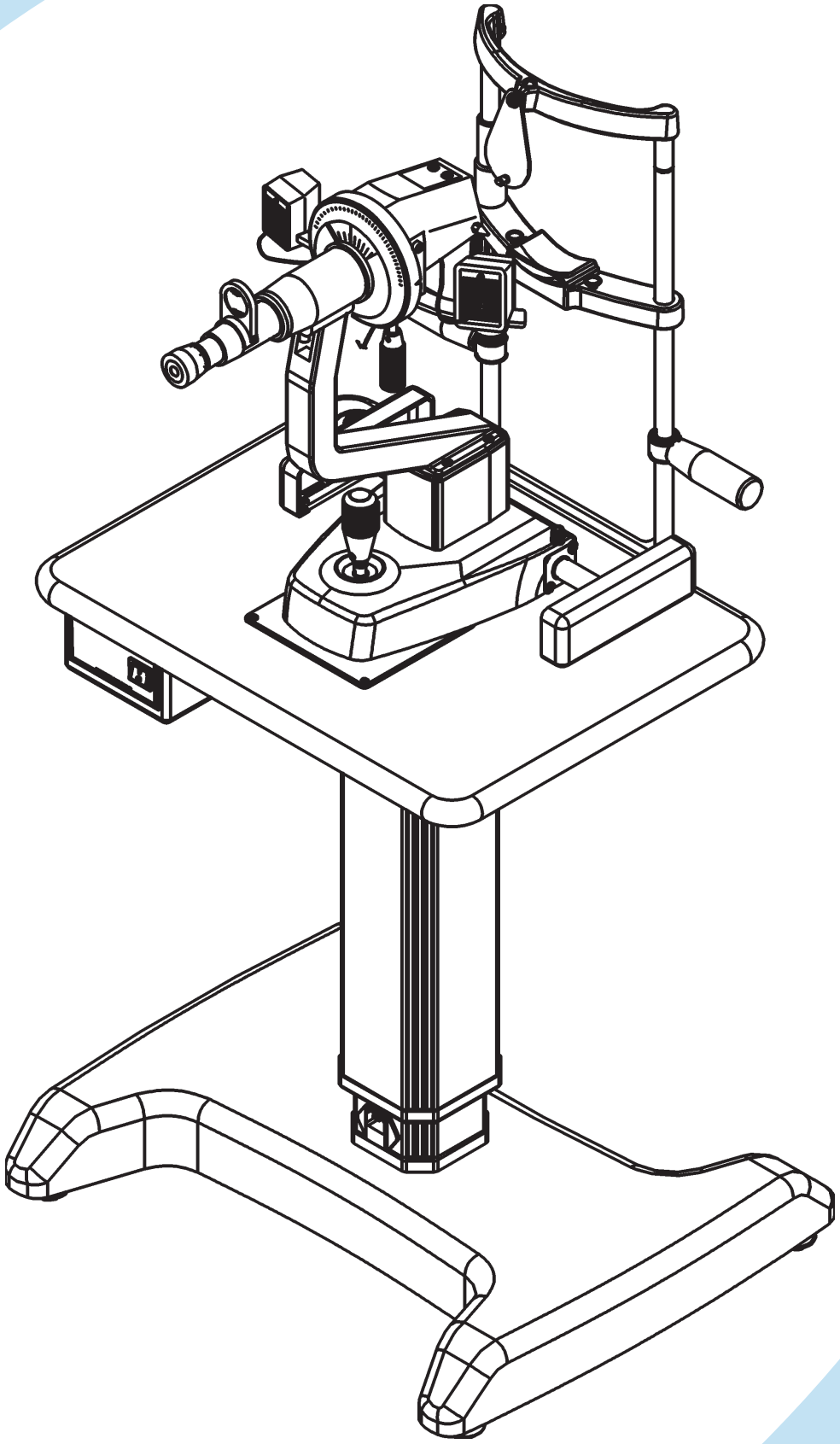
Ophthalmometer JVL/1



CSO OPHTHALMIC

Instructions for Use and Maintenance

The Javal-type Mod. JVL/1 Ophthalmometer is a high-performance instrument. In order to use it efficiently and in complete safety we recommend reading this manual carefully before beginning installation and heeding all the safety warnings provided herein and on the instrument labels.

- Check that your mains voltage is the same as that reported on the instrument data plate. Should the values differ, contact your customer service or the manufacturer (see INSTALLATION section). Your entire electrical system must comply with CEI/IEC standards (CEI 64-4 E, Electrical Systems for Medical Use). In case of doubt, contact your electrical installation and maintenance service.

- Never use multiple plugs, adapters, or extension cords to connect the instrument plug to the mains socket.

- When unplugging the instrument from mains power supply, even in an emergency, grasp the plug only; never pull the cord to disconnect the plug.

- Never touch the power cord with wet hands. Check frequently that the cord is so placed as not to be stepped on or crushed by weights. Never knot the cord.

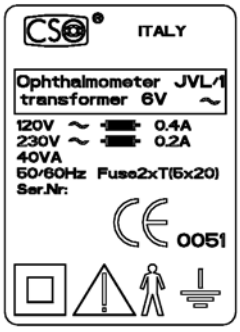
- A damaged power cord can cause fires or electrical shocks. Check frequently that it is in good condition. If it becomes necessary to replace the power cord originally supplied with the instrument, contact your supplier.

- Do not perform any repairs or maintenance work on the instrument or the electrical system beyond what is explained in this manual.

