Study on handheld autorefractor technologies

Technical report

ATscale
GLOBAL PARTNERSHIP FOR ASSISTIVE TECHNOLOGY
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Members of the Technical Working Group:

- Dr Scott Mundle, International Agency for the Prevention of Blindness (IAPB)
- Ms Sumrana Yasmin, SightSavers International
- Dr Reshma Parmanand, Fred Hollows Foundation
- Dr Ving Fai Chan, University of Belfast, UK
- Mr Yudha Dhoj Sapkota, IAPB

Contributing authors from the Study Team:

- Dr Srinivas Marmamula, Principal Investigator, L V Prasad Eye Institute, Hyderabad, India
- Dr Santosh Moses, Co-Principal Investigator, IQVIA
- Dr Rohit Khanna, L V Prasad Eye Institute
- Hemant Chaudhry, IQVIA
- Dr Stephanie Berrada, IQVIA
- Dr Aneesha Ahluwalia, IQVIA
- Mr Winston Prakash, L V Prasad Eye Institute

Technical reviewers

- Stuart Keel, Technical Officer, Vision and Eye Care Programme, WHO
- Andreas Mueller, Technical Advisor, Vision and Eye Care Programme, WHO
- Mitasha Yu, Consultant, Vision and Eye Care Programme, WHO
- Simona Minchiotti, Technical Advisor, Eye and Vision Care, ATscale
- Dr. Dechen Wangmo, Technical Advisor, Eye and Vision Care, ATscale

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Together we are a dedicated team, working to make assistive technology more accessible to people in need.

Abbreviations

AR	Autorefractors
ATscale	Assistive Technology for Global Partnership
CHW	Community Health Worker
D	Diopter
ECCF	Eye Care Competency Framework
eREC	Effective Refractive Error Coverage
FDA	Food & Drug Administration
HHAs	Handheld Autorefractors
IAPB	International Agency for the Prevention of Blindness
IPEC	Integrated People-Centered Eye Care
LMICs	Lower Middle-Income Countries
LVPEI	L V Prasad Eye Institute
SE	Spherical Equivalent
SER	Spherical Equivalent Refractive Error
URE	Uncorrected Refractive Error

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Executive summary

Background and context

Uncorrected Refractive Errors (UREs) are a major global public health issue, affecting over 88 million people. Traditional refraction methods such as retinoscopy and subjective refraction are the gold standards, but handheld autorefractors are emerging as practical alternatives, especially in low-resource settings. Handheld autorefractors have evolved significantly since the 1970s, now offering compact, battery-powered, and user-friendly designs. They are increasingly integrated with wavefront technology, Artificial Intelligence, and telemedicine capabilities, enabling accurate and scalable vision screening. The vision devices are particularly useful in remote areas, allowing community health workers to conduct eye examinations and transmit data to specialists. This model supports mobile eye clinics, reducing urban-rural disparities in vision care.

The global autorefractor market was valued at $1.9 billion in 2023 and is projected to reach $5.2 billion by 2032. This includes the market for handheld devices, which is expected to grow to $1.2 billion by 2033. The growth is driven by rising demand, aging populations, and increased awareness of eye health. ATscale commissioned a large-scale study in Ethiopia, Nepal, and Nigeria to evaluate the clinical effectiveness and scalability of handheld autorefractors. Conducted by IQVIA and L V Prasad Eye Institute, the study aimed to compare these technologies with traditional methods, assess prescription alignment, and explore the feasibility of public health deployment.

Methodology

This large-scale scientific study was a prospective and observational study conducted in two phases: a clinical phase and a stakeholder consultations phase. The aim was to gather insights into key enablers and barriers for scaling novel autorefractor technologies. Ethical protocols were followed, including written informed consent and data confidentiality for the studies.

Scope of the study 2024

- Countries: Ethiopia, Nepal, and Nigeria; three sites were selected, one per country for implementation of the study.
- Technologies: Six technologies were studied – Eccentric Photorefraction, Wavefront Aberrometry, Badal Optometer, Shack-Hartmann Wavefront Sensing, SynchroScan, and Auto Fogging.
- Study Participants: The participants were recruited from the study sites and met the following inclusion criteria: above 5 years of age, visual acuity improving to at least 6/12 with refraction and absence of any other ocular pathology.

Sampling design

Based on minimum sensitivity of 50% for a screening test with 20% precision and an expected refractive error prevalence of 6%, six groups, each with 200 participants, took part in the study, with one group for each of the six technologies (devices). A total of 1200 participants were recruited for the study.

Data collection methods

- Potential study participants underwent a complete eye examination, including manual refraction by an optometrist to determine their eligibility to participate in the study.
- Eligible participants then underwent auto-refraction by a community health worker using two handheld autorefractors. A comprehensive eye exam, including a fundus examination, was performed by an ophthalmologist.

Data analysis	The data analysis was conducted using Stata/SE 14 for Windows software (StataCorp LLC, TX, USA). Mean Spherical Equivalent Refractive error obtained by the gold-standard manual subjective refraction was compared with that obtained by means of handheld autorefractors using Student's t-tests. A p-value of <0.05 was considered statistically significant.
Stakeholder consultations	Interviews were conducted with industry experts, eye care specialists, and leading organizations in eye care and public health. Stakeholder consultations took place in India, Pakistan, Indonesia, and Kenya to discuss the potential implications of the study findings.

Key findings

Sensitivity and specificity of handheld autorefractors

KEY CONCEPTS

- Refraction: Objective (retinoscopy) and subjective methods used to assess vision.
- Spherical Equivalent (SE): Combines spherical and cylindrical power to estimate refractive error.
- Diagnostic Accuracy: Ideal threshold is ≥70% sensitivity and specificity.

MYOPIA (NEAR-SIGHTEDNESS)

- Eccentric Photorefraction works best for myopia.
- Auto Fogging Technology works well with definition 1 of myopia (SER worse that -0.50 D)
- Wavefront Aberrometer works best with both definitions of myopia.

HYPEROPIA (FAR-SIGHTEDNESS)

- Auto Fogging Technology works well with both definitions of hyperopia.

BEST PERFORMER

- SynchroScan Technology: Strong diagnostic accuracy. Works well with both definitions of myopia and hyperopia.

WORST PERFORMER

- Badal Optometer (low sensitivity).

CONCLUSION

Autorefractor technologies in the study displayed sensitivity of over 70% and specificity within the range of 80-90% for refractive errors discovered using subjective refraction. Similar levels of sensitivity and specificity were achieved by autorefractor technologies compared with retinoscopy. Overall, it was concluded that the device with SynchroScan provides the best sensitivity and specificity for all refractive errors. So these innovative technologies offer immense potential for screening false-positive cases, thereby reducing the time and effort required for prescribing spectacles. In low-resource settings, where mass screening is required, handheld autorefractor technologies can play a critical role in reducing the burden of subjective assessments.

Alignment of prescriptions with the gold standard and feasibility of prescribing spectacles using handheld autorefractors alone

KEY CONCEPTS

Clinically acceptable range: ±0.50 D in SER is considered acceptable for spectacle prescriptions.

CLINICAL ACCURACY & AGREEMENT

Top-performing technologies:

- Eccentric Photorefraction: Lowest mean difference in SER, narrow limits of agreement -> high precision.
- Shack-Hartmann Wavefront Sensing and SynchroScan: Moderate agreement with the gold standard.

PERFORMANCE ACROSS AGE GROUPS

- 5-16 years: large variability was noted for all the technologies.
- 17-28 years: 3 out of 6 devices performed well.
- 29–39 years: 4 out of 6 devices performed well.
- 40+ years: 5 out of 6 devices performed well.
- Older age groups showed:
  - Less variability -> better suitability for refractive correction.
- SynchroScan Technology:
  - Most consistent across all age groups.
  - Recommended for scaling in community settings.

STUDY LIMITATIONS

- Cycloplegic refraction was out of scope.
- Astigmatism was not evaluated.
- Small sample sizes in high refractive error groups -> results not generalizable.

CONCLUSION

Devices with Eccentric Photorefraction, Shack-Hartmann Wavefront Sensing Aberrometer and SynchroScan technologies provided the lowest mean difference in SE within clinically acceptable limits (±0.50 D) compared to the gold-standard SE. There was better alignment in prescriptions by these devices when compared with subjective refraction.

Overall, SynchroScan and Shack-Hartmann Wavefront Sensing technologies followed by Eccentric Photorefraction emerged as the most age-resilient devices, delivering consistent performance across all age groups, and have potential for on-the-spot prescription of spectacles (except in children of 5-17 years) in low-resource settings based on Spherical Equivalent refraction. It is suggested that readymade or ready-to-clip glasses be provided based on readings from the above-mentioned autorefractor technologies. However, it should be considered that visual acuity must improve to 6/9 or 6/6 after prescription. Further, prescriptions should not be made in case the eye power is +/- 3D. In low-resource settings with limited human resources and large-scale community-based programmes these devices can be used by community health workers or allied healthcare professionals with minimal training. Furthermore, the devices were found to perform well in non-cycloplegic settings, which is an important consideration for refractive error and spectacle provision activities at scale (cycloplegia is not feasible in community settings).

Potential scalability

KEY CONCEPTS

Scalability of technology and innovation is dependent on several factors, including adoption by users, effectiveness, costs, technical capacities, and an environment that is favourable to the implementation of technology solutions. Beyond diagnostic accuracy, the practical utility of handheld autorefractors in real-world settings is determined by factors such as portability, ease of use, time efficiency, maintenance and battery life, regulatory environment, and required level of operator skill.

SYNCHROSCAN TECHNOLOGY

- Strong alignment with subjective refraction.
- Best sensitivity and specificity for both myopia and hyperopia.
- Performs well in non-cycloplegic settings.

- Most age-resilient: consistent across paediatric, working-age, and older populations.
- Suitable for community deployment and low-resource settings for programmes at scale.

SHACK-HARTMANN WAVEFRONT SENSING

- Uses Shack-Hartmann sensor to capture light distortions across the pupil.
- Measures both lower- and higher-order aberrations.
- Open-field design reduces user-induced errors.
- High sensitivity for myopia, minimal variability across age groups.
- Can be operated by minimally trained allied health professionals.

ECCENTRIC PHOTOREFRACTION

- High precision.
- Lower cost.
- Light weight.
- Can be operated by minimally trained allied health professionals.

SCALABILITY & PUBLIC HEALTH IMPACT

- Study conducted in collaboration with national governments and public health facilities.
- Use of simplified protocols and local healthcare personnel enhanced capacity and accountability.
- Findings support future scale-up of autorefractor-based refractive error programmes and on-the-spot provision of spectacles.

The study concluded that handheld autorefractor technologies have strong potential to scale up refractive error services and spectacle provision in public health settings due to their diagnostic accuracy, portability, ease of use, and minimal capacity-building requirements. These devices can be easily operated by allied health professionals such as community health workers, primary health nurses, ophthalmic clinical officers, school nurses, and other healthcare staff who may not have any specialized training in eye-care service delivery. However, countries will have to consider factors such as costs, skill transfer, regulations, and supply chain that are critical for scale-up. Similarly, the study demonstrated that these devices can be easily operated by allied healthcare professionals with minimal training. When used with on-the-spot prescription of spectacles, handheld autorefractor technologies based on Spherical Equivalent refraction have immense potential to improve access to refractive error services and spectacle provision.

Recommendations

Based on the key findings of the study, the key recommendations for potential scale-up in countries are as follows:

Key recommendations	Timeframe*	Key stakeholders
Address information asymmetry in handheld autorefractor technology from demand and supply perspectives	Medium to long term	Global partners, manufacturers, national governments
Enable a policy environment conducive to competency-based refractive error team approaches in order to facilitate task-sharing	Short to medium term	Health ministries, national eye programmes, regional public hospitals, national public hospitals
Couple the use of proven handheld autorefractors with ready-to-clip spectacles in order to simplify spectacle provision in large-scale community-based programmes (e.g. eye-health programmes in schools)	Short to medium term	Global institutions, ministries and eyecare programmes, NGOs
Create a regulatory system and procurement mechanism to ensure that quality products are introduced in the local market with after-sale services for repair and maintenance	Short to medium term	National regulatory authorities, procurement authorities, professional and hospital associations
Be flexible and attentive to evolution of the medical device industry in order minimize autorefractor costs	Medium to long term	Manufacturers, procurement authorities, professional and hospital associations
Manufacturers should invest to develop handheld technology that works well for children	Medium to long term	Manufacturers

*Short term: within 1 year; medium term: 1-2 years; long term: 3-4 years.

1. Introduction

Globally, more than two billion people experience vision impairment, with over one billion individuals having avoidable vision impairment.[1] It is a striking fact that 90% of people with vision impairment reside in low- and middle-income countries (LMICs), where service provision is weakest.[1] Uncorrected Refractive Errors (URE) are a leading cause of vision impairment in both children and adults[2] and are responsible for vision impairment in about 88.4 million people.[3] URE has far-reaching consequences across different age groups and is a crucial public health threat with widespread social implications.

WHO reports that two-thirds of people in low-income countries who need spectacles do not have access to them,[4] highlighting how poor access to refractive services and affordable spectacle provision drives the disproportionate vision impairment burden of LMICs. Effective refractive error coverage (eREC) shows substantial unmet need globally despite modest gains, again underscoring low access to refractor error services in LMICs, attributable to gaps in workforce and spectacle provision[5] mainly in primary care.

1. Burton, M. J., et al. (2021). The Lancet Global Health Commission on Global Eye Health: vision beyond 2020. The Lancet Global Health, 9(4), e489–e551
2. https://www.who.int/publications/i/item/9789241516570. Last Accessed 24th November 2024.
3. Fricke TR, Tahhan N, Resnikoff S, Papas E, Burnett A, Ho SM, Naduvilath T, Naidoo KS. Global prevalence of presbyopia and vision impairment from uncorrected presbyopia: systematic review, meta-analysis, and modelling. Ophthalmology. 2018;125(10):1492–1499. doi: 10.1016/j.ophtha.2018.04.013
4. World Health Organization. (2023). SPECS 2030: Improving access to spectacles. WHO
5. Liu, Y., et al. (2025). Effective refractive error coverage (eREC): global and regional estimates, 2000–2020. The Lancet Global Health, 13(2)

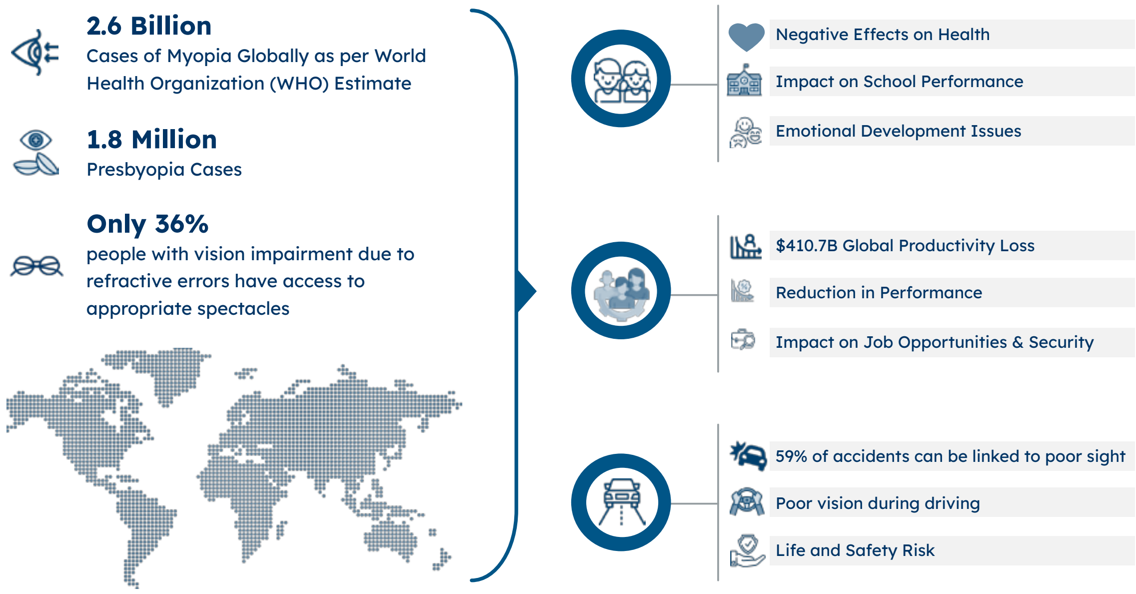

Figure 1: Uncorrected Refractive Errors: Prevalence, Access, and Global Impacts

Traditional refractive error processes versus autorefraction

Traditionally, refractive error correction has relied on conventional methods such as retinoscopy, subjective refraction, and cycloplegic refraction, which are considered gold standards. Retinoscopy and subjective refraction techniques require skilled optometrists or ophthalmologists, limiting the ability to scale services in resource-constrained settings. The major guidelines[6] do not include cycloplegic drops in routine school/community screening due to considerations of logistics, consent, side-effects, and scope-of-practice; cycloplegia is reserved for diagnostic examinations after referral.

In recent decades, technological innovations such as autorefractors have offered potential for significant expansion of refractive services in LMICs, addressing the above-mentioned challenges. Autorefractors are devices that objectively measure refractive error. Autorefractors have evolved from bulky

6. WHO (2024) – Vision & Eye Screening Implementation Handbook, IAPB School Eye Health Guidelines (2024), AAO Clinical Statement / AAPOS alignment (2022): Vision Screening for Infants & Children.

tabletop units in the 1970s to modern handheld devices using advanced optics such as wavefront sensing. These portable models offer fast, accurate measurements and are particularly suited for field settings.[7]

In many low-resource regions, a lack of ophthalmologists, optometrists, and the use of expensive equipment has left a huge gap in vision care.[8] Handheld Autorefractors can play a crucial role by bringing refractive errors assessments to communities that previously had little access. Simply put, these portable devices have potential to enable more widespread vision screening in remote and underserved areas, identify individuals in need of vision correction and ensure they have access to appropriate spectacles.

