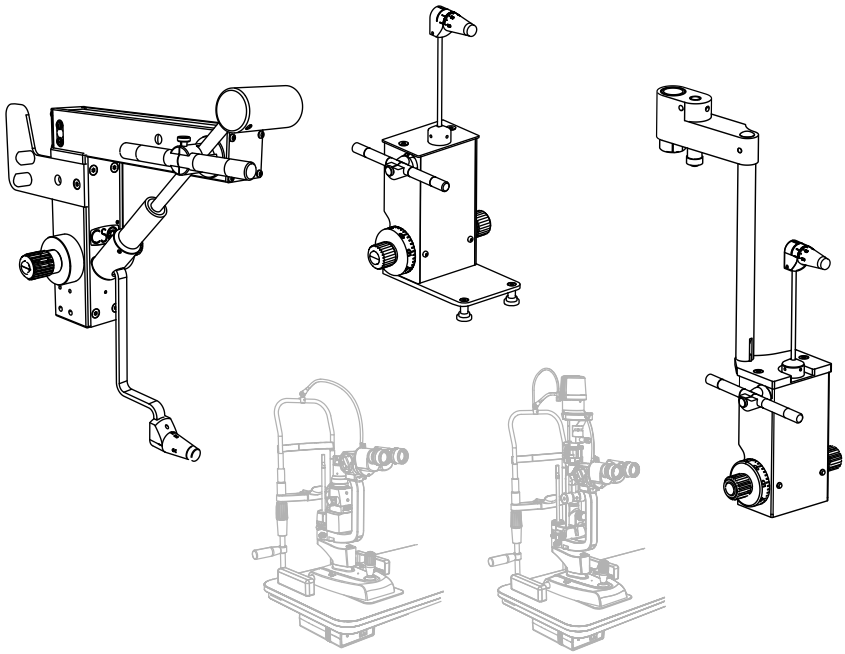
COSTRUZIONE STRUMENTI OFTALMICI



Applanation tonometers

INSTRUCTIONS FOR USE

Z800 / F900 / A900

COSTRUZIONE STRUMENTI OFTALMICI

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TONOMETRIIFUENGCSO0102032024

CE 0051

ENG

1 INTRODUCTION

The device is the result of extensive research, conducted with experts to ensure the product's technical innovation, quality and design.
The device can be easily used in ophthalmology to measure the intra-ocular eye pressure.

1.1 SYMBOLS

The following symbols may be displayed in the instructions for use, on the package or on the device:

Symbol	Meaning
	Caution
	Read the instructions for use
	General obligation
	Note. Useful information for the user
	General prohibition sign
	Manufacturer
	CE Marking (Directive 93/42/EEC) Identification number of the notified body (IMQ)
	Medical device

1.2 GENERAL WARNINGS

THESE INSTRUCTIONS FOR USE ARE REFERRED TO Z800, F900 AND A900 DEVICES.

DEVICE Z800 IS AN ACCESSORY COMPATIBLE WITH SLIT LAMP SL9800.

DEVICES A900 AND F900 ARE ACCESSORIES COMPATIBLE WITH SLIT LAMP SL9900.

In the instructions for use, the devices are identified as Z800, F900 or A900.
When not specified, the indications are applicable to all the devices.

THE ORIGINAL TEXT IS IN ITALIAN.

Before using the device or after a long period of non-use, carefully read these instructions for use. Follow the directions provided in the instructions for use and on the device.

Always keep these instructions for use in an accessible and nearby place. If you decide to sell this device to a new user, remember to include these instructions, complete and readable.

Keep the original box and packaging, as the free-of-charge support service does not cover damage resulting from inadequate packaging of the device when sent back to an authorised Service Centre.

Check for potential damage to the device caused by transport/storage prior to its use.

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

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

1.3 REFERENCE REGULATIONS

1.3.1 EU DIRECTIVES

- Directive 93/42/EEC and subsequent modifications and integrations concerning medical devices
- Regulation (EU) 2017/745 of the European Parliament and Council of 5 April 2017 on medical devices (to the extent applicable)
- Directive 2012/19/EU on waste of electric and electronic equipment (WEEE)

1.3.2 TECHNICAL STANDARDS

- IEC 60601-1 - “Medical electrical equipment - Part 1: General requirements for basic safety and essential performance”.
- UNI EN ISO 15004-1 - “Ophthalmic Instruments. Fundamental requirements and test methods - Part 1: General requirements applicable to all Ophthalmic devices”.
- UNI CEI EN ISO 14971 - “Medical devices. Application of risk management to medical devices”.
- UNI EN ISO 8612 - “Ophthalmic instruments - Tonometers”.

1.3.3 QUALITY MANAGEMENT SYSTEM STANDARDS

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

1.4 WARRANTY

The Manufacturer is responsible for the compliance of the device with EU Directive 93/42/EEC as amended by 2007/47/EC for:

- performance
- safety and reliability
- CE marking

The Manufacturer rejects all responsibility for:

- installation and start-up that is not carried out in compliance with the directions and precautions reported in the instructions for use
- use that fails to comply with the instructions for use or precautions reported in the instructions for use

- use of accessories or spare parts not provided or suggested by the Manufacturer
- repairs and safety checks not carried out by expert, qualified and trained personnel authorised by the Manufacturer
- failure of the electrical system of the premises where the device is installed to comply with the technical standards, laws and regulations in force in the country where the device is installed
- direct or indirect consequences or damage to objects or persons caused by the misuse of the device or erroneous clinical analysis originating from its use

The Manufacturer guarantees the device for 24 months after the invoice date. The warranty covers the replacement by the Manufacturer or an authorised Service Centre of components and materials and the corresponding labour. Shipping and transport costs are to be paid by the customer.
The warranty does not cover:

- repairs of faults originating from natural disasters, mechanical shocks (fall, collision, etc), negligence, misuse, maintenance or repairs carried out using non-original materials
- any other misuse or use not intended by the Manufacturer
- damage caused by service failings or inefficiencies due to causes or circumstances out of the Manufacturer's control
- wear and/or deterioration of parts due to normal use and parts that might break due to misuse or maintenance carried out by personnel not authorised by the Manufacturer.

To request maintenance interventions or obtain technical information about the device, contact an authorised Service Centre or the device Manufacturer directly.

The customer will not be refunded for damage caused by device downtime.

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

CAUTION
Do not use the device if visibly damaged. Regularly inspect the device for signs of damage.

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

CAUTION
Danger of falling device. Check that the device is correctly fixed to the slit lamp. Pay attention during the device assembly operations. In case of accidental fall, check the calibration and, if necessary, contact the Manufacturer.

CAUTION
Before any measurements, the surface of the measuring prism that enters into contact with the cornea must be inspected for damage. In case of anomaly, replace the prism.

CAUTION
The measurement must only be carried out with undamaged, clean and disinfected prisms. Otherwise, damage to the patient's cornea may occur.
If the measuring prism is not intact, detergent or disinfectant residues could enter the cracks and cause irritation and corrosion on the corneal surface. Hence, the measuring prism must be accurately rinsed with water after disinfection and must be checked to make sure that it is not damaged in any way.
Incorrect disinfection can also cause cross-contamination between patients and operator, as well as damage to the measuring prism.
For indications on the cleaning and disinfection procedures, refer to paragraph "Measuring prism disinfection" on page 51.
The only person responsible for not observing the cleaning and disinfection procedure is the user.

When using a reusable measuring prism, always disinfect it both before and immediately after carrying of the measurement on the patient's eye surface.
When using a disposable measuring prism, before use always make sure that the package is intact and the content is sterile. Make sure to dispose of the disposable measuring prism immediately after the exam.

CAUTION
If possible, avoid carrying out the measurement if the patient shows ocular infection or injured corneal surface.

Only touch the measuring prism with disposable gloves. Only touch the measuring prism at the sides. Never touch the part that will be in contact with the patient's eye surface.

The measuring prism must not be disinfected together with other instruments or medical devices.

Do not use the measuring prism beyond two years from the date indicated on the production batch details written on the package.

For patients affected by infective diseases always use disposable measuring prisms.

It is forbidden to disinfect and reuse disposable measuring prisms.

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 variations in temperature and humidity.

It is forbidden to use the device outdoors.

The measurement precision is affected by corneal rigidity variations and changes. The rigidity can be due to differences in the corneal thickness, to intrinsic structural factors or refractive corneal surgery. Keep these factors into account during the evaluation of the intraocular pressure.