- Do not use the instrument near water and be careful not to spill liquids on any part of it. Avoid damp and dusty locations and locations subject to brusque changes in temperature and humidity.

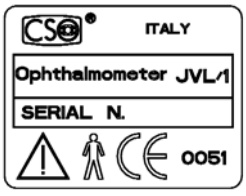
- Disconnect the instrument from the mains power supply before cleaning and/or disinfecting.

- The instrument neither generates nor receives electromagnetic interference when used in proximity to other devices; no preventive or corrective measures need therefore be taken.



Data plate on power supply

BRIEF DESCRIPTION OF THE INSTRUMENT – USES



Data plate on ophthalmometer

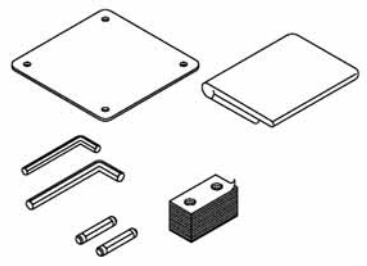
The Javal-type Mod. JVL/1 Ophthalmometer permits maximum-precision measurement and detection of the:
- Radius of curvature of the cornea
- Refractive power of the cornea
- Corneal astigmatism
- Direction of the axes of the two measured meridians

on a broad area of the cornea (3.4 mm) with a lighted measurement scale.

Perfectly corrected optical systems ensure high-quality viewing and great instrument versatility.
The Javal-type targets are equipped with complementary red and green filters that give white coloration to overlapping parts to permit precise matching and greater precision in measurement..
The right-angle movement base is commanded by a new joystick for simultaneous control of all instrument movements.

The Javal Ophthalmometer family instruments are designed to measure the physical-geometric parameters of the human eye and therefore for use by specialists for diagnostic purposes. They may also be used by professional opticians within the limits of their competence and in respect of the relevant laws and regulations in force.
The instruments must be used only in spaces for medical use (in particular, spaces suitable for use of Type "B" devices with applied parts); for example, in ophthalmology clinics or in optics or optometry laboratories and/or centers. The electrical system powering the instrument must comply with the relevant laws and regulations in force in the country of use.

The instrument is delivered in special packing. When unpacking, check that all the components listed below are included:



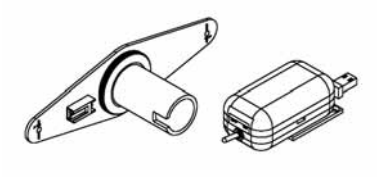
a) One table top (18) (not supplied with the combined version) on which are assembled:
- One transformer box (8) with lighted main switch (19), and power supply connection cord.
- Two guides for the right-angle movement base.
- One slide plate for the positioning device.
- One recessed socket.

b) One right-angle movement base (1).

c) One optical head (2).

d) One chin rest (3) (not supplied with the combined version).

e) This instruction manual.



Kit for 30° fixation point

f) An accessory kit containing:
- two guards for the guides (7).
- one 50D test cornea.
- one protective cover.
- one socket wrench.
- one spare scale illumination lamp.
- one fuse.

Accessories

The instrument is supplied complete with the accessories listed below.
- one protective cover.
- 50D test sphere with contact lens support.
- spare lamps.
- chin rest papers.
- fuses.

On request, a 30° fixation point for directing the patient's gaze for certain tests: code 100101300.

OPERATING CONDITIONS

As long as the ophthalmometer remains in its original packing it may be exposed to the environmental conditions listed below, for a maximum of 15 weeks during shipping and warehousing, without suffering damage.

Temperature between -10 °C and +60 °C;
atmospheric pressure between 500 hPa and 1060 hPa;
relative humidity between 10% and 90%.

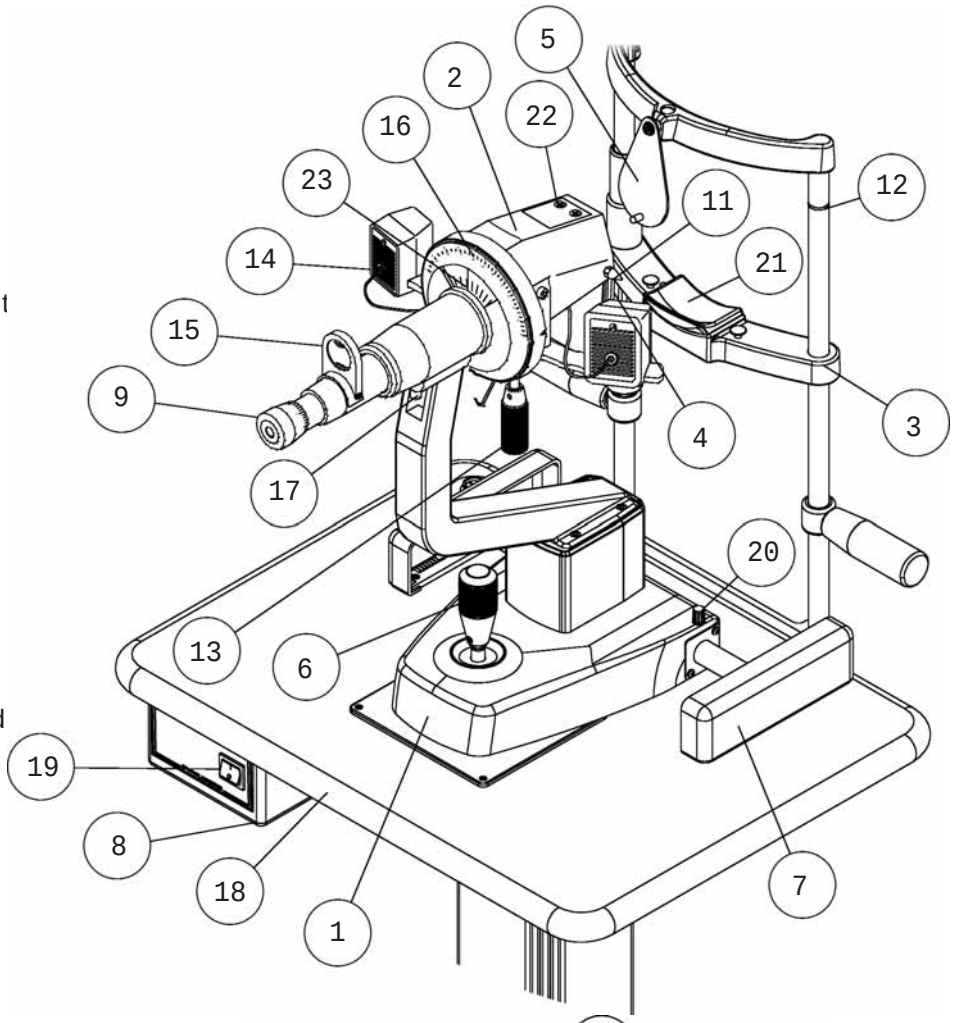
Ambient conditions for operation are:

