Mobile Pediatric Autorefractor

"plusoptiX A12C"

reddot award 2014
winner

"plusoptiX A12R"

User Manual

Release: 2015-10-16

CE 0123

Please read this user manual before the use of the device! It explains the functions of the device. Once the device has been switched on, additional information can be called up by touching the blue "i" button on screen. This additional information describes the individual screenshots in detail.

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1 Use According to Purpose and Responsibility of the Operator

Please observe the directions in this user manual. In doing so, you will avoid risks and obtain correct measurement results. The symbols used have the following meanings:

Read this user manual.

Warning notes are designated using this warning symbol.

Mobile Pediatric Autorefractor "plusoptiX A12C" and "plusoptiX A12R" comply with the specifications of Guideline 2007/47/EG for medical devices.

Mobile Pediatric Autorefractor "plusoptiX A12C" and "plusoptiX A12R" comply with the specifications of an application part of type B in EN 60601-1.

Only connect Mobile Pediatric Autorefractor "plusoptiX A12C" and "plusoptiX A12R" to the supplied medical power adapter MES30B-3P1J.

On/Off button (pressure-operated)

The device can be stored and transported at temperatures from 0°C to +50°C (32°F to 122°F). A temperature between +10°C and +50°C (50°F to 122°F) with non-condensing air humidity between 20% and 80% is required for operation.

Do not discard the device in household rubbish. Please send the device to Plusoptix (Plusoptix GmbH, Neumeyerstrasse 46, 90411 Nuremberg, Germany) for environmentally friendly disposal. Plusoptix will reimburse you the costs for return of the device.

Use according to purpose

Mobile Pediatric Autorefractor "plusoptiX A12C" and "plusoptiX A12R" measure the sphere, cylinder, axis, gaze and pupil diameter in both eyes simultaneously (binocular) in a non-dilated pupil (miosis). These measurement values are used to calculate gaze asymmetry and inter pupillary distance.

Anisometropia can only be detected in miosis reliably by means of a binocular refraction measurement. In this regard, it is irrelevant whether the child accommodates during measurement, as the refraction differential of both eyes remains constant, despite accommodation.

The spherical measurement values take into account +1.00 dpt to compensate for the accommodation on the camera at a distance of one meter. Manual correction is not required.

⚠️ **Note**:
The interpretation of the measurement values for recommending therapy is reserved exclusively for the eye care professional.

⚠️ **Note:**
The measurement values may not be used directly for the prescription of glasses or contact lenses.

Responsibility of the operator

- The operator must ensure that only trained users operate the device.

- At a minimum, the training must consist of reading this user manual and instruction in the use of the device. A user already trained can perform instruction in the use of the device. In addition, training is offered by Plusoptix and authorized Plusoptix distributors.

- The operator is responsible for ensuring that external devices connected to Mobile Pediatric Autorefractor "plusoptiX A12C", "plusoptiX A12R" respectively, complies with the EN 60601-1 and EN 60601-1-1 norms together with the device.

- The operator is responsible for ensuring that in the case of servicing or a warranty claim, Mobile Pediatric Autorefractor "plusoptiX A12C", "plusoptiX A12R" respectively, is only opened by Plusoptix or an authorized Plusoptix distributor. Opening the device exposes you to a risk of an invisible electric shock. In addition, the device warranty becomes null and void, as does the approval as a medical device.

2 Commissioning the Device

Thank you for purchasing a Mobile Pediatric Autorefractor "plusoptiX A12C", "plusoptiX A12R" respectively. Plusoptix is the world leader in the development, production and distribution of medical devices for pediatric ophthalmic examination. Please contact us should you have further questions after reading the user manual.

2.1   Checking the scope of delivery

The device is supplied in a cardboard box with foam padding that protects the device from damage. If the device packaging shows signs of damage at the time of delivery, please inform the seller of the device immediately.

Figure 1: Device in cardboard box (plusoptiX A12C)

Please check that the contents of the packaging are complete at time of delivery. The scope of delivery includes:

- User Manual for plusoptiX A12
- Mobile Pediatric Autorefractor "plusoptiX A12C" or "plusoptiX A12R"
- Medical power adapter MES30B-3P1J
- 110V/230V power cord (in compartment under the "plusoptiX A12C" or "plusoptiX A12R")
- 6 x rechargeable AA batteries
- SD card (inserted into device)

Optional accessories:

- +3,00dpt. lenses for accommodation test
- Carrying case for plusoptiX A12
- Wireless label printer "plusoptiX P12" for plusoptiX A12

If the delivery is incomplete, please inform the seller of the device immediately.

2.2   Learning about the device

During a measurement, the device records a series of images. To attract the attention of the child during the measurement, the device plays a "warble" sound. The speaker required for this is located behind the vertical slits on the front side of the device.

Figure 2: Front view of the device (plusoptiX A12C)

The camera lens and the LEDs required for illuminating the images are located behind the black protective shield with the stylized face. This face is also used as a fixation aid.

> ⚠ **Note**:
> If a child is not looking at the camera lens in the middle behind the hexagon during the measurement, this can lead to a cancellation of the measurement or incorrect measured values of the visual symmetry. Therefore do not use any other external fixation aids!

> ⚠ **Note**:
> To prevent the protective shield from becoming dirty, we recommend that you do not touch it. If the protective shield does become dirty, read chapter 5 "Maintenance, Calibration, Servicing and Warranty" for cleaning instructions.

⚠️ **Attention**:
If you need to put the device on its rear side, e.g. to insert or replace the rechargeable batteries, please place a soft cloth under the device.

plusoptiX A12C has a 5.7 inch screen with capacitive touch sensor located on the rear side of the device. To activate one of the functions displayed on the screen, all you need to do is gently touch the screen. The screen and touch sensor are protected from damage behind a thin glass shield.

plusoptiX A12R has a 4.3 inch screen with resistive touch sensor located on the rear side of the device. To call up a function displayed on the monitor screen, it is sufficient to tap the screen with the tip of your finger or with your finger nail. Screen and touch sensor are protected behind a thin transparent plastic cover.
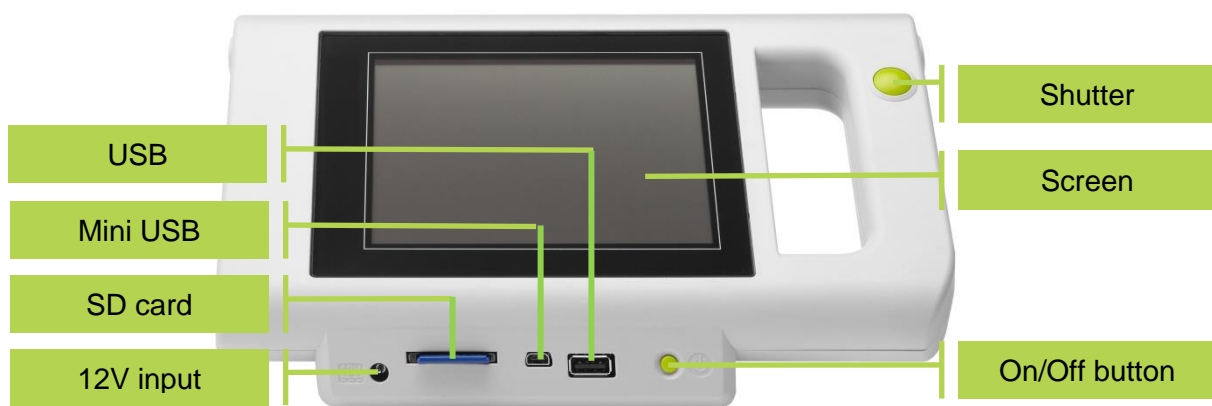
Figure 3: Rear view of the device (plusoptiX A12C)

Two green buttons are visible – the On/Off button (on the right side below the screen), and the Shutter (on the handle to the right, next to the screen). Chapters 2.4 "Switching the device on and off" and 3.4 "Starting a measurement and positioning the camera" deal with the functions of these buttons.

The device has three interfaces – USB, Mini-USB and SD card – which are located in the center below the screen. Chapters 4.1.11 "SD card and USB interfaces" and 4.1.12 "Mini-USB interface" explain how to use these interfaces.

⚠️ **Note**:
All interfaces are mounted upside down. This means that all media (i.e. USB flash drives, Mini-USB plugs and SD cards) must be connected with the upper side facing down.

The left lower edge contains the connection for the 12V charging cable of the medical power adapter.

2.3   Inserting and charging the rechargeable batteries

Battery compartment

Type plate

Figure 4: Battery compartment view of the device (plusoptiX A12C)

⚠️ **Attention**:
If you need to put the device on its rear side, e.g. to insert or replace the rechargeable batteries, please place a soft cloth under the device.

To insert the batteries, please put the device on a level working surface on its rear side.

⚠️ **Attention**:
If you insert batteries other than those supplied, you should exclusively use rechargeable Nickel Metal Hydride NiMH/AA HR6 batteries with a capacity of at least 1900 mAh and a quick-charge rate of min. 1 A.

Now remove the battery compartment cover using a 1-cent coin, and insert the supplied rechargeable batteries.

⚠️ **Note**:
When inserting rechargeable batteries, please ensure that the contacts are located on the correct side.

⚠️ **Note**:
The type plate with the serial number (S/N 120xS-xxx-xxxx xxxx) is located under the battery compartment. If you contact us regarding extended service or warranty questions, please remember to always quote the serial number of your device. The S/N number helps us to answer your question quickly.

After inserting the rechargeable batteries, close the battery compartment cover and place the device in front of you. Now connect the medical power adapter with its power cable to the wall socket and check whether voltage is present (green light diode at the top of the medical power adapter lights up). Then connect the 12V charging cable of the medical power adapter to the device.

The inserted rechargeable batteries will now be charged automatically. The charging time of the batteries depends on the charge level of the batteries. The maximum battery charging time is 3 hours for the supplied rechargeable batteries.

2.4   Switching the device on and off

To switch on the device, briefly press the On/Off button. The screen switches on immediately and the device is booted. The device is ready for use after approx. 25 seconds. After inserting the batteries, the date and time settings page is displayed on the screen.
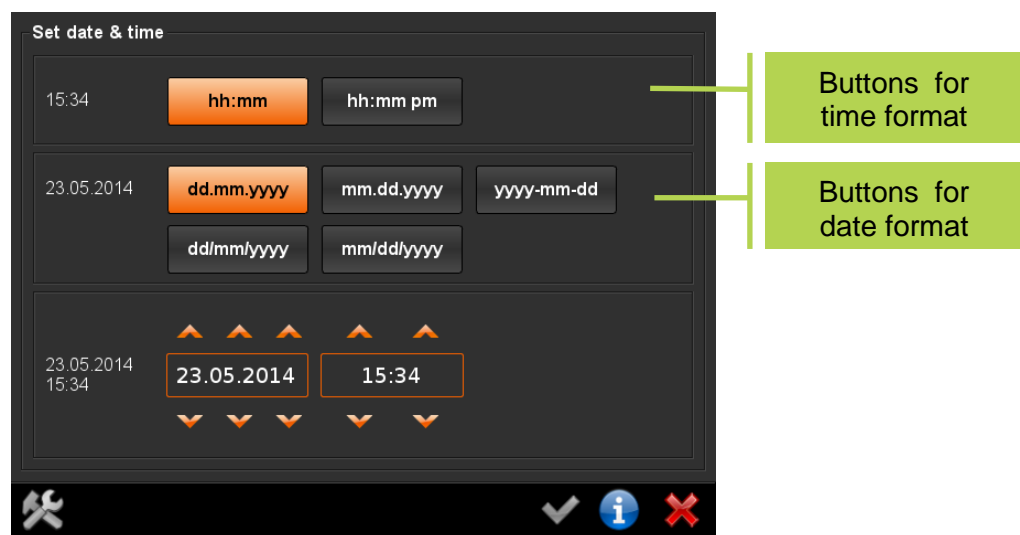
Screenshot 1: Setting date and time

The time and date format selected is highlighted in color (1). Set the current date and time by touching the orange arrows (2 or 3). Use Checkmark button (4) to confirm your entries. You can change the date and time as well as the display formats at a later stage in Settings (5) (see chapter 4.1.2 "Customize basic settings").

Note:
If the device is not used for 30 seconds, the screen switches off automatically (stand-by mode). Touch the screen to reactivate it. If the device is not used for 5 minutes, the device switches-off completely. To switch on again, you need to press the On/Off button. These two time windows can be individually adjusted in Settings (5) (see chapter 4.1.2 "Customize basic settings").

To switch off the device, briefly press the On/Off button. The screen switches off immediately and the device is shut down. If the screen does not switch off, press and hold the On/Off button until the screen switches off.

1) dd.mm.yyyy   2)   3)   4)   5)

2.5 Screen displays and help texts

All screen displays are designed in the same manner. The Header is located at the top, the Information section in the center, and the Navigation bar at the bottom.

Figure 5: Switching between a screen and the help text

The **header** contains:

- the date and time at the left
- the WLAN- (1) and battery status (2) at the right
  The WLAN information (1) is only displayed if the WLAN is activated in the Settings. This function is only available for the plusoptiX A12C. The battery status symbol (2) flashes when the 12V charging cable is connected and the rechargeable batteries are charged.
- a warning symbol (3), which appears when the rechargeable batteries need to be charged or the WLAN-reception is interrupted.

In the **Navigation Bar** active buttons are displayed in color and inactive buttons are displayed in gray. They include:

- the button with the tools (4), to reach the Settings
- the button with the lock (5), to lock the screen.
  This is only displayed when the screen lock is activated in the Settings.
- the button with the green tick (6), to confirm and to save and
- the button for Cancel (7), which cancels without saving.
- the blue information button (8), to open a Help screen.
  The Help screen provides an explanation of the buttons in the respective screen view. To save space, the buttons are replaced by consecutive numbers in the text (as shown here). At the bottom of the Help screen it is shown which buttons the numbers represent. All buttons that are displayed in the Help screen are inactive. They are only displayed in color for illustration purposes.

1) 2) 3) 4) 5) 6) 7) 8)

3   Performing Measurements

Mobile Pediatric Autorefractors "plusoptiX A12C", "plusoptiX A12R" respectively, measures both eyes simultaneously (binocular) in 0.5 seconds at a distance of one meter (3.3 feet). Therefore even small children with a short attention span can be measured starting at the age six months. The simultaneous measurement of both eyes also enables a reliable comparison of the measurement values of both eyes.

3.1   Environmental considerations

The device uses infrared light to perform measurements. The same infrared light is part of sunlight and emitted by all incandescent light sources such as light bulbs and halogen spots. This infrared light is invisible to the human eye and nonhazardous. To obtain accurate measurements it is important to avoid interfering infrared ambient light in the examination room. Curtains, blinds or shutters should be closed to exclude sunlight. Switch off all heat-emitting light sources. However, examination room does not need to be dark. Cold light sources such as energy saving lamps or neon tubes do not affect measurement results.
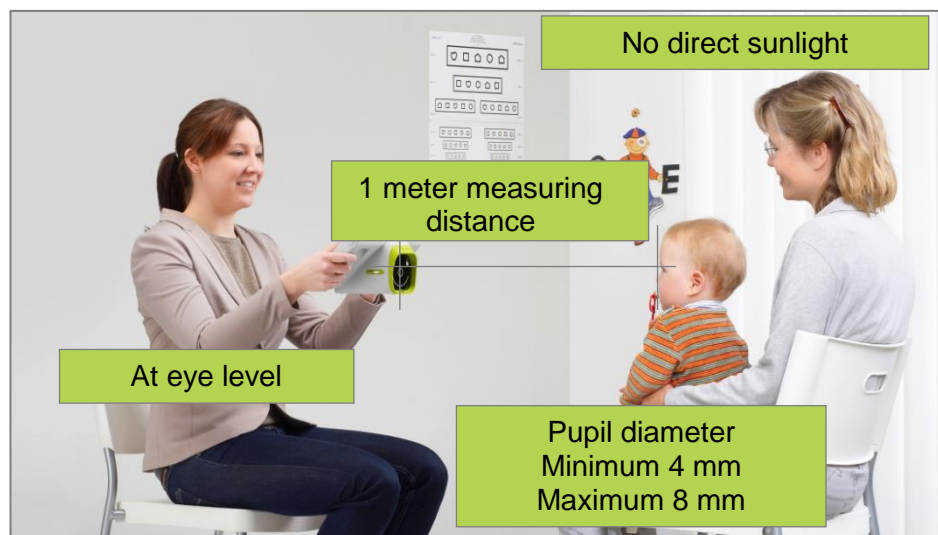
Figure 6: Measuring environment

To be able to perform a measurement, the child must look at the device. Ensure that the child is sitting straight and does turn his head across the shoulder. The child's knees and nose must point towards the camera.

The attentiveness of small children is attracted by playing a special "warble" sound on the device. However, this works only if the child is not distracted by other persons or objects in the examination room. Ensure that you close the door to the examination room and avoid activities that divert the child's attention such as walking around or snapping your fingers. Do not use additional fixation aids!

The attention span of small children is extremely short. Take advantage of the fact that the examination room is new to the child. An unusual "warble" sound in this unfamiliar environment always evokes interest. Enter the patient data into the device before calling the child into the examination room or after completing the measurement. Avoid protracted information exchange with parents before the measurement.