2.2 DEVICE IDENTIFICATION

2.2.1 REGISTRATION DATA IN THE LIST OF MEDICAL DEVICES

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

2.2.2 DEVICE DATA PLATE

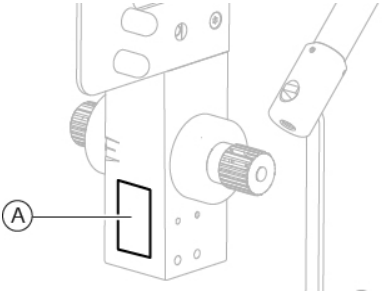


Fig. 1 - Tonometer Z800 plate position

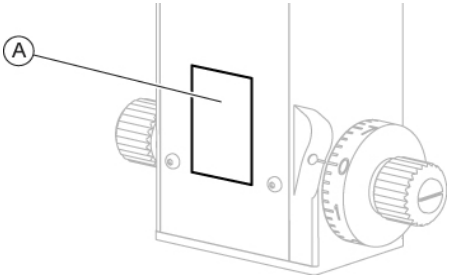


Fig. 2 - Tonometer A900 plate position

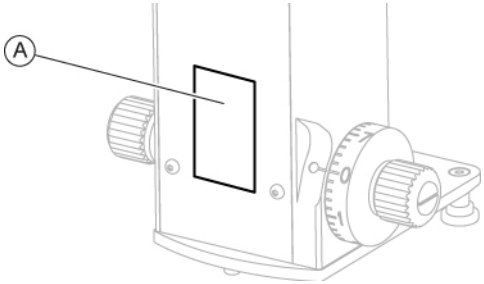


Fig. 3 - Tonometer F900 plate position

Pos	Description
A	Device data plate

Fig. 4 - Tonometer A900 data plate Fig. 5 - Data plate for tonometer Z800

Fig. 6 - Tonometer F900 data plate

2.3 INTENDED USE

The applanation tonometer is an accessory device for slit lamps that allows to measure the intraocular eye pressure, for the diagnosis of some ophthalmological diseases. The intraocular pressure measurement is useful to evaluate the patient's risk of developing glaucoma.
The applanation tonometer works according to the "Goldmann method": the measurement of the intraocular pressure is given by the required force to maintain a uniform applanation of the corneal surface.
The intraocular pressure measurement is conducted on the patient by means of the measuring prism in contact with the patient's cornea. During the exam, the measuring prism is installed on the tonometer arm support. The tonometer is installed on the slit lamp.
Because of the direct contact with the corneal surface, it could be necessary to apply a local anaesthetic in the patient's eye.
High precision measurement device. The average deviation (standard) in every single exam is ± 0,5 mmHg approximately.
The scleral stiffness must not be considered, as the small volumetric displacement of 0.56 mm^3 increases the intraocular tension of only 2.5% approximately.
Tonometers must be installed on the slit lamp using their support accessory.
Tonometers A900 and Z800 can be left on the slit lamp even when they are not in use. If necessary, they can be placed in front of the microscope during the exam.
The device has no known contraindications.

The CSO applanation tonometer is an accessory suitable for the majority of slit lamps, also from other suppliers.

2.4 MEDICAL DEVICE CLASSIFICATION

Technical data	Value
Classification in compliance with annexe IX to the 93/42/EEC Directive and subsequent modifications	Class Im

2.5 ELECTROMEDICAL DEVICE CLASSIFICATION

Classification in compliance with technical specification IEC 60601-1

Technical data	Value
Type of protection against direct and indirect contacts	Not applicable
Applied parts	Not applicable
Degree of protection against humidity	IP20 (no protection against infiltration by liquids)
Sterilisation or disinfection method	This device can be disinfected
Degree of protection in the presence of anaesthetics or flammable detergents	No protection
Degree of electrical connection between device and patient	Not applicable
Use conditions	Continuous operation

2.6 ENVIRONMENTAL CONDITIONS

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

CAUTION

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

2.7 DISPOSAL AT THE END OF THE USEFUL LIFE

Instructions for the correct disposal of the device pursuant to European Directives 2012/19/EU and 2011/65/EU regarding the reduction of the use of dangerous substances in electrical and electronic equipment, as well as waste disposal.
At the end of its useful life, the device must not be disposed of with urban waste. The device may be delivered to designated separate collection centres set up by the municipal administration or to dealers that offer this service. Separately disposing of an electrical device prevents potential negative consequences for the environment and health caused by improper disposal and allows the materials it is made of to be recycled so as to attain significant savings in energy and resources.

The user must consider the potentially dangerous effects for the environment and human health arising from the improper disposal of the whole device or its parts.

Should the user wish to dispose of the device at the end of its useful life, the Manufacturer facilitates its potential reuse and recovery and the recycling of the materials contained therein. This prevents the release of hazardous substances into the environment and promotes the conservation of natural resources. Before disposing of the device, it is crucial to take into consideration European and national regulations, which prescribe the following:

- not to dispose of it as urban waste, but separate its parts, seeking advice from a firm specialised in the disposal of electrical/electronic equipment or the local administration in charge of 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 as the new device, the Distributor or Manufacturer is legally required to collect the old device.
- if the user decides to dispose of a used device placed on the market after 13 August 2005, the Distributor or Manufacturer is legally required to collect it.

- the Manufacturer takes care, by joining the appropriate technological waste disposal consortium, of the treatment and recycling of the used device collected, bearing any costs.

The Manufacturer is available to provide the user with information regarding the dangerous substances contained in the device, the recycling of these substances and the potential reuse of the used device.
Strict administrative sanctions for those failing to comply are provided for by law.
For specific information about disposal in countries other than Italy, contact your local Dealer.

3 DEVICE DESCRIPTION

3.1 SUPPLY DESCRIPTION

Z800 device

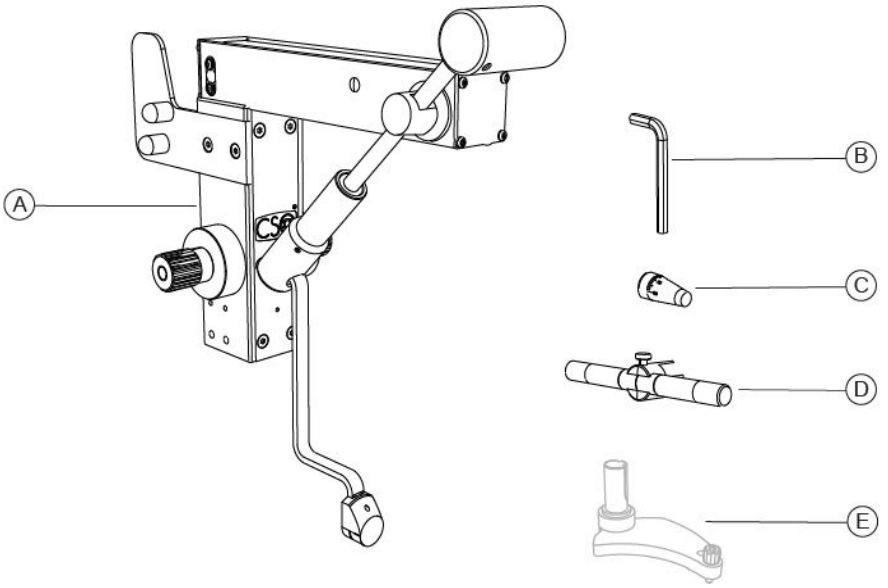


Fig. 7 - Supply description

Pos	Name
A	Device
B	Hexagon wrench
C	Measuring prism
D	Operation check accessory
E	Tonometer support (optional*)

A900 device

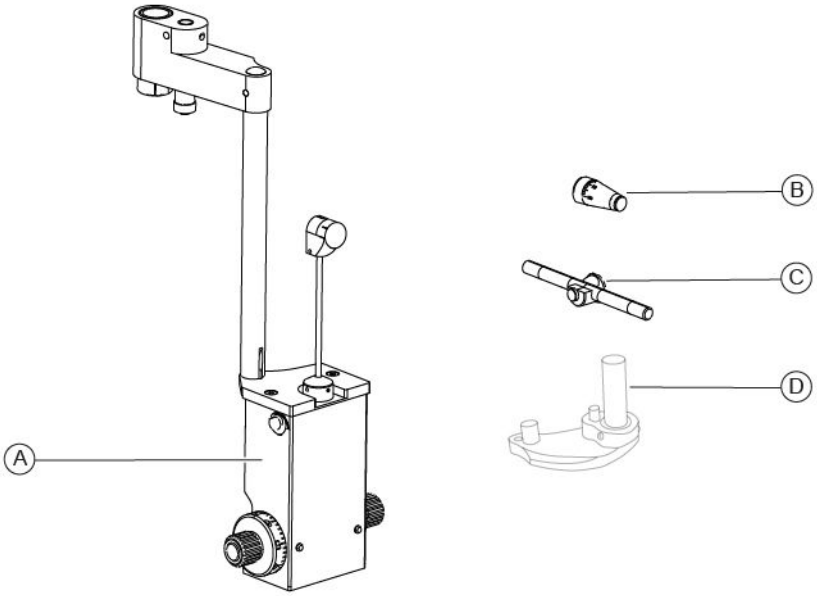


Fig. 8 - Supply description

Pos	Name
A	Device
B	Measuring prism
C	Operation check accessory
D	Tonometer support (optional*)

F900 device

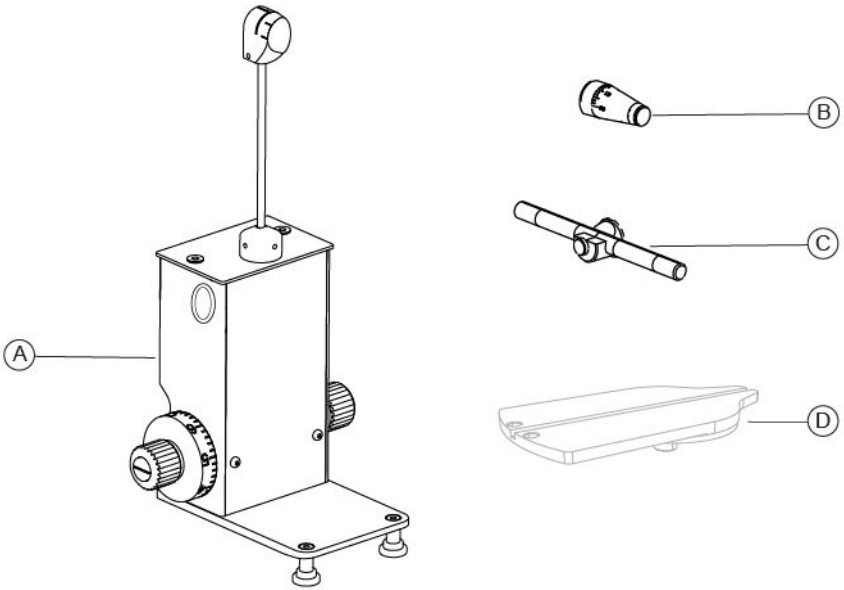


Fig. 9 - Supply description

Pos	Name
A	Device
B	Measuring prism
C	Operation check accessory
D	Tonometer support guide (optional*)

Optional: accessory not provided with the basic supply.
Accessories marked with (*) are essential for the proper functioning of the device. The support model might differ depending on the microscope model used on the lamp.

