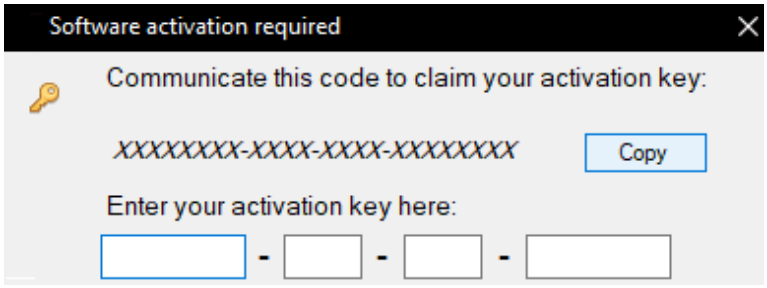


Fig. 32 - Take note of the request code

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.

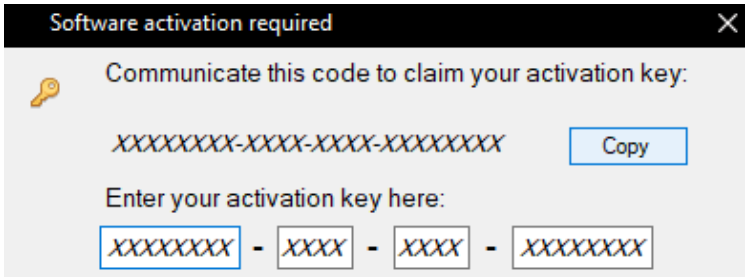


Fig. 33 - Enter the activation code

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.

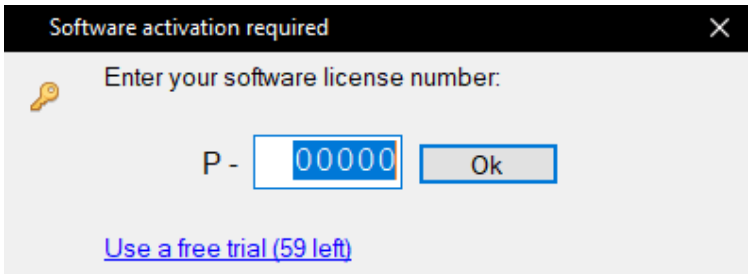


Fig. 34 - Enter the P-number

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 30.**

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.

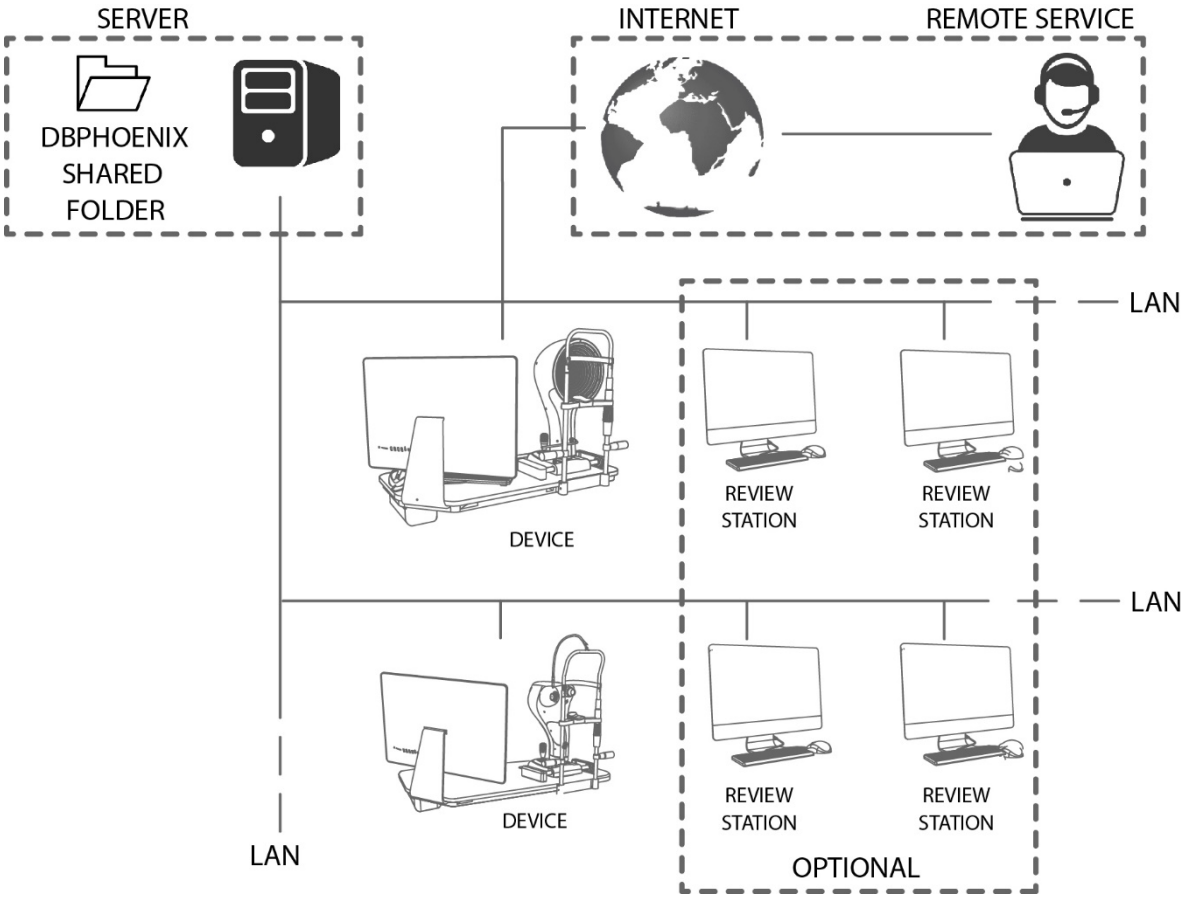


Fig. 35 - LAN path

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. 36 - Click on *Settings*

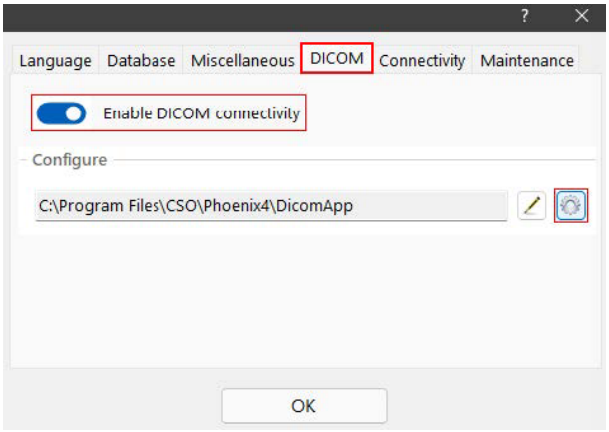


Fig. 37 - DICOM tab

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 ( ).

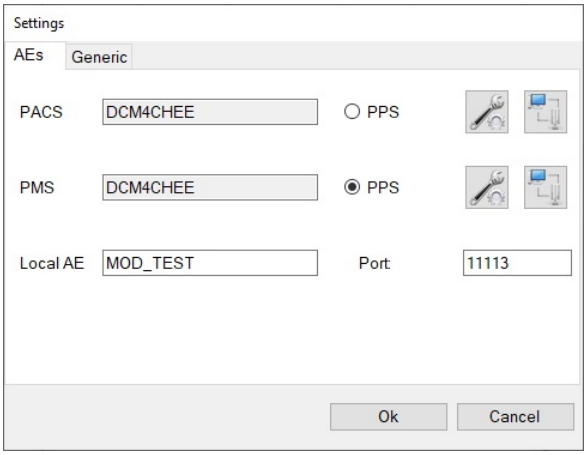


Fig. 38 - AE parameters

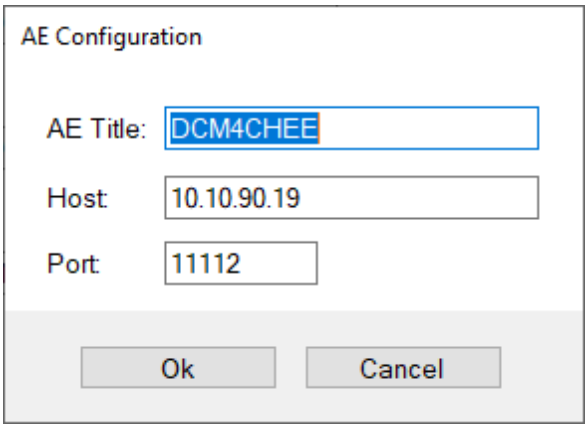


Fig. 39 - AE configuration

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*.

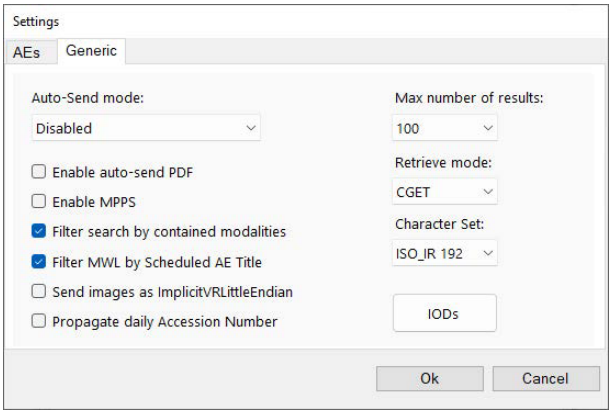


Fig. 40 - General settings

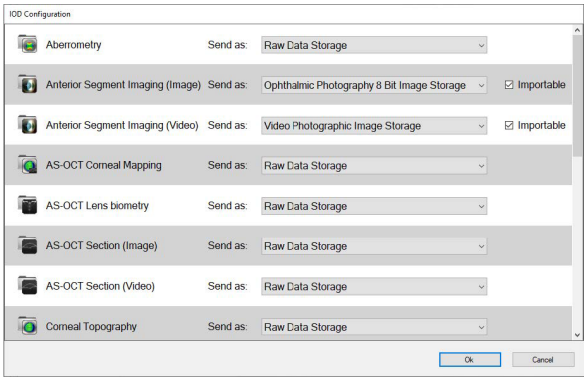


Fig. 41 - IODs

4.5.5 UPDATING THE PHOENIX APPLICATION SOFTWARE

Read the instructions on the guide before using the Phoenix application software.

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

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 37** and **"Backup of the database archive and restoration of patient examinations" on page 37.**

Operating system	Versions of the Phoenix application software	
	4.0.1.8	**4.1.4.7**
Windows 10 Home or Pro 64 bit	X (*)	X (*)
Windows 11 Home or Pro 64 bit		X (*)

(*) Starting from version 4.0 of the Phoenix application software, the installation of *Microsoft .NET Framework 4* 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.

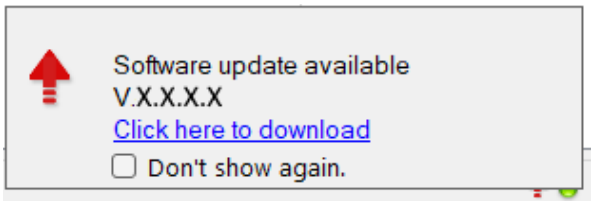


Fig. 42 - Download the update

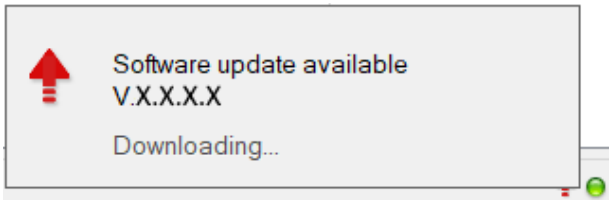


Fig. 43 - Download in progress

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

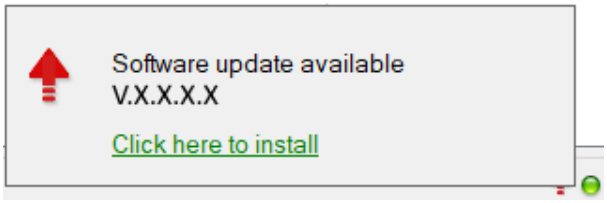


Fig. 44 - Install the update

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

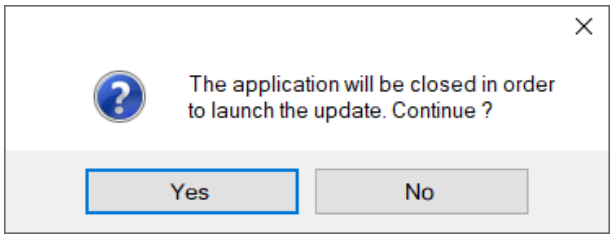


Fig. 45 - Confirm and start the update procedure

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.

1 Turn the power switch of the power supply unit to ON.
2 Turn on the PC.
3 Start the Phoenix application software.
4 Wait until the main screen of the application software is displayed.
5 Click NEW PATIENT and enter their personal data. If the patient is already present in the database, you can automatically search for their surname by typing it into the command prompt. A new examination will be created automatically.
6 Select the device to be used.
7 The image acquisition screen will open. It is now possible to acquire the image.
8 If the device is started for the first time or after a long period of non-use, the device calibration shall be performed. Follow the calibration instructions described in paragraph **"Device calibration" on page 38.**

4.7 DEVICE CALIBRATION

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

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

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

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

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

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

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

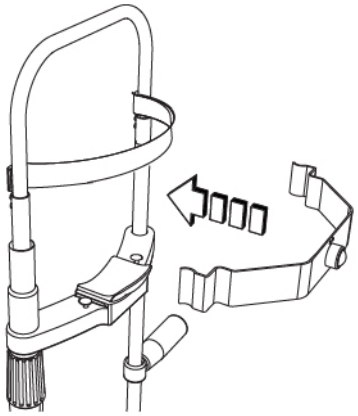


Fig. 46 - Place the calibration tool

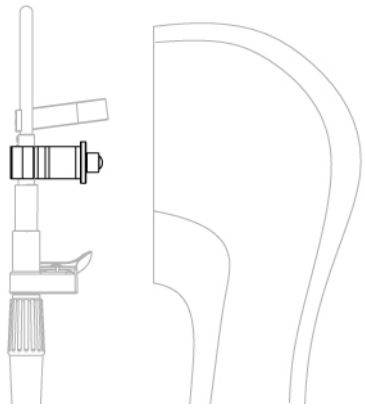


Fig. 47 - Align the calibration tool

4 Start the Phoenix application software.
5 From the main screen, select the desired device in the devices list.
6 Click on the calibration button.

