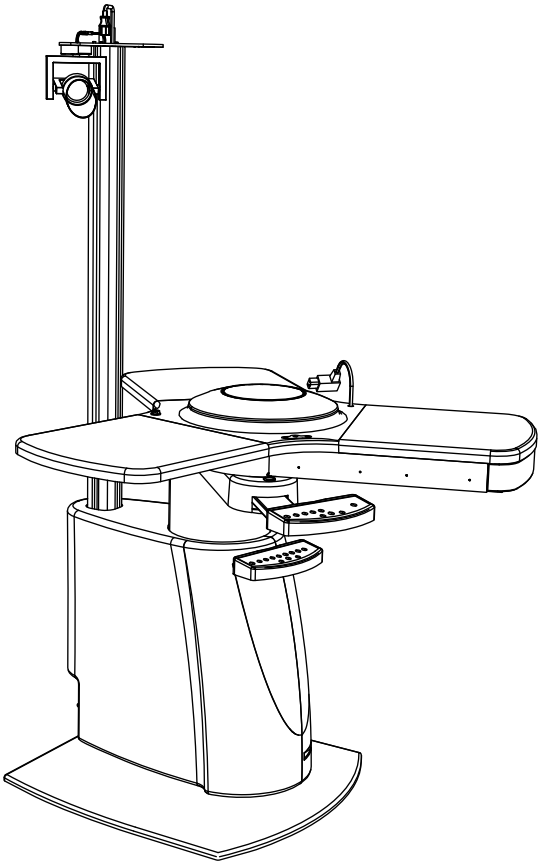
COSTRUZIONE STRUMENTI OFTALMICI



ETOILE II

Ophthalmic unit

INSTRUCTIONS FOR USE

COSTRUZIONE STRUMENTI OFTALMICI

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EN

1 INTRODUCTION

The device is the result of a long research period, conducted by experts to give the product technical innovation, quality and design.
Ophthalmic units are characterized by their practicality compatible with a wide range of devices for the modern ophthalmological diagnostic. Thanks to an attentive selection of the materials and a wide range of available colours and customizations, it is possible to create a harmonious and comfortable working environment both for the operator and the patient.

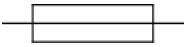
1.1 SYMBOLS

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

Symbol	Meaning
	Caution
	Danger of electric shock
	Read the instructions for use
	General obligation
	Note. Useful information for the user
	General prohibition sign
	Manufacturer

CE	CE Marking (EU Regulation 2017/745)
MD	Medical device
	Waste disposal in compliance with the Directive 2012/19/EU (WEEE), and 2011/65/EU (RoHS II)

1.1.1 DEVICE SYMBOLS

Symbol	Meaning
	Type B applied part
	Fuse

1.2 GENERAL WARNINGS

THESE INSTRUCTIONS FOR USE REFER TO THE OPHTHALMIC UNIT MODEL ETOILE II ("OPHTHALMIC UNIT" FROM NOW ON).

THE ORIGINAL TEXT IS IN ITALIAN.

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

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

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

Before using the ophthalmic unit, check that there is no sign of damages due to transport or an incorrect storage, that could compromise the correct functioning of the ophthalmic unit.

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

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

1.3 NORMATIVE REFERENCES

1.3.1 COMMUNITY DIRECTIVES

- Regulation (EU) 2017/745 of the European Parliament and of the Council of 5th April 2017 on medical devices
- Directive 2012/19/EU on waste electrical and electronic equipment (WEEE)

1.3.2 TECHNICAL STANDARDS

- IEC 60601-1: 2005 + A1:2012 - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
- EC 60601-1-2:2014 Edition 4 - Collateral Standard: Electromagnetic disturbances - Requirements and tests.
- UNI CEI EN ISO 14971:2012 - Medical devices. Application of risk management to medical devices.

1.3.3 QUALITY MANAGEMENT SYSTEMS STANDARDS

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

1.4 WARRANTY

The Manufacturer is responsible for the device conformity to the Regulation (EU) 2017/745 of April 5th 2017 for:

- features
- safety and reliability
- CE marking

The Manufacturer refuses any responsibility for:

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

The Manufacturer guarantees the device for 24 months after invoicing. The Warranty includes the substitution, at the Manufacturer's or an Authorized Service Centre, of components and materials and the relative labour. The shipping and transport fees are to be paid by the client.

The warranty does not cover:

- repairs of faults originating from natural disasters, mechanical shocks (fall, hit, etc), electrical system faults, negligence, improper use, maintenance or reparations carried out with non-original materials
- any other improper use or not intended by the Manufacturer
- damages caused by service lack or inefficiency, originating by causes or circumstances out of the Manufacturers control
- the parts subject to usage and/or deterioration originating from the normal use and those that might be broken because of an improper use or maintenance carried out by personnel non-authorized by the Manufacturer.

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

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

1.5 MANUFACTURER IDENTIFICATION

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
Electric shock danger. Do not let water fall on any part of the device. Do not immerse any part of the device into the water or other liquids.

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

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

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

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

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

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

CAUTION

Electric shock risk. Do not leave the power supply cables in contact with sharp corners or objects. Always collect and fasten the power supply cables.

CAUTION

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

CAUTION

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

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

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

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

It is forbidden to use the device outdoors.

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

2.2 DEVICE IDENTIFICATION

2.2.1 REGISTRATION DATA IN THE MEDICAL DEVICES LIST

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

2.2.2 DEVICE DATA PLATE

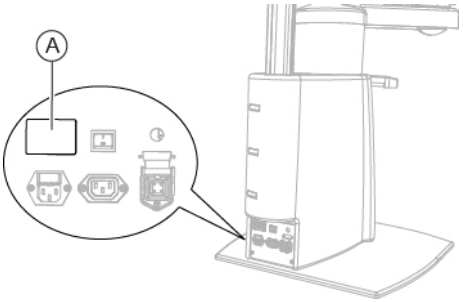


Fig 1 - Data plate position

Pos	Description
A	Device data plate

Fig 2 - Device data plate

2.3 INTENDED USE

The ETOILE II ophthalmic unit is a working station which allows to place three devices on the rotating table top.
Thanks to the table top rotation, you can easily and efficiently pass from one device to the other.
The ophthalmic unit is equipped with three keypads from which instruments can be used and all functions can be programmed for a fast and comfortable use.
It is also possible to command the chair elevation directly from the unit keypad.
For compatible models, it is also possible to command the table elevation directly from the keypad.

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

The accessories must be compliant to the norm IEC 60950-1 Information technology equipment - Safety - Part 1: General requirements.
If the accessories are installed in the patient area it is necessary to install an isolation transformer compliant with the directive IEC 60601-1:2005 + A1:2012 - "Medical electrical equipment - Part 1: General requirements for basic safety and essential performance".

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

Patient area: any volume in which a patient with applied parts can intentionally or unintentionally come into contact with other electro-medical devices or electro-medical systems or with foreign masses and masses or with other people in contact with these elements.