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

3.1.1 TONOMETER Z800

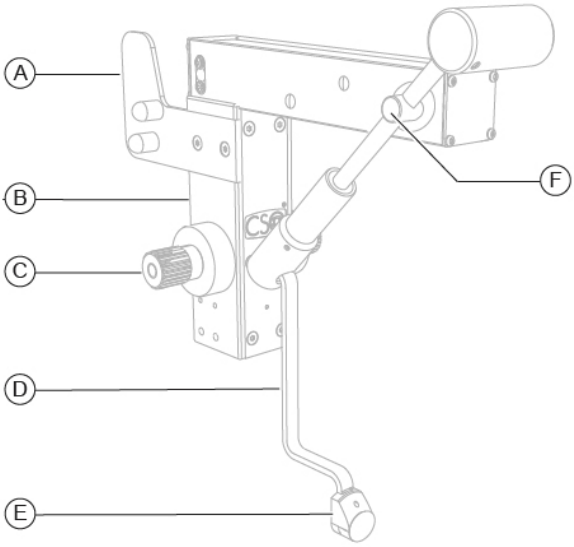


Fig. 10 - Tonometer Z800

Pos	Description
A	Resting arm support
B	Tonometer Z800 body
C	Measuring scale knob
D	Arm
E	Measuring prism support
F	Operation check accessory compartment

3.1.2 TONOMETER A900

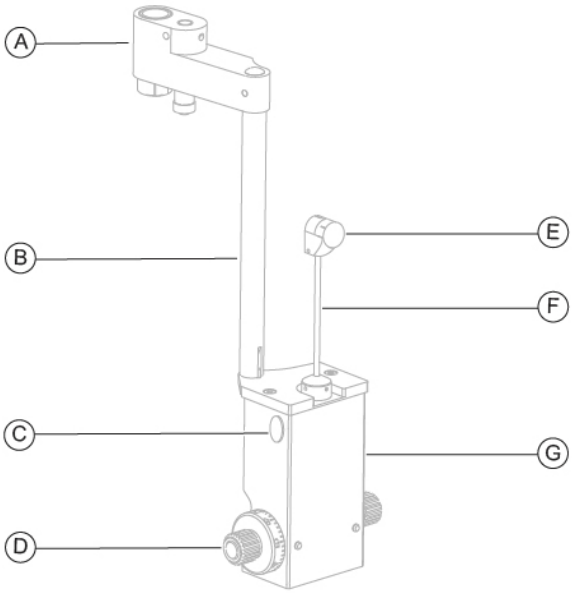


Fig. 11 - Tonometer A900

Pos	Description
A	Fastening connection for tonometer A900
B	Connection support
C	Operation check accessory compartment
D	Measuring scale knob
E	Measuring prism support
F	Arm
G	Tonometer A900 body

3.1.3 TONOMETER F900

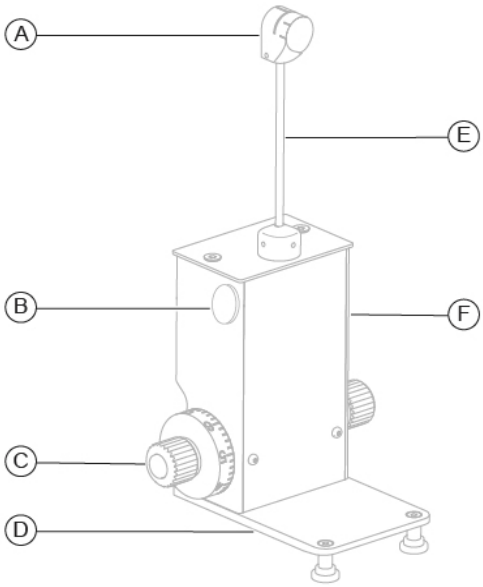


Fig. 12 - Tonometer F900

Pos	Description
A	Measuring prism support
B	Operation check accessory compartment
C	Measuring scale knob
D	Support
E	Tonometer F900 body
F	Arm

3.2 TECHNICAL DATA

Tonometer Z800

Technical data	Value
Measuring force	Generated through the spring force
Installation	On the support pin above the slit lamp microscope
Measurement range	Between 0 and 80 mmHg (between 0 and 10,64 kPa)
Measurement variation	≤ 0.49 mN
Weight	0.85 kg (without accessories)

Overall dimensions

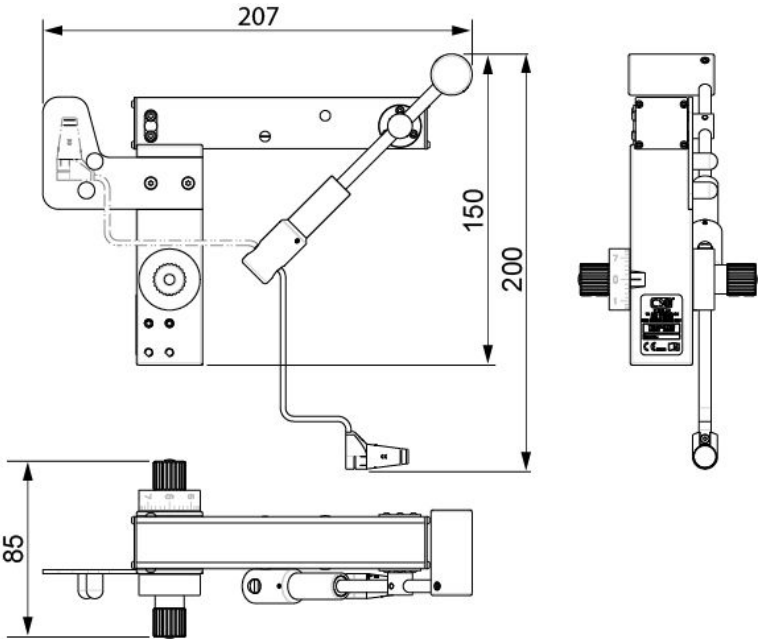


Fig. 13 - Overall dimensions

Tonometer A900

Technical data	Value
Measuring force	Through the lever weight
Installation	On the support pin above the slit lamp microscope
Measurement range	Between 0 and 80 mmHg (between 0 and 10,64 kPa)
Measurement variation	≤ 0.49 mN
Weight	0.82 kg (without accessories)

Overall dimensions

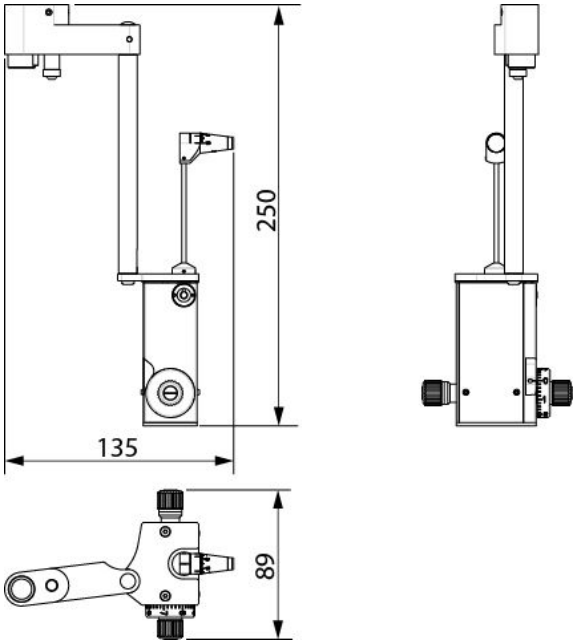


Fig. 14 - Overall dimensions

Tonometer F900

Technical data	Value
Measuring force	Through the lever weight
Installation	Insertion in the guide on the slit lamp arm
Measurement range	Between 0 and 80 mmHg (between 0 and 10,64 kPa)
Measurement variation	≤ 0.49 mN
Weight	0.48 kg (without accessories)

Overall dimensions

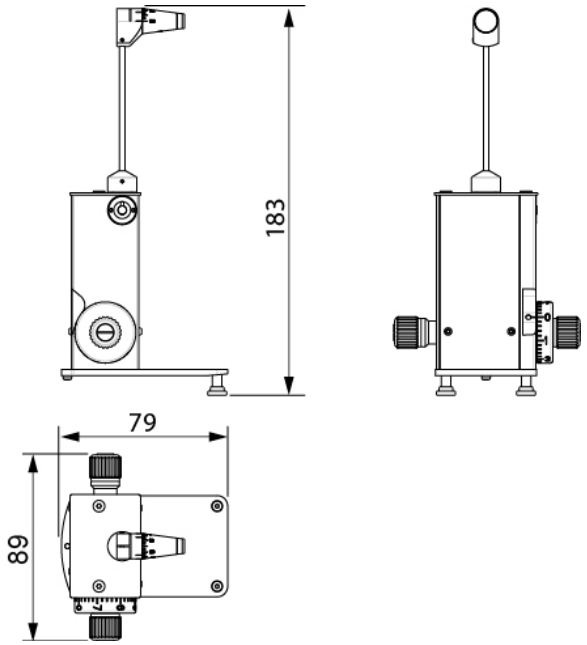


Fig. 15 - Overall dimensions

4 DEVICE USE

4.1 HOW TO INSTALL THE TONOMETER Z800 ON THE SLIT LAMP

1 Install the tonometer support above the microscope, in its compartment. Fasten it using the screw on the support.
2 Place the tonometer on the support pin.

