PlenOptika

WHITE PAPER

Achieving accurate autorefraction with a handheld wavefront autorefractor

QuickSee technology overview and review of clinical results

The QuickSee handheld autorefractor

Takeaways in Focus

- **Limited availability of adequate autorefraction equipment contributes to the global burden of uncorrected refractive error.**
- **Wavefront aberrometry technology, in handheld format and combined with other key usability features, demonstrates accuracy equal or superior to desktop autorefractors.**
- **QuickSee helps perform clinically accurate autorefraction in clinical and low resource settings alike.**

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The global need to dramatically expand eyeglass prescription access

Uncorrected Refractive Error (URE) is a top cause of poor vision worldwide, with more than an estimated 2.5 billion people lacking access to glasses they need, and 650 million people considered visually impaired due lack of adequate refractive error correction[1]. It can be easily diagnosed and corrected with a pair of prescription lenses—such eyeglasses can cost as little as US$2.00 per pair—but in many parts of the world people have limited or no access to eye care facilities where a trained professional can conduct sight measurement and write eyeglass prescriptions.

The accessibility of eye care services is also uneven in developed countries like the United States. People living in rural areas and low-income communities are at higher risk for vision problems compared to urban and wealthier people. Geographic isolation and life in medically underserved areas also add to the issues of financial barriers and lack of insurance coverage[2].

Improving access to eye care services with autorefraction tools

Autorefractors, medical instruments that provide an objective measurement of the refractive errors in a patient's eyes, are a critical tool that help eye care providers to make the subjective refraction more reliable and efficient (e.g., by providing an accurate starting point for subjective refraction).

A key limitation of desktop autorefractors is their accessibility, which hinders the potential impact of autorefraction outside of well-equipped clinics. As a result, in many community and global health settings, such as health centers, elderly home care, workplace screenings, and schools, eye care providers must rely on visual acuity charts or perform retinoscopy to assess a patient's refractive errors. The former is useful only for screening and the latter requires years of training for proficiency. Autorefraction could be particularly useful in these set-

tings because it provides an accurate estimation for cylinder and axis, saving substantial time for the eye care practitioner and the giving them the confidence to make prescriptions patients need.

Furthermore, fast, accurate autorefraction could be useful in a range of other common settings, such as optical retail shops, pre- and post-operative surgery, and high-volume clinics where throughput is critical.

For an autorefractor to have the desired impact in such settings, it must have key performance and usability features.

Required features for a handheld autorefractor

Accurate and reliable
- Provide an accurate point for subjective refraction
- Age independent, works with patients as they are

Easy to use
- Works fast
- Simple training
- Doesn't require patient feedback

Works anywhere
- Calibration free and durable
- Any lighting condition
- Not dependent on constant electrical supply

Optical techniques for autorefraction

Photorefraction is the easiest technique—it is "point and shoot" and takes only a few seconds—but it is highly dependent on distance from the patient and ambient lighting conditions, so it tends to suffer from inaccuracy. Photorefraction is used mainly for screening and not as an accurate starting point for subjective refraction.

Eccentric refraction is typically not as accurate as wavefront aberrometry for cylinder and axis measurements, which are the components of refraction that take the longest to manually measure. Eccentric refraction is negatively affected by blinking and patient eye movement because only a few measurements are taken.

Wavefront aberrometry provides the most comprehensive method to measure ocular aberrations and refractive errors. Until development of QuickSee, wavefront aberrometry was not available in a compact, widely-affordable format.

The PlenOptika Wavefront Refraction Engine (WRE)

To dramatically expand access to prescriptions for eyeglasses with high quality autorefraction, especially outside a well-equipped exam room, PlenOptika developed the QuickSee handheld autorefractor. QuickSee's combination of the open view binocular design, wavefront aberrometry, and robust measurements produce clinically accurate autorefraction measurements, in a durable handheld format suitable for use in a wide range of eyecare settings.

The patented PlenOptika Wavefront Refraction Engine™ performs continuous data analysis to precisely determine low-order refractive errors, making QuickSee as accurate as the high-end clinical desktop autorefractors and demonstrating excellent agreement with subjective refraction[2].

Binocular, open view
QuickSee's open view design provides a natural viewing experience and a verified minimization of accommodation and anisometropic effects[3, 4, 5]. This is of particular importance when measuring young people with high accommodation capabilities.

Robust measurements
QuickSee completes measurements in 10 seconds, during which patients are able to blink, allowing them to refresh their tear film and feel more comfortable. In comparison to conventional autorefractors, which typically take a single or a few measurements, QuickSee's advanced algorithms achieve strong agreement with subjective refraction. The QuickSee software is specifically designed to detect changes in the eye (such as movement, focusing, and blinking) during measurements, increasing the measurement's accuracy.

