Pediatric Autorefractor plusoptiX A09

INSTRUCTION MANUAL

(Version 5.0.20.0)

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1. Safety instructions

Please read all of the instructions in this manual by all means in order to avoid any danger to life and health, to achieve reliable measurement results and to obtain the device in good working conditions.

1.1 Warning and Symbols

ATTENTION: This symbol is intended to advise the user of the presence of important operating or maintenance requirements.

Service or repair to be performed by qualified authorized personnel only. There are no user serviceable parts inside the instrument. Opening this device can expose the user to harmful invisible electrical shock.

Note: Disassembly of plusoptiX A09 device will void the warranty. Refer all servicing to Plusoptix authorized service representatives listed in the section Service and Maintenance (Chapter 11).

Do not sterilize the plusoptiX A09 device or any of the components.

CAUTION: Use of controls or adjustments or performance of procedures other than those specified herein may result in wrong measurements.

Use only with IEC 60601-1 approved printers or keep printer out of patient vicinity.

Double insulated power supply.

The CE mark on this device indicates that it has been tested and conforms to the provisions noted within the 2007/47/EG Medical Device Directive.

At the end of life time (electronic waste): Please ship your device back to the company you have purchased it from. The company will refund the shipping cost.

ESD sensitive device: Discharge human body by touching a grounded plane or use ground strips before installation or touching the connectors.

This symbol shows that this product keeps the requirements for an application part type B of EN 60601-1.

1.2 Handling of the plusoptiX A09

The plusoptiX A09 is an optical electronic measuring device. The construction and functionality of the plusoptiX A09 is very similar of a video camera / camcorder. So, please handle the device as carefully as you would use your own camcorder. If you follow this advice, the plusoptiX A09 will last you for many years without any trouble.

1.3 Exclusive use of the plusoptiX A09

The exclusive use the plusoptiX A09 device is to measure refractive data, asymmetry of the corneal reflexes, pupil size and pupil distance in real time. Both eyes are measured at the same time (binocular) from one meter (3.3 ft) away from the child.

Note: Detecting anisometropia in miosis is only possible with a binocular measurement of refractive data in real time, like with the plusoptiX A09. And in this case it is not important whether the children are accommodating during the measurement, because the refractive difference between both eyes is always the same. The measurement is from one meter distance to the patient and so +1.00 dpt accommodation is included into the measurement result.

The measurement results can only be translated into a prescription for glasses/contact lenses by a licensed eye care professional and are not to be taken directly for a prescription.

1.4 Operation of the plusoptiX A09

Check all cable connections from the mains as well as the VGA cable between the plusoptiX A09 device and the monitor and, if present, the connection between keyboard, mouse and network are in good conditions every time before switching on the system.
Make sure that any cables or connectors which show any damage are replaced before switching on the plusoptiX A09 system.

Use only the delivered medical power adapter MES30B-3P1J and the delivered cables.

The plusoptiX A09 complies with the requirements of the directive of medical devices 2007/47/EG.

1.5 Duties of the operator

The operator must ensure that only personnel who have been trained in handling of the plusoptiX A09 are permitted to operate the system. All users must read the operating manual and take note of the safety instructions and provisions.

Note: Training courses on the operation of the plusoptiX A09 subject to safety notes and provisions for medical products are available on request.

Where the operator connects systems other than those supplied by Plusoptix, he should ensure that these comply with norms EN 60601-1 and EN 60601-1-1 in conjunction with the plusoptiX A09.

2. Delivery

The plusoptiX A09 device is delivered in a paper carton. The following information is printed on the carton:

Only 5 cartons on each other	This side up	Fragile	Keep dry	Carton manufactorer	CE conform	Recycleable

Inside the paper carton the measuring device is placed in a preformed inset to avoid damages to the plusoptiX A09 device during transportation.

Paper carton size:	51 cm x 41 cm x 20 cm (20 inches x 16 inches x 8 inches)
Preformed insert:	Polyurethane foam (volume weight 28 kg / CBM)
Weight:	3.5 kg (7.7LB) carton including plusoptiX A09 device

In case the paper carton shows any damages which may be caused by external force during transportation, e.g. careless loading or unloading, please do not accept the delivery and inform the company you have purchased the device from.

2.1 Storage

The plusoptiX A09 device can be stored in the original package when the storage room fulfils the following requirements:

Temperature: 0°C to +50°C (32°F to 122°F)
Humidity: 10% to 85% (no condensation)

Keep the plusoptiX A09 device away from any heat source.

2.2 Unpacking

Open the carton only in position „This side up“.

After unpacking the plusoptiX A09 please check that all items are delivered which are listed on the delivery note. Missing items can only be replaced when a claim has been forwarded to the company you have purchased the device from within one week after accepting the delivery.

Note: Please keep the original packing material in case later transportation may be required.

Do not store the packing material in a room with an open fire place.

2.3 Setting up

When you set up the plusoptiX A09 make sure that no cable can be reached by children.

Protect the plusoptiX A09 from direct sunlight.

3. Connecting and switching on the system

3.1 Connection

For operation, the plusoptiX A09 must be connected to a monitor and keyboard with a mouse. The monitor must fulfill the following system requirements:

Resolution: 1024 x 768 pixels
Interface: VGA

Four (4) USB ports of type A are available on the plusoptiX A09 for connecting e.g. keyboard, mouse, printer or USB-sticks.

Where a monitor is already available at a workstation, a switch (monitor switch TK 207 by "Trendnet") can be used to connect this monitor to the plusoptiX A09. This allows you to save space by using the monitor for your practice network and for the plusoptiX A09.

The plusoptiX A09 can also be attached to your practice network using an RJ-45 connection (network cable) via a GDT interface. Plusoptix supplies the software required for operation via a GDT interface at no charge, should you wish to connect the plusoptiX A09 to your network. In this case please consult your practice network support personnel.

Fig. 1: Connect the VGA cable from the monitor to the plusoptiX A09. The keyboard and mouse can be connected to the plusoptiX A09 by means of a USB cable or a wireless USB adapter. Attach the 12V DC connector to the plusoptiX A09 and the medical power unit to a 110 – 220 V AC (50 – 60 Hz) power plug. Ensure that the power plug is switched off after close of business. This is a precaution in case a short-circuit occurs during night-time which may cause a fire.

Fig. 2: Location of the connectors on the plusoptiX A09

Fig. 1

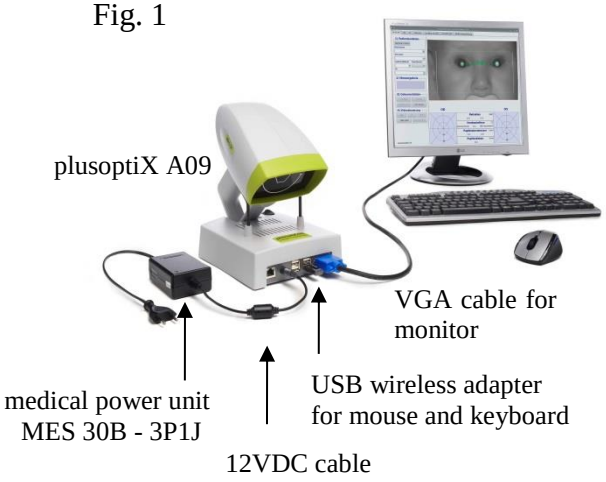
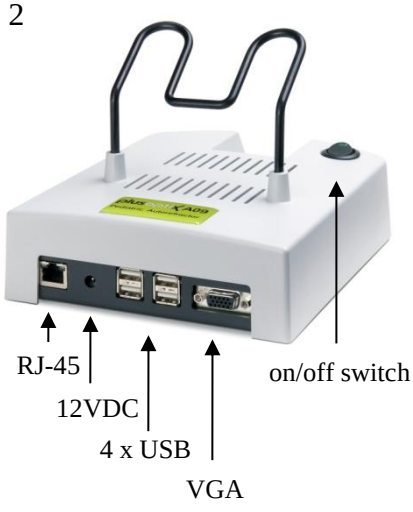


Fig. 2



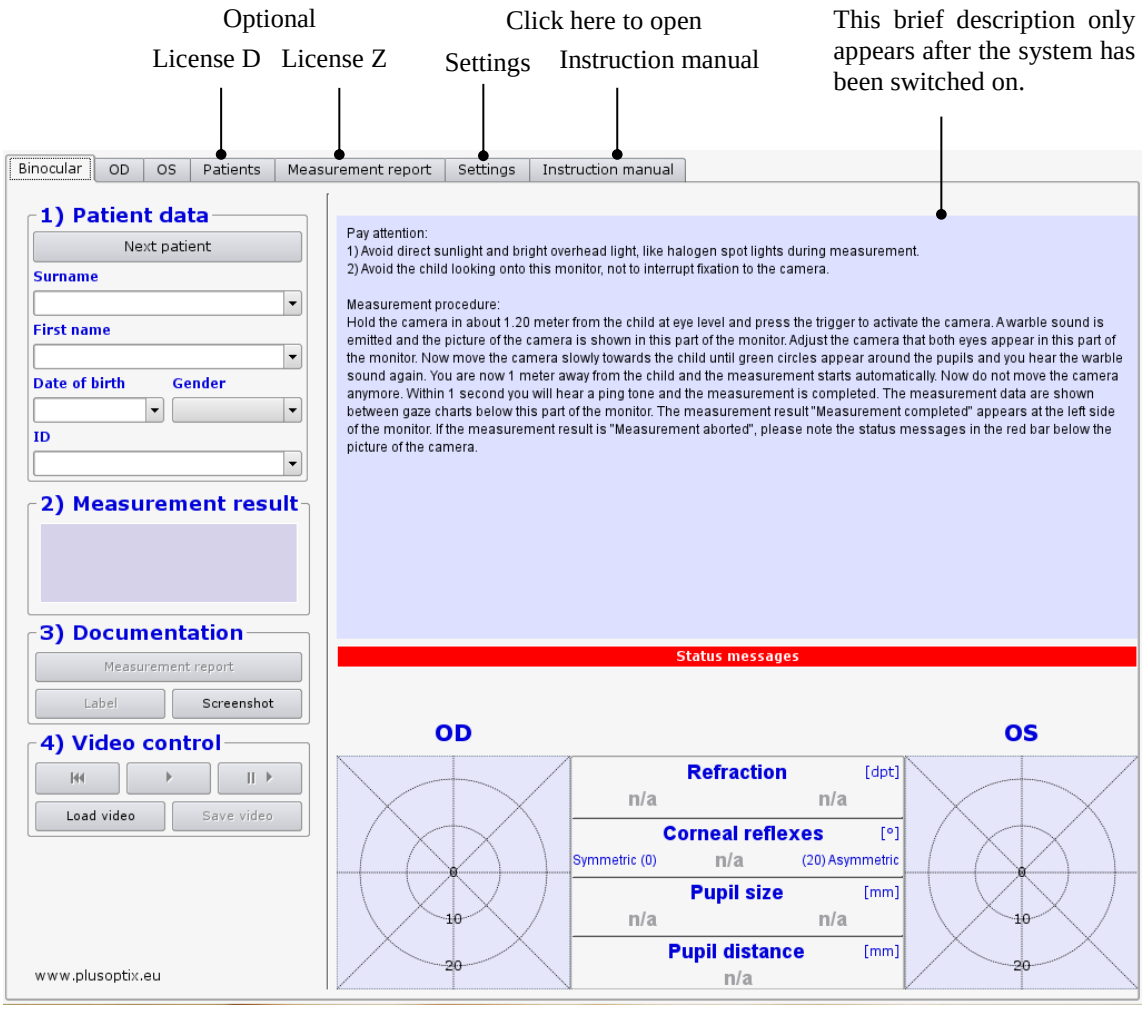
3.2 Switching on the system

Switch on the monitor before you switch on the plusoptiX A09 (see Fig. 2 on page 8 for the on/off switch).

After loading the software (approx. 1.5 minutes) the “Plusoptix Start Page” appears. You can now start measurements.

Note: When using the system for the first time, first click on “Settings” to adjust the settings as required for operation.

Plusoptix Start Page



Please make sure that no USB-stick is inserted in the plusoptiX A09 during switching on, because it can lead to problems during booting. The USB adapters from keyboard and mouse as well as probably connected printers are excluded from this.

4. Settings

For the first start-up it is recommended to adapt settings e.g. general (basic settings), printer, network (GDT), your address and system to the conditions of your practice. With the exception of the general settings appears at each page a security query, where you have to type in “YES”, to perform settings if you are authorized to do that. If you are not authorized click on “Cancel”. Then you just can have a look at the existing settings and not perform any settings.

4.1 General (Basic settings)

Click on “Settings” and then on "General" to perform basic settings.

Click here to switch the video image on the monitor from black and white to false colours. You can see the brightness profile of the pupils in colour (Brückner test).

Click here to test the volume of the warble sound.

