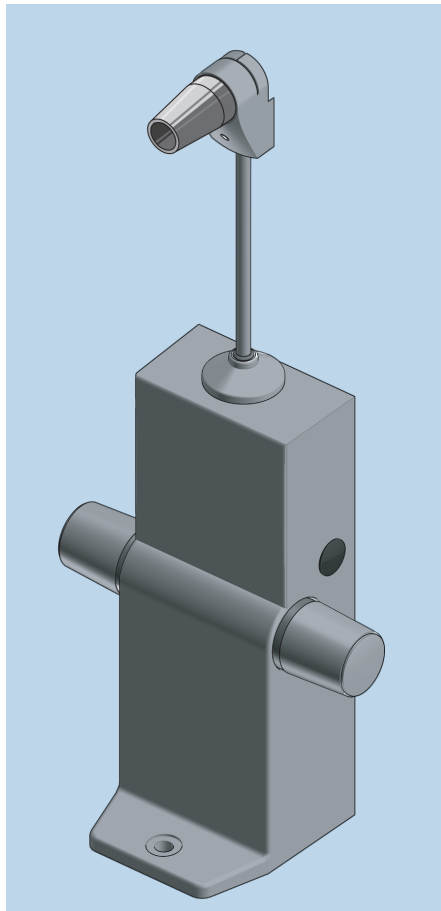


AT 030

Applanation tonometer

Documentation set



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**Instruction for use
AT 030 Applanation tonometer**

[319300-9120-000-GA-GB-240320]

1

**Instructions for use and disinfection
of tonometer measuring prisms**

[319300-9231-000-AddGA01-GB-240320]

2

Contents

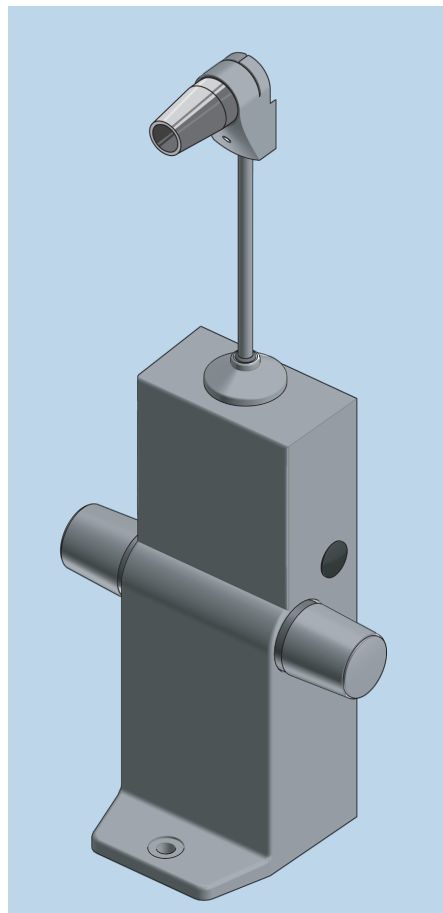
Instruction for use
AT 030 Applanation tonometer
[319300-9120-000-GA-GB-240320]

1

AT 030

Applanation tonometer

Instruction for use



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1 Notes on the instructions for use

1.1 Product name

AT 030 applanation tonometer is referred to as "device" in these instructions for use.

1.2 Scope of application

The present instructions for use apply to AT 030 applanation tonometer with the following labeling:

- Reference number: 319300-9120-000

1.3 Purpose and storage of the documentation

These instructions for use explain the safety features, functions and performance parameters of the device. They contain instructions on the safe use of the device and identify measures for its care and maintenance.

Correct operation of the device is imperative for its safe and successful functioning.

- ▶ Read these instructions for use before setting up and using the device the first time.
- ▶ Keep the instructions for use accessible for all users at all times.
- ▶ Pass the instructions for use to future owners of the device.

1.4 Questions and comments

- ▶ If you have questions or comments concerning these instructions for use or the device itself, contact ZEISS Service.

You can find the ZEISS contact partner for your country on the following website: www.zeiss.com/med

1.5 Conventions in this document

Certain types of information are specially marked in this document for better recognition.

1.5.1 Conventions in all text areas

- This is a list.
 - This is a second level list.

This is a cross-reference: Questions and comments [▶ 5].

This is **highlighted text**.

This is `software code or program text`.

Names of software dialogs, fields or menus, and software messages are marked by quotation marks:

- "View" menu.
- "Do you want to save the settings?"

The steps in menu and file paths are separated by slashes:

- "File / Save as"
- "My documents / Documents"

Keys, buttons, knobs, levers and other operating controls are marked by square brackets:

- [START] key
- [Next] button

1.5.2 Conventions in a course of action

WARNING!

This is warning information about hazards that can cause death or severe injuries if not avoided.

The warning message names the possible consequences.

- ▶ This is a measure with which hazards can be prevented.

CAUTION!

This is warning information about hazards that can cause injuries if not avoided.

The warning message names the possible consequences.

- ▶ This is a measure with which hazards can be prevented.

NOTE

This is warning information about hazards that can cause property damages if not avoided.

The warning message names the possible consequences.

- ▶ This is a measure with which hazards can be prevented.

- This is a requirement that must be met before the start of a sequence of actions.

1. This is a command.

2. **CAUTION! This is a warning message about hazards that can occur during a single action.** This is a command.

⇒ This is the result of a sequence of actions.

1.6 Applicable documents

Please also refer to the instructions for use for additional components and accessories to be used with this device.

2 Safety notes

2.1 Intended user profile

The device may only be installed, operated, used and maintained by persons who have the necessary training, knowledge and experience to do so. Please also adhere to the national qualification guidelines applicable in your country.

Persons who operate the device must have knowledge of basic ophthalmic examination and diagnosis methods as well as of ophthalmic optics. This includes, among others, persons belonging to the following occupational groups or their national equivalents:

- Ophthalmologist
- Optometrist

2.2 Area of use

2.2.1 Indication for use

The AT 030 applanation tonometer is for measuring the intraocular pressure of a seated patient.

2.3 Responsibilities and duties of the operator

Operating personnel

The device may only be operated by instructed and trained personnel.

- ▶ Ensure that the operating personnel have been trained and instructed.
- ▶ Ensure that the operating personnel have read and understood the instructions for use.
- ▶ The instructions for use should be readily accessible to the operating personnel at all times.
- ▶ To facilitate access for the entire operating personnel: If necessary, request further copies of the instructions for use from ZEISS.
- ▶ Define the required skills for handling the device and provide information on who is authorized for which activities.
- ▶ Define rules for reporting errors and damage, and provide information on these. Notification to manufacturers and authorities [▶ 8]
- ▶ Regularly check compliance with the national laws and regulations concerning accident prevention and occupational health.

Maintenance and inspection

- ▶ To ensure safe operation of the device and reach the expected service life: Observe the maintenance and inspection intervals that are specified in these instructions for use.

Modifications to the product

Modifications to the product or failure to follow the manufacturer's instructions may substantially reduce the expected service life and significantly increase the risks associated with the use of this device and are thus not permitted.

Accessories and additional equipment

- ▶ If you want to connect accessories or additional equipment to the device: Contact your ZEISS representative [▶ 5].

2.3.1 Messages to manufacturer and authorities

If a serious incident occurs in connection with this medical device affecting the operator or another person, the operator (or person responsible) must report this serious incidence to the manufacturer or seller of the medical product. In the European Union, the operator must report this serious incident to the responsible authorities in the applicable country.

2.4 Measures and duties of the operator

Ambient conditions

- ▶ Make sure that the installation conditions and the operation of the device comply with the surgical requirements:
 - Low vibration
 - Clean environment
 - Avoid extreme mechanical loads
- ▶ Do not store or use this device in damp areas. Do not expose the device to water splashes, dripping water or sprayed water.
- ▶ Ensure that no liquids can enter the device.

Symbols and labels

- ▶ Observe the symbols and labels attached to the device.

Transport

- ▶ When assembling or transporting the AT 030 applanation tonometer, the measuring element must be set to 2.0 using the rotary knob. Only in this way the measuring arm with the measuring prism holder will be at a defined position.
- ▶ Transport the device over long distances (e.g. move, return for repair, etc.) only in original packaging or special return packaging.
- ▶ Contact your dealer or ZEISS Service.

2.5 Maintenance measures

Maintenance procedures (maintenance and repairs) which are not specified in these instructions for use may only be carried out by persons authorized by Carl Zeiss Meditec and solely according to the service instructions issued by Carl Zeiss Meditec. For planning and implementing these maintenance and care procedures please contact ZEISS Service or your local dealer.

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3 Description of the device

3.1 Package check list

The scope of delivery of the AT 030 applanation tonometer includes the following components:

- AT 030 applanation tonometer
- Box with measuring prisms and test weights
- Documentation set

3.2 Device marking

Labels	Explanation
	AT 030 type label
	 Manufacturer
	 Date of manufacture
	 Disposal advice for EU
	AT 030 identification label
	REF Catalog/part number
	SN Serial number
	Label with manufacturing date
	Sign with scale value

3.3 Structure of the device

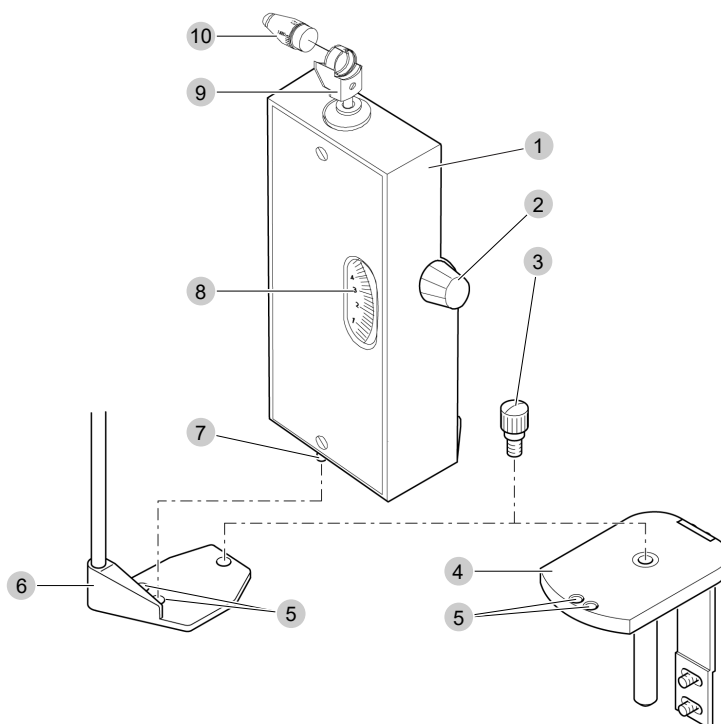


Figure 1: Control elements of the AT 030 applanation tonometer and the swivel-mounted/fixed tonometer holder

1	AT 030 applanation tonometer	2	Rotary knob of graduated drum
3	Knurled screw	4	Base plate of fixed tonometer holder
5	Alignment holes	6	Base plate of swivel-mounted tonometer holder
7	Centering pin	8	Readout scale
9	Extensible measuring prism holder	10	Measuring prism

3.4 Functional description

The AT 030 applanation tonometer may only be used according to its indication for use if it is used in combination with a slit lamp. In this combination, the slit lamp fulfills the following functions: mechanical attachment of the tonometer, illumination and magnified observation of the produced measuring pattern. During operation, the ZEISS slit lamp does not have any impact on the applanation tonometer, neither has the applanation tonometer any impact on the functioning of the ZEISS slit lamp.

Following ZEISS slit lamps are compatible to AT 030: SL 120, SL 130, SL 220, SL 800 and ZEISS VISULAS laser slit lamps.