Wavefront aberrometry versus eccentric autorefraction and photorefraction
Wavefront aberrometry captures additional refractive information that is unavailable to traditional autorefractors and photoscreeners. This optical technique assesses both low- and high-order aberrations, thereby achieving a more comprehensive measure of refractive errors.

QuickSee: Accurate autorefraction anywhere

QuickSee is a handheld, open-view autorefractor that uses wavefront aberrometry to precisely determine refractive errors. It enables vision care professionals and their supervised technicians to conduct the objective refraction measurements faster than with a traditional desktop autorefractor (binocular measurements are made in 10 seconds) and it provides an easy transition to subjective refraction. It is an FDA Class 1 510(k) exempt (low risk) and CE marked medical device commercially available internationally.

QuickSee objectively measures the refractive errors by shining a light into the patient's eyes then measuring the wavefront pattern reflected back through the eyes' lens and cornea. Distortions in the light waves represent specific vision errors of patients' eyes, such as nearsightedness, farsightedness, and astigmatisms.

QuickSee has been tested by teams at Johns Hopkins University, New England College of Optometry, Aravind Eye Care System (India), Harvard School of Public Health, Two-BillionEyes (non-governmental organizations), and others. Over 3,000 patients participated in the studies with the use of the device. Studies published in peer-reviewed journals demonstrate its high specificity and sensitivity, showing QuickSee measurements comparable to traditional autorefractors and optometric exams (see Clinical study results: highlights, below).

QuickSee at a Glance	
Device Dimensions	11x6.5x3.25 in (28x16.5x8.25 cm) / 2.3lb (1kg)
Accommodation Control	Open view
Spherical Range	-10D to +10D, increments of 0.01D, 0.125D, 0.25D
Cylindrical Range	-6D to +6D, increments of 0.01D, 0.125D, 0.25D
Axial Range	0-180°, increments of 1, 5, 10 degree
Interpupillary Distance Range	47–78 mm continuous
FDA Status	Class I
Dilation / Cycloplegic Requirements	None
Ambient Illumination Requirements	None

For complete technical and clinical specifications, visit https://plenoptika.com/technology/

For research findings, visit https://plenoptika.com/publications/

Clinical study results: highlights

QuickSee is within < 0.5 D of subjective refraction for 80-90% of adult patients

QuickSee provides the same accuracy as a desktop autorefractor. Desktop autorefractors measurement range is -25 to +25 diopters; QuickSee covers -10 to +10 diopters, which addresses the needs of over 95% of adult populations. QuickSee is within < 0.25 D (excellent agreement) and < 0.5 D (good agreement) of subjective refraction for 70-75% and 80-90% of adult patients, respectively, whereas desktop autorefractors are usually within < 0.25 D and < 0.5 D of subjective for 50-60% and 80-90% of these patients, respectively[2, 5].

Table 1 (below) provides published data of QuickSee's agreement with subjective refraction, and Table 2 provides highlights of the published research.

Prescription quality[4, 7, 8]

- QuickSee accuracy enables effective and impactful outreach service.
- Accurate starting point for subjective refraction.
- Eyeglass prescriptions provided by QuickSee provided a visual acuity as good as subjective refraction[4, 8].
- QuickSee has high sensitivity and specificity for refractive error-based risk factors for amblyopia[7].

Validation of handheld autorefraction accuracy[2]

- Excellent agreement between the measurements obtained with QuickSee and the prescriptions based on subjective refraction in an adult population.

Comparing handheld autorefractors[9]

- QuickSee had the shortest learning curve for both practitioners and subjects and demonstrated the most accurate measurements of the three handheld devices tested.

Assessment of a wavefront aberrometry-based handheld autorefractor[5]

- The collective high order aberration (HOA) measurements from QuickSee showed no significant difference from the commercial desktop wavefront aberrometer, and the contribution of HOA to the total wavefront error showed good inter-device reliability.

Refracting children[6]

- QuickSee is superior to the Topcon KR-8800 at measuring children without cycloplegia.
- Cycloplegic free autorefraction with QuickSee was more accurate than desktop autorefraction, which means QuickSee better for pediatric vision exams because accommodation is reduced.
- The spherical equivalent refraction obtained by QuickSee agreed within 0.5 D of the subjective refraction in 71% (NC) and 70% (C) of the cases. The high level of agreement with subjective refraction turns the device into a useful autorefraction tool for school-age children.

The QuickSee handheld autorefractor is equally suitable for objective measurement in modern clinical settings and mobile care / global health care initiatives.