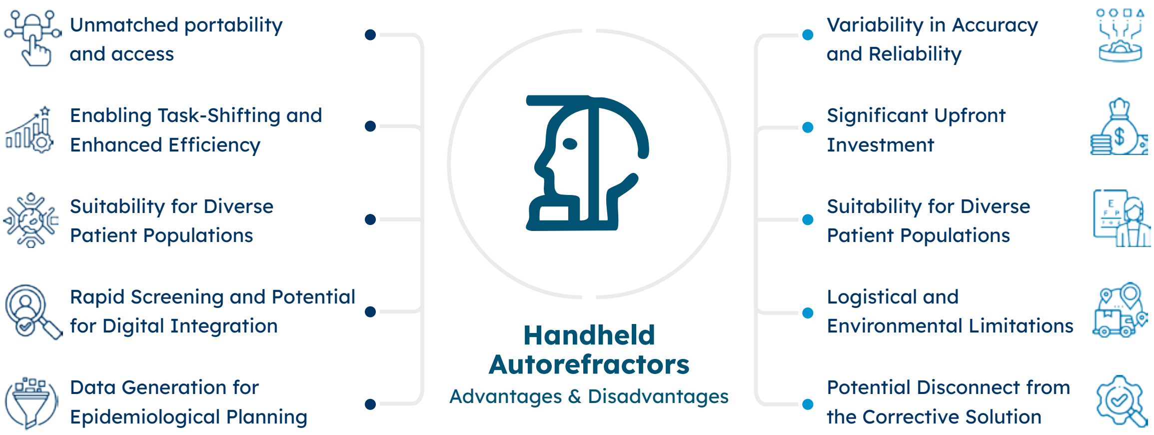

Figure 2: Advantages and Potential Limitations of Handheld Autorefractors

Handheld autorefractors are specifically designed to be compact, battery-powered, and simple to operate, making them ideal for field use. They can be carried to rural villages, schools, and health camps without the need for specialized infrastructure. Many models are low-cost compared to traditional clinic-based autorefractors, and some even connect to

7. Agarwal A, Bloom DE, deLuise VP, Lubet A, Murali K, et al. (2019) Comparing low-cost handheld autorefractors: A practical approach to measuring refraction in low-resource settings. PLOS ONE 14(10): e0219501. https://doi.org/10.1371/journal.pone.0219501
8. Agarwal A, Bloom DE, deLuise VP, Lubet A, Murali K, et al. (2019) Comparing low-cost handheld autorefractors: A practical approach to measuring refraction in low-resource settings. PLOS ONE 14(10): e0219501. https://doi.org/10.1371/journal.pone.0219501

smartphones or are available as all-in-one units, making them economically and logistically feasible for NGOs or public health programmes. Their operation is easy to learn, so general healthcare workers or trained community health workers or allied healthcare professionals can use them to assess an individual's refractive error and identify the needed prescription within minutes.[9] The resulting decentralization of eye examinations makes it possible to carry out large-scale vision screening drives, reaching people who might never visit an eye hospital.

In recent years, advancements in handheld autorefractor technology have significantly improved the accuracy and reliability of refractive error measurement, narrowing the gap with traditional retinoscopy. Many devices have been found to produce clinically acceptable prescriptions in many settings, even among children and in community environments. Importantly, these innovations enable the possibility of "direct-to-dispense" models, where patients can receive spectacles on the spot without requiring confirmatory retinoscopy or lengthy subjective refraction.

While caution remains regarding their universal replacement of gold-standard methods, the new technologies represent a major step toward simplifying and decentralizing refractive error services, opening the door to faster, more affordable, and more accessible spectacle provision in underserved populations.

In view of the scarcity of robust data regarding handheld autorefractors, ATscale decided to carry out a study aimed at exploring their potential for expanding refractive error services through task-sharing to mid-level providers. Specifically, the study examines whether these devices, by combining technology, portability, accuracy, and user-friendly interfaces, can reliably support a direct-to-dispense model, where patients receive spectacles immediately without requiring confirmatory retinoscopy or subjective refraction by specialist personnel. This evidence is critical to

9. World Health Organization. (2023). SPECS 2030: Improving access to spectacles. WHO.

inform policy, as handheld autorefractors could help to overcome the workforce and infrastructure barriers that currently constrain access to refractive error correction in low- and middle-income countries.

Evolution and market landscape of handheld autorefractors

Evolution of handheld autorefractors

Autorefractors trace their conceptual roots back to the 17th and 18th centuries, and to the Scheiner and optometer principles, which used pinhole light and converging lenses to gauge refractive error.[10] The first practical automated devices appeared in the 1970s and 1980s as computing power and infrared optics advanced, enabling quicker, more reliable measurements than could be obtained by traditional retinoscopy. The earliest models were bulky table-top units with alignment and accommodation limitations, but they became clinical staples during the 1990s and 2000s due to improved usability and accuracy.[11] The 2000s brought a paradigm shift with the emergence of portable, handheld autorefractors. These devices leveraged Hartmann–Shack or eccentric infrared photorefraction methods to provide fast, field-deployable assessments, significantly expanding access in remote and underserved settings.

10. Bhardwaj, V., & Rajeshwari, K. (2021). Refractive Errors and Methods of Correction. In StatPearls. StatPearls Publishing. Retrieved from https://www.ncbi.nlm.nih.gov/books/NBK580520/
11. Cademix Institute of Technology. (2022). Autorefractor in Optometry. Retrieved from https://www.cademix.org/autorefractor-in-optometry/

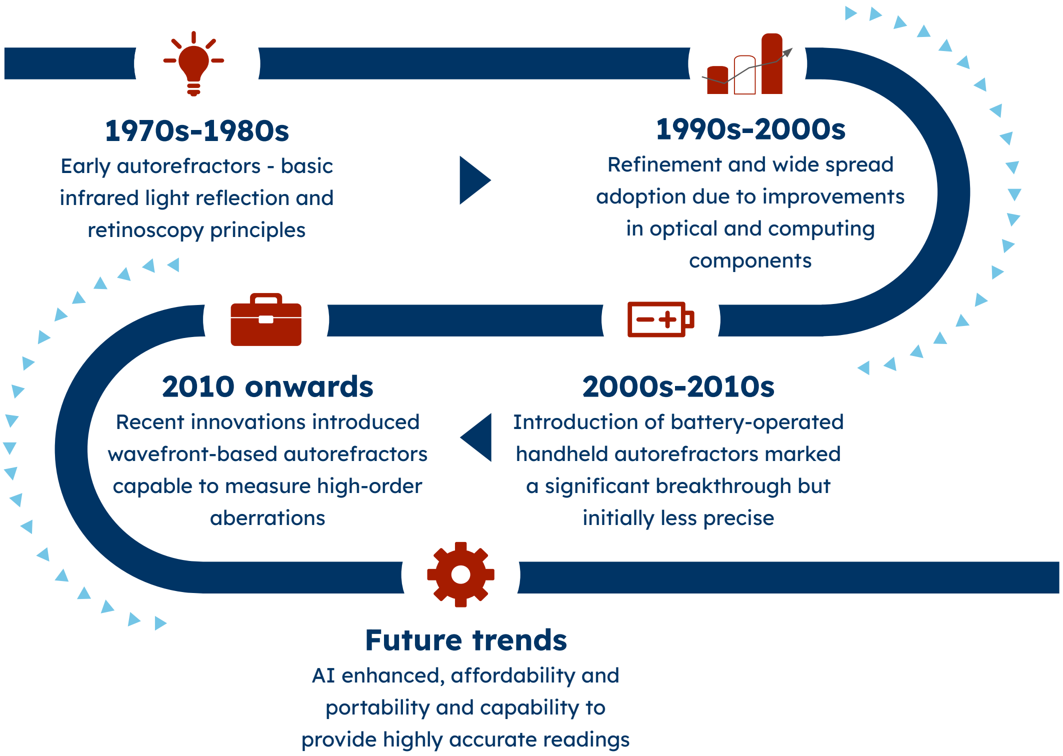

Figure 3: Evolution of Handheld Autorefractors

Recent autorefractor models (including handheld units) increasingly incorporate wavefront technology to improve measurement precision. Wavefront Aberrometry analyses how light travels through the eye, detecting subtle optical aberrations for a more detailed refraction profile.[12] Artificial intelligence (AI) and machine learning are being integrated into autorefractors in order to automate and enhance the refraction process. Intelligent algorithms can automatically refine measurements, ensure proper alignment/focus, and even suggest optimal lens prescriptions based on big data trends.

These smart features improve consistency (reducing human error) and make the devices easier to use for technicians.[13] For example, AI-aided auto-focus and auto-alignment features are now available to assist the operator,[14] speeding up examinations and enabling less experienced staff to perform reliable eye tests.

12. Handheld Autorefractors Market Size, Future Growth and Forecast 2033
13. Handheld Autorefractors Market Size, Future Growth and Forecast 2033
14. Handheld Autorefractors Market Report | Global Forecast From 2025 To 2033

The last decade has seen advances that make autorefractors more compact and user-friendly. Handheld models are now lightweight, battery-operated, and often come with intuitive interfaces. Many devices offer wireless connectivity (to transfer data or integrate with electronic health records) and can be operated via touchscreen or even smartphone apps.[12] Portable devices mean that eye examinations can be brought to the patient instead of the patient having to visit an eye clinic. In addition, new photorefraction techniques (where a camera analyses the reflection of light on the retina) are used in some handheld autorefractors, enabling quick non-contact examinations, which are ideal for children or patients who have difficulty with traditional machines.[15] These innovations are expanding the context in which autorefractors can be used.

The last two decades have seen the emergence of many handheld autorefractor models using various technologies, some of which have not stood the test of time. Published literature on the use and effectiveness of these new technologies has accumulated over recent decades, but remains inadequate for reaching conclusions on many questions.

Market landscape

The global autorefractor market (all types) was valued at around $1.9 billion in 2023 and is projected to reach ~$5.2 billion by 2032. The handheld autorefractor segment is a significant and growing portion of this total and is expected to approach $1.2 billion by 2033.[16] The growth reflects steady expansion of demand for eye care worldwide.

15. Cademix Institute of Technology. (2022). Autorefractor in Optometry. Retrieved from https://www.cademix.org/autorefractor-in-optometry/
16. Handheld Autorefractors Market Report | Global Forecast From 2025 To 2033

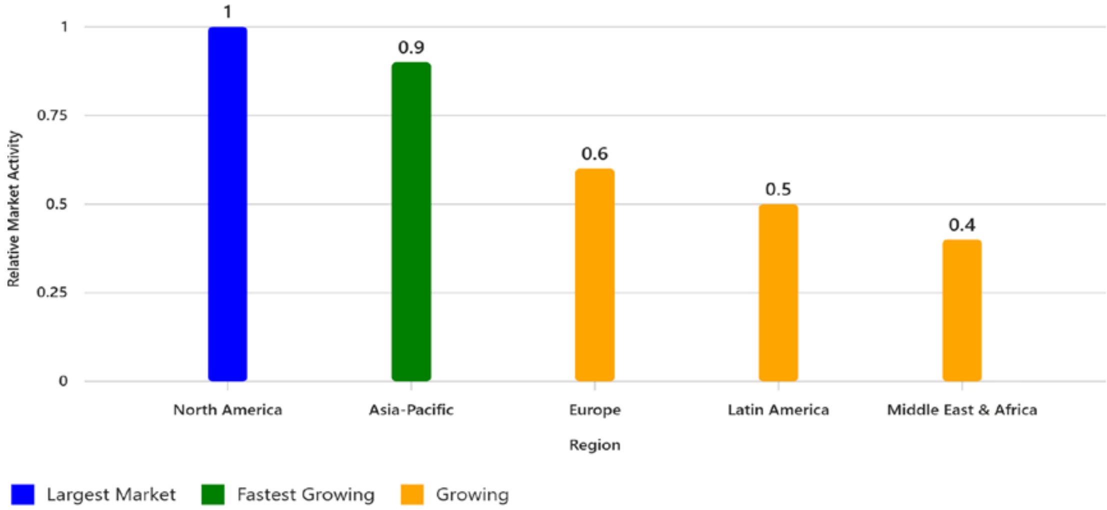

Figure 4: Regional Market Trends for Autorefractor Technologies

North America currently holds the largest share of the autorefractor market (a result of advanced eye-care infrastructure, a large optometrist base, and high healthcare spending).[17] However, the Asia-Pacific region is the fastest-growing market, driven by large populations in need of vision care, improving healthcare access, and increasing investment in eye-health services in countries like China and India.[15] Other regions (Europe, Latin America, Middle East and Africa) are also seeing market growth driven by increasing global awareness of the importance of vision care.

The industry is served by established ophthalmic device manufacturers and also by emerging innovators focused on portable and low-cost autorefractors, which are designed to cater to resource-limited markets. Industry competition is fuelling strategic partnerships and product innovation, and companies are collaborating to expand product offerings and global reach.[18] Many manufacturers are also localizing production and leveraging online distribution to reduce costs and improve device availability.[15,16]

17. Autorefractor Market Size, Share, Trends Report 2032 | MRFR
18. Handheld Autorefractors Market Size, Future Growth and Forecast 2033

Rising rates of myopia, hyperopia, astigmatism and other refractive errors worldwide are the main drivers of demand. As populations age, vision issues that are age-related (presbyopia, cataracts) become more common, increasing the volume of eye examinations that are needed.[19] At the same time, public awareness of eye health is improving: more people are seeking regular eye check-ups and vision screenings. This trend, combined with lifestyle factors such as prolonged screen time (leading to eye strain in younger age-groups),[20] is contributing to growing demand for eye and vision-care services, including services provided by autorefractor devices.

Emerging economies are investing in healthcare infrastructure and eye-care services, expanding the market for vision diagnostic tools. Government and NGO-led initiatives for blindness prevention often include vision screening programmes, which require portable refractive assessment tools. As a result, demand is rising not just in high-income markets but also in developing regions where large populations have uncorrected vision issues. The Asia-Pacific market, for instance, is seeing very rapid growth due to these factors.[21]

Other integrated platforms such as telehealth models are being embraced in eye care, allowing patients to have refractive measurements taken in community settings or at home using handheld devices, with the results reviewed remotely by eye specialists.[18] This has accelerated a trend towards mobile eye clinics and the use of compact, easy-to-transport autorefractors.

To summarize, the autorefractor market is witnessing robust growth globally, propelled by the urgent need to address widespread vision impairment. Technological advancements – particularly the rise of portable, high-precision autorefractors – are transforming how and where eye examinations are conducted. Handheld autorefractors and novel refraction technologies are not only a growth segment of the market, but also a game-

19. Handheld Autorefractors Market Research Report 2032
20. Handheld Autorefractors Market Size, Future Growth and Forecast 2033
21. Autorefractor Market Size, Share, Trends Report 2032 | MRFR

changer for delivering eye care in both advanced and low-resource settings. The combination of strong demand (due to demographic and lifestyle trends) and continuous innovation by industry players focusing on accuracy, affordability, and portability suggests that autorefractors will play an increasingly vital role in global vision care in the coming years.[18]

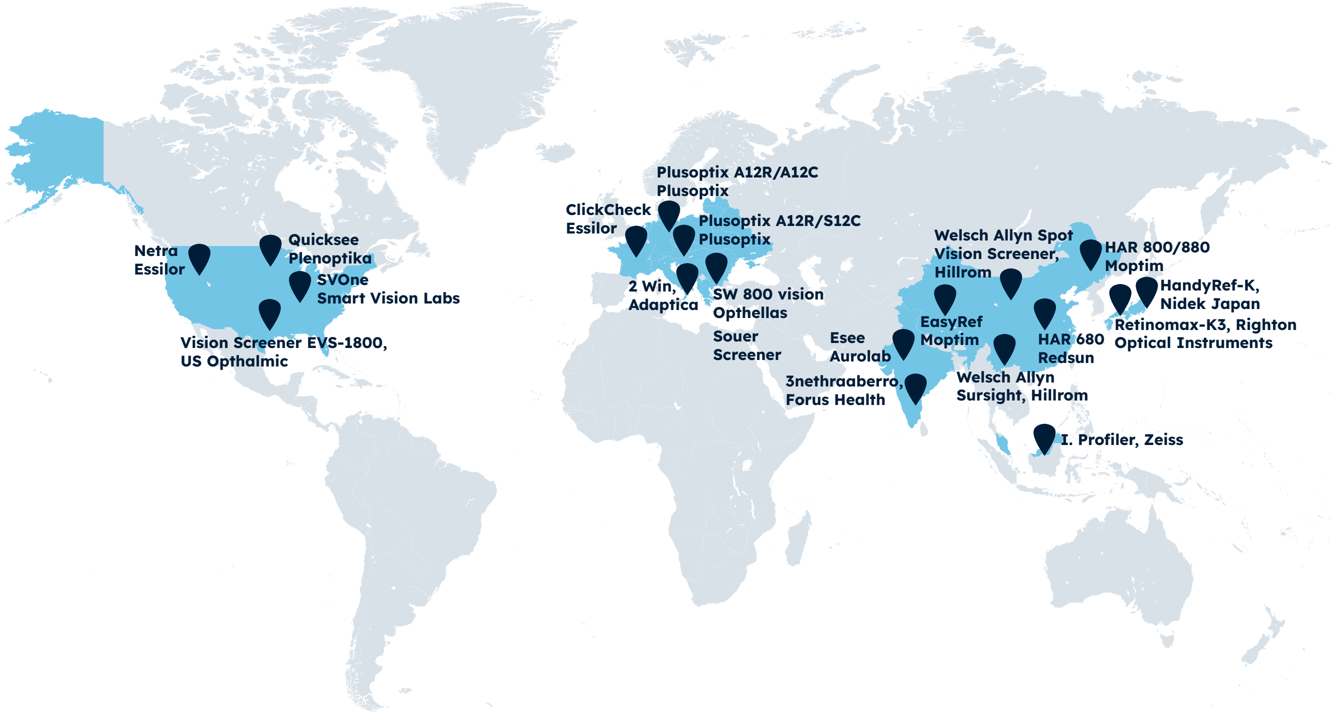

Figure 5: Overview of Autorefractor Technology and Other Novel Technologies (Non-Exhaustive List)

Rationale and objectives of the study

Previous studies have demonstrated that handheld devices can be effectively utilized in low-resource settings both as a refraction screening tool and as a diagnostic device in epidemiological investigations.[22,23] Some of the most widely used and marketed devices have been subjected to studies by eye-care organizations and manufacturers to establish their

22. Samanta A, Shetty A, Nelson PC. Better one or two? A systematic review of portable automated refractors. J Telemed Telecare. 2022 Jul;28(6):404-411. doi: 10.1177/1357633X20940140. Epub 2020 Aug 10. PMID: 32778005.
23. Agarwal A, Bloom DE, deLuise VP, Lubet A, Murali K, Sastry SM. Comparing low-cost handheld autorefractors: A practical approach to measuring refraction in low-resource settings. PLoS One. 2019 Oct 15;14(10):e0219501. doi: 10.1371/journal.pone.0219501. PMID: 31614363; PMCID: PMC6794120.

effectiveness in mass screening across different age groups and to show how they facilitate prescribing of spectacles. As improving technology offers greater accuracy in the measurement of refractive errors, the perception is growing among experts of the potential of handheld devices to simplify on-the-spot prescription of spectacles. On the other hand, there has been anecdotal evidence of limited accuracy of the devices, raising doubts as to whether handheld technologies can be used alone to prescribe spectacles. The situation is complicated because very many and various types of handheld autorefractors are now available from manufacturers across the globe, differing in the technology, features, scope, price and applications, making it difficult for implementers of eye-testing programmes to choose a device that is suitable for their requirements/needs.