The AT 030 applanation tonometer was designed for ZEISS slit lamps according to the principle applied by Professor Goldmann. The measuring device, containing a measuring prism with built-in optical doubling system, is mounted on the slit lamp using a dedicated tonometer holder and the applanation surface is observed through the microscope of the slit lamp.

Further progress has been achieved by the use of a comparatively small applanation surface requiring only small measuring forces, as introduced by Professor Goldmann.

Professor Goldmann discovered that the counteracting forces of corneal rigidity and capillary attraction of tear fluid neutralize each other at an applanation surface of 3.06 mm diameter, so that the applied force corresponds to the intraocular pressure.

The AT 030 works on the principle of force variation due to the expansion of a spring. Therefore, it does not require any maintenance or readjustment.

The measurement accuracy and repeatability of the AT 030 measuring results corresponds to the requirements of ISO 8612:2009.

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4 Installation

4.1 Installation safety

NOTE

Damage during assembly, cleaning and transport

The device can be damaged during assembly, cleaning and transport if the measuring arm with the measuring prism holder is not at a defined position.

- ▶ When assembling, cleaning or transporting the AT 030 applanation tonometer, the measuring element must be set to 2.0.

NOTE! The device may be used only for seated patients, i.e. in horizontal measuring direction.

4.2 General information

The device can be mounted on ZEISS slit lamps by using a special tonometer holder. Special tonometer holders have been specifically developed for the use of the AT 030 with ZEISS slit lamps and can be purchased separately.

The tonometer holder permits observation of the measuring prism through the left or right eyepiece of the slit lamp microscope. For this purpose, AT 030 is plugged into the alignment holes on the base plate.

The easily replaceable measuring prism of AT 030 contains an optical system that divides the image of the applanation surface in two halves.

The measuring force applied to the eye via the measuring prism can be adjusted between 0 mN and 78 mN by turning the rotary knob of the graduated drum. The scale value is 0.98 mN.

For movements towards the patient, the device has a spring-loaded stop to avoid injuries arising from inadvertently coming too close to the eye. Restricted visual acuity of the operator can be compensated for by using adjustable eyepieces on the slit lamp.

4.3 Mounting the device on SL 800 slit lamp using the swivel-mounted tonometer holder on the stereomicroscope or Fundus VarioView

NOTE

Damage due to improper assembly

- ▶ After assembly, make sure the device and tonometer holder are firmly seated.

Action

1. Position the tonometer holder with the guide pins on the stereomicroscope or, if mounted, on the Fundus VarioView such that the mounting pivot points to the headrest
2. Attach the mounted tonometer holder using the size 3 screwdriver, supplied.
3. Attach the device to the base plate of the tonometer holder and fix it by means of the knurled screw.
4. Ensure that the centering pin is securely seated into one of the two alignment holes. Select the alignment hole on the side where the eyepiece is to be used. If the tonometer holder is adjusted correctly the measuring prism will be visible in the center of the eyepiece.

HINT: The applanation tonometer with the base plate of the swivel-mounted tonometer holder can easily be swung out of the optical path by turning it laterally to the right around its vertical axis A. This enables unhindered work with the slit lamp. Additionally, the extensible measuring prism holder can be pushed into the tonometer. The measuring prism holder should then be in its bottom end position.

4.3 Mounting the device on SL 800 slit lamp using the swivel-mounted tonometer holder on the stereomicroscope or Fundus VarioView

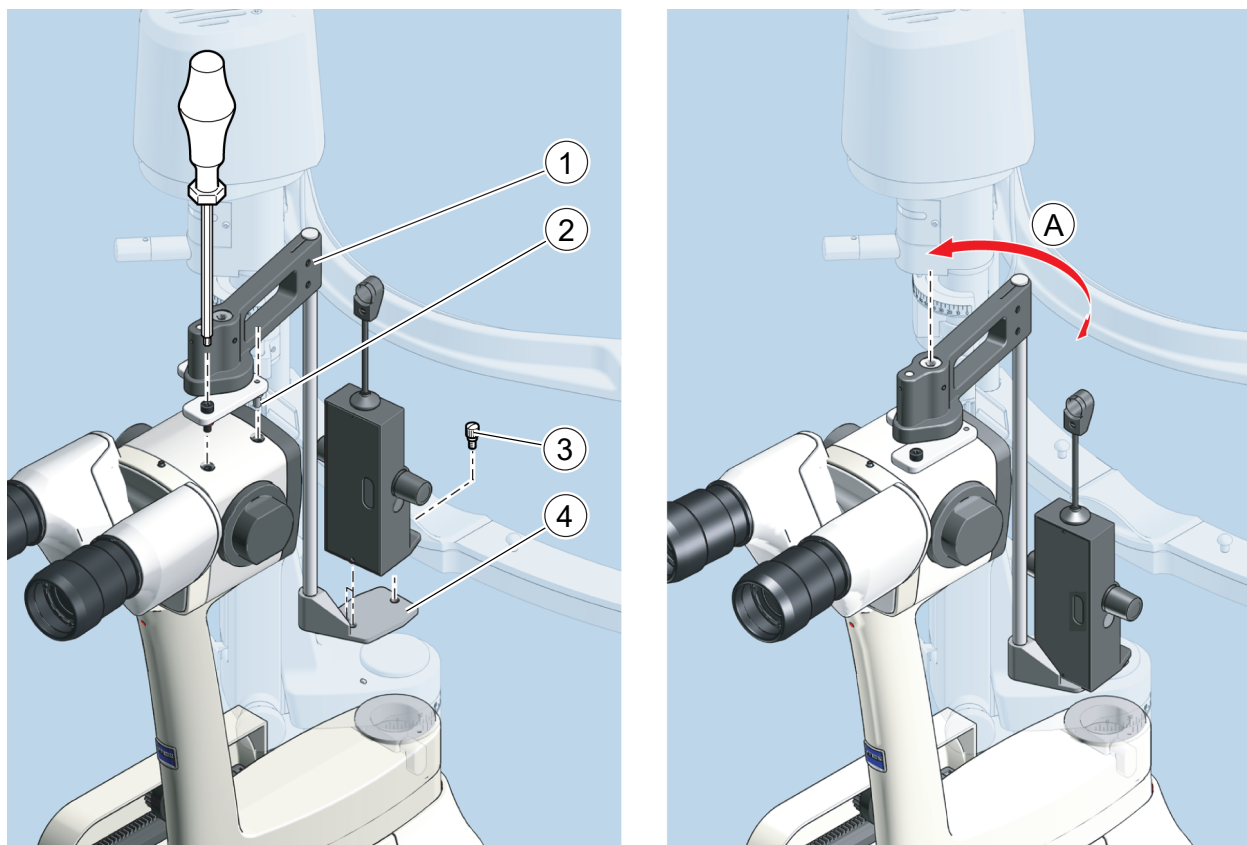


Figure 2: Mounting the AT 030 to the SL 800 slit lamp with swivel-mounted tonometer holder

1	Swivel-mounted tonometer holder	2	Guide pin
3	Knurled screw	4	Base plate of tonometer holder

4.4 Mounting the device to the SL 120, SL 130 and SL 220 slit lamps using the swivel-mounted tonometer holder behind the stereomicroscope

NOTE

Damage due to improper assembly

- ▶ After assembly, make sure the device and tonometer holder are firmly seated.

NOTE! If accessory units have been mounted between the microscope and tube, the tonometer holder must always be attached directly to the microscope!

Action

1. Remove the binocular tube from the slit lamp.
2. Attach the tonometer holder to the slit lamp.
3. Attach the applanation tonometer to the base plate of the tonometer holder and fix it by means of the knurled screw.
4. Ensure that the centering pin is securely seated into one of the two alignment holes. Select the alignment hole on the side where the eyepiece is to be used. If the tonometer holder is adjusted correctly the measuring prism will be visible in the center of the eyepiece in use.

HINT: The applanation tonometer with the base plate of the swivel-mounted tonometer holder can easily be swung out of the optical path by turning it laterally to the right around its vertical axis A. This enables unhindered work with the slit lamp. Additionally, the extensible measuring prism holder can be pushed into the tonometer. The measuring prism holder should then be in its bottom end position.

4.4 Mounting the device to the SL 120, SL 130 and SL 220 slit lamps using the swivel-mounted tonometer holder behind the stereomicroscope

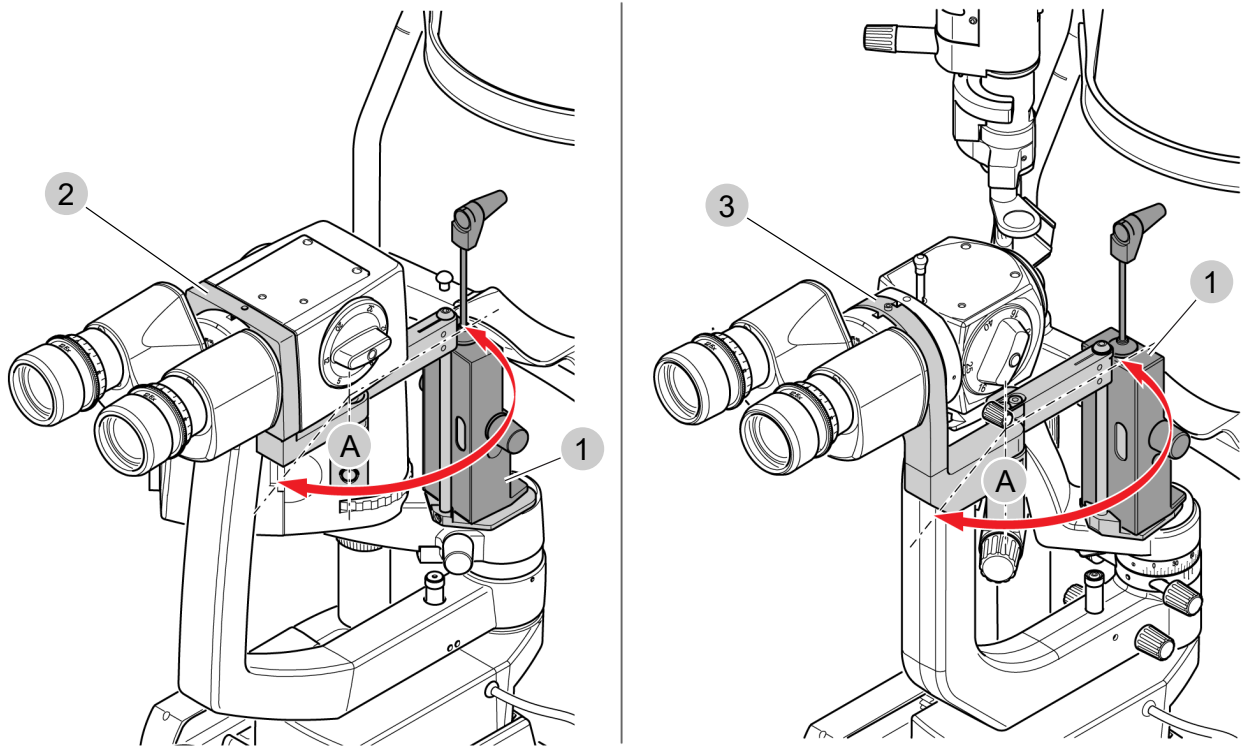


Figure 3: Mounting the AT 030 on ZEISS slit lamps with swivel-mounted tonometer holder behind the stereomicroscope e.g. SL 120 (left) and SL 220 (right)

1	AT 030 applanation tonometer	2	Swivel-mounted tonometer holder, version a (square mounting interface)
3	Swivel-mounted tonometer holder, version b (round mounting interface)	A	Vertical axis

4.5 Mounting the device on SL 120, SL 130, SL 220, and ZEISS VISULAS laser slit lamps using the fixed tonometer holder

NOTE

Damage due to improper assembly

- ▶ After assembly, make sure the device and tonometer holder are firmly seated.