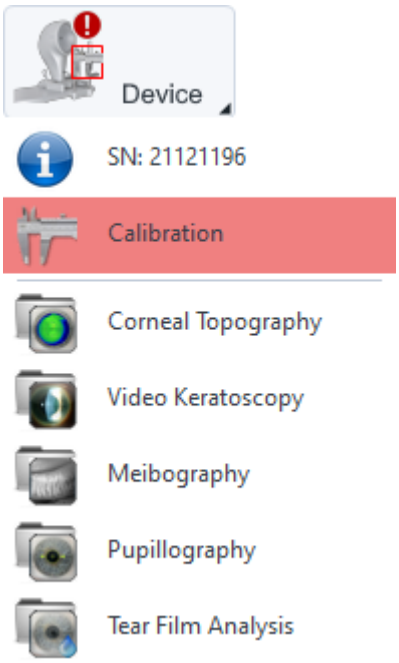


Fig. 48 - Click on the calibration button

Curvature Calibration

Curvature calibration is necessary to permit the program to correctly measure the curvatures.

1 Carefully acquire an image of the calibration sphere. If the acquisition is not satisfactory a message will ask to repeat the procedure.
2 After having successfully calibrated you should capture some images of the calibration sphere, creating a patient and a test exam to verify correct instrument calibration.
3 If the processed measurements are not found to be reliable, repeat the entire calibration procedure.

Focus-based devices calibration

1 To acquire an image press the joystick button and move the topographer slowly forward until the image defocuses again. During this movement make sure that the cross remains near the center of the rings. Passing through the focus the software captures the best image and the calibration will be accepted by the software.

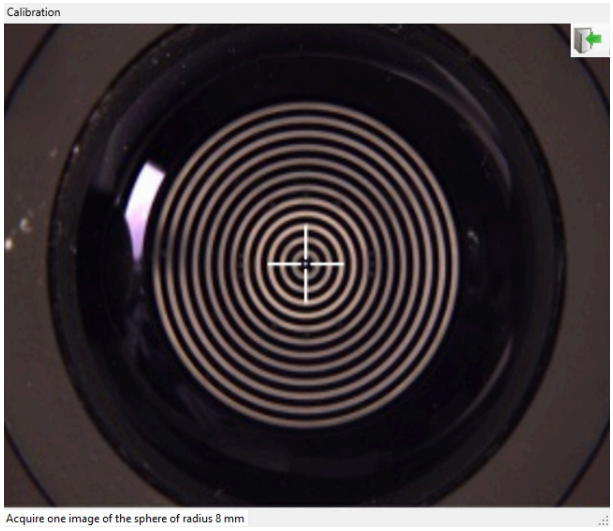


Fig. 49 - Focus-based topographer: curvature calibration

Triangulation-based devices calibration

To perform calibration of triangulation-based devices, follow the steps below:

1 Move the topographer forward or backward: when the device is too far or too close to the calibration sphere vertex the slits appear disjointed or overlapping in the calibration sphere periphery.

2 Instead, when the slits are aligned and overlapping in the center the device will be at the right distance: make sure that the cross remains near the center of the rings and that the rings are not corrupted and press the spacebar to grab the image.

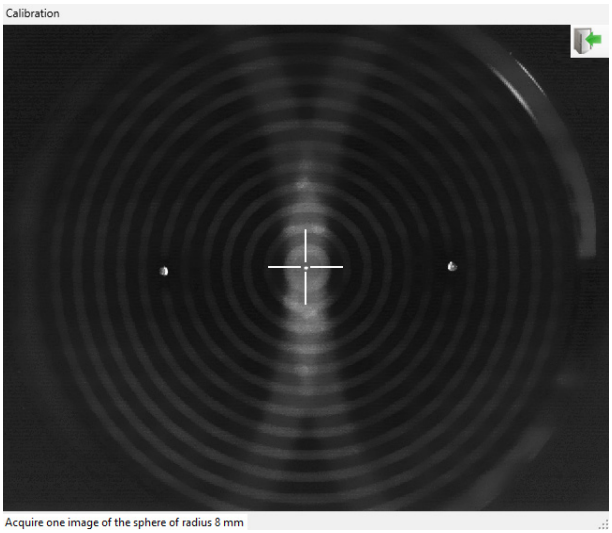


Fig. 50 - Triangulation-based topoaberrometer: curvature calibration (correct alignment)

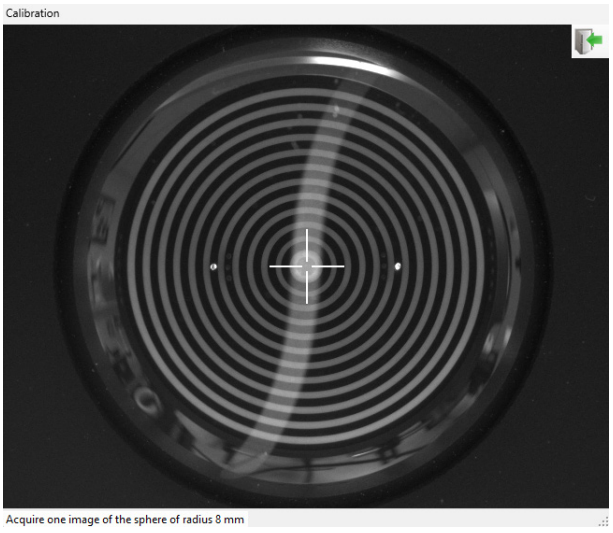


Fig. 51 - Triangulation-based topographer: curvature calibration (correct alignment)

4.8 DEVICE CALIBRATION CHECK

Automatic calibration check

To perform the automatic calibration check, follow the steps below:

1 Click  button to start a new Calibration check procedure.
2 To perform a "Calibration check", the device must already be calibrated.
3 Without Calibration performed, Calibration check button will not be visible.

Calibration tool's curvature manual check

To perform the calibration tool's curvature manual check, follow the steps below:

1 Create a test patient and examination, then acquire some images of the test eye.
2 Click on  icon and select the Corneal topography examination.
3 Press the combination CTRL+T on the keyboard to activate the "Test Eye" mode.
4 After acquiring the images, press the  button and reprocess the acquired examinations.
5 Open the acquisitions, on the Settings panel select "millimeters" as unit of measurement.
6 Verify the displayed values: the measured radius on "Tangential Anterior" map should be 8 mm +/- 0.03 mm.

4.9 FUNCTIONAL TEST OF THE DEVICE

After installing the application software or the device, carry out a functional test of the device. This operation must be performed by a person familiar with the device application.

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.

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

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 must be carried out regularly.

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

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

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

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

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

5.2.2 CLASSIFICATION OF THE CRITICALITY OF THE DEVICE

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

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

5.2.3 DEVICE CLEANING

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

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

The device must be regularly cleaned.

The device is provided with a cover for protection from dust, especially during periods of non-use.

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

For more information about suitable cleaning products, read paragraph **"Recommended products for cleaning and disinfection" on page 43.**

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.

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

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

For more information about suitable cleaning products, read paragraph **"Recommended products for cleaning and disinfection" on page 43.**

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.

5.2.6 DEVICE EXCURSION CHECK

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

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 not indicated in the instructions for the Technical Assistance.

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 **"List of spare parts and accessories" on page 73.**

The electrical safety check shall be carried out in accordance with the IEC 62353 standard after any operation requiring electronic components to be replaced or the device protective shells to be removed.

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.

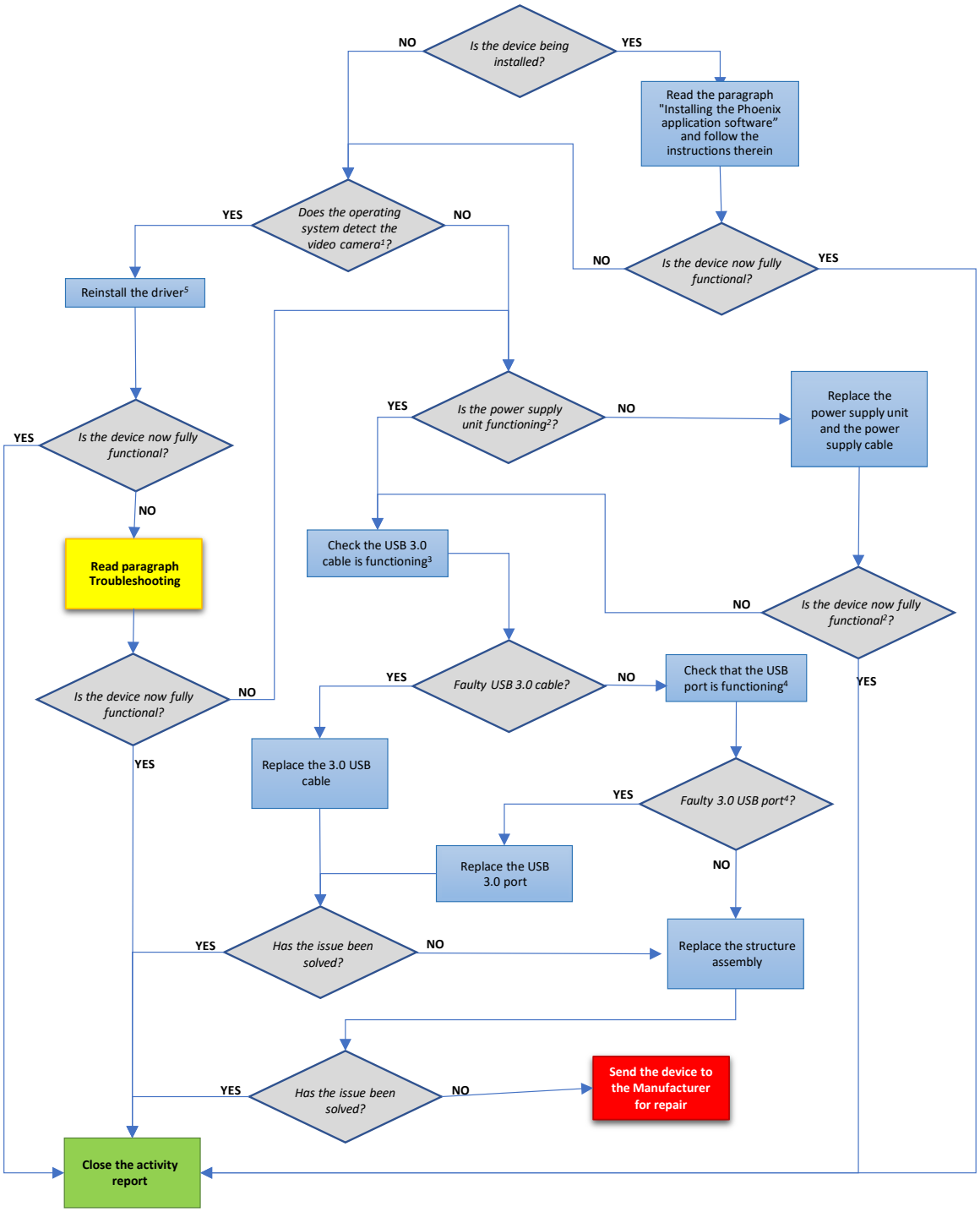
It is prohibited to use a powered screwdriver for any components' fixing or adjusting procedure.

6.2 FLOW CHARTS

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

Only use original spare parts to replace device components. The code is indicated within the **"List of spare parts and accessories" on page 73.**

The Phoenix software cannot detect the device



[1] Access "Device manager" and check that the Aria A15S-TA SuperSpeed Camera video camera is properly detected.
[2]Check the power switch of the power supply unit is set to ON.
[3]To check the USB 3.0 cable operation, connect it to another PC.
[4]Access "Device manager" and remove the USB 3.0 port from the devices list. Restart the PC and check that no errors are reported in the USB 3.0 cable connection.
[5] Manually install the driver from: *C:\Program Files\CSO\Phoenix4\Live\Drivers (MaestroUSB3 vx.x.x.x.exe).*

6.3 MESSAGES OF THE APPLICATION SOFTWARE

ID	Message	Solution
PHANT+001	The Database is not accessible	Allow the required authorisations (administrator privileges) in the folder "DBPhoenix".
PHANT+002	Error reading offset 0xF0F01104	USB 3.0 cable disconnected or non-functioning. – Check that the USB 3.0 cable is properly connected. – If the problem persists, replace the USB 3.0 cable. Follow the procedure described in paragraph **"Replacing the USB 3.0 cable" on page 51.** If the problem persists, follow the instructions given in the paragraph **"Flow charts" on page 45.**
PHANT+003	Device connected to a 2.0 USB port	The device is connected to a 2.0 USB port. – Connect the USB 3.0 cable to a USB 3.0 port. – Check that the USB 3.0 cable is properly connected. If the problem persists, replace the USB 3.0 cable. Follow the procedure described in paragraph **"Replacing the USB 3.0 cable" on page 51.**
PHANT+004		–

For any message of cases which are not included in the list, please ask the Manufacturer for information.
Send the following data to the Technical Assistance:

- 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 7.**

6.4 TROUBLESHOOTING

ID	Issue	Solution
ANT+001	The Phoenix application software requires activation	– Check that the power supply cable of the device and/or the power supply cable of the power supply unit are properly connected. – Check that the power switch of the power supply unit is set to ON. – Check that the USB 3.0 cable is properly connected. – If the problem persists, replace the USB 3.0 cable. Follow the procedure described in paragraph **"Replacing the USB 3.0 cable" on page 51.** – If the problem persists, follow the instructions given in the paragraph **"Flow charts" on page 45.**
ANT+002	The Phoenix application software doesn't detect the device	– Follow the indications given in paragraph **"Flow charts"on page 45.**
ANT+003	The image is out of focus or the device is not calibrated	– Check the correct focusing of the device using the supplied calibration tool. Carry out the device calibration as described in paragraph **"Device calibration" on page 38.**
ANT+004	The acquired image is not clear	– Check that the optical path of the shooting unit is clean. – Check the room lighting.