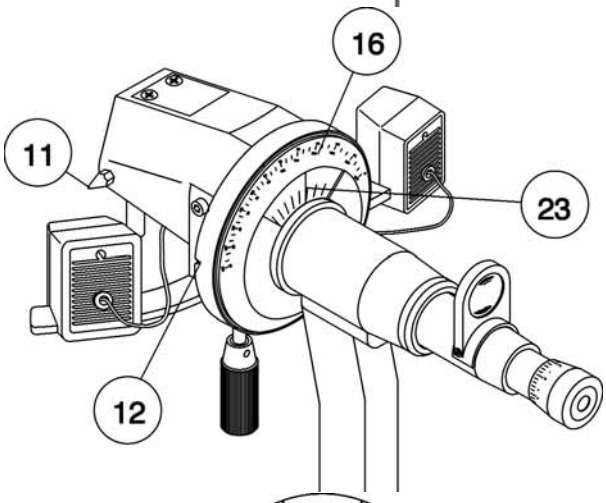
Temperature between +15 °C and +30 °C;
atmospheric pressure between 700 hPa and 1060 hPa;
relative humidity between 30% and 75%.

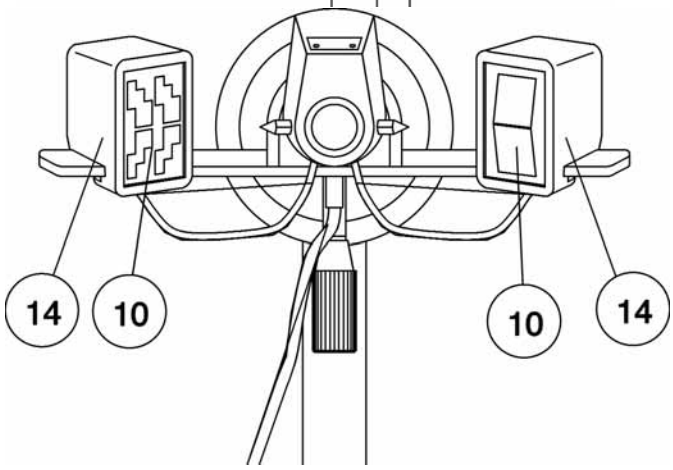
Attention!

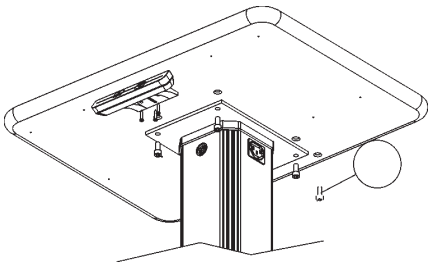
Before examining any patient, clean the forehead rest and the chin rest with a clean cloth. Before each examination, remove the top strip of paper from the chin rest pack. If necessary, clean the forehead rest and the chin rest with a cloth dampened with alcohol.

1. Right-angle movement base
2. Optical head
3. Chin rest
4. Collar for adjusting chin rest height
5. Patch for covering the eye not under examination
6. Joystick controlling right-angle movement and elevation (x,y,z) of the base
7. Guards
8. Power supply transformer
9. Sight eyepiece
10. Javal-type targets
11. Markings for leveling patient eyes
12. Sight-focusing targets
13. Collar for moving the targets
14. Target projectors
15. Magnifier for scale reading
16. Meridians (axes) reading scale
17. Lock screws for securing the optical head to the base
18. Table top
19. Main power switch
20. x-y movement locking device
21. Chin rest papers
22. Access cover for scale illumination lamp.
23. Powers and corneal curvature radii scale
24. Fuse holder/voltage changer unit
25. Chin rest lock screw