Action

1. Remove the cap from the swivel arm of the slit projector.
2. Plug the centering pivot of the tonometer holder into centering aperture so that mounting plate faces the patient side.
3. Attach the applanation tonometer to the base plate of the tonometer holder and fix it by means of the knurled screw.
4. Ensure that the centering pin is securely seated into one of the two alignment holes. Select the alignment hole on the side where the eyepiece is to be used.

NOTE! The measuring prism must be visible in the center of the eyepiece being used. Correct any lateral misalignment of the tonometer by slightly turning the tonometer holder.

If the correct position of the tonometer has been found, fasten the tonometer holder with the two fastening screws in the holes provided.

HINT: If the device is used on ZEISS slit lamps using the fixed tonometer holder it cannot be swung out of the observation path. The device may, however, be easily removed from the slit lamp prior to diagnosis or treatment by loosening the knurled screw. The tonometer holder can remain on the slit lamp.

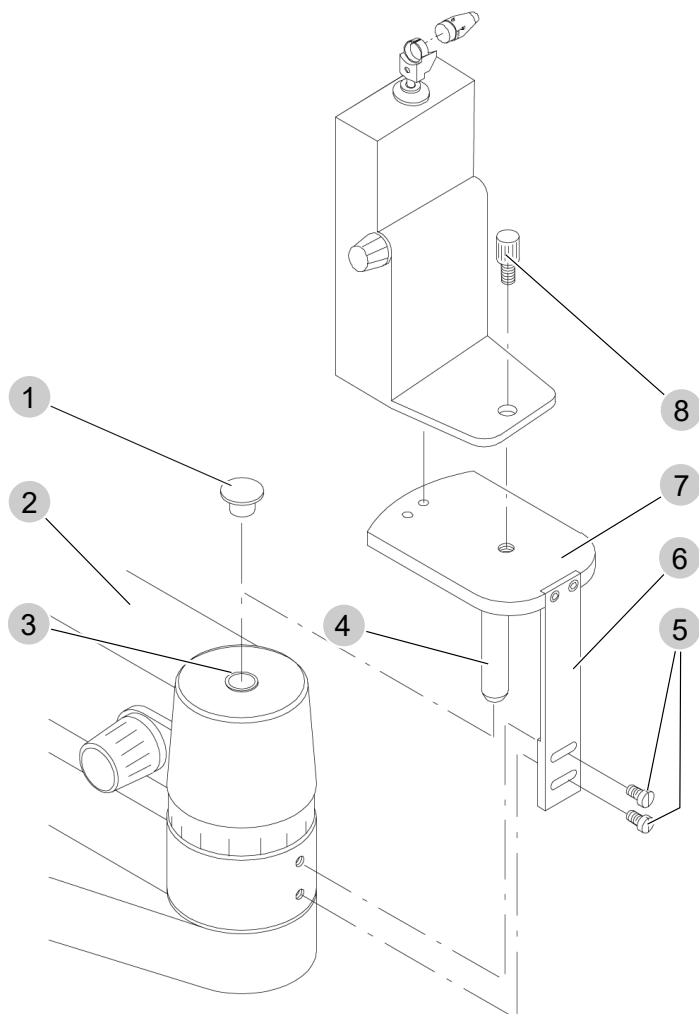


Figure 4: Mounting the AT 030 to ZEISS slit lamps using the fixed tonometer holder

1	Cap	2	Swivel arm of slit projector
3	Centering aperture	4	Centering pivot
5	Fixing screws	6	Mounting plate
7	Tonometer holder base plate	8	Knurled screw

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5 Daily startup

5.1 Preparation safety

CAUTION!

Risk due to contaminated or damaged measuring prisms

The patient may be injured by contaminated or damaged measuring prisms.

- ▶ Never use damaged measuring prisms!
- ▶ Only use clean, residue-free and undamaged measuring prisms.
- ▶ Prior to every use, the contact surface of the measuring prism must be inspected for contaminants and damage (scratches, cracks or sharp edges). This must be performed with a slit lamp microscope at a medium magnification (e.g. 12x or 16x).

CAUTION!

Risk of non-compliance with contraindications

The patient may be injured or suffer complications if the contraindications are ignored.

- ▶ The device should not be used if the patient is susceptible to the anesthetic used for the tonometry.
- ▶ Utmost caution is also advised with patients suffering from corneal epithelium lesions.
- ▶ Utmost caution is also advised with patients with keratitis, infection of the cornea or penetrating eye injuries.

CAUTION!

Risk due to measuring errors

Measurements with a damaged tonometer may be faulty.

- ▶ Check the tonometer for visible damage as described in the chapter Checking the tonometer [▶ 44].

Prior to using the device, the user must ensure that it is in a good condition and fully functioning. Furthermore, the user must follow the instructions in the user manual.

NOTE! The tonometric measurement should be taken in a darkened room and the slit lamp operated at normal lamp intensity. Only under these conditions is it possible to reproducibly observe the weakly shining inner edge of the fluorescein ring. To ensure that the scale can also be seen in darkened rooms, it is set against a green fluorescent background.

NOTE! The actual measuring process should take no longer than 30 seconds, otherwise the pressure will be reduced by flowing processes.

5.2 Measuring spherical corneal surfaces

With a spherical cornea, the applanation surface is a circle. The optical system generates two fluorescein semicircles to be coincided.

The measuring prism has a graduated scale. The measuring prism holder has a white and a red index line.

With spherical cornea, rotate the measuring prism until the 0° line of the angle scale coincides with the white index line of the measuring prism holder. In this case, the line of coincidence of the measuring prism is horizontal.

5.3 Measuring toric cornea surfaces

With a toric cornea, the applanation surface is an ellipse. The coincidence of the half ellipses provides correct pressure values only if the surface of the ellipse is equal to the surface of the applanation circle. This condition is to be met for a definite angular position of the major semi-axis of the ellipse with regard to a principal direction of curvature of the cornea. The calculation shows that an astigmatism of below 3 D is negligible for tonometer measurement. With higher astigmatism, correct measurements are taken at an angle of about 43° between the major diameter of the ellipse and the direction of the minor principal section.

The measuring prism has a graduated scale. The measuring prism holder has a white and a red index line.

Astigmatism is taken into account as follows:

Action

- ▶ With an astigmatism up to 3 D, rotate the measuring prism until the 0° line of the angle scale coincides with the white index line of the measuring prism holder. In this case, the separating line of the measuring prism is horizontal.
- ▶ With astigmatism above 3 D, the axial position of the lower refracting principal section (larger radius of curvature) must be known from a previous measurement with an ophthalmometer. Set the corresponding axis angle at the angle scale of the measuring prism to the red index line of the measuring prism holder. In this setting, the separating line of the measuring prism forms an angle of 43° to the horizontal.

5.4 Preparing for measurement

CAUTION!

Risk due to improper locking of the slit lamp

The patient may be injured if the slit lamp moves during the measurement.

- ▶ Ensure that the instrument table is horizontal to avoid movement of the slit lamp with attached measuring prism towards the patient.

NOTE! Always anesthetize both eyes to avoid eyelid blinking.

NOTE! The application of too much fluorescein solution results in readings that are too high, whereas too little fluorescein solution results in narrow semicircles, thus producing readings that are too low.

Action

- ▶ Calm the patient to take away his/her fear of the examination as this fear may cause an increased intraocular pressure. Therefore, do not use the result of the first trial measurement on both eyes, but take the average of the subsequent three measurements of each eye to obtain a reproducible result.
- ▶ Administer usual anesthesia of the cornea of the patient's eye prior to measurement.
- ▶ Then apply a drop of fluorescein solution to the conjunctival sac of the patient's eye, using a strip of blotting paper as necessary, to produce a green fluorescing band of liquid around the measuring surface in the following measurement.
- ▶ Ask the patient to look towards the front surface of the measuring prism. If necessary, the fixation lamp can be used to calm the eyes.
- ▶ Record the date and time of each tonometer measurement and the period that has passed since the last application of pressure-reducing substances.

5.5 Measurement with AT 030

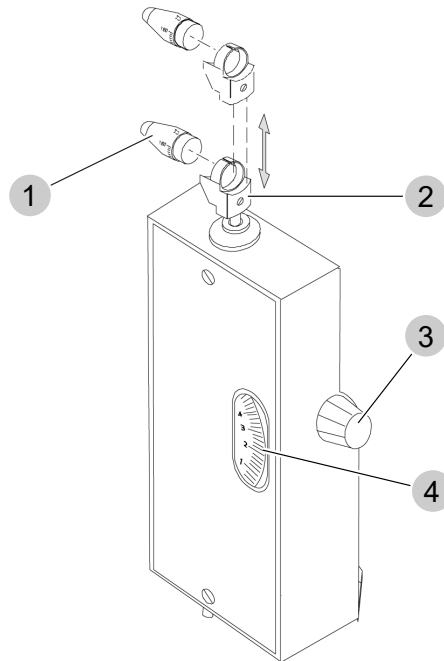


Figure 5: Controls of the AT 030

1	Measuring prism	2	Extensible measuring arm with measuring prism holder
3	Rotary knob of graduated drum	4	Readout scale

Action

1. Position the patient's head in front of the slit lamp using the height adjustment of the head rest so that the eyes are level with the red marking of the head rest. The patient's head must be pressed firmly against the head rest.
2. Insert the clean and disinfected measuring prism into the measuring prism holder as far as it will go. Hold the measuring prism holder while doing so. Make sure that the extensible measuring arm does not collide with the front or back limit position of the motion range.

NOTE! The measuring prism has a graduated scale. The measuring prism holder has a white and a red index line. Please note the corresponding angle adjustment when measuring spherical and toric curved corneal surfaces (see also Measuring spherical corneal surfaces [▶ 24] and Measuring toric cornea surfaces [▶ 24]).

3. Pull the extensible measuring arm with measuring prism holder up to the upper end position and then rotate it by 90° towards the patient's side. The upper end position is reached after overcoming a slight resistance.
4. Position the applanation tonometer in the beam path. Set the rotary knob of the graduated drum to scale reading 1 so that the measuring prism is in its front end position.
5. Swivel the slit projector about 60° to the side. Open the slit completely and switch the blue filter on. Swivel in the optional yellow filter to observe the measuring pattern with improved contrast.
Observe the measurement through the selected eyepiece at a medium magnification (e.g. 12x or 16x).
6. Ask the patient to open his/her eyes wide. You can assist by splaying out the patient's eyelid with thumb and forefinger. Take care, however, not to exert inadvertent pressure on the bulbus. The fingers should rest only on the bony eye socket.
7. Adjust the measuring prism using the joystick of the slit lamp vertically and horizontally to the patient's eye.

NOTE! The axis of the measuring prism is set at an angle of approx. 6° to the axis of the slit lamp. Ask the patient to look towards the measuring prism so that the measuring prism can touch the corneal vertex centrally.

