SA COSTRUZIONE STRUMENTI OFTALMICI



AS-OCT SERVICE MANUAL **MS-39**



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1 INTRODUCTION

The device MS-39 is the result of a long research period, 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

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

Symbol	Meaning
\triangle	Caution
A	Danger of electric shock
	Components sensitive to electrostatic discharges (ESD)
	Read the instructions for use
0	General obligation
i	Note. Useful information for the user
\bigcirc	General prohibition sign
	Manufacturer
CE	CE Marking (Directive 93/42/EEC)
MD	Medical device
X	Waste disposal in compliance with the Directive 2012/19/EU (WEEE) and 2011/65/EU (RoHS II)

1.1.1 DEVICE SYMBOLS

Symbol	Meaning
Ҟ	Type B applied part
	Class II device

1.2 GENERAL WARNINGS

THE INFORMATION GIVEN IN THESE INSTRUCTIONS FOR THE TECHNICAL ASSISTANCE REFER TO THE MS-39 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 on the device not mentioned in the instructions for the Technical Assistance.



Keep this manual close by for future consultation.

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



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

1.3 NORMATIVE REFERENCES

1.3.1 EU DIRECTIVES

- Directive 93/42/EEC and subsequent modifications and additions concerning medical devices
- 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 from electrical 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: Protection against light hazards"
- 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: <u>https://service.csoitalia.it/index.php</u>.

Together with the malfunction or fault description, the following information shall also be sent:

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

1.5 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 shall 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 power or connection cables if you have wet hands.

DANGER

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

CAUTION

Always keep the device out of the reach of children.

CAUTION

Danger of stumbling and falling. Do not leave free cables in a place where people could walk.

CAUTION

If a strange smell comes from the device, if the device emits heat or smoke, turn off the device immediately. Do not continue to use a damaged device or damaged part. Danger of injuries.

CAUTION

The power grid shall have a residual-current device ($I\Delta n=30mA$) and circuit breaker (Vn=230V) to protect the device. Place the device so that the power socket is easily accessible.

It is forbidden to carry out any maintenance on the device not mentioned 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 cable not authorized by the device Manufacturer.

The device is classified following the 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 the Italian Ministry of Health website at this page: <u>Ministero della Salute - Ricerca dispositivi</u>

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 - Data plate of the power supply unit

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 the technical specification IEC 60601-1

Technical data	Value
Type of protection against direct and indirect contacts	Class I
Applied parts	Туре В
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 inflammable detergents	No protection
Degree of electrical connection between device and patient	Devices with part applied to the patient
Use conditions	Continuous functioning

2.5 ENVIRONMENTAL CONDITIONS

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



CAUTION

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

2.6 DISPOSAL AT THE END OF THE USEFUL LIFE



Warnings for the correct disposal of the device in accordance with Directive 2012/19/EU and Directive 2011/65/EU relating to the reduction of the use of hazardous substances in electrical and electronic equipment, as well as waste disposal.

At the end of its useful life, the device shall not be disposed of as urban waste. The device may be delivered to designated waste sorting centres set up by the municipal administration or to dealers that offer this service. Separately disposing of an electrical device prevents possible negative consequences for the environment and health, caused by its improper disposal, and lets the materials it is made of to be recycled so as to achieve significant savings of energy and resources. The symbol of the crossed-out wheeled bin is shown on the data plate of the device. The graphic symbol of the crossed-out wheeled bin indicates the obligation to separately collect and dispose of the electrical and electronic equipment at the end of their useful life.



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

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

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

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The Manufacturer is available to provide the user with information regarding the dangerous substances contained in the device, the recycling of these substances and the potential reuse of the used device.

Strict administrative sanctions for transgressors are provided for by law.

For specific information about the disposal in countries other than Italy, contact the local Dealer.



3 DEVICE DESCRIPTION

3.1 SUPPLY DESCRIPTION



Fig. 5 - Supply description

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



Optional: accessory not provided with the basic supply.



3.1.1 DEVICE



Fig. 6 - Device

Pos	Description		
Α	Upper right cooling fan		
В	Device		
С	Right protective shell		
D	Placido Disk		
E	Ring		
F	USB 3.0 cable		
G	Sliding rod		
н	Joystick button		
I	Plate		
J	Upper left cooling fan		
К	Power Supply circuit board		
L	Left protective shell		
М	Lower cooling fan		
N	Joystick		
i	For the full list of parts and their features, refer to the "Spare parts and accessories list" on page 84.		

3.1.2 POWER SUPPLY UNIT



Fig. 7 - Power supply unit

Pos	Description	
Α	Data plate	
В	Power supply unit	
С	Power indicator light	
D	Power switch	
Е	Connector of the device power supply cable	
F	Connector of the power supply unit power supply cable	
G	Power supply cable of the power supply unit	
Н	Device power supply cable	



3.1.3 CHIN REST



Fig. 8 - Chin rest

Pos	Description
Α	Chin rest support (*)
В	Handle
С	Chin cup adjustment knob
D	Chin cup
Ε	Forehead rest
F	Chin rest structure



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



3.1.4 PERSONAL COMPUTER

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

(internet in the second second

Read the document "Minimum PC requirements" which can be downloaded from the website <u>www.csoitalia.it</u> under the section "Documents - Software download" (registration required). Read the instructions for use of the application software.



Fig. 9 - Personal Computer



The PC shall comply with standard IEC 62368-1 "Information technology equipment - Safety - Part 1: General requirements".

If the PC is installed in the patient area it is necessary to install an isolation electrical supply compliant with the 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.

Accessories (printer, modem, scanner, etc.) shall be installed outside the patient area.



The accessories shall comply with standard IEC 62368-1 "Information technology equipment - Safety - Part 1: General requirements".

