TOPCON

OPHTHALMIC UNIT
IS-100

USER
MANUAL

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1. INTRODUCTION

This User Manual contains important and essential information for the correct handling of the ophthalmic unit IS-100, manufactured by ANCAR and proper maintenance of the same.

It also contains safety instructions that must be faithfully followed to avoid accidents to people and to the unit.

1.1. USE OF THE MANUAL

1.1.1. Symbols used in the manual

Throughout the manual there are various symbols and warnings that alert and notify the degree of importance of certain texts. The ones used are presented and explained below.

1.1.1.1. Warnings throughout the manual

DANGER CALLS ARE A MEANS OF ATTRACTING ATTENTION TO ESSENTIAL OR CRITICAL INFORMATION.

WARNINGS INCLUDE INFORMATION ON CONDITIONS, PRACTICES OR PROCEDURES THAT MUST BE OBSERVED TO PREVENT:

- PERSONAL INJURY.
- DISABLING OF THE DEVICE.

Calls for caution are used to describe the conditions, practices or procedures that must be followed to avoid:

- Damaging equipment.
- Destroying equipment.
- Endangering health in the long-term.

Notes are used to highlight information of particular importance or interest that:

- Must be remembered.
- Facilitates a correct decision.
- Otherwise it is hard to find.

These are descriptions of both procedures and characteristics in which it is advisable to consider the possible repercussions in the environment of certain actions or choices, mainly of products to be used.

1.2. PLATES AND LABELS

The following labels are put on the unit:

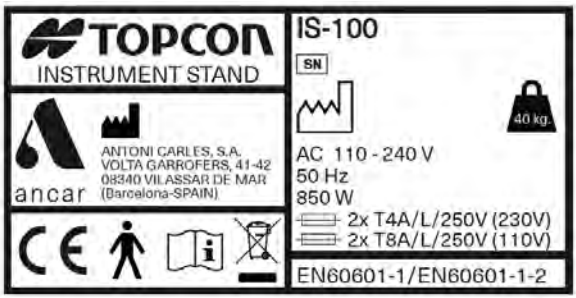


Figure 1-1. Ophthalmic Unit plate IS-100.

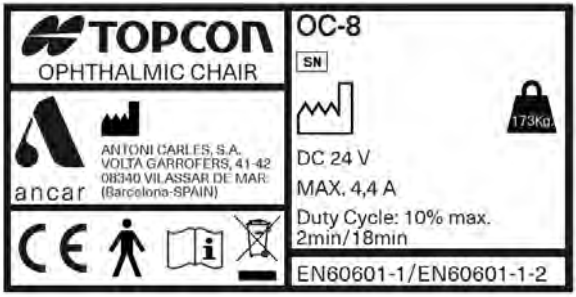


Figure 1-2. Ophthalmology chair plate OC-8.

Figure 1-3. Warning in the entrance area at 110-240 V.

Figure 1-4. Please refer to the user manual.

Figure 1-5. Type B electrical classification.

Figure 1-6. Foot entrapment hazard.

1.3. GLOSSARY

Table 1-1. Glossary.

TERM	DEFINITION
ANCAR	Acronym of the company ANTONI CARLES, S.A.
EM	Electromagnetic
EMC	Electromagnetic compatibility.
Ophthalmic	Related to the eyes.

1.4. GENERAL CONSIDERATIONS

THIS USER MANUAL SHOULD BE CONSIDERED AN INTEGRAL PART OF THE UNIT AND MUST STAY WITH IT THROUGHOUT ITS LIFE CYCLE.

THE PEOPLE IN CHARGE OF THE UNIT MUST READ AND UNDERSTAND THE MANUAL IMPERATIVELY BEFORE ITS COMMISSIONING AND USE.

The user is in charge of keeping the unit in perfect operating conditions, cleaning.

The ophthalmic unit, manufactured and designed by ANCAR, is a class I device, according to Directive 93/42/EEC (as amended in accordance with 2007/47/EEC). See EC Declaration in the Annex.

TOPCON reserves the right to make improvements or modifications to the unit without prior notice.

1.4.1. Intended use of the unit

The IS-100 unit is foreseen to facilitate support and positioning of ophthalmic instruments used during examination and diagnosis of patients. To do this, it has electronically regulated power contacts and patient seating using an electric lifting group.

1.4.2. Foreseeable misuse of the unit

TOPCON/ANCAR is not liable for material damages suffered by the unit or personal injury that may be caused by the misuse of the same.

Below are a number of uses for which the unit is not designed:

- To support or hold furniture or other materials.
- For interventions in operating theatres.
- To access elements at heights.
- Lean or sit on the junction box or the tabletop.
- Hang from the lamp.