6.5 PART REPLACEMENT

Any part replacement operation shall only be carried out by qualified and trained technical personnel.

To replace the device parts, use original spare parts only. The code is indicated within the **"List of spare parts and accessories" on page 73.**

6.5.1 REPLACEMENT OF THE POWER SUPPLY UNIT

Material and warnings:

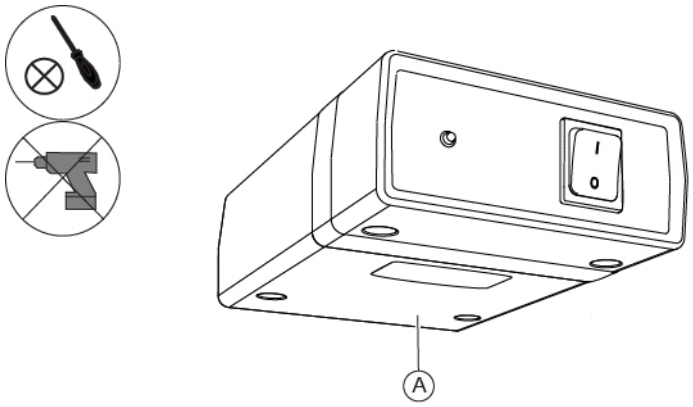


Fig. 52 - Power supply unit

Pos	Description	Code
A	Power supply unit (PSP2402)	103103900

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

Before carrying out the replacement, make sure you have all the tools and materials required for the installation.

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, lock 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.

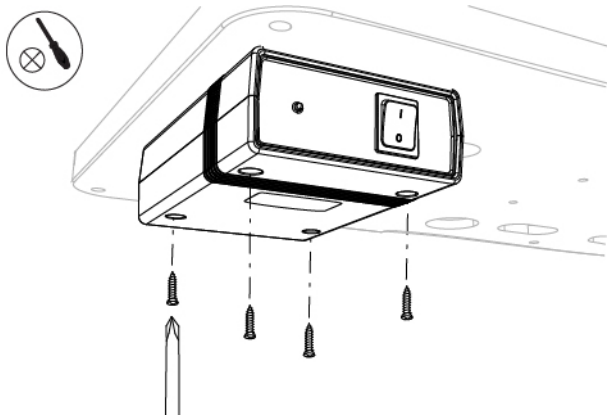


Fig. 53 - Unscrew the screws

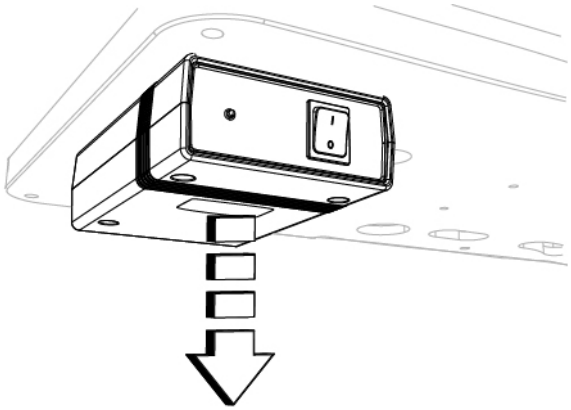


Fig. 54 - Remove the power supply unit

6 For assembly, follow the procedure in reverse order.

When the operation is complete, carry out the electrical safety test as described in the paragraph **"Electrical safety check" on page 69.**

6.5.2 REPLACEMENT OF PROTECTIVE SHELLS

Material and warnings:

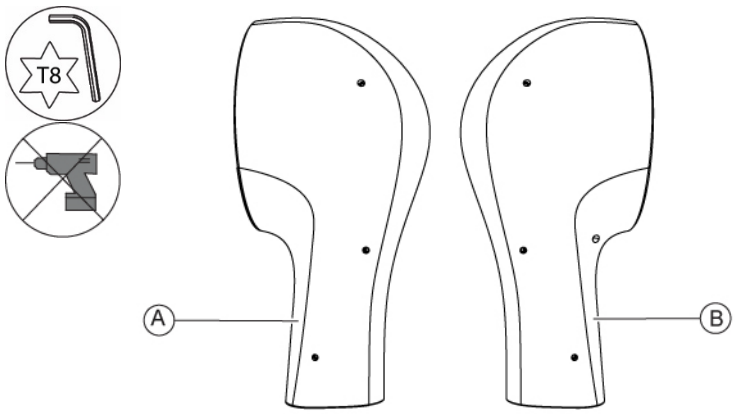


Fig. 55 - Left and right protective shells

Pos	Description	Code
A	Left protective shell	100136565S
B	Right protective shell	100136564S

Before carrying out the replacement, make sure you have all the tools and materials required for the installation.

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

Disassembling and assembling procedure for the protective shells:

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

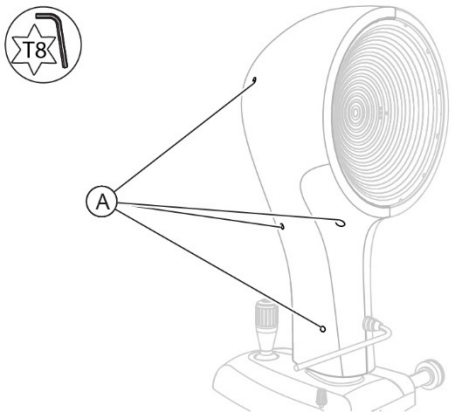


Fig. 56 - Unscrew the screws

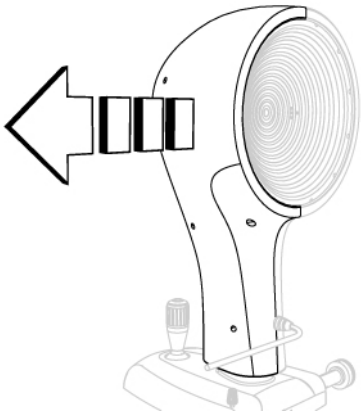


Fig. 57 - Remove the right protective shell

3 Unscrew the four screws (B) of the left protective shell.
4 Remove the left protective shell.

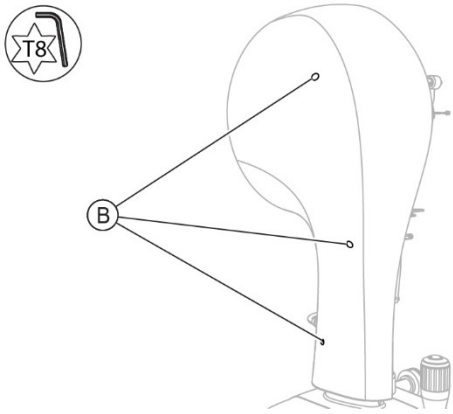


Fig. 58 - Unscrew the screws

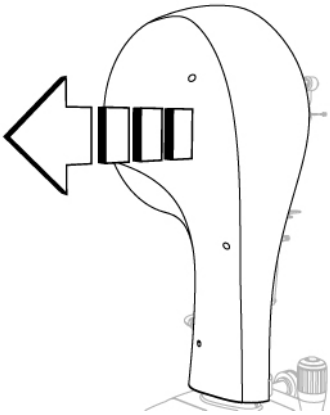
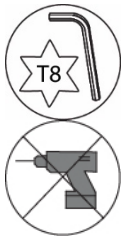


Fig. 59 - Remove the left protective shell

5 For assembly, follow the procedure in reverse order.

6.5.3 REPLACING THE USB 3.0 CABLE

Material and warnings:



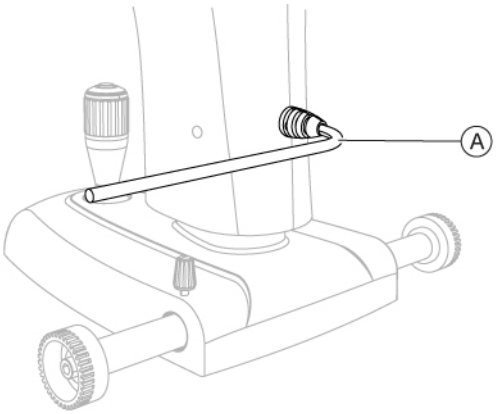


Fig. 60 - USB 3.0 cable

Pos	Description	Code
A	USB 3.0 cable	3020804

Before carrying out the replacement, make sure you have all the tools and materials required for the installation.

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 protective shells as described in paragraph **"Replacement of protective shells" on page 49.**
2 Cut the cable ties (A).
3 Unscrew the two screws (B).
4 Remove the cable clamp (C).

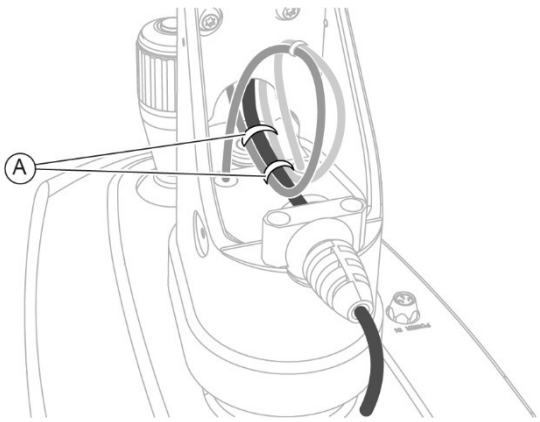


Fig. 61 - Cut the cable ties

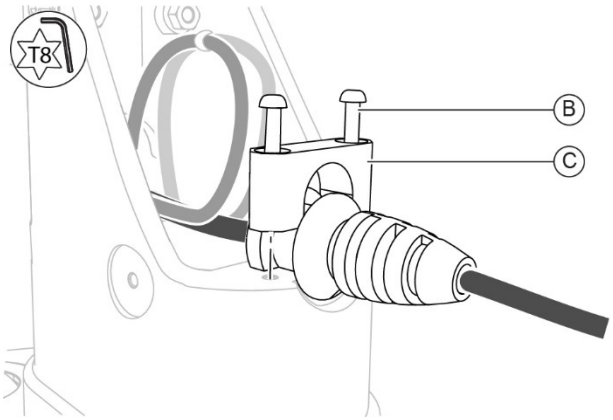


Fig. 62 - Remove the cable clamp

5 Cut the cable ties (D) that fasten the connection cables.
6 Disconnect the USB 3.0 cable (E) from the Power-in connector (F).

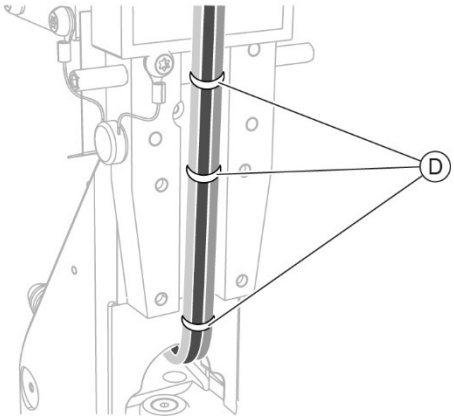


Fig. 63 - Cut the cable ties

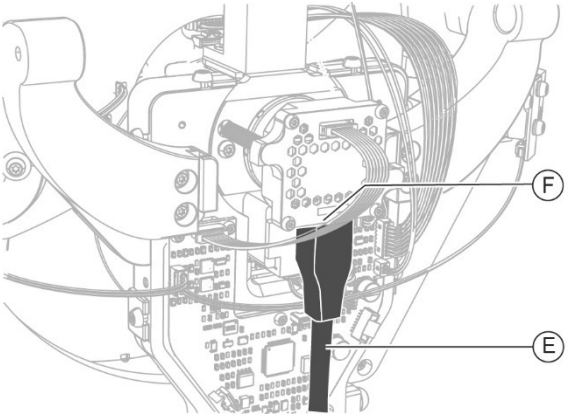


Fig. 64 - Disconnect the cable

7 Remove the USB 3.0 cable.

Assembling procedure for the USB 3.0 cable:

1 Connect the USB 3.0 cable (E) to the Power-in connector (F).
2 Place three new cable ties (D) on the connection cables.

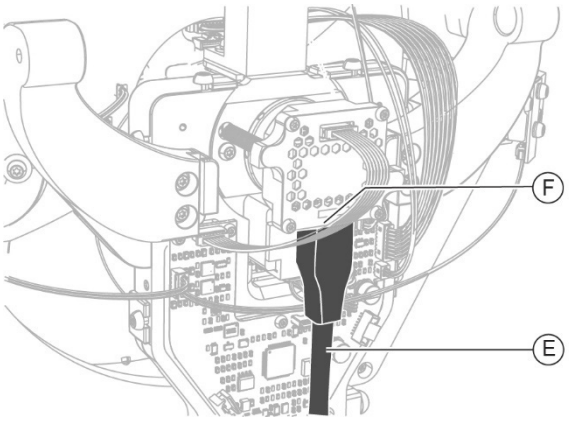


Fig. 65 - Connect the cable

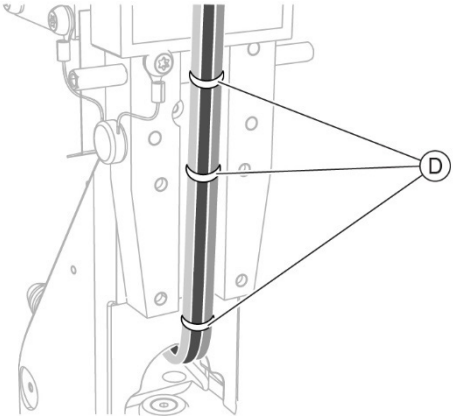


Fig. 66 - Place the cable ties

3 Place the cable clamp (C).
4 Screw in the two screws (B).
5 Place two new cable ties (A) to fasten the connection cables.