If the accessories are installed in the patient area it is necessary to install an isolation electrical supply compliant with the 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	
Mains power	External power supply unit 24 VCC In: 100-240 VAC - 50/60 Hz - 4 A Out: 24 VDC 4 A	
Network cable	with C14 socket	
Dimensions (Height x Length x Depth)	505 x 315 x 251 mm	
Weight	10.4 kg	
Chinrest stroke	70 mm ±1	
Minimum height of the chin cup from the work surface	23 cm	
Base movement (x, y, z)	105 x 110 x 30 mm	
Working distance	74 mm	

Light sources

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

Topography

Technical data	Value
Placido Disk	22 rings
Measured points	31.232 (anterior surface) 25.600 (posterior surface)
Topographic covering	ø 10 mm
Accuracy	Class A based on UNI EN ISO 19980

Section

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

INSTALLATION 4

ASSEMBLING THE INSTALLATION ACCESSORIES ON THE TABLE TOP 4.1



Fig. 10 - Installation accessories on the table top

Pos	Description
Α	Front edge of the table top (Patient side)
В	Left guide rail
С	Sticker pad
D	Sliding plate
Е	Inserts for fixing the chin rest on the underside of the table top
F	Right guide rail
G	Rear edge of the table top (Operator side)

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Procedure for assembling the installation accessories on the table top:

- Install the right and left guide rails on the table top. Use self-tapping screws Ø 2.9 x 13.
- Install the sliding plate on the table top.
 Use self-tapping screws Ø 2.2 x 2.9. Alternatively, apply the adhesive plate (code 100710100).



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 installation on the table top

- 3 Carefully clean the surface of the table top.
- 4 Verify the sticker pad position respectively to the central axis (A).
- 5 Remove the protective film. Place the sticker pad between the two guides and the sliding plate.



Respect the indicated distances while placing the sticker pad on the table top.



Fig. 12 - Distances for installing the sticker pad



Fig. 13 - Place the sticker pad

4.2 INSTALLING THE DEVICE



CAUTION

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

- 1 Install the guides, the sliding plate and the sticker pad 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. 14 - Place the power supply unit

- 4 Place the device on the table top and align the cogwheels on the guide rails.
- 5 Install the two wheel covers on the guides on the table top.



Fig. 15 - Place the device

Fig. 16 - Install the wheel covers





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



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



Fig. 17 - Place the chin rest

Fig. 18 - Correct height of the eye level indicator

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



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



Fig. 19 - Loosen the grub screws of the chin rest



Fig. 20 - Maximum adjustment height of the rods

10 Carry out the electrical connections between the components.



Fig. 21 - Device connections

Pos	Name
Α	USB 3.0 connection cable between the device and the PC
В	Power supply cable of the power supply unit
С	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.







CAUTION

POSITIONING OF ELECTRICAL CABLES

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



CAUTION

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



DANGER

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



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

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



The power socket located on the lower part of the column of the ophthalmic table is specific for the connection to the power grid. One of the power sockets placed 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.

Select Se	tup Language	×
	Select the language to use during the installation.	
	English	\sim
	OK Cancel	

Fig. 22 - 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.

Setup	_		×
Select Destination Location			
Where should be installed?		Ć	
Setup will install into the following folder.			
To continue, click Next. If you would like to select a different folder, click Browse.			
C:\Program Files \CSO\	В	rowse]
At least 197.4 MB of free disk space is required.			
Ne	ext >	Can	cel

Fig. 23 - Select the destination path

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



13



12 Click on *Next* to continue.

Setup	_		×
Select Start Menu Folder Where should Setup place the program's shortcuts?		(
Setup will create the program's shortcuts in the following Start Menu folder.			
Software	Br	owse	

	< Back	Next >	Cancel
Fig. 24 - Select the desti	nation pa	th	

Click on *Install* to start the installation procedure.

Se	tup			_		×
Rea	Idy to Install ietup is now ready to begin installing on your computer.					Ð
(lick Install to continue with the installation, or dick Back if you wa	int to review of	r change a	ny setti	ngs.	^
	C:\Program Files \CSO \ Software Setup type:					
	custom Selected components:					
	Application Start Menu folder:					
	3011/0812					
						~
Į	<			_	>	
		< Back	Insta	I	Ca	incel

Fig. 25 - Start the installation



14 When the prompt pop-up appears on the screen, if you want to download the demo database, click on *Yes*.

An internet connection is required to download. Otherwise, the installation procedure ends.

The demo database is created in C:\DBPhoenix. If another *DBPhoenix* folder is already present in the path, the demo database will not be installed.

 Setup - Phoenix4 version 4.1.1.5 Installing Please wait while Setup Installs Phoenix4 on your computer. 	- ×
Setup Po you want to download and install a samples database? Yes No	
	Cancel

Fig. 26 - Download the demo database

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



Fig. 27 - Complete the installation

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

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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.



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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.

🖟 Microsoft Visual C++ 2008 Redistributable Setup - 🗆 🗙	nicrosoft Visual C++ 2010 x64 Redistributable Setup 🦳 🗌
License Terms	Welcome to Microsoft Visual C++ 2010 x64 Redistributable Setup Please, accept the license terms to continue.
Be sure to carefully read and understand all the rights and restrictions described in the license terms. You must accept the license terms before you can install the software.	MICROSOFT SOFTWARE LICENSE TERMS
MICROSOFT SOFTWARE LICENSE TERMS	MICROSOFT VISUAL C++ 2010 RUNTIME LIBRARIES WITH SERVICE PACK 1
MICROSOFT VISUAL C++ 2008 RUNTIME LIBRARIES (X86, IA64 AND X64) These license terms are an agreement between Microsoft Corporation (or based on where you live, one of its affiliates) and you. Please read them. They apply to the software named above, which includes the media on which you received it, if any. The terms also apply to any Microsoft	These license terms are an agreement between Microsoft Corporation (or based on where you live, one of its affiliates) and you. Please read them. They apply to the software named above,
Print Press the Page Down key to see more text.	✓] I have read and accept the license terms.
1	
☐ I have read and accept the license terms.	For more information, read the <u>Data Collection Policy</u> .
< Back Install > Cancel	2 Install Cancel

Fig. 28 - 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.

🖽 Windows Security	×
Would you like to install this device software?	
Name: Alkeria www.alkeria.com Imaging devices Publisher: Alkeria, Srl	
Always trust software from "Alkeria, Srl".	Don't Install
You should only install driver software from publishers you trus decide which device software is safe to install?	it. <u>How can l</u>
Fig. 29 - 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.

Welcome to the Setup Wi	zard		
The installer will guide you through the step	os required to insta	a'	
WARNING: This computer program is prote Unaufhorized duplication or distribution of t or criminal penalties, and will be prosecuted	acted by copyright his program, or any d to the maximum e	law and internationa portion of it, may re- extent possible under	Irreaties. sult in servere civil the law.