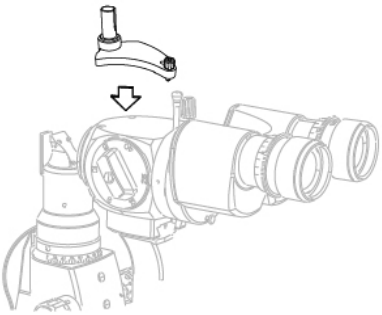


Fig. 16 - Positioning the tonometer support

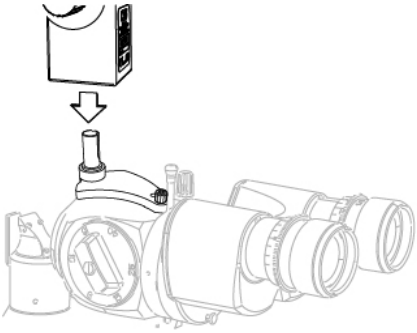


Fig. 17 - Positioning the tonometer Z800

3 Free the arm from the protection support and move it from the resting position to the measurement position.

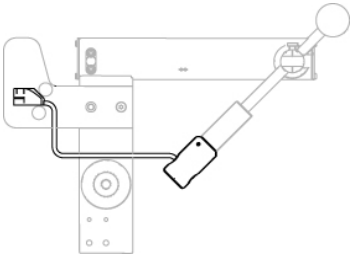


Fig. 18 - Arm in resting position

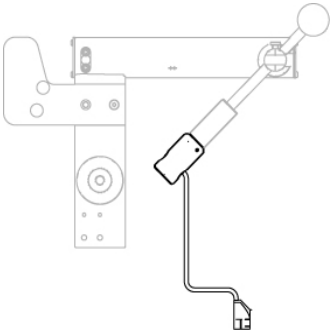


Fig. 19 - Arm in measurement position

4 Adjust the measuring prism support position to align it with the microscope shooting channel.

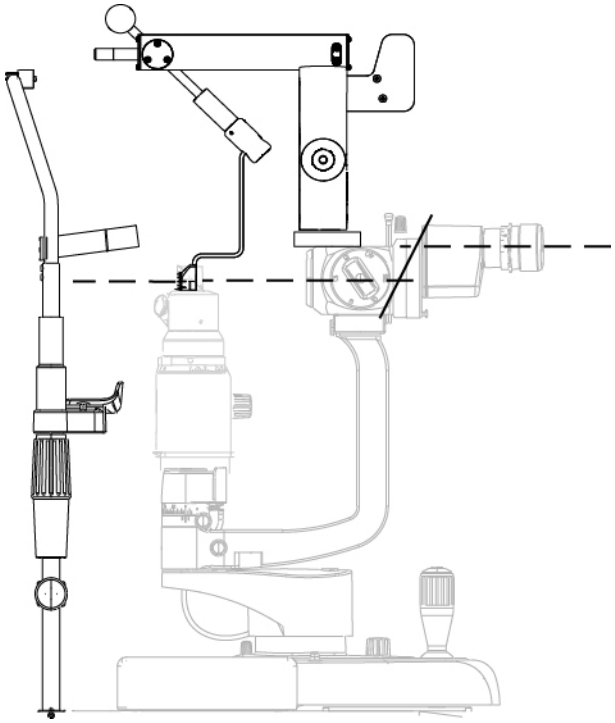


Fig. 20 – Aligning the measuring prism support with the microscope

5 If the alignment is incorrect, place the tonometer in the correct position and fasten using the screws (A) under the measuring scale knob.

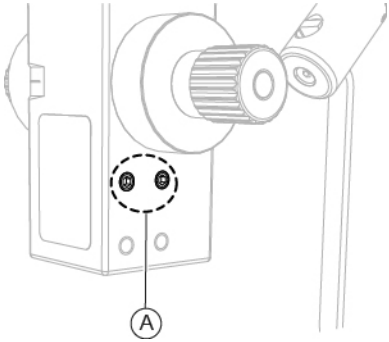


Fig. 21 - Adjustment points for the prism support

4.2 HOW TO INSTALL THE TONOMETER A900 ON THE SLIT LAMP

1 Turn the lighting head of the slit lamp to the left or right at an angle of 90°.
2 Install the tonometer support above the microscope, in its compartment. Fasten it using the screw on the support.
3 Place the tonometer A900 connection support on the tonometer support.

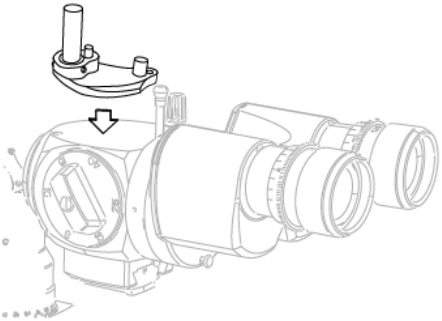


Fig. 22 - Positioning the tonometer support

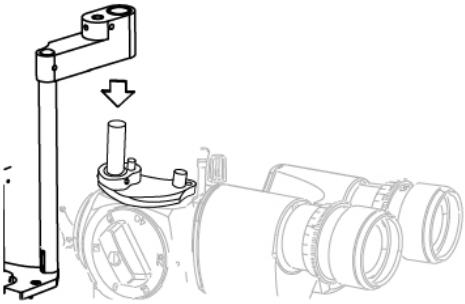


Fig. 23 - Positioning the tonometer A900

4 Turn the tonometer and position the measuring prism in measurement position. A blocking position ensures the correct positioning of the tonometer during the measurement.

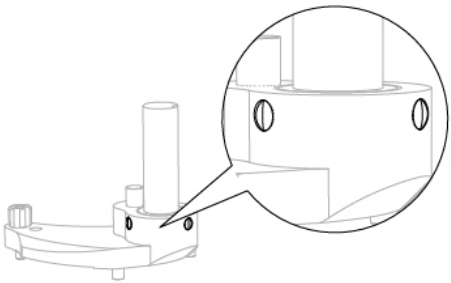


Fig. 24 - Measurement/rest blocking position

4.3 HOW TO INSTALL THE TONOMETER F900 ON THE SLIT LAMP

1 Turn the lighting head of the slit lamp to the left or right at an angle of 90°.
2 Remove the lid on the slit lamp arm and place the support in its compartment.
3 Place the tonometer F900 on the tonometer support guide.

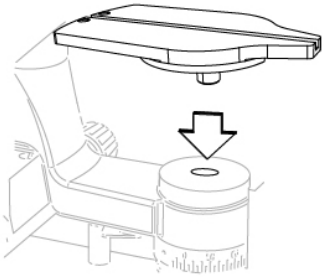


Fig. 25 - Positioning the tonometer support

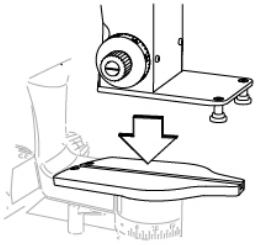


Fig. 26 - Positioning the tonometer F900

4 On the support guide of the tonometer are two holes that allow correct tonometer positioning, by aligning the measuring prism with the microscope left or right shooting channel (operator's left or right eye).

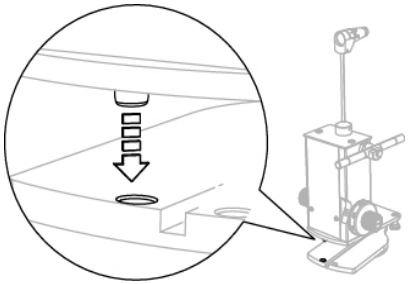


Fig. 27 - Positioning to align the measuring prism with the microscope left shooting channel (operator's left eye)

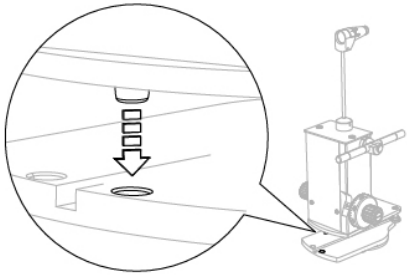


Fig. 28 - Positioning to align the measuring prism with the microscope right shooting channel (operator's right eye)

4.4 HOW TO PREPARE THE SLIT LAMP (Z800)

The microscope must be adjusted so that the measuring prism semi-circles can be observed and clearly focused during the measurement.