3.2 Preparing for a measurement

After setting date and time, the start screen is displayed every time the device is switched on.
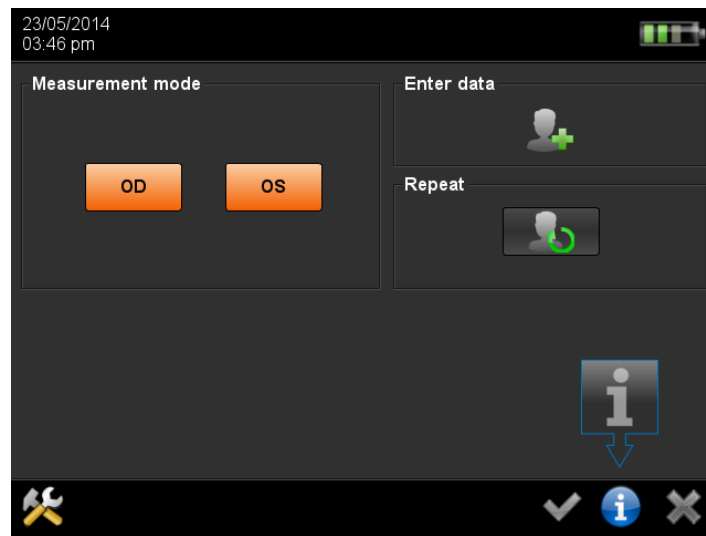
Screenshot 2: Start screen (plusoptiX A12C)

Buttons (1) and (2) are highlighted in orange to show that a binocular measurement is being performed. To perform a monocular measurement, touch buttons (1) or (2). Buttons (3) and (4) are not shown by plusoptiX A12R.

You can start a anonymous measurement by pressing the Shutter (see chapter 3.4 "Starting a measurement and positioning the camera").

The plusoptiX A12C possesses a patient database. To enter new patient data (see chapter 3.3 "Entering patient data"), or to call up patient data that has already been saved (see chapter 4.1.8 "Retrieve patients from database"), touch button (3) to move to patient data entry.

1)   2)   3)   4)

3.3 Entering patient data (only plusoptiX A12C)

To be able to uniquely identify a patient in the database, you need to enter either date of birth, first name and last name, or an ID number. As an option, examination location and/or contact information can also be saved in the database (shown with a dotted line in the figure below).

Data entry with first name and last name   Data entry with ID number
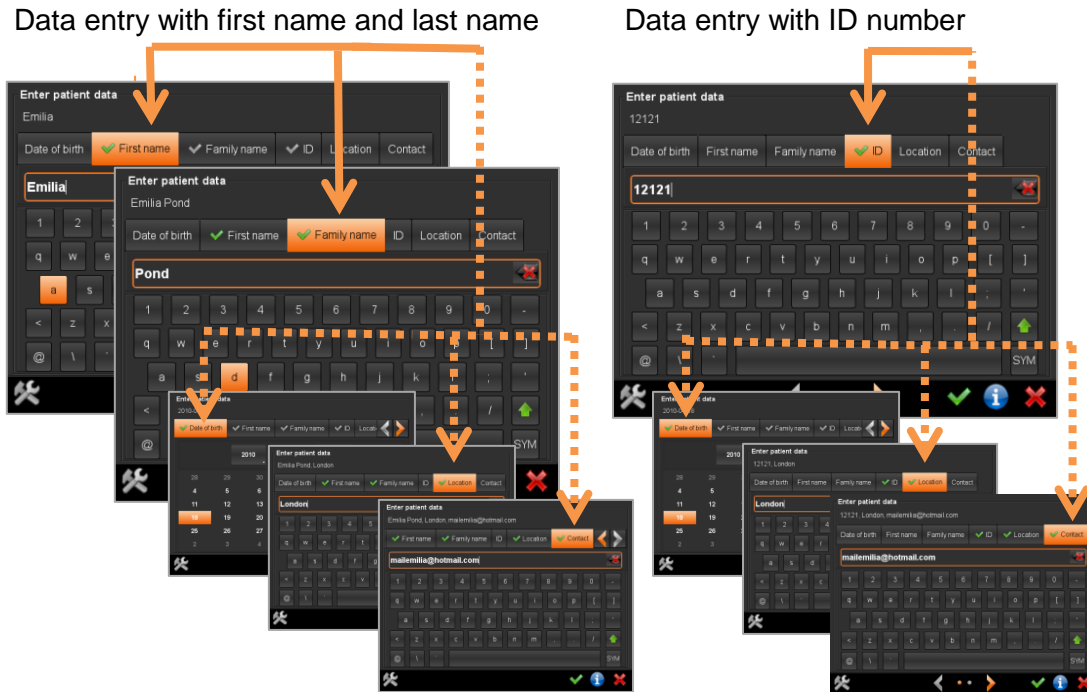
Figure 7: Overview of patient data input

⚠ **Note**:
Pressing the Shutter will start a measurement only, once the patient data has been entered completely.

You must enter either:
First name + Last name
or
ID number

Entries of date of birth, examination location and contact information are always optional.

You can enter the date of birth in any form you wish. Touch button (1) to enter the year of birth, button (2) to enter the month of birth and button (3) to enter the day of birth.

Screenshot 3: Entering the date of birth

After entering the date of birth, you will see a green checkmark (4) as confirmation on the tab.

You have to enter first name and last name or a patient ID number next. This additional information is necessary to be able to uniquely identify the patient in the database at a later stage. Simply touch the next tab (5) to move to the next input.

1)   2)   3)   4)   5)

Use the screen keypad to enter the patient data. Touch:

- the Caps Lock key (1) to switch back and forth between lower- and upper case typing
- the SYM key (2) to insert special characters
- the Backspace key (3) to delete the last character.

Please read chapter 4.1.14 "External mouse or keyboard" if you prefer this option for entering data.
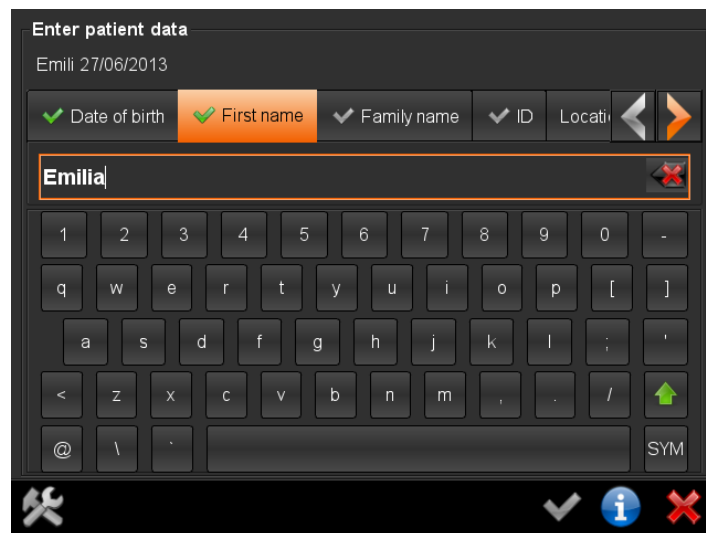
Screenshot 4: Entering a first name

Once all necessary patient data has been entered, that is, either date of birth and first name and last name, or date of birth and patient ID, the Checkmark button (4) in the navigation bar is activated.

You can now either perform a measurement by pressing the Shutter or save the patient data without performing a measurement. To save the data, simply touch the Checkmark button (4).

1)   2)   3)   4)

3.4 Starting a measurement and positioning the camera

Hold the device as you would hold a tablet PC and press the Shutter with your right thumb.

Figure 8: Holding the camera and operating the shutter

Place the device approximately 1.2 meters (4 feet) away from the child at eye level. Although the measurement distance is one meter (3.3 feet), a degree of practice is required to estimate this distance. It is easier to hold the device a little further away at the start of a measurement and then to move it slowly towards the child.

⚠️ **Note**:
The screen is fixed at a 45° angle to the camera axis. Tilt your wrists downwards to align the camera.

Figure 9: Aligning the device

Pressing the Shutter will start the camera and play back a "warble" sound. You can now see the camera image on screen.

Align camera so that both eyes can be seen on the screen. Then slowly move towards patient until camera picture on screen is in clear focus. In the beginning the pupils are framed with white boxes (i.e. the picture is blurred), then by red circles and finally by green circles. Stop moving once a green line is plotted in between both pupils and a second "warble" sound can be heard. The measurement starts at this point in time automatically.

A "ping" sound signals that the measurement is complete. In addition to the camera image, the measurement results are now also displayed on screen.

The picture is blurred. The head of the patient is seen almost completely, because the measurement distance is too big. Move the device towards the patient until the picture is in clear focus (see next picture).

The picture is in clear focus. Both pupils are framed by a green circle, the line between the pupils appears in green and an additional "warble" sound can be heard. The device is now one meter from the child, and the measurement begins automatically. This second "warble" sound ensures that the child continues to look at the camera during the measurement. Refrain from moving the device, and wait until the measurement is complete.

The picture is blurred. The eyes are close to the edge of the screen, because the measurement distance is too small. Move the device away from the patient until the picture is in clear focus (see previous picture).

Figure 10: Recognizing correct measurement distance

If you do not obtain measurement results, check whether the following measurement prerequisites are met:

a) Measurement distance is correct:
   Measurement distance must be in between 95 cm (3.1 feet) and 105 cm (3.9 feet). Check whether the camera image on screen is in focus. You should be able to see individual hairs of eyelashes and eyebrows on screen.

b) Patient is looking at the camera lens:
   The device and the patient's eyes must be aligned with one another. The patient must be looking at the hexagonal nose in the camera face. Therefore avoid additional fixation aids. Check whether green dots are plotted in Gaze charts.

c) Both pupils of the patient can be seen completely:
   Both pupils must not be covered by eyelids, eyelashes, eyebrows or long hair, for example. Check whether you can see both pupils completely on screen and that both are encircled in green.

d) Pupil sizes are between 4 and 8 mm:
   Both pupils must have a diameter in between 4 and 8 mm.

Note:
If a red error message is displayed, please read chapter 4.2.3 "Error messages when performing a measurement".

3.5 Checking and documenting measurement results

Screen size is limited and therefore measurement results are presented on two (plusoptiX A12R), three screens (plusoptiX A12C) respectively, for better readability. These three measurement result screens are:

- Check measurement results screen
- Review video screen
- Review database entries screen (nur plusoptiX A12C)

Note:
To exit these three measurement result screens, i.e. to return to the Start screen and to perform another measurement, you have to press the Shutter.

Touch orange arrows (1) and (2) located in Navigation bar to toggle in between measurement result screens. An orange dot in between the arrows (1) and (2) indicates which of the two, three respectively, measurement result screens is displayed.

Check measurement results screen

Review video screen

Review database entries screen (only plusoptiX A12C)

Figure 11: Overview of measurement result pages

If a anonymous measurement was performed, the measuring report can be saved manually by touching the printer button (3).

After touching the printer button (3) the patient data entry screen is displayed by plusoptiX A12C (see chapter 3.3 "Entering patient data (only plusoptiX A12C)"). PlusoptiX A12R displays a input field instead. The filled in data are saved by touching the green checkmark (4). PlusoptiX A12C saves the filled in data in the patient database, too.

1)   2)   3)   4)

If you do not want to print patient data in the Measurement report, touch Checkmark button (1) without entering any patient data. In this case Measurement report is saved anonymously.

If a SD card was inserted and patient data was entered before the measurement with plusoptiX A12C, a measurement report will automatically be saved on the SD card (see chapter 4.1.9 "Save and print a measurement report").

⚠️ **Note**:
Whenever you touch Print button (2), an additional print job will be added to print spooler. As soon as the compatible printer is connected (see chapter 4.1.10 "Compatible printers and network printing") it will print all print jobs in chronological order.

⚠️ **Attention**:
All print jobs in print spooler are deleted once device is switched off or switches off for power saving automatically. Measurement reports saved to a SD-card are not deleted when device is switched off or switches off for power saving.

Check measurement result screen

Measurement completed! Measurement results are displayed on screen immediately after a measurement was performed. "Measurement completed" is displayed in the status line.

Measurement aborted! After an inconclusive measurement, "Measurement aborted" is displayed in the status line.

Pupils not found! In this case a red error message is displayed above the status line and you will find additional information in chapter 4.2.3 "Error messages when performing a measurement".

To measure the same patient again, simply press the Shutter once to return to Start screen and a second time to start the next measurement for the same patient. You do not need to touch the screen during this process. There is no need to re-enter the patient data.

1) ✅ 2) 🖫

Measurement results are displayed separately for right eye (OD) and left eye (OS).
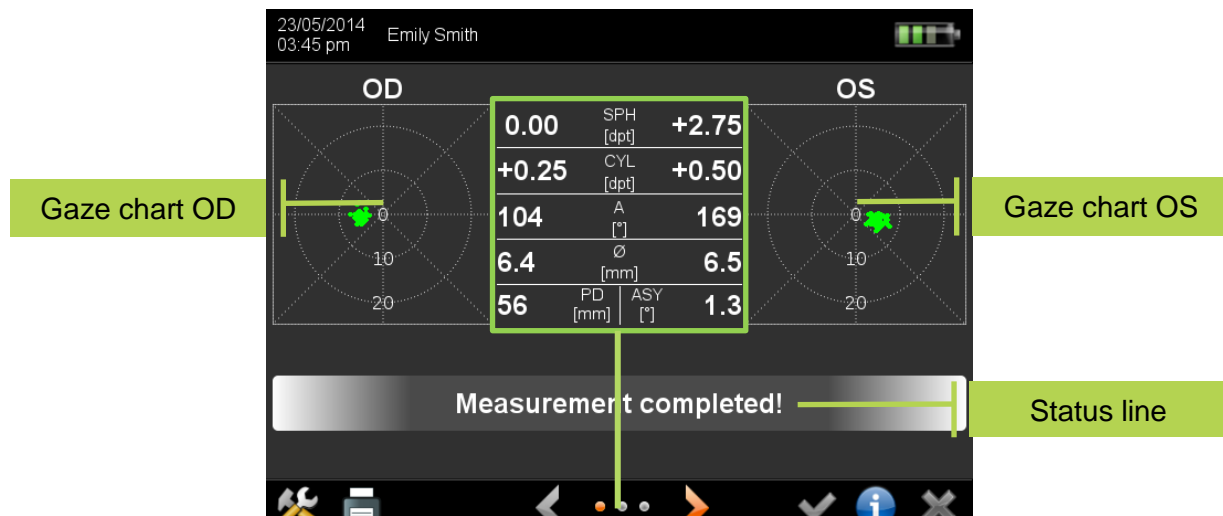
Screenshot 5: Check measurement result
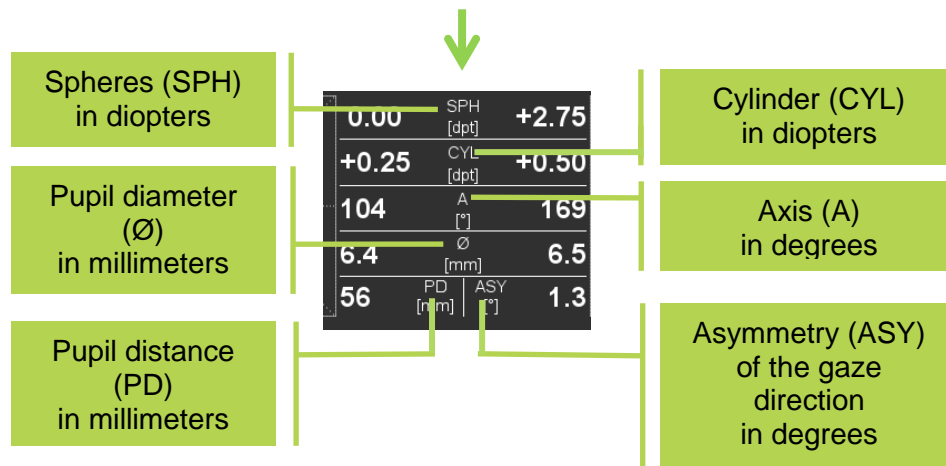
If measurement results exceed measurement range, only hyperopia (HYP) or myopia (MYO) is displayed instead of a quantitative numerical value.

Gaze charts are displayed for each eye on left and right screen borders. These illustrate the lines of vision during measurement. Red dots are plotted if an eye is aligned more than 10 degrees off camera axis (i.e. outside the inner circle). In this case measurement is aborted inconclusively.

⚠️ **Note**:
If a child is not looking at the camera lens in the middle behind the hexagon during the measurement, this can lead to a cancellation of the measurement or incorrect measured values of the visual symmetry. Therefore do not use any other external fixation aids!

The device compares the line of vision of both eyes and indicates the extent of Asymmetry (ASY) in between. In this regard, an ASY of 0° indicates perfect symmetry. Asymmetric lines of vision can be caused by strabismus or decentral fixation. The angle displayed on screen is not the angle of strabismus!

Review video screen

Touch Play button (1) in navigation bar to play back the entire measurement video in slow motion. During playback Play button (1) is replaced by Pause button (2). Touch Pause button (2) to interrupt playback and inspect a single picture closely. The inspection of images is primarily used for detecting media opacities that do not cause a measurement to abort. Touch Play button (1) to continue playback.

⚠️ **Note**:
Check after every measurement whether both pupils are equally bright and whether structures are visible within the pupils. If brightness is different or structures can be seen, the eyes need to be examined closely.
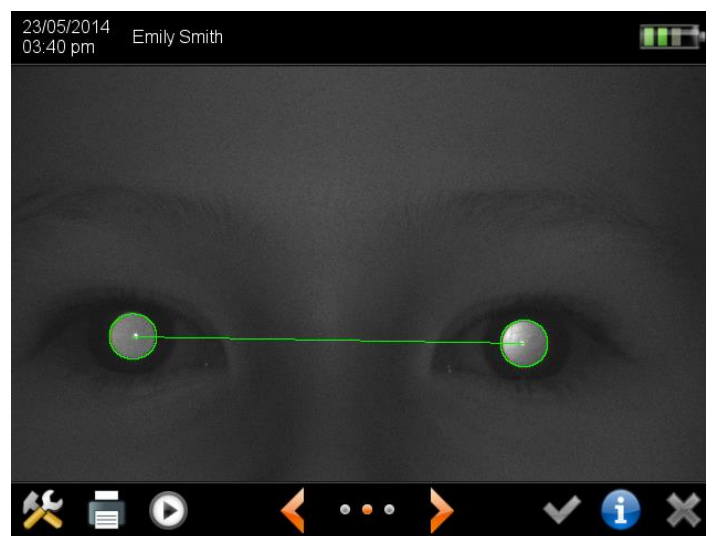
Screenshot 6: Review video screen

Video pictures can help identifying the reason for a measurement to abort. Pay attention to both pupils. They have to be visible entirely and must not be covered or partly covered by hair, eyelashes or eyelids for example.