Fig. 30 - 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.

					f	
Language	Database	Miscellaneous	DICOM	Connectivity	Maintenar	nce
📀 SQLite	MySQL					
SOLite	Database p	ath				
and and	C:\DBPhoen	ix\database.db3	l.		1	4
Advance	d options -					

Fig. 31 - Database configuration

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





4.5.1.1 ACTIVATION AND REGISTRATION OF THE PHOENIX APPLICATION SOFTWARE



- There are two license modules available.
- **DEFAULT**: includes the basic functionalities for all devices and pupillography functions.
- Sirius IOL: includes advanced topography, pupillography and IOL calculation functions.
- 1 Verify the device serial number.

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



Fig. 32 - Popup window



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

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. 33 - 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.

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

Sof	tware activation required	\times
P	Communicate this code to claim your activation key:	
	XXXXXXXXX-XXXX-XXXXXXXXXXXXXXXXXXXXXXX	
	Enter your activation key here:	

Fig. 34 - 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.

Soft	ware activation required	\times
P	Communicate this code to claim your activation key:	
	XXXXXXXXX-XXXX-XXXXXXXXXXXXXXXXXXXXXXX	
	Enter your activation key here:	
	XXXXXXXX - XXXX - XXXX - XXXXXXXX	

Fig. 35 - 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.

Sof	tware activation required	\times
Þ	Enter your software license number:	
	P - 00000 Ok	
	<u>Use a free trial (59 left)</u>	

Fig. 36 - 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.



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. 39 - 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 ($-\frac{1}{2}$).



Settings AEs (Generic			AE Configuration
PACS	DCM4CHEE	O PPS		AE Title: DCM4CHEE
PMS	DCM4CHEE	PPS		Host: 10.10.90.19
Local A	MOD_TEST	Port	11113	Port: 11112
		Ok	Cancel	Ok Cancel





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*.



ettings		IOD Configuration				
Es Generic		Aberrometry	Send as:	Raw Data Storage	~	^
Auto-Send mode:	Max number of results:	Anterior Segment Imaging (Image)	Send as:	Ophthalmic Photography 8 Bit Image Storage	e ~	Importable
Disabled \vee	100 ~	Anterior Segment Imaging (Video)	Send as:	Video Photographic Image Storage	~	Importable
Enable auto-send PDF	Retrieve mode:	AS-OCT Corneal Mapping	Send as:	Raw Data Storage	~	
Enable MPPS Filter search by contained modalities	Character Set:	AS-OCT Lens biometry	Send as:	Raw Data Storage	~	
Filter MWL by Scheduled AE Title	ISO_IR 192 V	AS-OCT Section (Image)	Send as:	Raw Data Storage	~	
Send images as ImplicitVRLittleEndian		AS-OCT Section (Video)	Send as:	Raw Data Storage	~	
Propagate daily Accession Number	lobs	Comeal Topography	Send as:	Raw Data Storage	~	

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Fig. 42 - General settings



4.5.5 UPDATING THE PHOENIX APPLICATION SOFTWARE

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



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



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



Before updating the Phoenix application software, make a backup of the patients archive currently used with the device. Follow the procedure described in paragraphs "Import and export of examinations" on page 37 and "Backup of the database archive and restoration of patient examinations" on page 37.

Operating system	Versions of the Phoenix application software			
	3.7	4.0.1.8	4.1.4.7	
Windows 7 Home Premium or Professional 32 bit with SPK1	Х			
Windows 7 Home Premium or Professional 64 bit with SPK1	Х			
Windows 8/8.1 Home or Pro 32 bit	Х	X (*)		
Windows 8/8.1 Home or Pro 64 bit	Х	X (*)		
Windows 10 Home or Pro 64 bit	Х	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 ($^{\bigcirc}$) at the bottom right of the main screen of the Phoenix application software. A red icon ($^{\diamond}$) 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. 44 - Download the update

Fig. 45 - Download in progress

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



Fig. 46 - Install the update

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



Fig. 47 - 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*.
- Click on the *Export patient* icon (⁽¹⁾).
 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 on NEW PATIENT and enter the personal data. If the patient is already present in the database, you can automatically search for their surname by typing it into the command prompt. A new examination will be created automatically.
- 6 Select the device to be used.
- 7 The image acquisition screen will open. Image acquisition can be now carried out.
- 8 If the device is started for the first time or after a long period of non-use, the device calibration shall be performed. Carry out the calibration as described in the paragraph **"Device calibration" on page 38.**





4.7 DEVICE CALIBRATION



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



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

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



Follow the instructions for calibrating the device provided in the Phoenix application software guide.

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



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

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



Fig. 48 - Place the calibration tool



Fig. 49 - 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. 50 - Click on the calibration button



It is highly recommended to calibrate the instrument and check the curvature of the test sphere at least once a month.

Curvature Calibration

Curvature calibration is necessary to permit the program to correctly measure the curvatures and is composed of two steps.

1 Position the instrument as illustrated and follow the instructions as reported on the windows.



Fig. 51 - Curvature calibration Step 1/2

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Fig. 52 - Curvature calibration Step 2/2

- 2 If the calibration procedure is performed correctly, a confirmation message will appear on screen.
- 3 After having successfully calibrated you should do an AS-OCT Topography exam of the 8mm sphere (eye test modality) to verify correct instrument calibration. If the processed measurements are not found to be reliable, repeat the entire calibration procedure. Last image represents the acquisition summary for a sphere after a correct calibration procedure.



Fig. 53 - Acquisition of a 8mm calibration sphere

4.8 TESTING DEVICE CALIBRATION

Automatic calibration check

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

- 1 Click $\square \square$ 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 V 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 Phoenix application software guide.



5 ORDINARY MAINTENANCE

5.1 SAFETY WARNINGS

Â

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 on the device not mentioned 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

\wedge

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



CAUTION

CAUTION

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



CAUTION

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



Cleaning and disinfection procedures shall be routinely carried out.



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

Device parts that do come into direct contact with the patient shall be thoroughly cleaned and disinfected after each use.

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



RECOMMENDED PRODUCTS FOR CLEANING AND DISINFECTION 5.2.1



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 takes into account both the sensitivity of the device to specific substances and the product's disinfecting effectiveness.

For cleaning and disinfection procedures, use products approved by the FDA or EC for medical devices or medical-surgical devices.

Abide by the products listed below, divided by category:

Use polyenzymatic solutions or neutral surfactant-based solutions. Detergents

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

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

5.2.2 CLASSIFICATION OF THE CRITICALITY OF THE DEVICE



CAUTION

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

This device is classified as "non-critical", since it only comes into contact with intact skin and therefore has a low infectious risk.