1. Rotate the arm with support to position the measuring prism support on the observation axis of the microscope.
2. Make sure that the eyepieces of the slit lamp are correctly adjusted to compensate for the operator's potential refractive error.
3. Correctly adjust the light intensity of the device.
4. Insert the blue filter in the slit lamp.
5. Completely open the slit diaphragm. The angle between the light source and the microscope should be 60° approximately in order to obtain a clear image without reflection.

4.5 HOW TO PREPARE THE SLIT LAMP (A900)

The microscope must be adjusted so that the measuring prism semi-circles can be observed and clearly focused during the measurement.

1. Rotate the connection support to place the measuring prism support on the observation axis of the microscope.
2. Make sure that the eyepieces of the slit lamp are correctly adjusted to compensate for the operator's potential refractive error.
3. Correctly adjust the light intensity of the device.
4. Insert the blue filter in the slit lamp.
5. Completely open the slit diaphragm. The angle between the light source and the microscope should be 60° approximately to obtain a clear image without reflection.

4.6 HOW TO PREPARE THE SLIT LAMP (F900)

The microscope must be adjusted so that the measuring prism semi-circles can be observed and clearly focused during the measurement.

1 Make sure that the eyepieces of the slit lamp are correctly adjusted to compensate for the operator's potential refractive error.
2 Correctly adjust the light intensity of the device.
3 Insert the blue filter in the slit lamp.
4 Completely open the slit diaphragm. The angle between the light source and the microscope should be 60° approximately in order to obtain a clear image without reflection.

4.7 HOW TO POSITION THE MEASURING PRISM

CAUTION
Incorrect cleaning of the measuring prism can cause cross-contamination between patients and operator as well as damage to the measuring prism. Disinfect the measuring prism as described in paragraph "Measuring prism disinfection" on page 51.

CAUTION
Detergent or disinfectant residues can cause eye irritations.

It is forbidden to use damaged measuring prisms. The contact surface of the measuring prism must be inspected for contaminants or damage (scratches, cracks and sharp edges) prior to every use. Perform the check with a slit lamp microscope at 10/16 magnification.

Do not use disposable measuring prisms after the expiry date indicated on the packaging.

When positioning the measuring prism, use disposable gloves.

4.7.1 POSITIONING THE REUSABLE MEASURING PRISM

Reusable measuring prisms must always be disinfected prior to every use. Disinfect the measuring prism as described in paragraph **"Measuring prism disinfection" on page 51**.
When using a reusable measuring prism for the first time, clean it and disinfect it before use. The measuring prism is not supplied already disinfected.
Never touch the measuring prism where it will be in contact with the corneal surface.

1 Make sure that the reusable measuring prism has been properly disinfected and stored in a sterile container.
2 Carefully pick up the measuring prism. Hold the measuring prism by the sides. Never touch the part of the measuring prism that will be in contact with the corneal surface.
3 Check that there is no damage on the measuring prism surface.
4 Insert the measuring prism on the tonometer arm support.
5 Move the measuring knob to position 1.

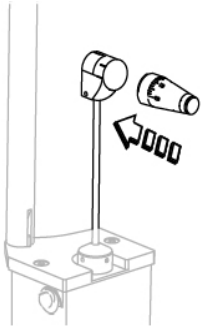


Fig. 29 - Inserting the measuring prism in the support

4.7.2 POSITIONING THE DISPOSABLE MEASURING PRISM

Disposable products are the best solution to prevent the spread of pathogens.

Do not use disposable measuring prisms after the expiry date indicated on the packaging.

The disposable measuring prism must be new and in its sterile package. The package must be intact before opening it.
Immediately dispose of the disposable measuring prism after use.

1 The disposable measuring prism must be new and sealed in its sterile package. The package must be intact.
2 Carefully open the disposable measuring prism package. Hold the measuring prism by the sides. Never touch the part of the measuring prism that will be in contact with the corneal surface.
3 Check that there is no damage on the measuring prism surface.
4 Insert the measuring prism on the tonometer arm support.
5 Move the measuring knob to position 1.

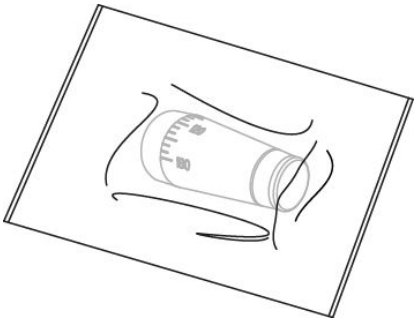


Fig. 30 - Disposable measuring prism package

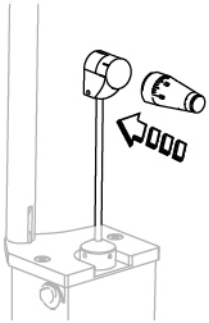


Fig. 31 - Inserting the measuring prism in the support

4.8 HOW TO PREPARE THE PATIENT

If the patient is wearing contact lenses, make sure that they have been removed before applying the anaesthetic drops.

1 Ask the patient to sit down.
2 Apply a local anaesthetic drop on the eye surface to be examined.
3 Apply sodium fluorescein 0.5% on the eye surface to be examined.

4 Show the patient how to position their face against the chin cup and forehead rest.
5 Check that the measuring prism support is correctly positioned in relation to the shooting channel.
6 Check that the eye is correctly positioned in relation to the shooting channel.
7 Ask the patient to look towards the front and keep the eyes open during the exam. If necessary, use the fixation target to help the patient to keep the eyes still.

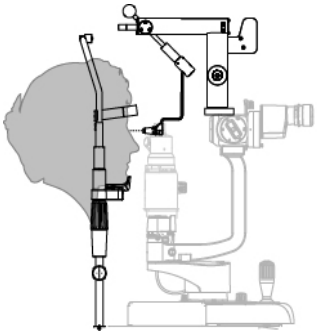


Fig. 32 - Position of the tonometer Z800 (SL9800)

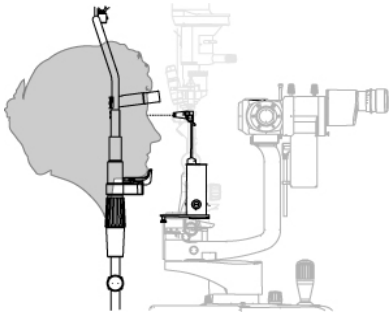


Fig. 33 - Position of the tonometer F900 (SL9900)

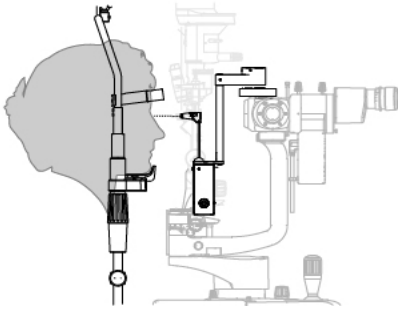


Fig. 34 - Position of the tonometer A900 (SL9900)

4.9 HOW TO MEASURE THE INTRAOCULAR PRESSURE

Tell the patient to keep the eyes open during the exam.

The measurement time should be as short as possible.

1. Ask the patient to open and close the eyes for a few seconds, so that the tear film is evenly distributed on the corneal surface.
2. Select the blue filter to activate the fluorescein.
3. Move the slit lamp forward until the measuring prism is in contact with the centre of the cornea.
4. Move the graduated scale to 1.
5. When observing the applanated surface with the microscope, you will see two semicircles of the same size. The two semicircles can have different sizes depending on the ocular pressure. When the tonometer is in the right position, the two semicircles are of the same size.

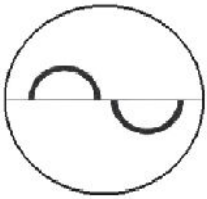


Fig. 35 - Image as seen on the microscope

6 Slowly turn the tonometer measurement knob until the semicircles are perfectly aligned.

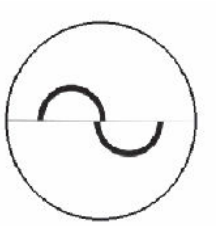


Fig. 36 - Correct alignment of the semicircles

4.10 HOW TO MEASURE THE INTRAOCULAR PRESSURE IN ASTIGMATIC PATIENTS

In case of irregular cornea, measurements can be taken on any meridian.
In case of patients with astigmatism exceeding 3 dioptres, the choice of the measuring prism position in relation to the flatter meridian is significant to improve measurement accuracy.
In order to measure the actual intraocular pressure, the Goldman's tonometry is based on the principle of the applanation of a surface of 7.354 mm^2, equal to a diameter of 3.06 mm of the corneal centre. However, the issue of the approximation of the measure taken on a toric corneal surface is recognised. The toric corneal surface appears as an ellipse with different diameters in different meridians.
Therefore, the applanation reaches the semicircle of the measuring prism in the flatter meridian before the one in the more curved meridian. The problem can be overcome by rotating the measuring prism by 43 degrees, indicated by the red mark on the measuring prism support, with respect to the flatter meridian.
Alternatively, a simple approach is to position the measuring prism in correspondence of the value of the average of the two meridians, the flatter and the more curved.

4.11 CORRECTING WRONG ACQUISITIONS

When observing the applanated surface with the microscope, the two semicircles should be of the same size and perfectly aligned.
Below are the possible causes for the semicircles in the wrong position, and possible solutions in order to display the correct position.