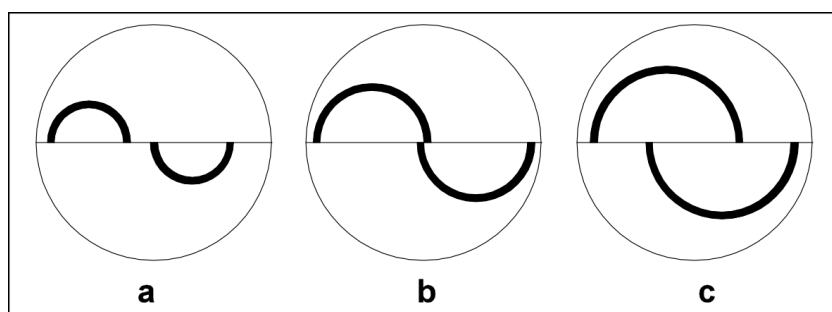


Figure 6: Measuring patterns produced by the applanation tonometer

8. Vary the measuring force by turning the rotary knob of the graduated drum until the inner edges of the green semicircles touch each other. The two semicircles must be of equal size, and pulsate uniformly. In this setting, the applanation surface has the nominal diameter of 3.06 mm. If the measuring force has been set too high, a different pattern appears, as in Figure c. If the measuring force has been set too low, the pattern will be as in Figure a.
9. Multiplied by 10, the value read directly from the scale of the graduated drum gives the intraocular pressure in mm Hg (see Conversion table for tonometer readings [► 28]).

5.6 Conversion table for tonometer readings

Scale reading	Pressure		
	mmHg	kPa*	mbar
0.2	2.0	0.27	2.7
0.4	4.0	0.53	5.3
0.6	6.0	0.80	8.0
0.8	8.0	1.07	10.7
1.0	10.0	1.33	13.3
1.2	12.0	1.60	16.0
1.4	14.0	1.87	18.7
1.6	16.0	2.13	21.3
1.8	18.0	2.40	24.0
2.0	20.0	2.67	26.7
2.2	22.0	2.93	29.3
2.4	24.0	3.20	32.0
2.6	26.0	3.47	34.7
2.8	28.0	3.73	37.3
3.0	30.0	4.00	40.0
3.2	32.0	4.27	42.7
3.4	34.0	4.53	45.3
3.6	36.0	4.80	48.0
3.8	38.0	5.07	50.7
4.0	40.0	5.33	53.3
4.2	42.0	5.60	56.0
4.4	44.0	5.87	58.7
4.6	46.0	6.13	61.3
4.8	48.0	6.40	64.0
5.0	50.0	6.67	66.7
5.2	52.0	6.93	69.3
5.4	54.0	7.20	72.0
5.6	56.0	7.47	74.7
5.8	58.0	7.73	77.3

Scale reading	Pressure		
	mmHg	kPa*	mbar
6.0	60.0	8.00	80.0
6.2	62.0	8.26	82.6
6.4	64.0	8.53	85.3
6.6	66.0	8.80	88.0
6.8	68.0	9.06	90.6
7.0	70.0	9.33	93.3
7.2	72.0	9.60	96.0
7.4	74.0	9.86	98.6
7.6	76.0	10.13	101.3
7.8	78.0	10.40	104.0
8.0	80.0	10.66	106.6
* 10 Torr = 1.333 kPa = 1333 N/m ²			

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6 Cleaning and disinfection

6.1 Safety when cleaning and disinfecting the device

NOTE! The following instructions are only valid for AT 030. For cleaning and disinfection of tonometer measuring prisms please refer to the instructions for use and cleaning and disinfection of tonometer measuring prisms.

NOTE

Damage during assembly, cleaning and transport

The device can be damaged during assembly, cleaning and transport if the measuring arm with the measuring prism holder is not at a defined position.

- ▶ When assembling, cleaning or transporting the AT 030 application tonometer, the measuring element must be set to 2.0.

NOTE

Damage due to improper cleaning and disinfection

Some cleaning agents and disinfectants may have an adverse effect on plastic components. Damage caused by such disinfectants is not covered by our warranty.

- ▶ Observe the national disinfection regulations.
- ▶ Use only disinfectants approved by the manufacturer for the treatment of plastics and painted surfaces.
- ▶ Do not use aggressive (e.g. acetone) or abrasive cleaning agents.

6.2 Cleaning

Only clean the outer surfaces of the AT 030. A cloth slightly moistened (not dripping) with diluted detergent is recommended for cleaning the casing.

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7 Maintenance

7.1 Metrological check

AT 030 applanation tonometer

All ZEISS applanation tonometers are metrologically checked and delivered in this state.

⚠ CAUTION!

Risk due to measuring errors

During the service life of the device the user is responsible for having it metrologically tested in compliance with national regulations.

- ▶ In the case of malfunctions, immediately remove the device from operation and consult ZEISS Service.

NOTE! In Germany, the Medical Devices Operating Ordinance requires the first inspection no later than 24 months after the end of the first year of use, or immediately in the case of impairment of the measurement function by external influences.

If you wish Carl Zeiss Meditec to perform the metrological check, please contact ZEISS Service or your local dealer.

NOTE! Please return only cleaned and disinfected device.

The device does not require any maintenance.

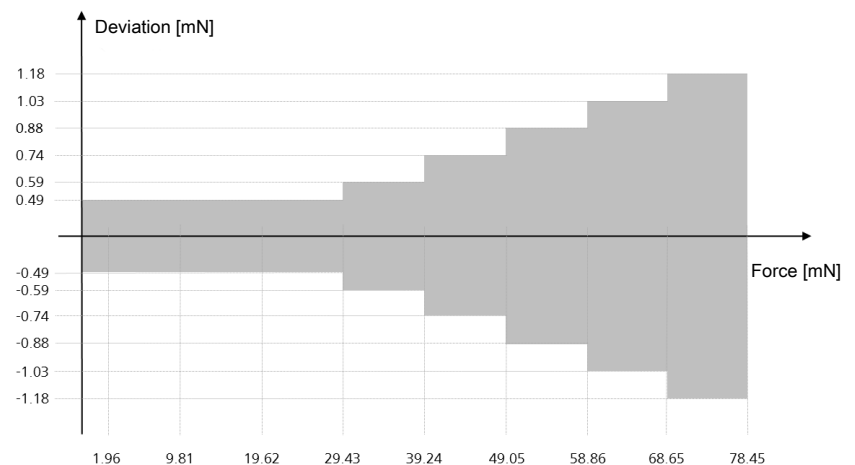


Figure 7: Maximum deviation of measuring accuracy in accordance with ISO 8612:2009

Tonometer holder

All tonometer holders are adjusted when delivered. With a viewing magnification of 12x or 16x, the rear surface of the measuring prism lies concentrically in the field of view of the eyepiece. In the center of the motion range of the measuring arm the front surface of the measuring prism is focused in the eyepiece.

Lateral and vertical deviations of 1 mm do not impact the pressure measurement precision.

In the case of greater deviations, first check the following:

Action

1. Is the tonometer positioned in front of the "correct" eyepiece?
2. Is the tonometer holder properly mounted?
3. Has the tonometer holder properly engaged in the operating position?

If these checks do not yield satisfying results, align tonometer holders which are mounted behind the stereomicroscope, as described in section Adjusting the swivel-mounted tonometer holder with square mounting interface (version a) [▶ 34] and Adjusting the swivel-mounted tonometer holder with round mounting interface (version b) [▶ 39]. It is not necessary to remove the tonometer holder with the AT 030 mounted from the slit lamp.

NOTE! If, in case of the swivel-mounted tonometer holder mounted on the stereomicroscope or Fundus VarioView and in case of fixed tonometer holders, these checks do not yield satisfying results, contact ZEISS Service.

Due to manufacturing tolerances (or wear) on the slit lamp it is possible that, although the tonometer holder has been adjusted accurately on one side, after shifting to the other side, the adjustment is unsatisfactory. In this case, repeat adjustments alternately on both sides until it is optimally adjusted in both positions.

NOTE! The adjustment steps can be carried out independently of each other in any order. If adjustment according to the above instructions is not successful, please contact ZEISS Service.

7.2 Adjusting the swivel-mounted tonometer holder with square mounting interface (version a)

Preparation

Action

- ▶ Mount the tonometer holder and AT 030 on the slit lamp.
- ▶ Put the AT 030 into the position for the right eyepiece.
- ▶ Set the eyepieces of the slit lamp to 0 D or your own correction value.
- ▶ Move the AT 030 to the measuring position.
- ▶ Illuminate the measuring prism with the slit lamp projector from the left to approx. 90°.

7.2 Adjusting the swivel-mounted tonometer holder with square mounting interface (version a)

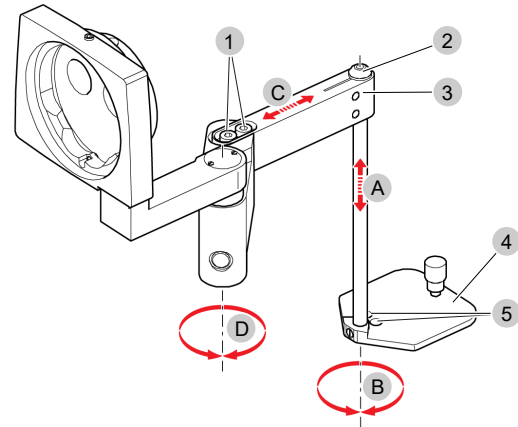


Figure 8: Adjusting options on the swivel-mounted tonometer holder, version a (square mounting interface)

1	Clamping screw for image focus	A	Height adjustment
2	Adjusting screw for height adjustment	B	Coaxial adjustment
3	Swivel arm	C	Image focus
4	Base plate	D	Lateral adjustment
5	Alignment holes		

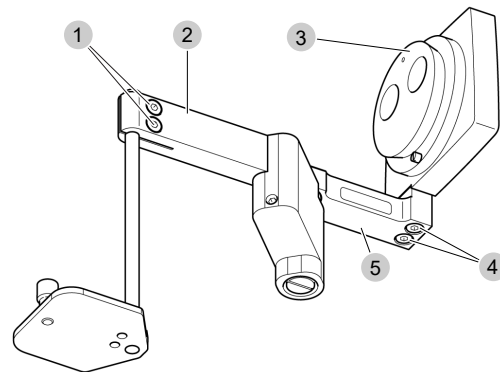
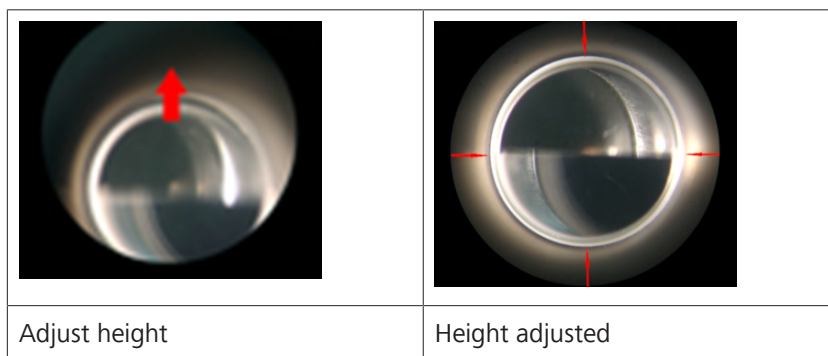


Figure 9: Clamping and adjusting screws on the swivel-mounted tonometer holder,

1	Clamping screws for height adjustment and coaxial adjustment	2	Swivel arm
3	Dovetail	4	Clamping screws for adjusting image focus and lateral adjustment
5	Swivel arm		

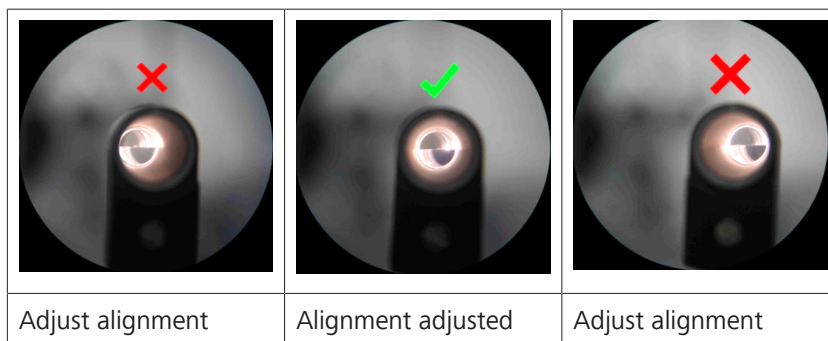
Setting the correct height in the field of view (height adjustment A)

- ▶ Set the magnification of the slit lamp microscope to a high magnification (e.g. 20x or 25x).
- ▶ Loosen the two clamping screws by approx. ½ turn.
- ▶ Unscrew the adjusting screw at the upper end of the rod by approx. 5 mm.
- ▶ Press on this adjusting screw and slide the rod with tonometer downwards, until the base plate is resting on the pivot joint of the slit lamp.
- ▶ Move the tonometer with measuring prism into the vertical center of the field of view by turning the adjusting screw to the right. Hold the tonometer, so that it cannot rotate laterally. Ensure the correct alignment of the measuring prism.
- ▶ Firmly retighten the two clamping screws alternately.
- ▶ Retighten the adjusting screw carefully.