For devices classified as non-critical, regular cleaning or low-level disinfection is sufficient. However, when the patient's condition is transmissible by direct contact or in the case of accidental exposure to body fluids, the device shall be disinfected with a higher-level disinfectant after cleaning.

5.2.3 **DEVICE CLEANING**

CAUTION

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



CAUTION

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

The device shall be regularly cleaned.



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

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

For more information about suitable cleansing products, read the 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.



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

- 1 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 cleansing products, read the 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

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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 on the device not mentioned 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 "Spare parts and accessories list" on page 84.



The electrical safety test shall be carried out in accordance with the EN60601-1 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.

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

6.2 FLOW CHARTS

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Technical Assistance.

Only use original spare parts to replace device components. The code is indicated within the **"Spare parts and accessories list" on page 84.**





NO Is the device YES being installed? Read the paragraph "How to install the Phoenix application software" and follow the instructions therein YES Does the operating NO system detect the video camera⁽¹⁾? NO Is the device YES now fully functional? Is the power NO YES supply unit working Check the operation of the USB 3.0 cable properly? Does the Phoenix Replace the power supply unit and the power supply cable application software detect the device? YES NO Faulty 3.0 USB cable? Check the operation of the USB 3.0 port of the PC YES Replace the USB 3.0 port YES Faulty USB 3.0 port⁽²⁾? NO YES Does the operating YES Is the device now NO system detect the fully functional? video camera(1)? NO Reinstall the drivers⁽³⁾ NO Send the device to Manufacturer for repair NO Has the issue been solved? YES Close the activity report

The Phoenix software cannot detect the device

¹⁾ Access "Device manager>image acquisition devices" and check that the acquisition devices (OCT4KSuperSpeed Camera) are correctly detected.

²⁾ Minimum functional requirement: USB 3.0 port with Texas Instruments or Intel chipset and HUB with power supply unit.

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³⁾ MaestroUSB3.exe drivers path: C:\Program Files\CSO\Phoenix4\Live\Drivers.



ID	Message	Cause	Solution
PHMS001	SW0001	The antivirus software installed on the PC prevents the Operating System to call <i>Mutex</i> objects.	 Check that there are no security settings or policies on the PC that are preventing the "ASOCT_Live.exe" process from working properly. Check that the Firewall or antivirus software installed on the PC is not preventing the "ASOCT_Live.exe" process from working correctly.
PHMS002	SW0002	The destination folder of the Monitor logs in the local filesystem cannot be created/read. The file corresponding to the current date logs is currently locked by another process or compromised.	 Check that there is no zombie instance of "ASOCT_Live.exe". Check that there are no security settings on the PC that are preventing the "ASOCT_Live.exe" process from working properly. End the process via Task manager>Details>Search "ASOCT_Live.exe">End task manager>Details>Search "ASOCT_Live.exe">End task. Delete the daily log file from the "C:\ProgramData\P4Data\Diagnostic\ASO CT_XXXXXXXXX\MonitorLogs\ml_XXXXX XXX.log" folder.
PHMS003	SW0003	The destination folder of the Online logs in the local filesystem cannot be created/read. The file corresponding to the current date logs is currently locked by another process or compromised.	 Check that there is no zombie instance of "ASOCT_Live.exe". Check that there are no security settings on the PC that are preventing the "ASOCT_Live.exe" process from working properly. End the process via Task manager>Details>Search "ASOCT_Live.exe">End task manager>Details>Search Delete the daily log file from the "C:\ProgramData\P4Data\OnlineLogs\ASOCT_XXXXXXX_XXXXX.xml" folder.
PHMS004	CM0001	Unclassified error occurred during the <i>Instrument diagnostics</i> procedure.	 Check that the "MaestroUSB3 CSO Ed." drivers are properly installed on the PC. Uninstall the "MaestroUSB3 CSO Ed." drivers. Restart your PC. Turn the power switch of the power supply unit to ON to turn on the device. Connect the device to the PC. Open the Phoenix application software: the

6.3 **MESSAGES OF THE APPLICATION SOFTWARE**

0 47/92 drivers will reinstall automatically.



ID	Message	Cause	Solution
PHMS005	CM0002	Error that occurs when there is insufficient bandwidth in the USB connection. The device is not connected to a USB 3.0 port. Issue related to the PC USB3 Controlle Chipset. USB 3.0 cable damaged. Issue related to the connected USB 3.0 extension cord (if installed).	 Check that the USB 3.0 cable is properly connected to a USB 3.0 port on the PC. Disconnect and connect the USB 3.0 cable again. Try connecting the USB 3.0 cable to a different USB port on the PC. Visually check that the USB 3.0 cable of the device is not damaged. Visually check that the extension cord (if installed) is not damaged.
PHMS006	CM0003	An error occurred while configuring the linear video camera. Issue related to the USB 3.0 cable. Issue related to the <i>band width limit</i> in the USB controller of the PC.	 Follow the troubleshooting steps described in Troubleshooting related to the error ID PHMS005. Turn the power supply unit of the device off and on again. Check that the power indicator light of the power supply unit is on (green colour). Check the correct operation of the device's cooling fans. Check for additional peripheral devices or CSO devices connected to the PC. If any, disconnect all other peripheral devices or CSO devices connected to the PC. Keep only the MS-39 device, keyboard and mouse connected to the PC. Start the Phoenix application software. If the problem persists, contact the CSO Technical Assistance.
PHMS007	CM0009	Errors occurred in the USB connection, related to the transmission and negotiation of USB packets.	 Follow the troubleshooting steps described in Troubleshooting related to the error ID PHMS005.
PHMS008	CM0010	Errors occurred at the USB physical level, related to the condition of the USB 3.0 cable and any disturbances that may occur in the transmission.	 Follow the troubleshooting steps described in Troubleshooting related to the error ID PHMS005.
PHMS009	CM0012	Device initialization error during the Instrument diagnostics procedure. An internal component is in an error state.	 Turn the power supply unit of the device off and on again. Check that the power indicator light of the power supply unit is on (green colour). Check the correct operation of the device's cooling fans. Follow the troubleshooting steps described in Troubleshooting related to the error ID PHMS005.
PHMS010	CM0013	Device drivers recognition/installation error during the <i>Instrument diagnostics</i> procedure.	 Follow the troubleshooting steps described in Troubleshooting related to the error ID PHMS004.