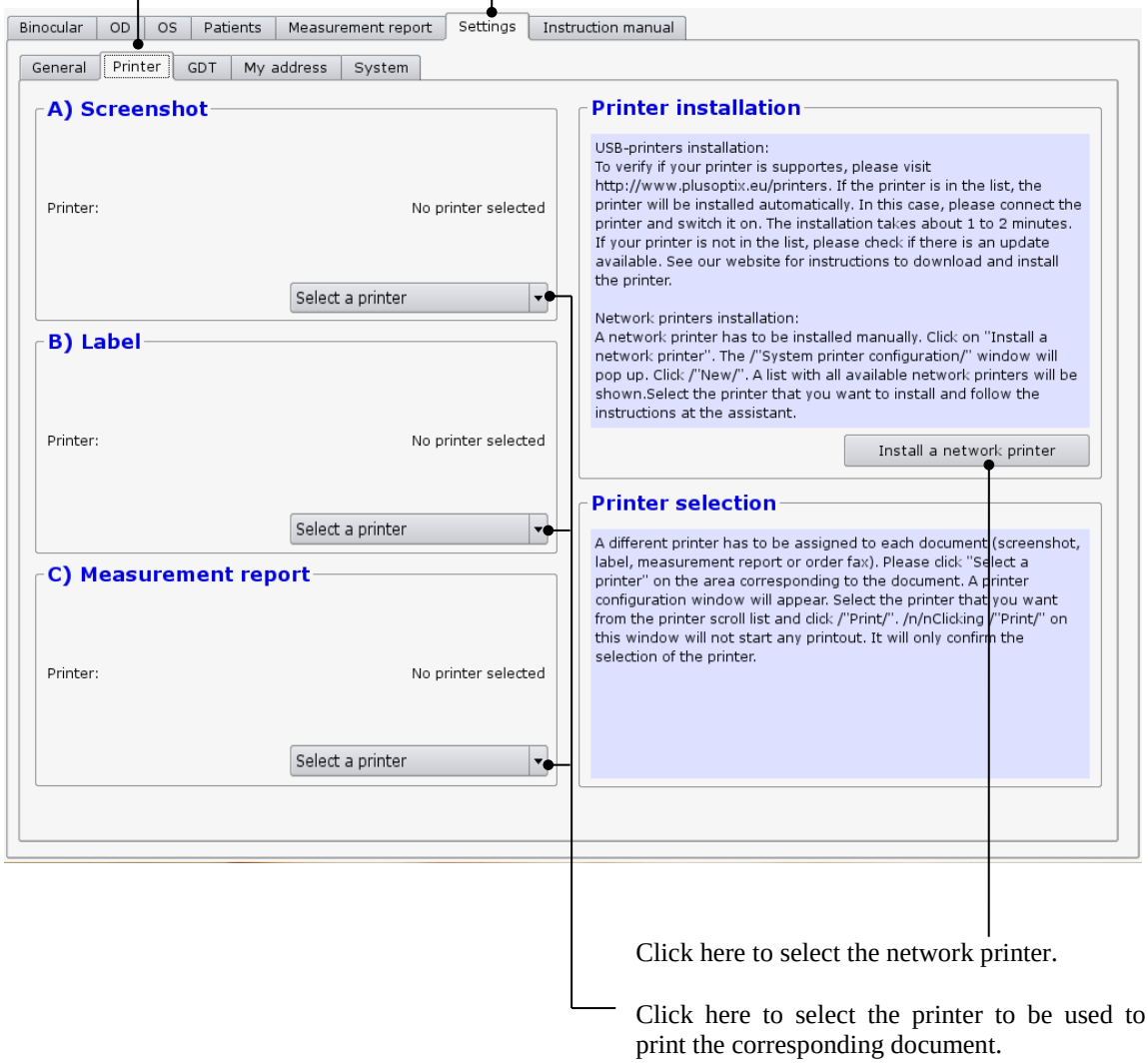
Click here and move the slide to the left using the mouse to decrease the volume of the warble sound, or to the right to increase the volume.

Click here to measure the astigmatism in minus cylinder or plus cylinder.

4.2 Installing a printer

To be able to print a screenshot, a self-adhesive label for the patient paper record or a measurement report (optional, License Z), suitable printer must be installed. You can attach the printer to the plusoptiX A09 directly via the USB or via your practice network.

Click on “Settings” and then on "Printer".



Click here to select the network printer.

Click here to select the printer to be used to print the corresponding document.

A pdf-printer (“PDF”) is already installed on the plusoptiX A09.
If you select the pdf-printer, it is necessary to insert a USB stick into one of the free USB ports on the plusoptiX A09. After a successful measurement and after clicking on “Measurement report” or “Screenshot” the document will be saved automatically on the stick. After about 10 seconds you can remove the stick from the device and print the document at a computer connected to a printer.

4.3 Practice network

To connect the plusoptiX A09 to an existing practice network, proceed as follows:

Click on “Settings” and then on "GDT".

Output format of the measurement results in the network - Parser: output in field identifiers
- Human readable: formatted text output

Adherence to GDT standard when transmitting measurement values. A selection can be made between formatted text and field identifiers 8410 to 8421.

Enter the name of the plusoptiX A09 in the network here.

The paths for data input to the plusoptiX A09 and for data export to the network are extracted from this value.

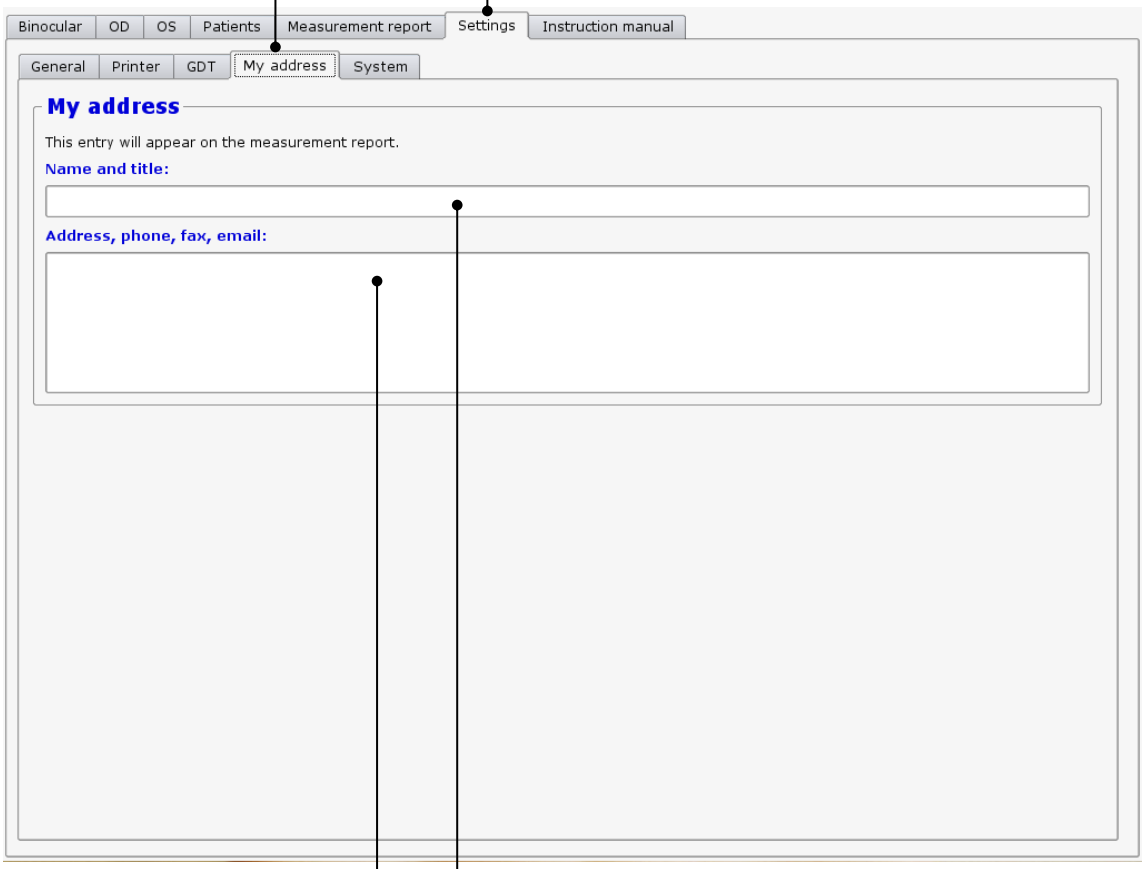
Identifiers for data exchange in the practice software.

Specifications for the GDT-standard is available at: http://www.plusoptix.eu/gdt

4.4 My Address (License Z, optional)

Enter the name, address, telephone, fax and email address of your practice here, to enable the details to appear on the measurement report.

Click on “Settings” and then on "My address".

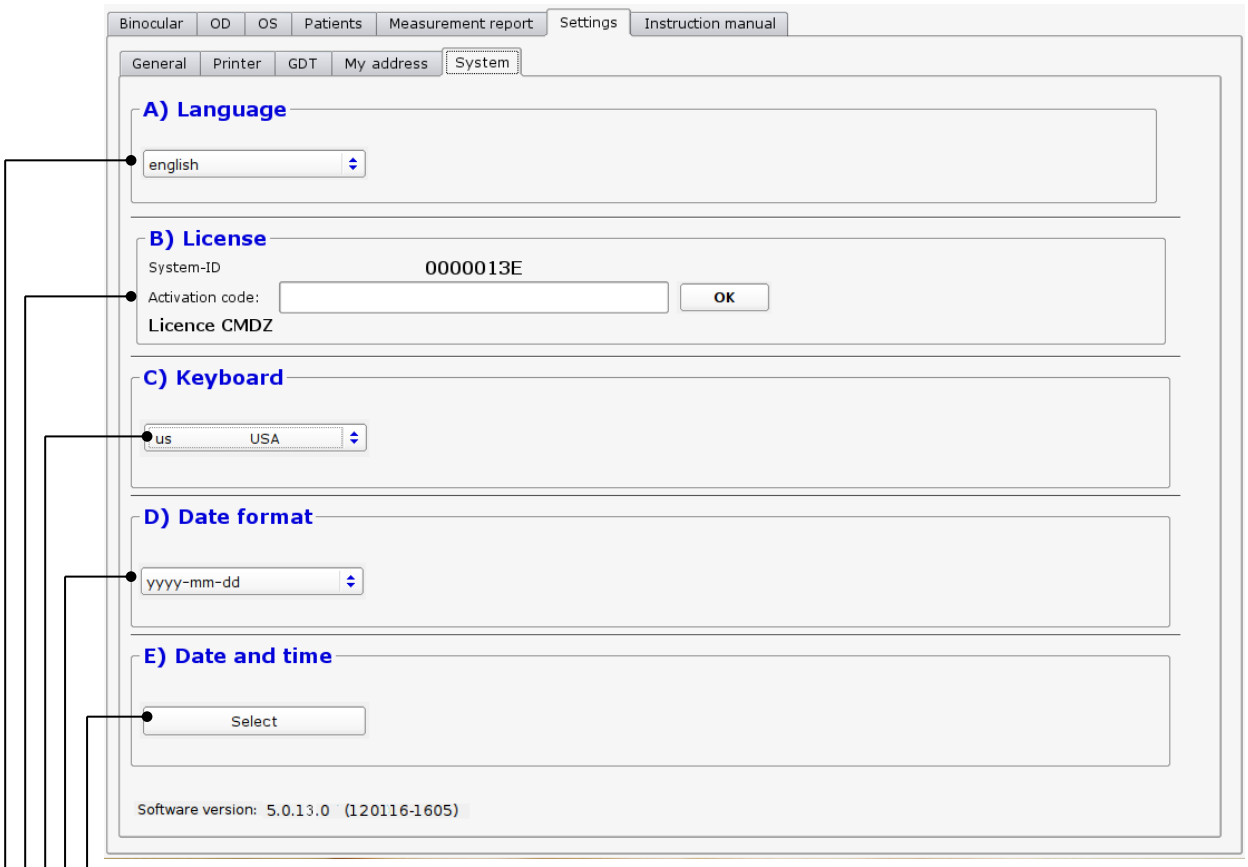


Click here to enter the name of your practice.

Click here to enter the address, telephone, fax and email address of your practice.

4.5 System

The system settings have been carried out by the company you have bought the device from. In case you would like to change some system settings, please proceed as follows:



Click here to set the current data and time of day.

Click here to select the date format for entering the date of birth.

Click here to set the keyboard layout.

Click here to activate additional licenses.

Click here to select the language for the operator interface.

Once you have performed all system settings, click on “Binocular” to return to the start page. You can then begin measurements.

5. Binocular measurement

5.1 Measurement procedure

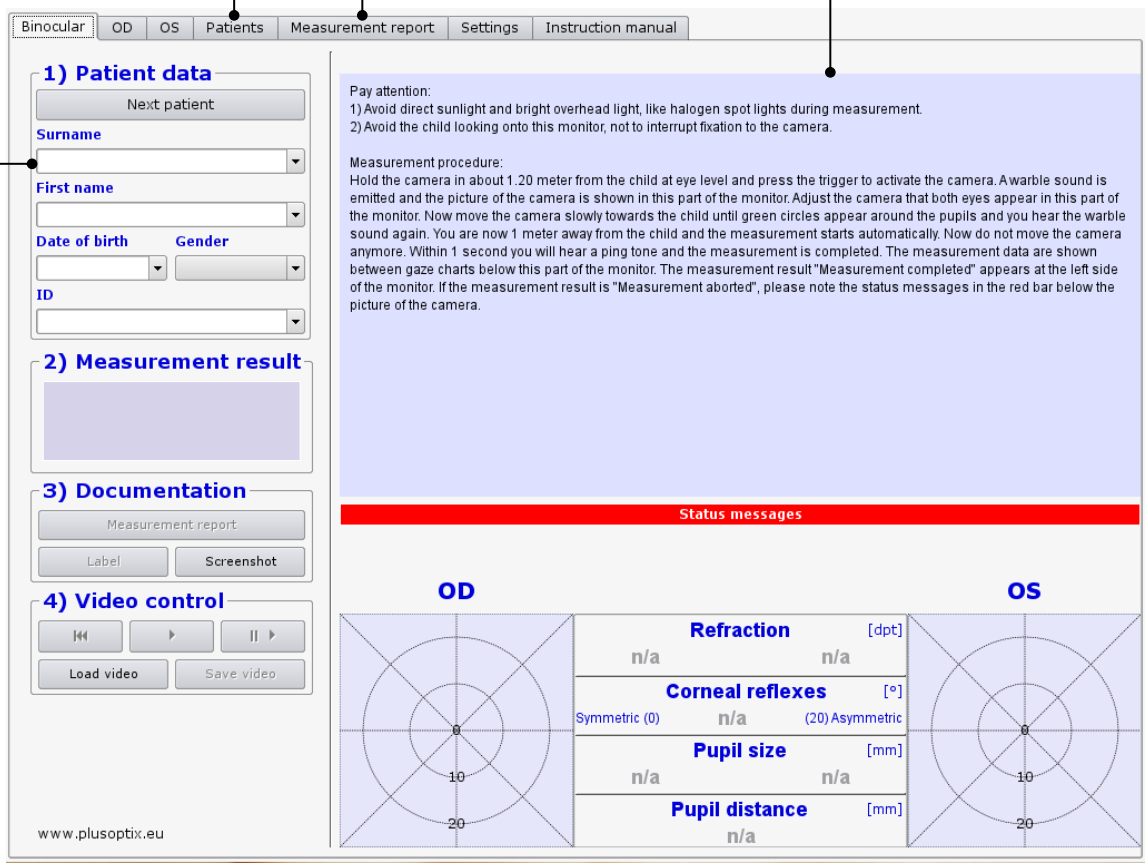
Step 1: If the plusoptiX A09 is not connected to a practice network and the measurement results are to be documented, please enter the patient data. This data should be entered before the child is seated for measurement.

