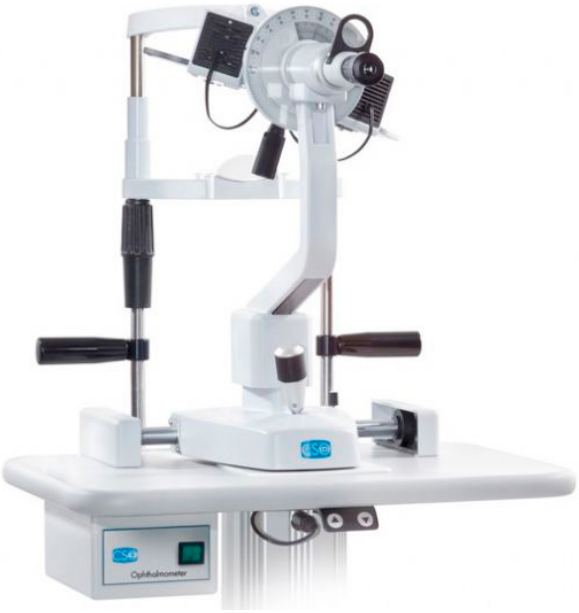
EN

OFTALMOMETRO



USER'S MANUAL

CONTENTS

INSTALLATION

1. GENERAL WARNINGS

- These instructions describe how to use the CSO JVL/1 Keratometer correctly.

WARNING!
Please carefully read this manual before using the device.

All CSO products have been manufactured with the greatest attention to functionality and safety. In particular The JVL/1 Keratometer is a high-performance device. To use the device effectively and safely, please read this user manual carefully before installing and using the device, and follow the instructions and warnings reported in the manual and on the device. Operators who have used the device previously, should check again the instructions reported in this manual. The manual must be readily available for consultation.

The original text of this manual is in Italian..

1.1. SYMBOLS

Explanation of Symbols:

Type B applied parts, in compliance with EN 60601- 1 standards.

Class II device (in compliance with EN 60601-1 standards). This means that the isolation from the mains supply is highly reliable, therefore no safety earthing connection is necessary

"Please refer to the instruction manual." It signifies that, for safety reasons, you need to consult the instruction manual before using the evice.

Fuse

CE 0051 Device classification in accordance with the rules set out in Annex IX of Directive 93/42/EC and subsequent amendments: Class I. Notified Body identification in charge of assessment (IMQ).

Disposal symbol incompliance with Directives 2002/95/EC, 2002/96/EC and 2003/108/EC.

Manufacturer

1.2. INTENDED USE AND OPERATING PROCEDURES

The Keratometer according to the Javal Model JVL/1 is an instrument used for the measurement and calculation with maximum accuracy of:

- Corneal curvature radius
- Corneal refractive power
- Corneal astigmatism
- Direction of the two meridian axis being measured.

Broad useful surface of the cornea for measurement (3.4mm), illuminated scale.
The use of absolutely accurate optical systems enables high-quality examination and great instrument versatility.
Javal mires are equipped with red and green complementary filters to colour overlapping parts in white allowing for an accurate juxtaposition and greater measurement accuracy.
The orthogonally moving base is equipped with a new kind of joystick that simultaneously controls all the device's movements .

Javal Keratometers are designed for the measurement of physical - geometrical parameters of the human eye, therefore they are intended for use by eye specialists for diagnostic purposes. It can also be used by professional opticians, for purposes related to their professional needs, in compliance with the laws in force. These devices can only be used in medical structures (only locations which can host equipment with type "B" applied parts), and notably in ophthalmologists' practices, or optics or optometry laboratories or centres. The electrical system which supplies power to the device must comply with the national legislation and standards in use in the Country of destination.

The JVL/1 Keratometer uses the new kind of joystick that simultaneously controls all the device's movements.

Main features.

- modern design;
- Use of absolutely accurate optical systems, allowing for high-quality examination and good performance of the instrument;
- High-precision measurements of:
- Corneal curvature radius
- Cornea refractive power
- Corneal astigmatism
- Direction of the two meridian axis being measured.
- Ample useful cornea surface for measurement (3.4mm)
- Javal mires are equipped with red and green complementary filters to colour overlapping parts in white allowing for an accurate juxtaposition and greater measurement accuracy;
- Illuminated scale.