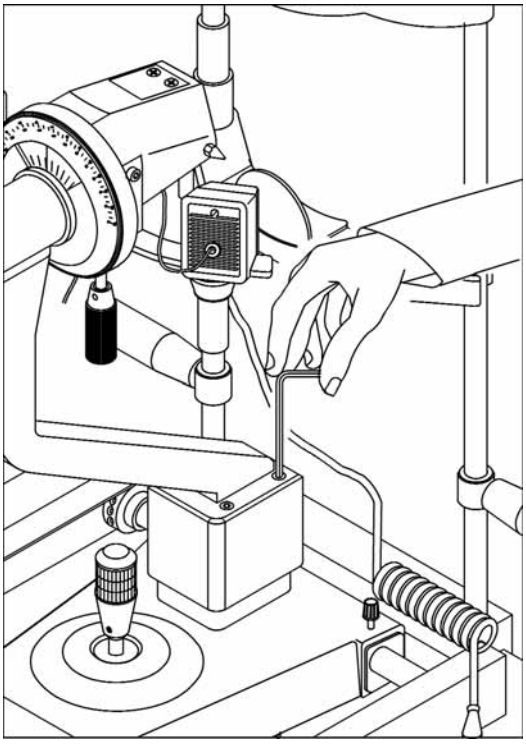




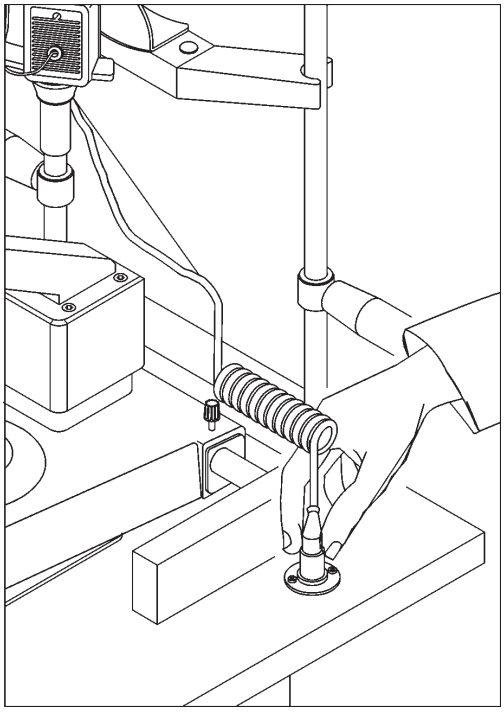




Steps 1 and 2: Securing the table top and the chin rest.



Step 4: Securing the ophthalmometer head to the base.



Step 5: Inserting the power cord in its socket.

The instruments are always supplied packed for best withstanding standard shipping and warehousing conditions. Should you notice defects attributable to shipping when unpacking the instrument, contact your installation service.
Proceed as described below to assemble the instrument:

1) Secure the table top to a table base. The instrument-holder plate underneath is ready for assembly. In this case,
a) Place the top over the plate and position the screws supplied with the instrument.
b) Screw down the four recessed hex-head screws to lock together.

2) Unscrew the two recessed hex-head screws under the chin rest. Position the chin rest with the holes aligned with the holes on the top Screw down the screws (25) using the wrench supplied as an accessory with the instrument..

3) Position the right-angle movement base on the guides on the upper part of the instrument-holder top. Check that the wheels are correctly aligned.
Tighten, using the knob located on the right of the base above the wheel axis. Secure the guards to the sides of the guides by inserting the tabs in the slots for that purpose.

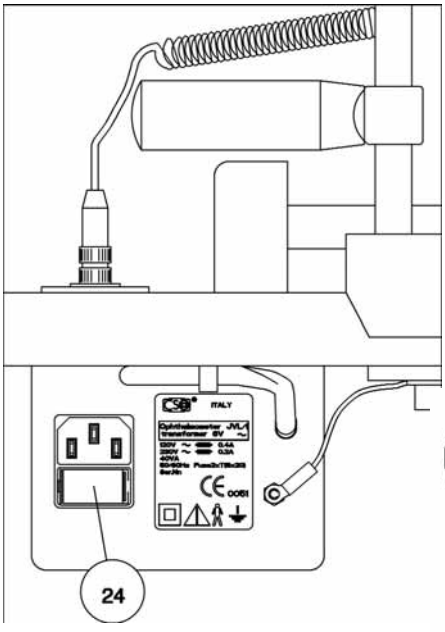
4) Position the ophthalmometer head arm, seating it securely in the recess at the top of the base support. Position the four screws and tighten down.

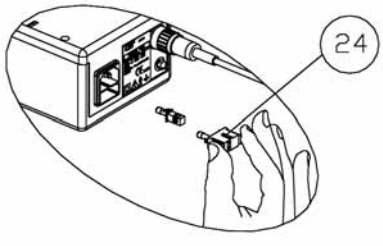
5) Insert the ophthalmometer head power cord plug in the socket on the instrument-holder top.

6) Check that the voltage changer (24) on the power socket is set to the correct mains supply voltage. If it is not, extract the box and rotate the changer until the desired voltage value appears in the window.

Attention! If the ophthalmometer is not equipped with a transformer box, check that your electrical supply is compatible with the technical data reported in this instruction manual.

7) Plug the power cord into the mains socket.