1.5. INTELLECTUAL PROPERTY

This user manual, including drawings, operating diagrams and annexes, are the intellectual property of ANCAR, which reserves the right to modify its content without having to update the preceding manuals.

They will not be accessible to third parties without its express authorisation. They are only available to users of the units.

It is not allowed to copy, publish and disseminate, in whole or in part, documents, or make them available to others, in particular, of competing companies and without the prior authorisation of ANCAR.

1.6. WARRANTY

- TOPCON/ANCAR shall not be liable for damages due to fire, natural disasters, actions undertaken by third parties or other accidents (caused by the negligence or misuse of the operator) or due to the use of the unit under unusual conditions.
- TOPCON/ANCAR shall not be liable for damage derived from inappropriate use of the device, such as loss of business or loss of profits.
- TOPCON/ANCAR shall not be liable for the results of diagnoses made by a doctor when using this device.

Devices manufactured by ANCAR are warranted for a period of 2 years, from the date of installation correctly recorded on the form in the website. During this period, ANCAR, assumes the repair or supply free of charge, of those parts of the device that, once verified, are recognised as defective. It shall not be liable for defects and their consequences, produced by:

- Natural wear.
- Inadequate cleaning or maintenance.
- Accidental knocks.

The right to compensation for damages and replacement of the entire device are also excluded.

TOPCON/ANCAR's liability ceases, automatically cancelling the warranty, in the following cases:

1. If within 30 days from the date of installation, registration is not formalised on the website.
2. If interventions on the device are not made by technicians certified by TOPCON/ANCAR.
3. If incorrect maintenance operations are made on the device, or non-original spare parts are used.
4. If the electrical installation required for the operation of the device is carried out not observing the indications in the maintenance or the provisions of the current standards of the country of use are not observed.
5. If non-authorised modifications are made on the device, or other medical devices and/or accessories not foreseen by TOPCON/ANCAR are connected.
6. In the case of a complaint about the conditions of the device delivered, the buyer may not delay or suspend payments.

Breach at the time of sale as a new product, of points 4 and 5, exempts TOPCON/ANCAR of liability relating to the CE mark, which shall be transferred to the seller, which should be considered for all purposes as assimilated to the manufacturer of the device.

The warranty for the integrated elements of other brands, will be that granted by each of the respective manufacturers, with TOPCON/ANCAR not assuming any liability or obligation in regard to this warranty.

Parts under warranty to be repaired or replaced must be sent to the warehouses of TOPCON/ANCAR with postage paid, indicating the device number they belong to.

It is necessary to complete a form provided by TOPCON, specifying the returned material.

The warranty is only valid if the appliance has been used correctly and installed by authorised technical personnel.

If within the warranty period a fault were to arise the cause of which is uncertain and may lead to the use of the warranty by the customer, the latter must promptly notify this to the TOPCON dealer.

TOPCON/ANCAR shall investigate the cause and chargeability of the damage and, in the meantime, it must keep the unit in the conditions it ended up in as a result of the fault.

TOPCON/ANCAR shall not be liable for defects caused by improper handling of the unit or non-compliance with the instructions contained in this manual.

The user of the ophthalmic unit is not authorised to make any repairs or replace any components. If assistance is needed, contact the TOPCON dealer.

1.7. SPARES

If spare parts are needed of any of the components of the unit, contact the dealer of the ophthalmic unit.

2. GENERAL

2.1. SAFETY

For the correct and safe use of the unit, it is necessary to identify the hazards the unit might have, as well as observe the safety measures defined by the user:

- Installation and handling of the products of TOPCON/ANCAR should be carried out by authorised personnel. In particular, electrical connections must be carried out only by qualified specialists.
- It is forbidden to perform any replacement or remove protective caps.
- Do not attempt to repair any material after a fault or damage and put it back into operation again. In these cases, it is essential to contact TOPCON's official dealer.
- No liability can be accepted for damage caused as a result of a misuse.
- Store or install the unit in a controlled environment the conditions of which conform to the specification below:
  - Temperature: 10 ºC - 40 ºC
  - Moisture: 30% - 75%
  - Atmospheric pressure: 700 hPa - 1060 hPa
  - Free from condensation and dust.
  - Not exposed to direct sunlight.
- In the event of an anomalous situation, disconnect the unit immediately and consult the technical support team.
- The unit must be installed in a place where it can be easily disconnected.
- Place the instruments centred on the tabletop, and if possible, fastened to it. Do not use them to move the tabletop.