Table 1: Agreement of QuickSee measurements with subjective refraction

Study	*QuickSee* Agreement with Subjective refraction ≤0.25D	*QuickSee* Agreement with Subjective refraction ≤0.5D	*Desktop Autorefractor* Agreement with Subjective refraction ≤0.25D	*Desktop Autorefractor* Agreement with Subjective refraction ≤0.5D
QuickSee versus Grand Seiko WR-5100K [3] *Non-cycloplegia, adult population*	SE: 71%	SE: 82%	SE: 63%	SE: 89%
QuickSee versus Topcon KR-8800 [4,*] *Non-cycloplegia, pediatric population*	–	SE: 71%	–	SE: 61%
QuickSee versus Topcon KR-8800 [4,*] *Cycloplegia, pediatric population*	–	SE: 70%	–	SE: 77%
QuickSee versus WaveScan 3.68 VIX [6] *Non-cycloplegic, adult population*	–	SE: 84%	–	SE: 70%

** Published thresholds were <0.5 D and <1 D*

Table 2: Highlights of published results

Study	Study design	# Patients (Age range)	Main conclusions
OVS Optometry and Vision Science Journal of the American Academy of Optometry **"Validation of an Affordable Handheld Wavefront Autorefractor"[2]**	Objective: Evaluate the commercial version of the QuickSee Flip in an adult population Device: Monocular, commercial version Methods: Compare the accuracy of the device with a high-end desktop autorefractor and with subjective refraction. Compare the Visual Acuity achieved by subjective refraction and the QuickSee refraction.	54 (33.9 ± 14.1 years)	Visual acuity resulting from correction based on the QuickSee device was the same as that achieved by Subjective refraction in 87% of the eyes. This resulting improvement in visual acuity is comparable to that reported for clinically established benchtop systems. Agreement between the three refraction components (M, J_0, J_{45}) provided by the autorefractor and subjective refraction is within 0.5 D in more than 85% of the cases The results of this work suggest that the QuickSee provides measurements that agree more closely with subjective refraction than other handheld autorefractors (Netra, Smart Vision One, Retinomax 3).
iovs investigative ophthalmology & visual science an ARVO journal **"Assessment of wavefront measurements from a low-cost, portable, aberrometry-based autorefractor"[5]**	Objective: to assess the measurement of both low- and high-order ocular aberrations from a low-cost portable wavefront aberrometer Device: binocular, commercial version Methods: refraction, pupil size, and Zernike coefficients were recorded for each eye	41 (53 ± 17 years)	The QuickSee and the Wavescan measured 84% and 70% of all eyes within 0.5 D of M from manifest refraction respectively. The total HOA wavefront error and the percentage contribution of the HOA to the total wavefront error showed good inter-device correlation (ICC3=0.79 and 0.91, respectively). The collective HOA measurements from a portable, low-cost autorefractor showed no significant difference from the commercial desktop wavefront aberrometer.

Study	Study design	# Patients (Age range)	Main conclusions
"Investigation of the accuracy of a low-cost, portable, auto-refractor to provide well-tolerated eyeglass prescriptions"[8]	Objective: to compare patient acceptance of eyeglasses prescribed using the QuickSee with that of eyeglasses prescribed via standard subjective refraction. Device: binocular, commercial version Methods: Participants were randomly assigned to use either the subjective refraction or QuickSee refraction-based eyeglasses first, followed by the other pair, and requested to wear each pair for a week.	400 (28.6 ± 6.5 years)	Strong agreement between the prescriptions from subjective refraction and QuickSee refraction was observed. Almost half the patients preferred glasses prescribed using QuickSee refraction only. This confirms the quality and effectiveness of QuickSee in prescribing accurate eyeglasses for refractive error corrections.
"Assesment of the QuickSee wavefront autorefractor for characterizing refractive errors in school-age children"[6]	Objective: Evaluate the commercial version of the QuickSee in pediatric population Device: binocular, commercial version Methods: Compare the accuracy of the device with a high-end desktop autorefractor and with Subjective refraction with and without cycloplegia. Compare the Visual Acuity achieved by subjective refraction and the QuickSee refraction.	123 (9.9 ± 3.3 years)	In this study, it is shown that the QuickSee works similarly with patients with and without cycloplegia, while the desktop autorefractor used in this work performs significantly better with patients under cycloplegia than with patients without cycloplegia. This may indicate that the binocular open view design of the device is effectively helping to control accommodation problem in most of the patients. In the non-cycloplegic group, 77% of subjects achieved the same (59%) or better (18%) VA with QuickSee correction than that achieved with the standard clinical protocol. This was largely replicated in the cycloplegic group, in which 74% of patients achieved the same (57.5%) or better (16%) VA than that provided by standard clinical protocol.
"Comparing low-cost handheld autorefractors: A practical approach to measuring refraction in low-resource settings"[9]	Objective: To compare and validate the accuracy and ease of use of handheld autorefractors against retinoscopic refraction by an ophthalmologist for assessing the visual acuity of older adults in India. Device: binocular, commercial version Methods: three different handheld devices were compared with cycloplegic retinoscopy and refraction done by an ophthalmologist.	190 (40 ± 88 years old)	The QuickSee device is inexpensive, had a short learning curve for both practitioners and subjects, and had the most accurate measurements of the three handheld devices tested. The QuickSee may be used successfully as refraction screening tools in epidemiologic studies of adults in India and as diagnostic tools in low-resource settings.
"Screening for refractive error in Kenya Schools with the QuickSee Handheld Autorefractor"[7]	Objective: to evaluate the performance of the QuickSee for diagnosing refractive error in children under non-cycloplegic conditions and to determine the optimal referral threshold for the device. Device: binocular, commercial version Methods: the performance was evaluated comparing the agreement with MR and computing sensitivity and specificity.	250 (16 ± 5 years)	The QuickSee provided high sensitivity (87.5%) and specificity (71%) values. The measurements provided by the QuickSee agreed within 0.5 D of the MR in 80.1% (M) of the cases, indicating high correlation between both refraction methods under non-cycloplegic conditions.