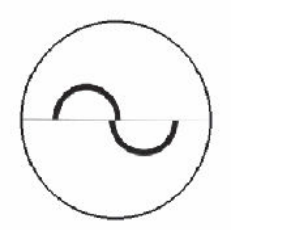
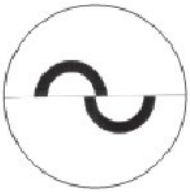
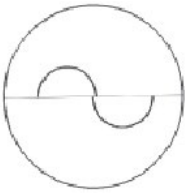
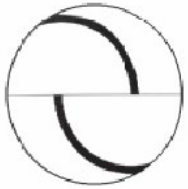


Fig. 37 - Correct semicircle position

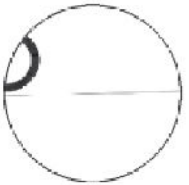
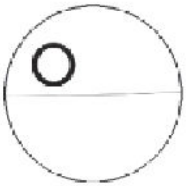
Fluorescein semicircle too wide or too small.

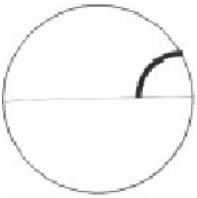
Image	Cause	Solution
	The image of the two semicircles is too wide. The intraocular pressure measurement might be higher than the actual intraocular pressure.	Carefully clean the measuring prism before positioning it again.
	The image of the two semicircles is too small. The intraocular pressure measurement might be lower than the actual intraocular pressure.	Carefully clean the measuring prism before positioning it again.

The measuring prism does not touch the cornea, or excessive pressure has been applied.

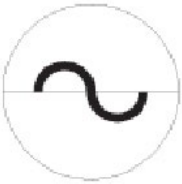
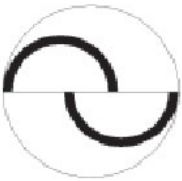
Image	Cause	Solution
	If the patient pulls their head back slightly, irregular movements of the eye occur. This will cause unstable contact between the measuring prism and the eye.	Ask the patient to stay perfectly still and fully open their eyes. Repeat the measurement.

The two semicircles are not displayed correctly.

Image	Cause	Solution
 	Wrong slit lamp position.	Adjust the slit lamp height and move it to the left with the joystick.

	The semicircles are too far to the right.	Move the slit lamp to the right with the joystick.
	The measurement is significantly higher than the expected ocular pressure.	Adjust the slit lamp height. Repeat the measurement.

The inner sides of the two semicircles are not aligned correctly.

Image	Cause	Solution
	The two semicircles are centred but the edges are not correctly aligned.	Increase the pressure by rotating the measurement knob.
	The two semicircles are centred but the edges are not correctly aligned.	Increase the pressure by rotating the measurement knob.
	The two semicircles are centred but the edges are not correctly aligned.	Excessive pressure applied. Reduce the pressure by rotating the measurement knob until the two semicircles are correctly aligned.

4.12 HOW TO READ THE MEASURING SCALE

The measuring prism contact surface has a diameter of 7.0 mm. It is flat with round edges to avoid possible damage to the corneal surface.
By rotating the measuring knob, the pressure on the eye is increased until a continuous applanated and regular surface is obtained.
The intraocular pressure expressed in mmHg is calculated by multiplying the value indicated by the knob position by 10.
The following table indicates the relationship between the measuring knob position, the force and pressure in the applanated surface.

Position on the measuring knob	mN	kPa	mmHg
1	9.81	1.33	10
2	19.62	2.66	20
3	29.43	39.9	30
4	39.24	53.2	40
5	49.05	66.5	50
6	58.86	79.8	60
7	68.67	93.1	70
8	78.48	10.64	80

4.13 HOW TO REMOVE THE MEASURING PRISM

When removing the measuring prism, use disposable gloves.

1 Carefully remove the measuring prism from the support.
2 If a reusable measuring prism has been used, clean it as described in paragraph **“Measuring prism cleaning” on page 51.**
3 If a disposable measuring prism has been used, dispose of it immediately.

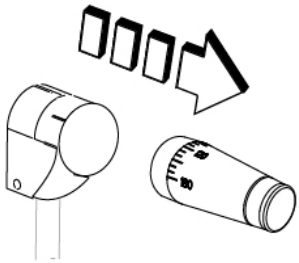


Fig. 38 - Measuring prism removal

4.14 HOW TO REMOVE THE TONOMETER Z800 FROM THE SLIT LAMP

1 Rotate the arm and place it on the protection bracket in the rest position.
2 Lift the tonometer to release it from the support pin.
3 Unscrew the screw and remove the support from the slit lamp.
4 Keep the device in a dry and safe place.

4.15 HOW TO REMOVE THE TONOMETER A900 FROM THE SLIT LAMP

1 Rotate the arm to the right. The tonometer can be left on the slit lamp.
2 Alternatively, lift the tonometer to release it from the support pin.
3 Unscrew the screw and remove the support from the slit lamp.
4 Keep the device in a dry and safe place.

4.16 HOW TO REMOVE THE TONOMETER F900 FROM THE SLIT LAMP

1 Lift the tonometer to release the support from the guide.
2 Remove the support guide from the slit lamp.
3 Keep the device in a dry and safe place.

5 ORDINARY MAINTENANCE

5.1 SAFETY WARNINGS

CAUTION
The device does not contain any parts requiring user intervention. Do not remove any parts of the device.

CAUTION
Reusable measuring prisms are not supplied already disinfected. Therefore, they must always be cleaned and disinfected before use. Carefully follow the instructions of this manual for the cleaning and disinfection of the measuring prism.

CAUTION
Due to the large number of variables (number of patients, treatment, type and concentration of the disinfectant used), it is impossible to provide exact information on how long a measuring prism can be used. Use the measuring prism in accordance with the indications given in these instructions for use. Damaged prisms must be replaced immediately.

The measuring prism must not be disinfected together with other instruments or medical devices.

It is forbidden to disinfect and reuse disposable measuring prisms. The cleaning and disinfecting procedure must only be carried out on reusable measuring prisms.

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

In the case of damage or malfunction or for any maintenance operations not indicated in the instructions for use, contact an authorised Service Centre or the device Manufacturer.

It is forbidden to follow the cleaning procedures listed below. They could damage the measuring prism:
- Using alcohol
- Using acetone
- Using UVA radiations
- Soaking the measuring prism in a fluid for more than 60 minutes
- Exposure to temperatures higher than 60°
- Disinfection procedures other than the one described in these instructions for use.

5.2 CLEANING AND DISINFECTION

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

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

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

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

Cleaning and disinfection procedures must be carried out regularly.

Device parts that do not come into direct contact with the patient must be cleaned at least once a day.
Device parts that do come into direct contact with the patient must be thoroughly cleaned and disinfected after each use.

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

5.2.1 RECOMMENDED PRODUCTS FOR CLEANING AND DISINFECTION

CAUTION
The products mentioned in this paragraph must only be used to clean and disinfect the device.
For the appropriate products to disinfect the measuring prisms, read the "Measuring prism disinfection" paragraph on page 51.

CAUTION
Danger of material damage. Do not use solvents, acidic or basic solutions (pH <4.5 or >8.0), abrasive or caustic substances, chlorine-based and chlorine-derived products.
The Manufacturer is not liable for any damage caused by using disinfectant products not indicated in this manual.

The choice of the most suitable product and procedures for the cleaning and disinfection of the device must take into account both the sensitivity of the device to specific substances and the effectiveness of the product.
For the cleaning and disinfection procedures, use products approved by the FDA or EC for medical devices or medical-surgical devices.
Use the products as listed below, divided by category:

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

For information about the use of the chosen product, follow the instructions provided by the manufacturer.

5.2.2 CLASSIFICATION OF THE CRITICALITY OF THE DEVICE

CAUTION
The device supplied is not sterile and must not be sterilised prior to use.

This device is classified as "non-critical" since it is only used on intact skin and therefore has a low infectious risk**.**
For devices classified as non-critical, regular cleaning or low-level disinfection is sufficient.
However, when the patient's condition is transmissible by direct contact or in case of accidental exposure to body fluids, the device must be disinfected with a higher-level disinfectant after cleaning.

5.2.3 DEVICE CLEANING

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

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

The device must be regularly cleaned.

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

For more information about suitable cleaning products, read paragraph **"Recommended products for cleaning and disinfection" on page 47.**

5.2.4 MEASURING PRISM CLEANING

CAUTION
Danger of material damage. Only use detergent and disinfectant products specifically approved for medical devices or medical-surgical devices.

When cleaning the measuring prism, use disposable gloves.

1 Carefully remove the measuring prism from the tonometer support.
2 Wash it with cold running water for 30-60 seconds. If necessary, use a neutral pH detergent (without irritating agents) and a disposable, soft and lint-free cloth. Always dab in the same direction.
3 Rinse the measuring prism. Check that all detergent and impurities have been removed. If there is still some dirt, repeat step 2.