- Do not leave the patient without direct supervision of staff. If necessary, disconnect the unit with the main switch.
- Both of the patient's feet must be on the footrest before operating the automatic lowering of the chair, in order to avoid potential entrapments.
- The parts touching the patient are the chair and the tabletop. Pay special attention to keeping these parts away from the live parts under normal conditions. Make sure there is no conductive connection to any metal parts that are not grounded.
- Do not remove covers or access the internal parts. Only the technical staff has the know-how to carry out installation or maintenance work, in particular repairs on the electronic control elements and the elevation of the chair.
- Do not place objects on the cover or the drawer (optional) underneath the tabletop, as when it is returned to its resting position the latter may become trapped.
- To avoid the installed instruments from suffering adverse effects, use of mobile phones and other devices that emit waves in the surroundings of the device while it is being used is discouraged.
- Before moving the tabletop in any way, make sure that no one is underneath, especially children.
- Do not place the patient on the footrest. Place him or her on the chair with the footrest in its vertical position.

2.2. MECHANICS

- Do not overload the tabletop. Observing the maximum weight to be borne by the tabletop prolongs the useful life of the components.
- Do not use the tabletop or the keyboard desk for sitting, to prevent damage to the unit and possible falls.

2.3. ELECTRICS

- When disconnecting the power outlet, do so carefully. Never pull the cable because this can cause cracks in the internal wires, resulting in a short circuit, electric shock or fire.
- The voltage socket must correspond to power specifications. Variations in the main voltage can affect the operation of the instrument.
- Before using the unit, connect all power cables properly and make sure they are in good condition.
- Do not handle the power socket with wet hands.
- To avoid the risk of electrocution, only connect the unit to supplies with a ground connection.

2.3.1. Electromagnetic Interference EMC

The ophthalmic unit is in conformity with the essential requirements, applicable to it, of the Medical Device Directive MDD 93/42/EEC, complying with the requirements of design and construction contained in the standards EN60601-1 and EN60601-1-2 regarding the Safety of Medical Electrical Equipment and Electromagnetic Compatibility, thus not causing electromagnetic disturbances, and complying with immunity standards. To avoid this, the unit requires special attention to the following requirements of the EMC regulation:

- It must be installed and configured in accordance with the EMC guidelines included in the applicable documentation.
- Mobile RF communication devices (e.g. cellphones) may affect the medical instrument.
- The use of accessories, transducers or cables other than those specified or supplied by the manufacturer may lead to an increase in emissions or a reduction in the protection of the unit from them.
- The unit should not be used near other equipment. Where this proximity is necessary, the entire system must be checked to ensure the final configuration is working properly.

- A minimum distance of 30 cm should be kept between cellphones and the unit.
- It is possible to avoid EMC interference by keeping a minimum distance away from the transmitting device, depending on the intensity of its signal.
- The unit is designed to operate in an electromagnetic environment, provided interferences are kept under control.
- Any of the described situations that does not meet the precautions mentioned might have a negative affect on the useful life of the product.
- Direct simultaneous contact between the user, the patient, and non-EM equipment is not foreseen.

2.4. GASES

The unit is classified as a device not designed to work in a potentially flammable environment. Therefore, it must not be located in operating theatres, in the presence of flammable anaesthetic gas with oxygen or nitrous oxide.

2.5. ENVIRONMENTAL MANAGEMENT

The user, as a producer of waste caused during the use of the device, is responsible for the proper management of the same according to the legislation in force.

All the materials used for packaging respect the environment and are recyclable: wooden pallet, cardboard, polyethylene bag and bubble film. Collection of the materials used favours the reduction of waste material.

TOPCON/ANCAR are committed to achieving the objectives of Directives 2011/65/EC and 2012/19/EC.

The symbol of the Figure 2-1 is only applicable for member states of the European Union. In order to avoid potential negative consequences for the environment and possibly for human health, this device has to be removed:

- In the member countries of the EU: according to WEEE (Waste Electrical and Electronic Equipment Directive).
- For the rest of the countries: according to local regulations and laws.

Figure 2-1. Environmental management

3. DESCRIPTION OF THE UNIT

The unit is designed to facilitate support and positioning of ophthalmic instruments used during examination and diagnosis of patients. To do this, it has electronically regulated power contacts and patient seating using an electric lifting group.

The Figure 3-1 shows the components of the unit.

1. Ophthalmic unit. See Section 3.2.1.
2. Ophthalmology chair. See Section 3.3.
3. Phoropter arm (optional).
4. Lens drawer (optional). See Section 3.4.
5. Support CV5000 PS (optional).
6. Near vision lamp (optional).