Literature concerning the utility, scalability, and reliability of handheld autorefractors in different geographies remains limited at the present time. Led by its vision to improve access to assistive technology in LMICs, ATscale, the Global Partnership for Assistive Technology, is committed to leveraging data and evidence in order to identify solutions that can accelerate and transform the provision of assistive technology. Accordingly, ATscale commissioned a large-scale study to determine the clinical effectiveness and feasibility of the use of handheld autorefractors for on-the-spot prescription of spectacles, especially in countries with low-resource settings and limited availability of eye-care specialists, and with a high burden of uncorrected refractive errors.

The study was undertaken by IQVIA, a leading global provider of healthcare consulting, research, data analytics and technology solutions, in collaboration with L V Prasad Eye Institute, a World Health Organization Collaborating Centre for the Prevention of Blindness, and with guidance from global experts in the eye-care sector.

OBJECTIVES

Broadly, the objective of the study was to assess the effectiveness of various handheld autorefractor technologies as compared with traditional methods of refraction and to determine the feasibility of scaling up these technologies in public health and low-resource settings.

Specifically, the three primary objectives of the study were:

- To compare the clinical effectiveness (sensitivity & specificity) of selected autorefractors, including novel technologies, versus other refraction devices (manual retinoscopy) in children and adults.
- To evaluate the alignment of prescriptions made using selected autorefractor technologies with subjective refraction and the feasibility of prescribing spectacles based on the results of autorefraction.
- To analyse the potential for scaling up the use of handheld technologies in public health settings, from technical, affordability, skill transfer, and regulatory perspectives.

GEOGRAPHIC SCOPE

The study was conducted in three selected LMICs of Africa and Asia, namely Ethiopia, Nepal and Nigeria. The rationale for selecting these countries is explained in Chapter 2 (Methodology).

STUDY TIMELINES

The study was initiated in September 2023 and was completed by February 2025.

2. Methodology

This chapter presents details of the study protocol and methodology, including the data management and analysis plan. The study used a phased approach, implementing sequential and concurrent activities, which are detailed below.

Selection of countries and study sites

The three countries Ethiopia, Nepal and Nigeria were selected based on prevalence of blindness and vision loss (high to moderate), prevalence of uncorrected refractive errors, and regional diversity (West and East Africa, Southeast Asia). It is also important that each of these countries are located in geographical regions, which are marked by high prevalence of vision impairments.

A comprehensive mapping exercise was conducted across the three countries to identify a suitable study site, one in each country. The study sites had to meet the following criteria: i) be a public health facility; ii) have community-outreach eye-care programmes; iii) have capacities for eye-care service delivery and research; iv) have adequate infrastructure; v) have available resources; vi) have sufficient patient load; and vii) agree to adhere to IQVIA's due diligence and compliance norms. After the facilities were confirmed to meet the criteria, they were enrolled, and formal agreements were signed.

Menelik Comprehensive Specialized Hospital in Ethiopia, Nepal Eye Hospital in Nepal, and the College of Health Sciences at the University of Abuja in Nigeria were selected as study sites.

Shortlisting of technologies

The shortlisting of devices was carried out based on a scoring system where each device was scored on a binary scale under various features. These included accuracy cut-off, sensitivity and specificity, power range measurements, portability, cost bracket, weight of the device and battery capacity.

Figure 6: Criteria Used to Shortlist Technologies

A universe of 29 devices and innovative technologies were comprehensively studied in order to identify their diagnostic accuracy and other technical and non-technical features. Sources for the data review included manufacturer dossiers, product catalogues, scientific literature as well as publications in peer-reviewed journals. These findings were also validated by eye-care experts and specialists. Input from experts of the Technical Working Group was also considered in making the final selection.

Scores were assigned objectively to each of the devices in a comprehensive scoring matrix. The selection and scoring criteria were as below:

Table 1: Selection Criteria for Autorefractor Technologies and Sources of Validation

Score	Price bracket ($)	Accuracy (D)	Weight (gms)	Time per measurement (seconds)
5	0 - 2000	<= 0.25	100 - 500	< 10
4	2001 - 4000	<= 0.5	550 - 1050	10 - 20
3	4001 - 6000	<= 0.75	1100 - 1600	21 - 40
2	6001 - 10,000	<= 1.0	1650 - 2150	41 - 60
1	10,001 & above	<= 1.5	> 2200	> 61

SOURCES OF VERIFICATION

- Manufacturer dossiers; product catalogues; validation with sales teams.
- Validation through desk reviews of scientific publications and peer-reviewed journal articles.
- Manufacturer dossiers; product catalogues.
- Manufacturer dossiers; product catalogues; validation through expert inputs (users) and scientific publications in peer-reviewed journals.

Six devices were initially shortlisted based on the scoring. Later, two were replaced owing to the non-availability of products and recommendations by the Technical Working Group to consider other comparable technologies based on the scoring system. The table below presents an overview of the selected technologies:

Table 2: Shortlisted Technologies

Technology	Brief description
Eccentric Photorefraction	This technology uses infrared light, which is projected onto the eyes from a given distance. The device measures the brightness of the light that is reflected back from the retina at the centre and periphery of the pupils. Refractive error is estimated based on characteristics of the reflected light.
Shack-Hartmann Wavefront Sensing (Wavefront Aberrometer)	A wavefront of light is projected into the eye and reflected back from the retina. The returning array of light is then captured by lenslets with different powers, enabling calculation of the defocus amount and of the refraction power needed for clear focus. Multiple entry points make it possible to detect and measure peripheral aberrations as well as refractive error. This technology is sensitive to eye movements and may produce erroneous readings if the eyes are moving.
Rotating Lens Dial Mechanism (Badal Optometer)	This mechanism involves a simple forward-backward shift between the lenses which would change the focal length depending on the distance from the eye of the person being tested. This distance is then converted into diopters to calculate required lens power of the spectacles to be prescribed.
Shack-Hartmann Wavefront Sensing	Same as for Wavefront Aberrometer (see above) with some design differences.

Technology	Brief description
SynchroScan Technology	SynchroScan Technology uses infrared rays to measure refractive errors. This is done by measuring the time taken for the infrared light to travel back and forth from its origin by tracing the ray path. Refractive power can be calculated on this basis. The technique is especially useful for dynamic measurements (when the eye is moving).
Optical Ray Wavefront Principal (Auto Fogging)	This technology utilizes an optical ray tracing mechanism, where infrared light is projected onto the eyes, and the reflected light path is measured using a sensor. The reflected light path is then compared, and the calculation is used to estimate the refractive error.

Study design

1200
Participants

400
Sample Size
Per Country

200
Participants Studied
Per Device

This was a prospective and observational study. Assuming a minimum sensitivity of 50% for a screening test with 20% precision and an expected refractive error prevalence of 6%, a sample of 150-180 participants was estimated for each handheld autorefractor device. Predicting a 10% drop-out or refusal rate, a total of 200 participants were recruited to each group. A total of 1200 participants aged five years and older were recruited in this way from outpatient clinics attached to the study sites in Ethiopia, Nepal and Nigeria.

Table 3: Study Groups: Disaggregated by Age

Group 1	Group 2	Group 3	Group 4
5-16 years	17-28 years	29-39 years	40 years and above

INCLUSION CRITERIA

- Willing to participate and give consent.
- Individuals who come for a general eye check-up, change of spectacles, with complaints of reduced vision.
- Visual acuity improving to at least 6/12 with refraction.
- Individuals who do not have any ocular pathology (known or diagnosed) such as cataract, corneal scar, retinal or optic nerve pathology.

EXCLUSION CRITERIA

- Individuals presenting with acute eye problems such as sudden loss of vision, infection, or red eyes.
- Individuals presenting for follow-up visits for any other ocular treatment other than refractive error.
- Visual acuity does not improve to 6/12 after refraction.
- Uncooperative participants.

Each country's study site was equipped with two handheld autorefractors from the shortlisted devices, following a detailed scoping review. Effort was made to recruit an equal number of participants from different age groups.

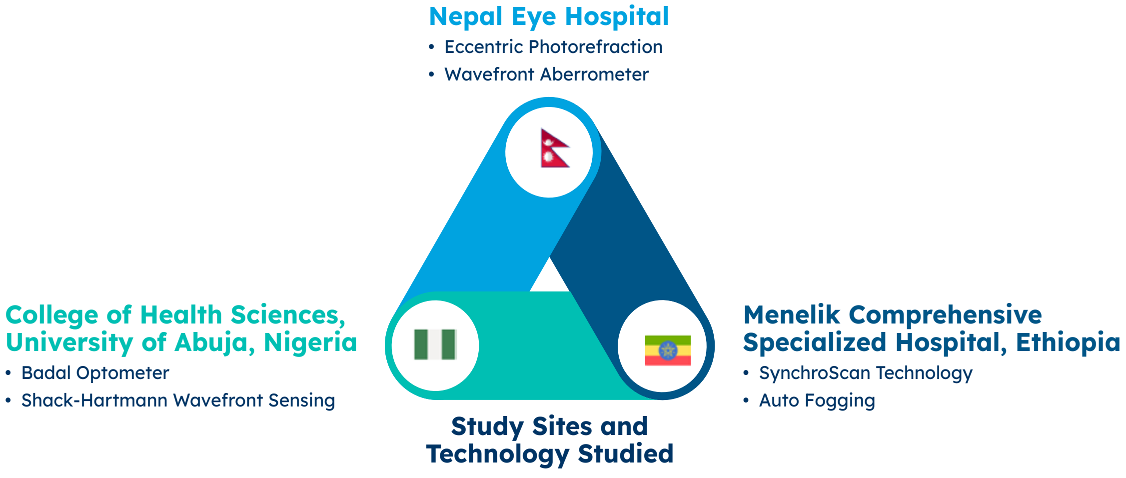

Figure 7: Study Sites and Technologies Studied at each Site

The table below gives an overview of the total study participants recruited at each study site along with details of their demographic and clinical characteristics.

Table 4: Demographic and Clinical Characteristics of Study Participants

	Ethiopia	**Nepal**	**Nigeria***
Total study participants	400	442	385
Mean age	30.6	28.9	28.9
Age range (years)	5 - 75	5 - 83	5 - 70
Age group: 5 - 16 years	99	118	104
Age group: 16 - 28 years	103	120	107
Age group: 29 - 39 years	93	97	67
Age group: 40 years and older	105	107	107
Refractive error status: Emmetropia	150	147	216
Refractive error status: Myopia	166	265	77
Refractive error status: Hyperopia	84	30	92

*In Nigeria, sample size was slightly less than 400 participants. This was due to the patient load and availability of eligible participants in the given time frame.

Training and pilot testing

A training phase of the study was carried out as part of a pilot study in each of the countries. The pilot study involved two critical phases: 1) Training, 2) Pilot data collection. A cadre of optometrists and eye specialists working in these hospital settings were trained in use of the handheld autorefractors. Additionally, non-specialists and allied healthcare professionals including nurses and community health workers underwent training on study protocols and use of autorefractor devices for conducting refraction.

Matters covered by the training phase included orientation of the study protocol, standard operating guidelines of the study, completion of data collection forms, and training in the usage and maintenance of handheld autorefractors. This was followed by hands-on training in operation of the devices and collection of data from participants. The pilot data collection was conducted for 10% of the sample size required at each of the study sites.

The capacity-building sessions were held on-site by eye-care specialists who ensured that the training was comprehensive and that all personnel felt confident in their ability to use the devices accurately and efficiently. These capacity-building workshops aimed to ensure that personnel of the partner facilities could perform precise and reliable autorefraction tests, manage the collected data, and maintain the devices effectively.

Data collection methods

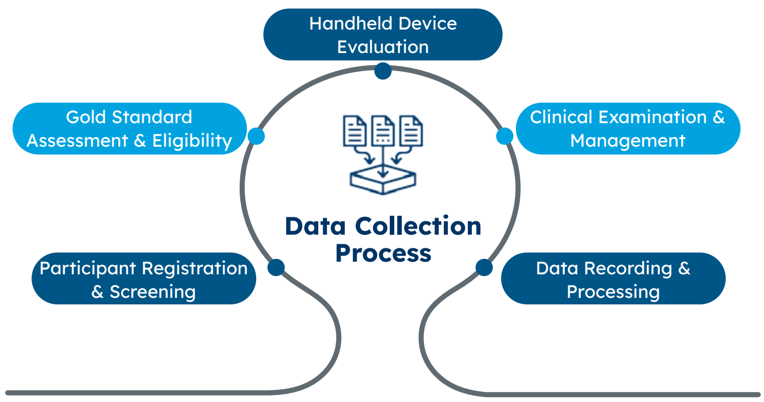

Figure 8: Data Collection Methods

Potential participants were identified by a study coordinator at the outpatient clinic in the study locations. In Nigeria and Nepal, study participants were also recruited through community outreach programmes. This approach was not feasible in Ethiopia due to the limited timeline for data collection, which was affected by delays importing the devices to the country. After initial registration, demographic details were collected. The participants underwent a complete eye examination, including manual refraction by an optometrist. Those who showed improvement to 6/12 using subjective refraction were considered eligible for the study. Subjective refraction by this optometrist was considered to be the gold standard. These readings were masked from the personnel performing the autorefraction in order to avoid any bias.

Autorefraction was performed on the eligible participants by community health workers, using two handheld autorefractors consecutively. After the autorefraction, a comprehensive eye examination, including a fundus examination, was performed by an ophthalmologist and managed in accordance with hospital protocols. The data were recorded on printed study forms, and data entry was performed using Microsoft Excel. All personal information and data of the patients was anonymized before sharing with data analysts for data cleaning and analysis.

The data collection form is available for further reference in Annex 1.

Post-analysis and drafting of the report included stakeholder consultations with respondents from the healthcare and life sciences industry, public health hospitals, and international non-governmental organizations working in the eye-care sector. In-depth interviews were conducted with stakeholders from India, Indonesia, Kenya and Pakistan. The objective of these stakeholder consultations was to discuss the potential implications of the study findings in scaling up technologies across LMICs. The areas of discussion included implications of findings for on-the-spot prescription of spectacles, the regulatory landscape for handheld autorefractors, supply chain management, funding, task-sharing and capacity building.

1. Implications of findings for prescription of eyeglasses
Discuss technical findings, evidence and conclusive insights

2. Country capacities and skills transfer
Human resources availability and training methods to build capacities of the non-specialists and allied healthcare professionals

3. Regulatory landscape
Implications on supply chain, scalability

4. Funding landscape
Costs and availability of funds

5. Recommendations for scalability in community and public health settings
Enabling factors and potential challenges

Figure 9: Key Areas of Stakeholder Consultations

Data analysis

Spherical equivalent refractive error (SER) was calculated by adding the sphere power to half of the cylinder power. Myopia (near-sightedness) was defined as SE < -0.50 D and hyperopia (far-sightedness) was defined as SE > +0.50 D. The refractive errors were also graded as low myopia (<-0.50 to <-3.0 D), moderate myopia (>-3.00 D), low hyperopia (>+0.50 to <+3.0 D), moderate hyperopia (>+3.00 D) and emmetropia (-0.50 to +0.50 D). More than a 0.50 difference in SER between handheld autorefractors and gold-standard values was considered a clinically significant difference in SER.

Two approaches were used to compare the gold-standard SER and the values obtained using handheld autorefractors. Agreement between the gold-standard SER and results obtained using handheld autorefractors was assessed using intraclass correlation coefficients (ICC) and sensitivity and specificity analyses. The mean differences in SER readings obtained from gold-standard subjective refraction and from handheld autorefractors were calculated and compared using Student's t-tests.

Data from the right eye was used for analysis. A p-value of <0.05 was considered statistically significant. The data analysis was conducted using Stata/SE 14 for Windows software (StataCorp LLC, TX, USA).

Ethical considerations

The Institutional Review Board of the Hyderabad Eye Research Foundation (HERF), L V Prasad Eye Institute, India, approved the study protocols. The study was also approved by local ethics committees in Nepal, Nigeria, and Ethiopia, where data collection took place. All participants provided written informed consent expressing their willingness to participate in the study.

Study limitations

- Comparing the results of cycloplegic refraction with handheld refraction results in children was beyond the scope of the study. Cycloplegic refraction uses eye drops prior to the examination to temporarily paralyze the ciliary (eye) muscles, preventing any adjustments in lens shape to focus on objects. The study did not use this technique.
- The performance of handheld autorefractors in astigmatic cases was not evaluated as it was beyond the scope of this study. Astigmatism is a common vision problem that causes blurred or distorted vision due to irregular shape of the cornea or lens of the eye. Astigmatism requires complex management and specialized trained staff.
- There were very few cases in refractive error groups of higher severity; hence, the results in these groups were not statistically valid and could not be generalized to this group.