Warning
Before examining a patient, clean the head rest and chinrest module with a clean cloth. After each visit, remove the outer paper layer on the chinrest. If necessary, rub the head rest and chinrest with a cloth slightly soaked in alcohol.

1.2.1. CLASSIFICATION

- MEDICAL DEVICE classification
  device classification in accordance with the rules set out in Annex IX of Directive 93/42/EC and subsequent amendments: Class I.

- ELECTROMEDICAL DEVICES Classification
  Type of protection against direct and indirect contact: Class II (*).
  Applied Parts: Type B.
  D egree of protection against humidity: Common device (no protection against water seepage) .
  Sterilization method: Disinfectable device.
  Degree of protection when used with anaesthetics or flammable detergents: No protection.
  Conditions of use: Continuous operation:
  Degree of electrical connection between the device and the patient: Devices with no parts applied to the patient.

  The JLV/1 KERATOMETERS are class II devices, therefore the earth connection and the socket earth serve as functional earth.

1.2.2. ENVIRONMENTAL CONDITIONS

As long as the device is kept in its original packaging, it can be exposed to the following environmental conditions without being damaged, and for a maximum period of 15 weeks during shipping and storage.

Operating conditions of use:
- Temperature between +10 °C and +35 °C;
- Atmospheric pressure 800 hPa to 1060 hPa;
- Relative humidity between 30% to 90%.

Storage conditions:
- Temperature between -10 °C and +55 °C;
- Atmospheric pressure 700 hPa to 1060 hPa;
- Relative humidity 10% to 95%.

Transport conditions:
- Temperature -40 °C to +70 °C;
- Atmospheric pressure 500 hPa to 1060 hPa;
- Relative humidity 10% to 95%..

Vibration, sinewave 10 Hz to 500 Hz, 0.5g
Shock 30g, time: 6ms
Bumb 10g. time: 6ms

1.2.3. REFERENCE STANDARD

The following reference standards have been applied for product design, production and control:

Community Directives
- DIRECTIVE 93/42/EEC “MEDICAL DEVICES” OF 14/06/1993 AND SUBSEQUENT AMENDMENTS
- DIRECTIVE 2002/96/EC “Waste Electrical and Electronic Equipment”

Quality Management System Standards
- UNI EN ISO 9001:2008 “Quality management systems - Requirements”
- UNI EN ISO 13485:2012 “Medical devices - Quality Management Systems - Regulatory Requirements”

Technical Standards
- EN 60601:1 STANDARDS - “PART 1: MEDICAL ELECTRICAL EQUIPMENT: GENERAL REQUIREMENTS FOR SAFETY”, third edition;
- EN 60601-1-2 - “Collateral standard: Electromagnetic Compatibility of Medical Electrical Equipment, 2001 edition;
- UNI EN ISO 15004-1: “Ophthalmic Instruments - Fundamental Requirements and Testing Methods - Part 1: General requirements applicable to all Ophtalmic Instruments”, 2009 edition;
- UNI EN ISO 15004-2: “Ophthalmic Instruments - Fundamental Requirements and Testing Methods - Part 2: Protection against light-related hazards”, 2007 edition;UNI EN ISO 15004-2: “Strumenti Oftalmici - Requisiti fondamentali e metodi di prova - Parte 2:
- UNI EN ISO 14971: 2012 “Application of risk management to medical devices”

1.2.4. WARRANTY

CSO S.r.l. is liable for the device being in compliance with the Community Directive 93/42/EEC as well as for the device performance, safety and reliability, and consequently for the CE marking.

CSO S.r.l. will not be liable under the following circumstances:

- installation and commissioning are carried out without following the instructions and precaution warnings reported in the manual;
- the device is not used following the instructions and precaution warnings reported in the manual;
- accessories or spare parts are used other than those supplied or recommended by CSO S.r.l.
- repairs and safety controls are not carried out by skilled, qualified, CSO S.r.l.-trained and -authorised personnel.;
- the electric system of the room where the device is installed does not fulfil the CEI standards and does not meet the applicable legal requirements.

CSO S.r.l. accepts no liability for direct or indirect consequences or for damages to property or harm to persons caused by the improper use of the device or by unsound clinical assumptions based on its use.