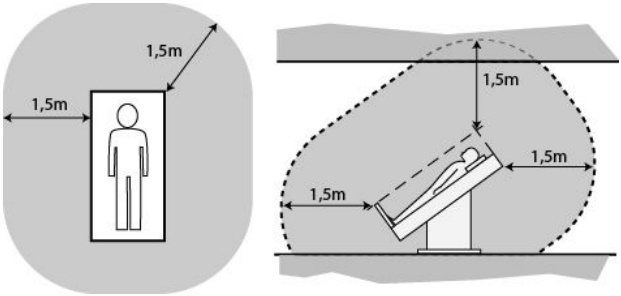


Fig 3 - Patient area

2.4 MEDICAL DEVICES CLASSIFICATION

Technical data	Value
Classification in compliance with the attached Regulation (EU) 2017/745	Class I

2.5 MEDICAL ELECTRICAL DEVICES CLASSIFICATION

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

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

2.6 ENVIRONMENTAL CONDITIONS

Phase	Technical data	Min	Max
Transport	Temperature	-10°C	+60°C
	Atmospheric pressure	500 hPa	1060 hPa
	Relative humidity	10%	90%
Storage	Temperature	-10°C	+55°C
	Atmospheric pressure	700 hPa	1060 hPa
	Relative humidity	10%	95%
Use	Temperature	+15°C	+30°C
	Atmospheric pressure	700 hPa	1060 hPa
	Relative humidity	30%	75%

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

2.7 DISPOSAL AT THE END OF THE USEFUL LIFE

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

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

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

- not to dispose as urban waste but collect it separately and address to a firm specialized in the disposal of electrical and electronic equipment or to the local administration in charge for waste collection.

- in the event that a new device is purchased from the same Manufacturer to replace an old one placed on the market before 13 August 2005, equivalent and with the same functions of the new device, the Distributor or Manufacturer are legally required to collect the old device.
- if the user decides to dispose a used device, put on the market after the 13th August 2005, the Distributor or the Manufacturer have to collect it.
- the Manufacturer takes care, by joining a consortium for electronic waste, of the treatment and the recycling of the used device by paying its costs.

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

2.8 MANUFACTURER DECLARATIONS

2.8.1 ELECTROMAGNETIC EMISSIONS

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

The copy of the documentation of the electromagnetic compatibility (EMC) can be demanded at any time to C.S.O. Costruzione Strumenti Oftalmici SRL.
The device is compliant with all the requirements of electromagnetic compatibility (EMC) decided by the norm CEI EN 60601-2-40 "Electromedical devices".
The device can be used in an electromagnetic environment where the disturbances of radio-frequency irradiated fields are controlled.

The device shall not be used near other devices that are not components of the device itself. In case it is necessary, you should make sure that their functioning in this configuration is regular and safe.
If the device performances are affected by other appliances, remove the cause of the interference. For any doubts or explanations contact the Manufacturer.

Do not use as device components other devices than dose indicated by the Manufacturer. They could cause an increase of the devices' emissions and a reduction of the device immunity. For any doubts or explanations contact the Manufacturer.

3 DEVICE DESCRIPTION

3.1 SUPPLY DESCRIPTION

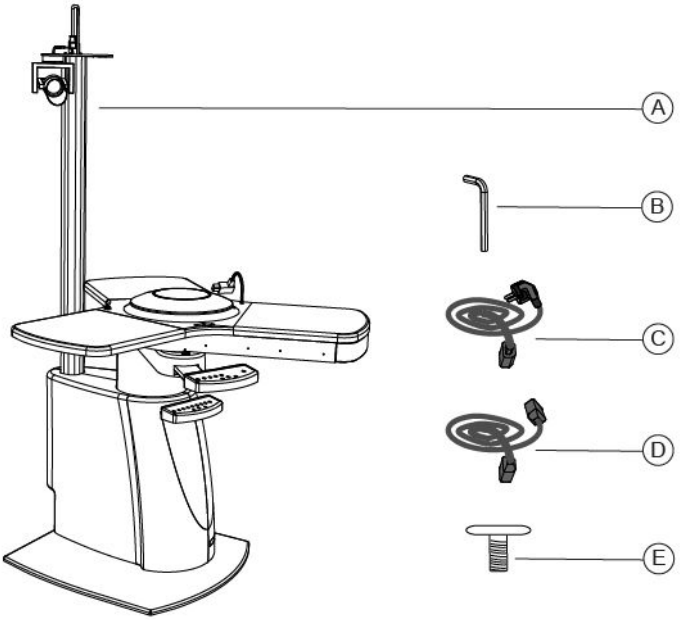


Fig 4 - Supply description

Pos	Denomination	Description
A	ETOILE II ophthalmic unit	The unit is composed of 3 table tops. Each table top allows to install one medical device. On the table top there is a second electronic tab protected by a dome. Under one of the table tops there is a lenses drawer.
B	Hex wrench	
C	Chair power cable	For connecting the chair to the ophthalmic unit
D	Power supply cable of the ophthalmic unit	For connecting the ophthalmic unit to the power supply
E	Counterweight handle	For lifting the counterweight placed inside the structure.

During installation, the handle might be left placed on the internal counterweight. Whenever possible, make sure the component is placed on the counterweight.

If requested, the ophthalmic unit can be personalised with the following accessories:

- ETOILE II ophthalmic unit, version with table top opening on the left
- accessories for placing the device on the table top
- chair with electrical elevation
- table top with electrical elevation (from 84 cm to 100 cm and from 74 cm to 90 cm)
- ceiling light with three LEDs (for column)
- self-balancing arm for phoropter
- support for phoropter arm
- support for column table top
- hook for ophthalmic electrode cap
- supports for column
- table top for LCD monitor (for column)
- digital video system
- table top for PC keyboard
- desks and drawers
- finishing with special materials

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

3.1.1 ETOILE II OPHTHALMIC UNIT

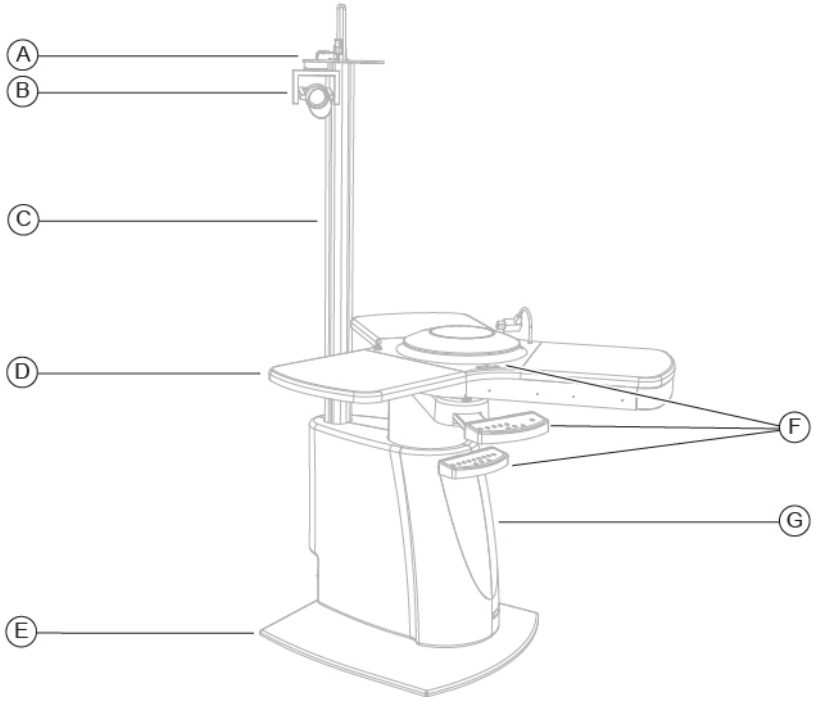


Fig 5 - ETOILE II ophthalmic unit

Pos	Description
A	Projector and spotlight support
B	Adjustable LED spotlight
C	Column
D	Arm with rotating table top in three positions
E	Structure base
F	Command keypad
G	Structure with protection carter