3. Sensitivity and specificity of handheld autorefractor technologies

The process of assessing the eye's refractive status is called refraction. There are two types of refraction, objective and subjective. Retinoscopy is an objective refraction process that measures a person's refractive error (near-sightedness, far-sightedness, or astigmatism) using a retinoscope and light. Subjective refraction, often carried out after objective refraction, involves manually evaluating refractive status using a combination of spherical and cylindrical lenses to find the best-corrected visual acuity for prescription of spectacles. In this study, retinoscopy and subjective refraction were taken to be the gold standard.

A Spherical Equivalent (SE) is an estimate of the eyes' refractive error, calculated independently for each eye. It is calculated by merging the spherical (near-sightedness or far-sightedness) and cylindrical (astigmatism, a common vision condition causing blurred vision) components of the refractive error. Spherical Equivalent Refractive Error (SER) is calculated by adding the sphere power to half of the cylinder power. For this study, there was no statistically significant difference in mean SER between both eyes. Data from the right eye was used for analysis. The unit for measuring refraction is the diopter (D).

Sensitivity and specificity of handheld autorefractors to detect myopia and hyperopia compared with manual objective retinoscopy

Diagnostic accuracy refers to how well a test identifies whether a condition is present or absent. Sensitivity (true positive rate) and specificity (true negative rate) are important components of diagnostic accuracy. Ideally, a diagnostic test should have a combination of at least 80% sensitivity and 80% specificity. However, a sensitivity and specificity combination of 70% can be considered suitable for detecting refractive errors.

KEY RESULTS FOR MYOPIA

Myopia is near-sightedness (short-sightedness). It is a common vision condition where close objects are seen clearly, but distant objects appear blurred. For the analysis, two definitions were used to define myopia: definition 1 (SER worse than -0.50 D); and definition 2 (SER worse than -1.0 D).

For myopia definition 1 (SE worse than -0.50 D), Eccentric Photorefraction, Wavefront Aberrometer, SynchroScan and Auto Fogging technologies had a sensitivity of more than 70%. All of the handheld autorefractors had a specificity of over 80% for myopia except Eccentric Photorefraction. Overall, Wavefront Aberrometer, SynchroScan, and Auto Fogging technologies had the best combination of sensitivity and specificity.

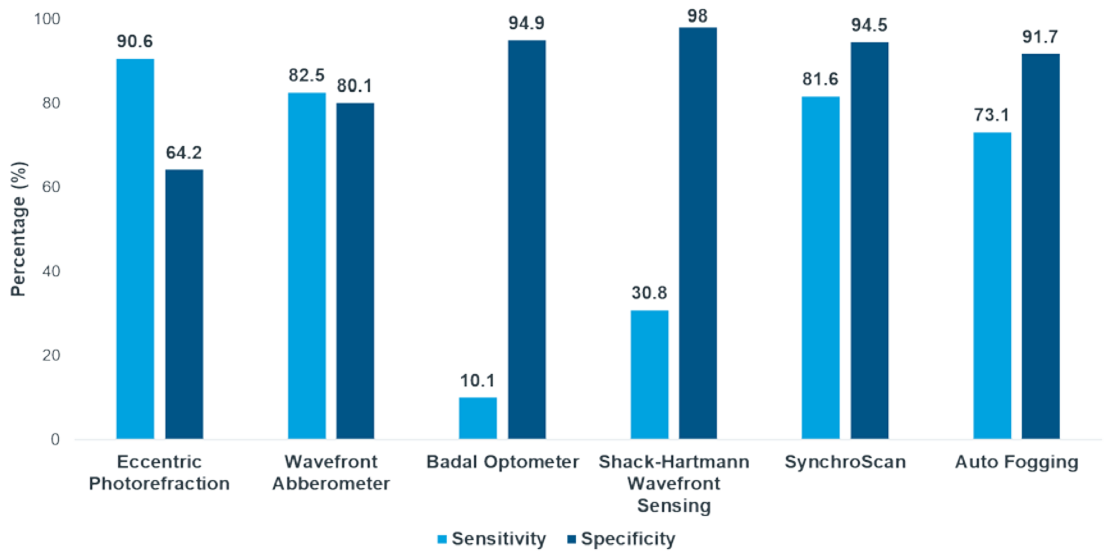

Figure 10: Sensitivity and Specificity for Myopia, Definition 1 (SE worse than -0.50 D), Comparison with Retinoscopy

For myopia definition 2 (SE <-1.0 D), similar results were noted. Eccentric Photorefraction, Wavefront Aberrometer, and SynchroScan technologies had the best combination of sensitivity and specificity.

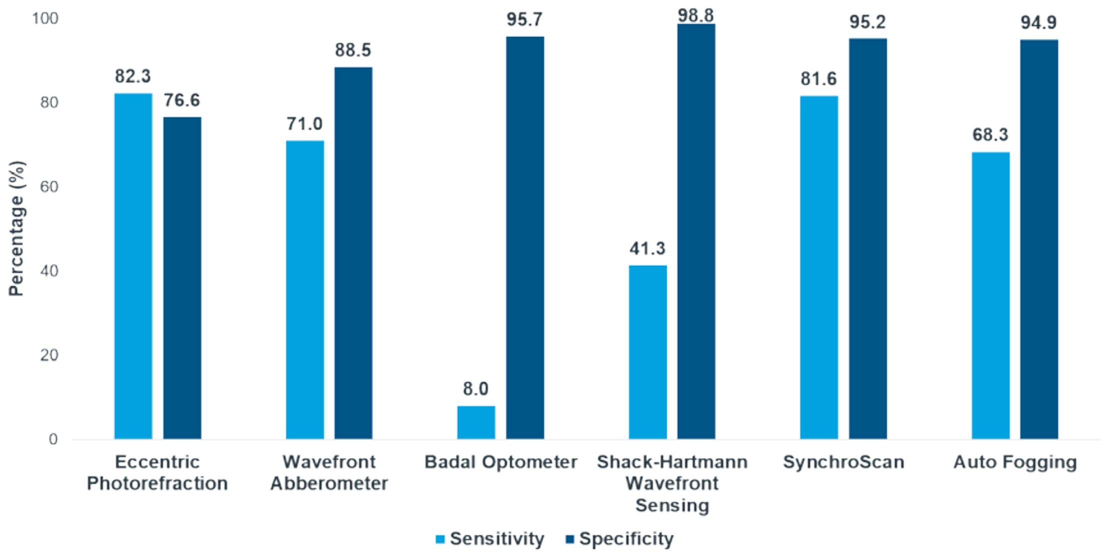

Figure 11: Sensitivity and Specificity for Myopia, Definition 2 (SE worse than -1.00 D), Comparison with Retinoscopy

KEY RESULTS FOR HYPEROPIA

Hyperopia or far-sightedness is a refractive error where distant objects are usually seen clearly, while objects close by appear blurred. For this analysis, two definitions were used to define hyperopia: definition 1 (SER more than +0.50 D); and definition 2 (SER more than +1.0 D).

For hyperopia definition 1 (SER>+0.50 D), the autorefractor technologies had high sensitivity of over 70% except the Eccentric Photorefraction and Wavefront Aberrometer. More than 80% specificity was achieved by all technologies except the Badal Optometer and Shack-Hartmann Wavefront Sensing. SynchroScan and Auto Fogging technologies had the best combination of sensitivity and specificity.

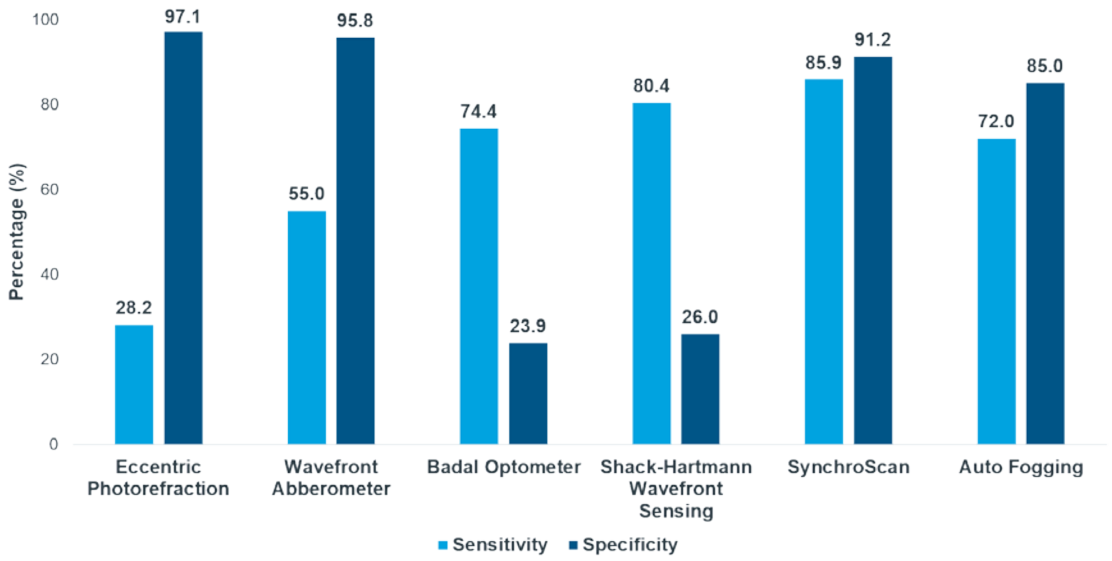

Figure 12: Hyperopia, Definition 1 (SE greater than + 0.50 D), Comparison with Retinoscopy

Similar results were obtained for hyperopia definition 2 (SE > +1.0 D). Overall, SynchroScan and Auto Fogging technologies had the best combination of sensitivity and specificity.

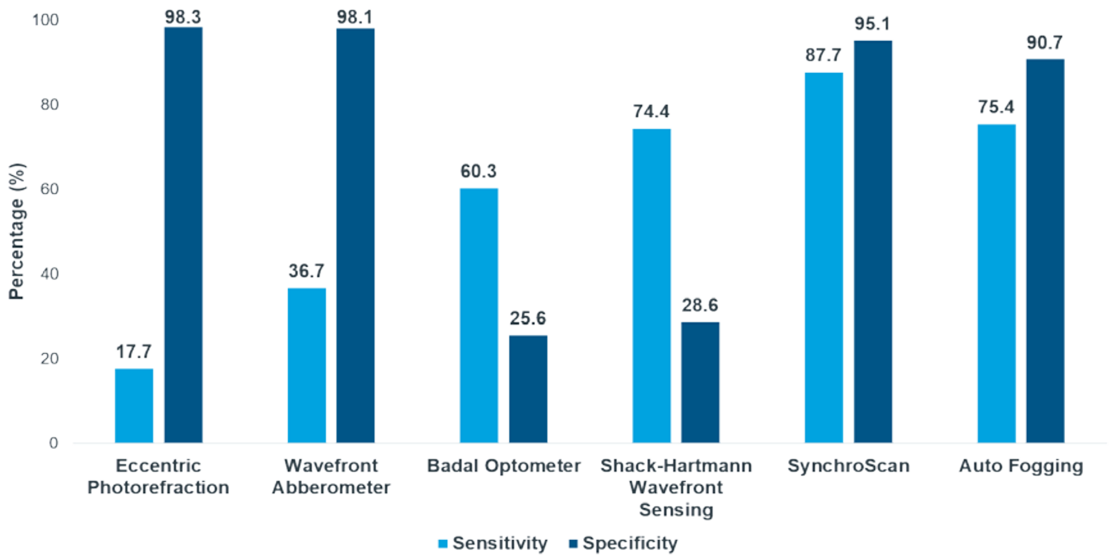

Figure 13: Hyperopia, Definition 2 (SE greater than +1.0 D), Comparison with Retinoscopy

Please refer to Table 8 in Annex 3 for more details on the findings.

Sensitivity and specificity of handheld autorefractors to detect myopia and hyperopia compared with gold-standard subjective refraction

KEY RESULTS FOR MYOPIA

As shown in Figure 15 below, Eccentric Photorefraction, Wavefront Aberrometer, and SynchroScan Technology had sensitivity above 70% for myopia definition 1 (SE <-0.50 D). By contrast, all handheld autorefractor technologies, except Eccentric Photorefraction, had specificity above 80%.

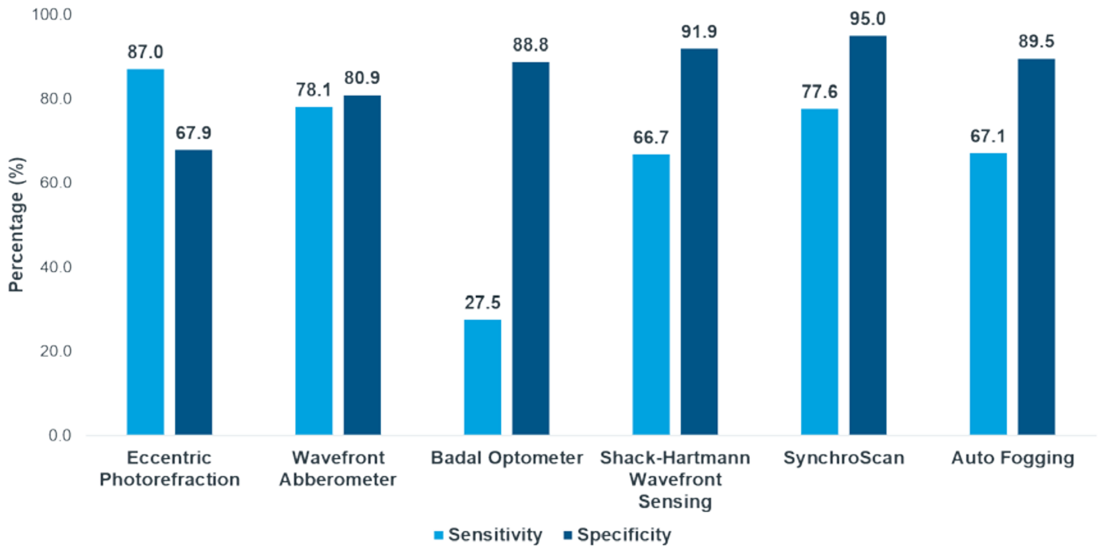

Figure 14: Sensitivity and Specificity for Myopia, Definition 1 (SE worse than -0.50 D), Comparison with Subjective Refraction

As shown in Figure 16 below, all handheld autorefractors except Wavefront Aberrometer, Badal optometer and Auto Fogging had a sensitivity of more than 70% for myopia definition 2 (SE <-1.0 D), while all handheld autorefractors except Eccentric Photorefraction had specificity of 90% or more. Badal Optometer had poor sensitivity for both definitions of myopia. Overall, SynchroScan Technology had the best specificity and sensitivity combination for both definitions of myopia.

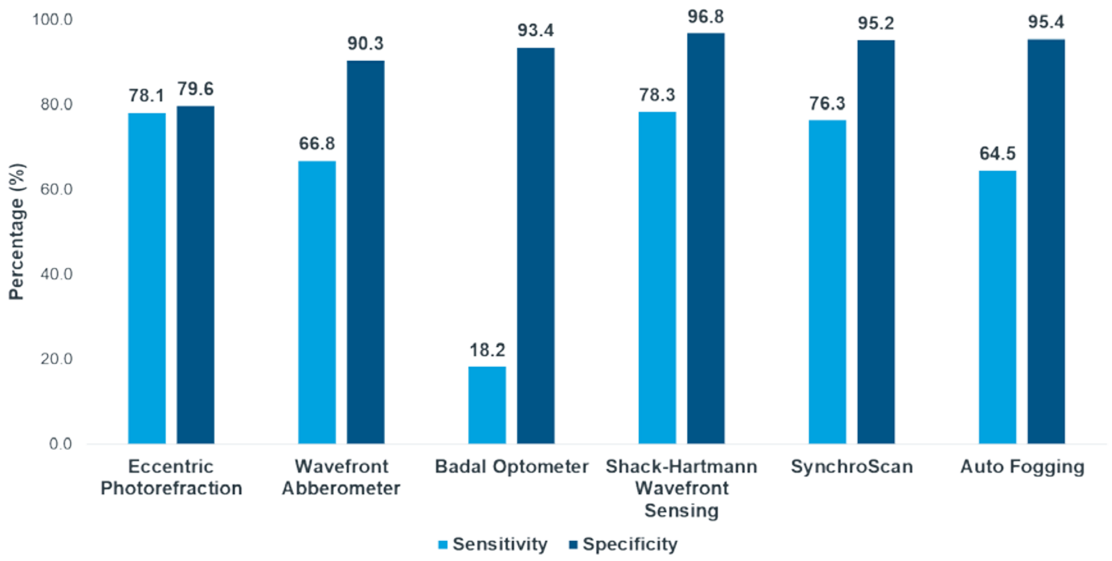

Figure 15: Sensitivity and Specificity for Myopia, Definition 2 (SE worse than -1.00 D), Comparison with Subjective Refraction

KEY RESULTS FOR HYPEROPIA

All autorefractor technologies had very high specificity of over 80% for hyperopia definition 1 (SE > +0.50D). However, only SynchroScan Technology had sensitivity of more than 70%. SynchroScan Technology also has the best combination of sensitivity and specificity.