ID	Message	Cause	Solution
PHMS011	CM0014	USB 3.0 cable disconnected. Device not powered during the <i>Instrument diagnostics</i> procedure.	 Follow the troubleshooting steps described in Troubleshooting related to the error ID PHMS005. Turn the power supply unit of the device off and on again. Check that the power indicator light of the power supply unit is on (green colour). Check the correct operation of the device's cooling fans.
PHMS012	SL0001	An error occurred during the initialization procedure of an internal component. An internal component is in an error state.	 Turn the power supply unit of the device off and on again. Carry out a test acquisition. Follow the troubleshooting steps described in Troubleshooting related to the error ID PHMS005. If the problem persists, contact the CSO Technical Assistance.
PHMS013	SM0001	An error occurred during the initialization procedure of an internal component. An internal component is in an error state.	 Turn the power supply unit of the device off and on again. Carry out a test acquisition. If the problem persists, contact the CSO Technical Assistance.
PHMS014	SM0002	An error occurred during the initialization procedure of an internal component. An internal component is in an error state.	 Turn the power supply unit of the device off and on again. Carry out a test acquisition. If the problem persists, contact the CSO Technical Assistance.
PHMS015	GV0001	An error occurred during the initialization procedure of an internal component of the Power Supply circuit board. The Power Supply circuit board is in an error state.	 Turn the power supply unit of the device off and on again. Check the correct power supply of the J4 and J5 connectors on the Power Supply circuit board. Follow the procedure described in the section "Check of the proper power supply of the J4 and J5 connectors and the replacement of the Power Supply circuit board" on page 67.
PHMS016	AL0001	The device has reached the maximum working temperature. Defective device cooling fans. Air vents blocked.	 Check the correct operation of the cooling fans of the device (noise). Make sure the air vents are clean. If the problem persists, contact the CSO Technical Assistance.
PHMS017	AQ0001	An error occurs while acquiring images from the OCT video camera. Issue related to the USB 3.0 cable. Issue related to the <i>band width limit</i> in the USB controller of the PC.	 Follow the troubleshooting steps described in Troubleshooting related to the error ID PHMS005. If the problem persists, contact the CSO Technical Assistance.



ID	Message	Cause S	olution
PHMS018	AQ0004	An error occurs while acquiring images – from the linear video camera. Issue related to the USB 3.0 cable. Issue related to the <i>band width limit</i> in – the USB controller of the PC.	Follow the troubleshooting steps described in Troubleshooting related to the error ID PHMS005 . If the problem persists, contact the CSO Technical Assistance.
PHMS019	PW0001	 Main power supply out of range. Issue related to the power supply unit or the power supply cable of the device. The issue can show up in the following - ways: Interruption of the video stream from a linear and/or OCT video camera. Blocking of an internal component of the device. 	Turn the power supply unit of the device off and on again. Check that the power indicator light of the power supply unit is on (green colour). Check the correct operation of the device's cooling fans. If the problem persists, contact the CSO Technical Assistance.
PHMS020	AA0001	An error occurred during the – initialization procedure of an internal component. An internal component is in an error state.	Contact the CSO Technical Assistance.
PHMS021	CM0004	An error occurred during the – initialization procedure of an internal component. An internal component is in an error state.	Contact the CSO Technical Assistance.
PHMS022	CM0005	An error occurred during the – initialization procedure of an internal component. An internal component is in an error state.	Contact the CSO Technical Assistance.
PHMS023	CM0006	An error occurred during the – initialization procedure of an internal component. An internal component is in an error state.	Contact the CSO Technical Assistance.
PHMS024	СМ0007	An error occurred during the – initialization procedure of an internal component. An internal component is in an error state.	Contact the CSO Technical Assistance.
PHMS025	CM0011	An error occurred during the – initialization procedure of an internal component. An internal component is in an error state.	Contact the CSO Technical Assistance.
PHMS026	GP0001	An error occurred during the – initialization procedure of an internal component. An internal component is in an error state.	Contact the CSO Technical Assistance.
PHMS027	GP0002	An error occurred during the – initialization procedure of an internal component. An internal component is in an error state.	Contact the CSO Technical Assistance.





ID	Message	Cause	So	ution
PHMS028	GV0002	An error occurred during the initialization procedure of an internal component. An internal component is in an error state.	-	Contact the CSO Technical Assistance.
PHMS029	GV0003	An error occurred during the initialization procedure of an internal component. An internal component is in an error state.	-	Contact the CSO Technical Assistance.
PHMS030	GV0004	An error occurred during the initialization procedure of an internal component. An internal component is in an error state.	-	Contact the CSO Technical Assistance.
PHMS031	GV0005	An error occurred during the initialization procedure of an internal component. An internal component is in an error state.	-	Contact the CSO Technical Assistance.
PHMS032	GV0006	An error occurred during the initialization procedure of an internal component. An internal component is in an error state.	-	Contact the CSO Technical Assistance.
PHMS033	GV0007	An error occurred during the initialization procedure of an internal component. An internal component is in an error state.	-	Contact the CSO Technical Assistance.
PHMS034	GV0010	An error occurred during the initialization procedure of an internal component. An internal component is in an error state.	-	Contact the CSO Technical Assistance.
PHMS035	GV0011	An error occurred during the initialization procedure of an internal component. An internal component is in an error state.	-	Contact the CSO Technical Assistance.
PHMS036	LT0001	An error occurred during the initialization procedure of an internal component. An internal component is in an error state.	-	Contact the CSO Technical Assistance.
PHMS037	LT0002	An error occurred during the initialization procedure of an internal component. An internal component is in an error state.	-	Contact the CSO Technical Assistance.
PHMS038	LT0003	An error occurred during the initialization procedure of an internal component. An internal component is in an error state.	_	Contact the CSO Technical Assistance.
PHMS039	LT0004	An error occurred during the initialization procedure of an internal component. An internal component is in an error state.	-	Contact the CSO Technical Assistance.