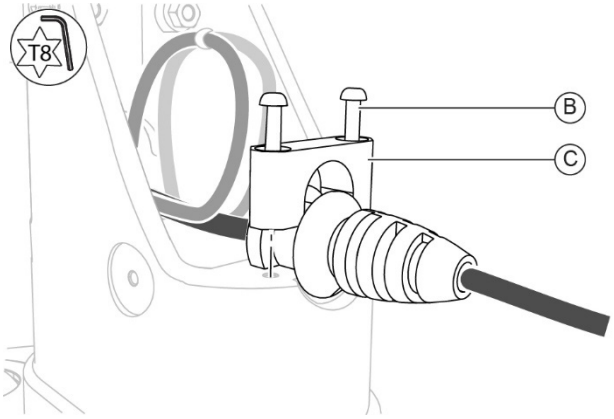


Fig. 67 - Place the cable clamp

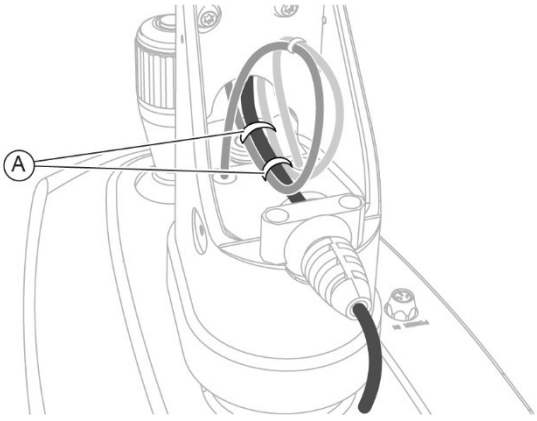


Fig. 68 - Place the cable ties

6 Install the protective shells as described in paragraph **"Replacement of protective shells" on page 49.**

When the operation is complete, carry out the electrical safety test as described in the paragraph **"Electrical safety check" on page 69.**

6.5.4 REPLACEMENT OF THE PLATE

Material and warnings:

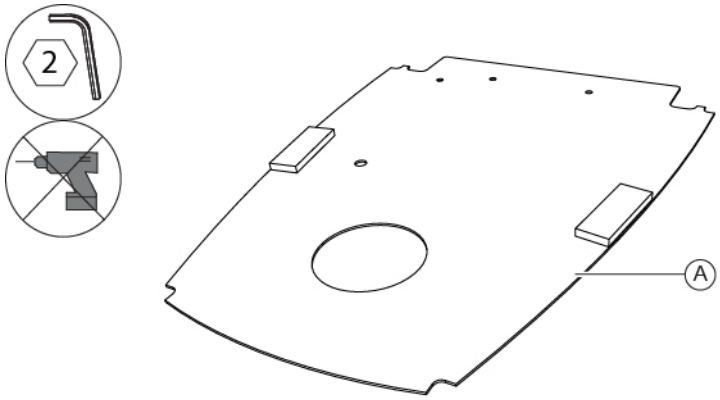


Fig. 69 - Plate

Pos	Description	Code
A	Plate	100270420

The described procedure shall be only read when a maintenance operation requires disassembling and/or reassembling the plate.
The plate is not supplied as a spare part, therefore it is not possible to request its replacement.

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

Before carrying out the replacement, make sure you have all the tools and materials required for the installation.

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

Disassembling and assembling procedure for the plate:

1 Place a soft cloth on a stable surface.
2 Place the device horizontally, so that the Placido disk is directed downwards.
3 Unscrew the four screws (A) M3x6 on the plate.

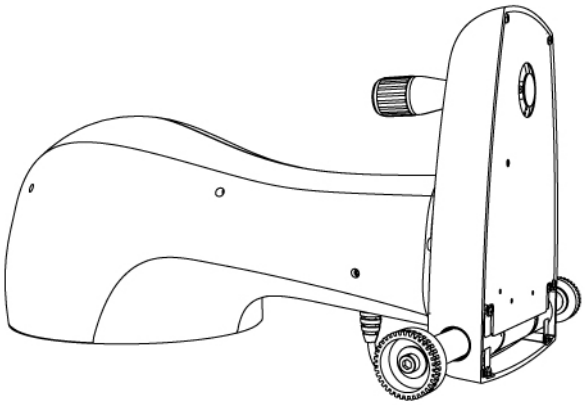


Fig. 70 - Position the device

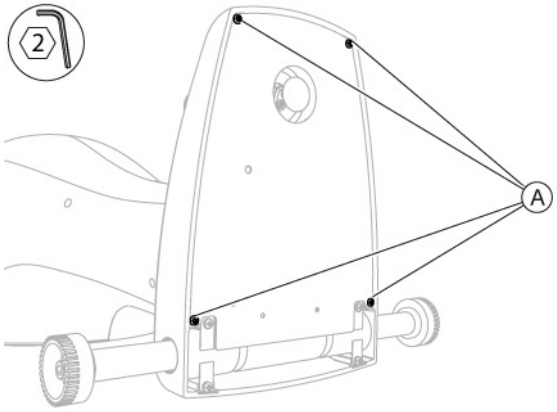


Fig. 71 - Unscrew the screws

4 Remove the plate.

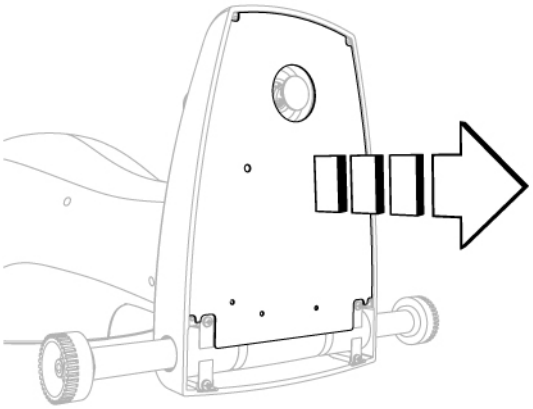


Fig. 72 - Remove the plate

5 For assembly, follow the procedure in reverse order.

When the operation is complete, carry out the electrical safety test as described in the paragraph **"Electrical safety check" on page 69.**

6.5.5 REPLACEMENT OF THE JOYSTICK

Material and warnings:

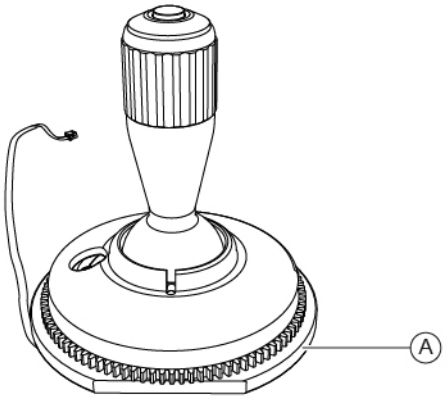


Fig. 73 - Joystick

Pos	Description	Code
A	Joystick	100113401

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

Before carrying out the replacement, make sure you have all the tools and materials required for the installation.

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

Disassembling and assembling procedure for the joystick:

1 Remove the plate as described in paragraph **"Replacement of the plate" on page 53.**
2 Disconnect the connection cable (A) between the joystick and the right/left sensor from the connector (B).
3 Unscrew the screws (C) that fasten the joystick to the base.

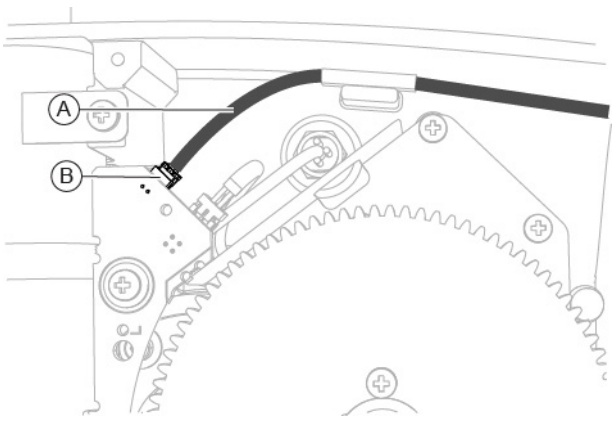


Fig. 74 - Disconnect the cable

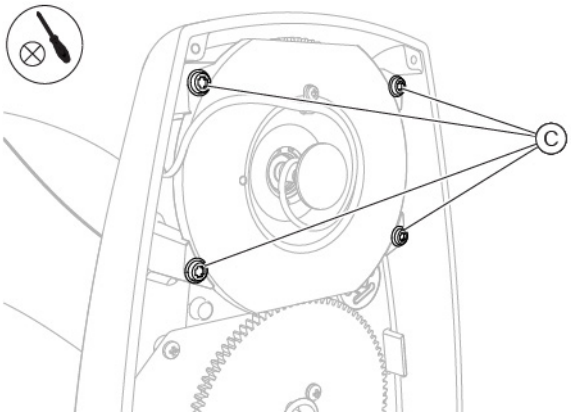


Fig. 75 - Unscrew the screws

4 Remove the joystick from the base. While removing the joystick, be careful not to damage the cable.

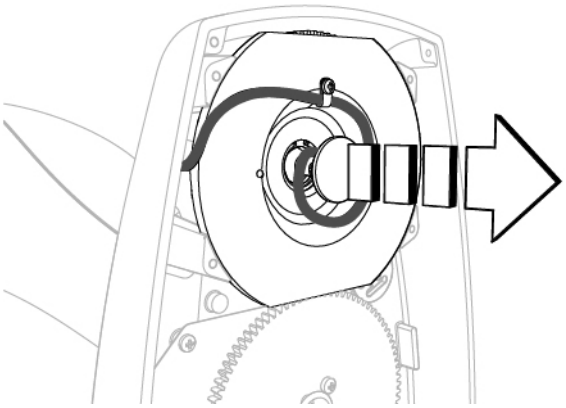


Fig. 76 - Remove the joystick

5 For assembly, follow the procedure in reverse order.

When the operation is complete, carry out the electrical safety test as described in the paragraph **"Electrical safety check" on page 69.**

6.5.6 REPLACING THE JOYSTICK BUTTON

Material and warnings:

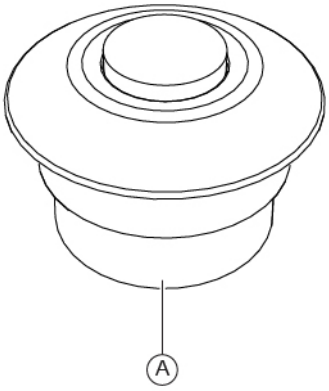


Fig. 77 - Joystick button

Pos	Description	Code
A	Joystick button	100258402

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

Before carrying out the replacement, make sure you have all the tools and materials required for the installation.

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

Disassembling and assembling procedure for the joystick button:

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

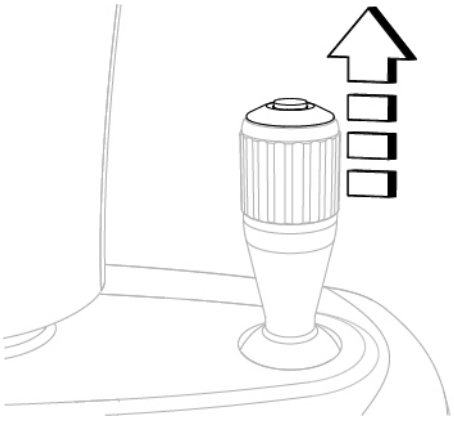


Fig. 78 - Pull out the joystick button

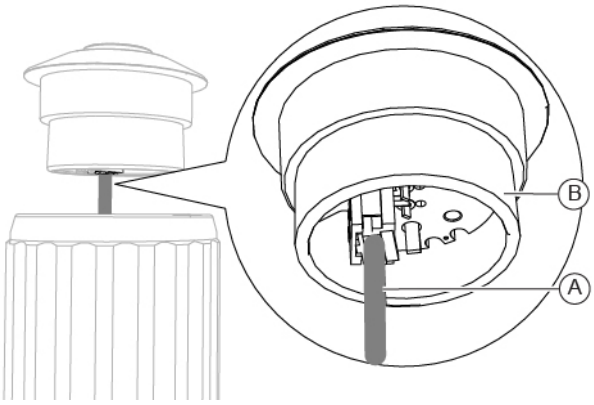


Fig. 79 - Disconnect the cable

3 For assembly, follow the procedure in reverse order.

When the operation is complete, carry out the electrical safety test as described in the paragraph **"Electrical safety check" on page 69.**

6.5.7 REPLACEMENT OF THE POSITION SENSOR AND THE POSITION SENSOR TUBE ASSEMBLY

Material and warnings:

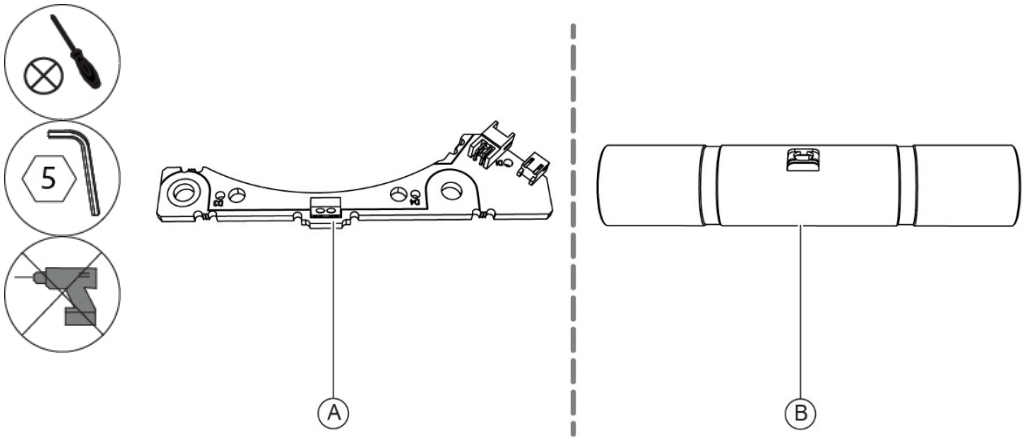


Fig. 80 - Position sensor and position sensor tube assembly

Pos	Description	Code
A	Position sensor	120270411
B	Position sensor tube assembly	100270426

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

Before carrying out the replacement, make sure you have all the tools and materials required for the installation.