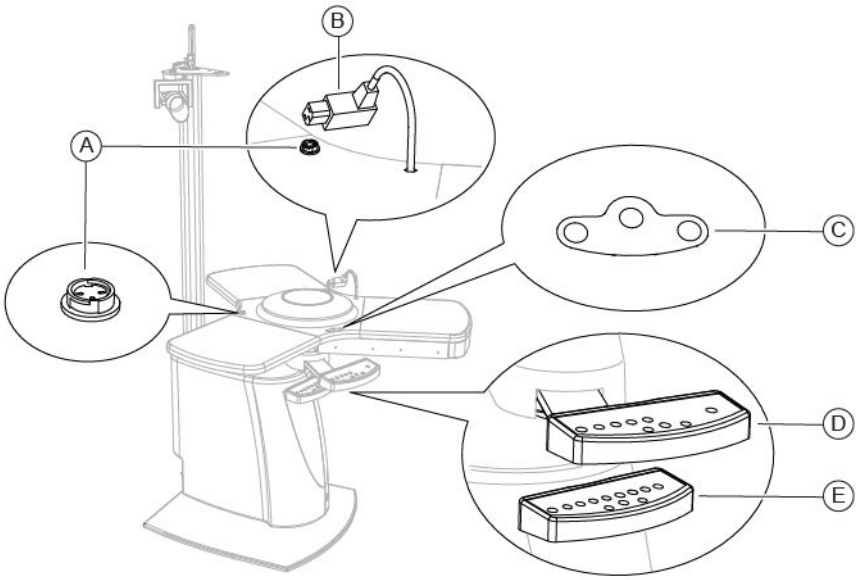


Fig 6 - Table top for devices

Pos	Description
A	Outlet for device
B	Outlet for device (120V or 230V depending on the model)
C	Keypad for the regulation of the slit lamp placed on the table top
D	Keypad placed on the table top arm
E	Keypad placed on the structure

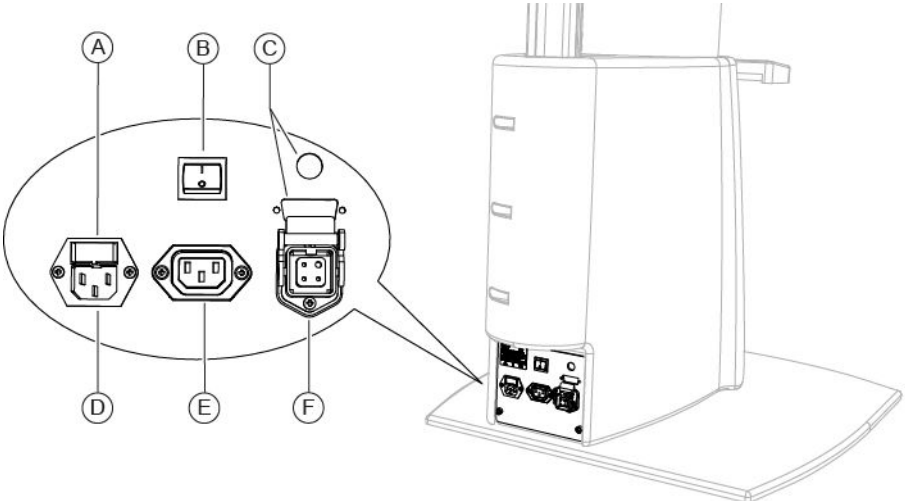


Fig 7 - Electrical connections

Pos	**Description**
A	Fuse drawer
B	ON/OFF button
C	Auxiliary joints
D	Power supply outlet for ophthalmic unit
E	Auxiliary power supply outlet
F	Power supply outlet for chair

3.1.2 COMMAND KEYPAD ON THE STRUCTURE

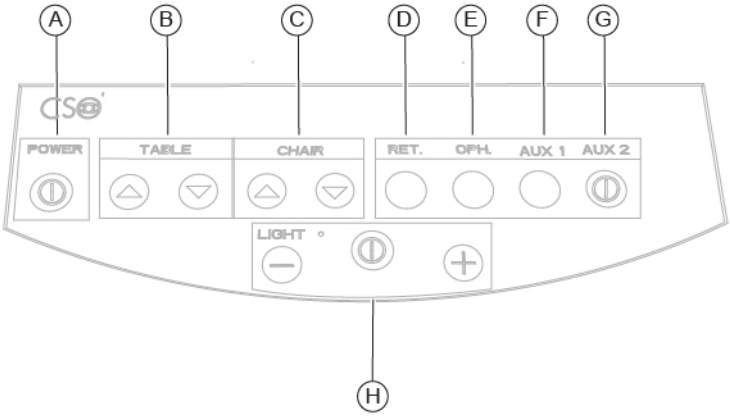


Fig 8 - Keypad

Pos	Function	Description
A	POWER	ON/OFF button for ophthalmic unit
B	TABLE	Buttons for adjusting table top elevation (only for compatible ophthalmic units)
C	CHAIR	Buttons for adjusting chair elevation
D	RET.	Activation/deactivation button for retinoscope connector
E	OPH.	Activation/deactivation button for ophthalmoscope connector
F	AUX 1	Auxiliary activation/deactivation button 230V
G	AUX 2	Auxiliary activation/deactivation button 230V
H	LIGHT	ON/OFF button for slit lamp and intensity adjustment buttons

Buttons AUX 1 and AUX 2 can be set by relays to turn on ambient light.

3.1.3 KEYPAD PLACED ON THE TABLE TOP ARM

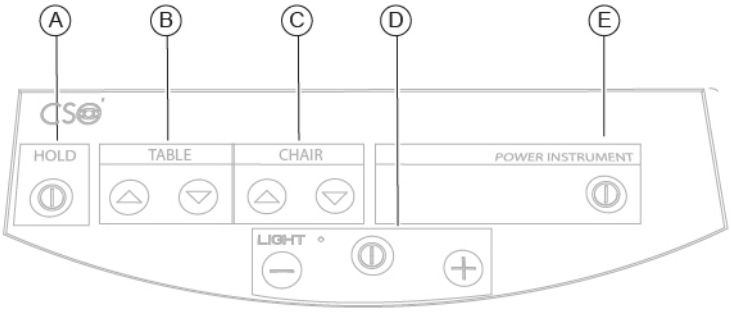


Fig 9 - Keypad

Pos	Function	Description
A	HOLD	Button for blocking the table top
B	TABLE	Buttons for adjusting table top elevation (only for compatible ophthalmic units)
C	CHAIR	Buttons for adjusting chair elevation
D	LIGHT	ON/OFF button for LED spotlight and intensity adjustment buttons
E	POWER INSTRUMENTS	ON/OFF button for devices

3.1.4 KEYPAD PLACED ON THE TABLE TOP

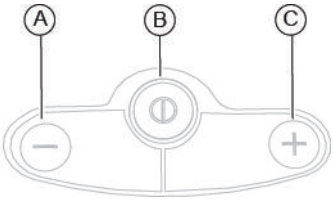


Fig 10 - Keypad

Pos	Function	Description
A	LIGHT	ON/OFF button for Slit Lamp
B	+	Light intensity adjustment button
C	-	Light intensity adjustment button

3.1.5 CHIN REST (OPTIONAL)

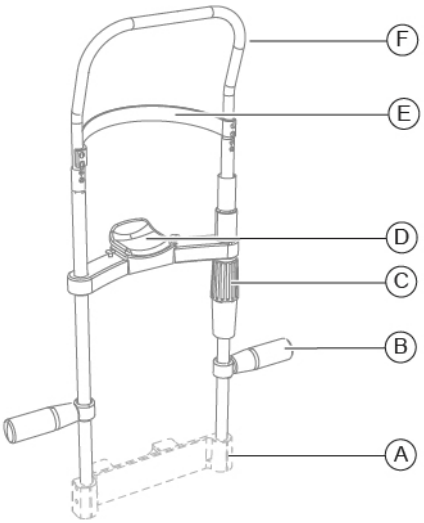


Fig 11 - Chin rest

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

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

Indications for using the chin rest are included in the instructions for use manual of the device. Chin rest models might differ depending on the device used.