Enter patient data. The following data are valid:
a) Patient data (Surname, first name, date of birth and gender) or
b) Patient data and ID or
c) ID and date of birth

This brief description only appears after the system has been switched on.

Optional

License D License Z

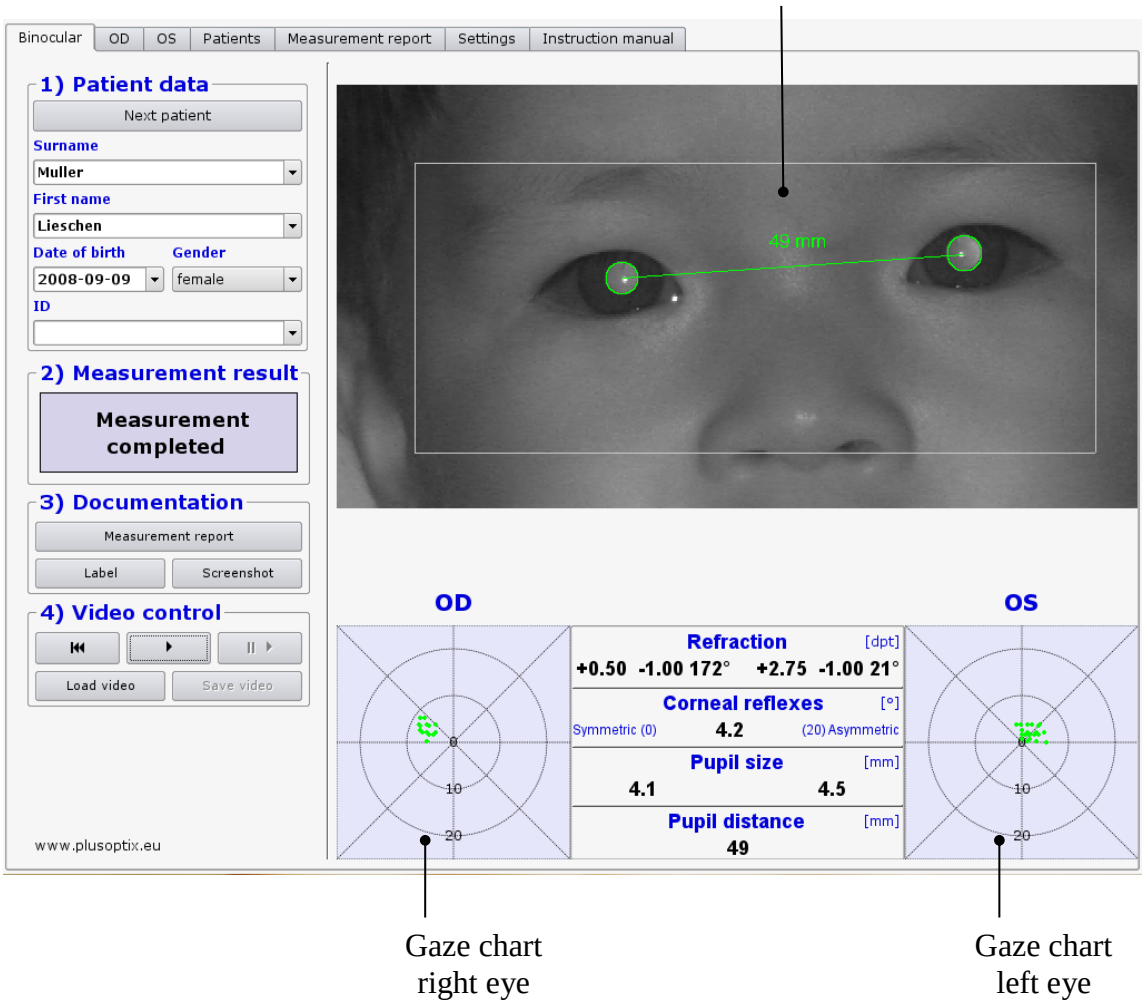


Step 2: Hold the camera approximately 1.20 metres (3.3 feet) away from the child at eye level and start the camera by pressing once on the trigger in the handle. A warble sound can be heard to draw the child's attention to the camera. Avoid the child observing the monitor. The attention span of young children is extremely short. Consequently, distractions during measurement such as the monitor image or other persons in the room should be avoided.

Camera

Note: You can repeat the warble sound as often as required during measurement to attract the attention of the child to the camera once again.

Step 3: Align the child's eyes in the white box on the monitor.



Now move the camera slowly forwards until you can see green circles around both pupils and you hear another warble sound. You are now 1 m from the child; the measurement will start automatically. Do not change the distance after this point. Within one second, a ping tone will signal the end of measurement. The measurement values will be displayed between the gaze charts, and the measurement result "measurement completed" appears at the left side of the screen.

Note: If the measurement result "Measurement aborted" appears, the following could be the cause:

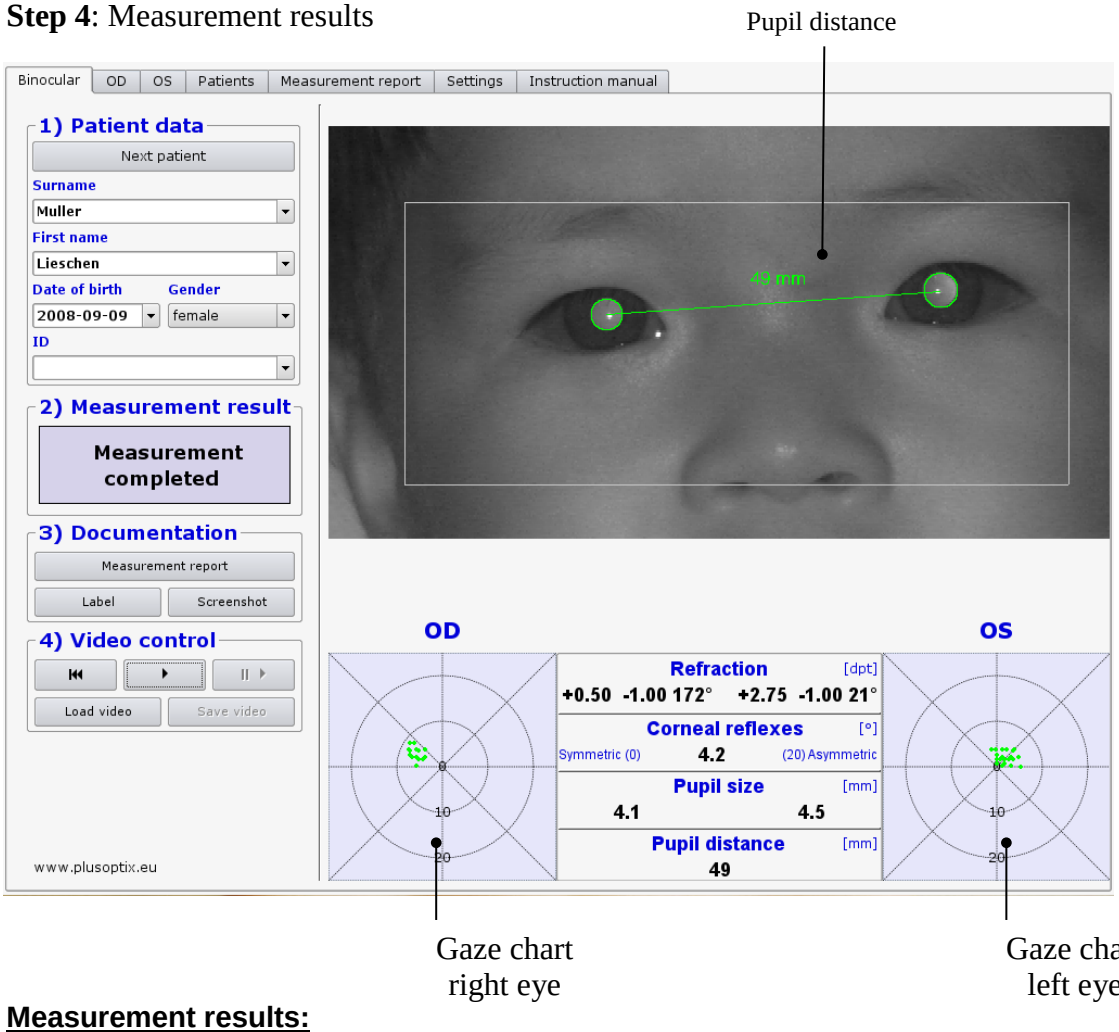
1. A white square around the pupil is a sign that the measurement distance of 1m ± 5cm was not adhered to. Use a tape measure to check the distance to the child and then start measurement again.
2. A red edge around the pupil is a sign that the pupil is too small. Reduce the light in the room to allow the pupils to dilate and repeat the measurement.
3. If the plusoptiX A09 does not find the pupils within 20 seconds, the measurement procedure is automatically terminated. The most common reasons for this are:

a) One or both pupils are not completely displayed on the screen, e.g. eyelashes or the eyelid is partially occluding the pupil. The mother should lift the child's eyelid gently. Repeat the measurement.

b) If the corneal reflexes appear on one gaze chart as red point clouds and on the other as green point clouds, the asymmetry of the corneal reflexes is ≥ 10 degrees. In this case, it is not possible to perform a binocular measurement. You can however measure the eyes individually (see 6. Monocular measurement).

c) One or both pupils show different brightness patterns. This indicates media blurring, corneal damage, a foreign particle or other reasons.

Step 4: Measurement results



Measurement results:

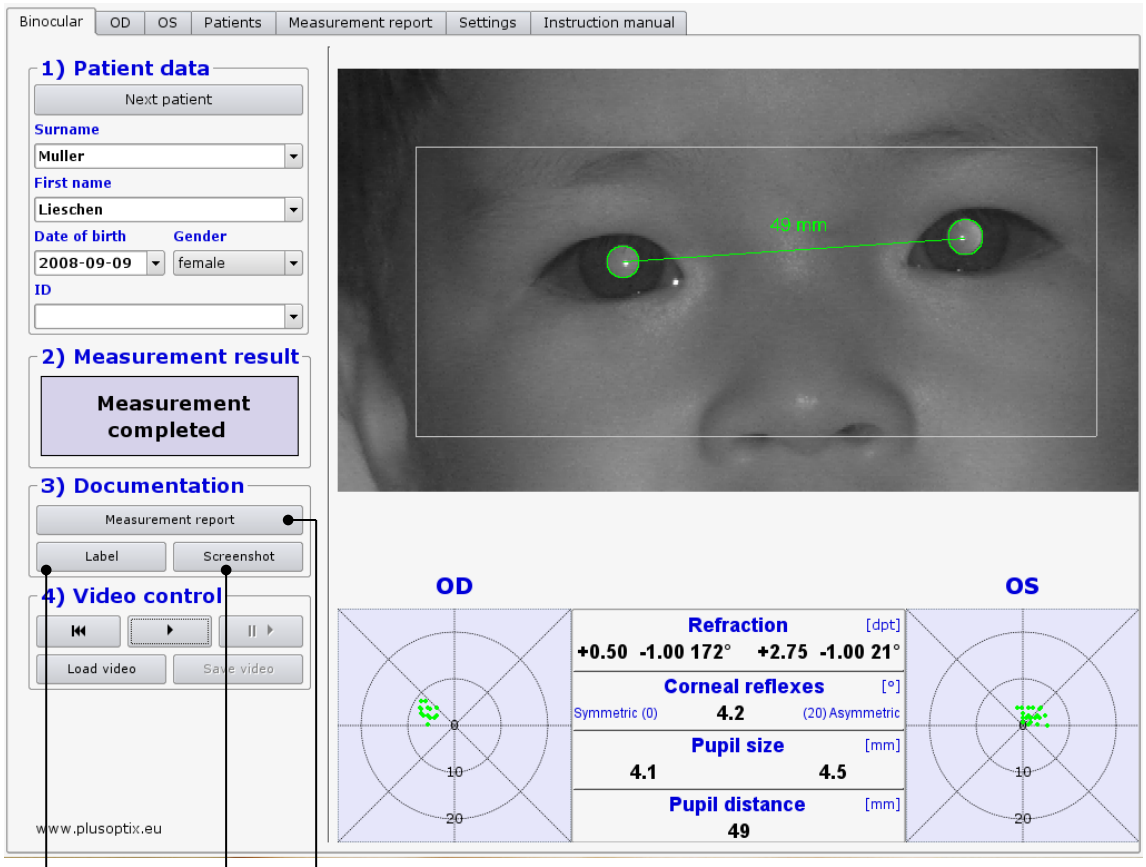
Refraction:	- Sphere [dpt] - Cylinder [dpt] - Axis [°]
Corneal reflexes:	Symmetry of corneal reflexes [°]
Pupil diameter:	Average [mm]
Pupil distance:	PD [mm]
Gaze chart:	Position of corneal reflexes in relation to pupil centre [°]

5.2 Documentation

The following documents can be printed:

- Measurement report (measurement results with comments)
- Measurement results on self-adhesive label
- Screenshot

To print one of these documents later, videos must be saved to archive the data. To do so, see chapter 5.4 Storing a video and 5.5 Loading a video.