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

Disassembling procedure for the position sensor:

1 Place the device horizontally, so that the Placido disk is directed downwards.
2 Remove the plate as described in paragraph **"Replacement of the plate" on page 53.**
3 Disconnect the connection cable (A) from the connector (B) of the position sensor.
4 Disconnect the connection cable (C) from the connector (D) of the position sensor.

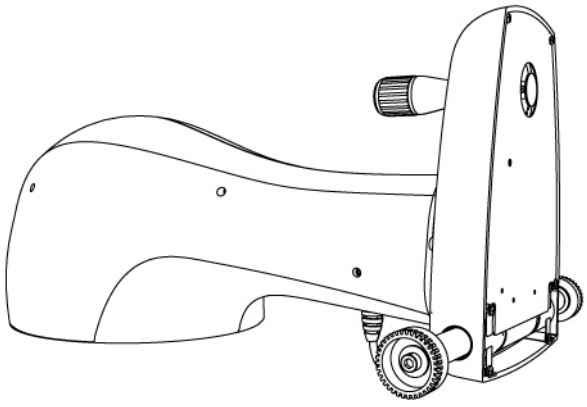


Fig. 81 - Position the device

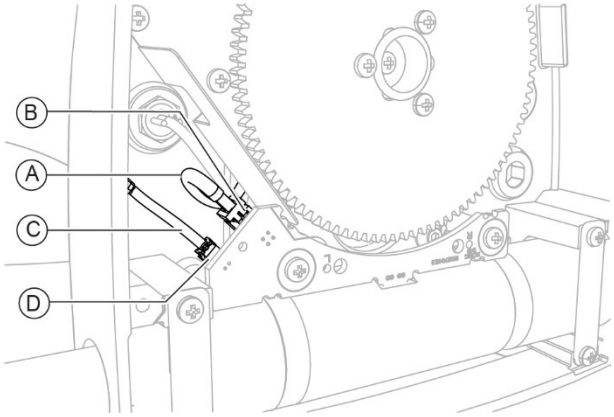


Fig. 82 - Disconnect the connection cables

5 Unscrew the screws (E).
6 Remove the position sensor.

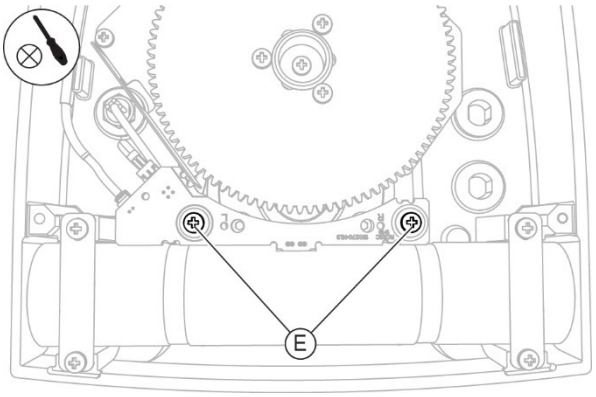


Fig. 83 - Unscrew the screws

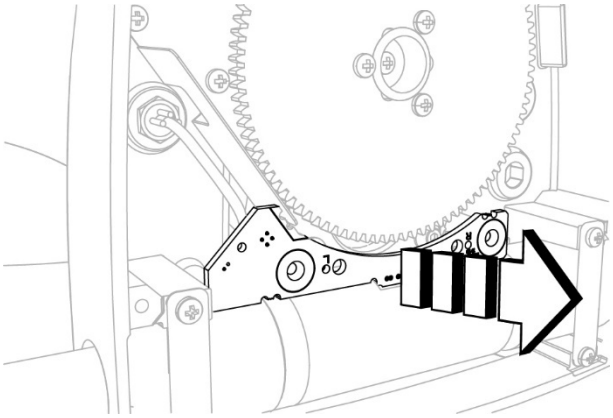


Fig. 84 - Remove the position sensor

Disassembling procedure for the position sensor tube assembly:

7 Unscrew the screw (F).
8 Remove the wheel (G).
9 Remove the rod (H).

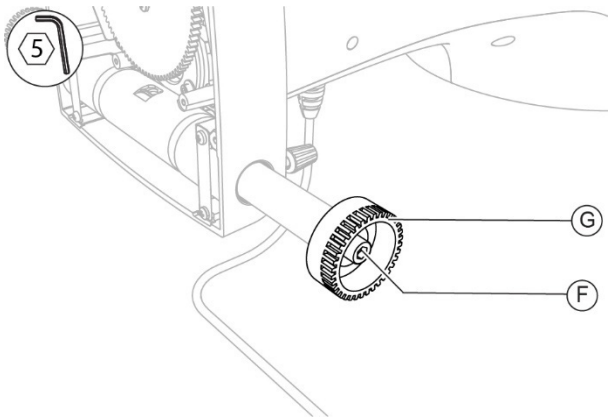


Fig. 85 - Unscrew the screws and remove the wheel

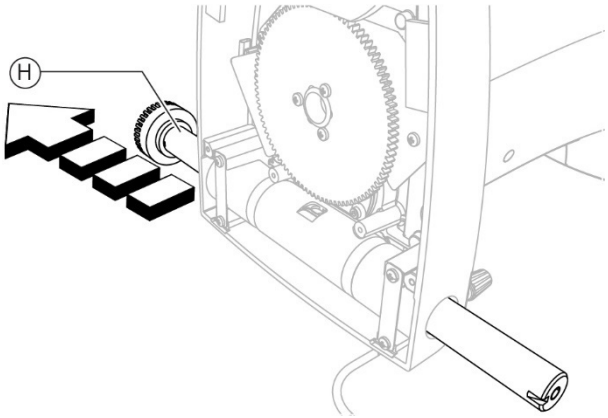


Fig. 86 - Remove the rod

10 Loosen the knob (I).
11 Unscrew the screws (J).
12 Remove the supports (K).

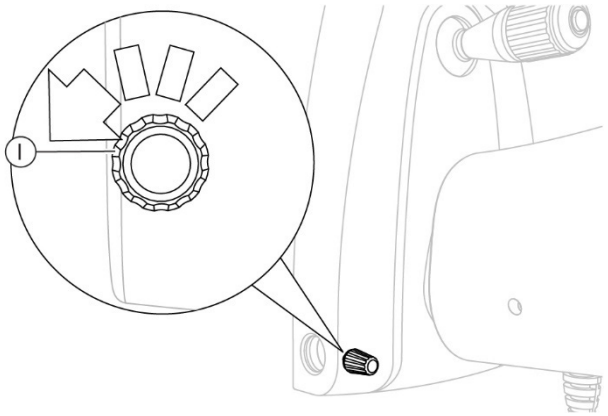


Fig. 87 - Loosen the knob

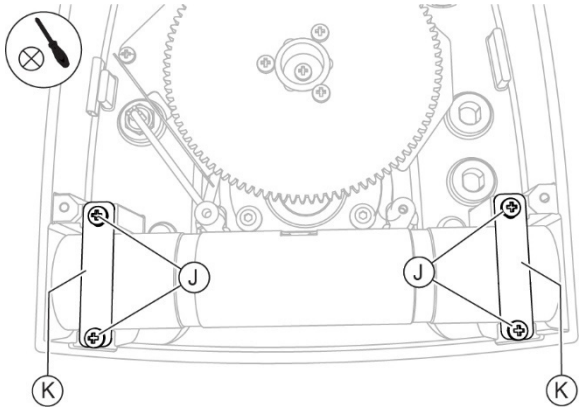


Fig. 88 - Unscrew the screws and remove the supports

13 Remove the position sensor tube assembly (L).

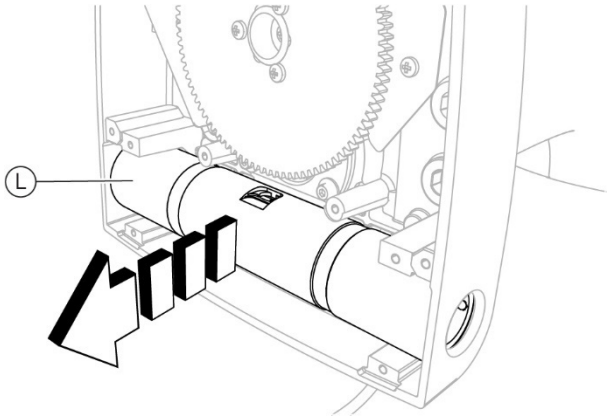


Fig. 89 - Remove the position sensor tube assembly

Assembling procedure for the position sensor tube assembly:

1 Align the hole (M) and the threaded hole (N).
2 Place the position sensor tube assembly (L) into the seat. The track (O) of the position sensor tube assembly (L) must face the operator.

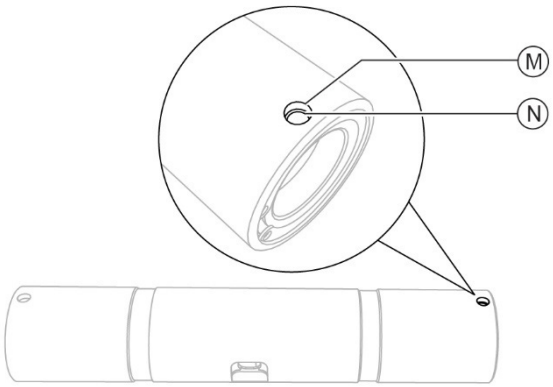


Fig. 90 - Align the holes

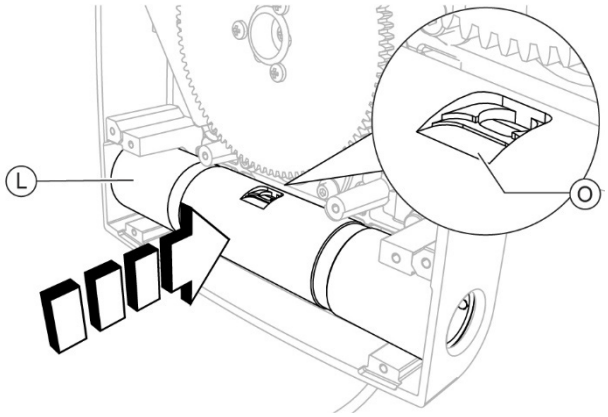


Fig. 91 - Place the position sensor tube assembly

3 Tighten the knob (I).
4 Insert the rod (H).

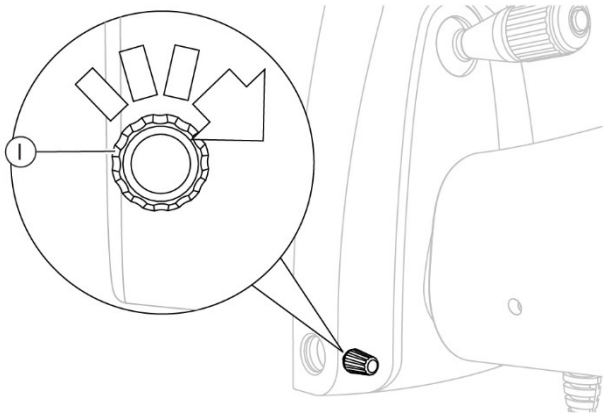


Fig. 92 - Tighten the knob

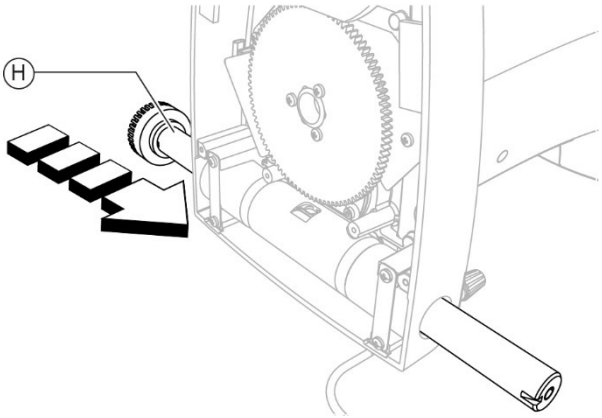


Fig. 93 - Insert the rod

5 Place the wheel (G).
6 Screw the screw (F).

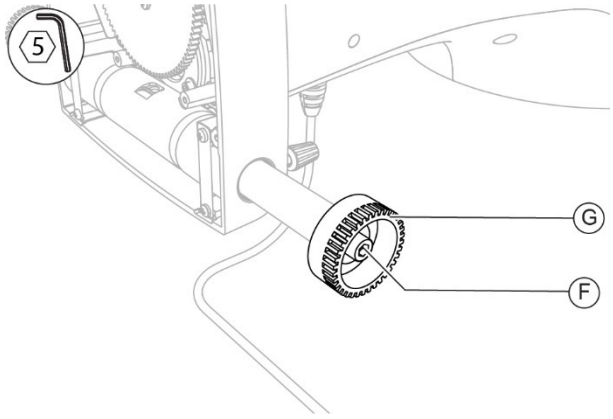


Fig. 94 - Place the wheel and screw in the screw

Assembling procedure for the position sensor:

7 Place the position sensor into the seat.
8 Screw in the screws (E).

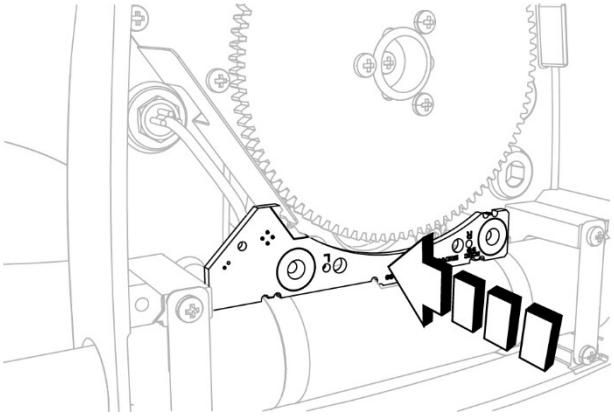


Fig. 95 - Place the position sensor

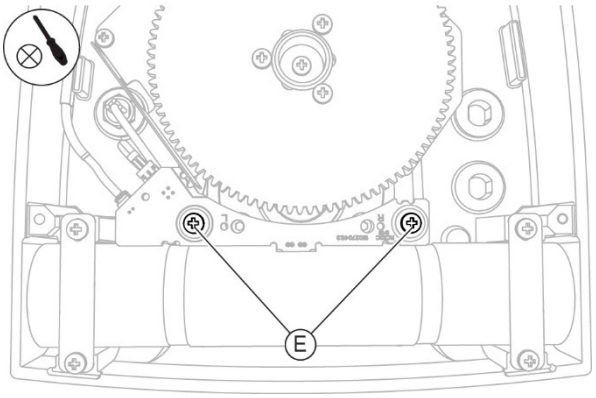


Fig. 96 - Screw in the screws

9 Connect the connection cable (C) to the connector (D) of the position sensor.
10 Connect the connection cable (A) to the connector (B) of the position sensor.