ID	Message	Cause	So	lution
PHMS040	LT0005	An error occurred during the initialization procedure of an internal component. An internal component is in an error state.	—	Contact the CSO Technical Assistance.
PHMS041	PD0001	An error occurred during the initialization procedure of an internal component. An internal component is in an error state.	_	Contact the CSO Technical Assistance.
PHMS042	SF0001	An error occurred during the initialization procedure of an internal component. An internal component is in an error state.	_	Contact the CSO Technical Assistance.
PHMS043	SF0004	An error occurred during the initialization procedure of an internal component. An internal component is in an error state.	-	Contact the CSO Technical Assistance.
PHMS044	SF0005	An error occurred during the initialization procedure of an internal component. An internal component is in an error state.	-	Contact the CSO Technical Assistance.
PHMS045	SL0002	An error occurred during the initialization procedure of an internal component. An internal component is in an error state.	_	Contact the CSO Technical Assistance.
PHMS046	SL0003	An error occurred during the initialization procedure of an internal component. An internal component is in an error state.	_	Contact the CSO Technical Assistance.
PHMS047	SL0004	An error occurred during the initialization procedure of an internal component. An internal component is in an error state.	-	Contact the CSO Technical Assistance.
PHMS048	SL0005	An error occurred during the initialization procedure of an internal component. An internal component is in an error state.	_	Contact the CSO Technical Assistance.
PHMS049	SL0006	An error occurred during the initialization procedure of an internal component. An internal component is in an error state.	-	Contact the CSO Technical Assistance.
PHMS050	SL0007	An error occurred during the initialization procedure of an internal component. An internal component is in an error state.	_	Contact the CSO Technical Assistance.
PHMS051	SL0008	An error occurred during the initialization procedure of an internal component. An internal component is in an error state.	-	Contact the CSO Technical Assistance.



ID	Message	Cause	So	lution
PHMS052	SL0009	An error occurred during the initialization procedure of an internal component. An internal component is in an error state.	-	Contact the CSO Technical Assistance.
PHMS053	SL0010	An error occurred during the initialization procedure of an internal component. An internal component is in an error state.	-	Contact the CSO Technical Assistance.
PHMS054	SL0011	An error occurred during the initialization procedure of an internal component. An internal component is in an error state.	_	Contact the CSO Technical Assistance.

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For any message of cases which are not included in the list, please ask the Manufacturer for information.

Send information about the issue encountered to the Technical Assistance. Follow the indications given in paragraph **"How to report malfunctions to the Manufacturer" on page 7.**

Provide a detailed description of the issue and of the system behaviour. When possible, also send explanatory photos and/or videos.

If an error message appears in the dialogue box, expand its details and paste the contents of the error message into the text of the e-mail.



6.4 TROUBLESHOOTING

ID	Issue	Solution
MS001	The Phoenix application software does not start	 The software cannot start and crashes before the first screen is displayed. Setting files are corrupt. Follow the procedure described (Windows 10/11): Delete the "CSO" folder from the logged in user's "AppData\Local\CSO" path. Delete the "CSO" folder from the "AppData\Roaming\P4" path. Restart the Phoenix application software.
MS002	The Phoenix application software requires activation	 USB 3.0 cable disconnected. USB 3.0 cable damaged. Power supply unit turned off or power supply cable disconnected. Check that the power switch of the power supply unit is set to ON. 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 USB 3.0 cable is properly connected. If the problem persists, replace the power supply unit. Follow the procedure described in the section "Replacement of the power supply unit" on page 56. If the problem persists, follow the instructions given in the paragraph "Flow charts" on page 45.
MS003	The Phoenix application software doesn't detect the device	 Follow the indications given in paragraph "Flow charts" on page 45.
MS004	The device does not start	 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. If the problem persists, replace the power supply unit. Follow the procedure described in the section "Replacement of the power supply unit" on page 56. If the problem persists, contact the CSO Technical Assistance.
MS005	The left/right position of the device is not detected when moving the base	 Before replacing any of the following components, make sure the sticker pad is positioned correctly. Check that the sticker pad is a different colour than the colour of the table top. Replace one of the following components: Plate. Follow the procedure described in the section "Replacement of the plate" on page 62. If the problem persists, contact the CSO Technical Assistance.
MS006	The joystick button does not work	 Replace the joystick button. Follow the procedure described in the section "Replacement of the joystick button" on page 66. If the problem persists, replace the joystick. Follow the procedure described in the section "Replacement of the joystick" on page 64. If the problem persists, contact the CSO Technical Assistance.



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ID	Issue	Solution
MS007	The image is out of focus or the device is not calibrated	 Check the correct focusing of the device using the tool supplied. Carry out the device calibration as described in paragraph "Device calibration" on page 38. If the problem persists, contact the CSO Technical Assistance.
MS008	The acquired image is not clear	 Check that the optical path of the shooting unit is clean. Check the room lighting.
MS009	The image is not displayed during acquisition	 Follow the procedure hereafter: Close the Phoenix application software. Turn the power switch of the power supply unit to OFF. Wait for 10 seconds. Turn the power switch of the power supply unit to ON. Restart the Phoenix application software.
MS010	The Placido disk flashes or does not work properly during image acquisition	 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. If the problem persists, replace the power supply unit. Follow the procedure described in the section "Replacement of the power supply unit" on page 56. If the problem persists, replace the Placido disk. Follow the procedure described in the section "Replacement of the Placido disk" on page 60.
MS011	The device cannot detect pupil measurement	 Carry out the device calibration as described in paragraph "Device calibration" on page 38.
MS012	Full auto-alignment failed.	 Contact the CSO Technical Assistance.





6.5 REPLACEMENT OF THE PARTS



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 **"Spare parts and accessories list" on page 84.**

6.5.1 REPLACEMENT OF THE POWER SUPPLY UNIT

Material and warnings:



Fig. 54 - Power supply unit

Pos	Description	Code	
Α	Power supply unit (PSP2404)	103106900	



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, fasten the table wheels. Lower the brake lever.
- 3 Disconnect the power supply cables from 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. 55 - Unscrew the screws

Fig. 56 - Remove the power supply unit

6 For assembly, follow the procedure in reverse order.





6.5.2 REPLACEMENT OF PROTECTIVE SHELLS OR RING

Material and warnings:



Fig. 57 - Left and right protective shell and ring

Pos	Description	Code	
Α	Left protective shell	103106519	
В	Right protective shell	103106520	
С	Ring	103106571	

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 or ring:

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



Fig. 58 - Unscrew the screws



Fig. 59 - Remove the right protective shell







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- 9 Unscrew the screw (H).
- 10 Disconnect the ground cable (I).
- 11 Remove the left protective shell.



Fig. 66 - Unscrew the screw and disconnect the cable



Fig. 67 - Remove the left protective shell

12 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 80.

6.5.3 REPLACEMENT OF THE PLACIDO DISK

Material and warnings:

Fig. 68 - Placido disk

Pos	Description	Code
Α	Placido disk	963106610



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 Placido disk:

- 1 Remove the protective shells as described in paragraph "**Replacement of** protective shells" on page 58.
- 2 Unscrew the three screws (A).
- 3 Unscrew the three screws (B).
- 4 Disconnect the connection cable (C) from the connector (D) of the OCT PSU 123106504 circuit board.