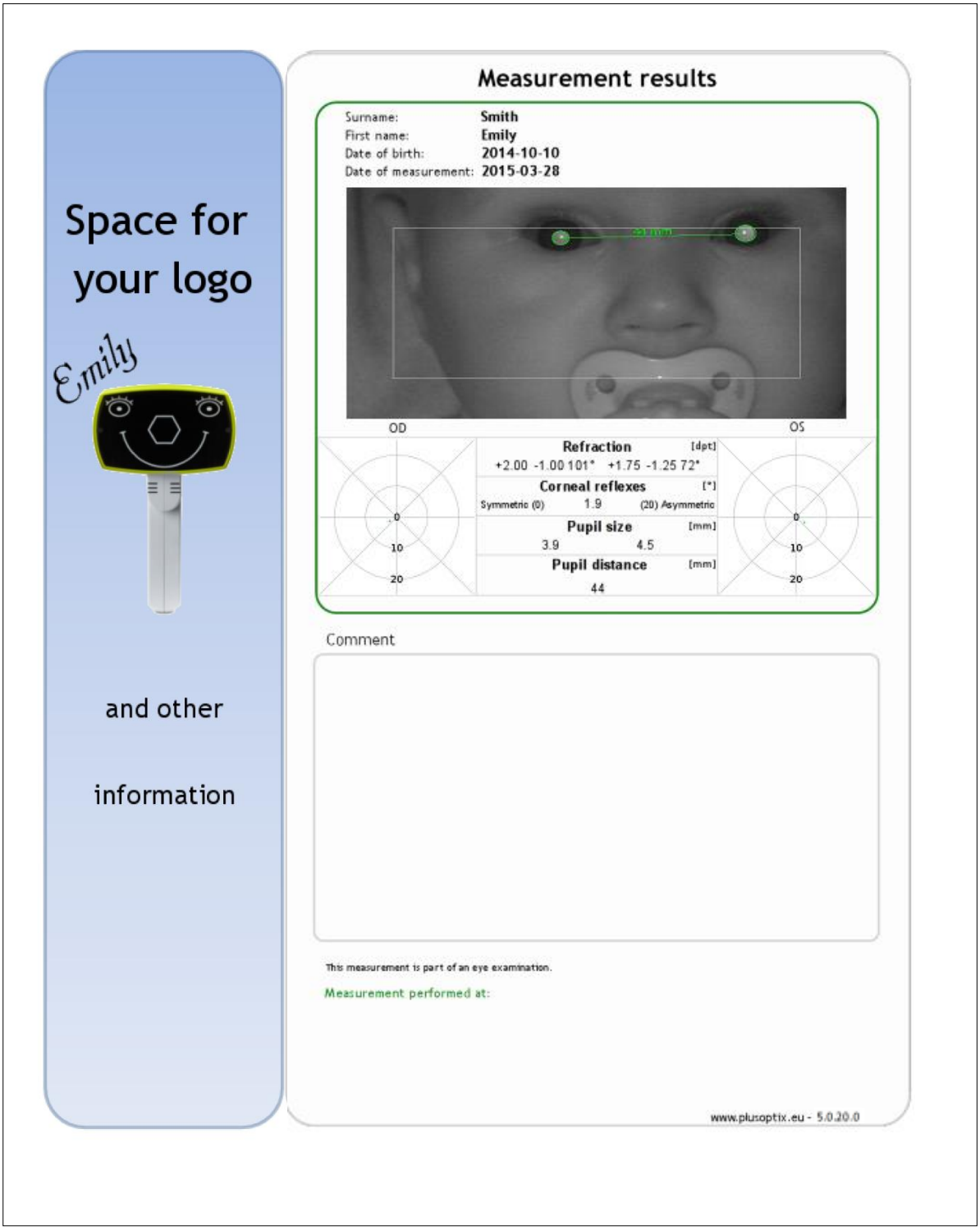
Click here to print the measurement report with the measurement results and your comments (optional, License Z).

Click here to print a screenshot.

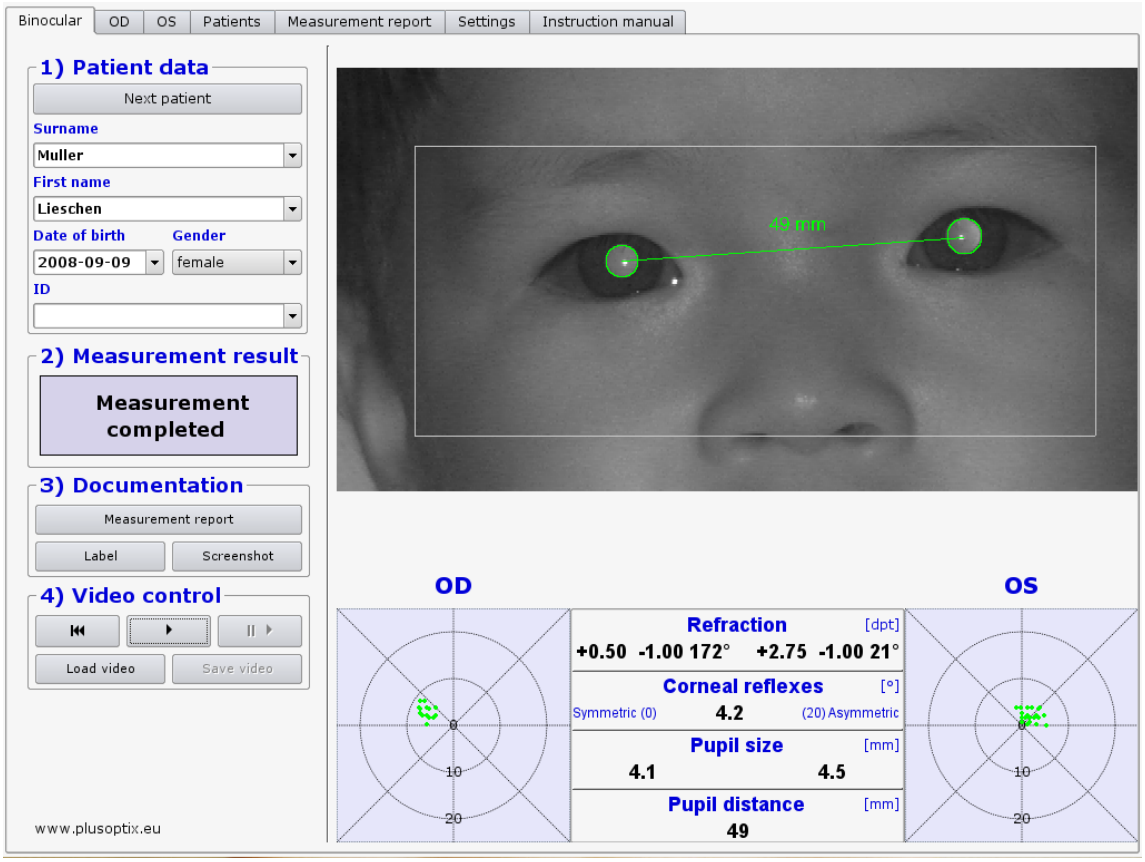
Click here to print a self-adhesive label for the patient record.

Examples of a measurement report, a screenshot and a self-adhesive label can be found on the following pages.

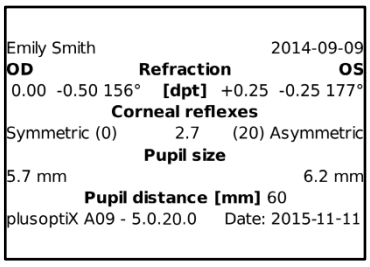
Measurement report (A4 and letter format)



Screenshot



Self-adhesive label



Printer: Dymo Label Printer

Label Size 54 x 25 mm, Order no. 11352 (Europe), order no. 30336 (America)

Note: The order no. can differ in your country.
Check it on: http://sites.dymo.com/pages/CountrySelector.aspx

5.3 Viewing the video of the last measurement

You can view the video in individual images directly after measurement to:

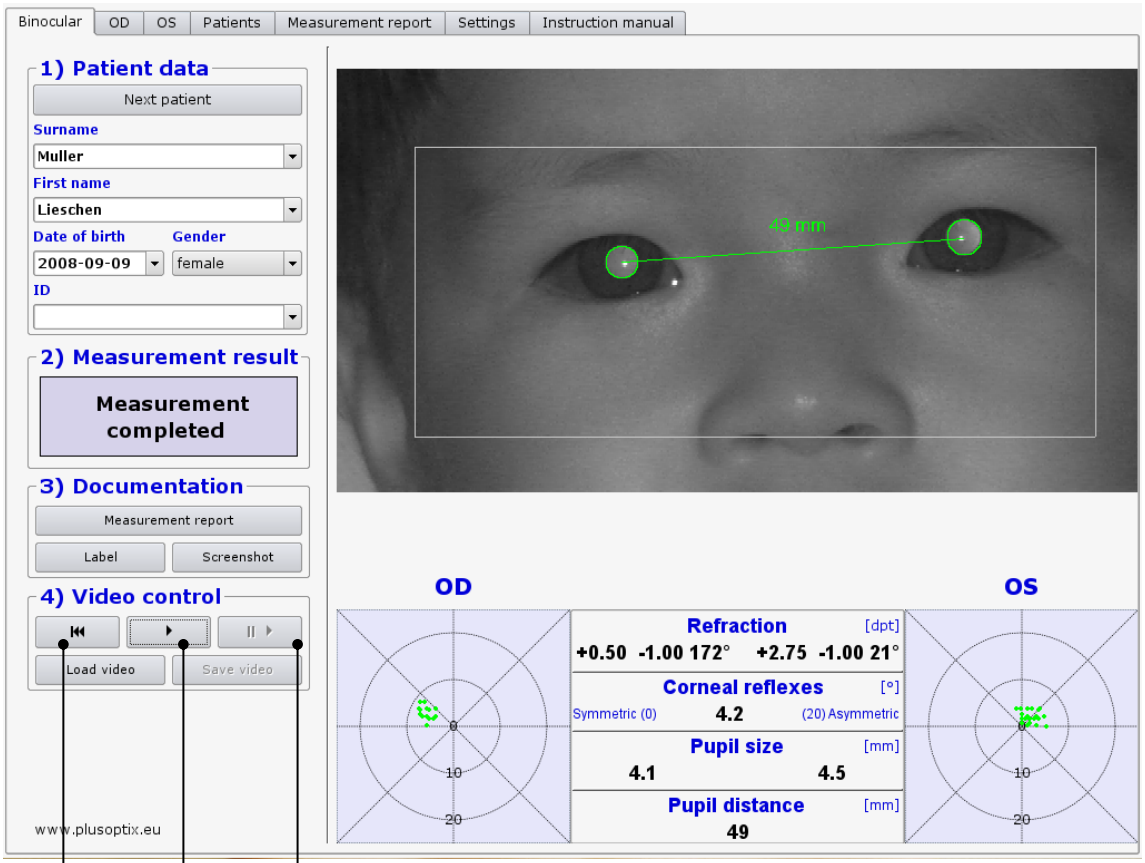
a) Detect media blurring

b) Detect strabismus in false colours

c) Trace eye movements

d) Test the infrared component in the room

To redisplay the measurements, the video must be replayed in real time again.



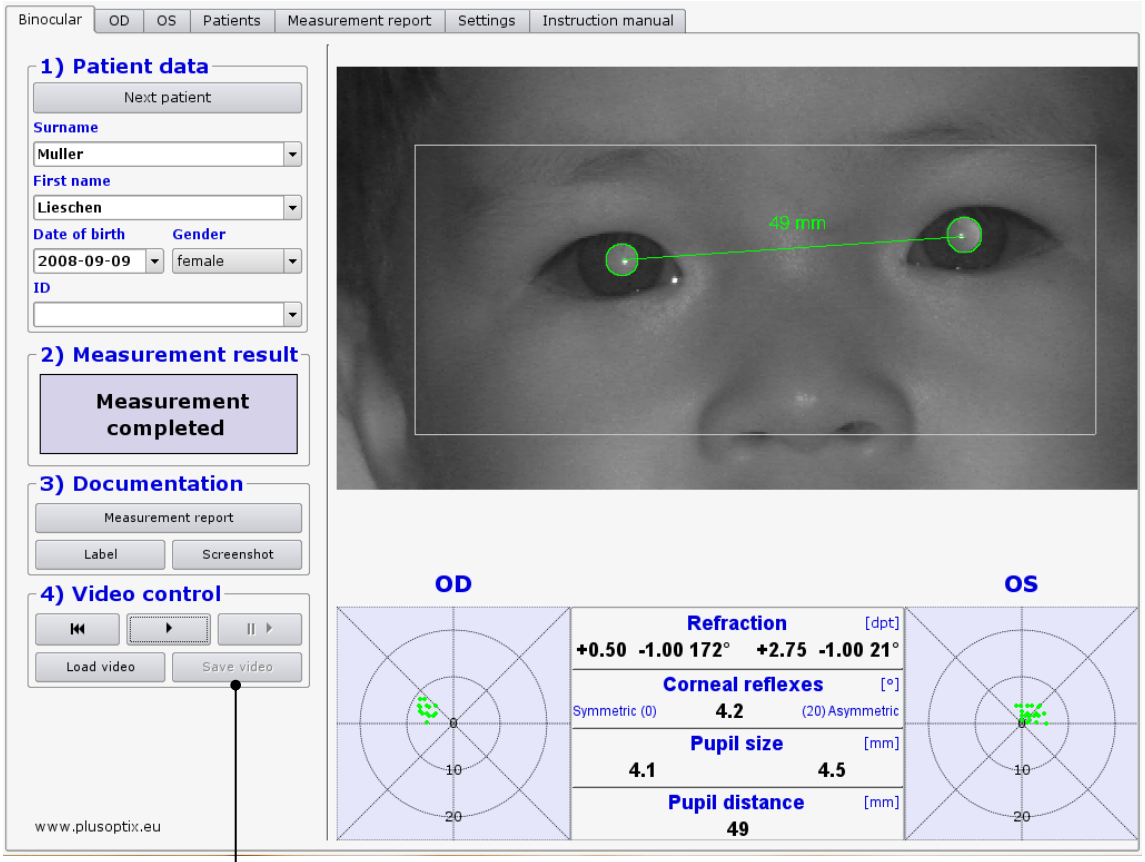
Click here to play back the video of the measurements in individual images. The available measurement values from each image are displayed on the screen.