3.1.6 CHAIR (OPTIONAL)

Different chair models are available accordingly to the client's choice. The base with telescopic column allows to adjust the elevation of the chair. It is possible to adjust elevation and position directly from the unit keypad, depending on the model.

Read the indications given in the instructions to use chairs.

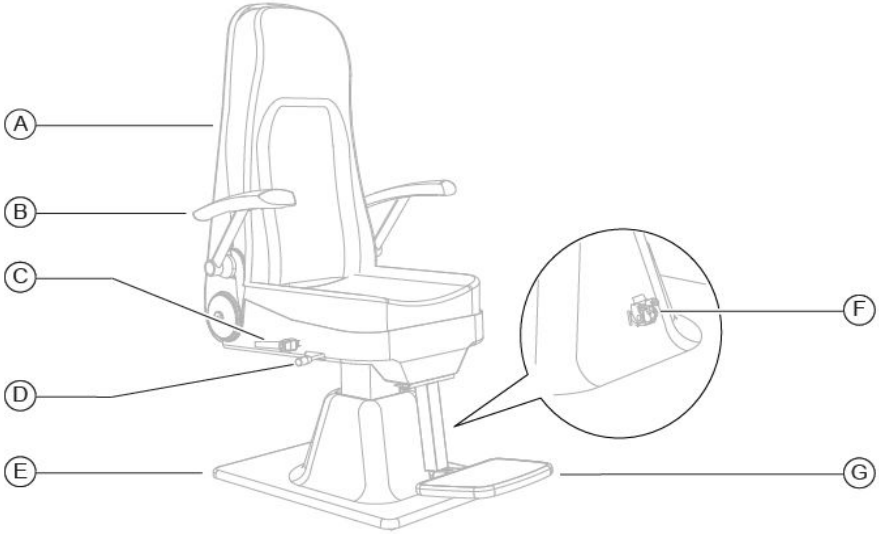


Fig 12 - Chair

Pos	Description
A	Chair
B	Movable arm
C	Lever for chair rotation
D	Lever for backrest reclining
E	Base with elevation
F	Outlet for connecting the chair to the ophthalmic unit
G	Footrest with adjustable baseplate

3.2 ACCESSORIES FOR PLACING THE DEVICE (OPTIONAL)

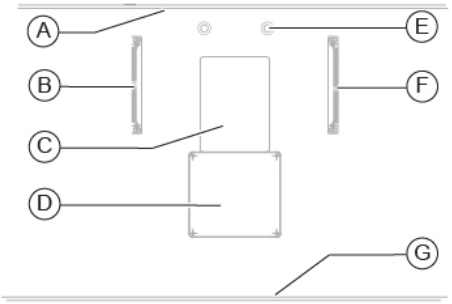


Fig 13 - Table top accessories

Pos	Description
A	Table top front edge
B	Left cogged guide
C	Sticker pad (for right/left alignment of the device)
D	Scrolling plate
E	Lower inserts for chin rest fixing
F	Right cogged guide
G	Table top rear edge

3.3 TECHNICAL DATA

Technical data	Version 230V	Version 120V
Supply voltage	230 Vac ±10%	120 Vac ±10%
Power frequency	50 Hz	60 Hz
Network fuses	4A T 5x20 mm	8A T 5x20 mm
Auxiliary sockets (chair and devices)	230 Vac 50 Hz	120 Vac 60 Hz
Maximum power absorbed by the auxiliary sockets	100 Va	100 Va
Maximum power absorbed by the ophthalmic unit	600 Va	600 Va
Voltage for devices on the table top	6 Vac or 12 Vac for Ophthalmometer and slit lamp 6Vac or 12Vac for fixation point of the chin rest 230 Vac for another diagnostic instrument	

Description	Value
Weight without electrical elevation	171 Kg
Weight with electrical elevation	174 Kg
Maximum size (LxPxH)	170x160x190 cm
Maximum weight for the table top	20 Kg
Maximum total weight for the table top arm	60 Kg

3.4 OPHTHALMIC UNIT BULK

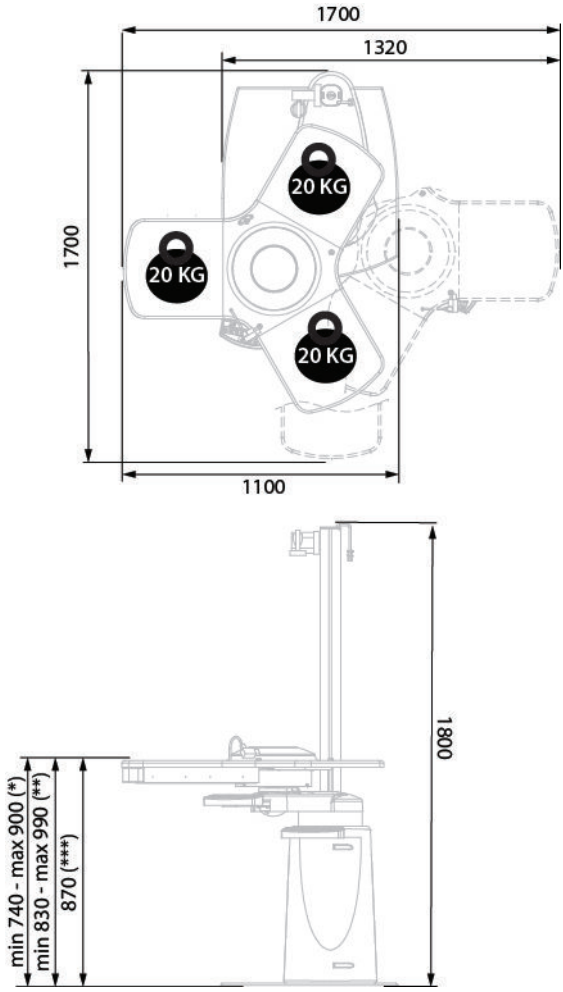


Fig 14 - ETOILE II ophthalmic unit bulk

(*) Electrical elevation of the handicap table top
(**) Electrical elevation of the table
(***) No elevation for the table top

4 DEVICE USE

4.1 HOW TO INSTALL THE OPHTHALMIC UNIT

For the ophthalmic unit installation procedure refer to the service manual. The installation has to be carried out by expert and competent personnel. The installation must be only carried out by expert authorised personnel.

4.2 HOW TO INSTALL STICKER PAD FOR PLACING THE DEVICE ON THE TABLE TOP

The ophthalmic unit allows to place two devices on the table top. Some devices, however, do not require installing further accessories to be placed on the table top. The chin rest support is fixed position: if you move the table top the chin rest will always be in front of the same device.

For the table top's configuration procedure for devices, please refer to the service manual.

1 Place the sticker pad between the two cogged wheels and the scrolling plate on the table top.
2 Verify the position respectively to the central axis (A).

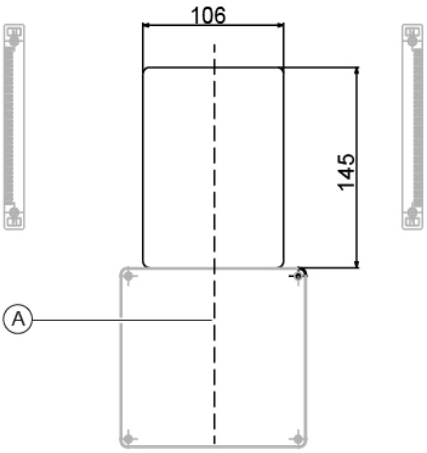


Fig 15 - Placing the sticker pad on the table top

4.3 HOW TO PLACE THE CHIN REST

On each table top, install chin rests depending on the position chosen for the devices.

1 Place the chin rest support under the table top.
2 Fasten screws (B) to the table top.
3 If a fixation point is provided, connect the cable to the outlet (A) placed under the table top.