1) 2)

Review database entries screen (only plusoptiX A12C)

Every measurement is documented in the database in chronological order, automatically. This listing shows at a glance how a patient's measurements have changed over time. Yellow entries indicate aborted measurements and green or red entries show successful measurements.

Screenshot 7: Review database entries screen

You can print or delete measurements from the database. Touch the measurement to be printed or deleted to enable Print button (1) and Delete button (2).

Screenshot 8: Printing or deleting measurements from database entry

Touch Print button (1) to add a print job to the print spooler. Multiple copies can be added to print spooler by touching Print button repeatedly (4) and (5). Once a compatible printer is connected, all print jobs in the print spooler are printed.

Touching Delete button (2) marks a measurement to be deleted (6). Multiple measurements can be marked to be deleted. All marked measurements will be deleted once you confirm by touching Checkmark button (7). Touch Cancel button (8) to abort without deleting.

3.6 Perform next measurement

Save or print the measuring results of the last measurement, before you perform the next measurement.

> ⚠ **Attention**:
> As soon as you press the shutter-release button, you delete the video of the last measurement as well as the measured values from the working memory (RAM). The last video can no longer be viewed and measurement results can then no longer be printed out or saved. Therefore save or print the measurement result, in case you want to access it later.

Press the shutter release button once to return to the Start screen. You can return directly to the Start screen from every measurement result page, Settings page or Help Text page.

As soon as you have returned to the Start screen a new measurement is started by pressing the shutter-release button:

- After a preceding anonymous measurement, a new anonymous measurement is started (plusoptiX A12C and plusoptiX A12R).

- After a cancelled measurement with patient data (plusoptiX A12C only) the device "remembers" the patient data of the last patient and the button (1) is preset. This "memory function" makes it possible to measure the same patient several times in succession, without having to enter the patient data again every time. By pressing the shutter-release button the preset patient is measured once again.
  This "memory function" can be deactivated by touching the button (1). By pressing the shutter-release button measurement then takes place anonymously.

- After a successful measurement with patient data (plusoptiX A12C only) the "memory function" and button (2) are deactivated. By pressing the shutter-release button measurement takes place anonymously.

- If new patient data are to be entered or called up from the database before the next measurement (plusoptiX A12C only), in both cases (i.e. after a cancelled or a successful measurement) this can be done by pressing the button (3).

1) 2) 3)

4 Practical Tips

These practical tips are divided into two categories: Handling clues and trouble shooting. You can read these sequentially or you can refer to the relevant sections only.

4.1 Handling clues

Handling clues explain additional features that are not essential for performing a measurement.

4.1.1 Adjust settings

In Settings you can tailor the device to your requirements. Touch Tool button (1) in Navigation bar to access and Cancel button (2) to exit settings. Cancel button (2) takes you back to the screen from which you called up settings initially.

plusoptiX A12C
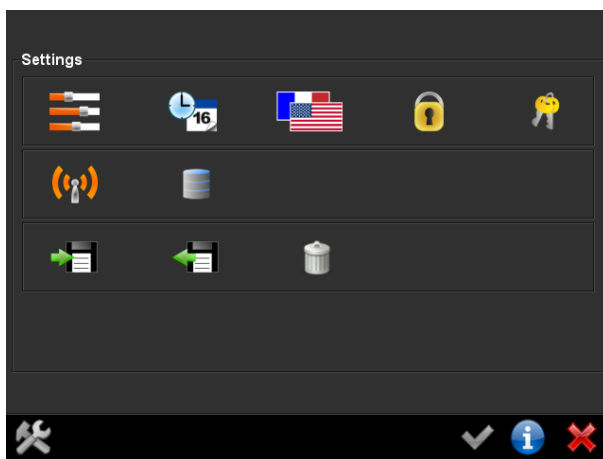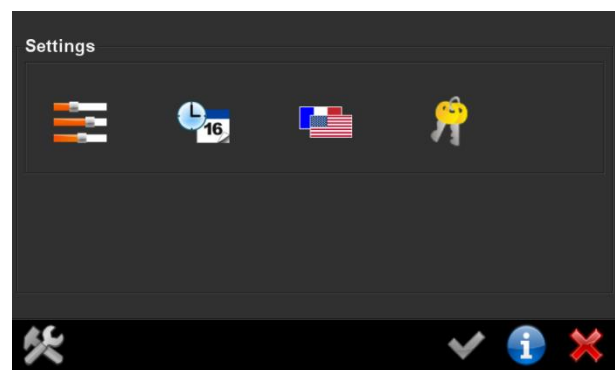
plusoptiX A12R

Screenshot 9: Settings overview

Available settings are:
- Customize basic settings (3) – see chapter 4.1.2
- Set date & time (4) – see chapter 2.4
- Choose language (5) – see help text
- Set-up screen lock (6) – see chapter 4.1.3 (only plusoptiX A12C)
- Configure software (7) – see chapter 4.1.13
- Activate WLAN (8) – see chapter 4.1.4 (only plusoptiX A12C)
- Connect to EMR (9) – see chapter 4.1.5 (only plusoptiX A12C)
- Export data (10) – see chapter 4.1.6 (only plusoptiX A12C)
- Import patient data (11) – see chapter 4.1.7 (only plusoptiX A12C)
- Delete database (12) – see help text (only plusoptiX A12C)
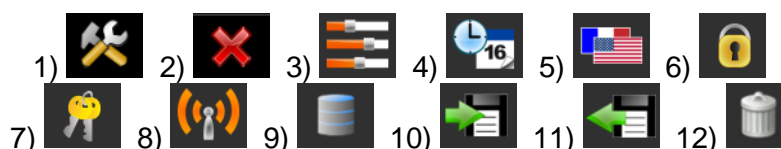
4.1.2 Customize basic settings

Touch Basic settings button (1) in Settings to move to this screen:
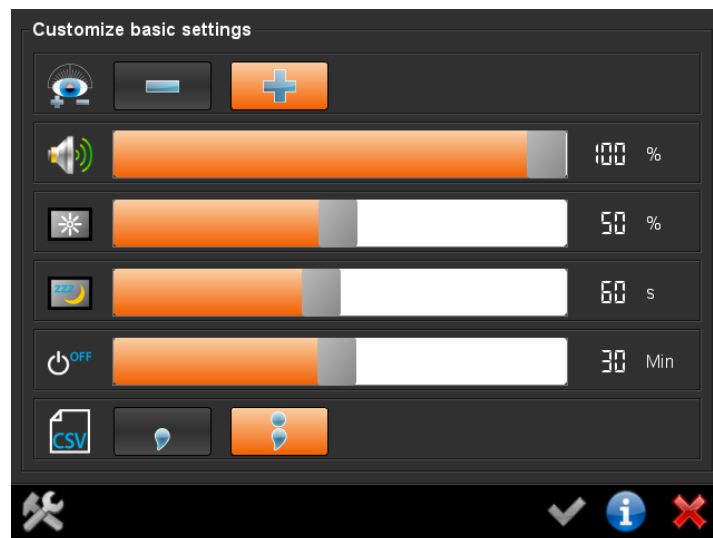
Screenshot 10: Basic settings

Basic settings include:

 Astigmatism display
Astigmatism can be displayed as a plus cylinder or a minus cylinder.

 Volume setting
A setting of 0% switches off the "warble" sound.

 Screen brightness
A lower screen brightness saves electricity and allows the rechargeable batteries to last longer.

 Time in seconds until the screen switches off after inactivity (screen saver)
Earlier switch-off saves electricity and allows the rechargeable batteries to last longer. The screen is switched on again after being touched. The last video file, measurement results and print jobs in printer spooler are retained when the screen switches off.

 Time in minutes until the device switches off after inactivity
Earlier switch-off saves electricity and allows the rechargeable batteries to last longer. The device must be switched on again by pressing the On/Off button. The last video file, measurement results and print jobs in printer spooler are deleted when the device switches off.

 Only plusoptiX A12C:
Use of a comma or semicolon as a separator in CSV files
The chosen separator is used for all CSV files that the device saves. Only CSV files that use the chosen separator can be imported. Using CSV files is described in chapter 4.1.5 "Connect to EMR", chapter 4.1.6 "Export data" and chapter 4.1.7 "Import patient data".

1)

4.1.3   Set-up screen lock (only plusoptiX A12C)

The screen can be locked to prevent unauthorized access to patient data saved in the device. To be able to lock the screen, screen lock must first be activated in Settings, and a six-digit PIN must be entered.

Touch Padlock button (1) in Settings to move to this screen:
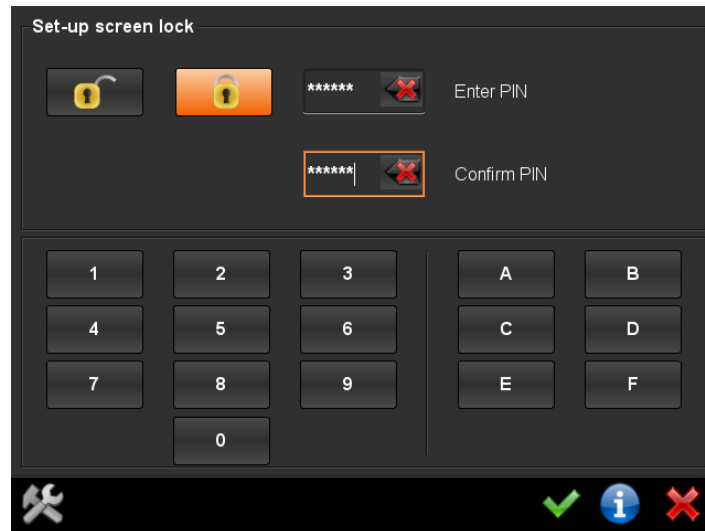
Screenshot 11: Setting up screen locking

Touch Screen lock button (2) to enter your six-digit hexagonal pin using the keyboard on screen. Then touch Checkmark button (3) to activate screen lock.

Once screen lock is activated, the padlock symbol (1) is displayed in the Navigation bar on every screen. Touch Padlock button (1) in the Navigation bar to lock screen. As soon as screen is locked, it can only be unlocked by entering the six-digit PIN.

 Note:
The padlock symbol is displayed in Navigation bar only if you have activated screen lock in Settings, first.

 Note:
Screen is locked automatically if the device is switched off or switches off. If the screen has switched off to save energy (screen saver), screen does not lock and data can still be accessed once screen is touched.

To deactivate screen lock, touch button (4), enter your PIN for confirmation and touch Checkmark button (3).

1)   2)   3)   4)

4.1.4 Activate WLAN (only plusoptiX A12C)

The device is equipped with a WLAN interface. This WLAN interface is used to connect to either a DHCP server. To save battery power WLAN interface is deactivated at delivery.

Note:
Switch on DHCP server before activating WLAN interface.

Touch WLAN button (1) in Settings to move to this screen:
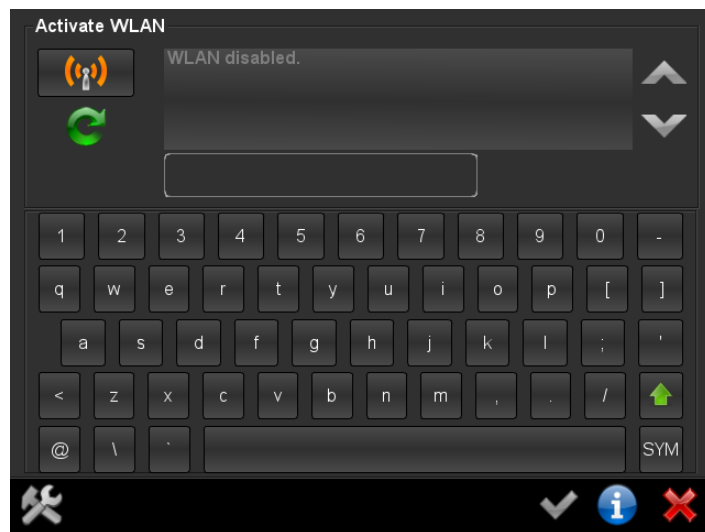
Screenshot 12: Activating WLAN

Touch button (2) to activate the WLAN interface.

1)   2)

The device then automatically searches for all available networks within range and displays these after approximately one minute. If there are displayed more than three available networks, you can scroll through the list by touching the Down arrow (1). Touching the Repeat button (2) will start the search for wireless networks again.
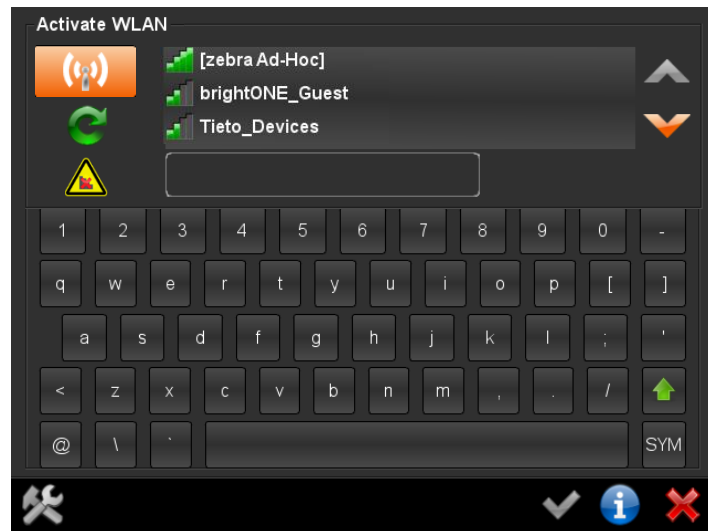
Screenshot 13: List of active WLAN connections

To de-activate WLAN interface, touch button (3). The device then switches off automatically, and you must switch it on again by pressing the On/Off button.

Once WLAN is activated it will automatically connect to the network each time the device is switched on.

1)   2)   3)

The warning symbol (1) indicates, that the WLAN network has not yet been set up. To select a wireless DHCP server, touch the appropriate entry on the screen. Confirm your selection with the green tick (2) in the Navigation Bar. After a short time the screen is closed automatically and the Settings screen appears. The plusoptiX A12C is now connected with your wireless DHCP server.
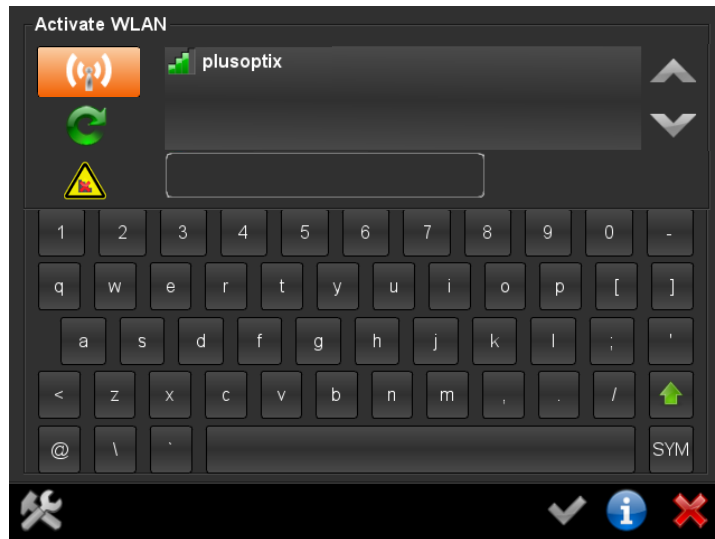
Screenshot 14: WLAN network without password

Some networks require the entry of a password (3). After entering the password, confirm your selection with the green tick (2) in the Navigation Bar.
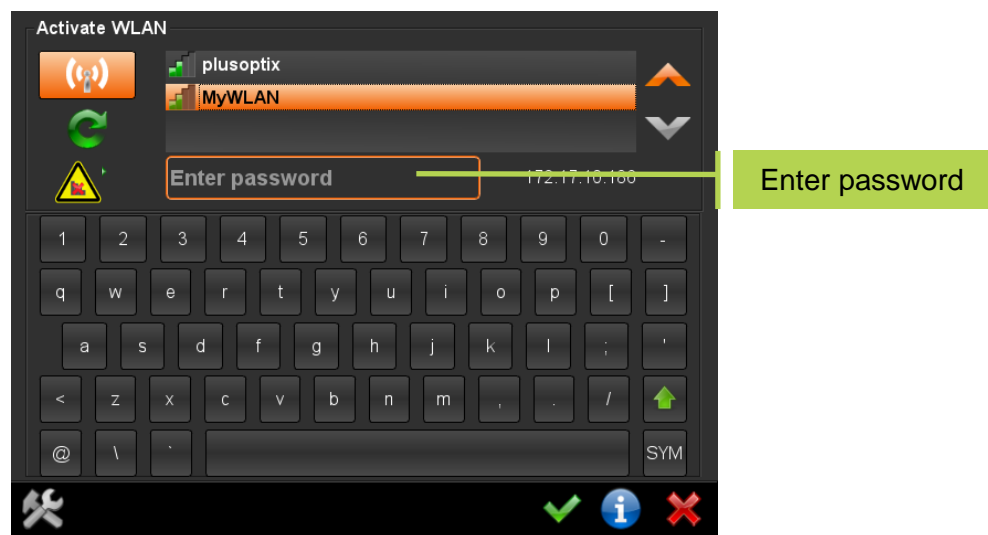
Screenshot 15: Enter password for WLAN connection