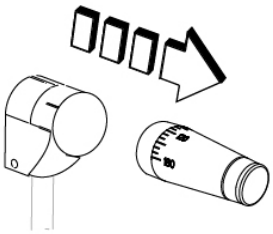


Fig. 39 - Measuring prism removal

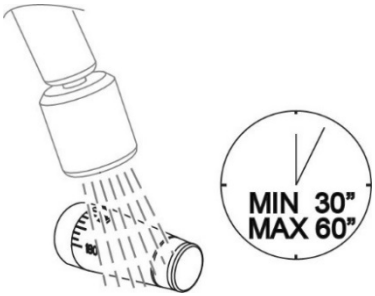


Fig. 40 - Measuring prism washing

4 Dry the measuring prism with disposable, soft and lint-free cloth.

5 Check that the measuring prism is perfectly clean and that there is no damage.

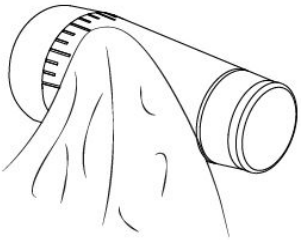


Fig. 41 - Drying the measuring prism

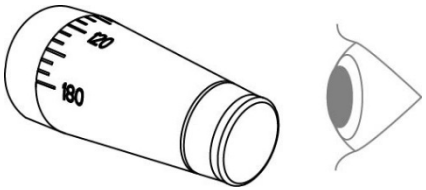


Fig. 42 - Visual inspection of the measuring prism

6 Place the measuring prism in a clean and dry container.

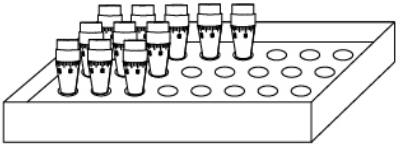


Fig. 43 - Measuring prisms container

5.2.5 MEASURING PRISM DISINFECTION

CAUTION
Danger of material damage. Incorrect disinfection can cause cross-contamination between patients and operator, as well as damage to the measuring prism. The Manufacturer is not liable for any damage to the device caused by misuse of the device itself or the disinfecting solution.

When disinfecting the measuring prism, use disposable gloves.

FOR THE LIST OF SUITABLE DISINFECTANTS TO CLEAN AND DISINFECT THE MEASURING PRISMS, SEE THE REPORT PUBLISHED BY THE AMERICAN ACADEMY OF OPHTHALMOLOGY ON THE FOLLOWING PAGE:

https://www.aaojournal.org/article/S0161-6420(17)31677-9/pdf *Disinfection of Tonometers: a Report by the American Academy of Ophthalmology, 2017;124:1867-1875.*

1 Fill a clean and disinfected container with the disinfectant solution. The disinfectant solution must completely cover the measuring prisms.
2 Place the measuring prisms in the container.

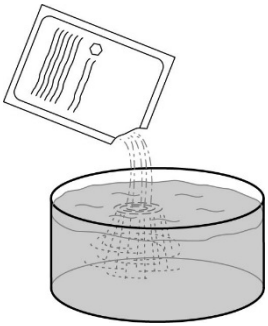


Fig. 44 - Filling the container with the disinfectant solution

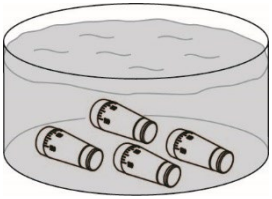


Fig. 45 - Soaking the measuring prisms in the container

3 The measuring prisms must not be on top of each other.
4 The measuring prisms must be completely immersed in the disinfectant solution.

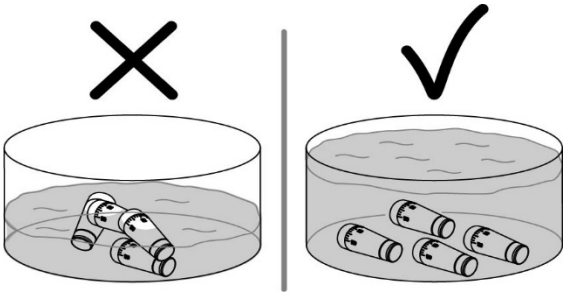


Fig. 46 - Checking the correct positioning of the measuring prisms

5 Let the disinfectant do its job, following the instructions of the manufacturer of the disinfectant solution.
6 After the indicated time has passed, remove the measuring prisms from the container and let them drip for a few seconds.
7 Place the measuring prisms in another clean and disinfected container.

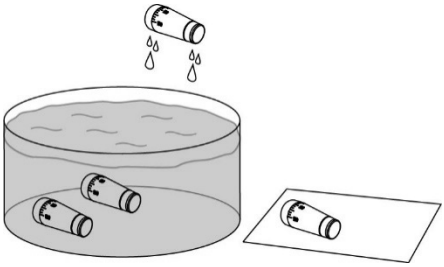


Fig. 47 - Removing the measuring prisms

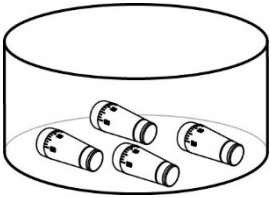


Fig. 48 - Placing the measuring prisms in a clean container

8 Keep the measuring prisms in the container and rinse them under running cold water for at least 10 minutes, but not more than 15 minutes.

9 Dry the measuring prisms one by one with a sterile disposable cloth.

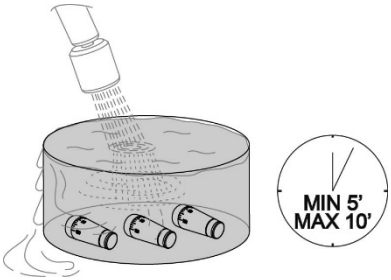


Fig. 49 - Rinsing the measuring prisms

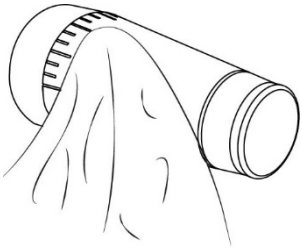


Fig. 50 - Drying the measuring prisms

10 Store the clean and disinfected measuring prisms in a hermetically sealed and sterile container.

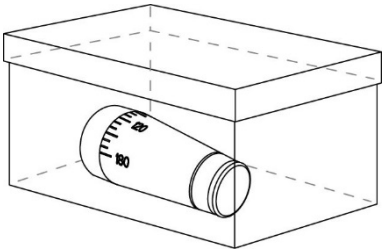


Fig. 51 - Measuring prisms container

5.3 TONOMETER OPERATION CHECK

CAUTION
If the device is outside the indicated calibration tolerances, contact the Technical Service for its repair and calibration.

In order to check that the device is working correctly, it is necessary to use the appropriate operation check accessory.

It is recommended to carry out the operation check every 30 days.

1 Place the operation check accessory on the tonometer.
2 The operation check accessory has 5 engravings (markings) on the body. The markings correspond to the values indicated on the measuring knob: 0 (central), 2, 6 (ends). The longer end of the operation check accessory must be positioned towards the operator for the F900 and A900 devices and towards the patient for the Z800 device.

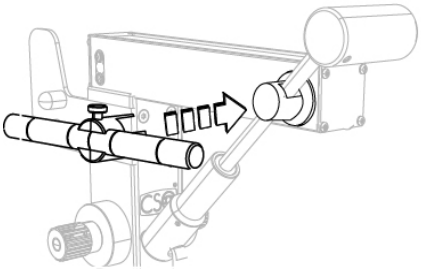


Fig. 52 - Positioning the operation check accessory on the tonometer Z800

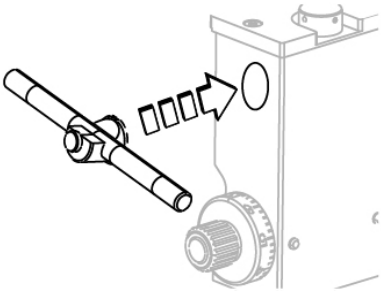


Fig. 53 - Positioning the operation check accessory on the tonometer A900 and F900

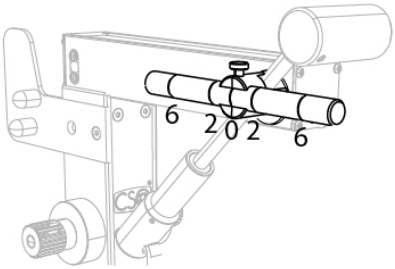


Fig. 54 - Marking on the operation check accessory (Z800)

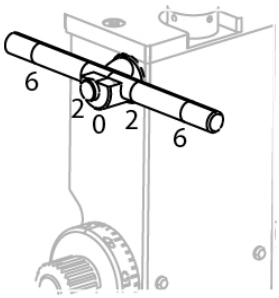


Fig. 55 - Marking on the operation check accessory (A900 and F900)

5.3.1 OPERATION CHECK WITH MEASURING KNOB ON 0

1 Position the operation check accessory in position 0 (central) and the measuring knob on the corresponding 0 value.
2 Turn the measuring knob and set it to a value of -0.05 (measure corresponding to the width of the calibration sign on the measuring knob).
3 The arm should move to the stop position facing the operator.
4 Turn the measuring knob and set it to a value of +0.05 (measure corresponding to the width of the calibration sign on the measuring knob).
5 The arm should move to the stop position facing the patient.