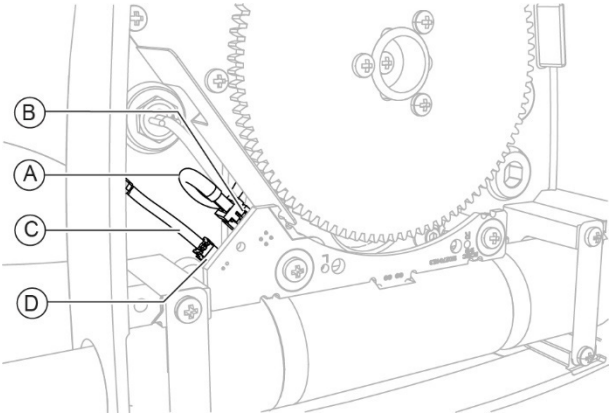


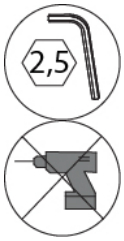
Fig. 97 - Connect the connection cables

11 Install the plate as described in paragraph **"Replacement of the plate" on page 53.**

When the operation is complete, carry out the electrical safety test as described in the paragraph **"Electrical safety check" on page 69.**

6.5.8 REPLACEMENT OF THE BASE

Material and warnings:



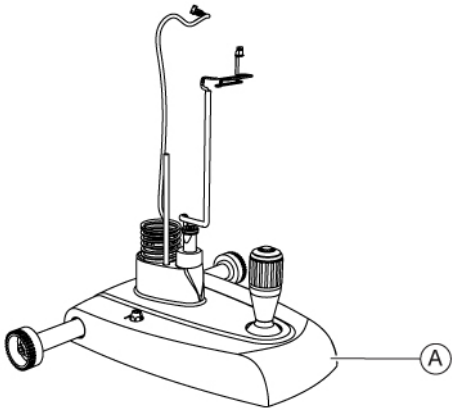


Fig. 98 - Base

Pos	Description	Code
A	Base	103107400

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

Before carrying out the replacement, make sure you have all the tools and materials required for the installation.

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

Base disassembling procedure:

1 Remove the protective shells as described in paragraph **"Replacement of protective shells" on page 49.**
2 Remove the USB 3.0 cable as described in paragraph **"Replacing the USB 3.0 cable" on page 51.**
3 Cut the cable tie (A) that secures the connection cable (B) and the connection cable (C).
4 Disconnect the connection cable (B) between the base and the Antares+ circuit board from the J15 connector (D).

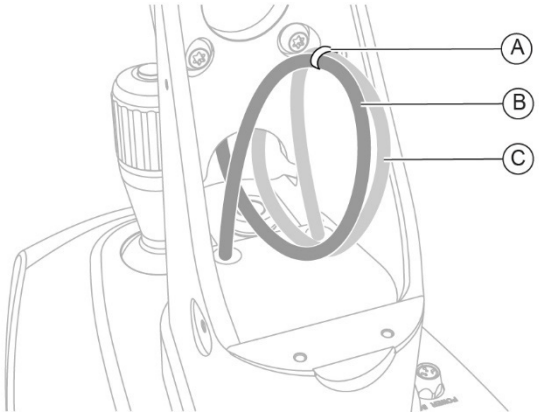


Fig. 99 - Cut the cable tie

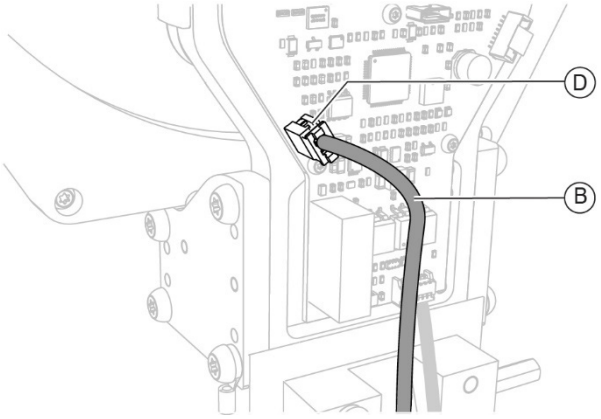


Fig. 100 - Disconnect the cable

5 Disconnect the connection cable (C) between the position sensor and the Antares+ circuit board from the connector J6 (E).
6 Unscrew the screw (F).

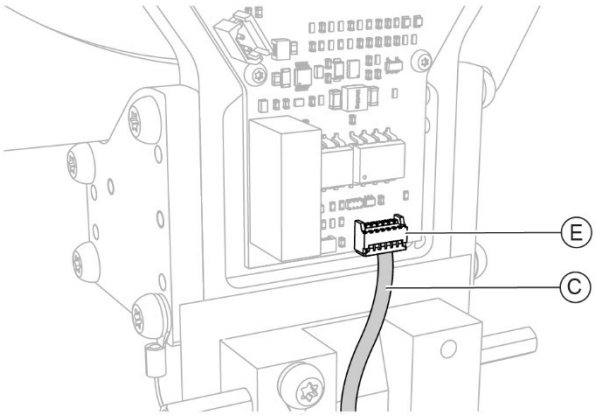


Fig. 101 - Disconnect the cable

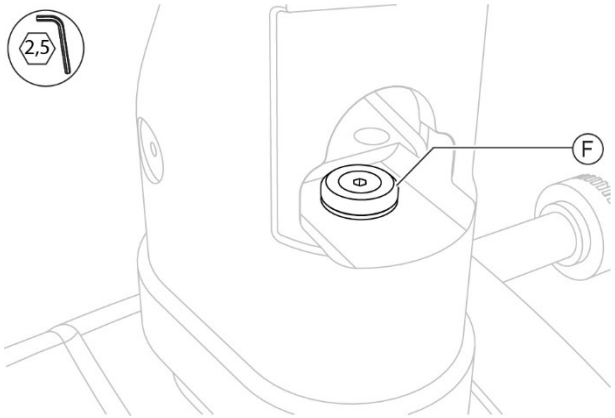


Fig. 102 - Unscrew the screw

7 Remove the structure assembly (G) from upwards.
8 When removing the structure assembly, be careful not to damage the connection cable (B) and the connection cable (C).

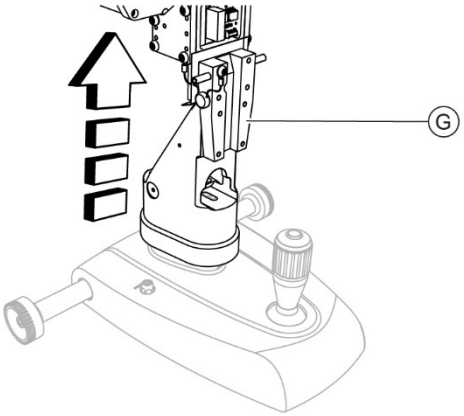


Fig. 103 - Remove the structure assembly

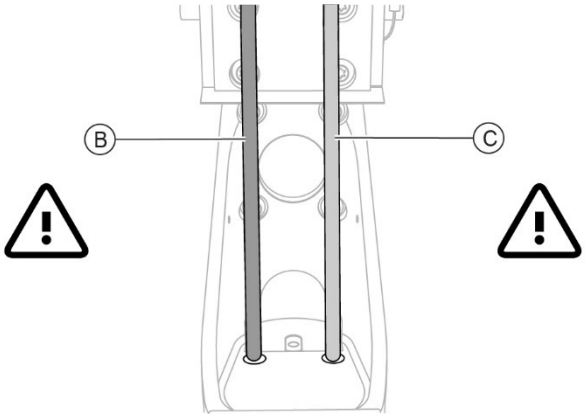


Fig. 104 - Remove the cables

Assembling procedure for the base:

1 Pass the connection cable (C) through the hole (I).
2 Pass the connection cable (B) through the hole (H).
3 Place the structure assembly (G) on the base.

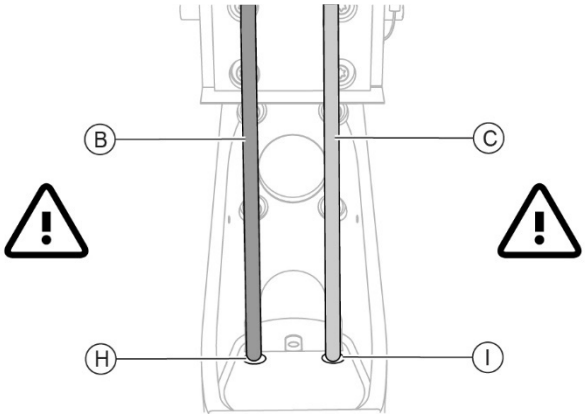


Fig. 105 - Pass the cables

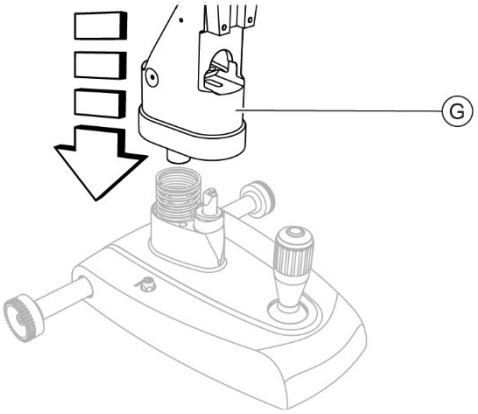


Fig. 106 - Place the structure assembly on the base

4 Screw the screw (F).
5 Connect the connection cable (C) between the base and the Antares+ circuit board to the connector J6 (E).

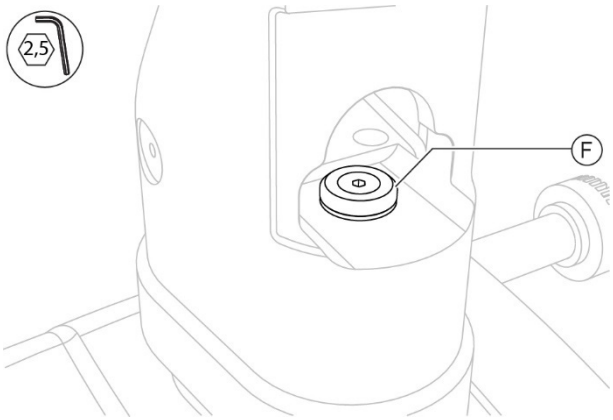


Fig. 107 - Screw in the screw

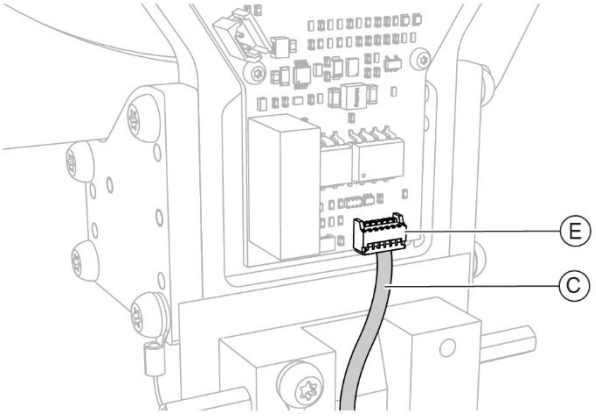


Fig. 108 - Connect the cable

6 Connect the connection cable (B) between the base and the Antares+ circuit board to the J15 connector (D).
7 Wind the connection cable (B) and the connection cable (C).
8 Place the cable tie (A).