Click here to play back the video of the measurement in real time.

Click here to rewind the video to the beginning.

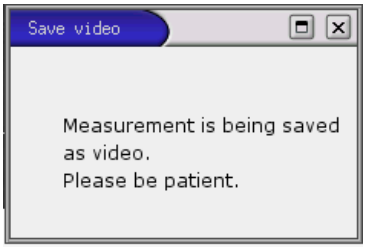
5.4 Storing a video

Videos are not stored in the plusoptiX A09, but are rather overwritten by the next measurement. If a measurement indicates particular issues such as media blurring, the video can be stored directly after the measurement on a USB stick or an external hard drive with a maximum current consumption of 0.5 A. To do so, insert a USB stick into one of the free USB ports on the plusoptiX A09 and proceed as follows:



1. Wait after insertion of the USB stick approx. 5 seconds until the "Save video" button becomes active.

2. Now click on "Save video". The "Save video" window appears on the monitor. The video is automatically stored on the USB stick and afterwards the window disappears again.



3. The "Save video" button will become active again after you perform the next measurement.

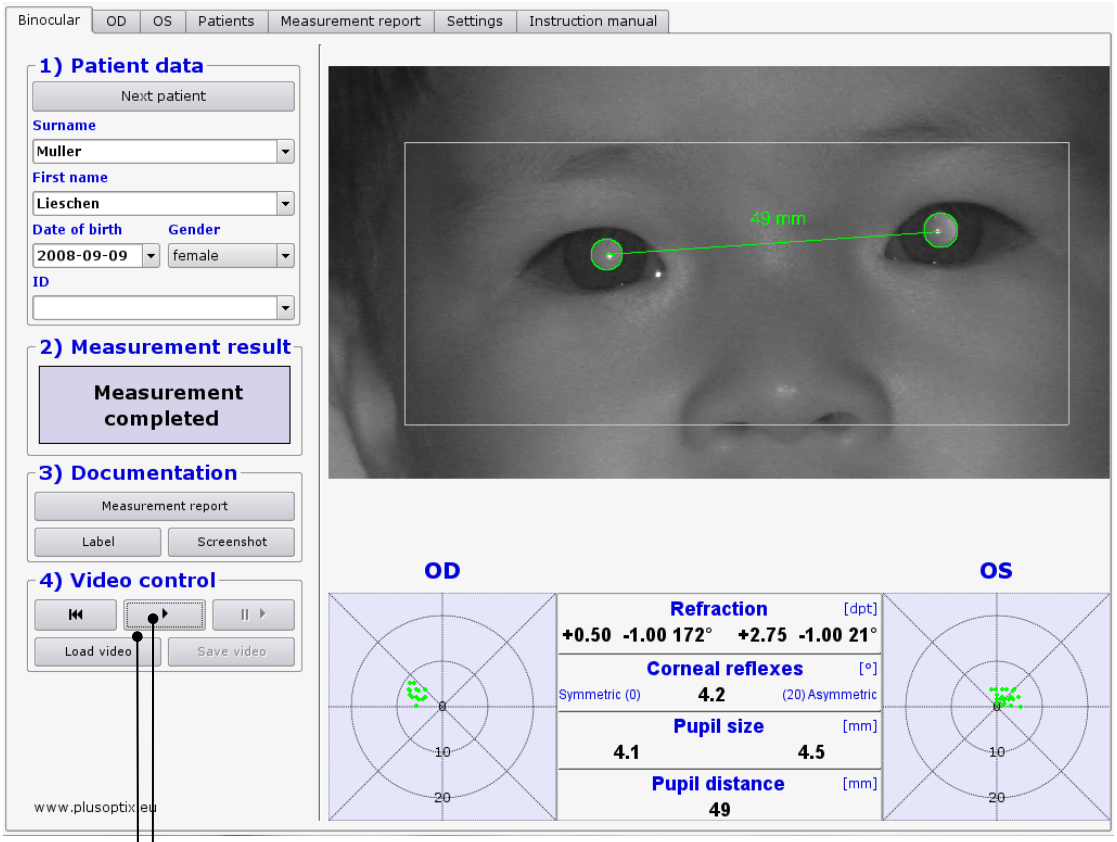
Replaying of the saved videos is only possible with the plusoptiX A09 (see 5.5 Loading a video).

Is there not enough storage space on the inserted USB-stick, following window appears:

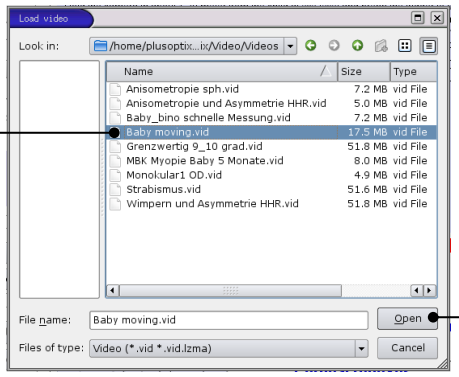
Click on “OK” and remove this USB-stick.
Take a new, empty USB-Sick and insert it into the plusoptiX A09 and click again on “Save video”, to save the video.
Keep the USB-stick to save the data, in case you would like to print out a document, like a measurement report, again.

5.5 Loading video

The plusoptiX A09 allows you to load videos directly from a USB stick and to view them. You can only play back videos that have been recorded and stored using the plusoptiX A09. To do so, insert a USB stick or an external hard drive with a maximum current consumption of 0.5 A into one of the free USB ports on the plusoptiX A09 and proceed as follows:



1. Wait after insertion of the USB stick approx. 5 seconds until the “Load video” button becomes active.
2. Now click on “Load video”. The window containing the available videos opens.



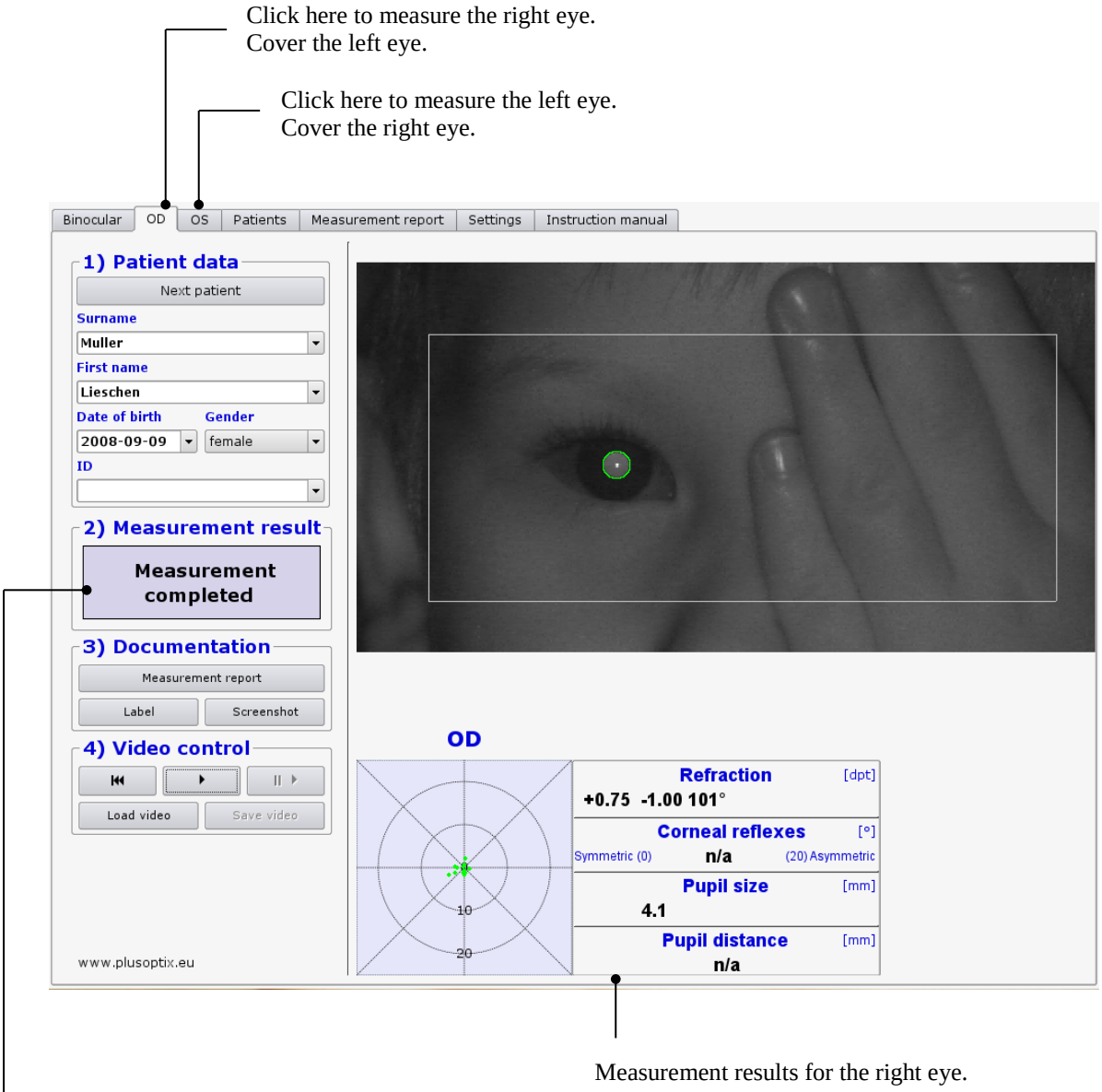
3. Select the video that you wish to play back and click on “Open”.
4. Click here to play the loaded video.

Do you replay a stored video, documents like a measurement report or a screenshot can be printed again.

6. Monocular measurement

Patients displaying asymmetric corneal reflexes ≥ 10º cannot be measured binocularly.

The monocular measurement function “OD” and “OS” allow you to measure each eye individually. The measurement is performed as for binocular measurement (see 5.1 Measurement).



Where the measurement system finds two pupils, the measurement is cancelled and “Measurement aborted” is displayed as the measurement result. In addition, the status message “Monocular: cover OD or OS” appears below the video image.

7. Switching off the system

First switch off the plusoptiX A09 using the on/off switch, followed by the monitor.

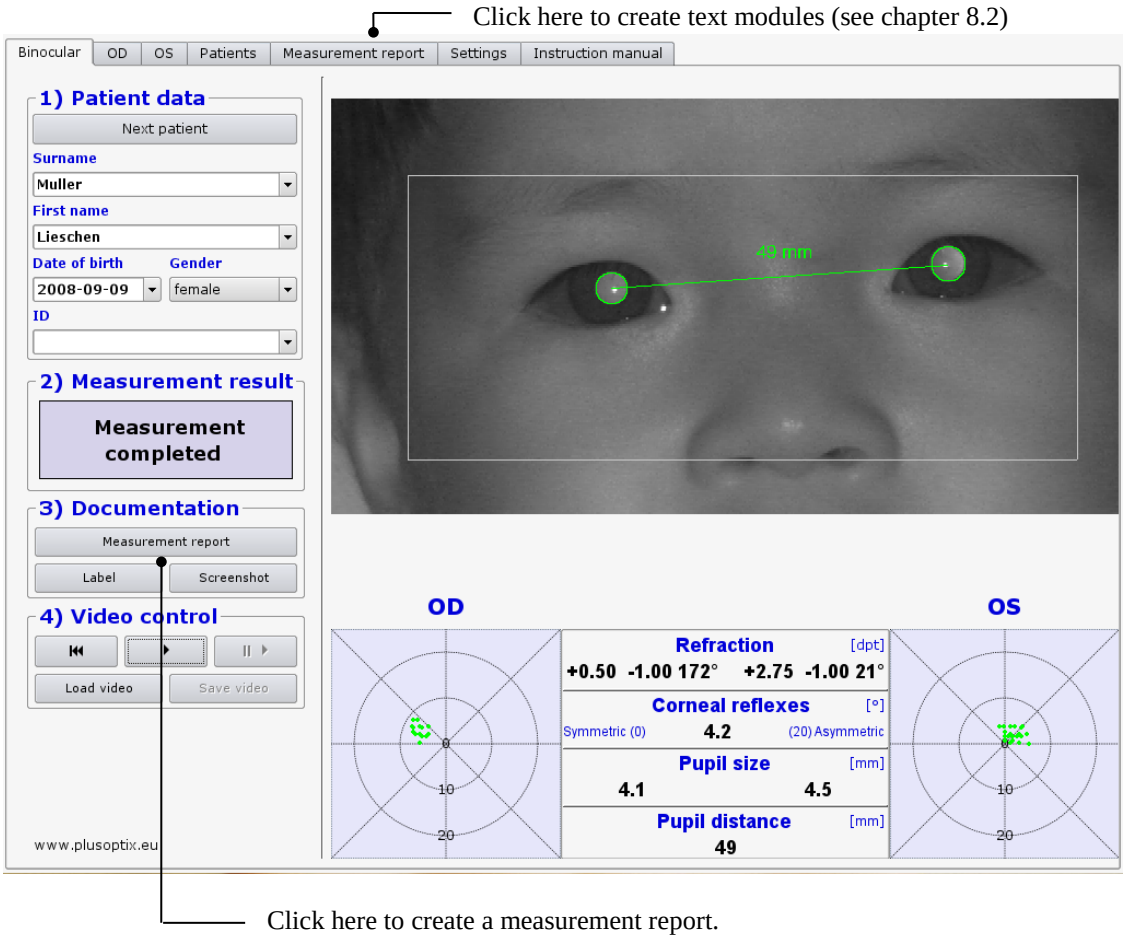
The on/off switch on the plusoptiX A09 flashes after switch-off until the program has been shut down completely.