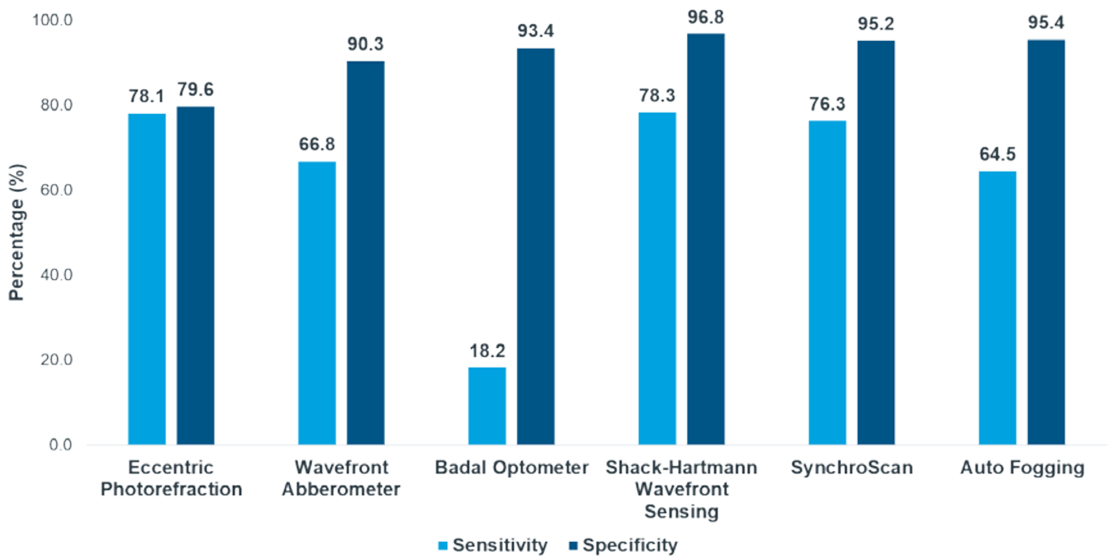

Figure 16: Hyperopia, Definition 1 (SE greater than + 0.50 D), Comparison with Subjective Refraction

The same results were obtained for hyperopia definition 2 (SE > +1.0 D). Overall, SynchroScan Technology had the best combination of sensitivity and specificity for both definitions of hyperopia.

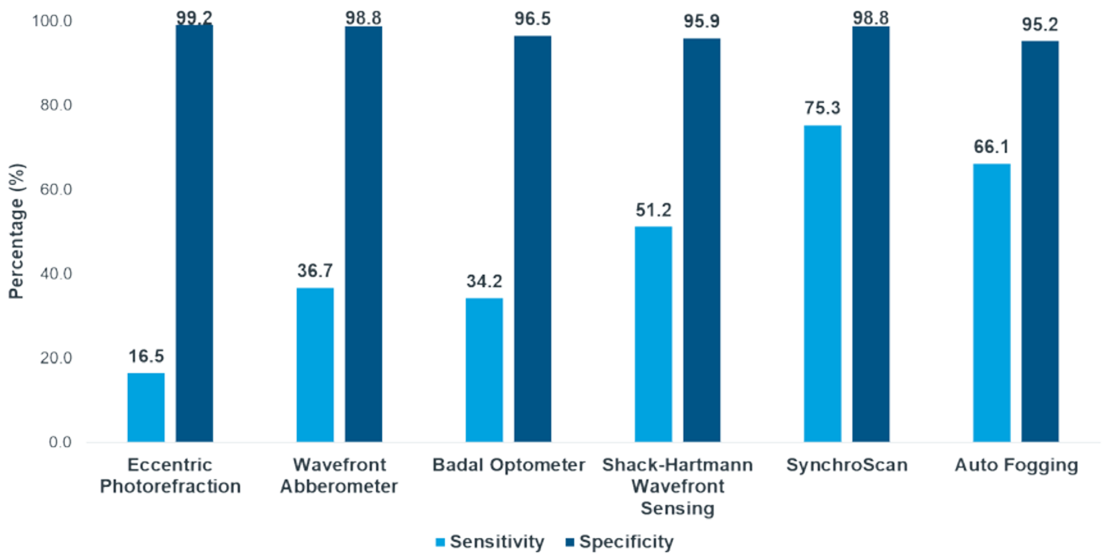

Figure 17: Hyperopia, Definition 2 (SE greater than +1.0 D), Comparison with Subjective Refraction

Please refer to Table 9 in Annex 3 for more details on findings.

Grading the sensitivity and specificity performance of handheld autorefractor technologies

A combination of sensitivity and specificity thresholds is used to grade the performance of handheld autorefractors compared to objective retinoscopy and gold-standard subjective refraction. Sensitivity and specificity of greater than 80% is graded as “ideal”, above 75% to 80% is graded as “acceptable”, and results between 70% and 75% are graded as “borderline”.

Table 5: Grading of Performance of Handheld Autorefractors Based on Sensitivity and Specificity

Parameter	Percent	Grading
Sensitivity	>80%	Ideal
Specificity	>80%	Ideal
Sensitivity	>75% to 80%	Acceptable
Specificity	>75% to 80%	Acceptable
Sensitivity	70% to 75%	Borderline
Specificity	70% to 75%	Borderline

OBJECTIVE RETINOSCOPY

Definitions	Eccentric Photorefraction	Wavefront Aberrometer	Badal Optometer	Shack-Hartmann Wavefront Sensing	SynchroScan Technology	Auto Fogging
Myopia, Definition 1 (SER worse than -0.50 D)		Ideal			Ideal	Borderline
Myopia, Definition 2 (SER worse than -1.0 D)	Acceptable	Borderline			Ideal	
Hyperopia, Definition 1 (SER greater than +0.50 D)					Ideal	Borderline
Hyperopia, Definition 2 (SER greater than +1.0 D)					Ideal	Acceptable

SUBJECTIVE REFRACTION

Definitions	Eccentric Photorefraction	Wavefront Aberrometer	Badal Optometer	Shack-Hartmann Wavefront Sensing	SynchroScan Technology	Auto Fogging
Myopia, Definition 1 (SE worse than -0.50 D)		Acceptable			Acceptable	
Myopia, Definition 2 (SE worse than -1.0 D)	Acceptable			Acceptable	Acceptable	
Hyperopia, Definition 1 (SE greater than +0.50 D)					Borderline	
Hyperopia, Definition 2 (SE greater than +1.0 D)					Acceptable	

Key takeaways

MYOPIA

- Eccentric Photorefraction works best for definition 2 of myopia (SER worse than -1.0 D).
- Wavefront Aberrometer works best for both definitions of myopia.

HYPEROPIA

- Auto Fogging Technology works well with definition 1 of myopia (SER worse than -0.50 D) and with both definitions of hyperopia.

OVERALL

- SynchroScan Technology works best across both definitions of myopia and hyperopia.

4. Implications for the prescription of spectacles

This section looks at clinical accuracy of refractive error measurement using handheld autorefractors when compared with subjective refraction. The clinical findings have been presented in terms of differences in the mean Spherical Equivalent refraction values between the autorefractor technologies and the gold standard (subjective refraction). A difference in Spherical Equivalent Refractive Error (SER) of more than ± 0.50 between handheld autorefractor technologies and gold standard values was considered clinically significant, and values within this range are considered clinically acceptable. This range is chosen based on the test-retest variability in refraction.

Clinical accuracy for handheld autorefractors refractive error measurement versus the gold standard (subjective refraction)

Alignment of prescription between autorefractor technologies and subjective refraction (gold standard) across refractive error conditions

Performance of Handheld Autorefractors in Myopia: Mean Difference in SER Compared to Gold Standard

Eccentric Photorefraction	Wavefront Aberrometry	Badal Optometer	Shack-Hartmann Wavefront Sensing	SynchroScan Technology	Auto Fogging Technology
0.42 (0.97)	0.64 (0.80)	-0.41 (3.60)	-0.53 (2.76)	0.19 (1.23)	0.52 (2.50)
n=220	*n=252*	*n=77*	*n=77*	*n=166*	*n=166*

Figure 18: Performance in Myopia: Mean Difference in SER when Compared to the Gold Standard (n refers to the sample size studied under this technology)

All except the Wavefront Aberrometer provided readings within the clinically acceptable limits for myopia (SER worse than -0.50 D). However, Wavefront Aberrometer readings are closer to the clinically significant value of 0.50D. It is also important to note that large standard deviations were recorded for the Badal Optometer (3.60 D), Shack-Hartmann Wavefront Sensing (2.76 D), and Auto Fogging technology (2.50 D), suggesting large variability in the readings.

All the handheld autorefractors except the Badal Optometer provided readings within clinically acceptable limits for hyperopia (SER more than +0.50 D). It should be noted that readings from the Badal Optometer are closer to the clinically significant value of 0.50D. However, large standard deviations were obtained for the Badal Optometer (3.30 D), Auto Fogging technology (2.43 D) and Eccentric Photorefraction (2.03 D), indicating large variability in the readings.

Please refer to Table 10 in Annex 3 for more details.

Performance of Handheld Autorefractors in Hyperopia: Mean Difference in SER Compared to Gold Standard

Eccentric Photorefraction	Wavefront Aberrometry	Badal Optometer	Shack-Hartmann Wavefront Sensing	SynchroScan Technology	Auto Fogging Technology
0.49 (2.03)	0.25 (1.20)	0.57 (3.30)	0.32 (1.21)	0.11 (1.34)	0.50 (2.43)
n=20	*n=26*	*n=92*	*n=92*	*n=84*	*n=84*

Figure 19: Performance in Hyperopia: Mean Difference in SER Compared to Gold Standard (n refers to the sample size studied using this technology)

Key takeaways

MYOPIA (SER < -0.50 D)

- All devices except the Wavefront Aberrometer[24] provided readings within clinically acceptable limits.
- High variability in readings was observed for:
  - Badal Optometer: SD = 3.60 D
  - Shack-Hartmann Wavefront Sensing: SD = 2.76 D
  - Auto Fogging Technology: SD = 2.50 D

HYPEROPIA (SER > +0.50 D)

- All handheld autorefractors except the Badal Optometer[25] provided readings within clinically acceptable limits.
- High variability in readings was observed for:
  - Badal Optometer: SD = 3.30 D
  - Auto Fogging Technology: SD = 2.43 D
  - Eccentric Photorefraction: SD = 2.03 D

24. Wavefront Aberrometer readings were closer to the clinically significant threshold of 0.50 D, but not within acceptable limits.
25. Badal Optometer readings were closer to the clinically significant threshold of 0.50 D, but not within acceptable limits.

Alignment of prescription between autorefractor technologies and subjective refraction (gold standard), based on severity of refractive error conditions

	Eccentric Photorefraction	Wavefront Aberrometry	Badal Optometer	Shack-Hartmann Wavefront Sensing	SynchroScan Technology	Auto Fogging Technology
Low Myopia	-0.40 (0.92) *n=189*	0.65 (0.80) *n=190*	0.73 (2.05) *n=54*	-0.20 (0.90) *n=54*	0.07 (0.80) *n=109*	0.57 (1.50) *n=109*
Moderate Myopia	0.53 (1.12) *n=31*	0.60 (0.86) *n=62*	-3.10 (4.94) *n=23*	-1.33 (4.83) *n=23*	0.40 (1.78) *n=57*	0.44 (3.75) *n=57*
Low Hyperopia	-0.24 (0.80) *n=17*	0.39 (1.18) *n=20*	0.33 (2.98) *n=87*	0.27 (1.04) *n=87*	-0.02 (1.39) *n=55*	0.41 (2.08) *n=55*
High Hyperopia	4.6 (2.13) *n=3*	-0.23 (1.25) *n=6*	4.68 (5.95) *n=5*	1.30 (2.99) *n=5*	0.36 (1.23) *n=29*	0.94 (3.00) *n=29*

Figure 20: Performance with Different Severities of Refractive Errors: Mean Difference in SER when Compared to the Gold Standard (n refers to the sample size studied under this technology)

- For lower grades of myopia (worse than -0.50 to <-3.0 D), devices with Eccentric Photorefraction, Shack-Hartmann Wavefront Sensing, and SynchroScan technologies provided readings within clinical acceptable limits of < ±0.50 D.
- For moderate myopia (>-3.00 D), SynchroScan and Auto Fogging technologies provided readings within clinically acceptable limits but with larger variations, mainly for Auto Fogging technology. Eccentric Photorefraction and Wavefront Aberrometer values were also closer to clinically acceptable limits with less variability.

Hyperopia was graded as low hyperopia (more than +0.50 to <+3.0 D) and moderate hyperopia (>+3.00).

- For lower grades of hyperopia (more than +0.50 to <+3.0 D), all the devices and technologies gave clinically acceptable results (<±0.50 D). However, large variability (more than +2.0 D) was noted for devices with Badal Optometer and Auto Fogging technologies.

- For higher grades of hyperopia (>= +3.0 D), devices using Wavefront Aberrometry and SynchroScan technologies provided clinically acceptable values (< ±0.50 D). However, the number of participants enrolled in this group was smaller, making the comparison across the results inconclusive.

Please refer to Table 11 in Annex 3 for more details on the findings.

Key takeaways

MYOPIA

Low myopia (< -3.0 D)

- Technologies within clinically acceptable limits (< ±0.50 D):
  - SynchroScan.
  - Shack-Hartmann Wavefront Sensing.
  - Eccentric Photorefraction.
- High variability (> 2.0 D): Badal Optometer.
- Conclusion: SynchroScan, Shack-Hartmann and Eccentric Photorefraction are best suited for low myopia.

Moderate myopia (> -3.0 D)

- Technologies within clinically acceptable limits (< ±0.50 D):
  - SynchroScan.
  - Eccentric Photorefraction.
- Issues noted:
  - Auto Fogging showed large variability though the readings were within acceptable limits.
  - The Badal Optometer showed large differences.
- Conclusion: SynchroScan had the most favourable results; Eccentric Photorefraction is also promising.

HYPEROPIA

Low hyperopia (< +3.0 D)

- Technologies within clinically acceptable limits (< ±0.50 D):
  - All.

  High variability (> +2.0 D):
  - Badal Optometer.
  - Auto Fogging.

  Note: Fewer participants were screened using Eccentric Photorefraction and Wavefront Aberrometry.
- Conclusion: All except Badal Optometer and Auto Fogging technologies are best suited for low hyperopia.

Moderate hyperopia (> +3.0 D)

- Technologies within clinically acceptable limits (< ±0.50 D):
  - Wavefront Aberrometry.
  - SynchroScan.

  Sample size caveat: There were fewer participants in this group, so comparisons were limited.
- Conclusion: SynchroScan is most suited for screening higher grades of hyperopia.

OVERALL

The device using SynchroScan Technology displayed the most clinical accuracy and alignment with the gold standard. Eccentric Photorefraction was second best.

Alignment of prescriptions between autorefractor technologies and subjective refraction across different age groups

	Eccentric Photorefraction	Wavefront Aberrometry	Badal Optometer	Shack-Hartmann Wavefront Sensing	SynchroScan Technology	Auto Fogging Technology
5-16 years	0.40 (1.20) *n=100*	0.60 (0.90) *n=114*	2.50 (4.20) *n=104*	0.02 (1.74) *n=104*	0.26 (1.42) *n=99*	0.73 (2.78) *n=99*
17-28 years	0.45 (0.96) *n=106*	0.78 (0.82) *n=116*	1.50 (2.64) *n=107*	-0.28 (2.00) *n=107*	0.27 (0.14) *n=103*	0.63 (2.80) *n=103*
29-39 years	0.90 (0.73) *n=82*	0.57 (0.76) *n=96*	0.98 (2.50) *n=67*	0.01 (0.90) *n=67*	0.27 (1.28) *n=92*	0.60 (1.76) *n=92*
40 and above	-0.13(0.81) *n=95*	0.30 (0.81) *n=98*	-0.87(1.58) *n=107*	0.04 (0.84) *n=107*	0.12 (0.81) *n=103*	0.25 (1.21) *n=103*

Figure 21: Performance across Different ages: Mean Difference in SER when Compared to the Gold Standard (n refers to the sample size studied under this technology)

In children (5 to 16 years) three of the technologies (Badal Optometer, Auto Fogging and Wavefront Aberrometer) gave readings outside the clinically accepted limits (±0.50 D). However, the Wavefront Aberrometer showed small variability compared to the other two technologies.

There were similar findings for the younger age group (17-28 years). Eccentric Photorefraction, SynchroScan, and Shack-Hartmann Wavefront Sensing provided results that were within the clinically acceptable limits. However, Shack-Hartmann Wavefront Sensing technology showed large variability.

For other age groups all of the technologies except the Badal Optometer and Auto Fogging were within or close to clinically acceptable limits although the Badal Optometer showed large variability.

It is important to note that in younger age groups, large variability was noted for all the readings obtained through both subjective refraction and autorefraction. This can be attributed to strong amplitudes of accommodation (the eye's ability to automatically adjust its focus to maintain a clear image of objects at varying distances) in younger individuals. This is corroborated by consistently lower variability in the older age groups. The Badal Optometer gave significantly different values across all age groups and showed a large variability compared to the gold-standard SER. The SynchroScan device gave consistent results across all age groups.

The conclusion based on the results is that SynchroScan and Shack-Hartmann Wavefront Sensing are well-suited for clinical assessments of refractive errors across all age groups and for prescribing spectacles in low-resource settings. Eccentric Photorefraction and Wavefront Aberrometer were in second place with borderline results. These findings hold true for clinical settings when other external factors, such as skill of the health workers, the environment, etc., are controlled.

Please refer to Table 12 in Annex 3 for more details on the findings.

Key takeaways

CHILDREN (5–16 YEARS)

- Clinically acceptable limit (±0.50 D):
    - All devices except Badal Optometer and Auto Fogging.
    - Large variability is noted for all technologies.
    - Wavefront Aberrometer has borderline results with lesser variability.
    - Shack-Hartmann Wavefront Sensing (most accurate but variable).
- Conclusion: Wavefront Aberrometer, Eccentric Photorefraction, Shack-Hartmann Wavefront Sensing and SyncroScan are preferred

YOUNG ADULTS (17–28 YEARS)

- Clinically acceptable alignment (±0.50 D):

- SynchroScan Technology.
- Eccentric Photorefraction.
- Shack-Hartmann Wavefront Sensing (accurate but large variability).

• Best alignment: SynchroScan Technology (closest to gold standard).

• Variability noted: Shack-Hartmann is accurate but showed more than ±1.0 D variation.

• Accommodation Effect: Younger age groups showed greater variability in readings due to:
  - Strong amplitudes of accommodation (natural focusing ability of the eye).
  - Older age groups showed more consistent results.