CSO S.r.l. warrants this product for a period of 24 months as stated by the date of manufacturing. The manufacturer agrees to provide, upon request, diagrams, lists of components, specific technical instructions useful to authorised and pre-trained personnel for maintenance and calibration.
This warranty covers the replacement, at CSO premises or at an authorised service centre, of components and materials, as well as the necessary working hours. Shipping and transportation charges shall be born by the customer.
This warranty does not cover consumable parts and/or parts likely to wear in normal operation (e.g. lamps, fuses, joystick rubber etc.) or parts damaged due to improper use or to inadequate maintenance.

OUT OF WARRANTY CONDITIONS

- Repairs of faults caused by natural disasters, mechanical shock (fall, impact, etc.), defects of the electrical system, neglect, improper use, maintenance or repairs carried out with non original material and/or by personnel not authorised by CSO S.r.l.
- Any use which is improper or other than the intended use foreseen by the manufacturer.

CSO S.r.l. shall not be liable for any service deficiencies or inefficiencies due to causes or circumstances beyond its reasonable control. Under no circumstances, shall the customer be entitled to down time damages.

For maintenance or technical information on the device, please contact one of CSO Technical Service Centres or CSO directly at::

CSO S.r.l.
Costruzione Strumenti Oftalmici
Via degli Stagnacci 12/E
50018 Scandicci (FI) - ITALY
phone: +39 055 722191 · fax: +39 055 721557
cso@csoitalia.it
www.csoitalia.it

1.3. SAFETY WARNINGS

⚠ WARNING!

- Make sure the electric system power supply voltage matches the voltage indicated on the computer data label. If the voltage does not match, contact the customer service or the manufacturer itself. (see chapter on INSTALLATION). The whole system must comply with CEI or IEC standards (CEI 64-4 standards for electrical systems in medical environments). Should you have any doubts, please contact the electrical installation and maintenance company in charge of your electrical system.
- Do not use multiple sockets, adapters or extension cables to connect the mains plug to the mains socket. To disconnect the device from the power supply, also in case of emergency, grab the plug of the power cable; do not pull the power cable to unplug the device.
- Do not touch the computer mains power cable with wet hands; make sure the mains power cable is not walked on or trapped under weights; do not tie the mains power cable.
- A damaged power cable can cause fire or electric shock. It must be checked frequently. If the supplied computer power cable needs to be replaced, please contact the supplier.
- Do not attempt to carry out any technical intervention on the device or on the system unless specified in this manual.
- Do not use the device in the proximity of water and avoid liquid spillage on any surface of the device. Avoid humid or dusty places or places which are subject to rapid fluctuations in temperature and humidity.
- Unplug the device from the power socket before cleaning and/or disinfecting.
- The device does not generate or receive electromagnetic interferences when operated near other devices; no preventive or corrective action is necessary.

1.4. DISPOSAL AT THE END OF LIFE

As per article 13 of Legislative Decree No. 151 of 25/07/05 implementation of the EU directives 2002/95/EC, 2002/96/EC and 2003/108/CE, on the restriction of hazardous substances in electrical and electronic equipment and on their disposal".

The device purchased is manufactured using special materials and substances. The device may contain hazardous substances potentially harmful to the environment or to human health if improperly disposed of into the environment.
To prevent any hazardous substances from being discharged into the environment and to promote the conservation of natural resources, the manufacturer -should the user want to get rid of the used device at endoflife- facilitates the possible reuse of the device and the recovery and recycling of its materials.
Public authorities adopt adequate measures to make sure that users, distributors and manufacturers contribute to the collection of electrical and electronic equipment, setting legal requirements for reusing, recovering or recycling said equipment.

In the case of disposal of the device, specific provisions of European and national law apply, and provide that:

- **the device shall not be disposed of as urban waste**, it shall be **collected separately**, by contacting a company specialising in the disposal of electrical/electronic equipment or the public authorities responsible for waste management;

- in the event that a new piece of equipment 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 equipment, the distributor or manufacturer is legally required to collect the old piece of equipment;
- if the user wants to get rid of a used piece of equipment, placed on the market after 13 August 2005, the distributor or manufacturer is legally required to collect it;
- the manufacturer shall take care of the transport, handling, recovery and/or disposal of the old equipment collected at its own charge.
- **the potentially harmful effects to the environment or human health due to any hazardous substance contained in electrical and electronic equipment or to the improper use of said equipment or its parts shall be taken into account..**
- The device described in this user manual is made of metal mechanical components, plastic material, electrical components and electronic boards. The manufacturer will provide the users with any information regarding the hazardous substances contained in the device and on the recovery and recycling of said substances, as well as on the possible reuse of the used device.