Step 6: Checking the supply voltage value on the voltage changer

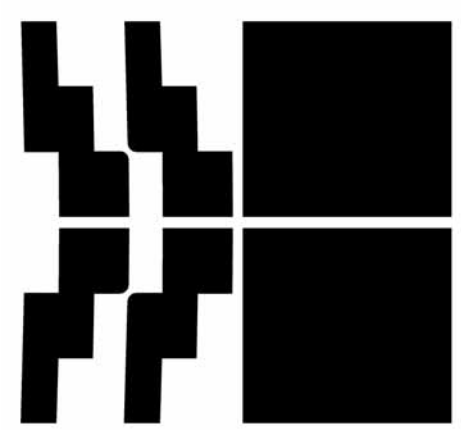


Fig. 1 - The median lines of the targets form a single straight line

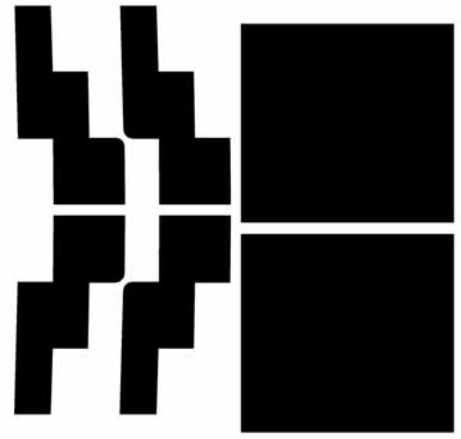


Fig. 2 - Targets not aligned for oblique astigmatism

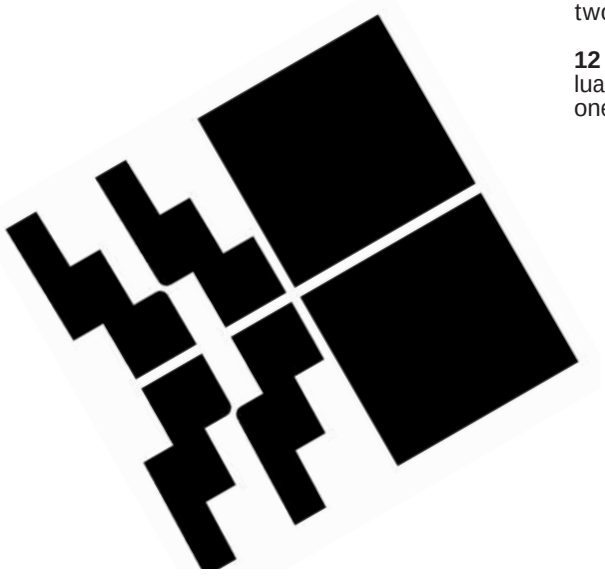


Fig. 3 Alignment in oblique astigmatism

Before beginning examination, set the eyepiece for the operator's refraction as explained below.

a Switch the instrument on with the main switch on the transformer box.
b Insert the test cornea in its lodging.
c Position the arc at 90° (horizontal).
d Center the sight on the test cornea, sighting through the notch, the sight hairs, and the test cornea.
e For centering, use the collar for adjusting chin rest height and the joystick for right-angle movement, and adjust the elevation of the instrument.
f Bring the center images of the targets into focus and use the joystick to center them on the test cornea.
g Rotate the eyepiece slowly until the target lines set obliquely on the focal plane inside the eyepiece come into focus.
h Check instrument calibration by making measurements on the 50D test cornea.

To run an examination on a patient:

1 - Seat the patient comfortably with his/her chin resting on the chin rest and forehead against the forehead rest.

2 - Use the collar to raise and/or lower the chin rest until the patient's eyes are aligned with the notches on the chin rest bracket. Cover the eye not being examined with the patch.

3 - Switch on the instrument and position the target-holder arc to 90° (horizontal).

4 - Center the sight on the cornea, viewing through the notch and the sight hairs. Invite the patient to fixate on the luminous point inside the sight.

5 - Use the joystick to center and focus the center target images.

6 - Use knob (13) to move the targets until their projections are in contact in the view. Check that the median lines of the targets are perfectly aligned with respect to each other so as to form a single straight line (see Fig. 1).

7 - Should the median lines not align (in the case of oblique astigmatism – see Fig. 2), rotate the target-holder arc until they coincide (see Fig. 3).

8 - The reading on the diopters and curvature radii scale will give the position of one of the two meridians (main meridian), the value of which is read on the axes disk. The position of the other axis will be at 90° with respect to the main meridian.

9 -Rotate the target-holder arc by 90°. If the eye being examined is astigmatic the two images will overlap (direct or second order astigmatism) or move away from each other (inverse astigmatism). In this case the meridian of the second reading is taken as the main meridian.

10 - Restore contact between the images of the two targets and repeat the reading on the diopters scale.

11 - The value of the corneal astigmatism will be given by the difference between the two readings.

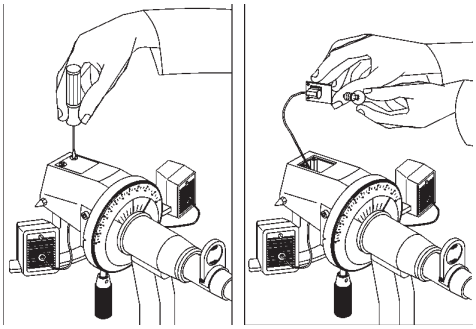
12 - In the case of direct astigmatism, the degree can be rapidly and approximately evaluated by counting the number of target steps that overlap. Each step corresponds to one diopter.

The Mod. JVL/1 ophthalmometer uses a new joystick that permits simultaneous control of all instrument movements.