If you are using a multiple socket outlet make sure that it is child-proof.

At the end of business day the monitor and the medical power unit must be separated from the power supply or you have to switch off the on/off switch at the multiple socket outlet. This is a precaution in case a short-circuit occurs during night-time which may cause a fire.

8. Printing the measurement report (License Z, optional)

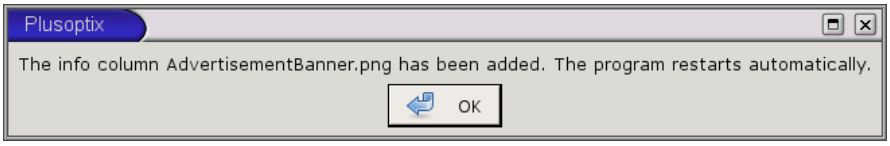
Is a printer installed and connected, the measurement results can be printed together with your comments. The comments can be stored as freely editable text modules.



8.1 Adding an info column

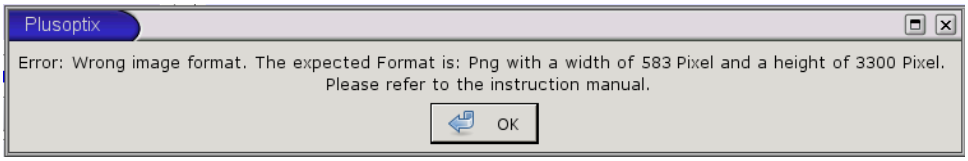
You can add a personal info column on the left side of the measurement report. To create the info column you need a computer and a graphic software or you authorize an illustrator to do this.
Note:

1. Create your information (text and images) with any graphic program in an exact dimension of 3.300 x 583 pixels.
2. Store this information as an image on the supplied USB stick. The name of the image may not contain any diacritical marks and must have a suffix of .png.
3. Switch on the plusoptiX A09 and wait until the start page appears.
4. Insert the USB stick into the plusoptiX A09. Following window appears.

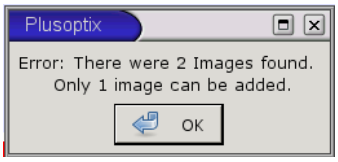


   Click on “OK”. The program restarts automatically.
5. Remove the USB stick.

Following error messages can occur inserting the info column:

1. 

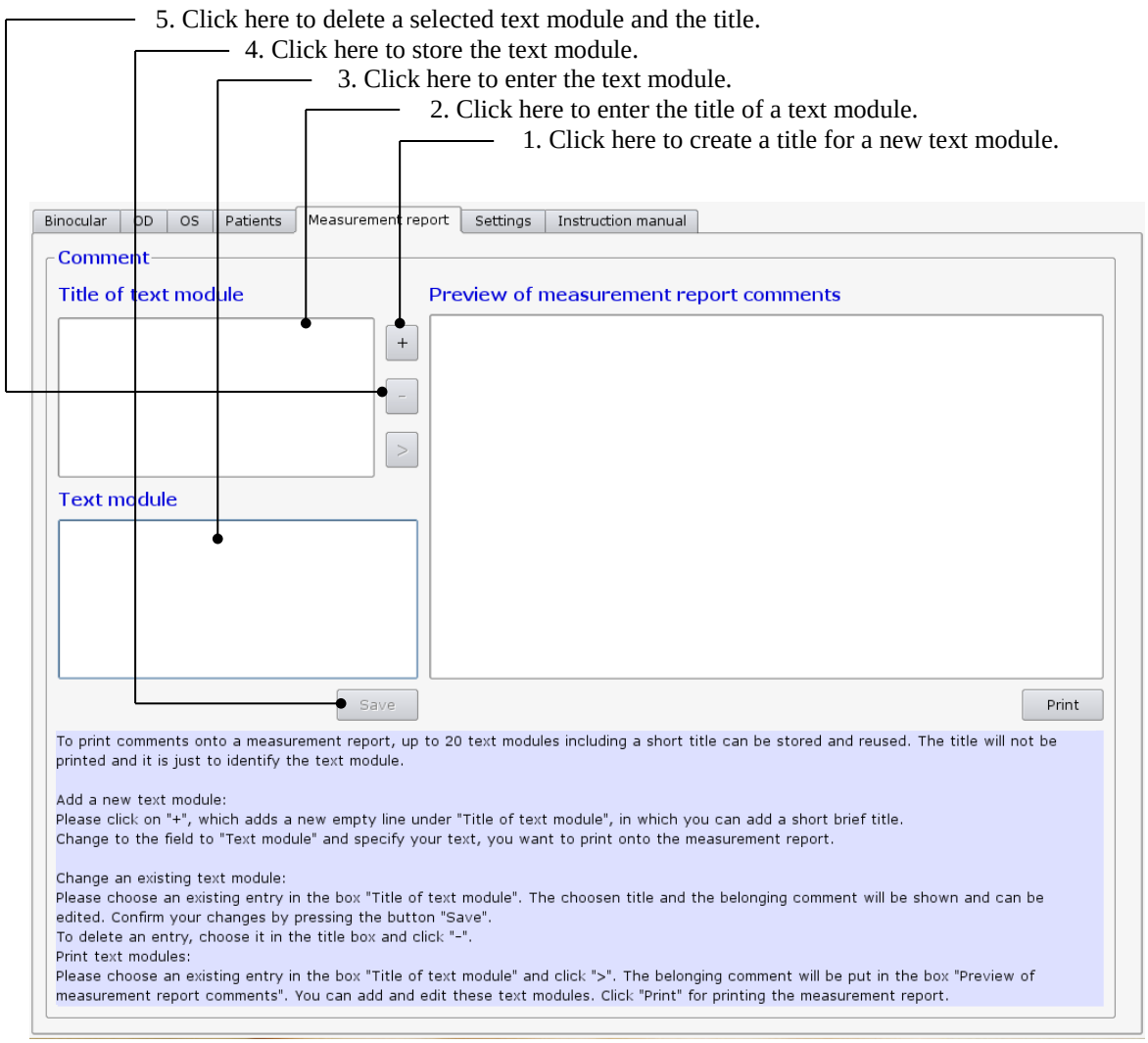
   The size of the inserted picture is not 3.300 x 583 pixels. Click on “OK” and change the size of your picture into the requested one.

2. 

   Two pictures are stored on the USB stick. Click on “OK” and remove one.

8.2 Creating text modules

You can enter a maximum of 20 different text modules. To do so, proceed as follows:

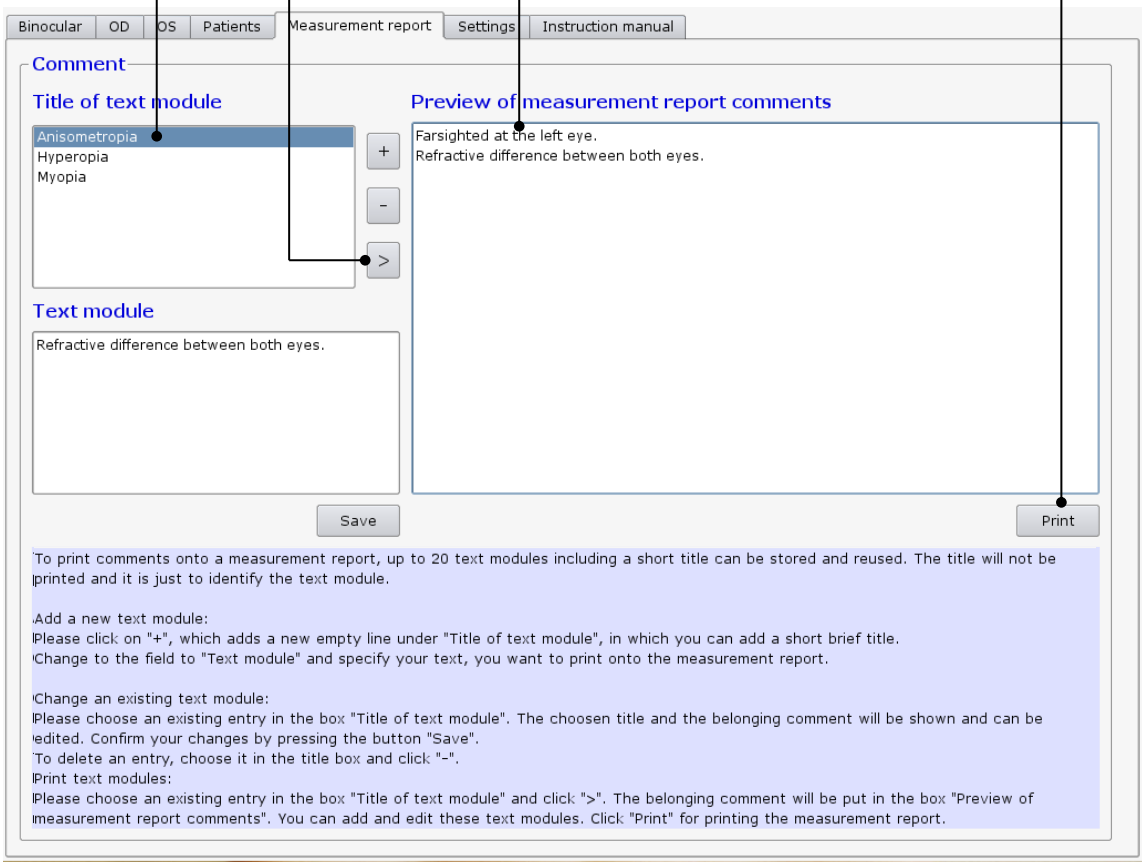


The title of the text modules is used only to call up the corresponding text module, and is not printed with the measurement report.

8.3 Printing the measurement report

You can add different text modules to the measurement report as comments and edit these before printing. To do so, proceed as follows:

1. Click here to select a text module to be printed on the measurement report.
2. Click here to transfer the selected text module to the field “Preview of measurement report comments”.
3. Click here to change the text.
4. Click here to print the measurement report with the comments.



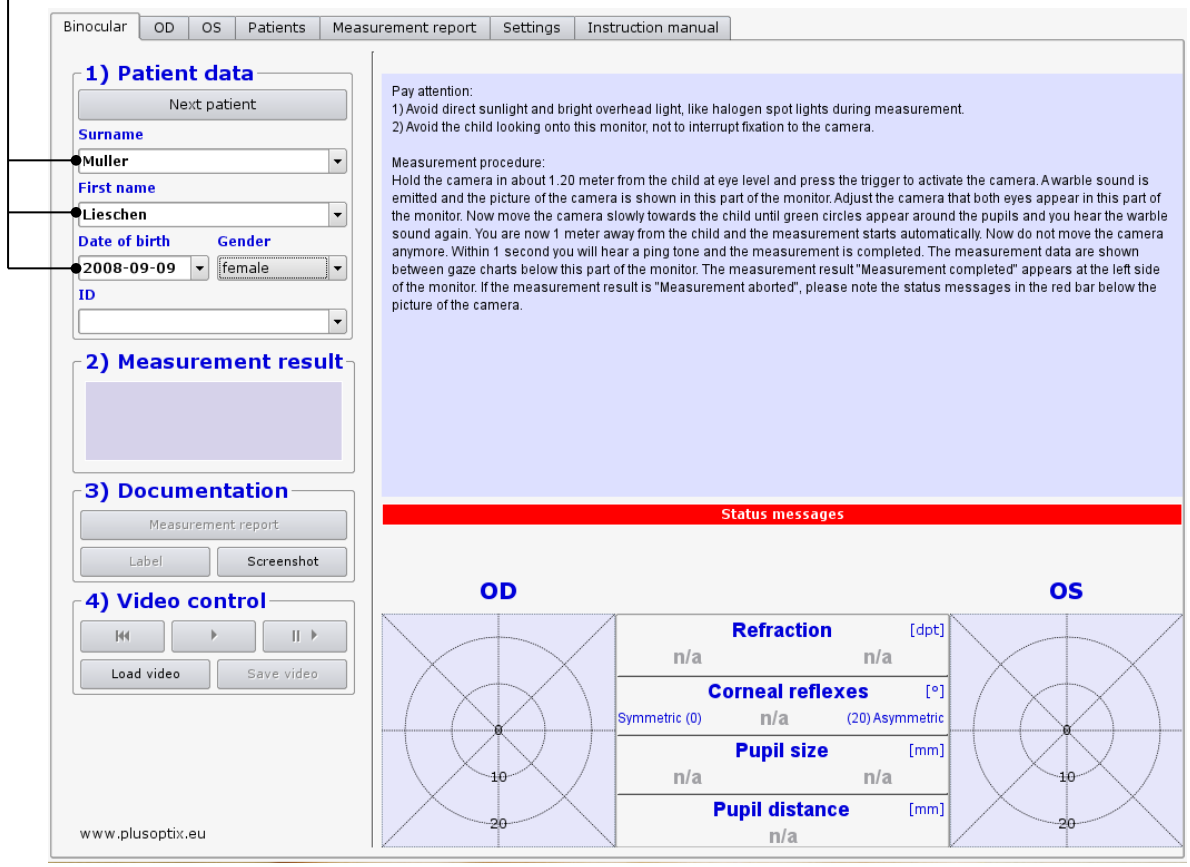
9. Patient database (License D, optional)

The patient database is an alternative to a practice network. You can use the database to store patient data and measurement results, and to compare measurement results with previous ones.