BADAL OPTOMETER

• Consistently showed significant differences and high variability across all age groups.

• Not recommended for accurate spectacle prescriptions.

OVERALL

SynchroScan, Shack-Hartmann Wavefront Sensing, and Eccentric Photorefraction were found to have better clinical accuracy across all age groups. The three devices performed well in children, as well as in the adult populations. However, measurement variability was noted for children owing to the methodological nuances of the study.

Potential implications of the clinical findings for prescription of spectacles using handheld autorefractors alone

Overall Performance of Handheld Autorefractors: Mean Difference in SER Compared to Gold Standard

Eccentric Photorefraction	Wavefront Aberrometry	Badal Optometer	Shack-Hartmann Wavefront Sensing	SynchroScan Technology	Auto Fogging Technology
0.22	0.60	1.02	-0.06	0.23	0.56
n=383	*n=424*	*n=385*	*n=385*	*n=397*	*n=397*

Figure 22: Overall Performance: Mean Difference in SER when Compared to Gold Standard (n refers to the total participants studied for this technology)

Eccentric Photorefraction, Shack-Hartmann Wavefront Sensing, and SynchroScan technologies provided the lowest mean difference in SER within clinically acceptable limits (± 0.50 D) compared to the gold standard SER. Devices equipped with SynchroScan and Shack-Hartmann Wavefront Sensing technologies demonstrated the most consistent and clinically acceptable performance (±0.50 D) across all age groups, from children to older adults. Eccentric Photorefraction also performed well, particularly in younger populations and in cases of moderate myopia, showing narrow limits of agreement, indicating better precision and lower measurement variability. Please Refer to Table 13 in Annex 3 for more details.

The process of prescribing spectacles involves several steps, with refraction being a key component. Manual refraction is complex and requires substantial numbers of trained personnel for its assessment. Handheld autorefractors offer a viable alternative for refractive screening programmes in low-resource settings. In controlled environments, if handheld autorefractors provide measurements within clinically acceptable limits, they can support the provision of spectacles by complementing subjective refraction. To this end, in addition to providing Spherical Equivalent refraction values within a clinically acceptable range (±0.50 D), handheld autorefractors should also achieve low measurement variability, ideally within one diopter.

This study showed variable performance across devices and autorefractor technologies evaluated by age group and refractive error status. In the paediatric age group (5-16 years), all devices except the Badal Optometer and Auto Fogging provided SE values within clinically acceptable limits (±0.50 D). Shack-Hartmann Wavefront Sensing and SynchroScan technologies showed the least deviation from retinoscopy, suggesting strong reliability in younger users. In the young adult groups (17-28 years), Eccentric Photorefraction, Shack-Hartmann Wavefront Sensing and SynchroScan technologies again showed good agreement with retinoscopy. However, in the 29-39 age group, only Shack-Hartmann Wavefront Sensing and SynchroScan technologies maintained accuracy within the clinically acceptable limits. Performance stabilized across most devices for participants aged 40 years and above. Most of the technologies (Eccentric Photorefraction, Wavefront Aberrometer, Shack-Hartmann Wavefront Sensing, SynchroScan and Auto Fogging) performed well in the older age groups (17 years and older) with less variability, suggesting their potential suitability for use in these age groups for refractive correction in underserved and low-resources contexts.

The Badal Optometer technology consistently failed to meet clinical accuracy thresholds and showed high variability across all refractive error categories and age groups, indicating its unsuitability for spectacle prescription.

While the research findings support the use of handheld autorefractors to complement spectacle provision programmes, especially in adult populations using spherical equivalent refraction (SER), the study also identified important limitations. Astigmatism was not evaluated, and the lack of cycloplegic refraction may affect the accuracy of results in younger participants. Furthermore, small sample sizes in high refractive error groups limit the generalizability of findings for those populations. It is also important to note that, while SER was used for comparison across age groups and refractive error magnitude, the study results only support the potential to provide ready-made or ready-to-clip spectacles based on spherical equivalent refractive errors and only for adults in low-resource settings. However, it should be noted that visual acuity is required to improve to 6/9 or 6/6 following prescription. Further, such prescriptions should not be made in case the eye power is +/- 3D.

Overall, SynchroScan and Shack-Hartmann Wavefront Sensing technologies, followed by Eccentric Photorefraction, emerged as the most age-resilient devices, delivering consistent performance across most age groups, from late adolescents to people of working-age and older populations. In particular, the strong performance of SynchroScan in both myopia and hyperopia, along with its resilience to age-related variability, positions it as a promising tool for broad-based vision screening.

In conclusion, three technologies (SynchroScan, Shack-Hartmann Wavefront Sensing, and Eccentric Photorefraction) could be applied in community-based refractive error correction initiatives in underserved or low-resource settings, due to their diagnostic accuracy and suitability for comprehensive refractive error screening across all age groups above 17 years.

Key takeaways

CLINICAL ACCURACY & AGREEMENT

- Top-performing technologies:
  - Eccentric Photorefraction: Lowest mean difference in SER, narrow limits of agreement -> high precision.
  - Shack-Hartmann Wavefront Sensing and SynchroScan: Moderate agreement with the gold standard.
- Clinically acceptable range: ±0.50 D in SER is considered acceptable for spectacle prescriptions.

IMPLICATIONS FOR PROVISIONING OF SPECTACLES

- Manual refraction is complex and training-intensive.

- Handheld autorefractors offer a viable alternative for spectacle prescriptions, especially in low-resource settings.
- Devices must deliver:
  - Accurate SER values (±0.50 D).
  - Low variability (≤1.0 D).

PERFORMANCE ACROSS AGE GROUPS

- 5-16 years: large variability was noted for all the technologies, limiting their suitability for refractive error correction in this age group.
- 17-28 years: 3 out of 6 devices performed well.
- 29–39 years: 4 out of 6 devices performed well.
- 40+ years: 5 out of 6 devices performed well.
- Older age groups showed:
  - Less variability -> better suitability for refractive correction.
- SynchroScan Technology:
  - Most consistent across age groups above 17 years.
  - Recommended for scaling in community settings.

USE OF SER IN LOW-RESOURCE SETTINGS

- SER enables ready-made or clip-on spectacle provision for individuals aged 17 and above.
- Useful for mass screening and quick provisioning to subjects with final corrected visual acuity of 6/6 or 6/9, and eye power not exceeding ± 3D.

STUDY LIMITATIONS

- Astigmatism was not evaluated.
- Cycloplegic refraction was not performed.
- Small sample sizes in high refractive error groups -> results not generalizable.

FINAL RECOMMENDATIONS

SynchroScan (best overall), Shack-Hartmann Wavefront, and Eccentric Photorefraction

SynchroScan Technology

- Suitable for on-the-spot spectacle prescriptions in low-resource settings.
- Can be operated by minimally trained allied health professionals.
- Performs well in non-cycloplegic settings (important for mass screenings).

Shack-Hartmann Wavefront

- Portable.
- Lower cost.
- Can be operated by minimally trained allied health professionals.

Eccentric Photorefraction

- High precision.
- Lower cost.
- Can be operated by minimally trained allied health professionals.
- Light weight.

Further research needed:

- To assess patient acceptance and satisfaction with autorefractor-based prescriptions.
- Comparison of SynchroScan with cycloplegic refraction in children.

5. Potential scalability – key factors beyond diagnostic accuracy

Scalability of handheld autorefractor technology depends on several factors, including adoption by users (awareness), effectiveness, cost, adequate technical capacities for its utilization, regulations and an enabling environment. It is evident from the qualitative study that these technologies are already being used in different settings, including low-resource settings. Hence, generating awareness about these technologies among eye care practitioners may not be one of the biggest challenges in terms of adoption and scalability. However, in many countries, due to stringent regulations, refraction can only be provided by eye specialists or optometrists. Regulatory changes will therefore be needed in order for non-specialized health workers to start to use handheld autorefractors, enabling task-sharing. Other important factors, in addition to technological advance and regulatory changes, should also be considered for scaling up these devices in public health settings, particularly capacity building and costs. These challenges are well worth meeting in view of the ease of usage and diagnostic accuracy, which handheld technologies offer in community settings.

Key features of devices

Beyond diagnostic accuracy, the practical utility of handheld autorefractors in real-world settings is determined by factors such as portability, ease of use, time-efficiency, battery life, and the required skill level of operators.

Table 6: Key non-technical features of selected technologies

PARAMETERS AND KEY FINDINGS

Technology	Eccentric Photorefraction	Wavefront Aberrometer	Badal Optometer	Shack-Hartmann Wavefront Sensing	SynchroScan Technology	Auto Fogging
Ease of use; weight	Closed design; weighs 800 grams	Open design; weighs around 1300 grams	Closed-view design; weighs around 130 grams	Weighs around 450 grams	Weighs around 2500 to 2700 grams	Weighs around 940-950 grams
Affordability (based on the price list from 2024)	Price: USD 6225	Price: USD 3600	Price: USD 55	Price: USD 2650	Price: USD 14,500	Price:12,000
Ease of training health workers for community settings	Suitable for community setting and can be easily used by allied health professionals with minimal training	Suitable for community setting and can be easily used by allied health professionals with minimal training	Suitable for community setting and can be easily used by allied health professionals with minimal training	Suitable for comprehensive screening and can be used by allied health professionals with minimal training	Well-suited for community level screening; easy to hold and use, with one-hand operation; innovative features to ease patient anxiety and view measurements	Well-suited for mass-screening; can be easily used by allied health professionals with minimal training
Battery requirements	Uses rechargeable batteries and automatically shuts down to save power when not in use	6-8 hours of operations on full charge; Bluetooth connectivity	Designed for high-volume screening events; non-electronic (does not need power supply)	Replaceable battery; Bluetooth connectivity; does not need consistent power supply	Rechargeable battery with battery life of about 140-180 minutes	Battery lasts up to 180 minutes
Time Taken for Measurement (seconds)	44 seconds (range: 20 to 180 seconds)	68 seconds (range: 23 to 180 seconds)	33 seconds (range: 5 to 180 seconds)	38 seconds (range: 9 to 180 seconds)	18 seconds (range: 10 to 40 seconds)	22 seconds (range: 10 to 40 seconds)

Enabling environment for task-sharing

Despite its potential to decentralize vision care, handheld autorefractor technology faces significant regulatory barriers in many low- and middle-income countries, especially across Africa, Latin America, Asia and Pacific, where the use of autorefractors and dispensing of spectacles based solely on autorefractor readings are governed by stringent regulations that reserve refraction use and prescription rights to qualified ophthalmologists or optometrists.

These rules, while designed to safeguard quality of care, often inadvertently constrain the scalability of refractive error services by preventing competency-based team approaches to refractive error, where the tasks are shared to mid-level providers and community health workers. A recent Delphi study in Kenya found that only formally qualified eye professionals are authorized to refract under current rules, even though all experts who were surveyed agreed that upskilling other cadres under supervision is desirable in order to meet needs.[26] In regions where eye health workforces are already scarce, such regulatory hurdles slow down the adoption of portable autorefractors in schools, primary care, and outreach programmes. Moreover, fragmented and inconsistent regulatory frameworks – often varying not only between countries but even within regions – create uncertainty for manufacturers and non-government organizations (NGOs) who are seeking to use innovative technology in service delivery models. As a result, even when effective portable technology exists, its use in large-scale screening and dispensing programmes is often delayed or prohibited, perpetuating unmet refractive needs in underserved areas.

To address regulatory challenges that constrain the large-scale adoption of handheld autorefractor technologies, countries could pursue a balanced reform strategy that safeguards quality while expanding access. More details are provided in the next chapter (Chapter 6).

26. Muma et al. BMC Health Services Research (2024) 24:115 https://doi.org/10.1186/s12913-024-10618-8

COMPONENTS OF TASK-SHARING

Task-sharing in public health practice requires much more than provision of the relevant technical device. Training, protocols, supervision, policy support, and community engagement are all critical.

Community health workers who are mobilized for eye-care need to be trained in basic eye screening and use of the autorefractor. Simple referral protocols must guide which readings require referral to an eye clinic (since autorefractors measure refraction but do not diagnose eye diseases) and supervisory eye-care professionals should be available for consultation if needed. In this study, the community health workers and other specialized and allied healthcare professionals were given practical training in use of the hand-held devices and standardized research protocols. A data collection workflow was established to ensure that lay personnel performing refraction with handheld autorefractors received supervisory support from optometrists and other specialists.

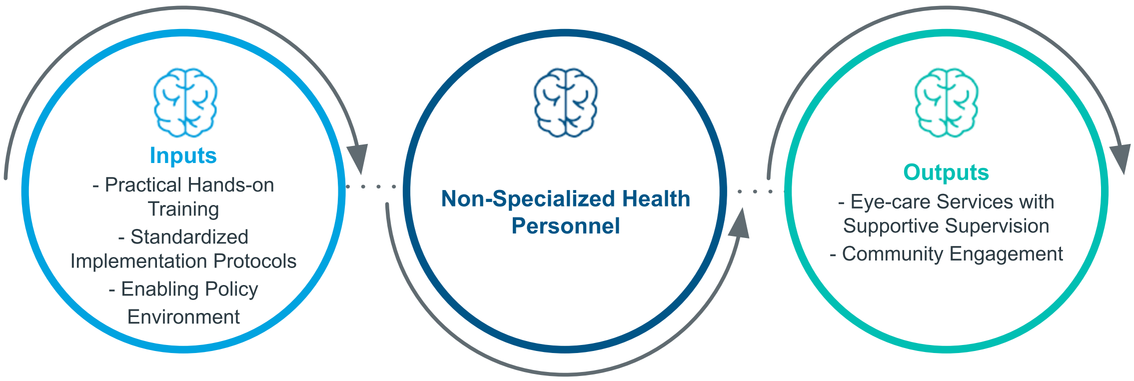

Figure 23: Key Components of Task-sharing in Eye Care

The steps that need to be taken in order to make best use of the health workforce through task-sharing have been set out in various frameworks, including WHO guidelines. The main steps are: invest in training programmes for community health workers; design clear guidelines and decision-support tools, which the workers can follow; set up supervision and referral networks to backstop the workers; ensure there is an enabling legal/regulatory environment for the workers to perform expanded roles; allocate the necessary resources (equipment and supplies); and foster community consent to receiving care from community health workers.[27] The technology itself is only one piece of the task-sharing puzzle.

IMPLICATIONS OF THE STUDY FINDINGS FOR TASK-SHARING

Resource constraints in LMICs have driven interest in "task-shifting" and "task-sharing" strategies, where certain clinical tasks are transferred from highly qualified eye specialists to less-specialized providers such as community health workers. Task shifting usually means moving specific duties to providers with fewer qualifications, while task sharing involves delegating tasks among a broader team (nurses, community health workers, etc.) so that care is delivered by people with the right mix of skills. The two concepts are often used together with the aim of optimizing use of the health workforce and extending services to underserved communities.[28] In the context of eye health, this means empowering community health workers or other lay personnel to perform basic vision screenings and refractions, which were once the sole domain of optometrists and/or ophthalmologists.

The approach aligns with the Eye Care Competency Framework (ECCF)[29] and Competency-Based Refractive Error Team (CRET)[30] of the World Health Organization (WHO). The ECCF sets out the expected or targeted performance of the eye care workforce across primary to tertiary levels of health care, which can enable quality care and integrated service delivery to meet the needs of the general public.

27. World Health Organization Regional Office for South-East Asia. Task sharing for the delivery of health services: policy brief. New Delhi: WHO SEARO; 2023. ISBN: 9789290314950. Available from: https://iris.who.int/bitstream/handle/10665/376079/9789290314950-eng.pdf?sequence=1
28. World Health Organization Regional Office for South-East Asia. Task sharing for the delivery of health services: policy brief. New Delhi: WHO SEARO; 2023. ISBN: 9789290314950. Available from: https://iris.who.int/bitstream/handle/10665/376079/9789290314950-eng.pdf?sequence=1
29. World Health Organization. (2022). Eye care competency framework. World Health Organization. https://iris.who.int/handle/10665/354241
30. World Health Organization. (2025). Competency-based refractive error teams- https://www.who.int/publications/i/item/9789240109209

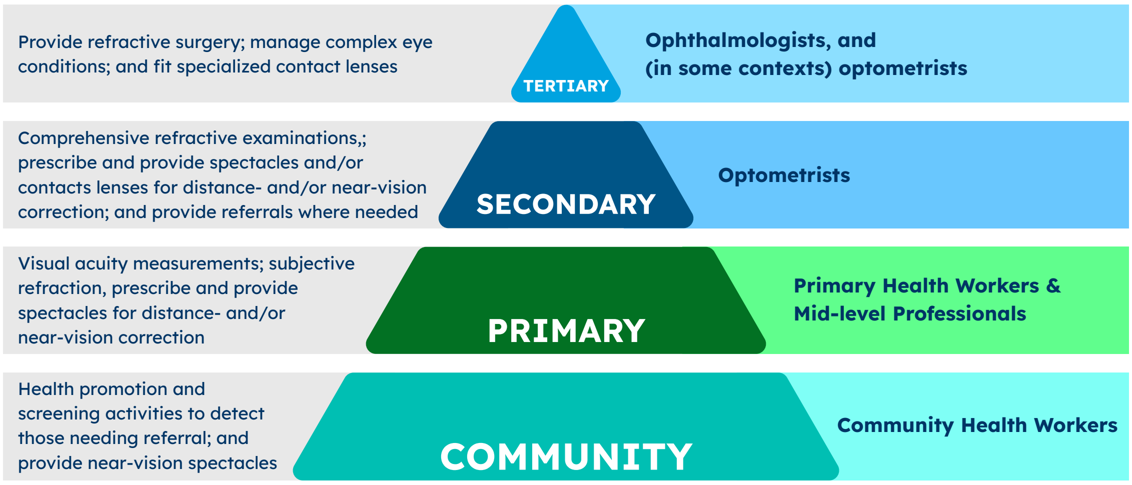

Figure 24: Refractive Error Personnel Integrated across All Levels of the Health System (as per WHO Guidelines)

The WHO framework also emphasizes that non-specialized healthcare personnel, with necessary minimal training, can help in providing integrated people-centred eye care (IPEC).

