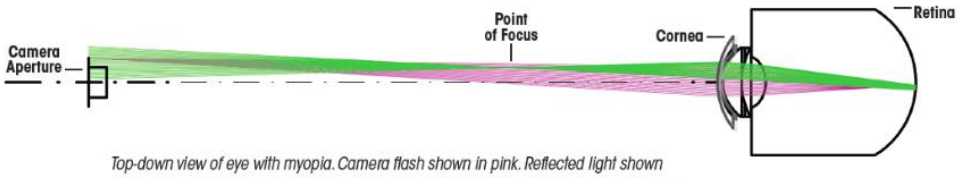
How is GoCheck Kids Clinically Validated and How are Referring Thresholds Set?

GoCheck Kids uses eccentric photorefraction - Eccentric photorefraction uses the iPhone's flash that is eccentrically positioned relative to the camera aperture. A bright crescent appears in the pupillary reflex when the child's eye has sufficient hyperopia or myopia along the meridian of the flash eccentricity and the app performs estimation of refraction through proprietary algorithms and provides immediate viewing of the results.

Principles of Photorefraction



Top-down view of eye with myopia. Camera flash shown in pink. Reflected light shown in green. Light refocuses between the eye and camera as it travels back toward the light source and aperture, causing the crescent to invert.

The photorefraction value is calculated using the delta crescent center methodology, where by the crescents are measured from the edge of the originating pupillary margin as they approach or cross the center of the pupil. The calculation is based on the position and size of the crescent, as well as the pupil size.

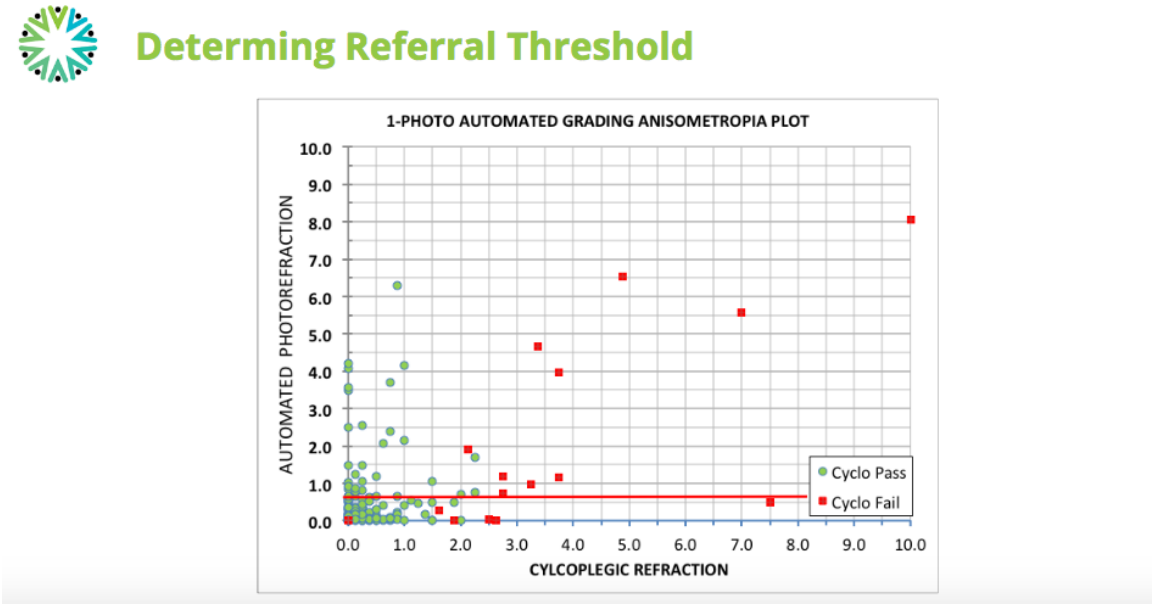
To clinically validate photoscreening the following takes place:

1.) Children who are being seen by pediatric ophthalmology are consented and the patient has an image taken with the app.
2.) That image is processed and a "photo refraction" value is determined.
3.) The child then receives a cycloplegic exam and the cycloplegic refraction is determined.
4.) The results of the cycloplegic exam are compared to the AAPOS criteria for referral (the pediatric ophthalmology group that has determined at which refractive level a child is most at risk for the development of amblyopia).