Setting the alignment (coaxiality B)

- ▶ Set the magnification of the slit lamp microscope to a low magnification (e.g. 5x or 6x).
- ▶ Loosen the two clamping screws.
- ▶ Observe the measuring prism through the right eyepiece and set the correct alignment of the measuring prism. Turn the tonometer, including the base plate, sideways around the rod.
- ▶ Firmly retighten the two clamping screws alternately.



If the same eyepiece is always to be used for tonometry, the adjustment is now finished.

If, however, both eyepieces are to be used alternately, the position of the AT 030 on the base plate must now be changed:

- ▶ Release the knurled screw and remove the tonometer.
- ▶ Set the tonometer with the centering pin into the other alignment hole of the base plate.
- ▶ Retighten the knurled screw.
- ▶ Check, whether the measuring prism is also correctly aligned in this eyepiece. If not, repeat the first four steps.

Setting/checking the correct focus position (image focus C)

- ▶ Set the scale on the tonometer to zero.
- ▶ To assess the focus sharpness apply a visible structure to one side of the front surface of the measuring prism (e.g. fingerprint, dust, graph paper).

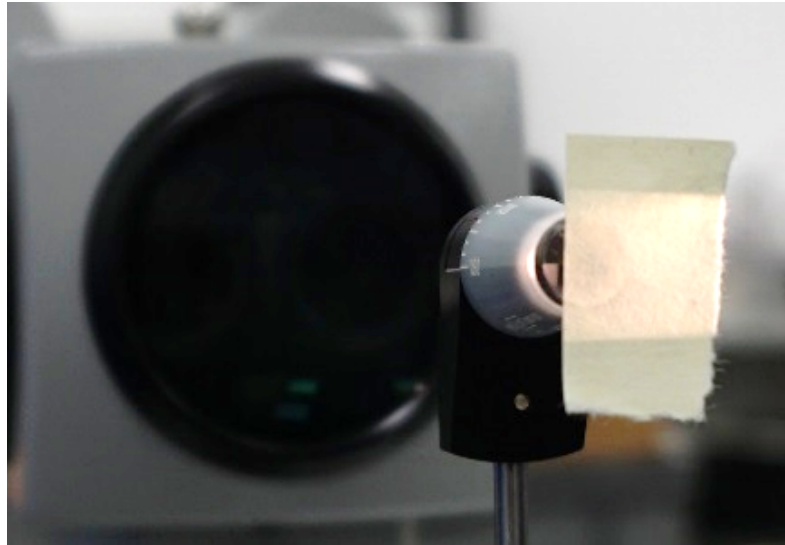
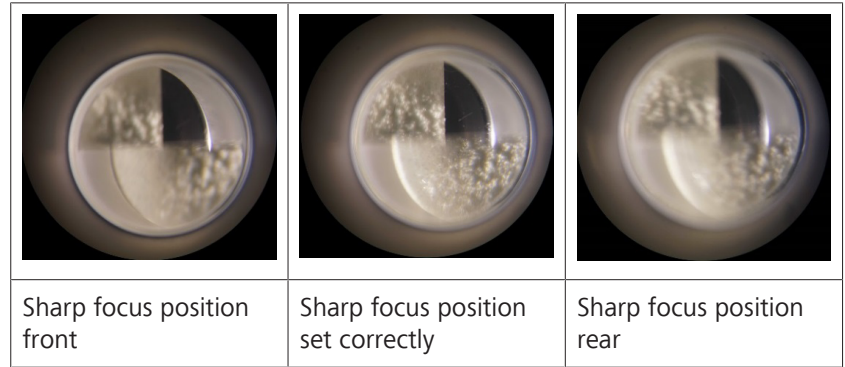


Figure 10: Structure on one side of measuring prism

- ▶ Set the magnification of the slit lamp microscope to a high magnification (e.g. 20x or 25x).
- ▶ Set the illumination using the slit projector from the left to about 90° so that the front of the measuring prism is illuminated.
- ▶ Check whether the sharp focus of the visible structure on one side is in the middle of the motion range by carefully swiveling the measuring prism from the front to the back stop.
- ▶ If the sharp focus position is not correct, loosen the two clamping screws by approx. ½ turn.
- ▶ Push the swivel arm including tonometer forwards or backwards in the slot until the sharp focus of the structure visible on one side is in the middle of the motion range. When moving the tonometer lift it slightly to avoid it tilting under its own weight.
- ▶ Retighten the clamping screws alternately. Start with the rear clamping screw. Make sure that the measuring prism is in the center of the field of view.
- ▶ Carry out a further check in accordance with step 5.

NOTE! The measuring prism must be visible in the center of the eyepiece.



Setting the lateral middle position in the field of view (lateral adjustment D)

- ▶ Set the magnification of the slit lamp microscope to a high magnification (e.g. 20x or 25x).
- ▶ Observe the measuring prism through the microscope (select proper eyepiece!).
- ▶ If the measuring prism is not centered in the field of view, loosen the two clamping screws on the bottom of the adapter.
- ▶ Adjust the measuring prism by swiveling the swivel arms horizontally in the elongated holes in the center of the field of view.
- ▶ Firmly retighten the clamping screws alternately.

7.3 Adjusting the swivel-mounted tonometer holder with round mounting interface (version b)

Preparation

Action

- ▶ Mount the tonometer holder and AT 030 on the slit lamp.
- ▶ Put the AT 030 into the position for the right eyepiece.
- ▶ Set the eyepieces of the slit lamp to 0 D or your own correction value.
- ▶ Move the AT 030 to the measuring position.
- ▶ Illuminate the measuring prism with the slit lamp projector from the left to approx. 90°.

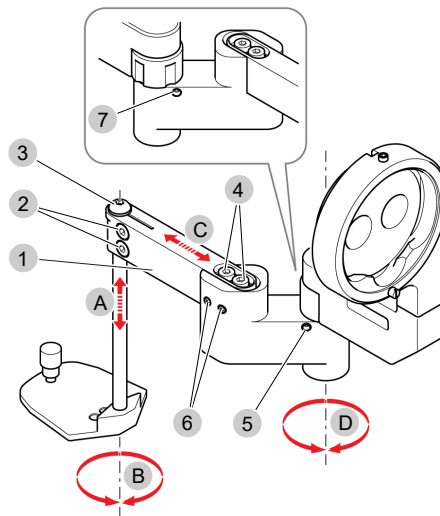
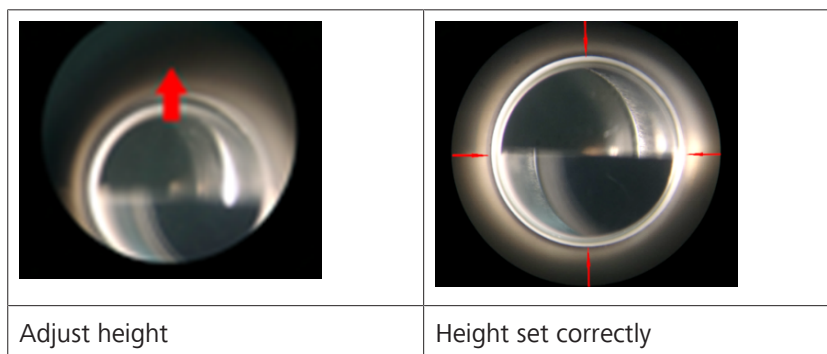


Figure 11: Clamping and adjusting screws on the swivel-mounted tonometer holder, version b (round mounting interface)

1	Swivel arm	A	Height adjustment
2	Clamping screw for height adjustment and coaxial adjustment	B	Coaxial adjustment
3	Adjusting screw for height adjustment	C	Image focus
4	Set screw for image focus	D	Lateral adjustment
5	Left set screw		
6	Set screw for image focus		
7	Base plate		

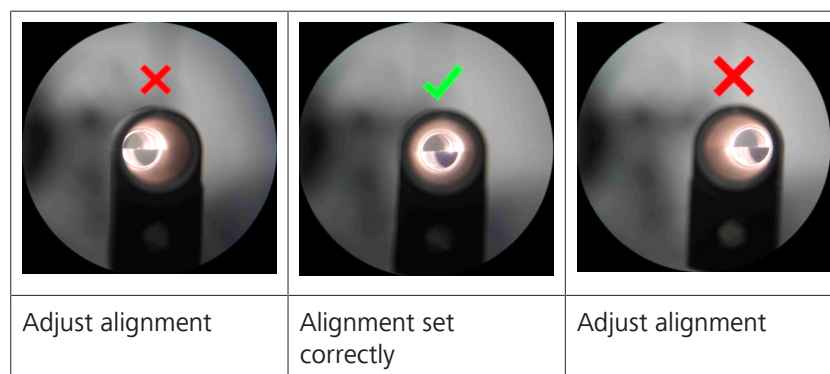
Setting the correct height in the field of view (height adjustment A)

- ▶ Set the magnification of the slit lamp microscope to a high magnification (e.g. 20x or 25x).
- ▶ Loosen the two clamping screws by approx. ½ turn.
- ▶ Unscrew the adjusting screw at the upper end of the rod by approx. 5 mm.
- ▶ Press on this adjusting screw and slide the rod with tonometer downwards, until the base plate is resting on the pivot joint of the slit lamp.
- ▶ Move the tonometer with measuring prism into the vertical center of the field of view by turning the adjusting screw to the right. Hold the tonometer, so that it cannot rotate laterally. Ensure the correct alignment of the measuring prism.
- ▶ Firmly retighten the two clamping screws alternately.
- ▶ Retighten the adjusting screw carefully.



Setting the alignment (coaxiality B)

- ▶ Set the magnification of the slit lamp microscope to a low magnification (e.g. 5x or 6x).
- ▶ Loosen the two clamping screws.
- ▶ Observe the measuring prism through the right eyepiece and set the correct alignment of the measuring prism. Turn the tonometer, including the base plate, sideways around the rod.
- ▶ Firmly retighten the two clamping screws alternately.



If the same eyepiece is always to be used for tonometry, the adjustment is now finished.

If, however, both eyepieces are to be used alternately, the position of the AT 030 on the base plate must now be changed:

- ▶ Release the knurled screw and remove the tonometer.
- ▶ Set the tonometer with the centering pin into the other alignment hole of the base plate.
- ▶ Retighten the knurled screw.
- ▶ Check, whether the measuring prism is also correctly aligned in this eyepiece. If not, repeat the first four steps.