The main features of the instrument are:
- modern design;
- use of precision-corrected optical systems that ensure excellent viewing quality and good instrument performance.
- maximum-precision measurement and detection of the:
  - radius of curvature of the cornea.
  - refractive power of the cornea.
  - corneal astigmatism.
  - direction of the axis on the two measured meridians.
- broad area of the cornea (3.4 mm) for measurement
- Javal-type targets equipped with complementary red and green filters that give white coloration to overlapping parts to permit precise matching and greater precision in measurement.
- Illuminated scale.

ROUTINE MAINTENANCE

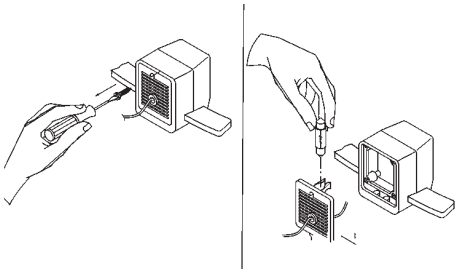
The maintenance operations illustrated below must all be carried out with the power cord unplugged from mains supply. For any other type of trouble that cannot be eliminated through the procedures described herein, contact your installation service.



Replacing the fixation point and scale illumination lamp

Replacing the Fixation Point and Scale Illumination Lamp
To replace the lamp proceed as explained below:

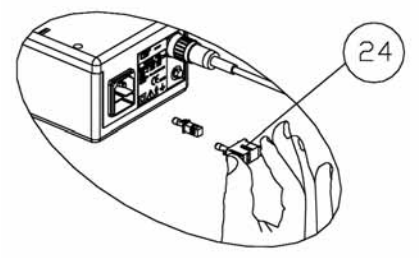
- Unplug the instrument from the power supply.
- Unscrew the two screws on the upper part of the instrument.
- Extract the access cover.
- Replace the lamp with a new 6V 3W E10 lamp. Attention! The old lamp may be very hot.
- Close the access cover and replace and tighten the screws.
- Plug in the instrument.



Replacing the target lamp

Replacing the Target Lamps
To replace the target lamps proceed as explained below:

- Unplug the instrument from the power supply.
- Unscrew the screw corresponding to the lamp to be replaced, on the rear of the target projector.
- Remove the screw and extract the rear cover and with it the lamp.
- Replace the lamp with a new 6V 10W lamp. Attention! The old lamp may be very hot.
- Replace the cover and screw down the screws.
- Plug in the instrument.



Replacing the mains fuses

Replacing the Mains Fuses
To replace the fuses proceed as explained below

- The fuses are located in the socket/voltage changer unit at the rear of the transformer.
- Before performing any work on the instrument, unplug it from the mains supply.
- Extract the voltage changer and remove the blown fuses.
- Replace the fuses with new fuses compatible with mains supply voltage as indicated on the transformer data plate (32).
- Replace the voltage changer.
- Plug in the instrument.

Protecting the Instrument from Dust

When the instrument is not in use, protect it from dust by replacing it in the carrying case. Periodically remove any dust that has accumulated on the instrument with a very soft cloth or a hand-operated pump.

The symbol (barred waste can)) shown in the figure and found on the exterior of the instrument indicates that the **electrical and electronic parts** of the end-of-life instrument must be **separated and disposed of as special waste**.

In accordance with Art. 13 of Leg. Decree No. 151 of 25 July 2005 implementing Directives 2002/95/EC, 2002/96/EC, and 2003/108/EC concerning reduction of use of dangerous substances in electrical and electronic equipment and disposal of electrical and electronic waste.

The instrument you have purchased is made using particular materials and substances. It may also contain substances having potentially dangerous effects on the environment and human health if released into the environment by improper disposal.
To avoid releasing dangerous substances into the environment and in order to promote conservation of natural resources, and should the user decide to dispose of an end-of-life instrument, the manufacturer will facilitate re-use and recovery and recycling of the materials it contains.
Government agencies have adopted measures obliging users, distributors, and manufacturers to contribute to collection of waste electrical and electronic equipment (WEEE) and prescribes that such equipment find re-use or be recovered or recycled.

When disposing of the instrument, remember that disposal is regulated by precise European and national laws and regulations that prescribe the following:
- **Do not dispose of as ordinary municipal waste**. For separate disposal contact a company specialized in disposal of waste electrical and electronic equipment or your local waste disposal agency for information.
- If a new instrument is purchased from the same manufacturer to replace an end-of-life instrument put on the market before 13 August 2005, of an equivalent type and performing the same functions as the new device, the distributor or manufacturer is required by law to take back the end-of-life device.
- If the user intends to dispose of a used device put on the market after 13 August 2005, the distributor or manufacturer is required by law to take back the device.
- The manufacturer is responsible for transporting, treating, and recovering and/or recycling any used equipment collected and for all relevant expenses.
- **Never forget that dangerous substances present in waste electrical and electronic equipment and/or improper use of same or parts of it can have potentially adverse effects on the environment and human health**. The instrument described in this manual contains metal and plastic mechanical parts, electrical components, and electronic circuit cards. The manufacturer is at user's complete disposition for any information requested regarding the dangerous substances contained in the instrument and recovery and recycling procedures and/or the possibility of re-using the end-of-life instrument.
Current legislation provides severe sanctions in the case of failure to respect disposal laws and regulations in force

Graphics Symbols

General warning of the duty to read the instruction manual carefully before installing and using the instrument.

Class II protection against direct and indirect electrical shocks

Type B protection against direct and indirect electrical shocks in accordance with EN 60601-1

Mark attesting to compliance with European Directive 93/42/EEC and approval of the notified standards organization No. 0051 (IMQ)

Fuse

Ground terminal. Connection to ground is ensured by the power cord supplied with the instrument.