If the device is already connected to a WLAN, a green Checkmark (1) is displayed instead of a Warning symbol. The name of the WLAN is marked in orange, and the IP address is displayed next to the password (2).
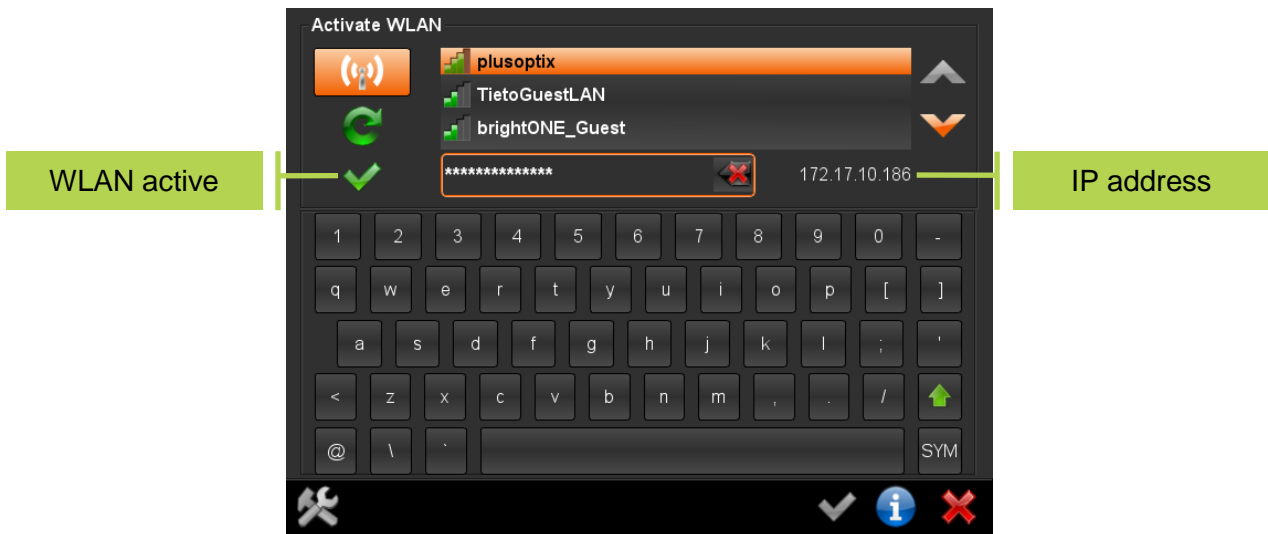
Screenshot 16: Active WLAN connection

If WLAN connection is malfunctioning, a Warning symbol is displayed below to the WLAN symbol (3).
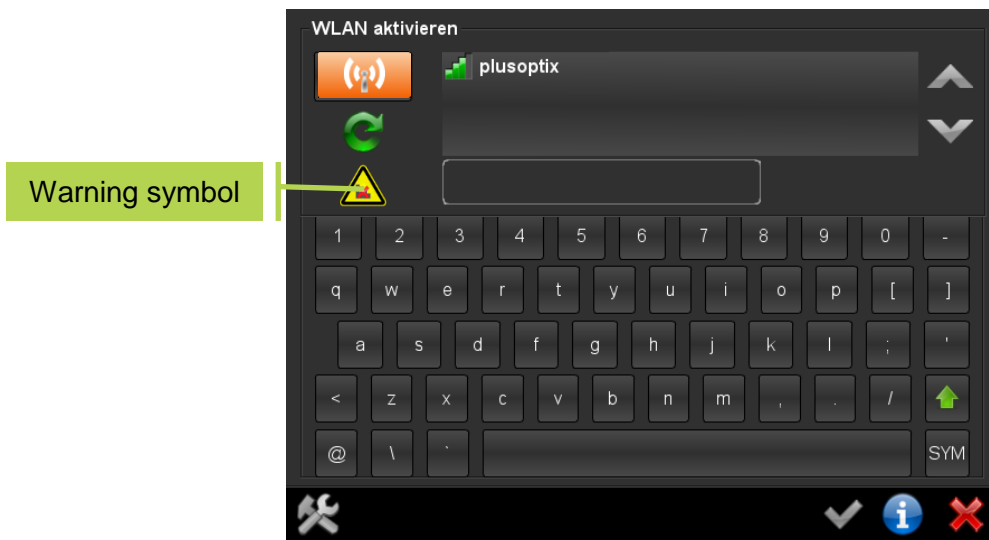
Screenshot 17: WLAN error messages

Warning symbol (4) indicates that password is incorrect.

Warning symbol (5) indicates that DHCP server has not allocated an IP address.

Warning symbol (6) indicates that DHCP server is out of range or that no WLAN network connection is established.

4.1.5 Connect to EMR (only plusoptiX A12C)

Connecting the device to your EMR (Electronic Medical Records) enables electronic importing of patient data and exporting of measurement results.

Note:
To ensure that data exchange works, your EMR system has to support this interface. Check with your EMR system provider if this Plusoptix device is compatible.

Please read chapter 4.1.4 "Activate WLAN" to connect the device to your wireless DHCP server, first. Then touch EMR button (1) in Settings to move to EMR set-up pages.

4.1.5.1 Transferring data in CSV format (only plusoptiX A12C)

Patient data can be imported from your EMR system in form of a simple CSV file. Touch CSV button (2) to choose CSV file format and confirm with the green Checkmark (3).
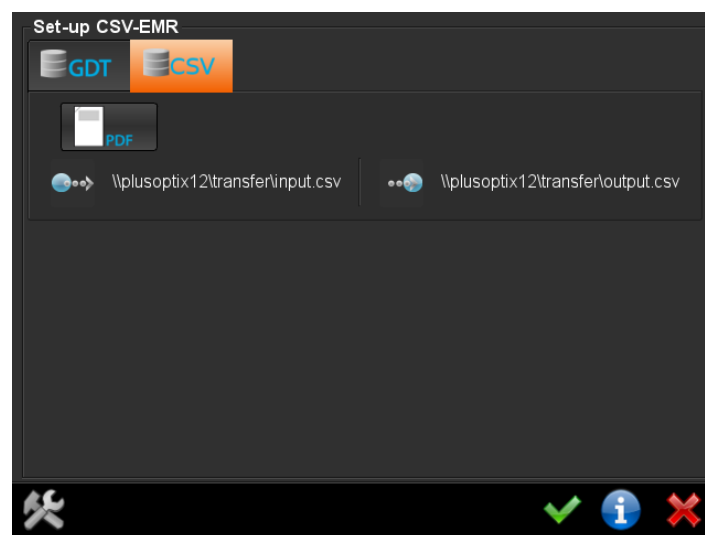
Screenshot 18: CSV settings for EMR integration

1) 2) 3)

Data fields in a CSV file have to:
- be separated using the separator "," or ";" as selected in Basic settings
- contain five separators (the separator after "contact" is an optional addition)
- adhere to this sequence: last name, first name, date of birth, patient ID, location, contact
- include either last name, first name and date of birth or patient ID, location and contact information are always optional
- use same date format as set in Date & time settings
- be positioned side by side in one single line

Examples of CSV data fields (import) are:
a) Smith,John,02/28/2010,,,
b) ,,10/16/2012,0123456789,,
c) Smith,Emily,03/08/2008,AB12CD24,London,mh@mail.uk
d) ,,06/18/2009,A12-B-34-C,EyeClinic,020-123456

Enable button (1) to save a measurement report (see chapter 4.1.9 "Save and print a measurement report") in the transfer folder as well. Where a patient ID number is used, the file name of the measurement report is:
<ID>-<date[YYYYMMDD]>-<timet[hhmmss]>.pdf
(e.g. 0123456789-20140130-124440.pdf)
Where no patient ID number but a patient name is used:
<last name>_<first name>-<date[YYYYMMDD]>-<time[hhmmss]>.pdf
(e.g. Smith_John-20140130-124440.pdf)
Note that in order to save a measurement report a SD-card has be connected to the device.

File names for input (2), i.e. patient data, and output (3), i.e. measurement result, files as well as transfer directory information are displayed on screen.

The information in the output file (URL\\plusoptix12\transfer\output.csv) is formatted this way:

Measurement date time,internal ID,last name,first name,date of birth,patient ID,location,contact,
OD_Sph,OD_Cyl,OD_Axis,OD_Pupil size,
OS_Sph,OS_Cyl,OS_Axis,OS_Pupil size,
asymmetry,pupil distance,monocular,measurement result,PDF file name,-1,reason of referral,

The "Monocular" field may contain values 1, 2 or 3. These values represent:
1 = Monocular measurement OD
2 = Monocular measurement OS
3 = Binocular measurement

The "Measurement Result" field may contain values 4 or 5. These values represent:
4 = measurement has started; measurement results are available
5 = measurement has started; no measurement results are available, i.e. aborted measurement

The field "PDF-filename" is only output if PDF-print has been activated in the Settings (see following chapter).

The field "reason of referral" contains "16777216". This entry is for statistical purposes and remains constant for each output data.

An example of an output file is:
01/30/2014 12:44:40,639,Smith,John,02/28/2010,,,,
0.81,-0.32,13.67,6.41,
4.90,-0.65,74.46,6.58,
1.33,56.55,3,4,Smith_John-20140130-124440.pdf,-1,16777216,

1) 2) \\plusoptix12\transfer\input.csv 3) \\plusoptix12\transfer\output.csv

4.1.5.2 Transferring data in GDT format (only plusoptiX A12C)

Touch GDT button (1) to choose GDT file format.
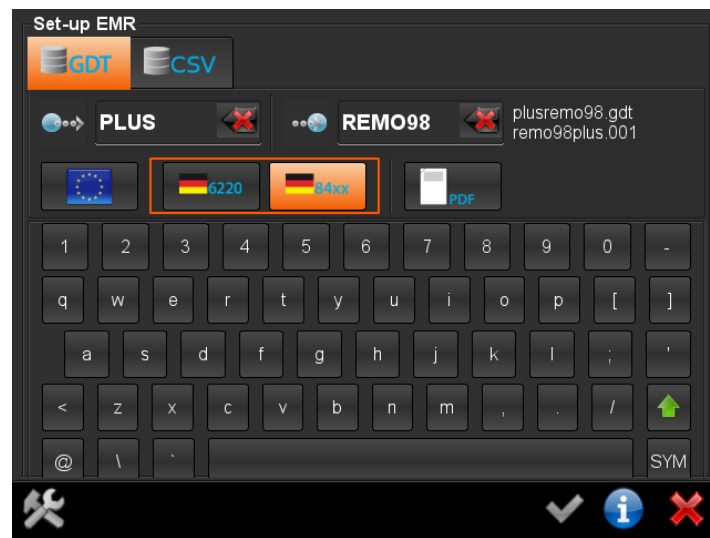
Screenshot 19: GDT settings for EMR integration

Text files are saved in a so-called transfer directory (URL:\\plusoptix12\transfer\) for data exchange. The names of these text files are comprised of sender and recipient identifiers. These identifiers (4 characters each) can be set by touching buttons (2) and (3). The file names used are displayed alongside these identifiers (4).

The file "plusremo.gdt" contains patient data from the EMR system, and the file "remoplus.001" contains measurement results from the first measurement of this patient. If the same patient is measured repeatedly, the file extension is incremented by one each time for each subsequent measurement ("remoplus001", "remoplus002" "remoplus003" etc.)

The measurement results that are saved in file "remoplus.001" can be formatted in different ways. Touch button (5) to use an extended GDT format. Using buttons (6) and (7), you can choose between the strict GDT formats with the results in 6220 (6) or 84xx tuple (7).

Using button (8) you can also save a measurement report (see chapter 4.1.9 "Save and print a measurement report") to the transfer directory. The file name for the measurement report is: "remoplus.001.pdf". Where additional measurements are performed for the same patient, a new measurement report is saved, too ("remoplus.002.pdf", "remoplus.003.pdf" etc.). Note that in order to save a measurement report a SD-card has to be connected to the device.

To save your settings, touch Checkmark button in navigation bar (9).

If the device receives patient data from the EMR system in the transfer directory, this data is displayed in Header on start screen (1) and under "Repeat Measurement" (2).
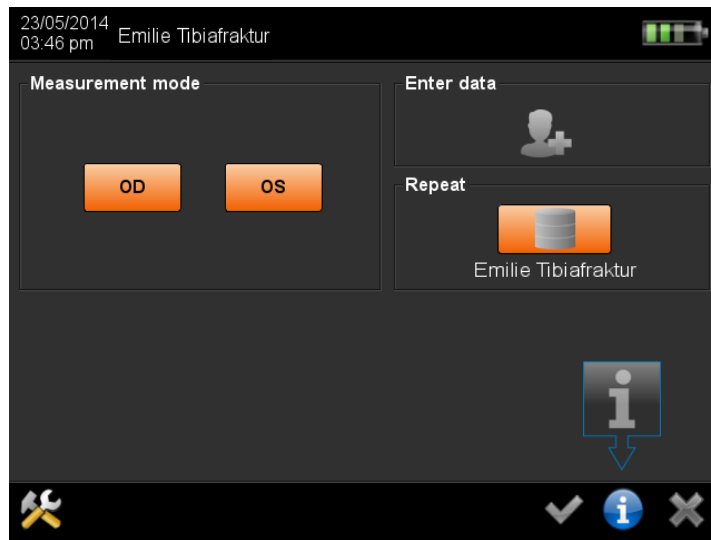
Screenshot 20: Start screen with an active connection to EMR

⚠️ **Note**:
Note that it is now impossible either to enter patient data manually or to retrieve patient data from the database. The associated button is grayed out (3).

1) 23/05/2014 03:46 pm Emilie Tibiafraktur   2) Emilie Tibiafraktur   3)

4.1.6 Export data (only plusoptiX A12C)

All patient data and measurement results are stored in the database. This database can be used to create backup copies and reports.

⚠ **Note**:
To save storage space, video files are not stored in the database. The last image for each measurement is stored together with the measurement report (see chapter 4.1.9 "Save and print a measurement report") on the SD card. In this manner, the database can contain up to 100,000 entries (patients or measurements).

Touch Export button (1) in Settings to move to this screen:
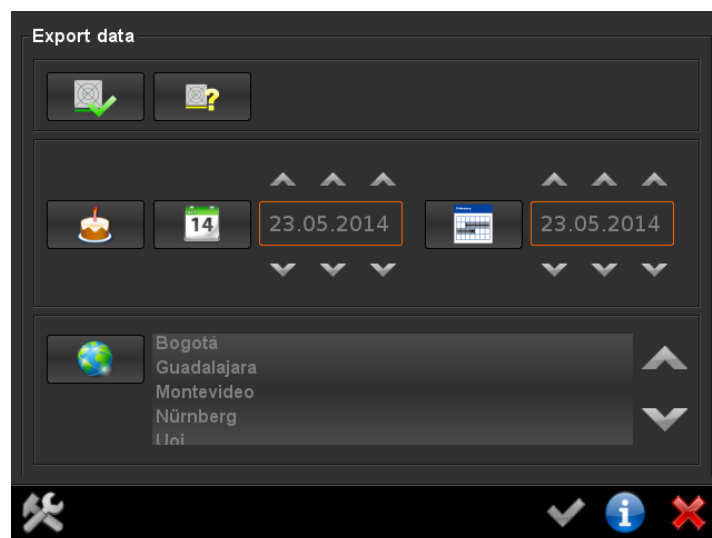
Screenshot 21: Saving a backup copy

To prevent data loss, you should save a copy of your database on a regular basis. To do so, connect an USB storage device and ensure that no filters are activated (i.e. none of the buttons on screen are highlighted in orange). Now touch Checkmark button (2). The entire patient database is now saved on the USB storage device as a DB file.

⚠ **Note**:
Checkmark remains inactive (3) until an USB storage device is connected.

This backup copy can be used to restore a database. To do so, connect an USB storage device containing the DB file in its root directory to the device. A prompt appears as to whether the saved database should be restored. Where multiple databases exist in the root directory of the USB storage device, the most recent (by save date) will be restored after confirmation.

1) 2) 3)

Note:
If you restore a database, a backup copy of the existing database is first saved to the USB storage device. The existing database is then overwritten with the database to be restored. The two databases (backup copy on the USB device and the existing database in the device) are not merged.

To create a report, first connect an USB storage device to the device and then define the scope of the report using data filters. To save a report, touch Checkmark button (1) in the navigation bar.

The filters have the following meaning:
(2) Report includes all successful measurements, i.e. measurement results are available.
(3) Report includes all aborted measurements, i.e. no measurement results were obtained.
(4) Report includes all patients with the set date of birth.
(5) Report includes all patients measured on the set date.
(6) Report includes all patients born (button (4) is active) or measured (button (5) is active) on the set dates or between these dates.
(7) Report includes all measurements that were performed at the set examination location.
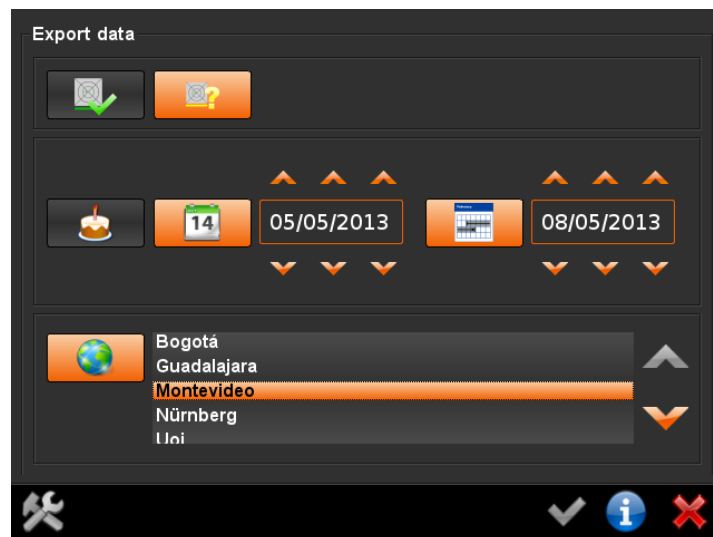
Screenshot 22: Generate a report

If you select filters that are active in screenshot 23 (active filters are highlighted in orange), a CSV file with all inconclusive measurements at the examination location of Montevideo, that took place in between 05/05/2013 and 05/08/2013 (both dates inclusive), will be created.