Fig. 69 - Unscrew the screws



Fig. 70 - Disconnect the connection cable

5 Remove the Placido disk.



Fig. 71 - Remove the Placido disk

6 For assembly, follow the procedure in reverse order.





6.5.4 REPLACEMENT OF THE PLATE

Material and warnings:



Fig. 72 - Plate

Pos	Description	Code
Α	Plate	100216413



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 on the soft cloth, so that the Placido disk is directed downwards.
- 3 Unscrew the four screws (A) M3x10 on the plate.



Fig. 73 - Place the device

Fig. 74 - Unscrew the screws



- 4 Move the plate slightly and disconnect the connection cable (C) between the joystick and the plate sensor from the connector (B).
- 5 Disconnect the connection cable (D) between the connector on the base and the plate sensor from the connector (E).
- 6 Remove the plate.



Fig. 75 - Disconnect the cables

- Fig. 76 Remove the plate
- 7 For assembly, follow the procedure in reverse order.





6.5.5 REPLACEMENT OF THE JOYSTICK

Material and warnings:



Fig. 77 - Joystick

Pos	Description	Code
Α	Joystick	103106402



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 62.
- 2 Unplug the connection cable (A) between the joystick and the sensor from the connector (B).
- 3 Unscrew the screws (C).



Fig. 78 - Disconnect the cable

Fig. 79 - Unscrew the screws



4 Remove the joystick.



Fig. 80 - Remove the joystick

5 For assembly, follow the procedure in reverse order.





6.5.6 REPLACEMENT OF THE JOYSTICK BUTTON

Material and warnings:



Fig. 81 - Joystick button

Pos	Description	Code
Α	Joystick button	103106401



CAUTION

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

Disassembling and assembling procedure for the joystick button:

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



Fig. 82 - Remove the joystick button



Fig. 83 - Disconnect the cable

3 For assembly, follow the procedure in reverse order.







6.5.7 CHECK OF THE PROPER POWER SUPPLY OF THE J4 AND J5 CONNECTORS AND THE REPLACEMENT OF THE POWER SUPPLY CIRCUIT BOARD

Material and warnings:



Fig. 84 - Power Supply circuit board

Pos	Description	Code
Α	Power Supply circuit board	103106612



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.

Check the correct power supply of the J4 and J5 connectors of the Power Supply circuit board:

- 1 Remove the protective shells as described in paragraph "**Replacement of** protective shells" on page 58.
- 2 Check that the power supply on the J4 (A) and J5 (B) connectors on the Power Supply circuit board is approximately 18 Vdc.
- 3 If the power supply on the J4 (A) and J5 (B) connectors is approximately 18 Vdc, reinstall the protective shells as described in paragraph "**Replacement** of protective shells" on page 58.
- 4 If the power supply on the J4 (A) and J5 (B) connectors is not approximately 18 Vdc, replace the Power Supply circuit board.







Fig. 85 - Power Supply circuit board

Disassembling and assembling procedure for the Power Supply circuit board:

- 1 Disconnect all the connection cables from the Power Supply circuit board.
- 2 Unscrew the screws (A).
- 3 Remove the Power Supply circuit board (B).



Fig. 86 - Unscrew the screws



Fig. 87 - Remove the Power Supply circuit board

- 4 For assembly, follow the procedure in reverse order.
- 5 When the installation is complete, reinstall the protective shells as described in paragraph "**Replacement of protective shells**" on page 58.







6.5.8 REPLACEMENT OF THE LOWER COOLING FAN

Material and warnings:



Fig. 88 - Lower cooling fan

Pos	Description	Code
Α	Lower cooling fan	333106510
В	Anti-vibration supports	4007580



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 lower cooling fan:

- 1 Remove the protective shells as described in paragraph "**Replacement of** protective shells" on page 58.
- 2 Loosen the screws (A).
- 3 Loosen the screws (B).







Fig. 89 - Loosen the screws

Fig. 90 - Loosen the screws

4 Loosen the screws (C).

5 Disconnect the connection cable (D) between the cooling fan (E) and the J10 connector (F) of the Power Supply circuit board.



Fig. 91 - Loosen the screws



Fig. 92 - Disconnect the connection cable

- 6 Unscrew the screws (G).
- 7 Remove the support (H) complete with cooling fan (E) downwards.
- 8 Cut the anti-vibration supports (I).
- 9 Remove the cooling fan (E).



Fig. 93 - Remove the stand complete with cooling fan



Fig. 94 - Cut the anti-vibration supports and remove the fan





Assembling procedure for the lower cooling fan:

- 1 Check that the fan blades (E) are correctly oriented. The airflow of the cooling fan must be directed towards the inside of the device.
- 2 Place the cooling fan (E) on the support (H).
- 3 Insert the anti-vibration supports (I).



Fig. 95 - Place the fan on the support



Fig. 96 - Insert the anti-vibration supports

- 4 Place the support (H) complete with cooling fan (E) into the seat.
- 5 Screw in the screws (G).
- 6 Connect the connection cable (D) between the cooling fan (E) and the J10 connector (F) of the Power Supply circuit board.



Fig. 97 - Place the cooling fan with the support



Fig. 98 - Connect the connection cable





- 7 Fasten the screws (C).
- 8 Tighten the screws (B).





Fig. 100 - Tighten the screws

- 9 Tighten the screws (A).
- 10 Install the protective shells as described in paragraph "**Replacement of protective shells**" on page 58.



Fig. 101 - Tighten the screws

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6.5.9 REPLACEMENT OF THE UPPER LEFT COOLING FAN

Material and warnings:



Pos	Description	Code
Α	Upper left cooling fan	333106510
В	Anti-vibration supports	4007580



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 upper left cooling fan:

- 1 Remove the protective shells as described in paragraph "**Replacement of** protective shells" on page 58.
- 2 Disconnect the connection cable (A) between the cooling fan (B) and the J14 connector (C) of the Power Supply circuit board.
- 3 Support the assembly (D) with one hand.
- 4 Unscrew the screw (E).
- 5 Remove the assembly (D).







Fig. 103 - Disconnect the connection cable



Fig. 104 - Unscrew the screw and remove the assembly

- 6 Unscrew the screws (F).
- 7 Remove the support (G) complete with cooling fan.
- 8 Cut the anti-vibration supports (H).
- 9 Remove the cooling fan (B).