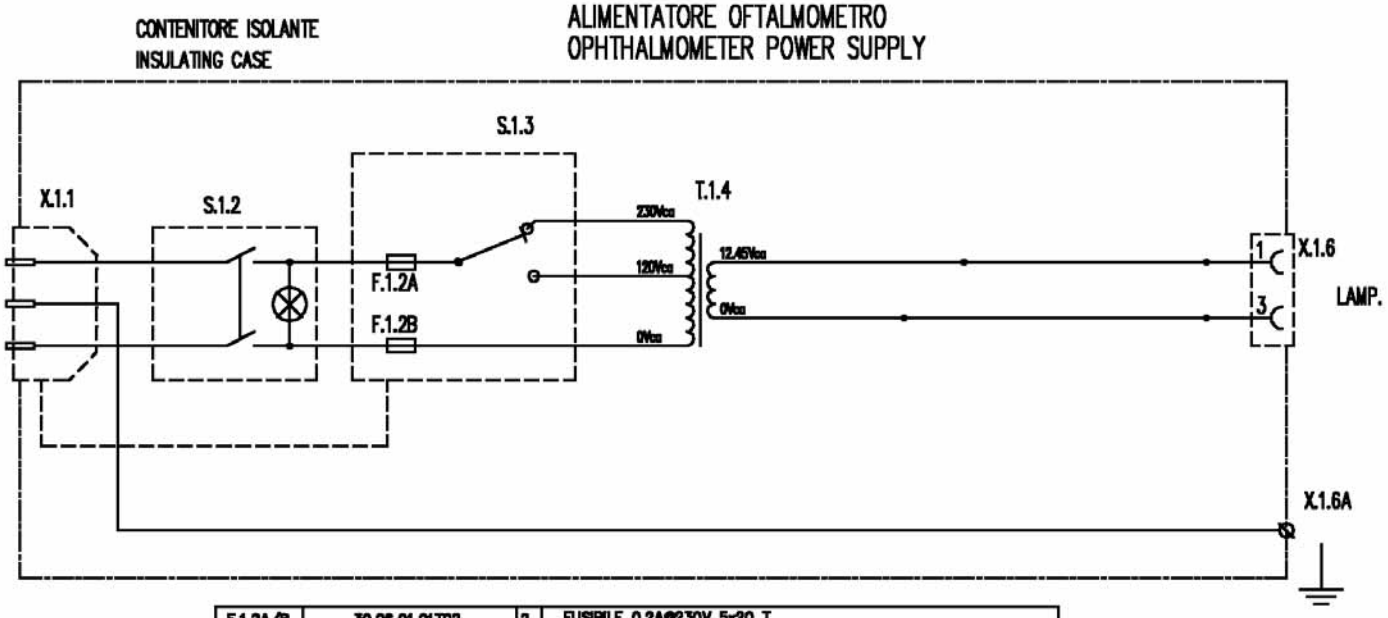
Ophthalmometer JVL/1

Measurement range	Diopters: from 30.00 to 60.00 D radii from 5.6 to 11.3 mm
Resolution	Diopters 0.25 D – Radius 0.05 mm
Measurement diameter	3.4 mm = 9 mm2
Scale graduation	TABO and INTERNATIONAL
Targets	Javal-type
Instrument base	Stoppable crossover movement
Chin rest	With height adjustment and eye patch
Mains voltage	120V AC / 60 Hz - 230V AC / 50 Hz
Instrument working voltage	6V AC
Target lamps	6V – 10W SV 8.5 -8
Scale illumination lamps	6V - 3W E10

Classification according to EN 60601 - 1/08/90

Class of protection against direct and indirect electrical shock	Class II
Type of protection against direct and indirect electrical shock	Type B
Compliance level for protection against humidity	Common devices (shell not protected)
Method of sterilization	Disinfectable devices
Compliance level for protection in the presence of inflammable anesthetics or detergents	No protection
Use conditions	Continuous service
Patient-coupled electrical equipment definition	Device with no parts applied to patient.

Block Diagram of Operation



F.1.2A/B	30.06.01.01T02	2	FUSIBILE 0.2A@230V 5x20 T
F.1.2A/B	30.06.01.01T04	2	FUSIBILE 0.4A@120V 5x20 T
X.1.6	30.02.06.3F010	1	CONNETTORE DI USCITA
X.1.1	30.02.03.020	1	INGRESSO RETE SCHURTER KEA 4301–2044
T.1.4	30.13.04.120	1	TRASFORMATORE 120–230/12.45V 25VA 50–60Hz
S.1.2	30.12.01.02.20	1	INTERRUTTORE DI ACCENSIONE CON LAMPADA SPIA
S.1.3	30.02.05.0250	1	SELETTORE TENSIONE DI RETE SCHURTER 4301.1014–39
X.1.6A	10.01.01.149	1	MORSETTO TERRA FUNZIONALE

CSO S.r.l. assumes responsibility for instrument compliance with European Directive 93/42/EEC, its performance, safety, and reliability, and therefore for CE marking.

CSO S.r.l. nevertheless declines said responsibility if:
- installation and start-up are not performed in accordance with the instructions and precautions set forth in this manual.
- the instrument is used in ways not in accordance with the instructions and precautions set forth in this manual.
- accessories and/or spare parts not supplied or recommended by **CSO S.r.l.** are used.
- repairs and safety checks are not performed only by competent, qualified, and suitably-trained personnel authorized by **CSO S.r.l.**
- the electrical system of the space in which the instrument is installed does not comply with CEI standards and the relevant laws and regulations in force.