Note:
Reports are always saved as a CSV table. CSV tables can be processed by all conventional spreadsheet programs.

1) 2) 3) 4) 5) 6) 7)

4.1.7 Import patient data (only plusoptiX A12C)

Patient data (i.e. a roster of patients) can be imported from a CSV table via the USB port.

Data fields in a CSV table to be imported have to:

- be separated using the separator "," or ";" as selected in Basic settings
- contain five separators (the separator after "contact" is an optional addition)
- adhere to this sequence: last name, first name, date of birth, patient ID, location, contact
- include either last name, first name and date of birth or patient ID, location and contact information are always optional
- use same date format as set in Date & time settings (e.g. 01/31/2013 or 31.01.2013)

	A	B	C	D	E	F
1	Family name	First name	Date of birth	Patient ID	Location	Contact
2	Smith	John	02/28/2010			
3				0123456789		
4	Smith	Emily	03/08/2008	AB12CD24	London	mh@mail.uk
5			06/18/2009	A-12-B-34-C	Exam room	020-123456

Figure 12: Example of a CSV table

Note:
The column titles in the first row are not imported. Although a patient's data is located in the first row of the CSV table, this first set of patient data is not imported.

Save your CSV table on an USB storage device and connect it to the device. Then touch Data import (2) in Settings (1). A list of all CSV tables that exist on the USB storage device will be displayed on screen. Select the CSV table to be imported and confirm your selection by touching Checkmark button in navigation bar (3).

Before patient data is imported, the device automatically checks whether the data records are consistent (e.g. no numerical values in the "last name" field). However, data entries that have been swapped around (e.g. first name instead of last name) are not automatically detected. As a result, you are prompted to check whether the patient data is displayed in the correct sequence. If this is the case, confirm the data import by touching Checkmark button (3) in navigation bar.

Note:
Imported patient data is always added to the entries already stored in the database. When importing patient data, no data is deleted.

1) 2) 3)

4.1.8 Retrieve patients from database (only plusoptiX A12C)

If you have already entered or imported patient data, you can retrieve a patient's data record from the database. To do so, proceed exactly as if you were entering data for a new patient.

Touch button (1) on start screen to move to patient data entry. Begin by entering the required patient information (e.g. first name, last name, patient ID, location or contact information).

As soon as a maximum of 4 data records with the same character string exist in the database, these are displayed in a short list. To select a patient from this short list, simply touch the corresponding entry in the short list.
If you make a mistake when entering patient information, you can delete the last character by touching Backspace button (2).

The name (or ID number) of the patient is then displayed in the header, and all measurement results for this patient to date are displayed in the information section. You can now start a new measurement by touching the Shutter.
As soon as the short list is displayed, you can add a new patient to the database (3), edit patient information for an existing patient (4) or delete a patient (i.e. all patient information and measurement results are deleted) (5).

Figure 13: Retrieving patients from the database

1) 2) 3) 4) 5)

4.1.9 Save and print a measurement report

A measurement report documents the measurement results and the last picture taken during the measurement. If an anonymous measurement was performed, the measurement report has to be saved manually by touching the printer button (1) in the navigation bar. After touching the printer button (1) the patient data entry template is displayed by plusoptiX A12C (see chapter 3.3 "Entering patient data (only plusoptiX A12C)"). PlusoptiX A12R displays a input field instead. Fill in the patient information that should be printed on your measurement report and then touch the green checkmark (2). The measurement report is then saved.

> ⚠️ **Note**:
> The connection of an external keyboard is necessary for the input of the patient data on the plusoptiX A12R.

To be able to allocate these PDF files to individual patients, the patient information is part of the file name. If a patient ID is entered instead of or in addition to the patient name, this patient ID forms part of the file name instead of the patient name. A date and time stamp is also included.
Example: Smith_Emily_20140527-114102.pdf

If patient data was entered or retrieved with plusoptiX A12C, a measurement report is automatically saved on the SD card at the end of the measurement.
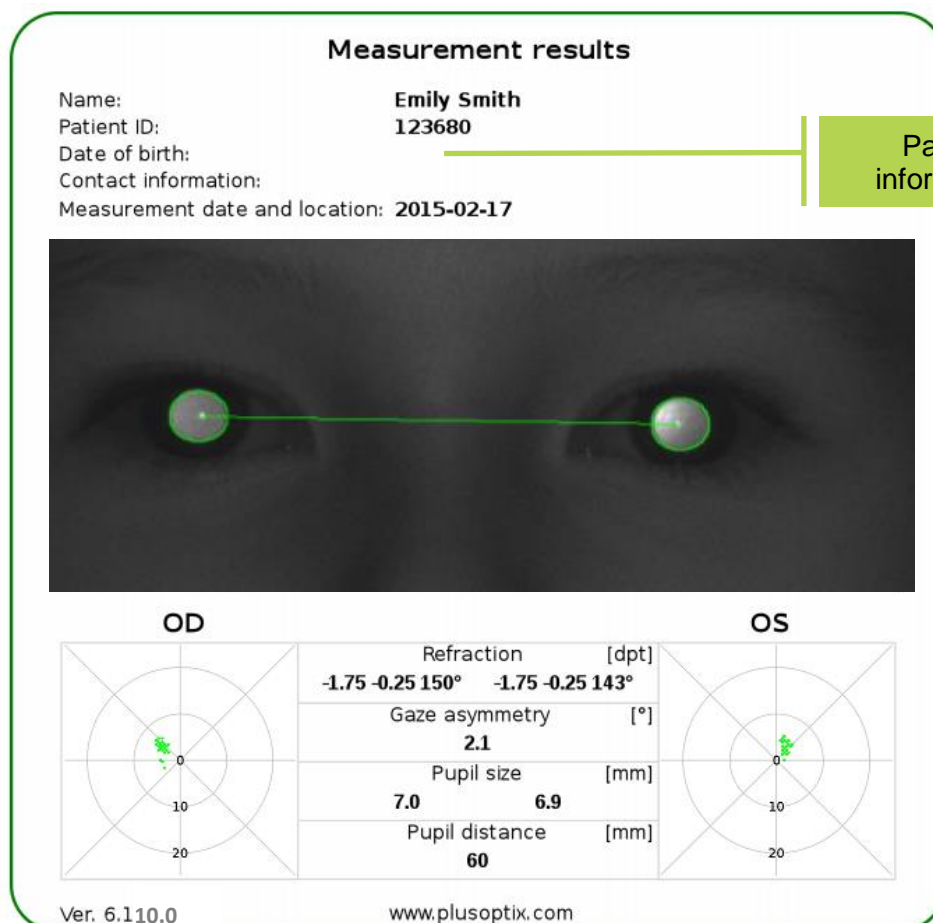
Figure 14: Measurement report (plusoptiX A12C)

1) 🖨️ 2) ✅

4.1.10 Compatible printers and network printing

For the documentation of the measuring results a self-adhesive label or a measurement report can be printed.

To print self-adhesive labels the driver software of two printers is pre-installed on the device. These printers are "plug-and-play" compatible, i.e. as soon as one of these printers is connected to the device, the device recognizes the printer automatically and after a restart the printer can be used. No software needs to be installed.

Note:
Other printers are not compatible and it is not possible to install their driver software. The attempt to install printer drivers terminates both the license as medical measuring device as well as the guarantee.

DYMO LabelWriter 450 and 450 TURBO

To create a printout with the DYMO LabelWriter 450 / 450 TURBO, you must connect the power supply unit to the DYMO printer and connect the printer to the device with a USB cable. Use DYMO labels of the size 54 x 70 mm (2 ⅛ x 2 ¾ in).

plusoptiX P12

The plusoptiX P12 is battery-powered and has an infrared interface. Hold the device pointed towards the infrared receiver of the plusoptiX P12 at a distance of approximately 1 m.

Note:
Sending print orders to the plusoptiX P12 over the infrared interface only works for devices from supplement "01D" in the serial number (e.g.: S/N 120xA-**01D**-xxxx xxxx).

Note:
Use only original paper available from Plusoptix or a Plusoptix authorised dealer.

A sample of the information printed on the self-adhesive label is shown in figure 15:

Name or ID	**First name Last name**	***31/12/2013**	Date of birth
	OD	OS	
OD	+0,75 dpt Sphere +0.25 dpt		OS
	-0,75 dpt Cylinder -2.25 dpt		
	176° Axis 87°		
	5.8 mm Ø pupil 4.5 mm		
	Pupil distance 56 mm		
	Gaze asymmetry 7.6 °		
Software version	Ver. 6.1.10.0 17/07/2015		Measurement date
	www.plusoptix.de		

Figure 15: Self-adhesive label sample

With every successful measurement a measuring report is saved on the SD card as PDF-file (see chapter 4.1.9 "Save and print a measurement report"). In order to then print out the measuring report on your network- or workplace printer, you must open the PDF-file of the measuring report from your workplace computer.

For this there are three different possible methods of access available:

- Connection via your DHCP WLAN server – see chapter 4.1.4 (only plusoptiX A12C)
  File access with URL:
  \\plusoptix12\pdf (Windows Explorer),
  smb://plusoptix12/pdf (Apple Finder)

- Connection via Mini-USB-cable – see chapter 4.1.12
  File access with URL: removable medium:\pdf

- Connect SD card directly to your workplace computer

Start Windows Explorer or Apple Finder and open the file to be printed. You can print out the file on any optional printer connected with your network or workplace computer.

⚠️ **Note**:
The connection over a Mini-USB cable is available for all A12x devices from the supplement "01F" in the serial number (Example: S/N 120xA-**01F**-xxxx xxxx).

⚠️ **Note**:
If the workplace computer displays the error message "Access denied", close Windows Explorer or Apple Finder and then restart the program.

4.1.11 SD card and USB interfaces

You can connect two storage media devices (one SD card and one USB storage device) to the plusoptiX device.

⚠ **Note**:
All interfaces are installed upside down. Therefore all connectors must also be turned around before being inserted (i.e. USB symbol faces downwards).

It is possible that a storage medium is not detected after being inserted. In this case, use a storage medium from another manufacturer. Non-functional storage media do not constitute a service or warranty claim.

⚠ **Attention**:
If you format a storage medium, all data saved on the storage medium will be lost. No backup copy is created!

All storage media must be formatted as FAT 32. If you insert a storage medium with a different formatting, and this medium is recognized by the device, you will be asked whether you wish to format the storage medium as FAT 32.

The advantage of a SD is that it fits flush with the device and does not protrude from the device housing. Consequently, the SD card can remain in the device during measurements.

All measurement reports (see chapter 4.1.9 "Save and print a measurement report") are saved exclusively on SD cards.

Database backup copies and reports are saved exclusively on the USB storage device (see chapter 4.1.6 "Export data").

⚠ **Note**:
All USB storage devices protrude from the device housing, and should therefore only be connected temporarily. Remove the USB storage device before performing a measurement.

Instead of a USB storage device you can connect a USB keyboard or mouse to the USB port alternatively (see chapter 4.1.14 "External mouse or keyboard").

4.1.12 Mini-USB interface

Attention:
To avoid damage to the device, do not connect any other external device to the Mini-USB port except your workplace computer.

The device features a 5-pole-Mini-B-USB port. This is used by Plusoptix as part of the production process and in the case of a service and warranty issue. The connection over a Mini-USB cable is available for all A12x devices from the supplement "01F" in the serial number (Example: S/N 120xA-**01F**-xxxx xxxx). Because of the technical design, devices with older serial numbers are not compatible.

It can be used to connect the device to your workplace computer. The device is portrayed as removable medium in your Windows-Explorer or Apple Finder.

Note:
All interfaces are installed upside down. Therefore all connectors must also be turned around before being inserted (i.e. USB symbol faces downwards).

The connection with Mini-USB is used for:

- Printing a measurement report (PDF file) – see chapter 4.1.10
  URL: removable medium:\pdf

- Download Software Updates – see chapter 4.1.13

Note:
To use the Mini-USB interface the WLAN interface must be deactivated. If there is an active WLAN connection, the Mini-USB interface is deactivated.

4.1.13 Download Software Updates

We recommend to check regularly, whether there is a new software version available to download. The latest software version can be downloaded either over WLAN or over a Mini-USB cable. If your device is already up-to-date, a corresponding is displayed.

Please take the following precautions to implement the software update:

- Insert a blank SD-card
- Connect the plusoptiX device to the power network
- Establish internet access (either over a WLAN-connection with your DHCP server or over a Mini-USB cable to your workplace computer)

Note:
Downloading Software Updates over a Mini-USB cable is available for all A12x devices from the supplement "01F" in the serial number (Example: S/N 120xA-**01F**-xxxx xxxx).

To download a software update to your device:

- Touch the button to configure the software (2) in the Settings (1)
- Touch the symbol (3) to download the current software
- Confirm with the green tick (4). You will be guided through the download with the help of status messages on the screen.

After the download the software update is saved on the SD-card and a confirmation is displayed. As soon as you acknowledge this with OK the device restarts automatically and thereby installs the software update.

Attention:
When saving the software update, all data stored on the SD-card are deleted! Therefore use only blank SD cards.
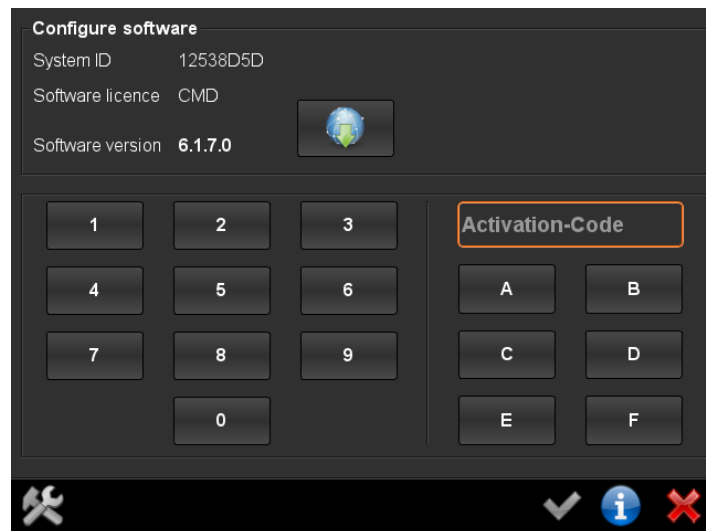
Screenshot 23 : Downloading Software Update

1) 2) 3) 4)

Downloading Software Update via WLAN (nur plusoptiX A12C)

With active WLAN-connection you will be guided through the update with the help of the following status messages (see Figure 16).

⚠ **Note**:
Depending on the signal strength of the WLAN- and the Internet connection, a software update over WLAN can take about 30-40 min.

An empty SD card and stable WLAN connection
are required to update software.
Connect device to power supply.
↵ OK   ✕ Cancel

Software update is being downloaded.
-Do not switch off this device.
-Do not disconnect power supply.
1%

New software version was downloaded sucessfully.
A software update SD card will be created.
All information on SD card will be deleted!
↵ OK   ✕ Cancel

Software update SD card is being created.
-Do not switch off this device.
-Do not disconnect power supply.
4%

Software update SD card created sucessfully.
Do not remove software update SD card.
Software update will be installed.
↵ OK

Figure 16: Software Update via WLAN

Downloading Software Update via Mini-USB-cable

If there is no WLAN-connection available, the software update can be downloaded via Mini-USB cable (see Figure 17).

⚠ **Note**:
Depending on the internet connection, a software update via Mini-USB cable can take about 15-25 min.

Action recommendations on the device   Action recommendations on your workplace computer

In order to update software a computer
with internet connection and an empty SD card are required.
Connect device to power supply.
↵ OK   ✕ Cancel

Connect device with mini USB cord to your computer.
Touch OK to confirm.
↵ OK   ✕ Cancel

A connection is being established with your computer. Please wait...
29%

Your computer has now access to a new drive.
Locate the drive under devices on your computer
and proceed to the subfolder corresponding to your
operating system (e.g. Microsoft vs. MacOSX).
Execute Plusoptix Image Downloader software in this subfolder.

Please open Windows Explorer or
Apple Finder and choose the
corresponding file folder.
File access with URL:
Removable medium\pdf

Name	Änderungsdatum	Typ
MacOSX	04.03.2015 09:09	Dateiordner
Windows	04.03.2015 09:09	Dateiordner
version.txt	04.03.2015 09:09	Textdokume

Start Plusoptix Image Downloader to
download the Software Update.

Name	Änderungsdatum	Typ
Tools	04.03.2015 09:09	Dateiordn
Plusoptix Image Downloader.bat	04.03.2015 09:09	Windows-

"Plusoptix Image Downloader"
"Downloading files needed for update. Please be patient."
3,9%

Software update is being downloaded.
-Do not switch off this device.
-Do not disconnect power supply.
-Do not disconnect mini USB connection.
52%

New software version was downloaded sucessfully.
A software update SD card will be created.
All information on SD card will be deleted!
↵ OK   ✕ Cancel

Plusoptix Update Downloader
ⓘ Download finished! Continue on Plusoptix device!
OK

Software update SD card is being created.
-Do not switch off this device.
-Do not disconnect power supply.
4%

Software update SD card created succesfully.
Do not remove software update SD card.
Software update will be installed.
↵ OK

←--→ Parallel processes

Figure 17 : Software Update via Mini-USB-cable

4.1.14 External mouse or keyboard

To simplify data entry, you can use an input stylus (i.e. touch pen). Alternatively, you can connect a USB mouse or USB keyboard. Connect your input device to the USB port. You can also connect wireless input devices as an alternative to cable-based input devices.