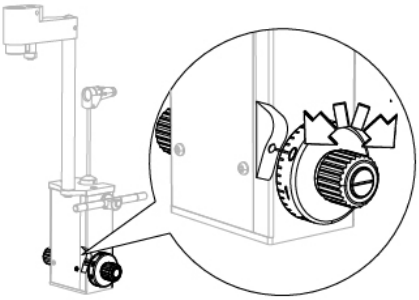


Fig. 56 - Tonometer A900 measuring knob

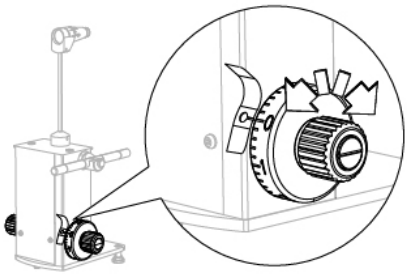


Fig. 57 - Tonometer F900 measuring knob

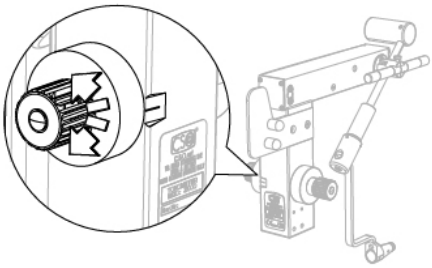


Fig. 58 - Tonometer Z800 measuring knob

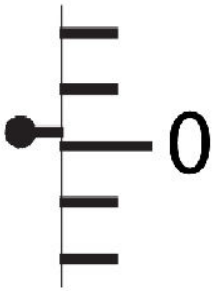


Fig. 59 - Position - 0.05

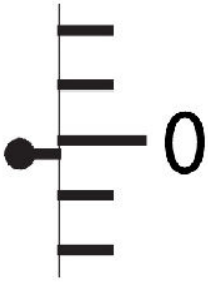


Fig. 60 - Position + 0.05

5.3.2 OPERATION CHECK WITH MEASURING KNOB ON 2

1 Position the operation check accessory in position 2 (first lateral marking) and the measuring knob on the corresponding 2 value.
2 Turn the measuring knob and set it to a value of 1.95 (measure corresponding to the width of the calibration sign on the measuring knob).
3 The arm should move to the stop position facing the operator.
4 Turn the measuring knob and set it to a value of 2.05 (measure corresponding to the width of the calibration sign on the measuring knob).
5 The arm should move to the stop position facing the patient.

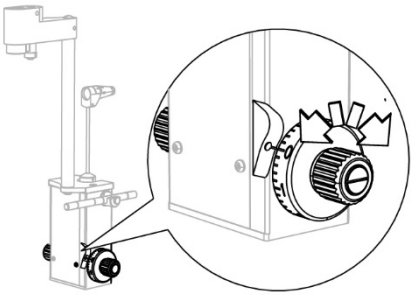


Fig. 61 - Tonometer A900 measuring knob

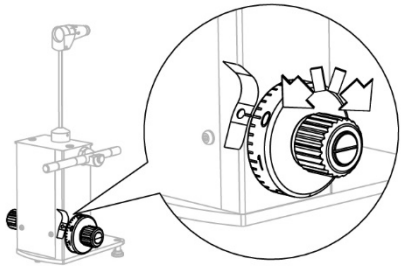


Fig. 62 - Tonometer F900 measuring knob

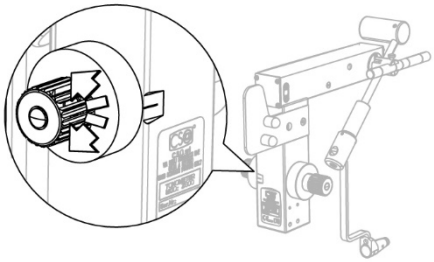


Fig. 63 - Tonometer Z800 measuring knob

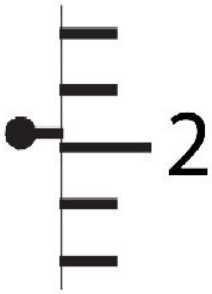


Fig. 64 - Position + 1.95

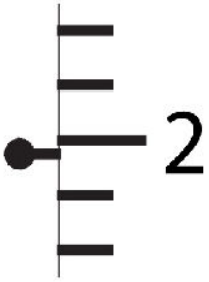


Fig. 65 - Position + 2.05

5.3.3 OPERATION CHECK WITH MEASURING KNOB ON 6

1 Position the operation check accessory in position 6 (second lateral marking) and the measuring knob on the corresponding 6 value.
2 Turn the measuring knob and set it to a value of 5.95 (measure corresponding to the width of the calibration sign on the measuring knob).
3 The arm should move to the stop position facing the operator.
4 Turn the measuring knob and set it to a value of 6.05 (measure corresponding to the width of the calibration sign on the measuring knob).
5 The arm should move to the stop position facing the patient.

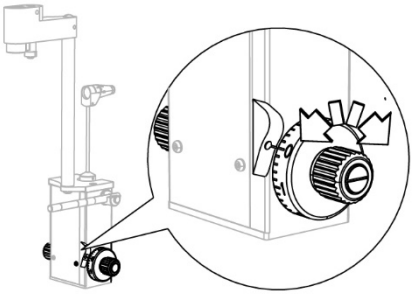


Fig. 66 - Tonometer A900 measuring knob

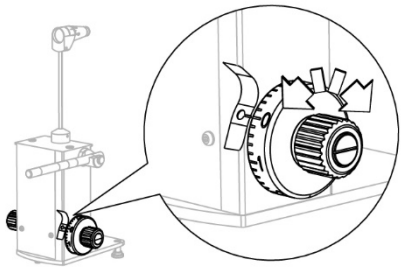


Fig. 67 - Tonometer F900 measuring knob

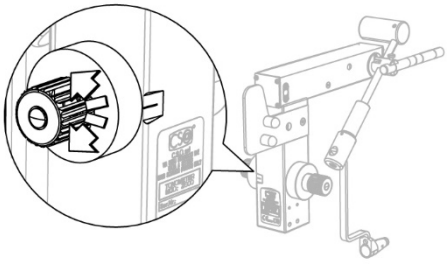


Fig. 68 - Tonometer Z800 measuring knob

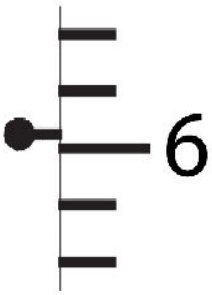


Fig. 69 - Position + 5.95

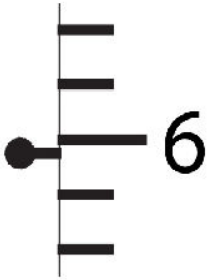


Fig. 70 - Position + 6.05

5.4 LIST OF SPARE PARTS AND ACCESSORIES

Tonometer

Code	Description
10200100	Applanation tonometer Z800
10200200	Applanation tonometer F900
10200220	Applanation tonometer A900

Support for tonometer F900

Code	Description
100203112	Support for tonometer F900. Only for lamp SL9900

Support for tonometer A900

Code	Description
100203100	Support for installation on microscopes 2x
100250303	Support for installation on microscopes 3x - 5x Galilean with internal zoom, new version
100212609	Support for installation on old version zoom micro-scopes

Support for tonometer Z800

Code	Description
100250302	Support for installation on microscopes 3x - 5x Galilean with internal zoom, new version
100203101	Support for installation on microscopes 2x - 3x - 5x Galilean, old version
100203102	Support (dominant left eye) for installation on microscopes 2x - 3x - 5x Galilean, old version
100212608	Support for installation on old version zoom microscopes

Measuring prism

Code	Description
102001110	Reusable measuring prism for tonometer
102003200	Disposable sterile measuring prism for tonometer (100 units package)

For spare parts or accessories not included in the list, ask the Manufacturer or local Dealer.

5.5 TROUBLESHOOTING

Issue	Cause	Solution	Note
The device is not stable during the measurement or during its positioning.	The blocking screws of the support are loose.	Tighten the screw of the device support with a suitable tool.	The device might have been hit. If necessary, contact the Technical Service for the calibration of the device.
Wrong vertical alignment of the device in relation to the microscope.	The fastening screws of the tonometer are loose (Z800).	Align the device with the microscope. Tighten the device locking screws with a suitable tool.	The device might have been hit. If necessary, contact the Technical Service for the calibration of the device.
Wrong horizontal alignment of the device in relation to the microscope.	The fastening screws of the tonometer are loose (Z800).	Align the device with the microscope. Tighten the device locking screws with a suitable tool.	The device might have been hit. If necessary, contact the Technical Service for the calibration of the device.
Wrong horizontal and vertical alignment of the device in relation to the microscope.	The arm is bent.	Contact Technical Assistance.	
The measuring prism is not correctly blocked in its compartment.	The measuring prism could be smaller than expected.	Adjust the locking tabs on the measuring prism support so that it fits correctly.	Some measuring prisms could be smaller than expected. Always only use CSO original spare parts.

Issue	Cause	Solution	Note
The measuring prism does not fit correctly in its compartment.	The measuring prism could be bigger than expected.	Adjust the locking tabs on the measuring prism support so that it fits correctly.	Some measuring prisms could be bigger than expected. Always only use CSO original spare parts.
The measuring prism does not allow a clear view of the applanation.	The material of the measuring prism is altered.	Replace the measuring prism with a new one.	Always only use CSO original spare parts.
The applanation is not correctly displayed during the measurement.	The slit lamp illuminator light is not in the correct position or is off.	Move the slit lamp illuminator light to the correct position. Turn on the light and adjust its intensity.	Read the indications given in the instructions for use of the slit lamp.
The applanation is not correctly displayed during the measurement.	The tonometer is not positioned correctly in relation to the eye being examined (F900).	Correctly position the tonometer in relation to the eye being examined.	Read the indications given in the instructions for use.
The applanation is not correctly displayed during the measurement.	Fluorescein not applied to the eye being examined.	Apply sodium fluorescein as indicated in the instructions for use.	Always use products compliant with current legislation.
The applanation is not correctly displayed during the measurement.	The arm is bent.	Contact Technical Assistance.	The device might have been hit.

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