Table 7: Range of Personnel Working across the Global Refractive Error Workforce (as per WHO guidelines)

Eye-care-specific training duration	<3 months	3-12 months	1-4 years	4-7 years	≥7 years
Levels health personnel can work at	Community	Community & Primary	Primary & Secondary	Primary & Secondary	Secondary and Tertiary
Occupation titles that can be made responsible for delivering refractive error services	Community health worker, eye health coordinator, school teacher, outreach worker, village health volunteer	Vision technician, ophthalmic administrator, optical assistant	Ophthalmic nurse, optician and other allied ophthalmic personnel	Optometrist	Ophthalmologist, optometrist.

One purpose of the ATscale study was to determine the feasibility of training non-specialized personnel, including community health workers, to use the handheld autorefractor devices, and to assess the outcomes at scale.

However, successful task-sharing in healthcare depends on more than reassigning roles; it requires appropriate training, supportive supervision, clear protocols, community acceptance, and crucially, the right technology and tools to enable non-specialists to work effectively.[31] Handheld autorefractor devices have emerged as a pivotal technology in this equation by making it possible for non-specialists to provide refraction services, which are typically a clinical task requiring specialized training, outside the clinic setting. However, this strategy, which is of great value in underserved or low-resource settings where access to qualified eye-care professionals is limited or unavailable, is only possible if clear regulatory frameworks are in place.

Key features of handheld autorefractors, such as affordability, ease of use, minimal training requirements, portability with robust battery life, and quick measurement time, are repeatedly highlighted in the literature as critical enablers for task-shifting refractive services to community health workers in LMICs.

A 2022 clinical study validating a portable wavefront autorefractor concluded it has "potential application in community vision screening without the need for highly trained personnel".[32] Field experiences back up this conclusion. For instance, in real-world high-volume settings, operators with minimal training have achieved accurate results, since the device itself guides alignment and refraction measurement automatically.[33] Ease of use is enhanced by such features as intuitive alignment aids and simple user interfaces.[18] This simplicity directly supports task-sharing, since community health workers or primary care nurses, who typically are not versed in refraction technique, are able to operate the autorefractor with confidence.

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31. World Health Organization Regional Office for South-East Asia. Task sharing for the delivery of health services: policy brief. New Delhi: WHO SEARO; 2023. ISBN: 9789290314950. Available from: https://iris.who.int/bitstream/handle/10665/376079/9789290314950-eng.pdf?sequence=1
32. Rao, D.P., Negiloni, K., Gurunathan, S. et al. Validation of a simple-to-use, affordable, portable, wavefront aberrometry-based auto refractometer in the adult population: A prospective study. BMC Ophthalmol 22, 498 (2022). https://doi.org/10.1186/s12886-022-02684-5
33. Frequently Asked Questions | QuickSee Free Pro Handheld Autorefractor, from PlenOptika

A landmark randomized trial in India (published 2021) found that spectacle prescriptions generated by a low-cost handheld autorefractor were just as accepted by patients as those generated from standard subjective refraction by an optometrist. This suggests that a properly designed handheld device can yield clinically acceptable results, reinforcing the idea that non-specialists using such technology can deliver quality outcomes. The authors noted that this could "radically expand access" to prescriptions in low-resource settings lacking specialists.[34]

All these features – low cost, user-friendliness, minimal maintenance (if available), quick results, and all-day battery-powered use – combine to make handheld autorefractors a practical tool for shifting refraction tasks to primary-care settings and directly contribute to task-shifting to community health workers in LMIC eye-care programmes. Early evidence from both grey literature and peer-reviewed studies as well as the findings of this report underscore their impact.

SUPPLIER NETWORK AND KNOWLEDGE

Access to the latest available information, handheld autorefractor technologies in many low- and middle-income countries is constrained by limited supplier presence and weak regional distribution networks. Literature such as the WHO policy brief on task-sharing in Kenya has also emphasized training and on-the-job support for non-physician health workers as facilitators and has highlighted that lack of equipment or supplies can be a major barrier to success.[35]

Most of the leading manufacturers are headquartered in North America, Europe, or East Asia, and have limited commercial footprints in Africa, Latin

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34. Joseph S, Varadaraj V, Dave SR, Lage E, Lim D, Aziz K, Dudgeon S, Ravilla TD, Friedman DS. Investigation of the Accuracy of a Low-Cost, Portable Autorefractor to Provide Well-Tolerated Eyeglass Prescriptions: A Randomized Crossover Trial. Ophthalmology. 2021 Dec;128(12):1672-1680. doi: 10.1016/j.ophtha.2021.05.030. Epub 2021 Jun 7. PMID: 34111444.
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America, and the Pacific. As a result, health systems and NGOs often struggle to source devices locally, relying on international procurement channels that increase costs, complicate servicing, and delay availability. The absence of regional suppliers or after-sales support also means that even when devices are procured, maintenance, calibration, and training become persistent bottlenecks, discouraging long-term adoption and use of the devices in national programmes.

This problem is compounded by a general lack of awareness among decision-makers and procurement agencies about the latest advancements in handheld autorefractor technologies. In the absence of up-to-date market intelligence, LMIC stakeholders often procure outdated models or models that are being phased out elsewhere and that may be less accurate, bulkier, or incompatible with modern service delivery models. These legacy solutions tend to be more expensive in the long run, both in the upfront cost and in sustaining operations without reliable parts and technical support. Addressing these barriers requires stronger market-shaping efforts, regional supplier networks, and knowledge-sharing platforms to ensure that LMICs have equitable access to cost-effective, future-ready solutions.

DEVICE MAINTENANCE AND BATTERY

Maintenance is a critical but often overlooked issue when scaling the use of handheld autorefractors in LMICs. Different models vary in their calibration requirements: some advanced devices feature automatic, real-time recalibration systems, ensuring stable accuracy without user intervention, while others require periodic recalibration at fixed intervals recommended by the manufacturer, ranging from every 6-12 months under regular use to every 2-3 years in ideal clinical conditions. In LMICs, where access to authorized service centres or shipping for recalibration is limited, these requirements can be a serious barrier. If recalibration is delayed or skipped, devices may drift from accurate measurement, reducing reliability and potentially eroding trust in large-scale screening programmes.

Battery replacement presents another challenge. Many handheld autorefractors rely on rechargeable lithium-ion batteries, which typically last 2-4 years depending on usage cycles. In settings with unreliable power supply, frequent charging can shorten battery lifespan, while replacement batteries may be difficult or costly to source locally. A device that requires frequent servicing or hard-to-find components risks becoming obsolete far earlier than its expected lifespan, especially in rural or resource-poor areas. Therefore, procurement decisions in LMICs must weigh not only upfront cost but also long-term maintenance feasibility. Models that minimize calibration needs, provide user-friendly recalibration procedures, or include durable, replaceable batteries are far better suited for these contexts, as they reduce dependency on external service networks and ensure that devices remain functional in the field for many years.

PRICE POINT VS. AFFORDABILITY

The price of autorefractor technologies, as indicated by the scoring system (Table 1), ranges from under $2000 for the most affordable options to over $10,000 for the most expensive. This wide cost range can significantly limit the provision and accessibility of these crucial diagnostic tools, particularly in LMICs, where healthcare budgets are often constrained. The high cost of certain devices can create a barrier to widespread adoption, preventing public health programmes and NGOs from acquiring a sufficient number of units to conduct mass screenings and deliver essential eye-care services to underserved populations. This financial limitation directly impacts the ability to address the significant burden of uncorrected refractive errors globally, hindering efforts to improve vision care access.

Several factors contribute to the high cost of autorefractor technologies. Manufacturers' pricing strategies are influenced by the complexity of the integrated technology, such as Wavefront Aberrometry, artificial intelligence, and advanced optics, which require significant investment in research and development. Additionally, the regulatory environment in some markets and the need for specialized components can drive up production costs. The market landscape, dominated by established ophthalmic device manufacturers and emerging innovators, also plays a role in pricing, with competition and strategic partnerships influencing product costs. While advancements aim to make devices more portable and user-friendly, the incorporation of cutting-edge features and the desire for high precision often translate into a higher price point, posing a challenge for widespread, affordable deployment in resource-limited settings.

INTEGRATION WITH OTHER IT-BASED PLATFORMS

In conjunction with telemedicine, handheld autorefractors extend the reach of eye-care providers. A technician or community health worker can travel to remote patients with a handheld unit, perform the refraction operation and upload the results via a connected app. An ophthalmologist or optometrist in a city can then review the data and provide a prescription or referral as needed. This model has started to take shape, allowing eye care to penetrate areas where there are no resident optometrists.[36] The model effectively creates mobile eye clinics, reducing urban-rural healthcare disparities in vision care. The task-shifted service is not “dead-end”: it produces outputs (a prescription or referral) that feed into the next steps of care (dispensing glasses or seeing specialized personnel for complex cases). In this way, handheld autorefractors serve as a linchpin technology that makes community-level refraction feasible without compromising outcome quality.

INTEGRATION WITH DIFFERENT SERVICE DELIVERY MODELS

With strong potential for task-shifting and task-sharing, handheld autorefractors can be seamlessly integrated into diverse service delivery models, significantly expanding access to vision care in low-resource settings.

36. Handheld Autorefractors Market Size, Future Growth and Forecast 2033

Service model	Operators	Integration potential
School screening	Teachers, nurses, volunteers	Rapid, mass screening; easy referral
Primary care clinic	Nurses, chws, mid-level staff	Community refraction; direct dispensing
Telehealth-supervised	Local technician/community health worker and remote optometrist	Remote reach; expert oversight

However, there are several important considerations and limitations that must be addressed when scaling up the integrated use of handheld autorefractors:

- Connectivity Challenges: Telehealth-supervised models rely on stable internet or mobile networks for transmitting refraction data and remote consultations. In many low-resource settings, intermittent connectivity can disrupt service delivery, delay prescriptions, and limit the reach of remote expert oversight.
- Regulatory Frameworks for Telehealth: Effective integration requires clear policies and legal recognition of remote prescribing and digital health records. Governments must establish robust regulatory frameworks to ensure data privacy, quality assurance, and accountability in telehealth-enabled vision care.
- Workforce Training and Supervision: Handheld autorefractors shift tasks to non-specialist personnel; therefore, ongoing training, supervision, and quality control are essential in order to maintain diagnostic accuracy and patient safety.
- Supply Chain and Referral Systems: Scaling up vision screening is only impactful if there is a reliable supply of affordable spectacles and well-defined referral pathways for complex cases that are identified during screening.
- Device Maintenance and Quality Assurance: Sustained impact depends on regular device maintenance, technical support, and procurement of validated, high-quality autorefractors.

Handheld autorefractors can dramatically expand access to vision care in low-resource settings when integrated thoughtfully into existing service models. Governments play a key role in enabling scale-up through policy, training, supply chain, and digital infrastructure, ensuring that limitations are addressed and the public health impact is maximized.

Key takeaways

- Handheld autorefractor technology fits into the task-sharing framework as a catalytic tool that lowers the skill barrier for a critical task (vision testing), enabling its delegation to less specialized health workers for on-the-spot provision of spectacles.
- The World Health Organization has explicitly noted that effective task shifting can occur by transferring tasks to “a person without formal training, trained for a specific task,” or by leveraging “medical technology” to perform tasks, or a combination of both.
- Handheld autorefractors essentially combine the two approaches named by the WHO in the previous point: they are medical devices that automate a complex clinical measurement, which allows a person with limited eye-care training (e.g. a community health worker) to perform that measurement reliably.
- Other factors, such as user interface or ease of use, enabling environment for task-sharing, supplier-base and knowledge, device maintenance and battery, price point, integration with other IT-based platforms, are also key determinants for scaling up the adoption of such technologies and for accelerating access to refractive error services and spectacle provision.

6. Conclusion and way forward

Conclusion

Most of the handheld autorefractor technologies, which were tested in the study, displayed sensitivity of over 70% and specificity within a range of 80-90% for refractive errors when compared with retinoscopy and subjective refraction. A few of the devices stood out as providing sensitivity and specificity for all refractive errors. The conclusion is that these technologies hold immense potential for screening false-positive cases, thereby reducing the time and effort required for prescribing spectacles. In low-resource settings, when there is a need for refractive error measurement and prescribing of spectacles at scale, handheld autorefractor technologies can play a critical role in reducing the burden of uncorrected refractive error and increasing access to spectacles.

Overall, SynchroScan Technology was found to have the best combination of sensitivity and specificity when compared to the gold standard (objective retinoscopy and subjective refraction). Across all devices, devices with Eccentric Photorefraction, Shack-Hartmann Wavefront Sensing Aberrometer and SynchroScan technologies provided the lowest mean difference in SE within clinically acceptable limits (±0.50 D) compared to the gold standard SE. There was better alignment in prescriptions by these devices when compared with subjective refraction.

The findings justify the conclusion that devices with SynchroScan, Eccentric Photorefraction and Shack-Hartmann Wavefront Aberrometer technology can be used for on-the-spot prescription of spectacles in low-resource settings based on Spherical Equivalent refraction among all age groups above 17 years of age, and with due regard for very high refractive error. It is suggested that readymade or ready-to-clip glasses can be provided based on the autorefraction readings, bearing in mind considerations of eye power and visual acuity.

In low-resource settings with limited human resources, these devices can be used by allied healthcare professionals with minimal training using a competency-based team approach. Furthermore, the devices were found to perform well in non-cycloplegic settings, which is an important consideration for mass-screening and work with large populations. However, it should be noted that these conclusions are based on evidence from this study, which focused on supply-side and technology perspectives. Further studies may be required to gather data on acceptance of prescriptions by patients and satisfaction with spectacle prescriptions provided by autorefraction alone.

The results of the study demonstrate the immense potential which handheld refractor technologies offer for use beyond screening. They enable task-sharing approaches that can improve the efficacy of eye and vision care programmes focused on refractive error and on-the-spot spectacle provision, thanks to their high diagnostic accuracy and performance across all age groups (except children), portability and design features, as well as ease of use in training non-specialized health workers to undertake refractive error operations. Such technologies, if used, in combination with ready-made or ready-to-clip spectacles, offer immense potential to simplify access to refractive error services and spectacles in resource-poor settings.

The study also underscores the importance of other factors (beyond diagnostic accuracy): an enabling policy environment for “task-sharing” and a “competency-based team approach” to refractive error; conducive regulatory and procurement systems; supplier network and knowledge; price point; and integration with other IT-based platforms that determine the adoption of these technologies in any context.

Key recommendations

Below are some broad recommendations from country and stakeholder perspectives for potential scale-up of handheld autorefractive technologies, particularly in LMICs. The timeline includes three categories: short term (within 1 year); medium term (1-2 years); and long term (3-4 years).

1. Address information asymmetry
Demand and supply perspective to adopt most appropriate and cost-effective technology

2. Enabling policy environment for task-sharing
Competency-based refractive error team approaches

3. Coupling technology with spectacle provisioning
Proven handheld autorefractor with ready to clip spectacles

4. Enabling regulatory environment
Including procurement systems to ensure quality of products and after-sale services

5. Affordability
Multifaceted - market competition, transparent pricing, competitive standardization, support manufacturers

6. Research & development
Invest in technologies optimized that meet the physiological needs of children’s eyes for pediatric refractionaddress information asymmetry

Figure 25: Broad Areas of Recommendations

1. Address information asymmetry

Addressing information asymmetry from demand and supply perspectives is critical in order to ensure that governments and health programmes in LMICs adopt the most appropriate and cost-effective handheld autorefractor technologies.

Although many handheld-refractor technologies are available globally, there are serious challenges to procurement of the devices by buyers and to the ability of suppliers to reach the market. Manufacturers have limited information about demand, sales channels and country procurement announcements and portals. On the buyers' side, countries have to rely on distributors with limited exposure to the various technologies that are available in the market. During implementation of the study, it was also found that stringent import processes and bureaucratic red tape, particularly in low-resource settings such as the African region, often led to disruptions in procurement.

Key interventions	• Collaborate with manufacturers and suppliers to create a market intelligence platform/information guide to show a list of devices, manufacturer details, focal points for sales, specifications and prices etc. • Countries should create a single-window clearance system for handheld refractor technologies in order to ease customs and other related barriers and should learn from best practices in other countries for the import of medical devices and equipment. • Countries should develop policy briefs and technical documents to support policy advocacy with the relevant local ministries and/ or departments to enable a simpler regulatory ecosystem for the import of such devices.
Implementation timeframe	Medium to long-term.
Key stakeholders	Manufacturers, customs and excise departments, national governments.

2. Enabling policy environment for task-sharing

A competency-based refractive error team approach that facilitates task-sharing, will greatly assist scale-up of handheld autorefractor technology, accelerating access to refractive error services.

Stakeholder consultations revealed that handheld autorefractors are currently operated in large part by specialized trained health workers, including optometrists, ophthalmic nurses and ophthalmic clinical officers. Involvement of other healthcare staff, such as community health workers and non-health workers, is very limited or non-existent. However, the present study has demonstrated that community health workers and other healthcare staff can be trained to use handheld autorefractor technologies in low-resource settings. This fact highlights the potential of these devices for future scalability in lower-and-middle income countries.

Key interventions	• It is of key importance to enable policy environments, which promote task-sharing and continuous education programmes on the adoption and use of the new technologies. • Adoption of competency-based team approaches can facilitate the adoption of the handheld technology and scale up refractive error services. • Design of teaching methodologies in the use of autorefractor technology by primary healthcare workers should be part of the competency framework.
Implementation timeframe	Short to medium term.
Key stakeholders	Health ministries, national eye programmes, regional public hospitals, national public hospitals.

3. Coupling with easy-to deploy-spectacle technology

Coupling the use of proven handheld autorefractors with "ready-to-clip" spectacles can simplify the provision of spectacles, especially in population-based programmes.