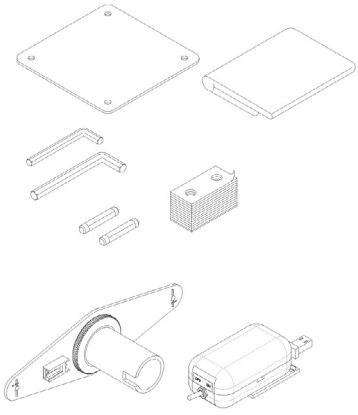
Violations shall be punished by the current legislation with serious administrative sanctions.

2. SUPPLY PACKAGE

The device is delivered packaged. When removing the device from the packaging check that all the following components are present:

a) One table top (18) (not supplied with the twin version) on which are mounted
- one transformer box (8) with main illuminated switch (19), mains supply cable;
- two orthogonally moving slide guides for the base;
- one sliding plate for the positioning device;
- One built-in socket.

b) One complete base with orthogonal movements (1)
c) One head (2)
d) One chinrest module (3) (not supplied with the device for twin tables).
e) These instructions for use.
f) A series of accessories including:
- two guards for the slide guides (7);
- one 50D tester cornea;
- one protection cover;
- one Allen wrench;
- one protective fuse.



Accessories supplied
The system is supplied with the following accessories:
- Dust cover

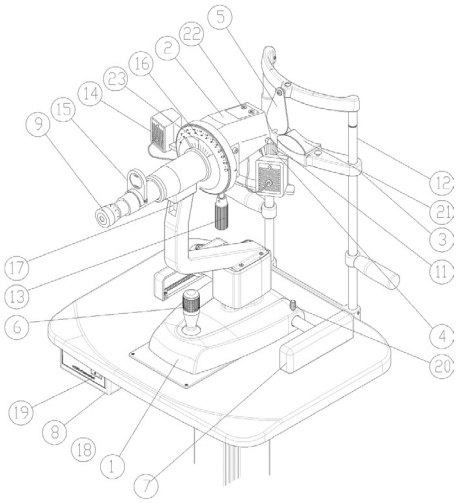
- Control sphere with 50D contact lenses support
- Chinrest paper
- Protective fuses

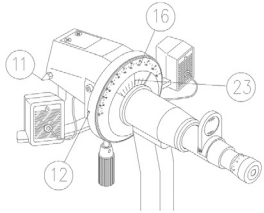
Optionals

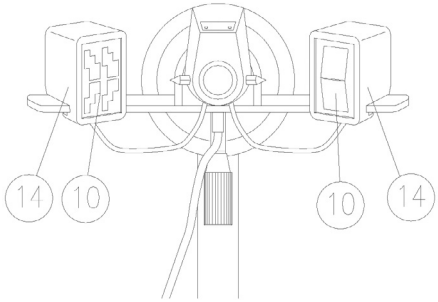
- Fixation point at 30° to aim the patient's gaze during specific exams code. 100101300.

Legend

1. Orthogonally moving base
2. Head
3. Chinrest module
4. Chinrest lifting handle
5. Occlusor for the eye not being examined
6. Joystick for base orthogonal movements and lifting (x,y,z)
7. Guards
8. Power transformer
9. Telescope eyepiece
10. Javal miresl
11. Grading marks for patient's eye alignment
12. Viewfinders for telescope pointing
13. Control handle to drag mires
14. Mires projectors
15. Magnifying lens for scales
16. Meridians scale (axes)
17. Head-to-base fastening screw
18. Surface table
19. Power switch
20. x-y movements locking
21. Chinrest
22. Cover
23. Corneal Power and radius of curvature scale
24. Fuse box / voltage switch unit
25. Chinrest module fastening screw

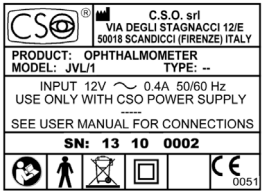






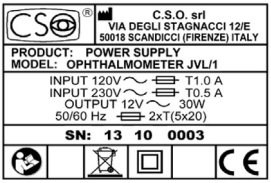
2.1 IDENTIFICATION NAMEPLATE

Data reported on the nameplates:
- Manufacturer's name.
- Device name.
- Serial number.
- Month and year of manufacture.