9.1 Entering patient data

Enter patient data. The following data are valid:

a) Patient data (Surname, first name, date of birth and gender) or
b) Patient data and ID or
c) ID and date of birth



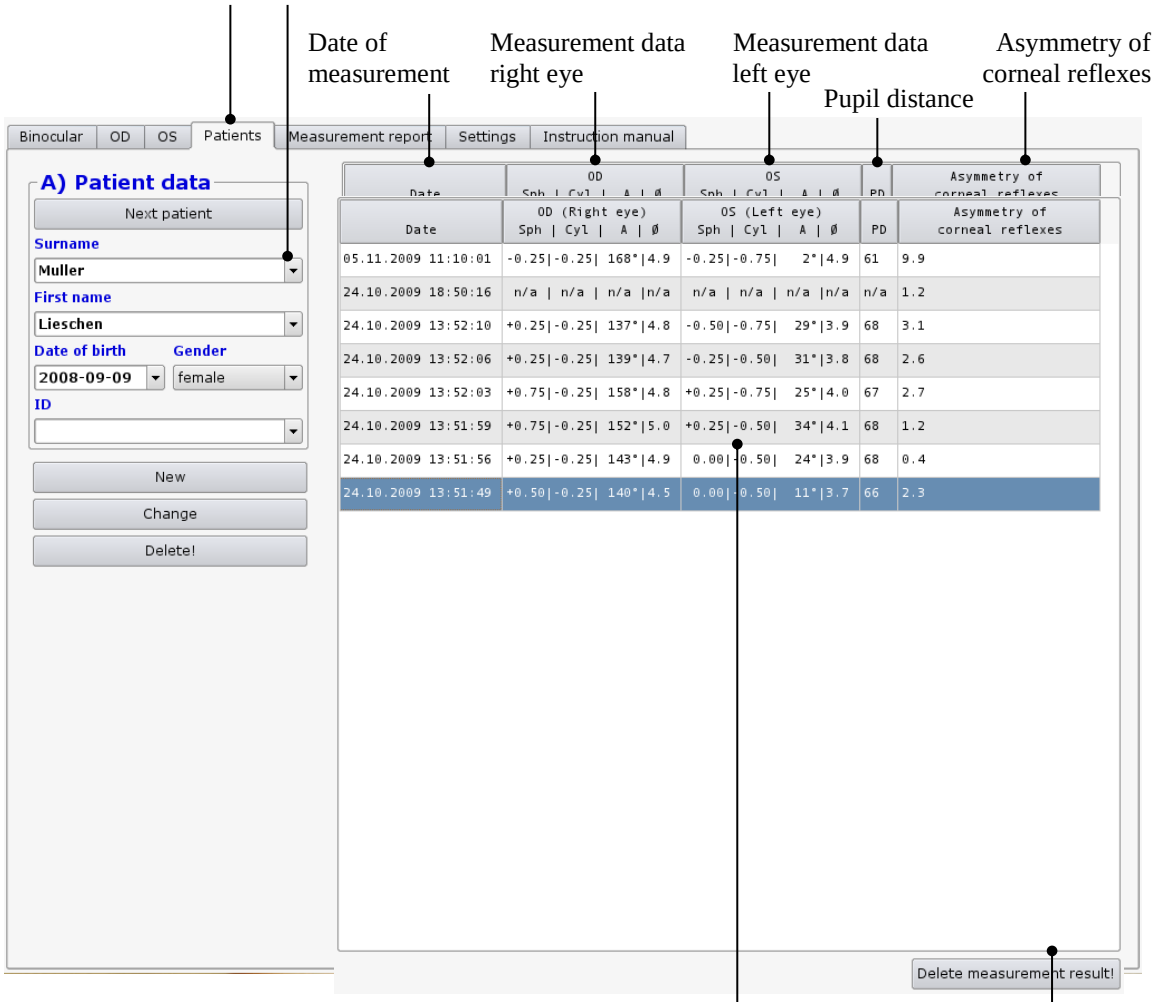
To add a new patient to the database, enter the patient data in its entirety and then perform the measurement. The measurement values will be automatically stored together with the patient data.
If you enter two "John Smith" records with the same date of birth, the ID (patient number or medical insurance number) must also be entered to allow for differentiation.

Note:

- Before measuring a new patient, please do not omit to delete the patient data entered using the key "Next patient" and to enter the data for the new patient or to search the date with the scroll key.
- To select an existing patient, enter the first letter of the patients' name in the surname box (e.g. "S" for Smith). All patients' names beginning with this letter will appear and you can scroll for your patient. The more letters you enter, the faster your search will be (e.g. "Smi").

9.2 Measurement data

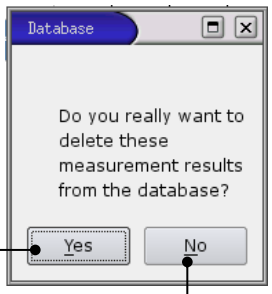
Click on “Patients” and enter the entire patient data or scroll down to the patient to have a look at these existing measurement data. The data are listed chronologically.



If you would like to delete measurement data, proceed as follows:

1. Click on the line you would like to delete. The line will be marked blue.
2. Then click on “Delete!”.

   Afterwards a window with a security query will appear.



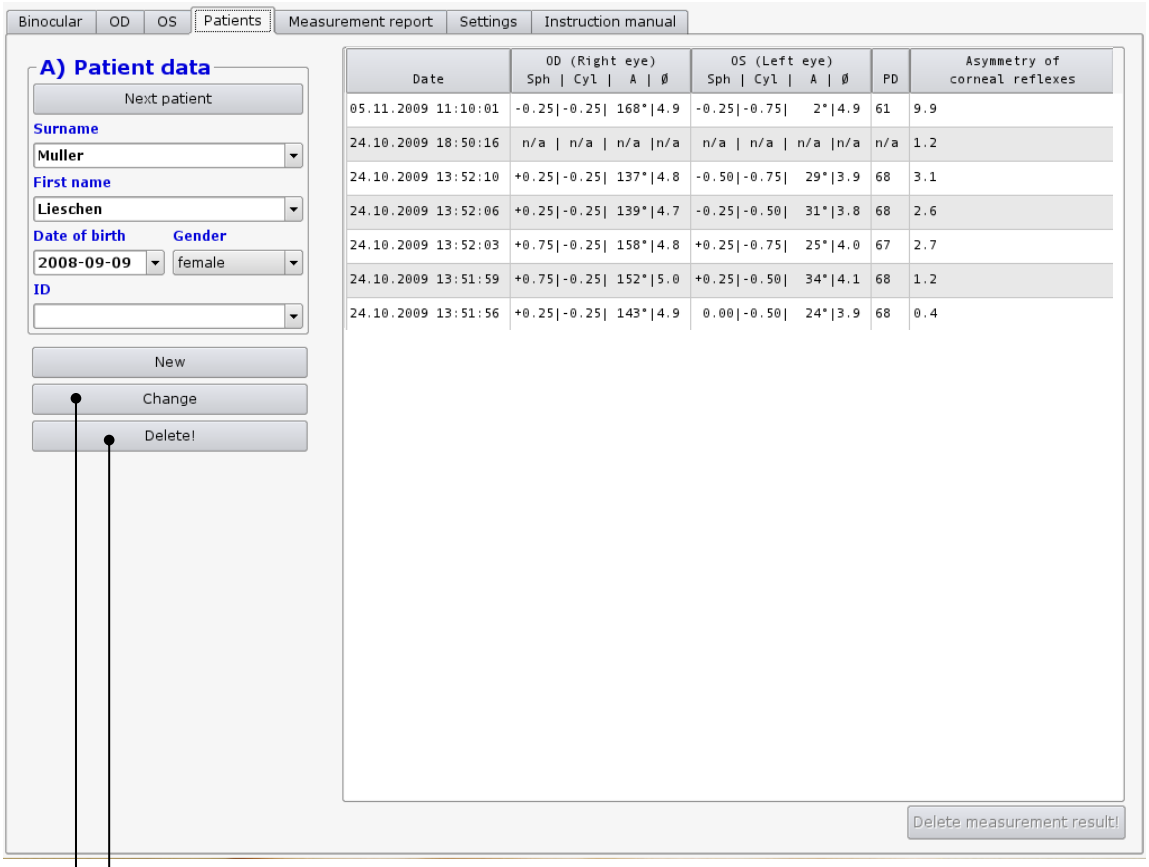
3. Click on “Yes” and the marked line will be deleted.

   If you would like to cancel this procedure, click on “No”.

9.3 Deleting or modifying patient data

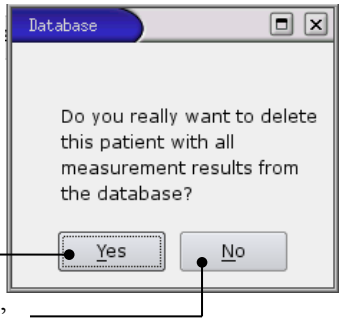
To delete a patient record from the database, i.e. this patient data including measurement results, proceed as follows:

1. Call up the patient to be modified.



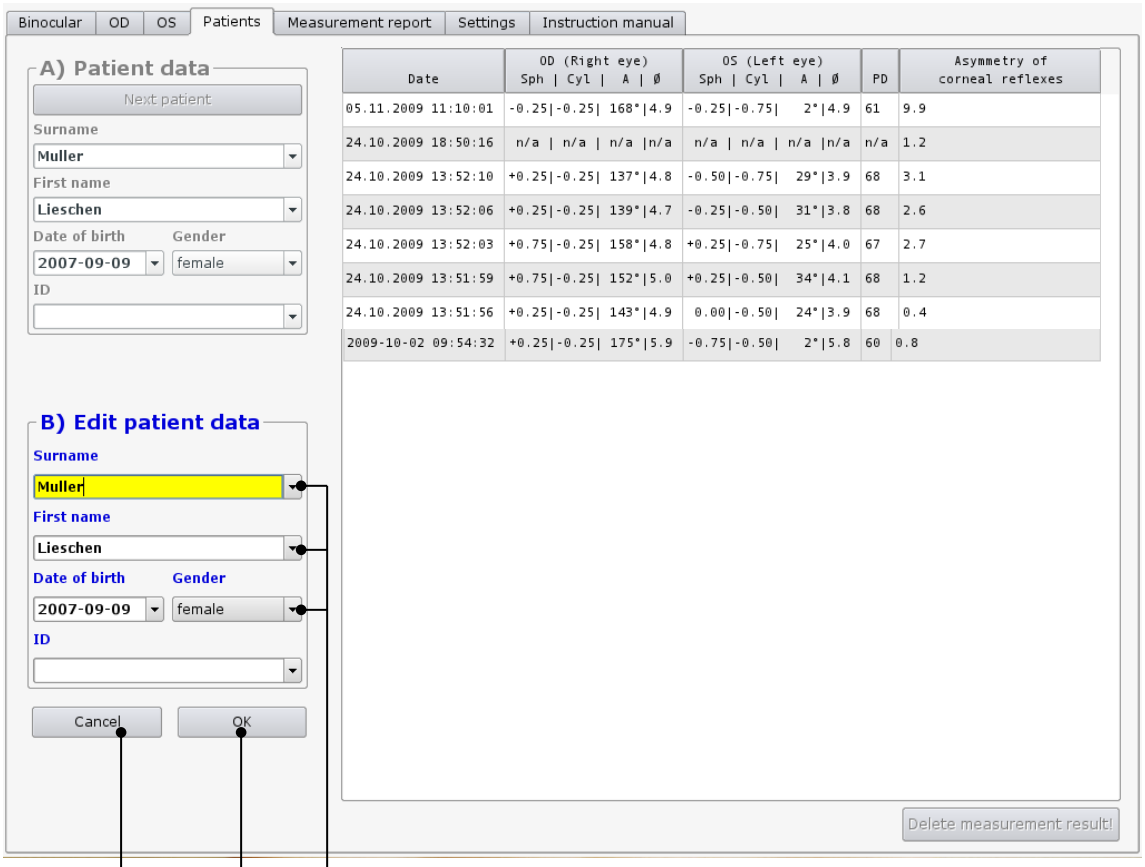
2. Click here to delete the selected patient data record.

Afterwards a window with a security query will appear.



3. Click on “Yes” and the patient data will be deleted.
4. If you would like to cancel this procedure, click on “No”.
5. To modify the patient data record, click on “Change” and a new window will appear “B) Edit patient data”.

The following page describes how you can modify the patient data record.



1. Click here to perform changes.
2. Click here to store changes.

Click here to cancel the procedure.

9.4 Backing up measurement results

The system provides an option to back up the measurements on a regular basis. To do so, insert the supplied USB stick into a free USB port on the plusoptiX A09. The data is automatically saved on the stick. The space available on the stick is sufficient to store about 10 years' worth of data.

Please ensure that you remove the USB stick from the plusoptiX A09 after the back up, as this could lead to problems at boot time.

10. Warranty

The plusoptiX A09 is supplied with a 12-month guarantee, starting from the data of the delivery note.

All work processes at Plusoptix are included in a quality management system, thus providing the highest degree of assurance of error-free materials and workmanship. Should the plusoptiX A09 fail during the guarantee period or the method of operation not be in accordance with the operating instructions, Plusoptix will repair or exchange the system at no charge.