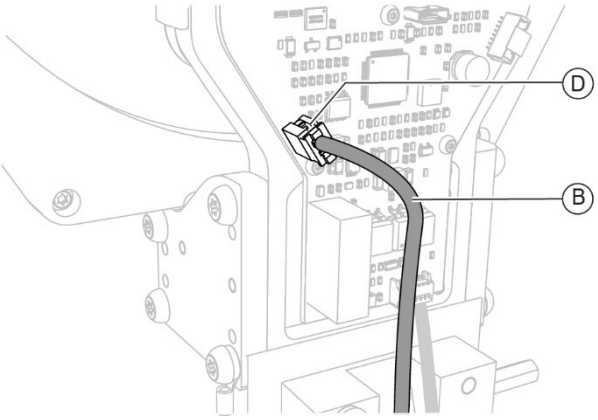


Fig. 109 - Connect the cable

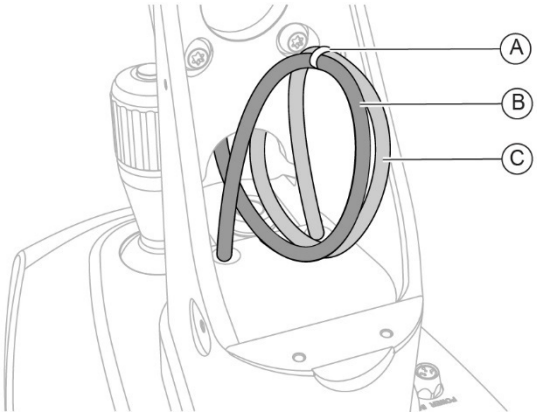


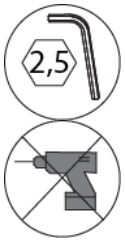
Fig. 110 - Place the cable tie

9 Install the USB 3.0 cable as described in paragraph **"Replacing the USB 3.0 cable" on page 51.**
10 Install the protective shells as described in paragraph **"Replacement of protective shells" on page 49.**

When the operation is complete, carry out the electrical safety test as described in the paragraph **"Electrical safety check" on page 69.**

6.5.9 REPLACEMENT OF THE STRUCTURE ASSEMBLY

Material and warnings:



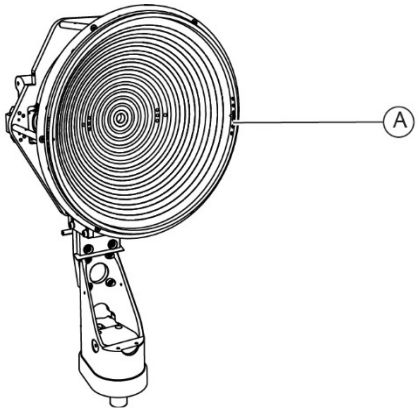


Fig. 111 - Structure assembly

Pos	Description	Code
A	Structure assembly	Contact the Technical Assistance Service

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

Before carrying out the replacement, make sure you have all the tools and materials required for the installation.

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

Disassembling procedure for the structure assembly:

1 Remove the protective shells as described in paragraph **"Replacement of protective shells" on page 49.**
2 Remove the USB 3.0 cable as described in paragraph **"Replacing the USB 3.0 cable" on page 51.**
3 Cut the cable tie (A) that secures the connection cable (B) and the connection cable (C).
4 Disconnect the connection cable (B) between the base and the Antares+ circuit board from the J15 connector (D).

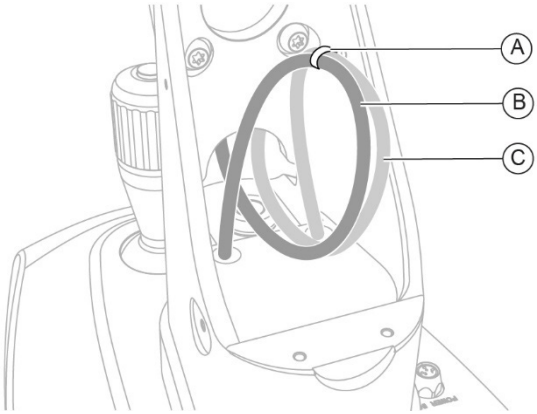


Fig. 112 - Cut the cable tie

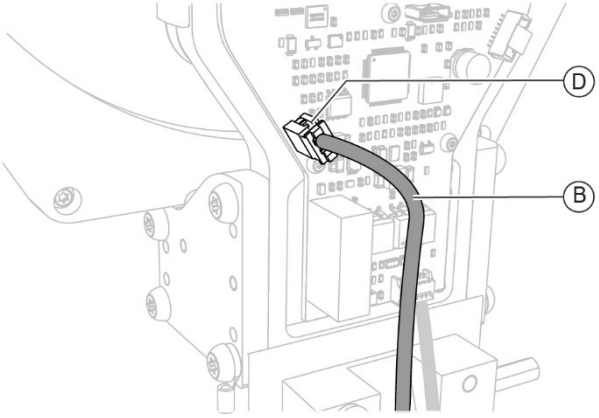


Fig. 113 - Disconnect the cable

5 Disconnect the connection cable (C) between the position sensor and the Antares+ circuit board from the connector J6 (E).
6 Unscrew the screw (F).

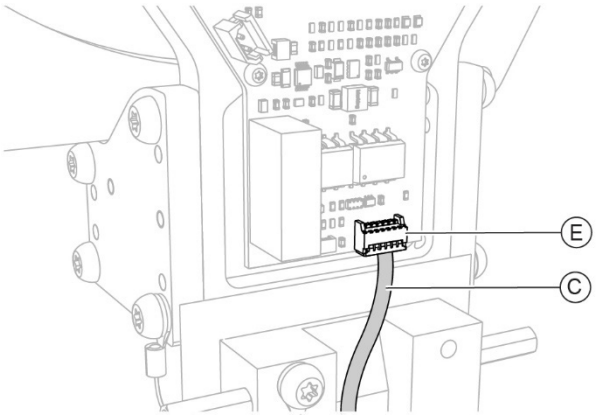


Fig. 114 - Disconnect the cable

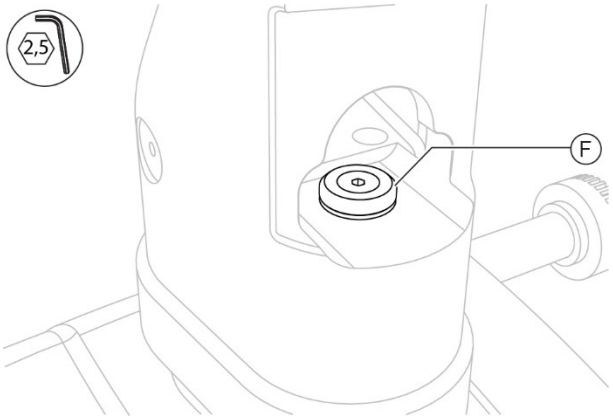


Fig. 115 - Unscrew the screw

7 Remove the structure assembly (G) from upwards.
8 When removing the structure assembly, be careful not to damage the connection cable (B) and the connection cable (C).

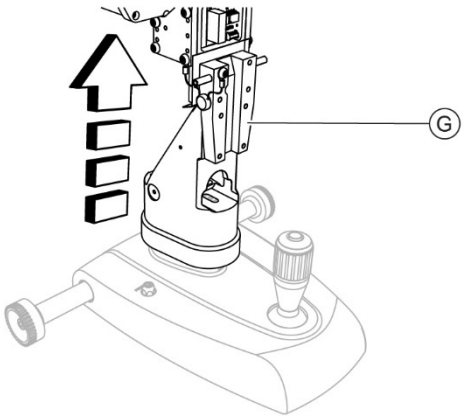


Fig. 116 - Remove the structure assembly

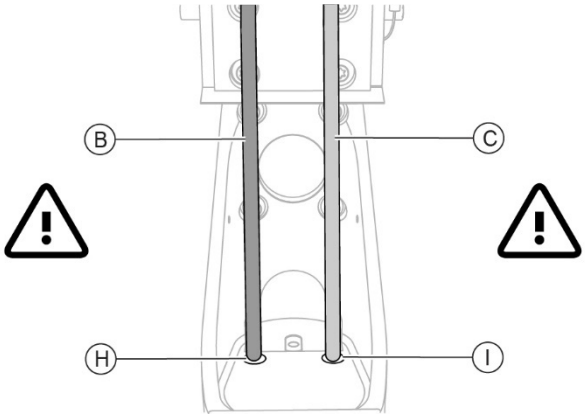


Fig. 117 - Remove the cables

Assembling procedure for the structure assembly:

1 Pass the connection cable (C) through the hole (I).
2 Pass the connection cable (B) through the hole (H).
3 Place the structure assembly (G) on the base.

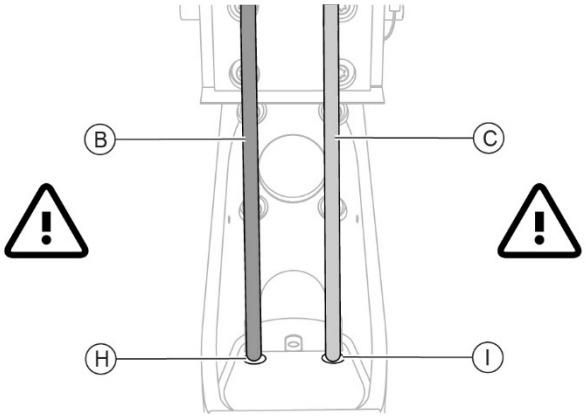


Fig. 118 - Pass the cables

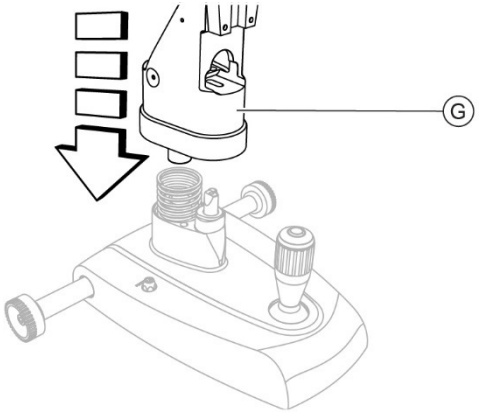


Fig. 119 - Place the structure assembly on the base

4 Screw the screw (F).
5 Connect the connection cable (C) between the base and the Antares+ circuit board to the connector J6 (E).

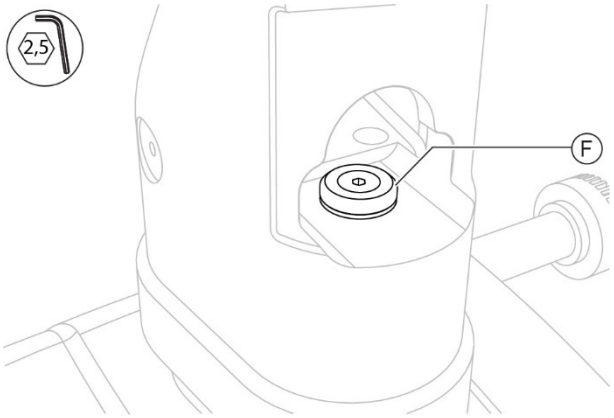


Fig. 120 - Screw in the screw

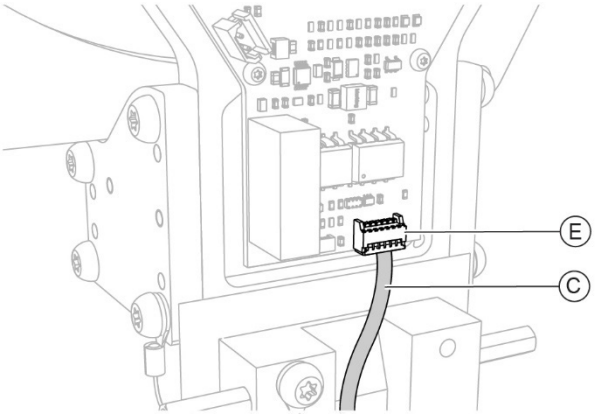


Fig. 121 - Connect the cable

6 Connect the connection cable (B) between the base and the Antares+ circuit board to the J15 connector (D).
7 Wind the connection cable (B) and the connection cable (C).
8 Place the cable tie (A).

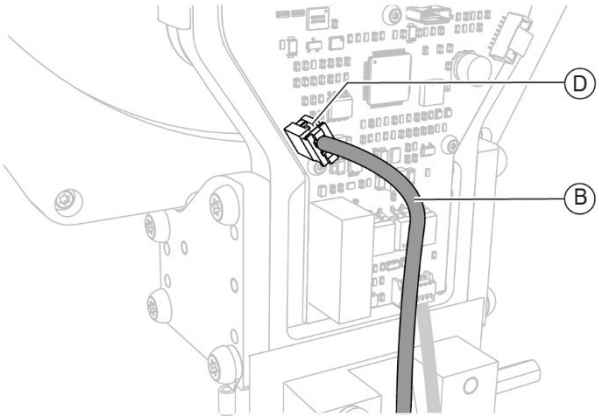


Fig. 122 - Connect the cable

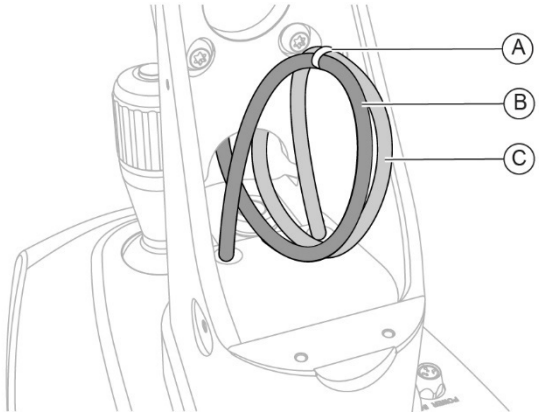


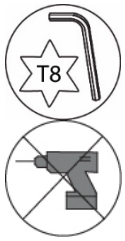
Fig. 123 - Place the cable tie

9 Install the USB 3.0 cable as described in paragraph **"Replacing the USB 3.0 cable" on page 51.**
10 Install the protective shells as described in paragraph **"Replacement of protective shells" on page 49.**

When the operation is complete, carry out the electrical safety test as described in the paragraph **"Electrical safety check" on page 69.**

6.5.10 REPLACEMENT OF THE RING

Material and warnings:



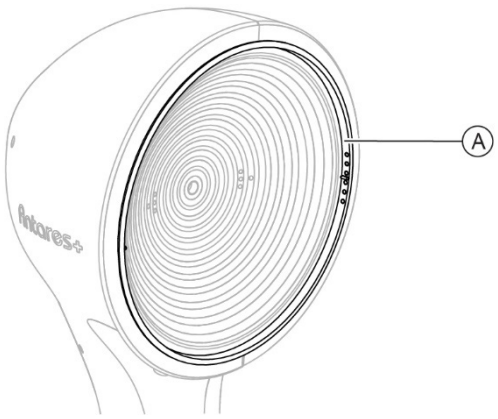


Fig. 124 - Ring

Pos	Description	Code
A	Ring	103107518

Before carrying out the replacement, make sure you have all the tools and materials required for the installation.