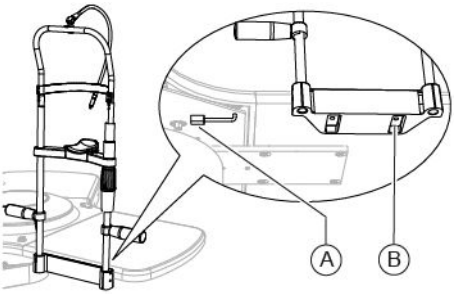


Fig 16 - Chin rest placement

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

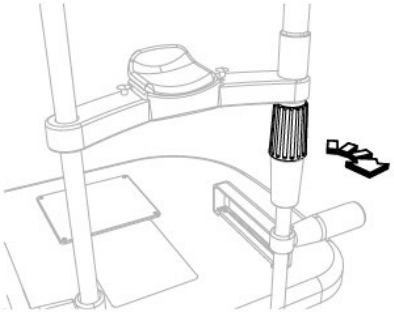


Fig 17 - Knob rotation

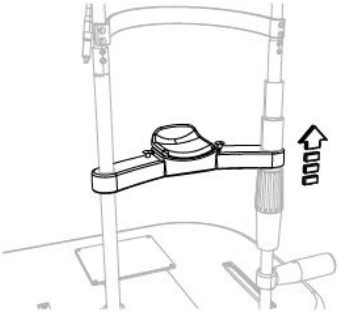


Fig 18 - Placing the chin cup

4.4 HOW TO PLACE DEVICES ON THE TABLE TOP

Do not place devices weighing more than 20 Kg on each single table top.

The Slit Lamp shall be placed in line with the outlet (A) on the table top (B). This position allows for adjusting the intensity by using the keypad (C) placed on the table top.

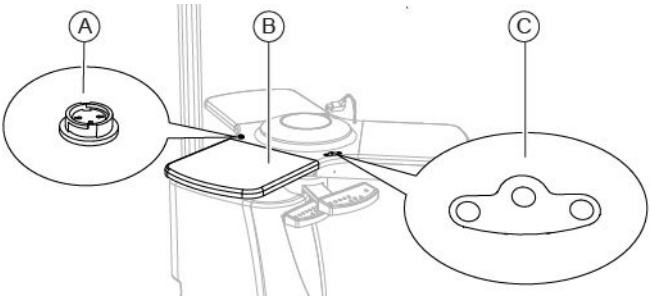


Fig 19 - Power connectors for slit lamp

The device with 230V power shall be placed in line with the outlet (D) on the table top (E).

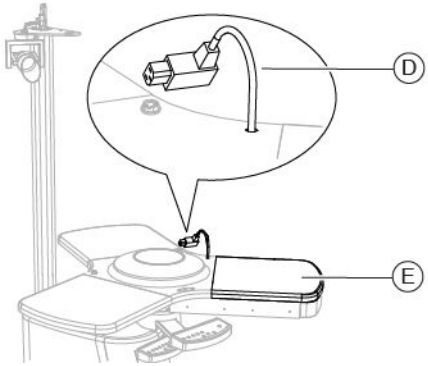


Fig 20 - 230V power connectors

1 Place the device on the table top and align the cogged wheels on the cogged guides.
2 Lock the two protection carters to the cogged wheels on the table top.

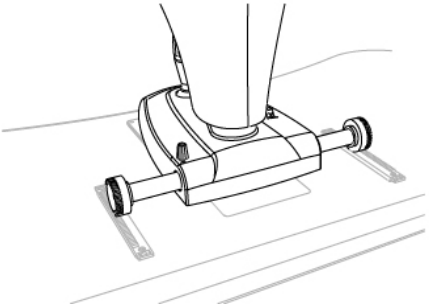


Fig 21 - Placement of the device

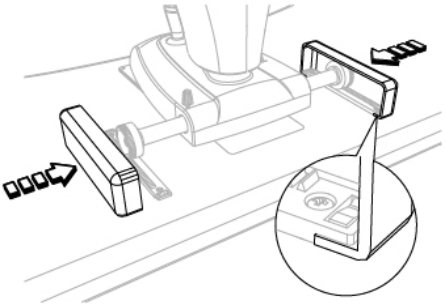


Fig 22 - Placing protection carters

3 Connect the device cables to both connectors placed on the table top. Connect the slit lamp to the outlet (A). Connect the other devices to the outlet (B) and (C).

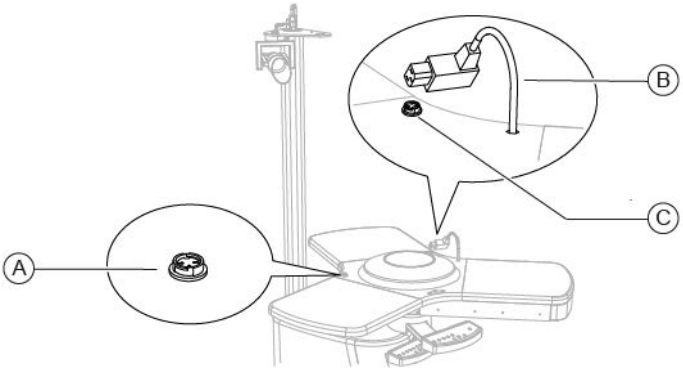


Fig 23 - Power supply ports on the table top

4.5 HOW TO CONNECT THE OPHTHALMIC UNIT

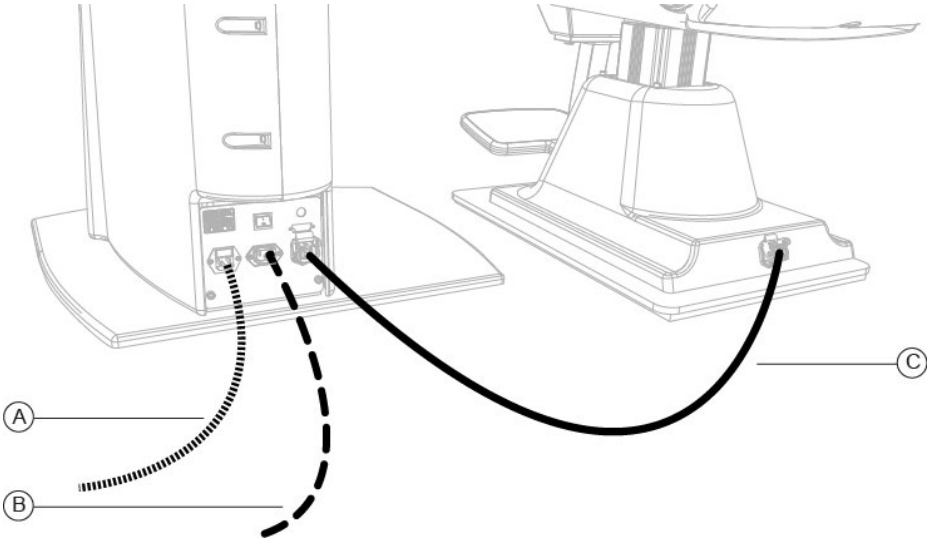


Fig 24 - Connecting the ophthalmic unit

Pos	Denomination
A	Power cable for connecting the ophthalmic unit to the power supply
B	Auxiliary power cable for connecting the ophthalmic unit to a device or an external accessory
C	Power cable for connecting the ophthalmic unit to the chair. The provision of the cable depends on the chair model.

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

4.6 HOW TO TURN ON THE OPHTHALMIC UNIT

1 Press the main switch of the ophthalmic unit on ON.
2 Press the POWER button on the structure keypad. The projector will automatically turn on when the unit does.
3 Place the table top arm in the desired position.
4 Rotate the table top to place the device to be used.