Note:
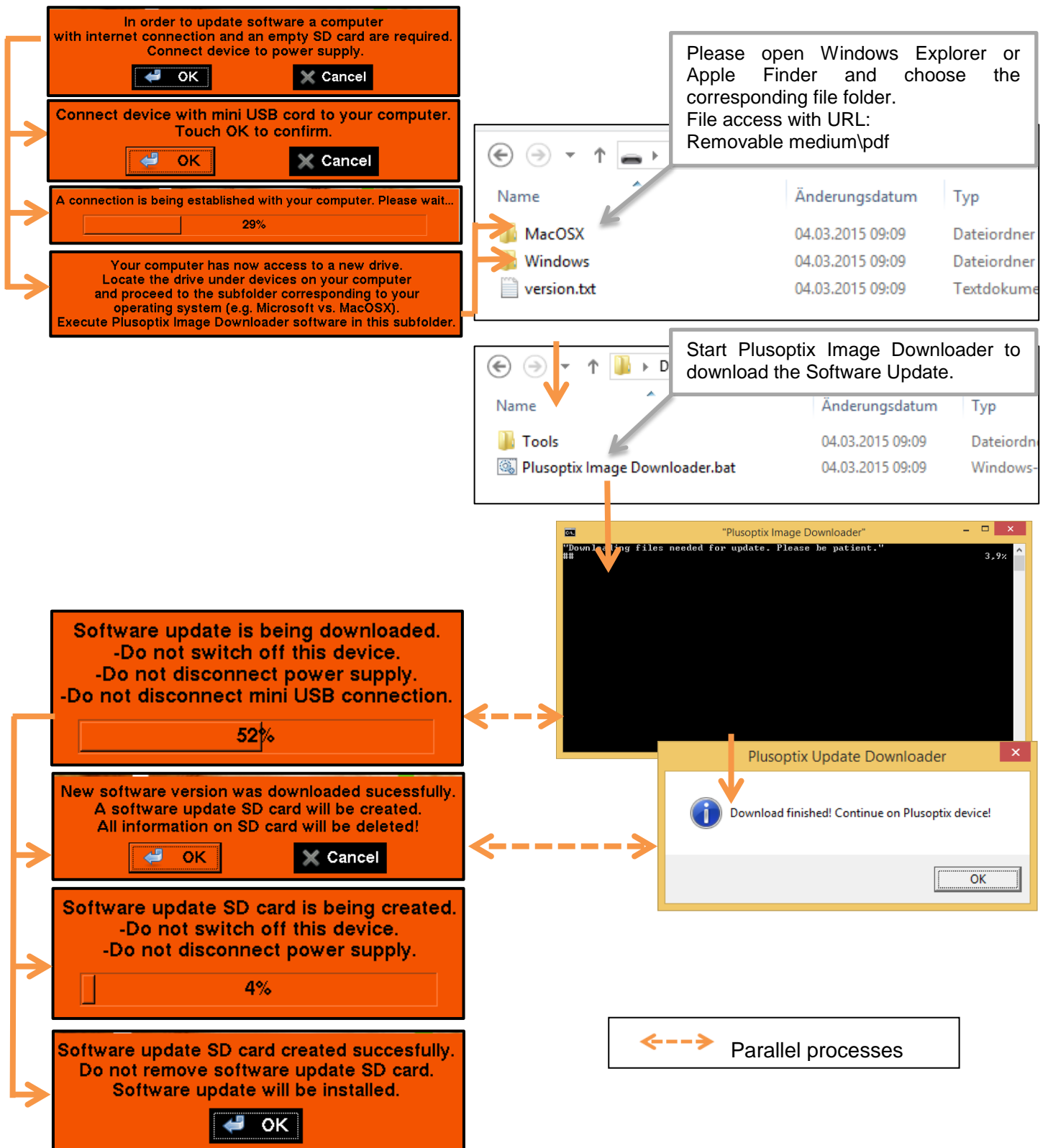All device ports are located upside down, that is, the plugs must also be turned around before being inserted (i.e. the USB symbol faces downwards).

If a connected mouse or keyboard malfunctions, please first check whether batteries are inserted. Then switch on the mouse or keyboard. If your input device still malfunctions, it is not supported by installed drivers. Use input devices from another manufacturer instead (e.g. Logitech or Microsoft).

Note:
Non-functional input devices do not constitute a service or warranty claim.

4.2 Trouble-shooting guide

Vast majority of service queries relate to malfunctions when switching device on, malfunctions when using touch screen or error messages when performing a measurement. It is only in rare cases that these malfunctions are caused by broken hardware. The following chapters provide a step-by-step guide for trouble-shooting.

4.2.1 Trouble-shooting when switching device on

a) The device cannot be switched on

If the device cannot be switched on, connect the power adapter to a plug and check whether the green LED lights up on the upper side of the power adapter. Now connect the 12V charging cable to the device. If the device now switches on, check whether rechargeable batteries are inserted (see chapter 2.3 "Inserting and charging the rechargeable batteries").

b) The device switches off again immediately

If the device switches off again immediately, the rechargeable batteries are likely to be discharged. Connect the 12V charging cable to charge the batteries. Check whether the power supply unit is receiving current (green LED on top of the power adapter lights up). You can use the device while it is being charged. To do so, simply switch the device on while the 12V charging cable is connected.

4.2.2 Malfunctions when using touch screen

a) Screen switches off suddenly

To save power, the device automatically switches the screen off after some time. Touch the screen to activate it again. If the screen is not activated by touching it, the device has switched off automatically. Simply switch it back on again by pressing the On/Off button.

> ⚠ Define in Basic settings after how many seconds the device should automatically switch off the screen and after how many minutes it should automatically switch off itself (see chapter 4.1.2 "Customize basic settings").

b) Buttons on screen do not function

Note:
Bear in mind that grayed out buttons on screen are deliberately inactive.

plusoptiX A12C:
Place the fingertip of your index finger flat on the screen to select a button. Do not tap on the screen with the fingertip or finger nail.

plusoptiX A12R:
Tap on the screen with the fingertip or finger nail.

Every time you touch the screen a small mouse pointer indicates the place in which the screen has been "hit". If you are unable to select a button by touching the screen, check the position of the mouse pointer on the screen. Ensure that the mouse pointer hovers above the button.

Please read chapter 4.1.14 "External mouse or keyboard" if you prefer this option.

c) Screen flickers during a measurement

If the camera lens of the device is too close to a person or an object, the integrated infrared LEDs automatically switch off. The camera image on the screen is then not exposed and shows up black. After a second, the devices switches on the infrared LEDs again and if the person or object is still too close to the camera, only a short white flicker appears on the screen before the infrared LEDs are switched off again.

Simply increase the distance between the camera lens and the person or object, and the exposure of the camera image will automatically adjust again.

4.2.3 Error messages when performing a measurement

If no measurement results are available, an error message and an action recommendation followed by a "Measurement aborted" status message are displayed.
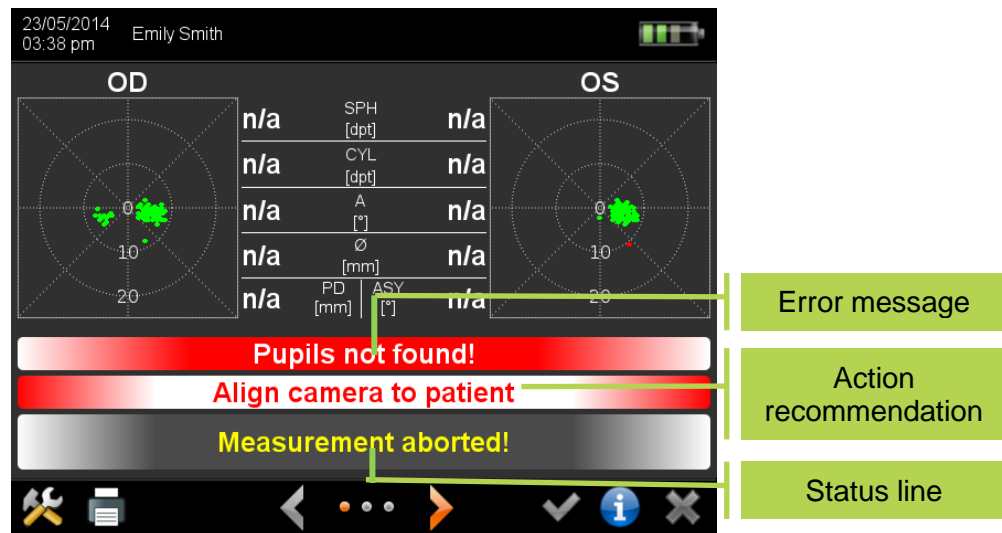
Screenshot 24: Measurement result page after a
"Measurement cancellation"

Note:
Causes of error recognized by the device are highlighted in red on the measurement result page and review video page. Check these two pages after every "Measurement aborted" status message to narrow down the cause of the error.
It is generally easier to identify causes of error on camera pictures rather than on the measurement result page.

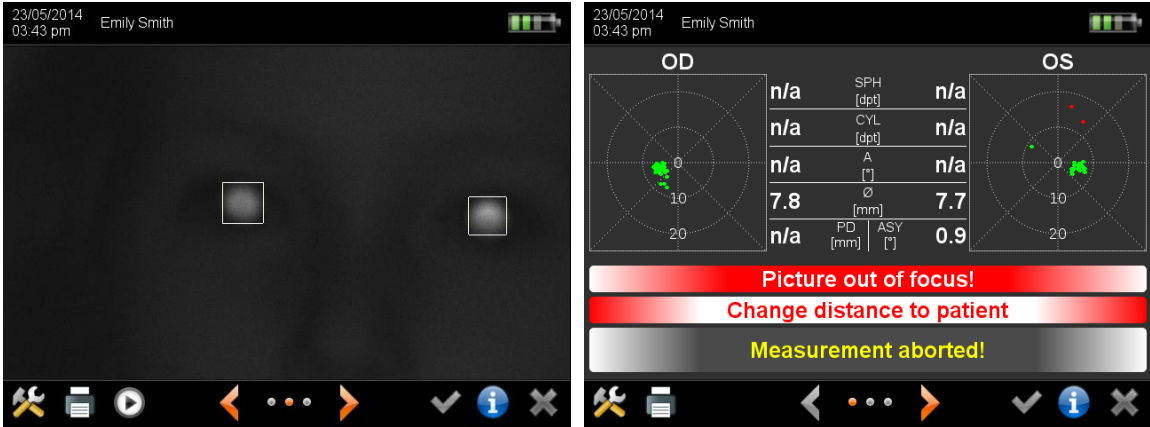The following overview provides a list of all error messages that are stored in the software:

a) "Picture out of focus"
b) "Patient does not focus on camera!"
c) "Pupils too big!"
d) "Pupils too small!"
e) "Pupils not found!"
f) "Too much IR ambient light!"
g) "Measurement incomplete!"
h) "Corneal reflexes are too dark!"
i) "Monocular: Cover OS!" or "Monocular: Cover OD!"

These errors are described below.

a) Picture out of focus
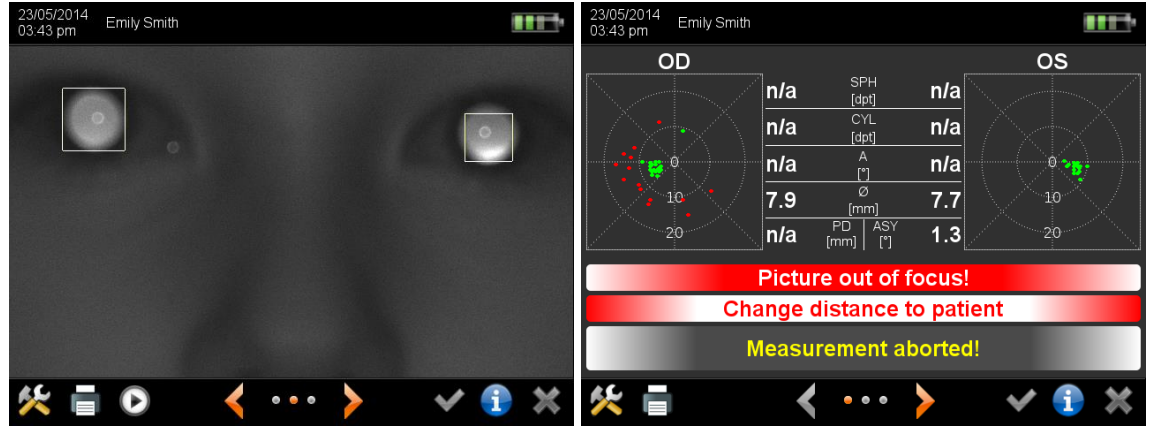
In this example the patient is too far away; besides the eyes, half the patient's face can be seen in the camera image.

In this example the patient is too close to the camera; both eyes are close to the left and right edges of the camera image.

Cause: This error message is displayed if the patient is too close to the camera or too far from it.

Reason: The camera is focused at a fixed measurement distance of 1 meter (3.3 feet) and measures from a distance of between 95 cm (3.1 feet) and 105 cm (3.5 feet).

Tip: You can determine the correct measurement distance on the basis of the camera image, which should appear in clear focus on the screen and every single hair of the eyebrows and eyelashes should be visible.

b) Patient does not focus on camera!
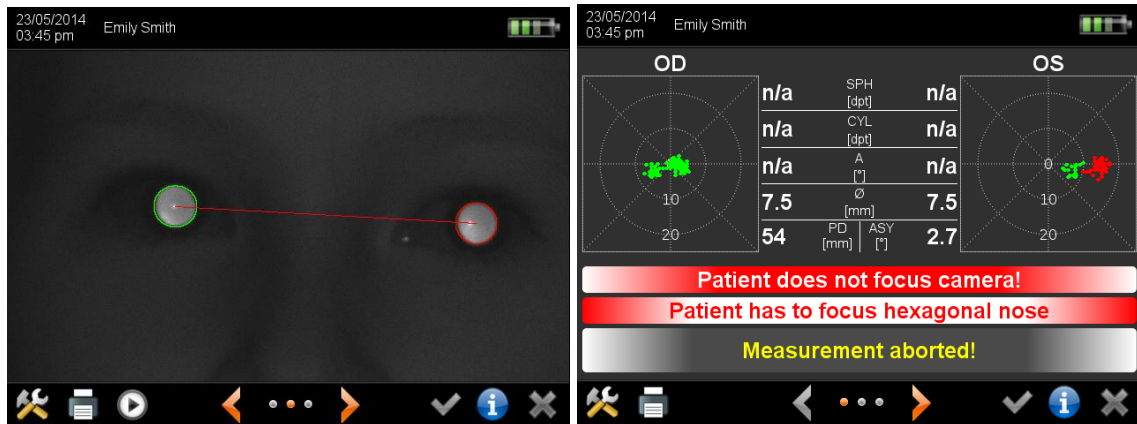
In this example the patient is looking to the left of the camera (from the patient's perspective). The red dots in the gaze chart illustrate this line of vision.

Cause: This error message is displayed if the patient is not looking at the hexagonal nose in the camera face.

Reason: To prevent incorrect refraction measurements in the periphery of the eye, both eyes must be directed at the center of the camera.

Tip: Position the child so that knees and nose are in line with the camera. Do not use any external fixation aids and remain calm. Both corneal reflexes must be located in the center of the pupils in measurement result page, neither of the two gaze charts may show red dots, but only green dots.

c) Pupils too big!
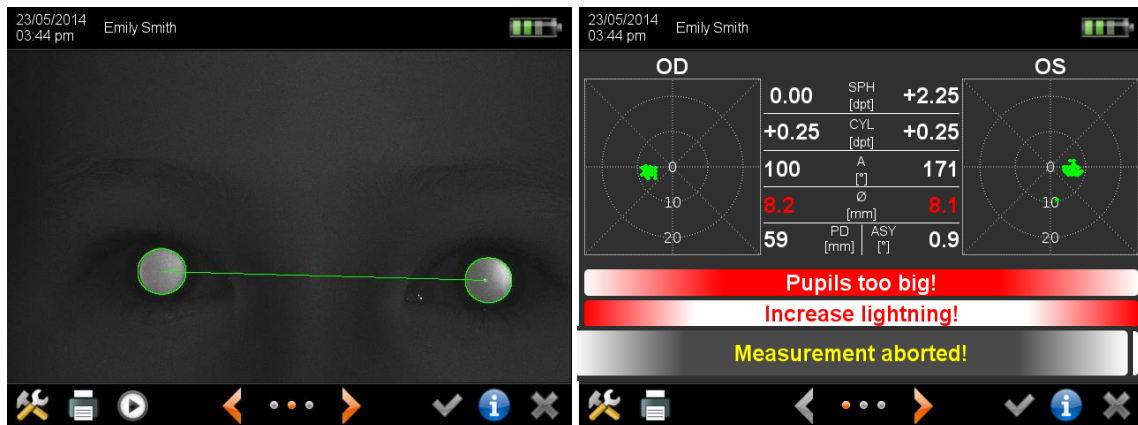
In this example the pupils are larger than 8.0 mm.