The guarantee is only supplied on new systems that have been sold by Plusoptix or an authorized sales partner of Plusoptix. Systems requiring repair can be returned to the authorized sales partner from whom the system was purchased. Before you return the device, please consider the advices in chapter 12.2 Trouble shooting. The customer is responsible for the transport costs of the system.

Note: A copy of the system delivery note must be included in the transport to ensure the validity of the guarantee claim.

The guarantee will not be provided on systems that have been damaged externally, and will be void in its entirety in the event of improper use, cleaning and transport as well as changes or intervention to the software and usage of the plusoptiX A09 contrary to the instructions. Claims under guarantee will also be void if the system is opened by persons not authorized by Plusoptix.

Note: Software updates during the guarantee period are supplied at no charge.

11. Service and maintenance

11.1 Service

For repairs or guarantee services, please send the plusoptiX A09 system in its original packaging to the company you have bought the device from or to:

Plusoptix GmbH
Service
Neumeyerstr. 46
90411 Nuernberg
Germany
Tel.: +49 - 911 - 598 399 - 20
Fax: +49 - 911 - 598 399 - 90

Plusoptix Inc.
2850 Paces Ferry Road
Suite 440
Atlanta, GA 30339
USA
Tel.: +1 – 800 – 488 - 6436

Note:
- The customer has to bare the transport cost for returning for repair to the company the device was purchased from or to Plusoptix.
- A copy of the delivery note must be attached to the transport for repair in order to prove the validity of the guarantee claim.

11.2 Maintenance

The plusoptiX A09 is maintenance-free. It is recommended that the system be covered with a cloth when not being used. Use only a lightly moist microfibre cloth to clean the system.

1. Do not use sprays, alcohol or other liquids to clean the plusoptiX A09.
2. Please use only a lightly moist microfibre cloth with a little cleaning liquid to clean the front panel of the system.

12. Practical tips

12.1 Measurement results

The major benefit of the plusoptiX A09 is that binocular measurements in miosis in children can be performed from a distance of one meter. Device accommodation is therefore unnecessary, and the measurement is non-stressful for the child, the parent and the examiner. A value of 1.00 dpt is taken into consideration for accommodation in the measurement, at a distance of 1 meter.

1. Myopia and astigmatism

   Neither myopia nor astigmatism is influenced by accommodation. Consequently, these measurement values have a tolerance of ± 0.50 dpt in 80% of cases and a tolerance of max. ± 1.00 dpt in the remaining 20% of cases, in comparison to retinoscopy in mydriasis.

2. Anisometropia

   Regardless of the accommodation status, an anisometropia can be detected with certainty, as both eyes are measured simultaneously (binocular).

3. Small-angle squint

   During every measurement, the corneal reflex for both eyes is displayed simultaneously. Where the corneal reflexes are asymmetric, the possibility exists that the child has a squint (Fig. 2). In the case of infants however, asymmetric corneal reflexes can also be measured by a fixation that is not yet fully developed. Due to the camera resolution and the measurement distance, asymmetries of less than 2 degrees cannot be reliably detected.

Fig. 1: Symmetric corneal reflexes

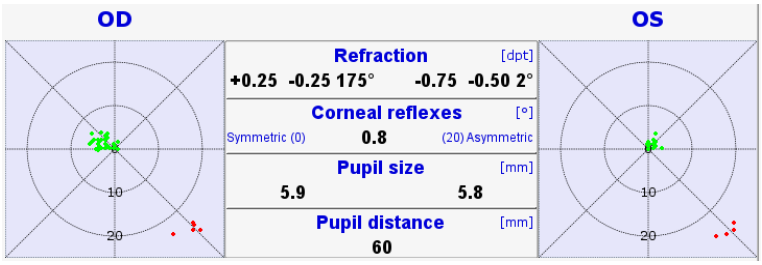
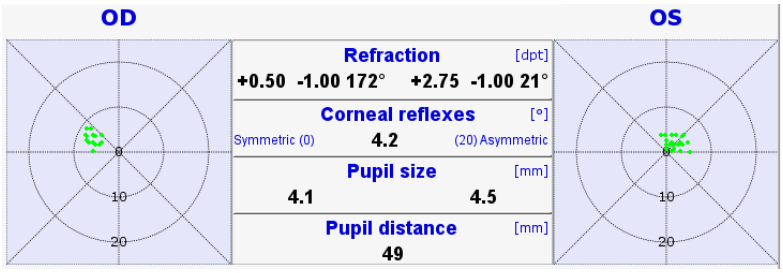


Fig. 2: Asymmetric corneal reflexes



4. Hyperopia

   A hyperopia can be either totally or partially compensated for by means of accommodation. As a result, a measurement in miosis does not provide exact values, respectively an existing hyperopia can be considerably underestimated. Regardless of this, a higher hyperopia can however possibly be detected in children older than 2 years by means of a measurement using +3.00 dpt lenses.

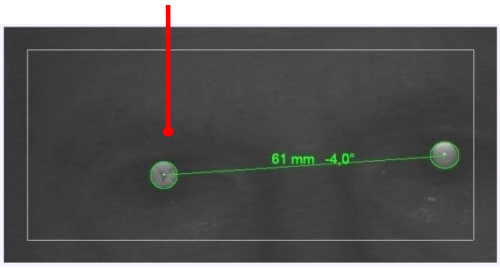
   Examples:

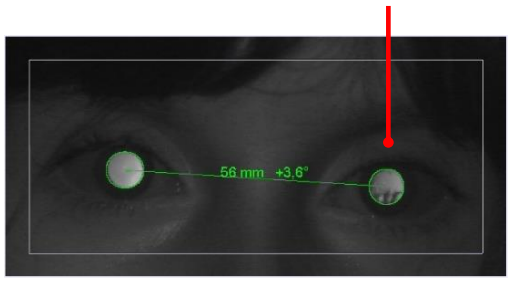
1st measurement value without lenses	2nd measurement value with +3.00 dpt lenses	Explanation
+0.75 dpt	+0.75 dpt	Accommodation of 3.00 dpt or more during the first measurement; the child has a hyperopia of +3.75 dpt or more.
0.00 dpt	-1.00 dpt	Accommodation of at least 2.00 dpt during the first measurement; the child has a hyperopia of at least +2.00 dpt.

   Measurement using +3.00 dpt lenses is not possible in children under two years of age These children can also be measured in cycloplegia with the plusoptiX A09, as the pupils are generally not larger than 8 mm. Note that 1.00 dpt must be subtracted from the spherical measurement values, as a value of 1.00 dpt is included in the measurement values for accommodation in miosis, at a distance of 1 metre.

5. Media blurring

   Where different brightness structures or black dots are detected in the pupils, media blurring, a foreign particle or corneal damage is indicated. The following images show clear cataract-like structures.





6. Nystagmus

   The plusoptiX A09 can be used to measure nystagmus in children in most cases, as the determination of refraction is performed at 50 Hz, i.e. every measurement is performed at 20 ms.

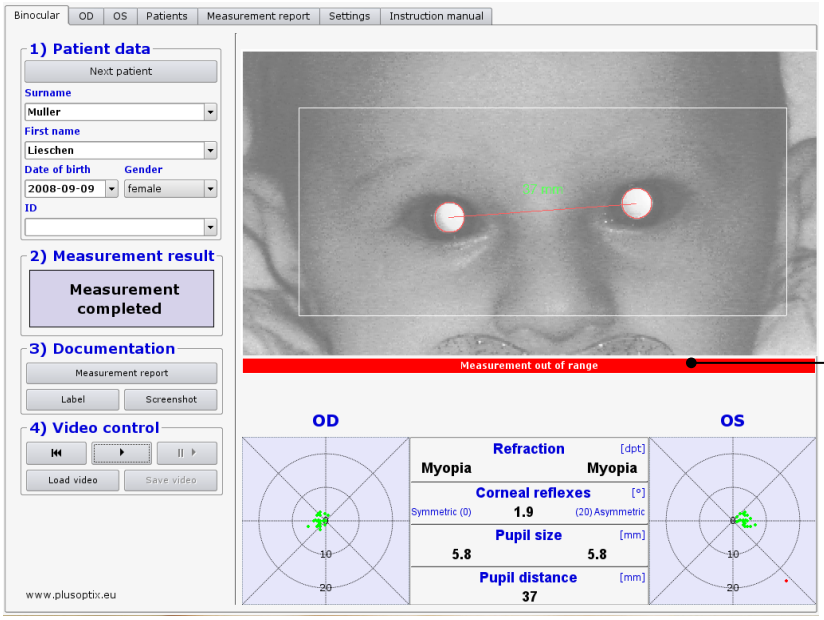
7. Anisocoria

   An anisocoria can be detected, as the plusoptiX A09 also indicates the pupil diameter of both eyes.

8. Measurement range

The measurement range of the plusoptiX A09 is between -7.00 dpt and +5.00 dpt and is based on the spherical equivalent of the measurement result. This measurement range can be extended by a max. ± 3.00 dpt by using flippers with plus or minus lenses.

9. Status messages



Status messages

Pupils not found	The plusoptiX A09 was unable to find pupils within 20 seconds. Restart the measurement procedure and ensure the correct distance to patient.
Pupil too large	One or both pupils are larger than 8.00 mm. Increase the lighting in the room to contract the pupils.
Pupil too small	One or both pupils are smaller than 4.00 mm. Decrease the lighting in the room to dilate the pupils.
Infrared noise	Infrared component in ambient light is too strong. Avoid direct sunlight and switch off "warm" light sources such as halogen or incandescent lamps.
Measurement out of range	If the spherical equivalent is ≥ +5.00 dpt the measurement value shows "Hyperopia". The child is very far-sighted. If the spherical equivalent is ≥ -7.00 dpt the measurement value shows "Myopia". The child is very short-sighted. In both cases please refer the child to an eye specialist.
Monocular:Cover OS!	In monocular mode, only one eye can be measured. Cover the patient's left eye.
Monocular: Cover OD!	In monocular mode, only one eye can be measured. Cover the patient's right eye.

12.2 Troubleshooting

1. The monitor does not work

   Check whether the power cable is connected to the power socket and whether it is switched on. Check also whether the monitor is connected and is switched on.

2. The plusoptiX A09 does not work.

   If the green control lamp on the on/off switch on the plusoptiX A09 casing does not illuminate, check that the medical power unit is connected to the power socket and the 12 V outlet with the plusoptiX A09, and that the on/off switch is in the "on" position.

3. The program no longer responds

   If the program no longer responds to commands, switch off the plusoptiX A09 at the on/off switch. Wait for 10 seconds until the switch is no longer flashing and then switch on the system again. The software is then rebooted, and the plusoptiX A09 will be ready for operation within approx. 1.5 minutes.

4. The monitor is switched on after the plusoptiX A09

   The plusoptiX A09 does not boot completely. Switch off again the plusoptiX A09 at the on/off switch. Wait for approx. 10 seconds until the switch is no longer flashing. Afterwards switch on the monitor and then the plusoptiX A09.

5. The message "Boot error" appears on the monitor after switching on the plusoptiX A09

   The plusoptiX A09 does not boot completely. Switch off again the plusoptiX A09 at the on/off switch. Check whether there is a flash drive or a printer with a card reader inserted into one of the 4 USB connectors. A connected USB flash drive and these types of printers are likely to disturb booting the device properly.

13. Specifications

Measurements

Refraction	binocular and monocular	
Spherical range	+5.00/-7.00 dpt in 0.25 dpt steps	± 0.25dpt
Cylindrical range	+5.00/-7.00 dpt in 0.25 dpt steps	± 0.25dpt
Axis	1-180° in 1° steps	± 15°
Pupil size	4.0 – 8.0 mm in 0.1 mm steps	± 10%
Pupil distance	mm in 1.0 mm steps	± 10 %
Time per measurement	0.02 s	
Measuring distance	1 m (± 5 cm)	
Fixation target	Warble sound	
Measurement principal	binocular, dynamic photosciascopy	

Interfaces and standards

Interfaces	1 x VGA, 4 x USB and 1 x RJ-45
Printers	Linux compatible
Standards	EN 60601-1

Power

Medical Power Adapter MES30B-3P1J	in 110-240VAC (50 - 60Hz), 0.8A
	out 12VDC 2.5A
plusoptiX A09 power consumption:	12VDC, 1A max.

Environmental requirements

Temperature	operating	10 to 35 °C (50 to 92 °F)
	storage	0 to 50 °C (32 to 122 °F)
Humidity	operating	20 - 80 % not condensing
	storage	10 - 85 % not condensing

Packaging

Size of carton	51 x 41 x 20 cm (20 x 16 x 8 inches)	
Weight	A09 device	2.2 Kg (4.9 LB)
	Carton	1.3 Kg (2.6 LB)
	Total	3.5 Kg (7.7 LB)

Guidance and manufacturer´s declaration – electromagnetic emissions/ immunity

The plusoptiX A09 is intended for use in the electromagnetic environment specified below. The customer or the user of the equipment should assure that it is in such an environment.

Emissions Test	**Compliance**	**Electromagnetic environment - guidance**
RF Emission CISPR 11	Group 1	The plusoptiX A09 uses RF Energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emission CISPR 11	Class B	The plusoptiX A09 system is suitable for use in all establishments, including domestic establishments and those directly connected to the public low Voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class B	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Class B	

Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – Guidance**
ESD IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material the relative humidity should be at least 30 %
Electric fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines	± 2 kV for power supply lines	Mains power supply should be that of a typical commercial or hospital environment
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power supply should be that of a typical commercial or hospital environment
Voltage Dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% 0.5 periods 0° 40% 5 periods 0° 70% 25 periods 0° 0% 250 periods 0°	0% 0.5 periods 0° 40% 5 periods 0° 70% 25 periods 0° 0% 250 periods 0°	Mains power supply should be that of a typical commercial or hospital environment
Power Frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.