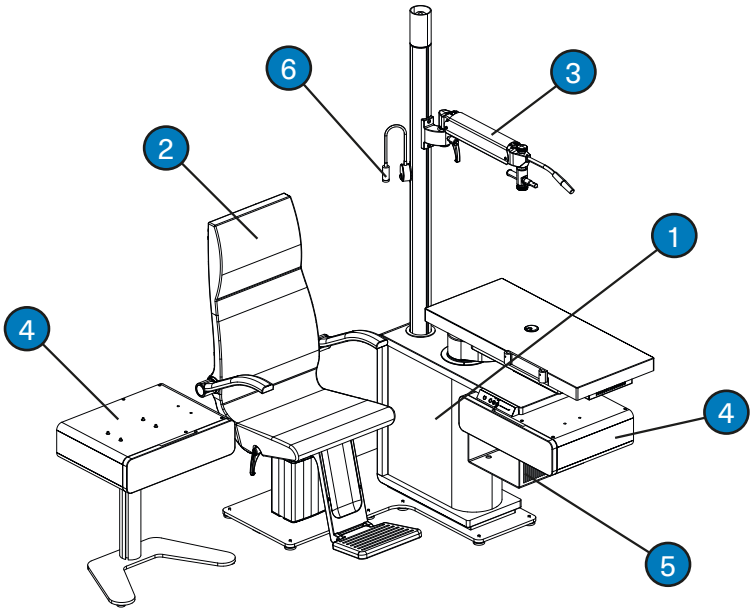


Figure 3-1. Components of the unit.

3.1. CHARACTERISTICS

3.1.1. Unit IS-100

CHARACTERISTIC	VALUE
Power supply	110-240 VAC / 50-60 Hz
Consumption	850 VA
Electrical classification	Class I / Type B
Maximum power of the first tabletop instrument	160 VA
Maximum power of the second tabletop instrument	150 VA
Slow start system (bulb protection)	Yes
Unit lamp output	24 VDC - 9 W
General protection (junction box)	220 V: 2 x F4A/L/250 V Ø5 x 20 mm 110 V: 2 x F8A/L/250 V Ø5 x 20 mm
Net weight	120 kg
Gross weight	140 kg
Maximum load on the tabletop	35 kg
Maximum acceptable load for support 3 (phoropter)	10.3 kg
Maximum acceptable load for support 3 (light, screen, etc.)	6 kg

3.1.2. Ophthalmology chair OC-8

CHARACTERISTIC	VALUE
30º rotation (patient access) with hand brake	Yes
2 armrests and reclining footrest	Yes
Minimum height	430 mm
Maximum height	630 mm
Maximum load	170 kg
Consumption	24 VDC / Max. 4.4 A
Electrical classification	Class I / Type B
Net weight	30 kg
Gross weight	50 kg
Work cycle	10% max / 2 min - 18 min

3.1.3. Unit dimensions

Figure 3-2 shows the dimensions of the unit, and also the maximum and minimum heights the chair can reach.

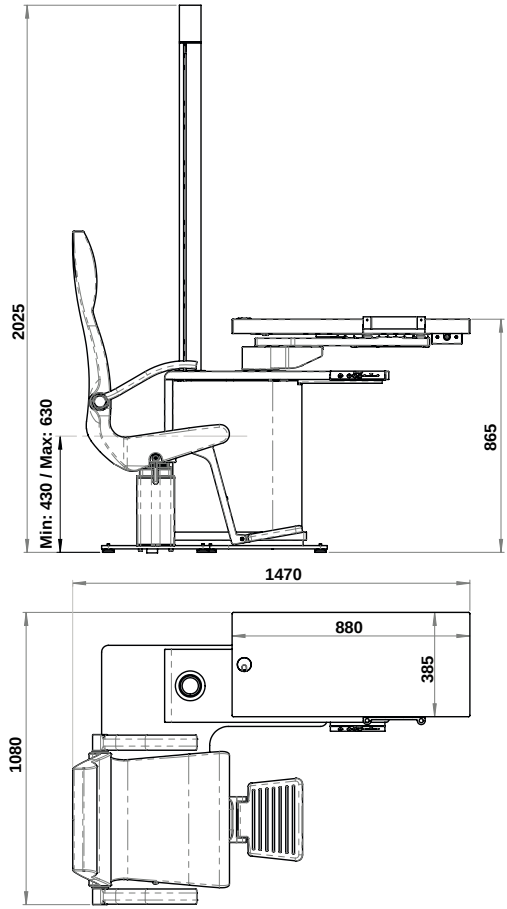


Figure 3-2. Dimensions of the unit.