Cause: This error message is displayed if one or both of the pupil diameters is larger than 8.0 mm.
Reason: In the case of large pupils, the pupillary reflex may be overexposed, which results in cancellation of the measurement without result. Where measurement results are nonetheless displayed, these have a larger tolerance.
Tip: Light up the examination room so that the pupils become smaller.

d) Pupils too small!
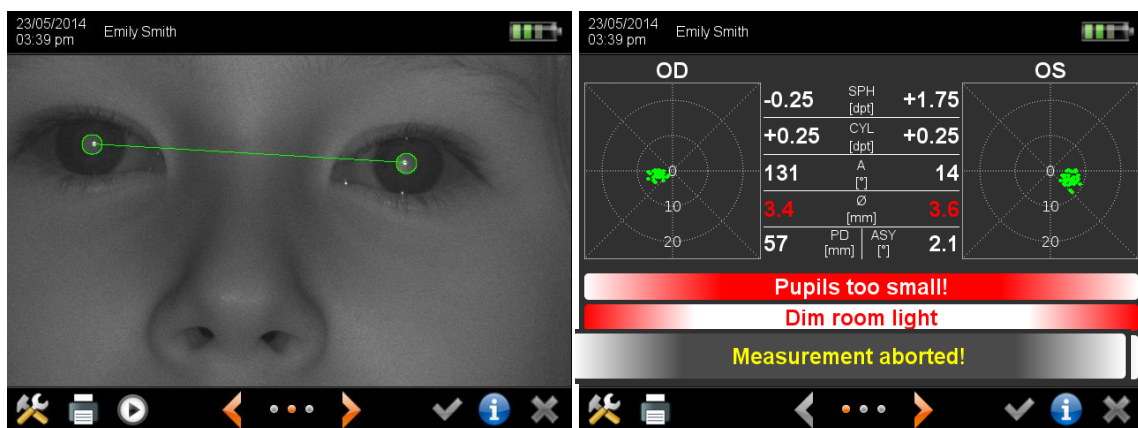
In this example the pupils are smaller than 4.0 mm.

Cause: This error message is displayed if one or both of the pupil diameters is smaller than 4.0 mm.
Reason: In the case of small pupils, the pupillary reflex may be underexposed, which results in cancellation of the measurement without result. Where measurement results are nonetheless displayed, these have a larger tolerance.
Tip: Darken the examination room so that the pupils become larger. Avoid making the examination room too dark, as children feel uncomfortable in such an environment and strain to look around. The examination room should at least be light enough to be able to read a newspaper.

e) Pupils not found!
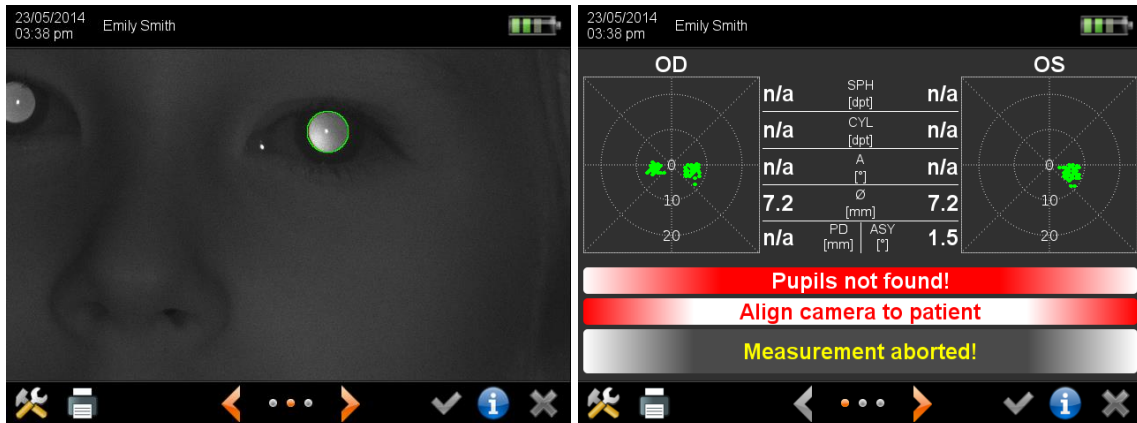
In this example both pupils are not completely visible on the camera image.
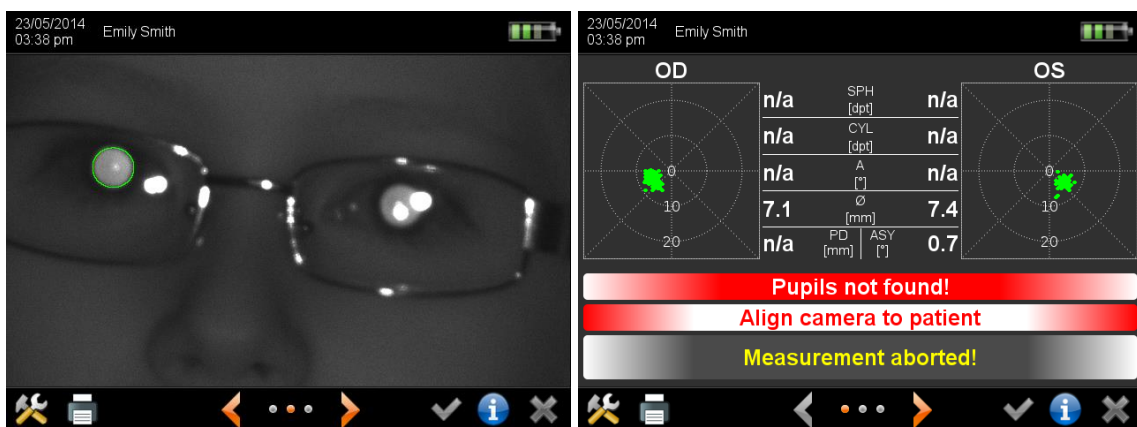
In this example the patient is wearing glasses and the pupils are partially covered due to infrared light reflections on the frame of the glasses and on the lenses.

Note:
The error message "No pupils found!" can have many other additional causes (e.g. scars on the cornea, media opacities, cataracts, keratoconus, retinal detachment etc.). The software is unable to independently determine why no pupils are found. For this reason, it is essential to check the camera image in the event of this error message.

Cause: This error message is displayed if the software is unable to recognize pupils in the camera image, the pupillary reflex appears unusual or the pupils are partially covered by hair, lashes or eyelids.

Reason: In order to perform a measurement, both pupils must be completely visible and the infrared light of the camera must be reflected from the cornea.

Tip: Before performing the measurement, push aside long hair from the face. Ask the child to open his eyes wide or to lift the chin should he be shy and looking down. When performing measurements over glasses, lift the temple arms off the ears so that the lenses tilt downwards. In this manner, the reflections are directed away from the camera image.

f) Too much IR ambient light!
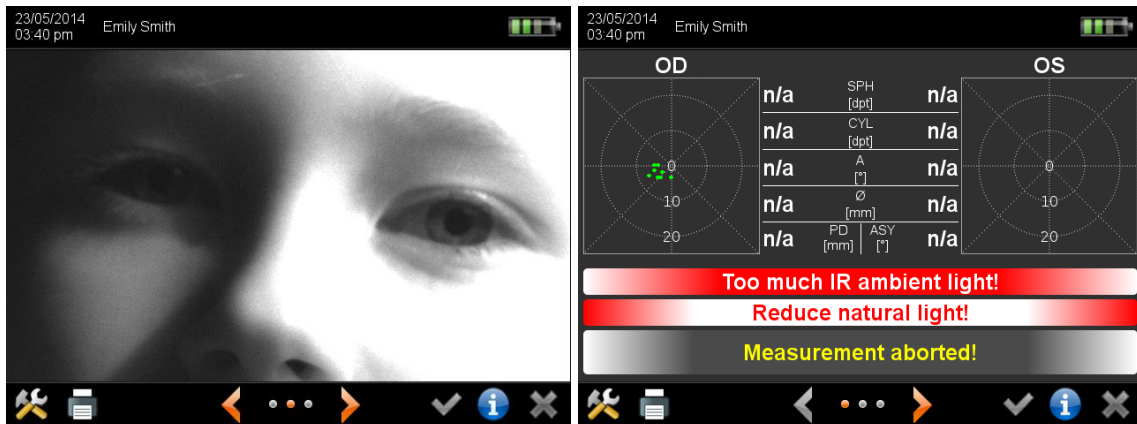
In this example the sun is shining onto the patient's face from the left side. This is apparent from the shadow caused by the nose.

Cause: This error message is displayed if too much infrared light is present in the examination room.

Reason: The measurement takes place with infrared light and other infrared light sources (e.g. sun, halogen lamps, globes etc.) are an interference factor.

Tip: Close the curtains to shut out sunlight, and switch off, dim or turn away light sources that radiate heat.

g) Measurement incomplete!
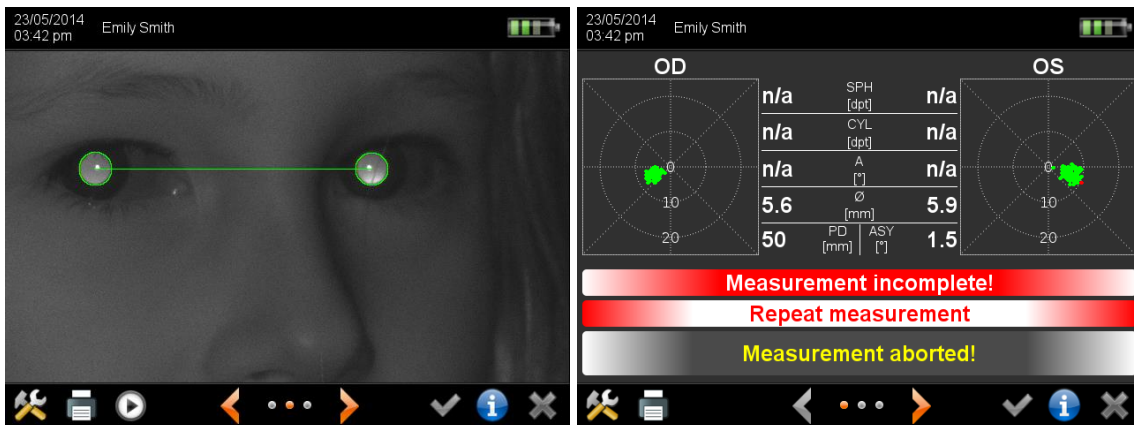
In this example the patient is sitting at an angle to the camera and is looking slightly over her right shoulder. This can be seen by the fact that the nose is visible from the side.
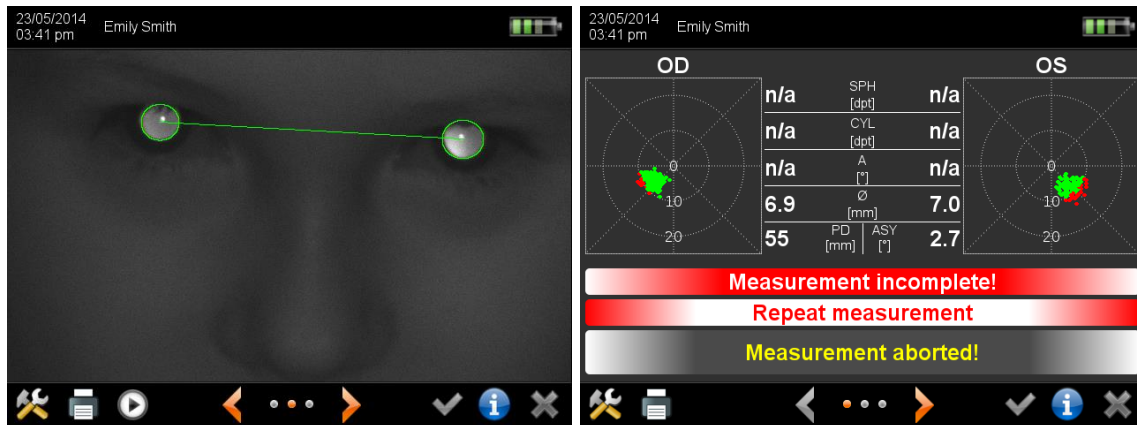
In this example the patient has tilted her head slightly down and is looking up into the camera. The pupils are partially covered by the upper eyelids.
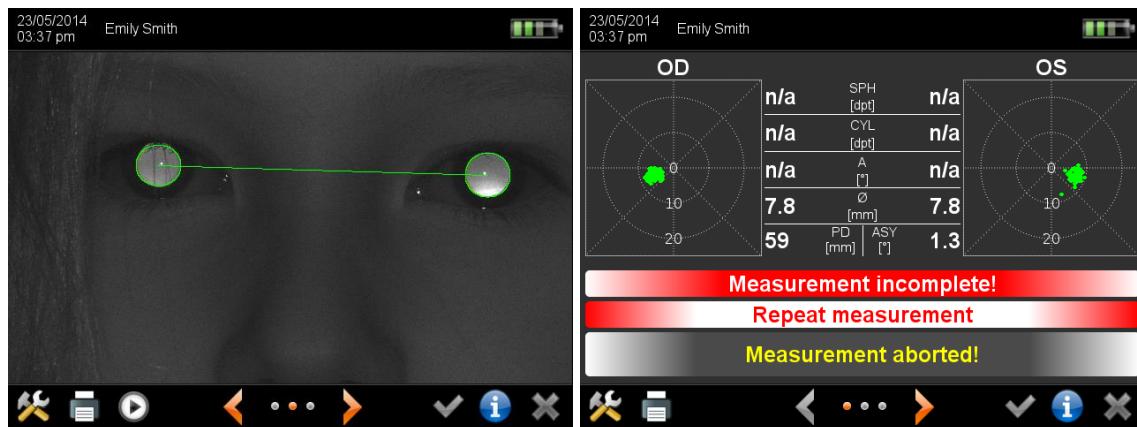
In this example the right pupil is covered by the upper eyelashes and the left pupil by hair.

Cause: This error message is displayed if a measurement has started but could not be completed.

Reason: Once a measurement has started it must be completed within 0.5 seconds (this corresponds to 360 camera images).

Tip: Immediately restart the measurement by pressing the shutter twice.
Position the child so that her knee and her nose are in line with the camera. Ask the child to lift her head, or hold the camera lower.

h) Corneal reflexes are too dark!
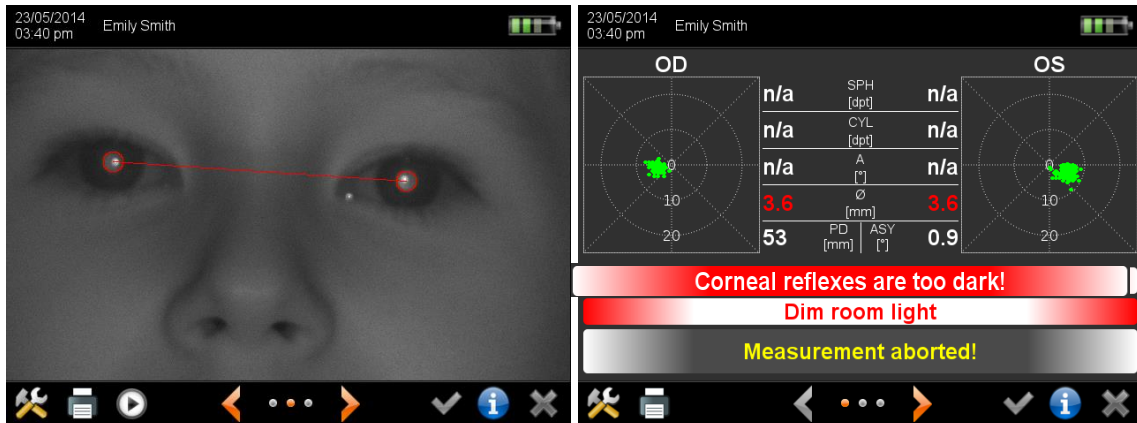
In this example too little infrared light is reflected from the retina.

Cause: This error message is displayed if the pupillary reflexes are too dark.

Reason: The measurement takes place with infrared light, which is reflected from the cornea. Where insufficient light is reflected from the cornea, a measurement cannot be performed.

Tip: Darken the examination room so that the pupils become larger and more infrared light is reflected to the camera.

i) Monocular: Cover OS!
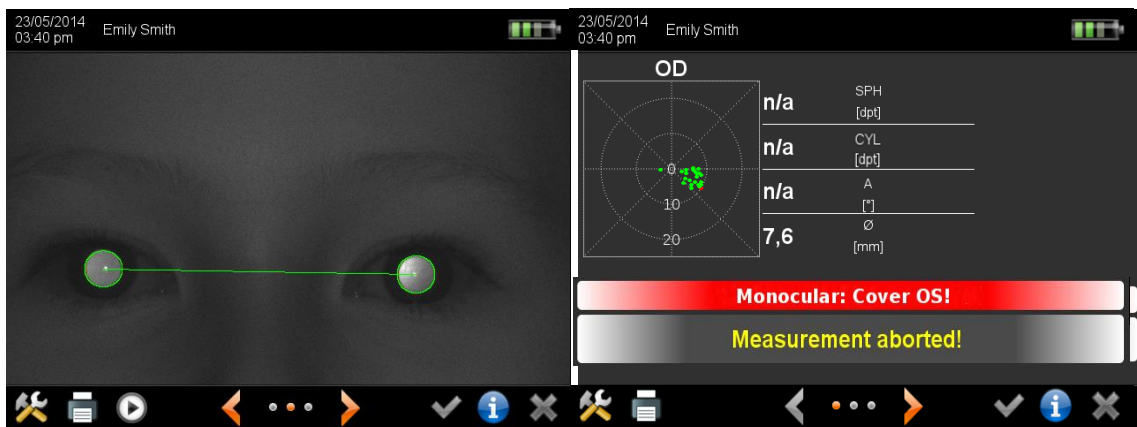
Monocular measurement was previously set on the start screen. If the camera then detects two pupils, the measurement is canceled.