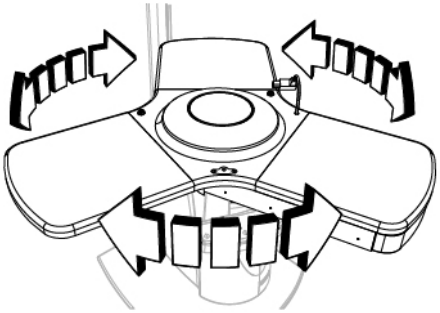


Fig 25 - Rotating the table top

5 Press the HOLD button (A) on the keypad placed on the table top arm to lock the arm and the table top in the desired position.
6 Press the POWER INSTRUMENT button (E) on the arm keypad to electrically activate the table top.
7 Press the CHAIR button (B) to adjust chair elevation.
8 Adjust table top elevation by pressing the TABLE button (C) on the arm keypad (Only for ETOILE II ophthalmic unit with table top elevation).
9 Adjust the spotlight intensity (D).

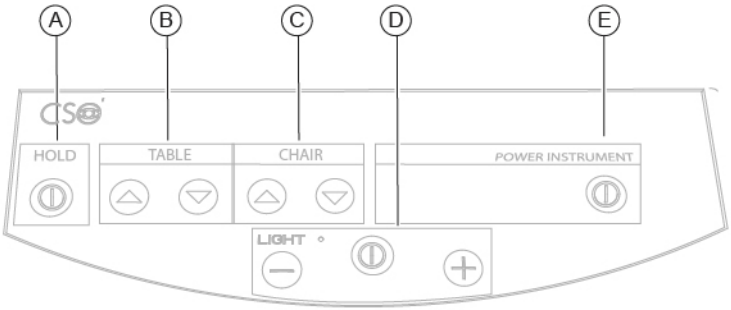


Fig 26 - Keypad on the arm of the table top

10 Press the ON/OFF button (B) on the table top keypad to turn on the devices placed on the table tops.

11 If using a Slit Lamp, adjust light intensity by pressing buttons (A) and (C).

Command functions for the table top keypad can be set during installation and programming operations.

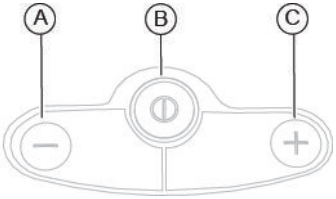


Fig 27 - Table top keypad

4.7 HOW TO RESET THE CHAIR

Chair settings can be reset by using the structure keypad or the arm keypad on the table top.

Structure keypad

1 Simultaneously press the chair adjustment buttons placed on the structure keypad.

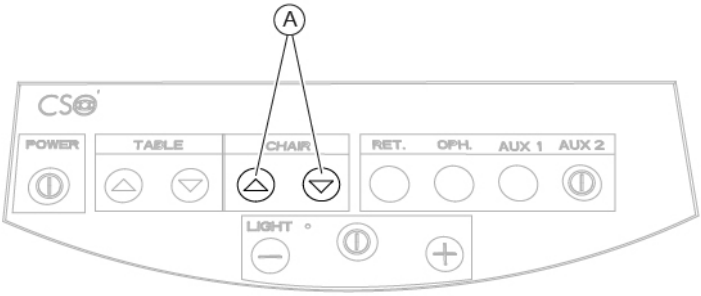


Fig 28 - Structure keypad

Keypad for the table top arm

1 Simultaneously press the chair adjustment buttons placed on the arm keypad.

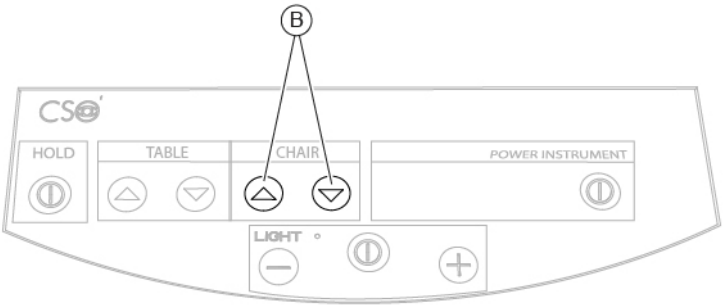


Fig 29 - Keypad on the arm of the table top

4.8 HOW TO SET FUNCTIONS

4.8.1 FUNCTIONS SETTING

1 Press the POWER button (A) on the structure keypad to turn on the ophthalmic unit.
2 Set the desired functions (e.g. AUX1, power instrument, light).
3 Press the POWER button (A) on the structure keypad to turn off the ophthalmic unit.
4 Press and hold the + button (B) on the structure keypad for 10 seconds circa. Wait for an acoustic signal.
5 Press the POWER button (A) on the structure keypad to turn on the ophthalmic unit. Functions are now set. To change functions repeat the indicated operations.

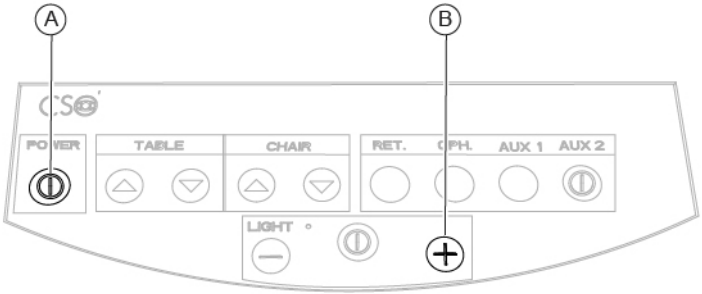


Fig 30 - Structure keypad

4.8.2 SETTING THE SLIT LAMP LIGHT INTENSITY

1 Press the POWER button (A) to turn on the ophthalmic unit.
2 Press the POWER INSTRUMENT button (E) on the arm keypad to turn on the table top.
3 Press the POWER button (A) to turn on the Slit Lamp.
4 Press + (C) and - (E) buttons to adjust the Slit Lamp light intensity.
5 Press the POWER button (D) to turn off the Slit Lamp.
6 Press and hold the + button (B) on the structure keypad for 10 seconds circa. Wait for an acoustic signal.
7 Press the POWER button (A) on the structure keypad to turn on the ophthalmic unit. Functions are now set. To change functions repeat the indicated operations.

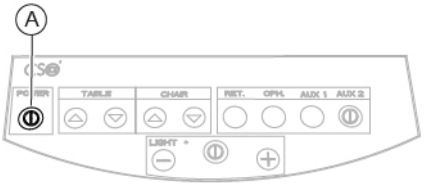


Fig 31 - Structure keypad

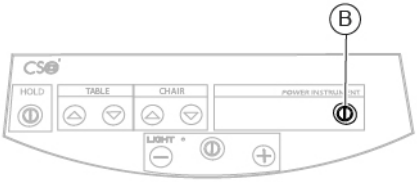


Fig 32 - Keypad on the arm of the table top

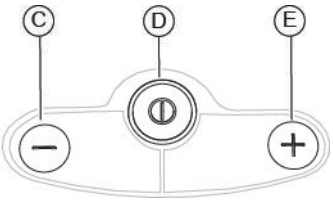


Fig 33 - Table top keypad

4.8.3 ADJUSTING THE SPOTLIGHT INTENSITY

1 Press the POWER button (A) to turn on the ophthalmic unit.
2 Press the LIGHT button (C) to turn on the spotlight.
3 Press + (B) and - (D) buttons to adjust the spotlight intensity.
4 Press the POWER button (A) to turn off the ophthalmic unit.
5 Press and hold the + button (B) on the structure keypad for 10 seconds circa. Wait for an acoustic signal.
6 Press the POWER button (A) on the structure keypad to turn on the ophthalmic unit. Functions are now set. To change functions repeat the indicated operations.