Setting/checking the correct focus position (image focus C)

- ▶ Set the scale on the tonometer to zero.
- ▶ To assess the focus sharpness apply a visible structure to one side of the front surface of the measuring prism (e.g. finger-print, dust, graph paper).

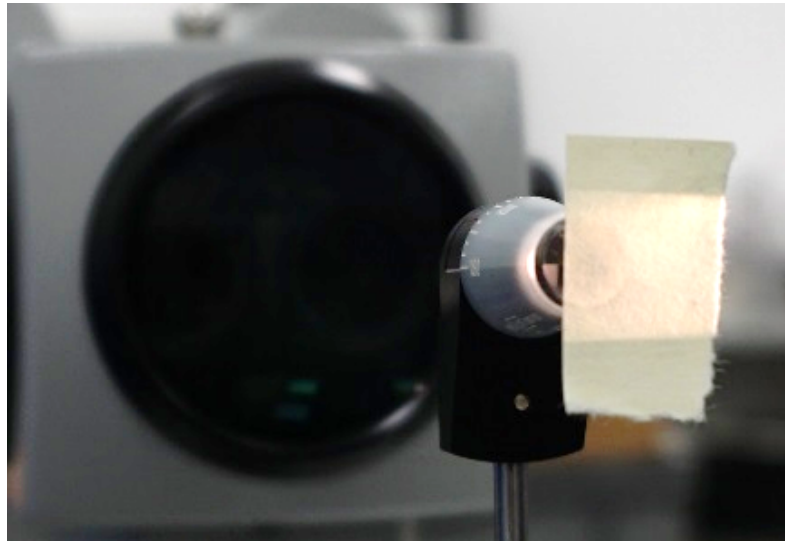
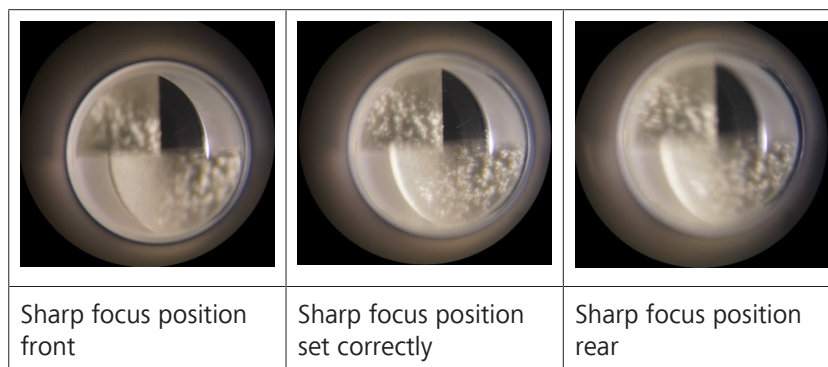


Figure 12: Structure on one side of measuring prism

- ▶ Set the magnification of the slit lamp microscope to 25x.
- ▶ Set the illumination using the slit projector from the left to about 90° so that the front of the measuring prism is illuminated.
- ▶ Check whether the sharp focus of the visible structure on one side is in the middle of the motion range by carefully swiveling the measuring prism from the front to the back stop.
- ▶ If the sharp focus position is only at the front (towards patient), the swivel arm with tonometer should be moved further forward:
 - ⇒ First loosen the two set screws by approx. ¼ turn.
 - ⇒ Then loosen the two clamping screws by approx. ½ turn.

- ⇒ Push the swivel arm including tonometer forwards in the slot until the sharp focus of the structure visible on one side is in the middle of the motion range. When moving the tonometer lift it slightly to avoid it tilting under its own weight.
- ⇒ Then retighten the screws: first, the two set screws, then both the clamping screws alternately, starting with the rear clamping screw.
- ⇒ Carry out a further check in accordance with step 5.
- ▶ If the sharp focus position is only at the rear (towards observer), the swivel arm with tonometer should be moved further to the rear:
 - ⇒ First loosen the two set screws by approx. ¼ turn.
 - ⇒ Then loosen the two clamping screws by approx. ½ turn.
 - ⇒ Push the swivel arm including tonometer backwards in the slot until the sharp focus of the structure visible on one side is in the middle of the motion range. When moving the tonometer lift it slightly to avoid it tilting under its own weight. When moving the tonometer lift it slightly to avoid it tilting under its own weight.
 - ⇒ Then retighten the screws: first, the two set screws, then both the clamping screws alternately, starting with the rear clamping screw.
 - ⇒ Carry out a further check in accordance with step 5.

NOTE! The measuring prism must be visible in the center of the eyepiece.



Setting the lateral middle position in the field of view (lateral adjustment D)

- ▶ Set the magnification of the slit lamp microscope to 25x.
- ▶ Observe the measuring prism through the microscope (select proper eyepiece!).
- ▶ If the measuring prism is to the right of the center of the field of view, proceed as follows:
 - ⇒ Loosen the right set screw slightly.

- ⇒ Then, tighten the left set screw.
- ⇒ The left set screw is only accessible if the tonometer holder is pivoted approx. 30° to the right from the stop notch.
- ▶ If the measuring prism is to the left of the center of the field of view, proceed as follows:
 - ⇒ Loosen the left set screw slightly.
 - ⇒ Then, tighten the right set screw. The left set screw is only accessible if the tonometer holder is pivoted approx. 30° to the right from the stop notch.
- ▶ Adjust alternately until the measuring body can be seen in the center of the visual field.
- ▶ Then retighten both set screws alternately.

Checking the achieved adjustment status

- ▶ Perform a final check of the adjustment status.
- ▶ If necessary, repeat the steps in sections Setting the correct height in the field of view (height adjustment A) and Setting the lateral middle position in the field of view (lateral adjustment D).
- ▶ If required, move the tonometer to the left alignment hole of the base plate and check the adjustment of the left eyepiece.

7.4 Checking the device

After transport of the device, check the condition of the device as follows:

Checking while mounted on slit lamp

- ▶ Move the tonometer to the measuring position.
- ▶ Set the scale reading to 0. The measuring prism can easily be moved back and forth.
- ▶ Set the scale reading to 1. The measuring arm with the measuring prism must move immediately towards the front end position.

NOTE! If the measuring arm with the measuring prism does not move to the front end position, discontinue using the device. Consult ZEISS Service. Please also observe the information in the Metrological check [▶ 33].

Action

Detailed check before mounting on the slit lamp

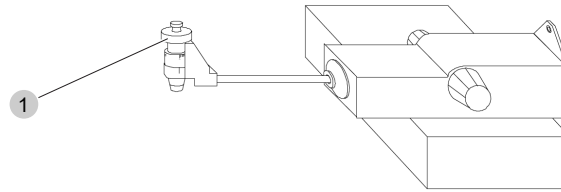


Figure 13: Checking the AT 030

1	Test weight
---	-------------

- ▶ Set the scale reading to 0.
- ▶ Take the 2 g and 5 g test weights out of the storage box.
- ▶ Put the AT 030 onto the open box with the scale facing downwards.
- ▶ Insert the measuring prism inversely up to the normal measuring position into the measuring prism holder.
- ▶ Place a test weight concentrically onto the measuring prism.
- ▶ Turn the rotary knob slowly from the 0°-position until the measuring arm with the weight oscillates weightlessly around its center position. Remove the test weight.
- ▶ Record the corresponding scale value.
- ▶ Repeat this procedure four times (two times each from the side of greater and smaller forces) and calculate the arithmetic average of the readings.

NOTE! The values obtained with both weights should be 2.0 ± 0.06 sc dlv. (2 g weight) and 5.0 ± 0.1 sc dlv. (5 g weight). If these values cannot be reproduced, discontinue using the tonometer and consult ZEISS Service. Please also observe the information in section Metrological check [▶ 33].

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8 Troubleshooting

Action

1. The axis of the measuring prism must coincide with the normal to the corneal surface. This is the case if the fluorescein semicircles are symmetrical to the separating line. The two fluorescein semicircles are visible in the center of the eyepiece and touch each other at their inner edges.

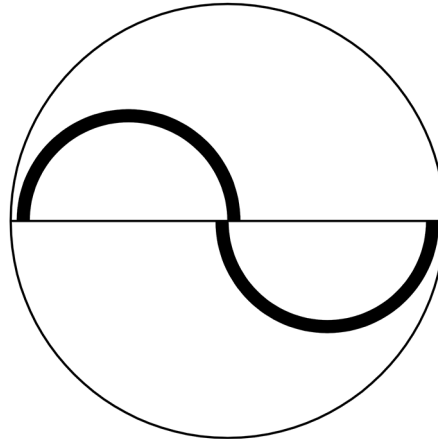


Figure 14: Correct measuring pattern

2. If this condition is not met, patterns as shown in the following figure will appear. These patterns require the slit lamp and thus the measuring prism to be repositioned laterally and vertically.

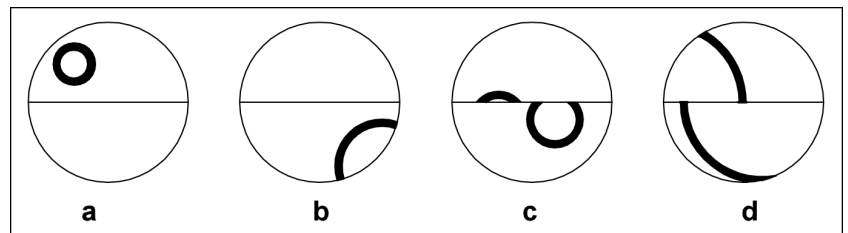

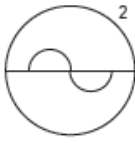
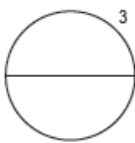
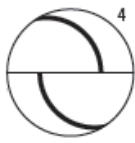
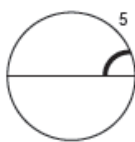
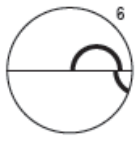
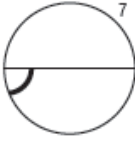
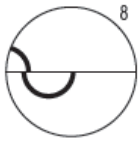
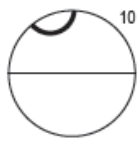
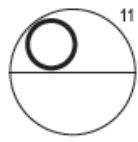
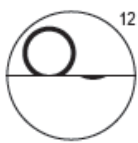
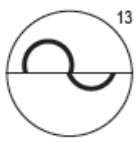
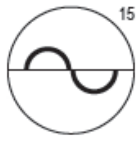
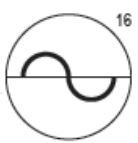
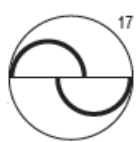


Figure 15: Measuring patterns requiring correction of the tonometer position

Possible faults and their remedies are described below.

