



Version 1.0

Instructions for Use

Intended Use

EyeTurn is software, loaded on a mobile phone that is intended to measure ophthalmic characteristics and to aid in the diagnosis of ophthalmic abnormalities.

Indications for Use

To be used by Ophthalmologists, Optometrists, and other qualified health care professionals. Clinical support staff can also use EyeTurn.

Recommendations Prior to Use

It is highly recommended that all persons, eye care specialists and healthcare professionals or clinical support staff, thoroughly review this document prior to patient usage. Interpretation of the measurement data generated is advised for eye care specialists and healthcare professionals only.

Contraindications of use

Some patients may experience momentary discomfort when exposed to flash photography. Use of EyeTurn App on patients with photosensitive epilepsy is at the discretion and professional judgment of the healthcare professional.

Create new patient record

After installation, the list view in the home screen is empty. In order to start with data collection the user needs to create new patient records by clicking the + button at the top right of the screen. Fields required for the saving of the new record are: patient name (or patient ID), date of birth, gender, and ethnicity. An optional comments field is available to store additional information. After saving a new patient record, this will appear in your home screen. The user is allowed to change each field in the record after creation.

Tip: To practice with the software and take quick measurements, create a dummy record called "AAA Quick measurement"

Tip: To quickly delete a record swipe left on the list view

Start a new session

From the main screen, select the patient that you want to measure. EyeTurn provides you the patient details and the available options for that record. Click on “New session” to start with a new measurement.

Tip: From this screen you can also access previous sessions or edit patient details

Hirschberg Test

The Hirschberg test is the default operation mode when starting a new session. It allows the user to take a picture of the patient’s eyes and performs an automated and objective Hirschberg measurement based on corneal reflection. Steps for a successful acquisition:

1. Position the phone at about 40 cm (16”) distances from the patient’s face
2. Turn the phone into landscape mode.
3. Ask the patient to look at the camera (black circle)
4. Avoid strong corneal reflections from external sources
5. Ask the patient to wide open the eyes and take the picture by clicking on the white circle
6. EyeTurn calculates the measurement and provides a result view after few seconds

Tip: With children use a colored sticker around the camera to attract their attention. Don’t cover the flash or the camera.

Dissociation Test (cover/uncover)

Cover test operation mode can be selected by the user after starting a new session. Click the toggle button on the top right corner where the camera icon is located. This mode enables a 2 seconds video recording which allows the examiner to perform a quick alternate cover or uncover test. Steps for a successful acquisition:

1. Position the phone at about 40cm (16”) distance from the patient’s face.
2. Turn the phone into landscape mode.
3. Ask the patient to look at the camera (black circle)
4. Avoid strong corneal reflections from external sources
5. Click on the red recording button to start the 3 seconds countdown
6. Cover the non-dominant eye. You will hear a sound at each second.
7. Uncover quickly when you hear the fourth beep, different from the previous.
8. In the next view select the frame where both eyes are visible by swiping or using the slider
9. Long tap to select the first frame where both eyes are fully visible
10. EyeTurn will process that frame and provide a result view after few seconds

Tip: Practice with the timing in this mode prior to any use with patients. You can do alternate cover with the countdown timing.

Interpreting the results

In the result view, EyeTurn provides information including: an image of the eyes with the overlay of corneal detection and center, strabismus angle in prism diopters, distance from center of each eye to the correspondent corneal reflection in mm. When reviewing the results make sure that: the green circle is not well aligned with the limbus, the red markers for the corneal reflection are not overlaid with the one generated by the flash light. If the image shows evident misalignment discard the results and retake the measurement.

Tip: In the result view you can type in additional information and comments for your records.

Exporting the results

EyeTurn is able to generate pdf reports for each patient you have on record. From the home screen click the button "Select" at the top left corner and choose which patients you want to export. The software will ask you if you want to protect the pdfs with a password. Type it in if you need to add security to the document otherwise just leave the field empty. The pdf generation might take some time depending on how many sessions and patients you are exporting. When done, the software provides you the available options for sending wirelessly the results.

Tip: you can export images and generated pdf results to a local machine by using iTunes[®] (iTunes is property and copyright of Apple[®])

Tip: in the pdf reports EyeTurn provides an estimate of accuracy for each single session. This number varies based on image resolution from the phone and distance to the subject. The examiner needs to check for the quality of fixation and correct identification of eyes properties (green and red circles in the image).

Troubleshooting

Problem	Solution
Eyes are not detected	This can happen if the shape of the eye presents abnormalities or you are taking the picture in portrait mode. Take the picture in landscape mode. If persists, try to disable the automatic eye detection and make sure the eyes are placed inside the square boxes in the video preview before capture
Image doesn't contain the correct number of eyes	Make sure you don't have other faces in the picture. If problem persists use the manual eye detection.
Corneal reflection not found	If using the manual eye detection, make sure the eyes are inside the boxes. If using the automatic eye detection, check for strong external light sources. Eventually change orientation of the patient while taking the picture
Don't find the pdf reports when connected to local machine	You need to first click the export button for the patient you need in order to have the pdf saved in your smartphone
Forgot the password for my pdfs	Generate the reports again with another password