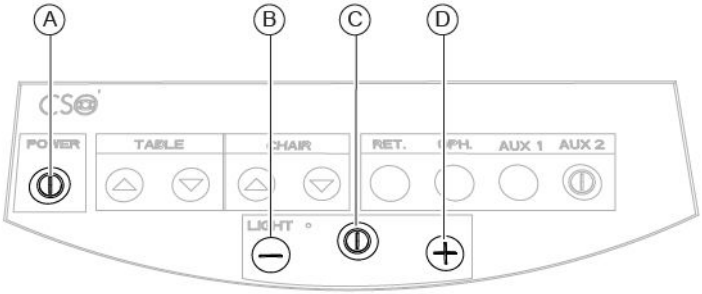


Fig 34 - Structure keypad

4.8.4 SETTING BUTTONS AUX1 AND AUX2

AUX1 and AUX2 buttons can have double or single function according to the settings programmed during the installation stage.
Furthermore, the AUX2 button simultaneously commands another function: an AUX2 INS switch (jumper8 connector on the electronic tab) which allows for both turning on an external lamp from a switch placed in the room and the AUX2 button.

1 When the ophthalmic unit is off, press the AUX1 (A) or AUX2 (B) button, then wait for an indicator to turn on and for an extended acoustic signal.

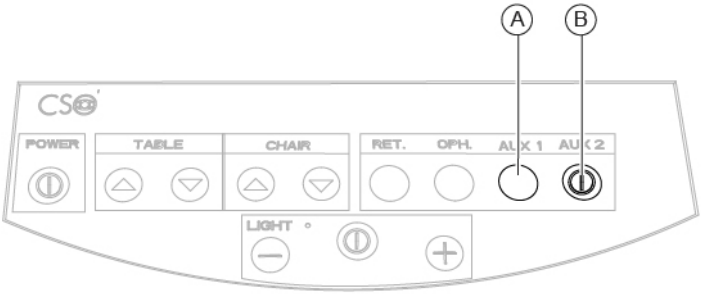


Fig 35 - Structure keypad

4.9 HOW TO USE THE AUX FUNCTION

The ophthalmic unit is equipped with two auxiliary outputs to directly power devices with a 230V supply (maximum absorbed power 100W).
The auxiliary outputs are placed on the power outlets module.
Press the POWER button on the ophthalmic unit keypad to activate auxiliary outlets.

4.10 HOW TO USE THE OFT AND RET BUTTONS

The OFT and RET buttons are connected to the 2V and 6V auxiliary ports.
To use these ports, connect the cable provided with the device to the jumper2 on the tab.

1 Press the OPH button (B) to activate the function or the auxiliary device. The LED will show the device is on.
2 Press the RET button (A) to activate the function or the auxiliary device. The LED will show the device is on.

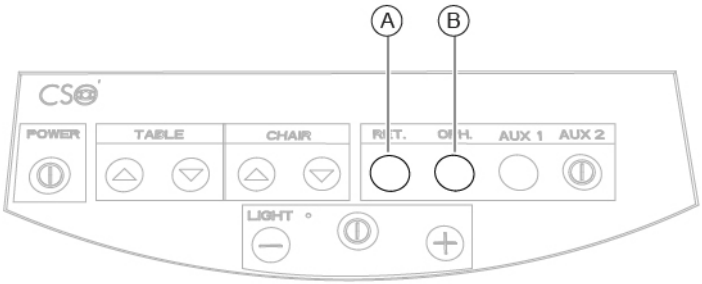


Fig 36 - Structure keypad

The operating voltage can thus range from 2,5V to 6V; such variation can be set by activating the jumper on the electronic tab:
- jumper4 and jumper5 to adjust the retinoscope voltage
- jumper6 and jumper7 to adjust the ophthalmoscope voltage.

4.11 HOW TO PLACE THE TABLE TOP TO EXAMINE THE PATIENT

1 Inform the patient to take a seat.
2 Manually place the arm and the table top in front of the patient.
3 Press the HOLD button to lock the arm and the table top in the desired position.

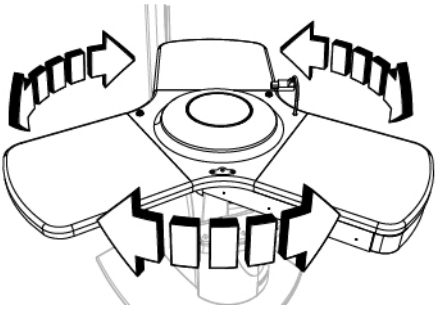


Fig 37 - Moving the table top

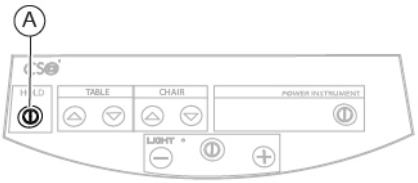


Fig 38 - Keypad on the arm of the table top

The table top can rotate at 360 degrees both clockwise and counterclockwise. If the video system is installed, the table top arm has a flush to avoid the complete rotation of the table top. (Optional accessory)

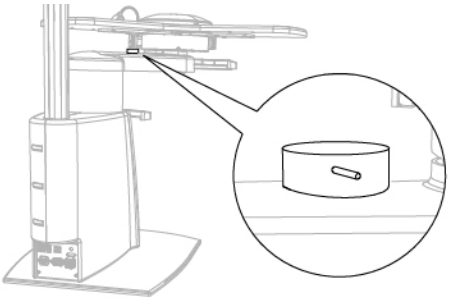


Fig 39 - Flush mechanism for video system (optional)

4 Check the patient's height respectively to the chin rest. Press the chair height adjustment button on the command keypad.
5 Perform the check-up with the medical device.

Refer to the device user manual and, if needed, the software user manual to perform medical investigations.

7 Once the check-up ends, place the table top in stand-by position. Tell the patient to get up.

4.11.1 HOW TO PLACE THE TABLE TOP TO EXAMINE MOBILITY IMPAIRED PATIENTS

1 Leave the table arm in stand-by position.
2 Place the chosen table top perpendicularly respectively to the column position.
3 Press the HOLD button to lock the arm and the table top in the desired position.
4 Place the patient in front of the table top.
5 Adjust the table top height and the chin rest height.

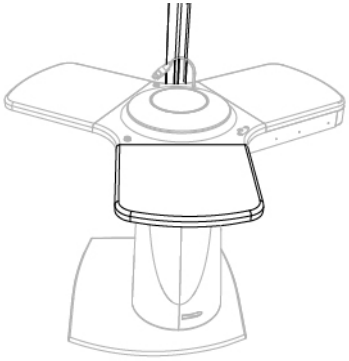


Fig 40 - Moving the table top

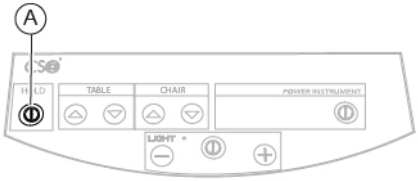


Fig 41 - Keypad on the arm of the table top

4.12 HOW TO TURN OFF THE DEVICE

CAUTION
Do not turn off the unit and do not disconnect the connection cable when it is in use.

Before turning off the ophthalmic unit, make sure the devices presenting an integrated operating system that needs to be turned off, if present, have been turned off.

1 Press the ON/OFF button on the arm keypad of the table top.
2 Press the ON/OFF button on the structure keypad of the ophthalmic unit.
3 Press the main switch of the ophthalmic unit on OFF.
4 Disconnect the power cable from the power supply.

4.13 HOW TO USE THE OPHTHALMIC UNIT IN THE EVENT OF ELECTRICAL FAILURE

The ophthalmic unit is provided with a system that allows for continuing tests even in the event of a circuit board failure. To restore the proper functioning of the ophthalmic unit, the electronic tab needs to be replaced.