Fault	Eyepiece image	Remedy
Fluorescein ring too wide/too small		
Fluorescein ring too wide: The measuring prism was not dried after cleaning or the eyelids touched the measuring prism during measurement. In this case, the reading is higher than the actual pressure.		Pull the slit lamp back and dry the measuring prism with a lint-free cloth (e.g. made from cellulose)

Fault	Eyepiece image	Remedy
<p>Fluorescein ring too small: The tear fluid has dried up during a longer measurement. In this case the pressure reading will be too low.</p>		<p>Let the patient blink and close his/her eyes several times and repeat the measurement.</p>
Incorrect distance to patient		
<p>No semicircles visible, only the separating line: The measuring prism does not touch the cornea! If the patient withdraws his/her head slightly, there will be irregular pulsations as the measuring prism touches the eye only intermittently. If the patient withdraws further, the fluorescein semicircles will disappear completely.</p>		<p>Instruct the patient to press his/her head firmly against the chin- and head rest.</p>
<p>Only parts of the two semicircles are visible as they are too large: If the slit lamp is pushed too far towards the patient or if the patient moves towards the slit lamp, the measuring arm hits against a damping spring. The applanation area is too large. Turning the measuring drum does not change the image.</p>		<p>Retract the slit lamp until the uniform pulsations of a correspondingly smaller area show the correct measuring position and pressure changes lead directly to surface changes.</p>
Position too far right/left		
<p>Only part of the upper semicircle visible: The measuring prism is not centered with the eye. The eye is too far right.</p>		<p>Move the slit lamp to the right using the control lever.</p>
<p>Whole upper semicircle and part of lower semicircle visible: The measuring prism is not centered with the eye. The eye is too far right.</p>		<p>Move the slit lamp to the right using the control lever.</p>
<p>Only part of the lower semicircle visible: The measuring prism is not centered with the eye. The eye is too far left.</p>		<p>Move the slit lamp to the left using the control lever.</p>

Fault	Eyepiece image	Remedy
<p>Only part of the upper semicircle and the entire lower semicircle are visible: The measuring prism is not centered with the eye. The eye is too far left.</p>		<p>Move the slit lamp to the left using the control lever.</p>
<p>Position too high (too low)</p>		
<p>Only part of a semicircle is visible in the upper (lower) half: The measuring prism is not centered with the eye. The eye is too far up (down).</p>		<p>Move the slit lamp upwards (downwards) using the control lever.</p>
<p>Full circle visible in the upper (lower) half: The measuring prism is not centered with the eye. The eye is too far up (down).</p>		<p>Move the slit lamp upwards (downwards) using the control lever.</p>
<p>Almost the whole circle visible at the top (bottom), part of semicircle visible at the bottom (top): The measuring prism is not centered with the eye. The eye is too far up (down).</p>		<p>Move the slit lamp upwards (downwards) using the control lever.</p>
<p>Two semicircle sections visible, larger visible at top (bottom): The measuring prism is not centered with the eye. The eye is too far up (down).</p>		<p>Move the slit lamp upwards (downwards) using the control lever.</p>
<p>Incorrect pressure</p>		
<p>Fluorescein semicircles touch at the outer boundaries: Pressure too low.</p>		<p>Turn the measuring drum knob and increase the pressure slightly.</p>
<p>The fluorescein semicircles form a ribbon: Slightly too little pressure.</p>		<p>Turn the measuring drum knob and increase the pressure slightly.</p>
<p>The fluorescein semicircles no longer touch at the outer boundaries: Much too much pressure.</p>		<p>Turn the measuring drum knob and lower the pressure slightly.</p>

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9 Technical specifications


9.1 Compliance

If modifications not authorized by the manufacturer are made to the device, this declaration ceases to be valid.

9.1.1 Directives with which the device is compliant

The device complies with the 93/42/EEC Medical devices directive (MDD)

Device class in accordance with the MDD: I (with measuring function)

The device is marked with 

9.1.2 Classification of the device

UMDNS No.: 16-809

The AT 030 applanation tonometer conforms to the ISO 8612:2009 standard.

9.2 Device data

	Value
Measuring prism	2 prisms for image splitting
Diameter of applanation surface	3.06 mm
Measuring force range of precision spring tonometer	0 mN to 78.4 mN
Scale reading	0.98 mN
Measurement accuracy	according to ISO 8612:2009 9.81 ± 0.49 mN 19.61 ± 0.49 mN 29.42 ± 0.49 mN 39.23 ± 0.59 mN 49.03 ± 0.74 mN 58.84 ± 0.88 mN 68.65 ± 1.03 mN 78.45 ± 1.18 mN

9.3 Dimensions and weights

	Value
Dimensions (W x H x D)	105 mm x 40 mm x 25 mm
Weight	245 g

9.4 Ambient requirements

	Value
Ambient conditions for intended use	
Temperature	+10 °C to +35 °C
Relative humidity	30 % to 75 % (no condensation)
Altitude	up to 3000 m above sea level
Ambient conditions for storage	
Temperature	-10 °C to +55 °C
Relative humidity	10% to 95%
Ambient conditions for transport in original packaging	
Temperature	-40 °C to +70 °C
Relative humidity	10% to 95%

10 Optional accessories

- Swivel-mounted tonometer holder
- Fixed tonometer holder

You can find the ZEISS contact partner for your country on the following website: www.zeiss.com/med

Use only accessories and spare parts which are approved by ZEISS for this device. When using accessories and spare parts that are not approved by ZEISS, safe operation of the device cannot be guaranteed.

A current and complete list of accessories can be obtained from your retailer.

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11 Disposal of the device

- ▶ Keep packing material in the event of a relocation or repair.
- ▶ If you would like to dispose of the original packing material, send it in for recycling via a recognized collection system.

The system contains electronic components.

- ▶ Dispose of the device properly and in accordance with national legislation.



In accordance with applicable EU guidelines and national regulations at the time at which the product was brought onto the market, the product specified on the consignment note is not to be disposed of via the domestic waste disposal system or communal waste disposal facilities.

- ▶ For more information about the disposal of the device, please contact the ZEISS contact partner in your country.

You can find the ZEISS contact partner for your country on the following website: www.zeiss.com/med

- ▶ If you resell the device or its components: Inform the buyer that the device is to be disposed of in accordance with the currently applicable regulations.

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Glossary

D

D (diopter) is the unit of measurement of the refractive power of optical systems.

kPa

Kilopascal: 1 kPa = 1000 Pa

mbar

Millibar: 1 mbar = 1 hPa = 100 Pa

MDD

Medical Device Directive

mm Hg

Millimeter of mercury column:
measurement of intraocular pressure

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**Instructions for use and disinfection
of tonometer measuring prisms**

[319300-9231-000-AddGA01-GB-240320]

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Instructions for use and disinfection of tonometer measuring prisms

Addendum

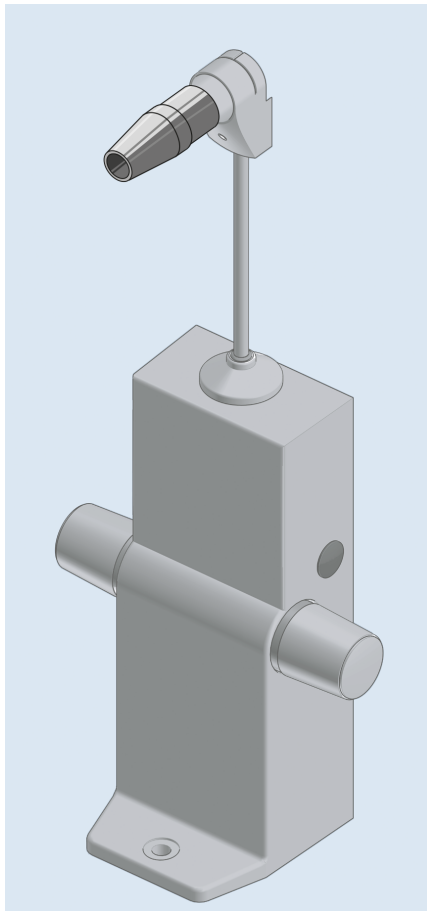


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1 Notes on the instructions for use

1.1 Scope of application

The present addendum applies to tonometer measuring prisms with the following identification:

- Reference number: 319300-9510-000

1.2 Intended use of the document

CAUTION!

Hazard due to improper use

- ▶ Read these instructions for use before setting up and using the product the first time.
- ▶ Observe the information on the safety of users and patients.

This document describes the correct cleaning and disinfection of tonometer measuring prisms. Correct cleaning and disinfection prevents the transmission of diseases to patients and users and mechanical damage. This process has been validated by an accredited testing laboratory to protect material and patients.

1.3 Questions and comments

- ▶ If you have questions or comments concerning these instructions for use or the device itself, contact ZEISS Service.

You can find the ZEISS contact partner for your country on the following website: www.zeiss.com/med

1.4 Conventions in this document

Certain types of information are specially marked in this document for better recognition.

1.4.1 Conventions in all text areas

- This is a list.
 - This is a second level list.

This is a cross-reference: Questions and comments [▶ 5].

This is **highlighted text**.

This is `software code or program text`.

Names of software dialogs, fields or menus, and software messages are marked by quotation marks:

- "View" menu.
- "Do you want to save the settings?"

The steps in menu and file paths are separated by slashes:

- "File / Save as"
- "My documents / Documents"

Keys, buttons, knobs, levers and other operating controls are marked by square brackets:

- [START] key
- [Next] button

1.4.2 Conventions in a course of action

WARNING!

This is warning information about hazards that can cause death or severe injuries if not avoided.

The warning message names the possible consequences.

- ▶ This is a measure with which hazards can be prevented.

CAUTION!

This is warning information about hazards that can cause injuries if not avoided.

The warning message names the possible consequences.

- ▶ This is a measure with which hazards can be prevented.

NOTE

This is warning information about hazards that can cause property damages if not avoided.

The warning message names the possible consequences.

- ▶ This is a measure with which hazards can be prevented.

This is a requirement that must be met before the start of a sequence of actions.

1. This is a command.

2. **CAUTION! This is a warning message about hazards that can occur during a single action.** This is a command.

⇒ This is the result of a sequence of actions.

2 Safety notes

2.1 Ambient conditions

Please follow the instructions of use for the appropriate devices.

2.2 Important general advice

CAUTION!

Risk due to contaminated products

Products listed in these instructions for use will not be shipped disinfected. The use of these products can lead to patient injuries.

- ▶ Clean and disinfect the products in accordance with these instructions for use prior to first use.
- Always follow all warnings and notes in the instructions for use of the applanation tonometer and measuring prisms.
- Carry out examinations only with undamaged, cleaned and disinfected measuring prisms.
- The measuring prisms used must not be damaged as they might otherwise damage the patient's cornea.
- Improper preparation can result in the transmission of diseases to the patient and user as well as damage to the measuring prisms.
- Residue from cleaning agents and disinfectants can irritate and burn the patient's eye.
- As a rule, the measuring prisms may be prepared together, but should not be prepared with any other products.

2.3 Operation, environment

- The operation and preparation must only be performed by qualified and trained personnel whose training is the responsibility of the operator.
- Appropriate professional assessment and caution are necessary.
- The safety instructions in the instructions for use of the applanation tonometers also apply.

2.4 Warranty and product liability

- The measuring prisms must be handled as described in the Safety notes [▶ 7].
- Improper handling can damage the product. This voids all guarantee claims.
- Continuing to use a product damaged by incorrect handling can lead to personal injury. In this case, the manufacturer accepts no liability.

2.5 Validated cleaning and disinfecting agents

The following cleaning and disinfecting agents have been used in several validations.

Cleaning agents

- Palmolive 0.08 %

Disinfectants

Product	Concentration	Exposure time	Rinsing
Hydrogen peroxide H ₂ O ₂	3 %	10 minutes	Rinse with cold water for 5 minutes
Sodium hypochlorite NaOCl	10 %	10 minutes	Rinse with cold water for 10 minutes

2.6 List of disinfectants with good material compatibility with ZEISS measuring prisms

The disinfectants listed below were only tested on their material compatibility with ZEISS measuring prisms.

NOTE

Damage due to improper cleaning and disinfection

The effectiveness of the disinfectants has not been tested for correct disinfection of the tonometer measuring prisms.

The sole purpose of the list below is to provide the user with a choice of suitable disinfectants which may be used for the validation of their own disinfection process.

ZEISS rejects all liability if any of the disinfectants mentioned in the list below is used without a proper validated cleaning and disinfection process.

The disinfectants may only be used with the concentration mentioned on the list below. Higher concentrations can damage the measuring prisms. In this case ZEISS rejects all liability.