Cause: This error message is displayed if the software detects two pupils in the camera image, in monocular measurement mode.

Reason: Although the software can distinguish between the left and the right eye, one eye must be covered to avoid any possibility of confusion (e.g. "OD" selected but "OS" to be measured).

Tip: In the case of squinting patients, the fixing eye can be measured without covering the eye with the squint if the camera is positioned in such a manner that only the fixing eye is visible in the camera image (that is, only one half of the patient's face). For monocular measurement of the squinting eye, however, the fixing eye must be covered so that the squinting eye fixes the camera.

5 Maintenance, Calibration, Servicing and Warranty

Mobile Pediatric Autorefractor "plusoptiX A12C" and "plusoptiX A12R" are optoelectronic measurement devices. The mechanical design and mode of operation can be compared to a video camera. By handling the device as carefully as your own video camera, your Mobile Pediatric Autorefractor "plusoptiX A12C", "plusoptiX A12R" respectively, will be operational for many years.

Maintenance and calibration
The device is maintenance-free and does not require calibrating. When not in use, store the device in its cardboard box to protect it from dirt and damage. Use a slightly damp microfiber cloth for cleaning.

Service
In the event that the device does not function properly, please first read chapter 4 "Practical Tips" for troubleshooting. Then contact your authorized Plusoptix distributor for support.

Warranty
The device comes with a 12-month ship-in warranty from the date of purchase. A warranty extension is available. Please contact Plusoptix or your authorized Plusoptix dealer if you want to purchase a warranty extension. The warranty becomes null and void in the case of external damage, improper use, incorrect cleaning, or transportation without device cardboard box. The warranty also becomes null and void if the device has been opened. Please note that neither the rechargeable batteries nor the SD card is included in the warranty scope. External devices such as a printer, keyboard and mouse are also not included in the warranty scope.

Returning the device
In the case of a service or warranty claim, please return the device in the device cardboard box at your own costs. We will then return the repaired device to you at our costs.

Shipping addresses of our service centers are:

in Europe:
Plusoptix GmbH
Neumeyerstrasse 46
90411 Nuremberg
Germany
Tel: +49-911-59 83 99-20

in North and South America:
Plusoptix, Inc.
2850 Paces Ferry Road, Suite 440
Atlanta, GA 30339
USA
Tel: +1-800-488-6436

6 Technical specifications

6.1 Measurements

Metered value	Measurement range and tolerance
Sphere	-7 to +5 dpt in 0,25 dpt increments ± 0,25 dpt
Cylinder	-7 to +5 dpt in 0,25 dpt increments ± 0,25 dpt
Axis	1 to 180° in 1° increments ± 15°
Spherical equivalent	-7 to +5 dpt in 0,25 dpt increments ± 0,25 dpt
Pupil diameter	4 to 8 mm in 0,1 mm increments ± 10%
Gaze asymmetry	in 0,1° increments ± 5°
Inter pupillary distance	in 0,1 mm increments ± 10%

6.2 Interfaces and standards

Interfaces	SD card, USB and Mini-USB
	WLAN (only plusoptiX A12C)
Monitor plusoptiX A12C	Screen Size 5,7", Ratio 4:3 (640 x 480 Pixel) Capacitive touch sensor
Monitor plusoptiX A12R	Screen Size 4,3", Ratio 5:3 (800 x 480 Pixel) Resistive touch sensor
Standard	EN 60601-1

WLAN interfaces standards (only plusoptiX A12C):

Physical layer	Supports 802.11 b and g standards
Network architecture types	Communication to wired networks via Access Points
Security	WPA and WPA2
Transmit power	802.11b/g: 50 mW (+17 dBm) typical
Frequency range	2.400 - 2.4897 GHz
Operating channels	1-11 for North America and others, 1-13 for Europe and others
Channels	Supports 802.11d. Will associate with any 802.11d-compliant AP, regardless of what channel is in use.
RX sensitivity	-86 dBm typical @ 11 Mbps, -82 dBm @ 6 Mbps, -69 dBm @ 54 Mbps
Data rates	802.11g: 6, 9, 12, 18, 24, 36, 48, 54 Mbps 802.11b: 1, 2, 5.5, 11 Mbps

6.3 Power supply and rechargeable batteries

Only use medical power adapter type MES30B-3P1J which is included in the delivery.

Medical power adapter (Type MES30B-3P1J)	Input	110 to 240 VAC (50 to 60 Hz), 0,8 A
	Output	12 VDC, 2,5A
Rechargeable batteries (Sanyo HR-3UTGB 1,2V)	Type / Size	Nickel metal hydride NiMH / AA HR6
	Wattage / Number	1900 mAh / 6 pieces

6.4 Ambient conditions for operation and storage

The device can be stored in its cardboard box. Do not store the cardboard box close to heat sources (radiators, heater blowers, etc.). If device is taken out of the cardboard box, do not place it in direct sunlight.

Storage	Temperature	0 to +50°C
	Humidity	10 to 80% noncondensing
Operation	Temperature	+10 to +50°C
	Humidity	20 to 80% noncondensing
Max. height	Max. height for storage	<2.000m (78740'')
	Max. height for operation	<2.000m (78740'')

6.5 Size and weight with and without cardboard box

plusoptiX A12C without cardboard box	Size	260 x 140 x 140 mm (10¼ x 5½ x 5½'')
	Weight	1,0 kg (35,27 oz)
plusoptiX A12C in cardboard box	Size	240 x 430 x 270 mm (9¾ x 17 x 10¾'')
	Weight	2,5 kg (88,18 oz)
plusoptiX A12R without cardboard box	Size	150 x 200 x 135 mm (6 x 7¾ x 5¼'')
	Weight	0,8 kg (28 oz)
plusoptiX A12R in cardboard box	Size	270 x 430 x 250 mm (10½ x 17 x 9¾'')
	Weight	2,3 kg (74 oz)

6.6 Guidance and manufacturer´s declaration – electromagnetic emissions/ immunity

The device is intended for use in electromagnetic environments as specified below. Owner and user of the device are responsible that a use in such an environment is assured.

This product conforms to the EMC standard (IEC 60601-1-2).

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:
- Reorient or relocate the receiving antenna
- Increase the separation between the equipment and receiver
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected
- Consult the dealer or an experienced radio/TV technician for help

Emissions Test	Compliance	Electromagnetic environment - Guidance
RF Emission CISPR 11	Group 1	RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emission CISPR 11	Class B	The device 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.

7 plusoptiX P12 (optional label printer)

Description

The plusoptiX P12 is a wireless, battery-operated printer with infrared interface. It is not included in the scope of delivery and has to be ordered separately.

⚠️ **Attention**:
The printer drivers are pre-installed on all A12x devices from the supplement "01D" in the serial number (Example: S/N 120xA-**01D**-xxxx xxxx).
Because of the technical design, devices with older serial numbers are not compatible.

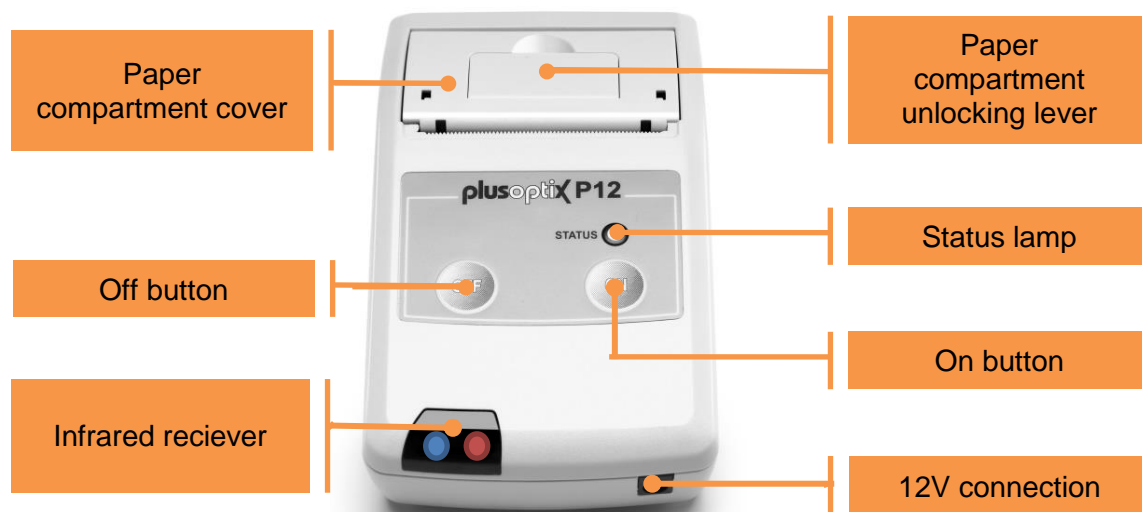| Paper compartment cover | | Paper compartment unlocking lever |
		Status lamp
Off button		On button
Infrared reciever		12V connection

Figure 18: Top of plusoptiX P12

Following switching-on, the status lamp flashes green and the printer is ready for operation. If it does not flash, the rechargeable batteries have to be charged (see "Inserting and charging rechargeable batteries").

If the status lamp flashes red, the paper compartment is not properly closed or a new roll of paper has to be inserted.

If the blue control lamp in the infrared receiver is illuminated, data is received by the plusoptiX S12x.

If the red control lamp is illuminated, the rechargeable batteries are being charged.

Checking scope of supply

The scope of delivery includes the plusoptiX P12, four rechargeable Nickel-metal hydride NiMH/AA HR6 batteries and a roll of self-adhesive labels.

⚠️ For charging the batteries, use the medical power supply MES30B-3P1J. That is the same power supply that is also used for charging the batteries of the plusoptiX A12x.

Inserting and charging rechargeable batteries

⚠️ **Attention**:
If you insert batteries other than those supplied, you should exclusively use rechargeable Nickel Metal Hydride NiMH/AA HR6 batteries with a capacity of at least 1900 mAh and a quick-charge rate of min. 1 A.
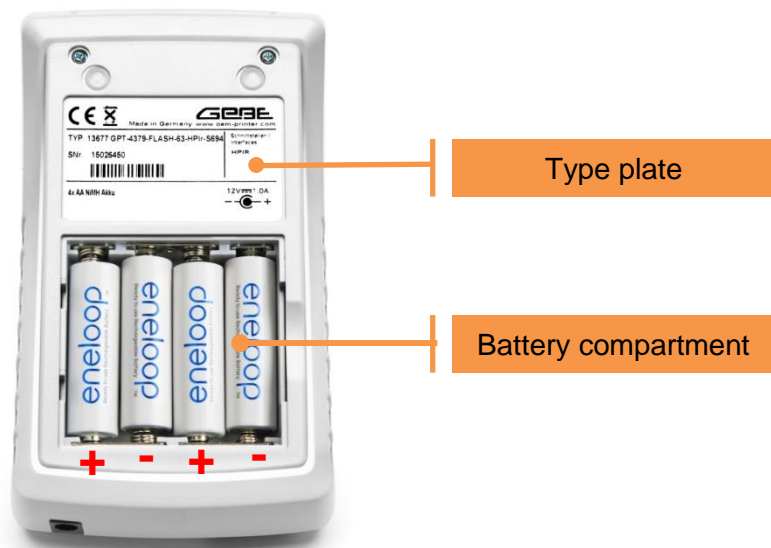

Figure 19: Bottom of plusoptiX P12

Inserting the batteries:

- Place the top side of the printer on a flat working surface
- Then remove the battery compartment cover with a 1-Cent coin and
- Insert the supplied batteries.

⚠️ **Note**:
Ensure when inserting the rechargeable batteries, that the plus and minus battery contacts are at the correct side. If you insert one or more batteries incorrectly by mistake, the printer will not switch on.

Charging the rechargeable batteries:

⚠️ **Attention**:
For charging the rechargeable batteries, exclusively use the power supply MES30B-3P1J supplied with your plusoptiX A12x.

To charge the batteries use the medical power supply unit MES30B-3P1J. This is the same power supply unit that is also used to charge the batteries of the plusoptiX A12x.

Once you have inserted the batteries, close the cover of the battery compartment and place the printer in front of you. Now connect the medical power supply with the power cable to the power socket and check if it is live (the green LED on the top of the medical power supply is on). Following this, connect the medical power supply to the printer.

The inserted batteries are now automatically charged. During the charging process, the red control lamp in the infrared receiver is on and turns off as soon as the batteries are completely charged. The maximum battery charging time of the supplied batteries is 4.5 hours.

Inserting paper

Open the paper compartment by slightly lifting the unlocking lever on the paper compartment cover.

Figure 20: Open cover and insert paper

Unwind a little paper from the roll, so that approx. 1 inch protrudes from the paper compartment. Ensure that the paper layers remain tightly wrapped about the roll core. Then place the paper roll in the paper compartment as shown. After this, close the cover of the paper compartment by pressing down on the cover. The cover engages audibly.

Note:
Use only original paper available from Plusoptix or a Plusoptix authorised dealer.

Switching printer on and off

To switch on, briefly press the On button. The printer starts immediately and is ready for operation as soon as the status lamp flashes green.

When not used, the printer automatically switches off after approximately 10 minutes. To switch it off manually, keep the Off button depressed for 3 seconds.

Printing

After each measurement with the plusoptiX A12x, any number of labels for documenting the measurement results can be printed out. To do so, align the plusoptiX A12x with the infrared receiver of the printer. The distance between plusoptiX A12x and the printer should be approximately 1 m (3,28 ft). As soon as you touch the printer symbol on the screen of the plusoptiX A12x, the data is transmitted and a label is printed out. To confirm the transmission, a blue control lamp lights up in the infrared receiver. Keep the device directed at the printer until the blue control lamp turns off.

> ⚠ **Note**:
> If the infrared transmission is interrupted during a printing order the print-out of the label is also interrupted. To obtain a complete print-out a new printing order has to be sent.

Cleaning

If the print quality should deteriorate it is necessary to clean the printing head, paper sensor, tear-off edge and drive roller. To do so:

- Open the cover of the paper compartment and remove the paper roll.
- If paper dust has accumulated in the paper compartment, clean it out with a vacuum cleaner with fitted brush
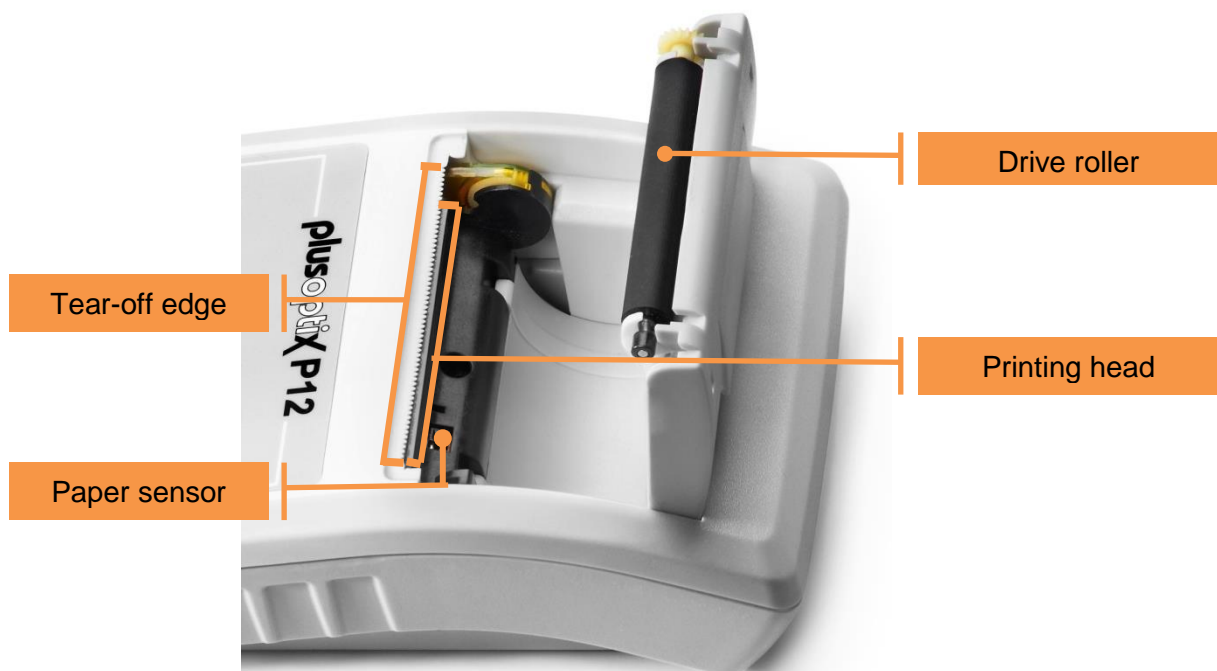- Clean the printing head and the drive roller with an ear bud lightly soaked in isopropanol alcohol (IPA).

Figure 21: Cleaning the plusoptiX P12

Technical details

⚠ **Attention**:
For charging the rechargeable batteries, exclusively use the power supply MES30B-3P1J supplied with your plusoptiX A12x.

Interface	IR-receiver	
Storage	Temperature	0 to +50°C
	Humidity	10 to 80% non-condensing
Operation	Temperature	+10 to +50°C
	Humidity	20 to 80% non-condensing
Dimensions	Dimensions	159.6 x 89.6 x 45.6 mm (6.28 x 3.53 x 1.8 in)
	Weight	0.35 kg (12.35 oz)

Power supply (MES30B-3P1J)	Input	110 to 240 VAC (50 to 60 Hz), 0.8 A
	Output	12 VDC, 2.5A
Rechargeable batteries (Sanyo HR-3UTGB 1,2V)	Type/Size	Nickel-metal hydride NiMH/AA HR6
	Power/Quantity	1900 mAh\/4 each