The following procedure can only be carried out by expert authorised personnel.

1 Identify failure causes.
2 Press the ON/OFF button on the keypad to turn off the ophthalmic unit.
3 Disconnect the power cable from the power supply.
4 Open the compartment related to the electronic tab.
5 Move the needed jumpers on the circuit board to keep using the ophthalmic unit in emergency mode.
Here follow the main Jumpers:

ETOILE II

Jumper	Description
Jumper JP8 from NORM to EMER	Allows for turning on all functions of the ophthalmic unit.
Jumper JP1 and JP2 from NORM to EMER (on the table tab)	Allows for turning on the devices placed on the table top
Jumper JP1 from NORM to EMER	Allows for chair elevation by using the up and down buttons
Jumper JP3 from NORM to EMER	Allows for table top elevation by using the up and down buttons
Jumper JP9 from NORM to EMER	Allows for turning on the spotlight

4.14 HOW TO MOVE AND DISASSEMBLE THE OPHTHALMIC UNIT

For the disassembly procedure refer to the installation manual.

For the ophthalmic unit disassembly procedure refer to the service manual. The procedure has to be carried out by expert and competent personnel. The disassembly procedure must be only carried out by expert authorised personnel.

Before disassembling and reassembling the ophthalmic unit make sure the power supply cable is unplugged.

4.14.1 TRANSPORTING THE OPHTHALMIC UNIT

For the ophthalmic unit transport procedure refer to the service manual. The procedure has to be carried out by expert and competent personnel. The transport procedure must be only carried out by expert authorised personnel.

The weight of some components of the ophthalmic unit exceeds 25 kg.
Always move the component considering its weight and the number of operators needed.

ETOILE II

Size	Weight
170x160x190	171 Kg

Components	Size (cm)	Components weight	Number of operators
Counterweight	8x8x38	37.4	2
Base	70x76x68	75	3
Structure	74x34x61	8	1
Arm	80x85x45	45.6	2
Column	8x8x130	5	1

ETOILE II with electrical elevation for the table top

Size	Weight
170x160x190	174 Kg

Components	Size (cm)	Components weight	Number of operators
Counterweight	8x8x38	18.7	1
Motor	13x11x38	8	1
Base	70x76x68	90.5	3
Structure	74x34x61	8	1
Arm	80x85x45	51.8	2
Column	8x8x130	5	1

CAUTION

Danger of objects damage. Be careful not to hit the electronic tab while moving it. Make sure the electronic tab is protected before moving it.

5 ORDINARY MAINTENANCE

5.1 SAFETY WARNINGS

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

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

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

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

5.2 DEVICE CLEANING

Clean the external parts of the unit using a damp non-abrasive cloth to avoid damaging the material. Use soap and water to remove stains on the table top.

CAUTION
Danger of material damages. Do not use solvents or diluents to clean the device.

5.3 NETWORK FUSES REPLACEMENT

CAUTION

Danger of material damages. The fuses have to be replaced only when the power cable is disconnected from the mains power. For any other kind of fault please contact the installation company.

1 Pull out the fuse drawer. Remove fuses to be replaced.
2 Check that the new fuses value is compatible with the voltage of the electrical system. Check the data reported on the power outlets.
3 Place new fuses into the fuse drawer.
4 Put back the fuse drawer in the ophthalmic unit module.
5 Connect again the power cable to the power supply.

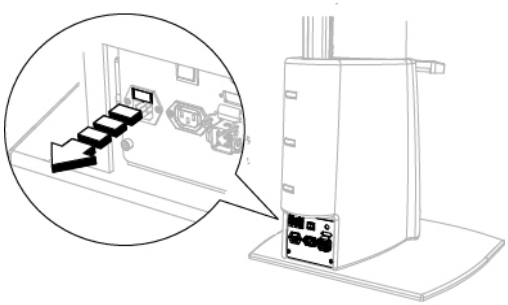


Fig 42 - Fuse drawer

5.4 SPARE PARTS AND ACCESSORIES LIST

To order spare parts or accessories, provide the product code as indicated in the list. If not included in the list, contact the Manufacturer or the local Distributor.

Code	Description
610540-HK4020	Bearing for rotation
100813121	Keypad
100811520	SPOT DIAPASON TWISTER
30080250010	Adjusting LED bulb
300202010	General ON/OFF switch
100813373	Table top
330801090	Flat cable
330803040	Chair cable
300502090	Up/down engine of the table top (230V)
300502091	Up/down engine of the table top (120V)
3014010	Magnet for arm rotation
3014020	Magnet for the basement
120813100	Electronic tab for the structure
120813300	Electronic tab for the dome
4109010	Decelerator
100813321	Keypad for the table top
100813322	Keypad for the table top arm
301304140	Basement transformer
301304221	Table top transformer
100813150	Rotation block group
610435-32007 (*)	Conical bearing for arm rotation
100813153 (*)	Rotation block bracket
100801029	Handle for counterweight lifting
100801027	Counterweight

The conical bearing for arm rotation, code 610435-32007, must be ordered together with the rotation locking bracket, code 100813153.

5.5 TROUBLESHOOTING

Issue	Cause	Solution	Note
The ON/OFF button on the keypad does not work	Power cable not connected to the power supply unit.	Connect the power cable of the unit to the power supply outlet. Press the main switch of the ophthalmic unit on ON.	Verify the connection between the ophthalmic unit and the mains power. Check the functioning of the fuses. Verify the connection of the keypad.
The chair does not respond to the commands	Power cable not connected to the ophthalmic unit.	Connect the power cable of the chair to the outlet on the chair base and on the outlets panel of the ophthalmic unit.	Check if keypad buttons are functioning. Check the up and down movement tension on the chair cable. Check that the chair motor is functioning properly by powering it separately.
The table top does not rotate	Bearings might be damaged.	Try lubricating with flux or spray grease	If the problem persists, check the bearings condition.
The table top does not lock into place	Magnets are not working properly. The magnet is not sliding properly in its seat. The magnet is not sufficiently blocking the plate.	Check the magnets voltage. Check their distance to the locking plate. Check the joint for the magnet sliding. Check the magnets gasket is not locked	If needed, operate on clamps. Replace the magnet which is not working properly.

Issue	Cause	Solution	Note
The unit turns off when the different functions are activated	The diode bridge (D1) is damaged or broken.	Check the diode bridge is functioning (input 12V alternate output 12V direct)	If the problem persists, replace the tab.
Instruments on the table top do not turn on	Check the F9 fuse. Check the voltage on the table top tab is functioning. Check fuses on the table top tab. Check the keypad on the table top.	If the problem is due to the circuit board on the table top, place jumpers J1 and J2 on the table top board, in emergency. Check the sliding contact or the cable condition (when dealing with a video system) placed under the dome of the table top.	If the problem persists, replace the electronic tab.
The keypad does not turn on	Connection cables are not connected properly.	Connect the connection cables properly.	Check cables connection. Check the keypad buttons' condition. Check the electronic tab is properly powered. If everything is functioning, select the EMER mode for the circuit board by moving the jumper.
The devices connected to the table of the ophthalmic unit do not work	Connection cables are not connected properly.	Connect the connection cables properly.	Check that the table top is connected. Check the output voltage. Connector on the table top. Check the right power has been programmed.

Issue	Cause	Solution	Note
The spotlight or the different outputs do not turn on.	Connection cables are not connected properly. The different devices might be off or not working	Connect the connection cables properly.	Check that the cables are connected properly. Check the output voltage for each peripheral device that is not working. Check the fuse for each relative output. Check the functioning of the connected units. If the problem persists, activate the emergency system for turning on the devices.

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