ZEISS rejects all liability if a disinfectant is used which does not appear on the list below.

- ▶ The efficacy of the disinfectants on ZEISS tonometer measuring prisms must be guaranteed by the user or the responsible person for reprocessing by validating their own disinfection process.

2.6 List of disinfectants with good material compatibility with ZEISS measuring prisms

Instructions for use and disinfection of tonometer measuring prisms

Disinfectants	Tested concentration	Aldehyde free	Containing aldehyde	Comments
NaOCl (sodium hypochloride)	0.0525 %	x		
NaOCl (sodium hypochloride)	2.5 %	x		max. 100 cycles of 1h
NaOCl (sodium hypochloride)	10 %	x		max. 100 cycles of 1h
NaOH (sodium hydroxide)	1 M (1 mol/l)	x		max. 100 cycles of 1h
H ₂ O ₂ (hydrogen peroxide)	3 %	x		
Acrylan®	1)	x		
Almyrol®	4 %	x		
Bodedex forte	1 %	x		
Bomix plus	2 %	x		
Cidex® plus	3.5 %		x	
Cidex® OPA	1)		x	
Dakin solution	1)	x		
Deconex 53 Instrument	2 %	x		
Deconex 53 Plus	4 %	x		
Endo Septol FF	5 %	x		
Gigasept® AF	4 %	x		
Gigasept® AF forte	5 %	x		
Gigasept® FF NEW	8 %		x	
Gigasept PAA concentrate	2 %	x		
Hibitane®	0.5 %	x		
Jiaen 6 % "Yoshida"	0.05 %	x		
Korsolex basic	5 %		x	

Disinfectants	Tested concentration	Aldehyde free	Containing aldehyde	Comments
Korsolex extra	4 %		x	
Mucocit®-T	6 %	x		
NU-CIDEX®	1)	x		
PeraSafe®	1)	x		
Peraxylens®	1)	x		
Perfektan® active	2 %	x		
Perfektan® TB	4 %	x		
Sekusept® Activ	2 %	x		
Sekusept® Activ NEU	1)	x		
Sekusept® forte S	3 %		x	
Sekusept® PLUS	4 %	x		
Stabimed®	2 %	x		
Sterihyde® L	2 %	x		
Tristel DUO	1)	x		
Tristel Sporicidal Wipes	1)	x		
1) Activated solution according to manufacturer's instructions				

2.7 Service life

How long can measuring prisms be used?

⚠ CAUTION!

Risk of exceeding the maximum service life

Exceeding the maximum service life of the tonometer measuring prisms may result in injury to the patient.

- ▶ Do not use the measuring prisms beyond the expiration date.
- ▶ Immediately replace damaged measuring prisms.

Due to the large number of variables to be considered (type and concentration of disinfectant used, number of patients, handling, etc.) it is practically impossible to specify how often and/or long a measuring prism can be used under safe conditions. The measuring prisms carry an expiry date (YYYY-MM). They must not be used beyond this date. ZEISS recommends a maximum service life of two years before the expiration date. This service life applies under normal conditions of use, i.e. when used in accordance with the instructions contained in this user manual. The service life starts with the first use. The above periods do not apply for damaged measuring prisms; these should be replaced immediately.

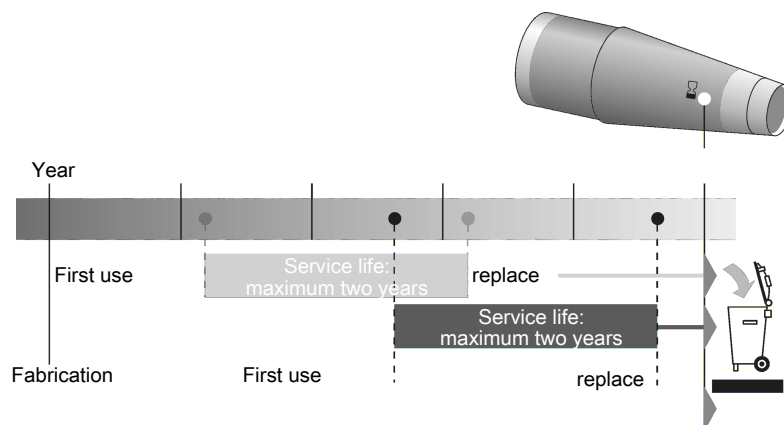


Figure 1: Overview of the service life of the measuring prisms

3 Cleaning and disinfection of reusable measuring prisms

CAUTION!

Risk due to improper cleaning and disinfection

The disinfectant used must satisfy two criteria:

- ▶ For material compatibility reasons, only agents approved by ZEISS may be used. The current material compatibility list can be found on the ZEISS homepage and is included with the tonometer and the measuring prisms. Should the operator decide to employ other disinfectants or procedures of his own accord, it must be ensured that the disinfection is not performed with agents containing alcohol or acetone and is never performed with UV radiation, steam or ethylene oxide.
- ▶ In terms of the disinfection performance, all disinfectants that are approved for instrument disinfection and that have been tested for their efficacy against all nosocomially relevant infectious agents can generally be used as long as they also satisfy the material compatibility requirements outlined above. The user is responsible for selecting the correct disinfectant and employing the correct concentration.

NOTE

Damage due to improper cleaning and disinfection

The tonometer measuring prisms may be damaged during cleaning and disinfection.

- ▶ Use only Hydrogen Peroxyde at a 3% aqueous solution or Sodium Hypochlorite (Household Bleach) at a 10% aqueous solution. These two solutions have been validated with mild soap (e.g. Palmolive 0.08%) as the cleaning agent.

3.1 Manual cleaning steps

For simple and safe disinfection, we recommend using containers with holders for several measuring prisms. In the following, cleaning and disinfection using Desinset by HAAG-STREIT is described. The use of other disinfection aids is at the user's own risk. Used instruments must be rinsed off after use before the residues dry up.

Action

1. Remove the measuring prisms from the tonometer holder (a) and clean under running water (drinking water quality) (recommended time 60 seconds).
2. Clean the measuring body with a pH-neutral cleaning agent until no more dirt is visible.
3. The cleaning agent must then be rinsed off well under running water (drinking water quality)! (recommended time 60 seconds) (b).
4. Dry the measuring prisms with a lint-free disposable cloth (c).
5. Perform visual checks for cleanliness and perfect working condition.
6. Place the cleaned measuring prisms in the Desinset plastic tray (d).

3.2 Disinfection steps

We recommend the use of a validated disinfectant (see chapter Validated cleaning and disinfecting agents [► 8]).

The operator accepts all liability for the use of other cleaning agents.

The maximum, material-compatible exposure time for the disinfectant is 60 minutes.

Action

1. Take the measuring prisms to be disinfected out of the plastic tray and place them on the lower tray (e) of a clean, disinfected Desinset plastic insert.

NOTE! The measuring prisms must not overlap.

2. Add at least 600 ml of disinfectant solution (f), so that the lower tray is completely immersed.
3. Place the disinfectant in one of the two Desinset measuring beakers.

WARNING! All measuring prisms must be completely immersed in the disinfectant solution. As the measuring prisms tend to float in the solution, they must always be placed in the lower tray of the Desinset insert.

4. Allow the disinfectant sufficient time to work as specified in the disinfectant manufacturer's instructions (g). The maximum, material-compatible exposure time for the disinfectant is 60 minutes.
5. Once the exposure time has expired, remove the plastic insert with the measuring prisms, allow it to drip dry (h) and then place it in the other clean and disinfected measuring beaker.

The disinfectant must be replaced as follows:

- When visibly soiled.
- Once a day or as specified by the manufacturer.

3.3 Rinsing and storage

CAUTION!

Risk due to contaminated or damaged measuring prisms

The patient may be injured by contaminated or damaged measuring prisms.

- ▶ Never use damaged measuring prisms!
- ▶ Only use clean, residue-free and undamaged measuring prisms.
- ▶ Prior to every use, the contact surface of the measuring prism must be inspected for contaminants and damage (scratches, cracks or sharp edges). This must be performed with a slit lamp microscope at a medium magnification (e.g. 12x or 16x).

Action

1. Place the clean and disinfected funnel on the plastic insert.
2. Rinse the measuring beaker and its contents with drinking-water quality running water for at least 10 and at most 15 minutes (i).
3. Remove the plastic insert with the measuring prisms (j) and dry the measuring prisms individually with a clean and sterile, soft, disposable cloth (k).
4. Store the cleaned and disinfected measuring prisms in the sealed and disinfected Desinset glass container (l) until their next use.

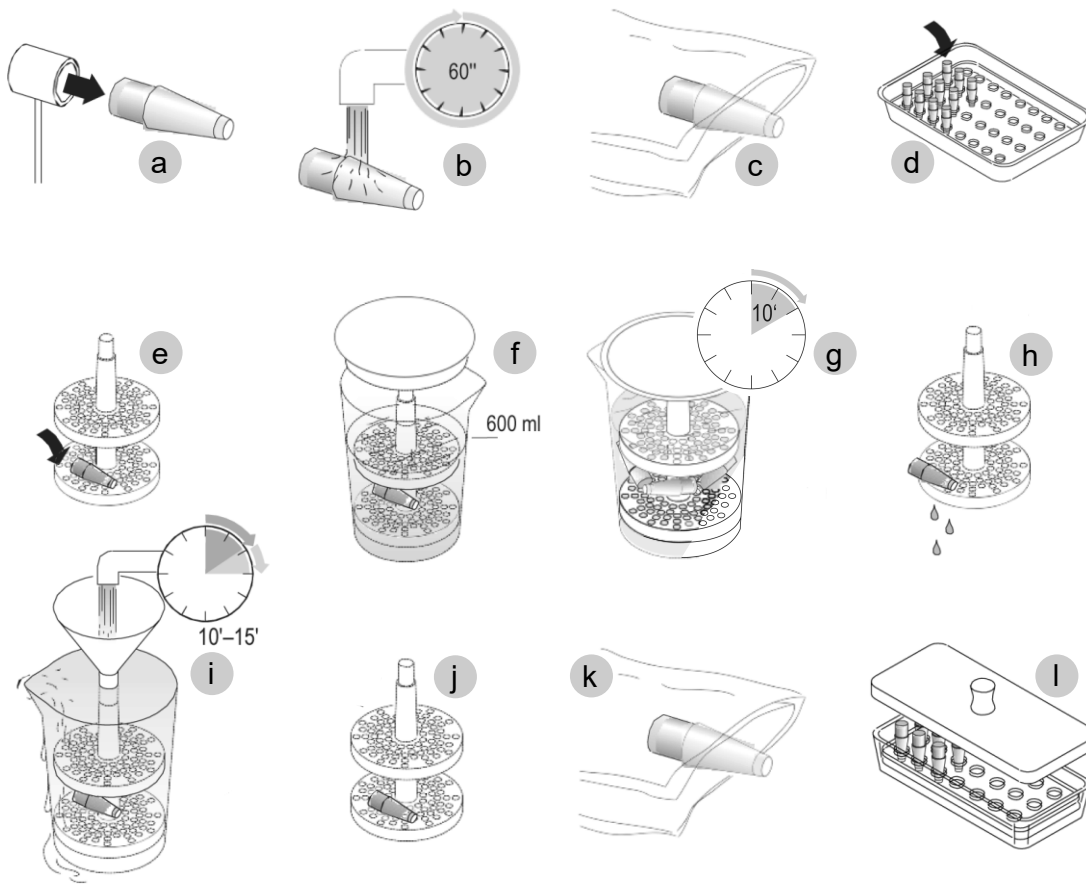


Figure 2: Steps for cleaning, disinfection and rinsing

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