2.2. POWER SUPPLY UNIT NAMEPLATE

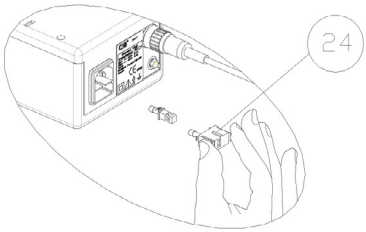
Data reported on the label:
- Manufacturer's name.
- Model of the power supply unit
- Serial number.



3. ROUTINE MAINTENANCE

All repair operations described below must be performed with the power cable of the unit disconnected from the mains outlet. In the event of faults that cannot be solved with the operations described below, please contact the installer company.

Replacing the mains fuses.
- To replace the power fuses, follow the instructions below;
- protective fuses are inside the transformer in the socket/voltage switch unit.
- Before taking any action, isolate the device from the electrical system by unplugging the mains supply;
- Take out the voltage switch and remove burnt fuses;
- Replace the fuses making sure that the fuse voltage matches the voltage indicated on the transformer nameplate (32);
- Replace the voltage switch.
- Plug the mains supply cable into the mains socket.



Protection against dust
When not in use, protect the system against dust. Dust accumulating on the device must be regularly removed with a soft cloth or blower.
Other maintenance operations (repairs, components replacement, assessment of internal components, etc.) fall within the exclusive competence of CSO Technical Service

⚠	**WARNING!** Do not use any thinners or solvents.
⚠	**WARNING!** If the product needs maintenance, contact the Technical Service authorised by CSO Srl.

4. USAGE

JVL/1 Keratometer:

a) Turn on the device using the switch on the transformer box.
b) Insert the tester cornea in its compartment.
c) Set the bow to 90° (horizontal)
d) Centre the telescope on the tester cornea looking through the grading mark, viewfinder, and tester cornea.
e) Use the lifting handle to move the chinrest, and use the Joystick for orthogonal movements and height adjustments to the instrument.
f) Focus the mires' central images and centre them on the tester cornea using the joystick.
g) Focus the Lubber's lines obliquely to the focal plane inside the eyepiece by slowly rotating it
h) Check the instrument calibration by making measurements on the 50 Dp tester cornea.

For a real exam on a patient, follow these steps:

1. Have the patient comfortably sit down with his/her chin on the chinrest and the forehead against the forehead rest.
2. Lift and lower the chinrest using the handle to align the patient's eyes to the markings on the chinrest rod, place the occlusor on the eye not being examined.
3. Turn on the instrument and set the mire-holder bow to 90° (horizontal)
4. Centre the telescope on the cornea looking through the graded marking and viewfinder, invite the patient to stare at the light point inside the telescope.
5. Using the joystick focus and centre the mires' central images.
6. Move the mires with the knob (13), so their projected view are in contact, verify that the mires meridian lines are perfectly aligned with one another to form one straight line (See Fig.1).
7. If the mires do not align (this will be a case of oblique astigmatism - see Fig.2) rotate the mire-holder bow until the meridian lines align (See Fig.3).
8. The scale on the dioptres and curvature radius indicates the position of one of the two meridians (the main meridian); its value will be displayed on the axes disk. The other axis is 90° from the main meridian.
9. Rotate the mire-holder bow by 90°. If the eye examined shows astigmatism, the two images overlap (direct or with-the-rule astigmatism) or they will get further (inverted astigmatism), then the main meridian is the one resulting from the second readout.
10. Restore contact between the two mires and repeat the reading using the dioptres scale.
11. The gradient between the two readings indicates the corneal astigmatism
12. In case of direct astigmatism, a rapid and approximate measurement of astigmatism is calculated using the number of overlapping mires steps. Each step corresponds to a dioptre.