Study	Study design	# Patients (Age range)	Main conclusions
BMJ Journals **"Quality of eyeglass prescriptions from a low-cost wavefront autorefractor evaluated in rural India: results of a 708-participant field study"[4]**	Objective: To assess the quality of eyeglass prescriptions provided by a QuickSee prototype operated by a minimally trained technician in a low-resource setting. Device: Monocular, 2nd prototype version Methods: Visual acuity (VA) and patient preference were compared between trial lenses set to two eyeglass prescriptions from (1) the QuickSee prototype autorefractor operated by a minimally trained technician and (2) subjective refraction by an experienced refractionist.	708 (35 ± 13 years)	Eyeglass prescriptions can be accurately measured by a minimally trained technician using a low-cost wavefront autorefractor in rural India. Data from 708 participants indicate a marginal difference in both prescription preference and resulting visual acuity between eyeglasses derived from subjective refraction versus QuickSee autorefraction (VA from QuickSee was on average only one letter worse). Among the 438 participants 40 years old and younger, there was no statistically significant difference in the preferences for eyeglasses derived from subjective refraction versus QuickSee autorefraction.

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Conclusion

Uncorrected Refractive Error (URE) is a top cause of poor vision worldwide, with more than an estimated 2.5 billion people lacking access to glasses they need, and 650 million people considered visually impaired due lack of adequate refractive error correction. Though eyeglasses are affordable and accessible globally, the limited availability of trained personnel and adequate equipment to perform vision measurements, pre-requisites for corrective eyeglass prescriptions, are major contributors to the global burden of low vision.

QuickSee is an affordable, durable, handheld autorefractor using wavefront aberrometry and algorithmic analysis of measurements that can be used both in and outside clinical settings to perform accurate objective refraction comparable to desktop autorefractors in a fraction of the time. Peer-reviewed studies demonstrate QuickSee's accuracy compared to traditional autorefractors and its agreement with the gold standard of quality, subjective refraction.

NGOs and vision care professionals have used QuickSee to examine patients at high volume and to efficiently facilitate accurate prescriptions for corrective eyeglasses. In the US and other developed nations, QuickSee helps vision care professionals bring accurate vision exams to the communities in need such as schools, nursing homes, community health centers, and rural/homebound patients, as well as to perform fast, convenient, accurate care in their clinics.

QuickSee
Accurate autorefraction anywhere

Accurate binocular measurements in 10 seconds

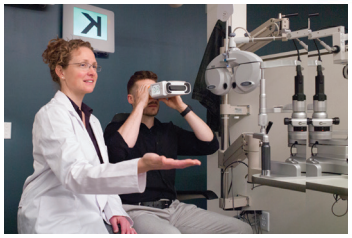
- Within < 0.25 D of subjective refraction for 70-75% of adult patients, and within < 0.5 D for 80-90%
- Accelerates subjective refraction accurate starting points
- Enables high throughput autorefraction

Accessible & easy to use

- Ideal for patients with mobility and/or physical challenges; ADA compliant
- Easy to learn
- Works anywhere
- Patient friendly

Handheld and field durable

- Calibration free
- Operates up to 8 hours on battery
- Can be used indoors and outdoors, in most light settings
- Operates in humid and dusty settings
- Includes hardened carrying case



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