Fig. 105 - Unscrew the screws and remove the support



Fig. 106 - Cut the anti-vibration supports and remove the fan

Assembling procedure for the upper left cooling fan:

- 1 Check that the blades of the cooling fan (E) are correctly oriented. The airflow of the cooling fan must be directed towards the outside of the device.
- 2 Place the cooling fan (B) on the support (G).
- 3 Insert the new anti-vibration supports (H).





MS-39MTENGCSO0009032025



Fig. 107 - Place the cooling fan







- 4 Place the support (G) complete with cooling fan into the seat.
- 5 Screw in the screws (F).
- 6 Place the assembly (D) into the seat.
- 7 Screw in the screw (E).





Fig. 109 - Place the cooling fan

Fig. 110 - Place the assembly and screw in the screw

- 8 Connect the connection cable (A) between the cooling fan (B) and the J14 connector (C) of the Power Supply circuit board.
- 9 Install the protective shells as described in paragraph "**Replacement of** protective shells" on page 58.



Fig. 111 - Connect the connection cable



When the operation is complete, carry out the electrical safety test as described in the paragraph **"Electrical safety check" on page 80.**





6.5.10 REPLACEMENT OF THE UPPER RIGHT COOLING FAN

Material and warnings:



Fig. 112 - Upper right cooling fan

Pos	Description	Code
Α	Upper right cooling fan	333106512
В	Anti-vibration supports	4007580



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 upper right cooling fan:

- 1 Remove the protective shells as described in paragraph "**Replacement of protective shells**" on page 58.
- 2 Disconnect the connection cable (A) between the cooling fan and the J12 connector (B) of the Power Supply circuit board.
- 3 Access the opposite side of the device.
- 3 Support the assembly (C) with one hand.
- 4 Unscrew the screw (D).
- 5 Remove the assembly (C).



Fig. 113 - Disconnect the connection cable



Fig. 114 - Unscrew the screw and remove the assembly

- 6 Unscrew the screws (E).
- 7 Remove the support (F) complete with cooling fan.
- 8 Cut the anti-vibration supports (G).
- 9 Remove the fan (H).



Fig. 115 - Unscrew the screws and remove the support



Fig. 116 - Cut the anti-vibration supports





Assembling procedure for the upper right cooling fan:

- 1 Check that the blades of the cooling fan (H) are correctly oriented. The airflow of the cooling fan must be directed towards the outside of the device.
- 2 Place the cooling fan (H) on the support (F).
- 3 Insert the new anti-vibration supports (G).



Fig. 117 - Place the cooling fan

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- 4 Place the support (F) complete with cooling fan into the seat.
- 5 Screw in the screws (E).
 - Pass the connection cable (A) between the two cable clamps (I).



Fig. 119 - Place the support and screw in the screws



Fig. 120 - Pass the connection cable





- 7 Place the assembly (C) into the seat.
- 8 Screw in the screws (E).
- 9 Connect the connection cable (A) between the cooling fan and the J12 connector (B) of the Power Supply circuit board.
- 10 Install the protective shells as described in paragraph "**Replacement of protective shells**" on page 58.





Fig. 121 - Install the assembly

Fig. 122 - Connect the connection cable

When the operation is complete, carry out the electrical safety test as described in the paragraph "Electrical safety check" on page 80.

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.



Medical device	MS-39	PSP2404
Description	AS-OCT	Power supply unit
Class	1	1
Туре	В	В
Number of applied parts	1	1
Test sequence	Class I 1B	Class I 1B

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 Document and keep evidence and measurements taken during tests.
- 5 The test concludes 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. 123 - Connect the tester inside the patient area

Pos	Name
Α	Connection between the device and the PC
В	Connection between the PC and the isolation transformer
С	Connection between the isolation transformer and the tester
D	Connection between the isolation transformer and the power supply unit
Ε	Connection between the tester and the power socket
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. 124 - Connect the tester outside the patient area

Pos	Name
Α	Connection between the device and the PC
В	Connection between the PC and the power socket
С	Connection between the tester and the power socket
D	Connection between the applied part and the tester
Е	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



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

ID	Test type	Procedure	Acceptability criteria
1	Check of the proper operation of the joystick button	Perform an acquisition by pressing the joystick button.	Check an image has been saved.
2	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.
3	Check of the proper operation of the joystick	Turn the joystick clockwise and counter-clockwise.	Check the device moves upwards and downwards smoothly.
4	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.
5	Check of the electronic components, the power supply unit and the power supply cables operation	Properly connect the power supply cables. Turn the power switch of the power supply unit to ON.	Perform an acquisition. Follow the procedure (step 11-16) described in paragraph "Device calibration" on page 38.
6	Check of the hardware operation	Start the Phoenix application software.	The device is detected by the software without errors.
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	Check of the proper operation of the fixation point LED	When the device is on.	Check the red fixation point LED is on.
10	Final check of the device	Check the operation of the Phoenix application software as a further verification of the previous points.	Check for compliance.
11	Testing device calibration	Follow the calibration instructions described in paragraph "Device calibration" on page 38.	Check for compliance.





7 SPARE PARTS AND ACCESSORIES LIST

Code		Description
300409135		Base power supply cable (1.5 m)
30010071D3F		Power cable of the power supply unit
101013-00		Isolation transformer 230V/230V Power supply cable 800 Va (maximum load)
103106900		Power supply unit (PSP2404)
4013090		Dust cover
4014010	0	Chin cup papers (50 pieces)
100130700 (V10)		Chin rest
4001050		Chin rest handle
100257731		Chin cup
100232741	E E	Forehead rest
100216816		Sticker pad
100710100	\bigcirc	Sliding sticker plate



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Code		Description
100710832 (V10)		Wheel cover (1 piece)
100210415		Guide rail (1 piece)
100210414	A REAL PROPERTY OF THE PROPERT	Cogwheel (1 piece)
103106401		Joystick button
103106402		Joystick
100216413		Plate (with sensor)
103106612		Power Supply circuit board
103106571		Ring





Code		Description
103106519 (V10)	ASS-39	Left protective shell
103106520 (V10)	* <u>MS</u> 39	Right protective shell
103106205		Calibration tool
963106610		Placido Disk
333106510		Upper left cooling fan Lower cooling fan
333106512		Upper right cooling fan

Code		Description
4007580		Anti-vibration supports



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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