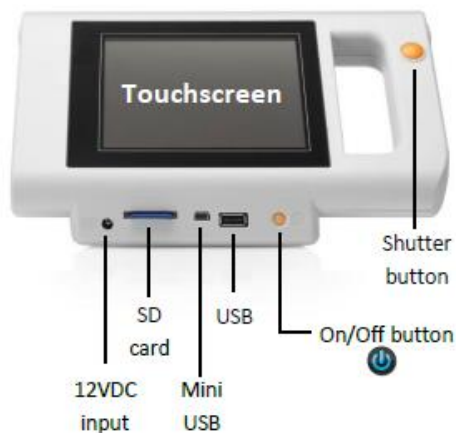


Position statements from Prevent Blindness and a 2016 policy statement published by the American Academy of Pediatrics noted that an instrument-based approach can be used in the medical home as an alternative to visual acuity screening for children ages 3 through 5 years. Instrument-based vision screening is not recommended for children ages 6+ at this time, as typically-developing children at this age should be able to complete a test of recognition visual acuity. Additional research in this area is needed.

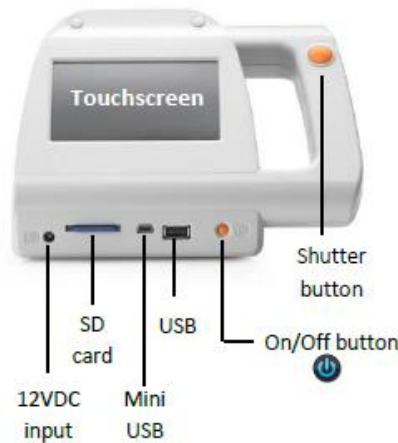


plusoptix S12C & S12R – Short Manual

plusoptix S12C

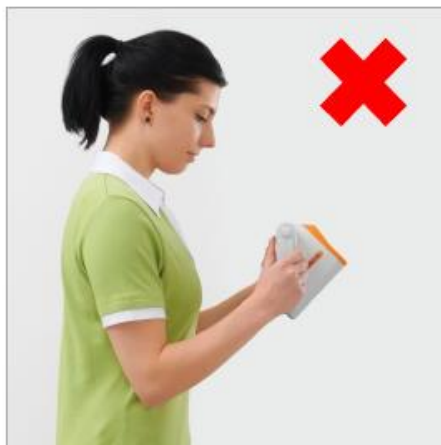


plusoptix S12R

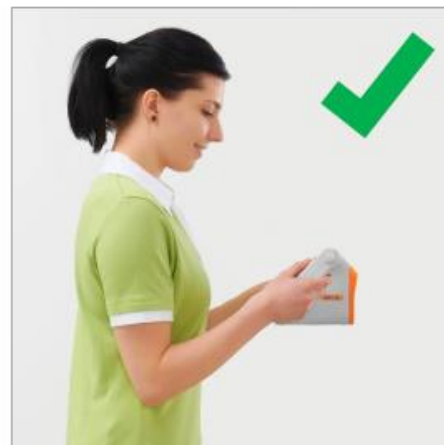


Handling of the device

wrong



right

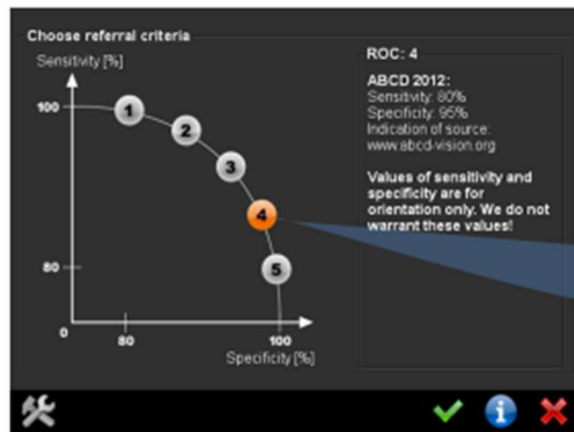


Measurement requirements

1. The examination room should only be slightly illuminated, i.e. no direct daylight. Halogen spotlights and light bulbs are emitting infrared light and should be switched off during measurements. Fluorescent lamps and energy-saving lamps are permitted for lighting the room.
2. Please make sure that the child is not distracted during the measurement.
3. Switch on the device . When the start screen appears, please select the age-group of the child and start the measurement by pressing the orange measurement button next to the screen.
4. The measurement is performed from a distance of one meter (+/- 5 cm) from the child. Start the measurement from approximately 1,2 m distance to the child. Move forward until the pupils are clear and outlined with green circles. At this moment the sound will appear again to signalize that the measurement starts now.
5. It is important to hold the camera on eye-level when performing a measurement. Please make sure that the pupils are not covered by eyelashes, the eyelid or hair. If no screening result appears, a status message will be displayed. In this case please follow the instructions, outlined on the rear side of this page.



Choose referral criteria



ROC 1: 99%/45%

ROC 2: 95%/75%

ROC 3: 85%/90%

ROC 4: 80%/95%

ROC 5: 80%/95%

Screening Result of plusoptiX S12C & S12R

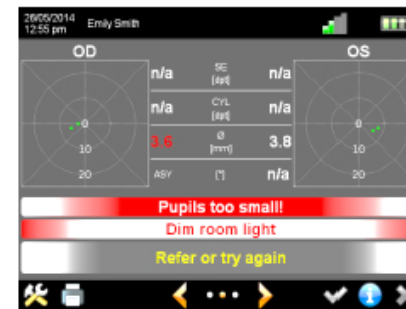


If the status message **“Refer”** is displayed, the child must be sent to an eye specialist for a complete eye examination.

If the status message **“Refer or try again”** is displayed, follow the instructions on the screen and measure again. If you get **“Refer or try again”** again, please send the child precautionally to an eye specialist.

If the status message **“Try again”** is displayed, the measurement was aborted because of a user error. In this case, please follow the instructions on the screen and measure again.

Status-messages



A status message will appear in case no measurement result is displayed on the screen.

← Failure message
← Instruction what to do
← Status message

Pupils not found: Restart the measurement on eye level of the child and make sure the pupils are not covered by hair, eyelashes or the eyelid.

Pupils too big: The size of one or both pupils is over 8 mm. Increase the lightning in the room so that the pupils get smaller.

Pupils too small: The size of one or both pupils is below 4 mm. Decrease the lightning in the room so that the pupils get bigger.

Camera picture out of focus: Please make sure to have the right distance to the patient (1m +/- 5cm).

Too much IR ambience light: Close the curtains to avoid too much daylight in the room.

Patient does not focus the camera: Please measure again and make sure the patient is focusing on the nose of the smiling face on the camera.

Measurement incomplete: The measurement result is n/a. Repeat the measurement and make sure that the pupils are not covered by hair, eyelashes or the eyelid.

Corneal reflexes are too dark: Dim room light so that the pupils get bigger.

A detailed description of the status messages and its reasons can be found in the user manual point 4.2.3. **“Error messages when performing a measurement”**.