CSO S.r.l. also declines any and all responsibility for direct or indirect consequences or damage to persons and/or things deriving from improper use of the instrument and/or from erroneous clinical evaluation of information derived from its use.

WARRANTY AND TECHNICAL ASSISTANCE

CSO S.r.l. guarantees this product for a period of 24 months from date of invoice. The manufacturer agrees to provide, on request, any diagrams, components lists, and/or detailed technical instructions that may be of use to authorized personnel previously trained in maintenance and calibration.
This warranty includes replacement, at CSO, of components and materials as well as relative labor. Shipping costs will be at the customer's expense.

Parts subject to wear and/or deterioration in normal use (for example, fuses, rubber parts of the joystick, etc.), and parts damaged by improper use or inadequate maintenance are not covered by this warranty.

CONDITIONS NOT INCLUDED UNDER WARRANTY

- Repair of damages caused by natural catastrophes, mechanical shock (dropping, crushing, etc.), defects in the user's electrical system, negligence, improper use, and/or maintenance/repairs performed using non-original materials and/or by persons not authorized by CSO S.r.l.
- Any type of improper use or use not specifically intended by the manufacturer.

CSO S.r.l. declines responsibility for any interruption or inefficiency in service due to causes or circumstances beyond its control.
The customer shall in no case have any right to compensation for damages suffered as a consequence of the unavailability of the instrument.

To request technical assistance with maintenance, contact a technical assistance center or directly contact:

CSO srl
Costruzione Strumenti Oftalmici
Via degli Stagnacci, 12/E
50010 Badia a Settimo - Scandicci (FI) - ITALY
Phone: +39 055-722191 - FAX +39 055-721557
cso@csophthalmic.com

REFERENCE STANDARDS

The following reference standards were applied in design, production, and testing of the product:

EU Directives
- **DIRECTIVE 93/42/EEC "MEDICAL DEVICES " of 14 June 1993**
- **DIRECTIVE 2002/96/EC "Waste Electrical and Electronic Equipment (WEEE) "**

Standards concerning Quality Management Systems
- **UNI EN ISO 9001:2000 "Quality Management Systems – Requirements."**
- **UNI EN ISO 13485:2004 "Medical Devices – Quality Management Systems - Clinical Requirements for Regulatory Compliance."**

Technical Standards
- **EN 60601-1 - "MEDICAL ELECTRICAL EQUIPMENT – PART 1: GENERAL REQUIREMENTS FOR SAFETY." 1991 edition as amended.e successive varianti;**
- **EN 60601-1-1 - "Medical Electrical Equipment – Part 2: Collateral Standard: Safety Requirements for Medical Electrical Systems." 1994 edition and successive modifications.**
- **EN 60601-1-2 - "Medical Electrical Equipment – Part 2: Collateral Standard: Electromagnetic Compatibility." 2001 edition.**
- **UNI EN ISO 15004 "Ophthalmologic Instruments – Basic Requirements and Verification Methods." 2000 edition.**
- **UNI EN ISO 14971:2004 "Risk Management for Medical Devices."**

C.S.O. srl - Costruzione Strumenti oftalmici with headquarters at
V. Degli Stagnacci 12/e - Cap 50010 Badia a Settimo - Firenze - Italia
manufacturers of the electromedical device
Ophthalmometer Model: JVL/1

in the person of its legal representative Sergio Mura and Giuseppe Matteuzzi

WHO ASSUMES

full personal liability for the following, hereby certifies

that the aforementioned product is designed and built in compliance with the requirements contained in:
Directive 93/42/EEC "medical devices" dated 14/06/1993,
using the following norms:

- *"**CEI EN 60601-1** Standard for electromedical devices" (2nd edition -1991 and subsequent modifications thereto).*
- *"**CEI EN 60601-1-2** (edition -2001) collateral standards for electromedical devices" as the reference for the electromagnetic compatibility.*
- *The product is class I, as the Directive 93/42/EEC, and it'a a measurement device.*
- *It is put in market with mark CE **0051**, including the code number of the notify body (IMQ) certificate n. 225/MDD.*

The complete test reports performed on one model taken from the series production, and the rest of the technical, production and quality assurance documents (as called for in attachment VII to directive 93/42/EEC) are on file in the CSO srl company archives.

Scandicci 04/04/06

Signature of the legal representative

CSO Srl is certified according to

UNI EN ISO 9001:2000
e **UNI EN ISO 13485:2004**

CE 0051

CERTIFIED
QUALITY SYSTEM
ISO 9001:200
ISO 13485
CSQ
n° 9120 - CSO1
n° 9124 - CSO2

CSO
OPHTHALMIC

CSO srl
Costruzione Strumenti Oftalmici
Via degli Stagnacci, 12/E
50010 Badia a Settimo - Scandicci , Firenze ITALIA
Phone: +39 055 722191 - FAX +39 055 721557

cso@csophthalmic.com
www.csophthalmic.com

edro21.com 1518

C.S.O. s.r.l.
Costruzione Strumenti Oftalmici

Via degli Stagnacci, 12/E
50010 Badia a Settimo, Scandicci - Firenze - ITALIA
Phone: +39.055.722191 - Fax +39.055.721557

www.csophthalmic.com
cso@csophthalmic.com

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