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

Disassembling and assembling procedure for the ring:

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

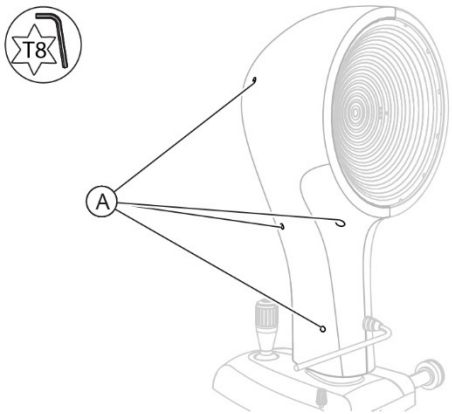


Fig. 125 - Unscrew the screws

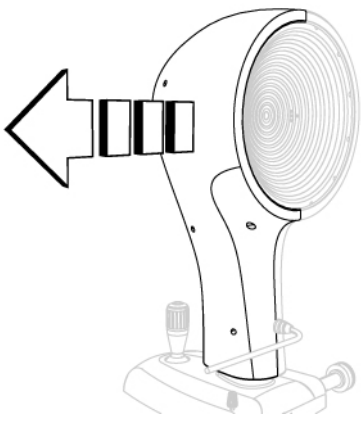


Fig. 126 - Remove the right protective shell

3 Remove the ring.

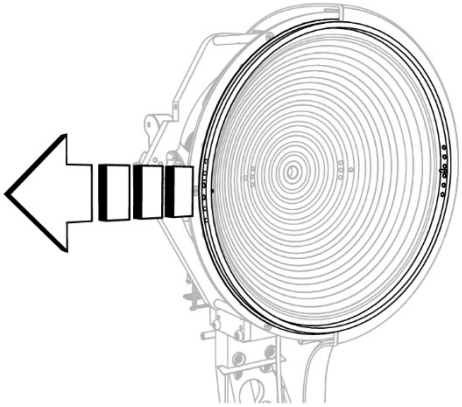


Fig. 127 - Remove the ring

4 For assembly, follow the procedure in reverse order.

6.6 ELECTRICAL SAFETY CHECK

The electrical safety test shall always be carried out after a technical intervention on the device, in compliance with IEC 62353 standard.

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

Do not touch the device during the test.

Medical device	Antares+	PSP2402
Description	Topographer	Power supply unit
Class	I	I
Type	B	B
Number of applied parts	1	1

1 Carry out a visual inspection of all components and cables to make sure that they are in proper condition.
2 For any doubt on the effectiveness of the isolation (such as multiple activation of the residual-current device or other protective devices in the medical field, or traces of liquid on the device that suggest the penetration of liquid), measure the isolation resistance with a test voltage of 500 V. The measured value shall not be less than 2 MΩ.
3 If the values are correct, the leakage current of the device must be measured. The residual current method is preferable. The device is working. Press the tip of the instrument again on the measuring points. The measured value must not exceed 0.5 mA.
4 Record and keep evidence of the tests and measurements taken during tests.
5 The test ends with a device operation test. This operation must be performed by a person familiar with the device application.

Procedure to carry out the electrical safety test:

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

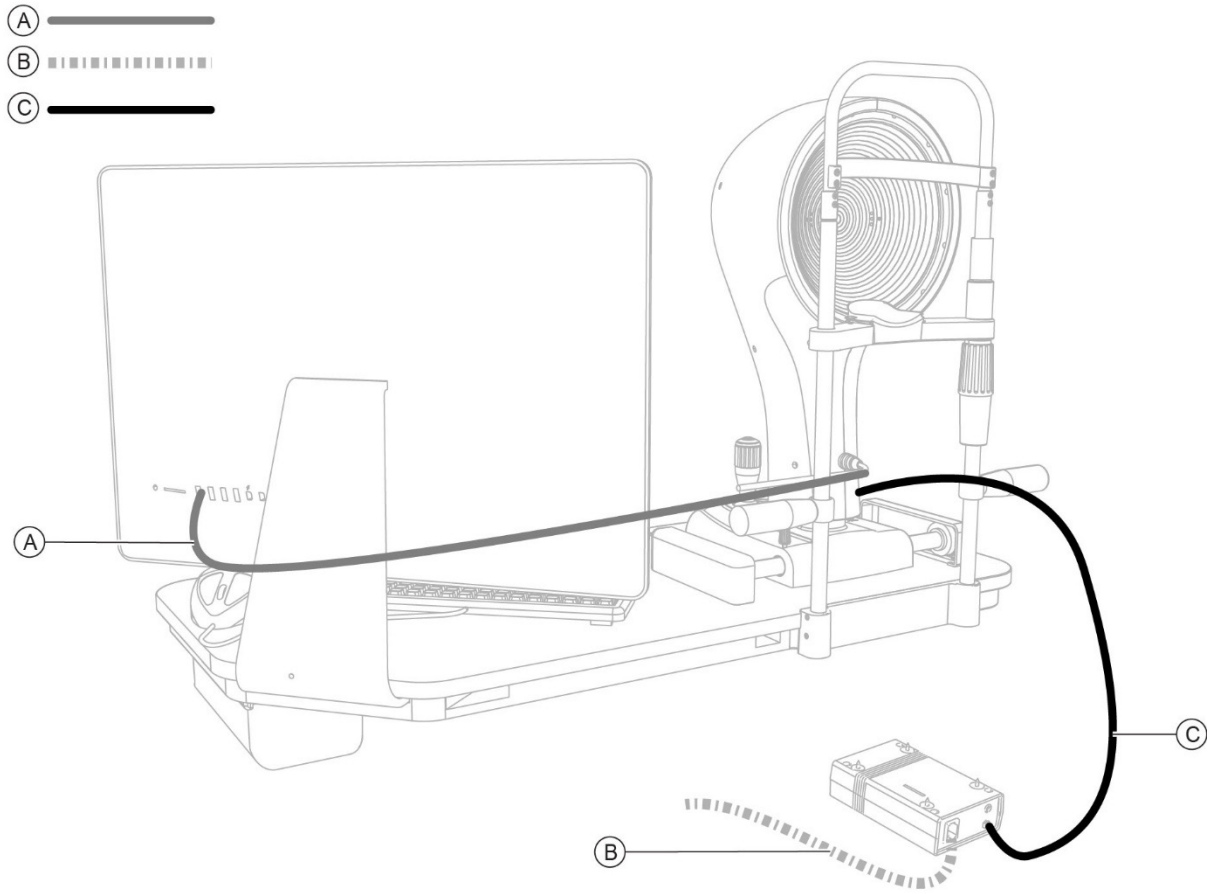


Fig. 128 - Connect the tester inside the patient area

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

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

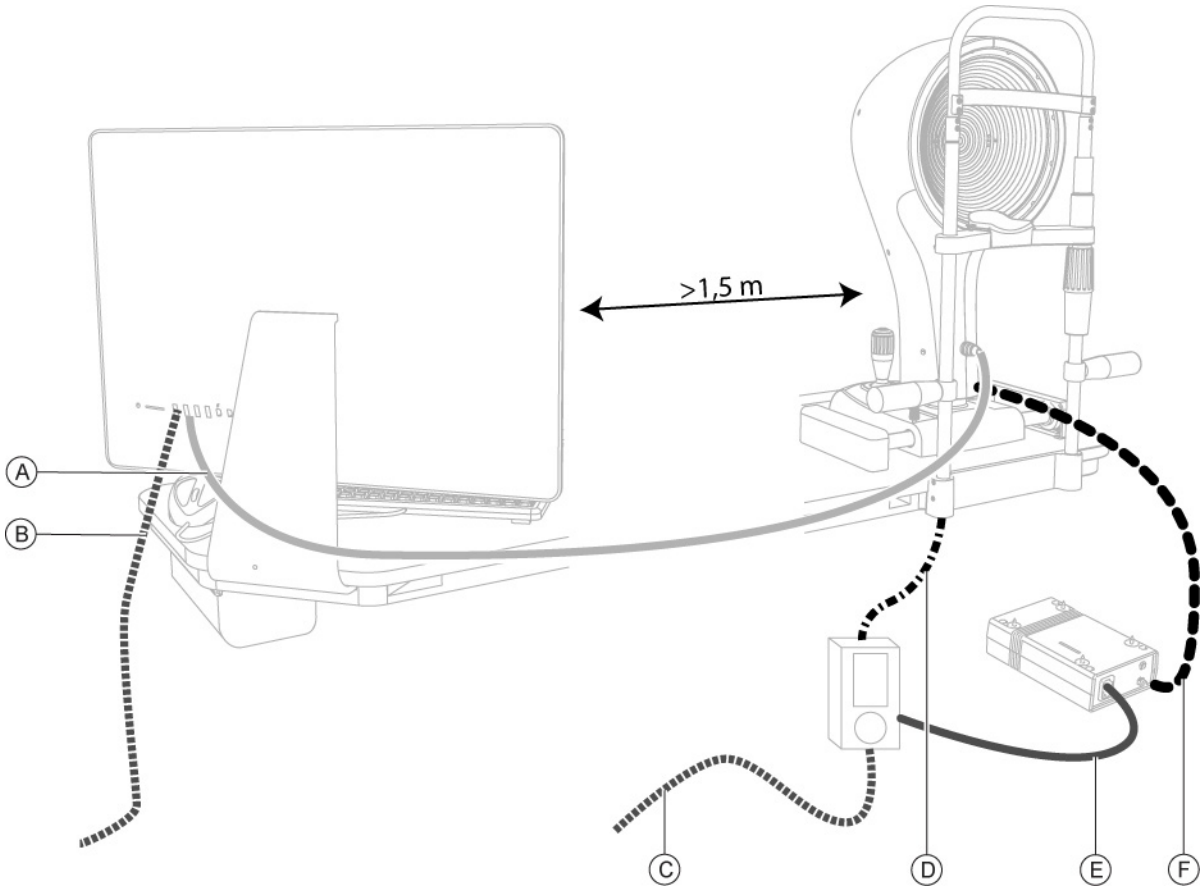


Fig. 129 - Connect the tester outside the patient area

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

3 Carry out the electrical safety test. Follow the instructions for use of the tester.
4 Print the test.
5 Check the test results are correct.
6 Include the test printing in the annexed documents of the activity report.

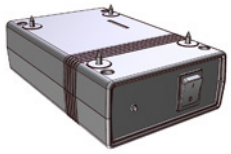
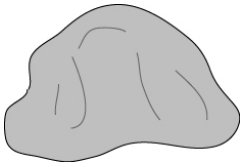
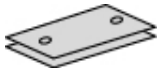
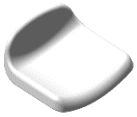
6.7 TESTING DEVICE OPERATION AFTER MAINTENANCE ACTIVITIES

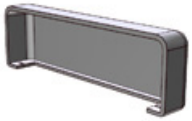
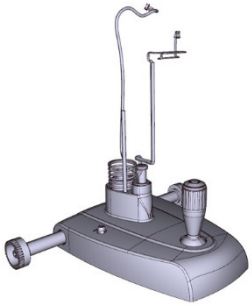
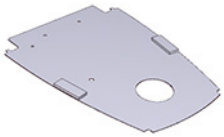
When the operation is complete, carry out the electrical safety test as described in the paragraph **"Electrical safety check" on page 69.**

After any maintenance activity, always check the device operation following the table below.

ID	Test type	Procedure	Acceptability criteria
1	**Check of the electronic components, the power supply unit, the power supply cables operation and the USB 3.0 cable**	Properly connect the power supply cables and the USB 3.0 cable. Turn the power switch of the power supply unit to ON.	Check if the green LED on the power supply unit is on. Check if the device is recognised by the application software without errors.
2	**Check of the hardware operation**	Start the Phoenix application software.	Check if the device is recognised by the application software without errors.
3	**Check of the proper operation of the joystick button**	Perform an acquisition by pressing the joystick button.	Check an image has been saved.
4	**Check of the proper operation of the base**	When the device is on, move the joystick back and forth, then left and right.	Check the base moves smoothly.
5	**Check of the proper operation of the joystick**	Turn the joystick clockwise and counter-clockwise.	Check the device moves upwards and downwards smoothly.
6	**Check of the right/left acquisition**	Carry out two acquisitions, one in the right position and one in the left position.	Check the two saved images show OD (Right eye), OS (Left eye) respectively.
7	**Check of the serial number correspondence**	Check that the serial number detected by the software matches the one on the device data plate.	The serial number detected by the software shall match the one on the device data plate.
8	**Check of the proper execution of the pupillography and the operation of the Placido disk**	Carry out the "Pupillography" examination and test the brightness settings of the Placido disk.	Selecting the different brightness intensities involves a corresponding visible variation of the Placido disk brightness intensity.
9	**Final check of the device**	Check the operation of the Phoenix application software as a further verification of the previous points.	Check for compliance.
10	**Device calibration check**	Follow the calibration instructions described in paragraph **"Device calibration" on page 38.**	Check for compliance.

7 LIST OF SPARE PARTS AND ACCESSORIES

Code		Description
3020804		USB 3.0 cable
30010071D3F		Power supply cable
101013-00		Isolation transformer 230V/230V Power supply cable 800 Va (maximum load)
103103900		Power supply unit (PSP2402)
4013090		Dust cover with CSO logo
4014010		Chin cup papers (100 pieces)
100130700		Chin rest
4001050		Chin rest handle
960130701		Chin cup
100232741		Forehead rest
100710100		Sliding plate

Code		Description
100710832		Wheel cover (1 piece) (colour V0)
100210415		Guide rail (1 piece)
100210414		Cogwheel (1 piece)
103107400		Base
100270420		Plate
100258402		Joystick button
100113401		Joystick
100136565S		Left protective shell (colour V0/AS3)

Code		Description
100136564S		Right protective shell (colour V0/AS3)
		Structure assembly
103107518		Ring
103107102		Diffusion filter
100136200		Calibration tool

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

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 require the obligation to notify the Manufacturer.

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