3.2. DESCRIPTION OF THE COMPONENTS

3.2.1. Ophthalmic unit

1. Tabletop. See Section 4.2.3.
2. Junction Box.
3. Light Column
4. Keyboard. See Section 4.2.1.
5. Base.

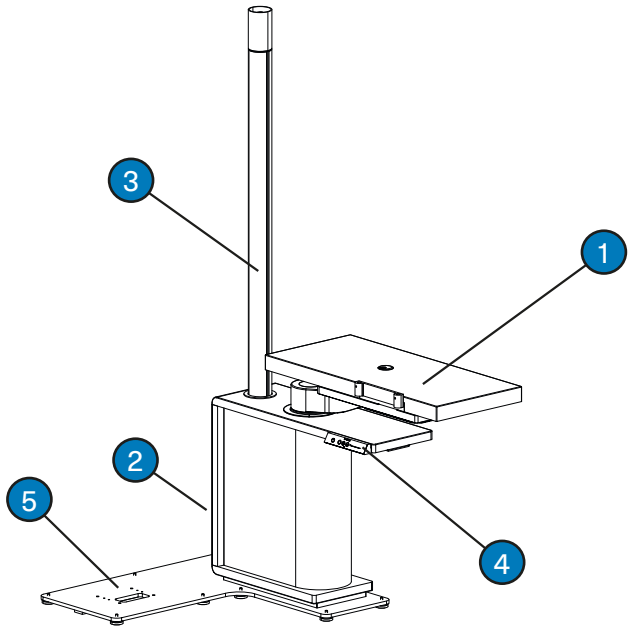


Figure 3-3. Ophthalmic unit.

3.3. OPHTHALMOLOGY CHAIR

The ophthalmology chair (Figure 3-4) has a variety of amenities for the comfort of the patient, listed below.

1. Chair.
2. Armrest.
3. Footrest (optional).
4. Hand manual.
5. Lifting column.

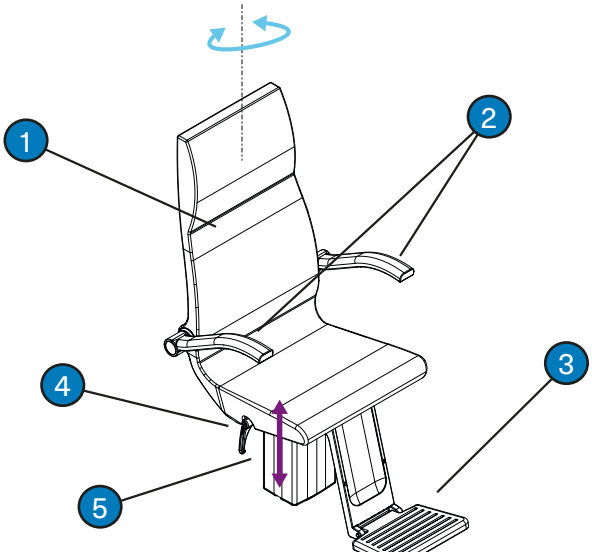


Figure 3-4. Ophthalmology chair.

The chair (1) has a vertical lifting group (5) to adjust its height, this adjustment is done using the keyboard. See Section 4.2.1.

It also has a hand brake (4) to lock and unlock its rotation.

3.4. LENS DRAWER (OPTIONAL)

The trolley (Figure 3-5) is an item designed to hold the test lenses in their drawer (2), in addition to providing a support tray for different items (1).

1. Drawer.
2. Support.

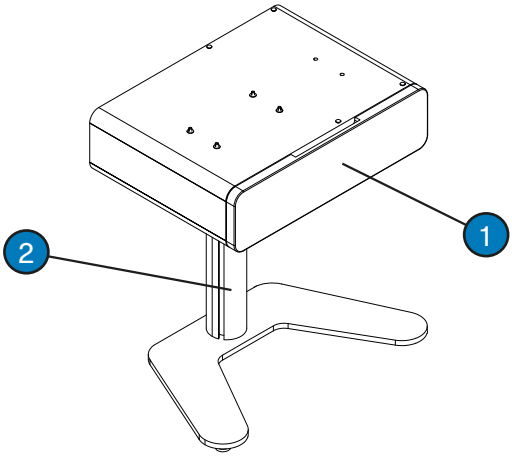


Figure 3-5. Lens drawer.

4. HANDLING OF THE UNIT

The user must know the operation and handling of the devices that make up the ophthalmic unit, as well as the usual operations to be performed.

4.1. NORMAL OPERATIONS

4.1.1. Switching on the unit

Switch the device on connecting it to the mains.

The light should be blue.

4.1.2. Switching the unit off

Disconnect the device from the mains at the end of the working day or if the unit is going to be without direct supervision of staff.