AAPOS Referral criteria:

Age, months	Astigmatism	Hyperopia	Anisometropia	Myopia
12-30	>2.0 D	>4.5 D	>2.5 D	>−3.5 D
31-48	>2.0 D	>4.0 D	>2.0 D	>−3.0 D
>48	>1.5 D	>3.5 D	>1.5 D	>−1.5 D

5.) The results of the photorefraction and the cycloplegic refraction are analyzed.



6.) If the cycloplegic refraction exceeds the AAPOS referral criteria, then the dot on the graph is red, and if that child was less than the referring criteria, the dot is green on the graph.

7.) The photorefraction value is then plotted.

8.) A photorefraction referral threshold is set (The red line is moved up or down to determine what the photorefraction referral threshold should be to provide the best values for sensitivity and specificity. You can see in this graph that the line is set at just slightly less than 1.00D of photorefraction. If we moved this bar up, say to 2.0D, you will see that we would have missed 3 more kids (red dots), which would decrease sensitivity , but we would have not sent ~7 kids that would have been false positives (increased specificity) so it is a trade off.

9.) The referral thresholds are then optimized for a balanced sensitivity and specificity.

10.) The graph above is for anisometropia - we do this same evaluation for all indicies, and then one for overall combin

So photorefraction is not an autorefraction, not a cycloplegic refraction, not a manifest refraction, but a refractive estimate based on capturing the red reflex, or retinsocopy-like reading.

Understanding the photoscreennng report:

If there are no crescents present in am image, the app will report 0.00D of photorefraction (because there is nothing to be detected). Keeping in mind that

most children are slightly hyperopic, but to avoid confusion with primary care and non-ophthalmology providers, the report displays 00.0D. As shown:

Cook Children's
Magnolia

gocheckKIDS

Visual Screening Report

Date of Report: **December 3, 2018**
ePhild: **RS160603**

Provider Name: **Frank McGehee**

No risk factors identified at this time

Test Date: 12/3/2018 Patient Age: 4
Taken with Device: FCGT64QTHG03

Refractive Data	Right	Left	Photorefraction Threshold*
Hyperopia (D)	0.00	0.00	1.75
Myopia (D)	0.00	0.00	2.00
Anisometropia (D)	0.00		1.25

Legend
XX.XX photorefraction in diopters (D), below risk threshold
XX.XX photorefraction in diopters (D), above risk threshold
*Photorefraction thresholds yield sensitivity and specificity compared to cycloplegic refraction using the 2013 AAPOS referral criteria

In a child with crescents present on the image, the crescents are measured using proprietary software and algorithms, the photorefraction is calculated and displayed as shown, in diopters of photorefraction:

Einstein Pediatrics
Vienna

gocheck KIDS

Visual Screening Report

Date of Report: **August 2, 2018**
ePhild: **MM180802**

Provider Name:

Risk factors identified

Test Date: 8/2/2018 Patient Age: 4
Taken with Device: 2017-02-40

Refractive Data	Right	Left	Photorefraction Threshold*
Hyperopia (D)	1.87	1.38	1.24
Myopia (D)	0.00	0.00	2.00
Anisometropia (D)	0.49		0.70

Legend
XX.XX photorefraction in diopters (D), below risk threshold
XX.XX photorefraction in diopters (D), above risk threshold
*Photorefraction thresholds yield sensitivity and specificity compared to cycloplegic refraction using the 2013 AAPOS referral criteria

The referring thresholds shown photorefraction thresholds that have been determined using the above methodology to yield the best sensitivity and specificity when calibrated using cycloplegic refraction.