5. TECHNICAL FEATURES - JVL/1 KERATOMETER

Measurement field	Dioptres 30.00 to 60.00 D- radius 5.6 to 11.3 mm
Resolution	Dioptres 0.25 D - Radius 0.05 mm
Measurement useful diameter	3.4 mm equal to 9 mm²
Scaling	TABO and INTERNAZIONALE
Javal	mires
Instrument base	Stoppable crossing movement
Chinrest	Height adjustment with occlusor
Instrument voltage	12V AC - 0.4 A 50/60 Hz
Input power supply unit	input: 120 V AC - T 1.0 A 230 V AC - T 0.5 A output: 12 V AC - 30 W - 50/60 Hz - 2 x T (5x20)
Size (HxWxD) mm	550x313x410
Weight approx Kg.	6.5

6. GUIDANCE AND MANUFACTURER 'S DECLARATION

6.1. ELECTROMAGNETIC EMISSION

TABLE 1 - Guidance and manufacturer's declaration – electromagnetic emission		
The equipment JLV/1 KERATOMETERS is intended for use in the electromagnetic environment specified below. The customer or the end user of the JLV/1 KERATOMETERS should assure that it is used in such an environment.		
Emission test	compliance	Electromagnetic environment - guidance
RF emission – CISPR 11	Group 1	The JLV/1 KERATOMETERS uses RF energy only for its internal function. Therefore its emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emission – CISPR 11	Class B	The JLV/1 KERATOMETERS is suitable for use in all establishments including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emission IEC 61000-3-2	Class A	The JLV/1 KERATOMETERS is suitable for use in all establishments including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes
Voltage fluctuation/flicker emission IEC 61000-3-3	Complies	The JLV/1 KERATOMETERS is suitable for use in all establishments including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes

6.2. ELECTROMAGNETIC IMMUNITY

Table 2 - Guidance and manufacturer's declaration – electromagnetic immunity.			
The equipment JLV/1 KERATOMETERS is intended for use in the electromagnetic environment specified below. The customer or the end user of the JLV/1 KERATOMETERS should assure that it is used in such an environment.			
Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 KV contact ±8 KV air	±6 KV contact ±8 KV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical Fast Transient/Burst IEC 61000-4-4	±2 KV for power supply lines ±1 KV for I/O lines	±2 KV for power supply lines Not applicable	Mains power quality should be that of a typical commercial or hospital environment
Surge IEC 61000-4-5	±1 KV differential mode ±2 KV common mode	±1 KV differential mode ±2 KV common mode	Mains power quality should be that of a typical commercial or hospital environment
Voltage Dips, Short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% Ut for 0,5 cycle 40% Ut for 5 cycles 70% Ut for 25 cycles <5% Ut for 5 sec	<5% Ut for 0,5 cycle 40% Ut for 5 cycles 70% Ut for 25 cycles <5% Ut for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the JLV/1 KERATOMETERS requires continued operation during power mains interruptions, it is recommended that the JLV/1 KERATOMETERS be powered from an Uninterruptible Power Supply or Battery.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment

Note: Ut is the AC mains voltage prior to application of the test level.

TABLE 3 - Guidance and manufacturer's declaration – electromagnetic immunity

The equipment JLV/1 KERATOMETERS is intended for use in the electromagnetic environment specified below.
The customer or the end user of the JLV/1 KERATOMETERS should assure that it is used in such an environment.

Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment - guidance
			Portable and mobile RF communication equipment should be used no closer to any part of the JLV/1 KERATOMETERS, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Conducted RF IEC 61000-4-6	3Vrms 150KHz to 80MHz	3 Vrms	Recommended separation distance. d = 1.167*sqrt (P)
Radiated RF IEC 61000-4-3	3V/m 80 MHz to 2,5 GHz	3 V/m a	d=1,167*sqrt (P) 80 MHz to 800 MHz d=2,333*sqrt(P) 800 MHz to 2,5 GHz Where P is the maximum output power rating of the transmitter in watts(W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m) Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 

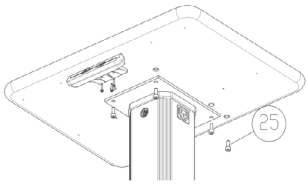
Note 1: at 80 MHz and 800 MHz, the higher frequency range applies
Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

B1. INSTALLATION AND COMMISSIONING

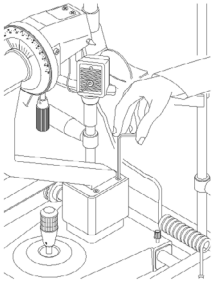
All equipment composing the system is always delivered packaged in optimal conditions to withstand standard transport and storage conditions. In the event that, when removing the device from its packaging, damages due to transport are detected, please contact the installer company or the manufacturer directly.