4.1.3. Switching off the unit for long periods

If the device is not going to be used for a long time, disconnect the plug from the mains.

4.2. OPERATING ITEMS

The user has the following items for operating the unit:

- Keypad. See Section 4.2.1.
- Phoropter arm (optional). See Section 4.2.2.
- Tabletop. See Section 4.2.3.

4.2.1. Keypad

The keyboard (Figure 4-1) incorporates two functions. On the one hand, it allows adjusting the chair's height, and on the other, it allows regulating the switching on of the LED light and its brightness.

The adjustment of the height of the chair is achieved by pressing the up (2) or down (3) buttons pressed.

The on/off button (1) lights up blue when the unit is on standby and green when it is in use.

1. Power On/Off.
2. Raise the chair.
3. Lower the chair.
4. Switch on LED light strip.
5. Reduce brightness LED light.
6. Increase brightness LED light.

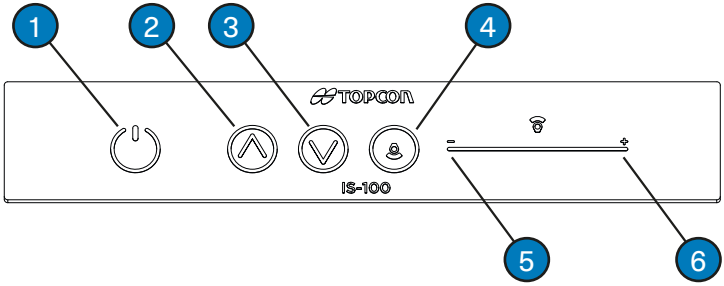


Figure 4-1. Keyboard.

4.2.2. Phoropter arm (Optional)

The phoropter arm (Figure 4-1) has different regulations that allow adjusting the position of the phoropter accurately to the patient's face. Table 4-1 lists possible adjustments the phoropter has and also the procedure on how to carry them out.

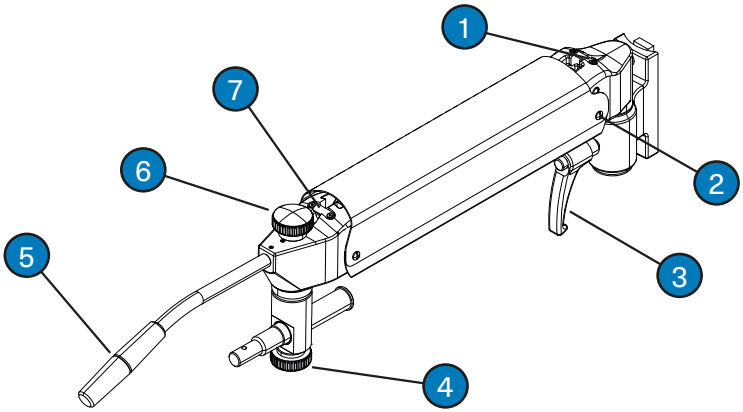


Figure 4-2. Adjustment of the phoropter arm.

Table 4-1. Adjustment of the phoropter arm.

ADJUSTMENT	PROCEDURE
Regulation force	1. Loosen the safety screw (2). 2. Turn the screw (1) with an Allen wrench to change the regulation force. 3. Adjust the safety screw (2).
Maximum vertical rotation	Turn the screw (7) to limit the vertical rotation. Tightening reduces the rotation.
Vertical position	Use the handle (5) to lock or unlock.
Lock vertical sliding	Use the slider (3) to lock the vertical position.
Horizontal position	Use the slider (4) to move the phoropter horizontally.
Horizontal direction	Use the slider (6) to lock the horizontal position.

4.2.3. Tabletop

THE BOTTOM OF THE TABLETOP HAS A SAFETY SENSOR FOR THE LEGS. IN CASE OF CONTACT, IT IMMOBILISES THE CHAIR LIFTING GROUP UPWARDS ALLOWING IT TO LOWER TO FREE THE LEGS.

The tabletop (3, Figure 3-3) has two types of movement:

- **Rotation:** the tabletop can turn 90º, ranging from the rest position to the work position.

If the tabletop has instruments installed, pick them up before turning it. Never turn it while it is extended to its maximum length.

The rotation of the tabletop activates the power supply of the instruments of the tabletop.

- **Horizontal sliding:** the tabletop can slide horizontally to position the instruments (first or second instrument). There is mechanical fixing to secure the position of the tabletop.

Depending on the position of the tabletop, the corresponding instrument remains electronically active. If this option is not required, the installer can deactivate it.

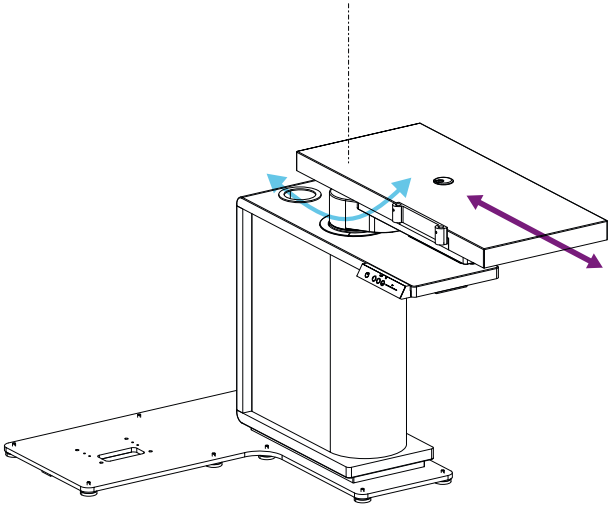


Figure 4-3. Movements of the tabletop.

5. TRANSPORT, INSTALLATION AND STORAGE

TRANSPORT, INSTALLATION AND COMMISSIONING IS CARRIED OUT BY TOPCON'S OFFICIAL DEALER.

IN THESE OPERATIONS ARE PERFORMED BY THE USER, TOPCON SHALL NOT BE LIABLE FOR ANY DAMAGE TO THE UNIT OR STAFF IN CHARGE OF THE OPERATION.

Installation of EM systems and their modification during their useful life must be assessed in line with the requirements of Standard IEC 60601-1 regarding the electrical safety of EM devices.

6. MAINTENANCE

6.1. INTRODUCTION

For correct maintenance of the ophthalmic unit you must contact TOPCON's official dealer. Work related to maintenance should be carried out by official technicians trained for such actions.

On the other hand, there are certain maintenance actions that should be carried out by the user. See Sections 6.2 and 6.3.

CARRY OUT THE OPERATIONS WITH THE DEVICE DISCONNECTED FROM THE MAINS.

DO NOT FLOOD OR WET THE DEVICE WITH WATER SINCE THERE ARE ELECTRONIC COMPONENTS INSIDE IT.

NEVER USE HOUSEHOLD DETERGENTS OR FOAM FOR CLEANING.

Clean the devices with a damp cloth and mild detergent. The use of chemicals can damage the following items:

- Wooden parts.
- Upholstery.
- Metal parts.

Do not apply the products directly on the device.

Advanced maintenance tasks can only be carried out by authorised technicians. Do not disassemble the unit or manipulate its internal components under any circumstances or remove the protective elements.

For disinfection, use specific products from the market or an aqueous solution with an alcohol base and components of quaternary ammonium, observing the action and drying time.

For disinfection of hard-to-reach areas, small objects, or small areas in the proximity of the patient that have been contaminated and are not likely to be disinfected by heat or immersion in a solution, apply the disinfectant as a spray.

It is recommended to use neutral products in order not to damage the most sensitive parts.

Apply cleaning products on a clean cloth and then clean the device with the cloth.

This section lists the maintenance operations than can be carried out by the user.

6.2. CLEANING

Use of abrasive cleaners, powders, scouring pads, steel wool, sandpaper, etc., during cleaning can damage the finish on the tabletop and permanently reduce the chemical and stain resistant laminate.

Use a damp cloth and mild detergent to clean the tabletop.

Given the chemical resistance of the laminate of the tabletop, the use of bleach, ammonium chlorides and other antimicrobials does not damage the surface.

6.3. CORRECTIVE MAINTENANCE

6.3.1. Thermal repair of superficial scratches on the tabletop

The procedure described in this section is only valid for the tabletop.

It is possible to repair any surface scratches the surface of the tabletop might have with the following procedure:

1. Put a paper towel on the scratched surface.
2. Spray the paper towel with water.
3. Iron the paper towel.

The iron should be at its maximum temperature.

The iron should not be on the surface of the tabletop for more than 5 seconds. In addition, during ironing, the iron must be kept in constant motion on the paper towel.

4. Remove the paper towel and dry the surface.
5. Repeat the operation as many times as necessary.

It is not possible to repair with this procedure scratches that have penetrated the protective surface of the tabletop.

6.3.2. Lifting motor of the chair not operational

If the manoeuvre of the lifting motor is not operational, it may be due to the activation of the thermal protection due to an overload, or a continuous job without respecting the work cycle.

The work cycle allows 2 minutes of work within a range of 18 minutes.