To assemble the device follow the instructions below:

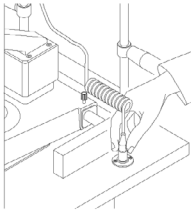
1. Secure the table top to a base; the instrument holder table is below the device ready for assembly - proceed as follows:
   a) Position the table on the base plate and insert the screws supplied;
   b) Fix the top to the bottom by tightening the four socket head screws
2. Unscrew the two socket head screws under the chinrest. Insert the screws in the chinrest module and align its holes with the holes of the table top. Tighten the screws (25) using the wrench provided with the device.
3. Place the base with orthogonal movements on the slides on top of the instrument holder table; make sure the wheels are aligned. Lock the device with the knob on the right side of the base, above the wheels axis.
4. Fix the guards (9) along the slides by inserting the tags into their slots.
5. Position the head arm to perfectly fit it to the indentation on the top of the base mount. Screw and tighten the four screws.
6. Connect the head power supply cable to the socket on the instrument table.
7. Make sure the voltage switch (24) on the mains socket is set to the proper voltage for the device to be connected. If this is not the case, remove the small drawer and turn the switch until the required voltage value is displayed. Warning! If the keratometer is supplied without a transformer box, make sure that connection to the power mains meets the technical requirements described in these user instructions.
8. Plug the power supply cable into the mains socket.



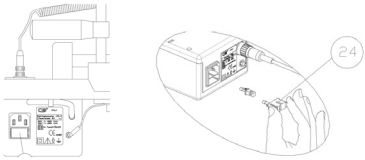
PHASE 1 AND 2: FIX THE SURFA CE TA BLE AND CHINREST MODULE



PHASE 4: FIX THE HEAD OF THE KERATO METERTO THE BASE

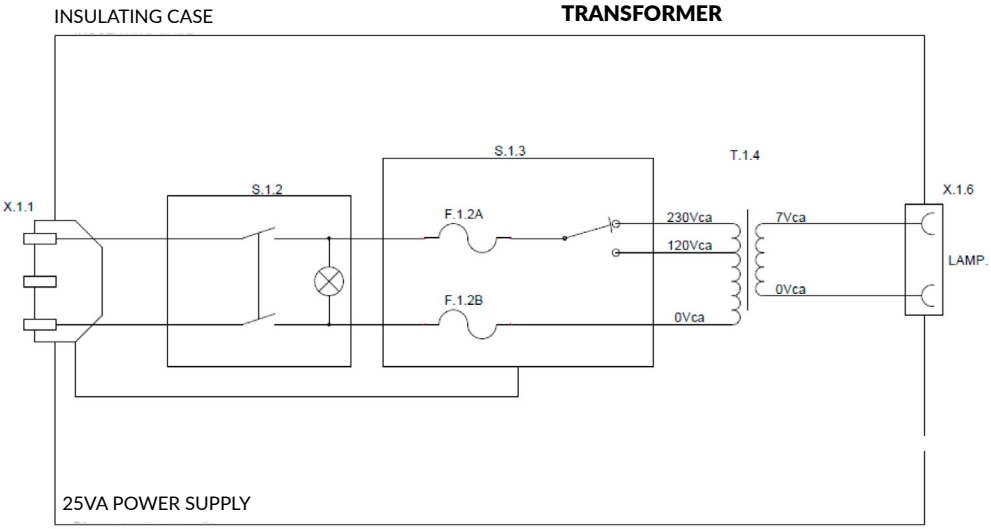


PHASE 5: PLUG IN THE POWER SUPPLY CABLE



PHASE 6: CHECKING THE OUTPUT VOLTAGE VALUE ON THE VOLTAGE SWITCH

B2. FUNCTIONAL BLOCK DIAGRAM



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