In order to solve this problem, carry out the following checks:

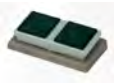
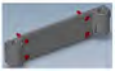
- Wait for the reset: if the fault is due to an overload of the lifting group, wait until the temperature drops.
- Check the corresponding fuses.

BEFORE REPLACING THE FUSES, DISCONNECT THE UNIT FROM THE POWER SUPPLY.

- Check that the supply voltage matches the specifications of the unit.
- Check the correct connection of the power supply wiring.

If, after these checks, the fault persists, contact the technical support service.

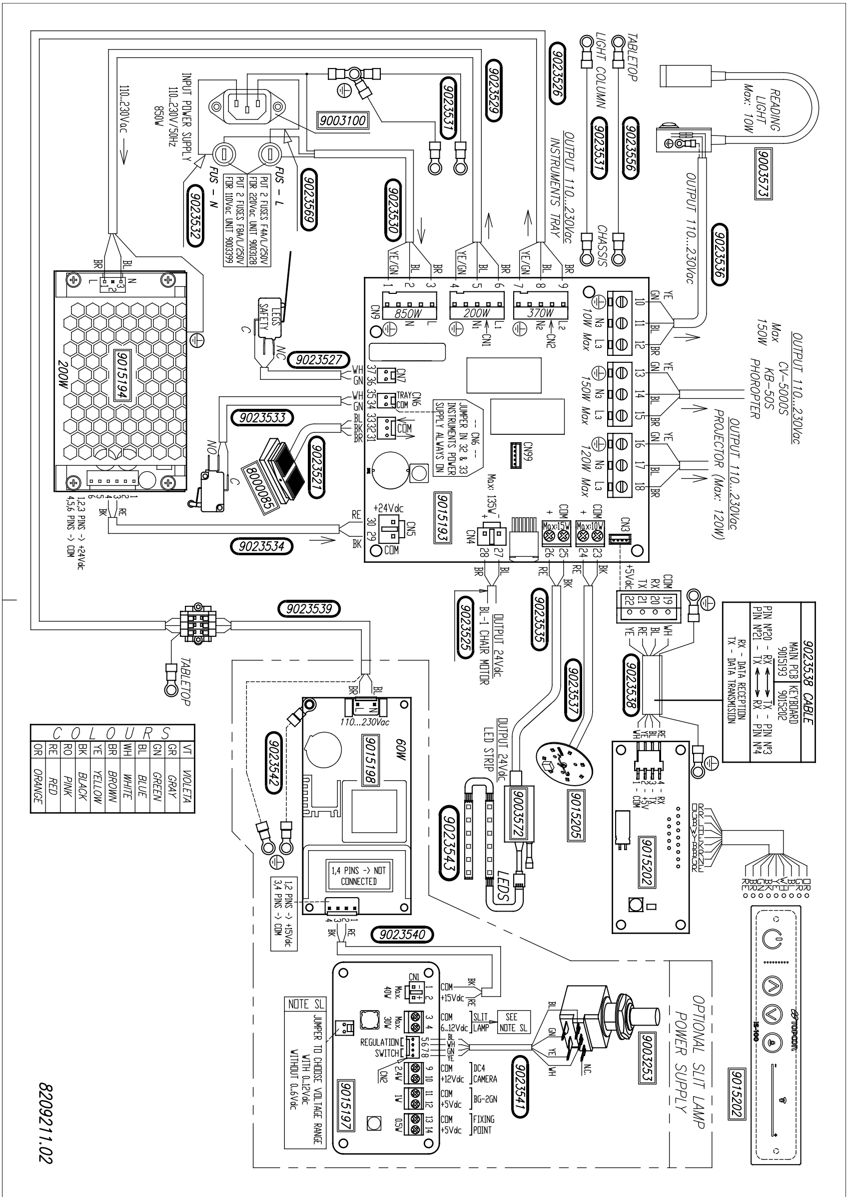
7. ACCESSORIES

ACCESSORY		ACCESSORY		ACCESSORY	
IS-100		TLD 100-XL		VT-671	
OC-8 Dark grey		RL-100		Projector support	
OC-8 Blue		PS clip CV-5000S		Foot switch for OC	
OC-9 Dark grey		'Satellite' support		Foot switch cable IS-100	
OC-9 Blue		Support TLD-100		Table extension edge	
TLD-100		Footrest OC-6/8		Auxiliary tray	
VT-670		PS-100		Chinrest	

8. ANEXOS

This section includes the following documents:

- Circuit diagram.



COLOURS	
VI	VIOLETA
GR	GRAY
GN	GREEN
BL	BLUE
WH	WHITE
BR	BROWN
YE	YELLOW
BK	BLACK
RO	PINK
RE	RED
OR	ORANGE