This study has established that devices with SynchroScan, Shack-Hartmann Wavefront Sensing technologies, particularly with open-view design, are effective in community settings and offer huge potential for on-the-spot provision of eyeglasses (Eccentric Photorefraction could also be effective, though to a lesser degree than the three technologies just named). Other studies have been carried out in different contexts and settings to establish the diagnostic accuracy of other autorefractor technologies.

Key interventions	• Global partners should develop an online and dynamic guide to inform countries about the technological advantages of different handheld devices, their design features, costs and diagnostic accuracy in different settings. • Before large-scale adoption of the technologies in eye-care programmes, countries should either rely on evidence published in reputed journals or platforms and/or facilitate pilot implementation of health technology assessment studies to explore the suitability of technologies for their context. • Ease of use by mid-level providers and community health workers with minimal training, speed of measurement, portability (weight, battery life, ruggedness), language support, user interface and integration with local workflows are the most important technical specifications to consider in selecting handheld autorefractor technologies. • Further behavioural studies should be carried out to understand compliance and patient satisfaction with spectacles prescribed using handheld autorefractors.
Implementation timeframe	Short to medium term.
Key stakeholders	Global institutions, ministries and eyecare programmes.

4. Regulatory environment and procurement system

Creating an enabling regulatory environment and procurement system to ensure that only quality products are introduced to the local market and that after-sale services for repair and maintenance are in place.

An enabling regulatory environment will play a crucial role in facilitating access to and integration of appropriate handheld autorefractors within national health systems. Regulations influence not only the availability and import of devices but also their quality assurance, certification, and inclusion in public procurement, distribution systems and service delivery frameworks.

Key interventions	• Develop a regulatory framework with key considerations such as ISO certifications, traceability, labelling, CE mark, etc., for safety, technical performance and clinical validity • Countries' procurement practices must consider pooled procurements, total cost of ownership (not just purchase price), including consumables, spare parts, calibration, and software updates. • Integrating the product flow for these devices in existing supply-chain management software. • Strengthen health product distribution networks. The focus should be on enhancing visibility, implementing robust inventory management and fostering strong supplier relationships.
Implementation timeframe	Short to medium term.
Key stakeholders	National regulatory authorities, procurement authorities, professional and hospital associations.

5. Multi-faceted approaches to make the technology affordable

Multi-faceted approaches based on evolution of the medical device sector are crucial in order to address high autorefractor costs.

Key strategies to make autorefractors more affordable, especially in LMICs, could include fostering market competition for affordable models through transparent pricing, component standardization, and supporting manufacturers that are focused on low-resource settings.

Key interventions	• Foster greater market competition, particularly for "essential" or "basic" models that offer core functionality at a lower price point. • Promote transparent pricing, standardize certain technical specifications to allow for interchangeable components, and support emerging manufacturers, especially those focused on designing devices specifically for low-resource settings. • Governments and public health organizations should leverage bulk procurement agreements and establish clear demand signals to incentivize manufacturers to produce more affordable devices. • Manufacturers should explore tiered pricing based on country income levels, as well as leasing or pay-per-use models rather than outright purchase. • Focus on reducing the total cost of ownership, beyond the initial purchase price, by emphasizing durable designs, readily available spare parts, and accessible maintenance training, in order to ensure long-term sustainability.
Implementation timeframe	Medium to long term.
Key stakeholders	Manufacturers, procurement authorities, professional and hospital associations.

6. Research and development for paediatric refraction

Handheld autorefractor manufacturers to further invest in designing technologies specifically optimized for the unique physiological characteristics of children's eyes to minimize the impact of accommodation.

This and previous studies have indicated that though almost all handheld autorefractor technologies (except the Badal Optometer) provided readings for refractive errors within the clinically acceptable limits, larger variability was noted for the paediatric age group (between 5-16 years). Cycloplegia, which would counter the greater elasticity of children's eyes for measuring purposes, was not performed in the study and is not feasible in large-scale public health settings.

Key interventions	• Manufacturers should focus on technological enhancements that can minimize the need for performing cycloplegic refraction in children. • Development of open-source or collaboratively designed autorefractor hardware and software could significantly reduce R&D costs. • Manufacturers/research institutions should continue investing in publication of literature in peer-reviewed journals for knowledge dissemination and in order to build a body of evidence around emerging technologies.
Implementation timeframe	Medium to long term.
Key stakeholders	Manufacturers.

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Annex 1: Study tool for clinical examination

Data Collection Form (Form 1)

(To be completed by Optometrist-1)

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Date of examination: ______ **Country Code** ______ **Centre Code** ______

Demographic Information

Name of the Participant ______________________ Unique Id ______

Father/Gaurdian's Name: ______

Age (In completed years) ________ Sex ______ Male(0)/ Female(1) **Education** ______

No education	0
Primary education	1
Secondary education	2
Undergraduate	3
Postgraduate	4

Section A: History (Tick the appropriate box)

A1: Ocular History
(Mention the most debilitating symptom if multiple symptoms reported)

Code	Symptoms
0	Headache
1	Blurred vision for distance
2	Blurred vision for near
3	Deviation of eyes
4	Eye Pain
5	Red eyes
6	Itchy eyes
7	Night blindness
8	No symptoms
9	Others -

A2: Systemic History	
0	None
1	Diabetics
2	Hypertension
3	Others specify

Section B: Vision Assessment **Examiner ID** ______

B1: Wearing corrective lenses? YES / NO [if no, go to B3 / if yes, continue with B2]

B2. Visual Acuity with Present glasses (Distance)

OD	OS	Binocular

(Move on to B4 if no glasses)

B3: Uncorrected Visual Acuity (UCVA) (Distance)

OD	OS	Binocular

B4: Presenting Near VA ______

B5: Present glasses power

	SPH	CYL	AXIS
OD			
OS			

Code	Visual acuity value	Near VA
1	6/6	N6
2	6/9	N8
3	6/12	N10
4	6/18	N12
5	6/24	N18
6	6/36	N24
7	6/60	N36
8	3/60	N60
9	2/60	<N60
10	1/60	
11	CFCF/HM	
12	PL/PR	
13	NPL	
14	Fix & follow	
99	Unable to assess	-99

Section C: Refraction Dry & with Cycloplegia **Examiner ID** [ ]

C1: Dry Retinoscopy [ ] **C2: Subjective refraction** [ ]

Done (0) / Unable to perform (1) / Not applicable (98)

	SPH	CYL	AXIS
OD			
OS			

	SPH	CYL	AXIS	BCVA	ADD	BC-Near Vision
OD						
OS						

C3: Cycloplegic table top autorefraciton [ ] **C4: Final spectacle prescription** [ ]

	SPH	CYL	AXIS
OD			
OS			

	SPH	CYL	AXIS
OD			
OS			

Section D: External / Anterior Segment Examination

D1: Anterior segment

If abnormal OD [ ] OS [ ]

Code	
0	Normal
1	Abnormal
-99	Undertermined

Section E: Lens, Vitreous and Fundus

E1: Lens

If abnormal OD [ ] OS [ ]

E2: Fundus

If abnormal OD [ ] OS [ ]

Section G: Cause of Impairment OD [ ] OS [ ]

0	No impairment (UCVA ≥ 6/9)
1	Refractive Error (UCVA ≤ 6/12 and BCVA/Pinhole BCVA ≥ 6/9)
2	Cataract
3	Other causes Specify

OD If others, specify ____________________ OS If others, Specify ____________________

Data Collection Form (Form 2)

(To be completed by Optometrist-2)

Date of examination: ☐ **Country Code** ☐ **Centre Code** ☐

Unique Id		Age (In completed years)	

Name		Sex		Male(0) / Female(1)

Dry Hand Held AR - 1 ☐ Time ☐

Done (0) / Unable to perform (1) / Not applicable (-99)

	SPH	CYL	AXIS
OD			
OS			

Dry Hand Held AR - 2 ☐ Time ☐

Done (0) / Unable to perform (1) / Not applicable (-99)

	SPH	CYL	AXIS
OD			
OS			

Dry table top auto refraciton ☐ Time ☐

	SPH	CYL	AXIS
OD			
OS			

Glasses prescription ☐

	SPH	CYL	AXIS
OD			
OS			

Name of the Examiner		Signature	

Data Collection Form (Form 3)

(Form 3 To be completed by non-technical examiner participating in study)

Date of examination: ☐ **Country Code** ☐ **Centre Code** ☐

Unique Id		Age (In completed years)	

Name		Sex		Male(0) / Female(1)

Dry Hand Held AR - 1 ☐ Time ☐

Done (0) / Unable to perform (1) / Not applicable (-99)

	SPH	CYL	AXIS
OD			
OS			

Dry Hand Held AR - 2 ☐ Time ☐

Done (0) / Unable to perform (1) / Not applicable (-99)

	SPH	CYL	AXIS
OD			
OS			

Dry table top auto refraciton ☐ Time ☐

	SPH	CYL	AXIS
OD			
OS			

Glasses prescription ☐

	SPH	CYL	AXIS
OD			
OS			

Name of the Examiner		Signature	

Annex 2: Key informant interview tool

Date of Interview:	
Respondent Name:	
Organization Name:	
Designation:	
Email ID:	

1. Does your organization/ hospital (or previous organization) use autorefractors? If yes, please mention the brand/make of the same. If no, is there a reason why you do not use these devices?
2. Which autorefractor are you using currently? List the technology. Did your organization use internal resources to procure it or was the procurement through external resources? How did you decide to buy the specific model of autorefractor that you have at your organization?
3. How often do you use autorefractors?
4. Do you think use of these devices works as well as manual refraction? If yes/no, why do you think so? Do you use autorefractors as the primary mode of testing for spectacles?
5. Who operates the autorefractors at your centre?
6. Do you think autorefractors can replace retinoscopes in community settings?
7. Would you recommend usage of autorefractors in community settings other than hospital settings for refractive error screening? Do you have any specific model that you would recommend?
8. Among the available technologies, which technology is preferred by you? Which technology is better to work with in community settings? Which technology is easier for skill transfer to field workers/ lay persons? Which technologies can be more affordable when purchased at scale? Which technologies are cost-effective from an operations perspective? Which technologies require minimum investment for upkeep, repair, and maintenance?
9. Have you trained eyecare/ non-eyecare workers in the use of any handheld autorefractor technologies? Which technologies are easy for field workers to learn in your experience? Which technologies require minimum education and skill set for field workers to be trained?
10. What are your recommendations and thoughts around the regulatory landscape for the autorefractors? What can potentially be done for ease of business?
11. What are your recommendations for potential scalability of this technology, specifically in LMICs? What are the key enablers and barriers?

Annex 3: Detailed tables of findings

Table 8: Sensitivity and Specificity of Handheld Autorefractors Relative to Manual Dry Retinoscopy by an Optometrist (Spherical Equivalent Refractive Error)

Technology	Eccentric Photorefraction	Wavefront Aberrometer	Badal Optometer	Shack-Hartmann Wavefront Sensing	SynchroScan Technology	Auto Fogging
Sample size	n=442	n=442	n=385	n=385	n=400	n=400

MYOPIA, DEFINITION 1 (SER WORSE THAN -0.50 D)

Technology	Eccentric Photorefraction	Wavefront Aberrometer	Badal Optometer	Shack-Hartmann Wavefront Sensing	SynchroScan Technology	Auto Fogging
Sensitivity* (95% CI)	90.6 (86.0 – 94.1)	82.5 (77.7 – 86.6)	10.1 (6.4 – 15.1)	30.8 (20.8 – 42.2)	81.6 (75.5 – 86.7)	73.1 (66.7 – 78.8)
Specificity* (95% CI)	64.2 (57.5 – 70.6)	80.1 (72.4 – 86.5)	94.9 (90.6 – 97.8)	98.0 (95.8 – 99.3)	94.5 (90.3 – 97.2)	91.7 (86.7 – 95.3)
PPV** (95% CI)	71.9 (66.2 – 77.1)	90.4 (86.3 – 93.6)	70.0 (50.6 – 85.3)	80.0 (61.4 – 92.3)	93.7 (89.0 – 96.8)	91.4 (86.3 – 95.1)
NPV*** (95% CI)	87.1 (81.0 – 91.8)	66.9 (50.1 – 74.0)	47.6 (42.3 – 52.9)	84.8 (80.6 – 88.4)	83.6 (78.1 – 88.1)	73.8 (67.5 – 79.4)

MYOPIA, DEFINITION 2 (SER WORSE THAN -1.0 D)

Technology	Eccentric Photorefraction	Wavefront Aberrometer	Badal Optometer	Shack-Hartmann Wavefront Sensing	SynchroScan Technology	Auto Fogging
Sensitivity (95% CI)	82.3 (76.1 – 87.4)	71.0 (65.2 – 76.2)	8.0 (4.5 – 12.9)	41.3 (27.0 – 56.8)	81.6 (74.5 – 87.4)	68.3 (61.0 – 75.0)
Specificity (95% CI)	76.6 (70.9 – 81.7)	88.5 (82.6 – 92.9)	95.7 (92.2 – 98.2)	98.8 (97.0 – 99.7)	95.2 (91.7 – 97.5)	94.9 (91.1 – 97.4)
PPV (95% CI)	72.8 (66.4 – 78.8)	91.2 (886.7 – 94.6)	65.2 (42.7 – 84.6)	82.6 (61.2 – 95.0)	91.2 (86.1 – 95.4)	91.9 (86.0 – 95.9)
NPV (95% CI)	85.0 (79.7 – 89.4)	64.3 (57.7 – 70.5)	52.5 (47.4 – 57.7)	92.5 (89.3 – 95.0)	89.4 (85.0 – 92.8)	78.5 (72.5 -82.9)

HYPEROPIA, DEFINITION 1 (SER GREATER THAN +0.50 D)

Technology	Eccentric Photorefraction	Wavefront Aberrometer	Badal Optometer	Shack-Hartmann Wavefront Sensing	SynchroScan Technology	Auto Fogging
Sensitivity (95% CI)	28.2 (19.7 – 37.9)	55.0 (38.5 – 70.7)	74.4 (65.6 – 81.9)	80.4 (71.1 – 87.8)	85.9 (77.7 – 91.9)	72.0 (61.1 – 80.5)
Specificity (95% CI)	97.1 (94.7 – 98.6)	95.8 (93.3 – 97.5)	23.9 (18.8 – 29.5)	26.0 (21.1 – 31.5)	91.2 (87.3 – 94.1)	85.0 (80.4 – 88.4)
PPV (95% CI)	74.4 (57.9 – 87.0) (61.4 - 92.3)	56.4 (39.6 – 72.2)	30.9 (25.7 – 36.6)	26.8 (21.8 – 32.3)	77.8 (69.2 – 84.9)	61.5 (52.1 – 70.4)
NPV (95% CI)	81.7 (77.6 – 85.4)	95.6 (93.1 – 97.3)	67.0 (56.6 – 76.4)	79.8 (70.2 – 87.4)	94.1 (91.4 – 97.0)	90.1 (86.0 – 93.3)

HYPEROPIA, DEFINITION 2 (SER GREATER THAN +1.0 D)

Technology	Eccentric Photorefraction	Wavefront Aberrometer	Badal Optometer	Shack-Hartmann Wavefront Sensing	SynchroScan Technology	Auto Fogging
Sensitivity (95% CI)	17.7 (10.0 – 27.9)	36.7 (19.9 – 56.1)	60.3 (48.1 – 71.5)	74.4 (58.8 – 86.5)	87.7 (77.9 – 94.2)	75.4 (63.1 – 85.2)
Specificity (95% CI)	98.3 (96.8 – 99.5)	98.1 (96.2 – 99.2)	25.6 (20.9 – 30.9)	28.6 (23.9 – 33.8)	95.1 (92.2 – 97.2)	90.7 (87.1 – 93.6)
PPV (95% CI)	73.7 (48.8 – 90.8)	57.9 (33.5 – 79.7)	15.9 (11.8 – 20.8)	11.6 (8.1 – 16.0)	80.0 (69.6 – 88.1)	61.2 (49.7 – 71.9)
NPV (95% CI)	84.7 (80.9 – 88.0)	95.5 (93.1 – 97.3)	73.4 (64.1 – 81.4)	89.9 (82.7 – 94.8)	97.2 (94.7 – 98.7)	95.0 (92.0 – 97.1)

*Sensitivity measures a test's ability to identify positive cases, while specificity measures its ability to identify negative cases.

**Positive Predictive Value (PPV) is the probability that a positive test result is accurate.

***Negative Predictive Value (NPV) is the probability that a negative test result is accurate.

Table 9: Sensitivity and Specificity of Handheld Autorefractors Relative to Subjective Refraction, Gold-standard SER (Spherical Equivalent Refractive Error)

Technology	Eccentric Photorefraction	Wavefront Aberrometer	Badal Optometer	Shack-Hartmann Wavefront Sensing	SynchroScan Technology	Auto Fogging
Sample size	n=442	n=442	n=385	n=385	n=400	n=400

MYOPIA, DEFINITION 1 (SER WORSE THAN -0.50 D)

Technology	Eccentric Photorefraction	Wavefront Aberrometer	Badal Optometer	Shack-Hartmann Wavefront Sensing	SynchroScan Technology	Auto Fogging
Sensitivity* (95% CI)	87.0 (81.9 - 91.1)	78.10 (73.5 - 82.6)	27.5 (21.6 - 34.2)	66.7 (55.1 - 76.9)	77.6 (71.2 - 83.2)	67.1 (60.5 - 73.3)
Specificity* (95% CI)	67.9 (61.3 - 74.0)	80.9 (73.3 - 87.1)	88.8 (83.2 - 93.0)	91.9 (88.2 - 94.7)	95.0 (91.0 - 97.7)	89.5 (84.1 - 93.7)
PPV** (95% CI)	73.2 (67.5 - 78.4)	90.2 (86.0 - 93.5)	74.0 (62.8 - 83.4)	67.5 (55.9 - 77.8)	94.0 (89.2 - 97.1)	88.6 (82.7 - 93.0)
NPV*** (95% CI)	83.7 (77.3 - 88.7)	62.1 (54.6- 69.3)	51.3 (45.6 - 57.0)	91.6 (87.9 - 94.4)	80.8 (75.1 - 85.6)	69.2 (62.9 - 75.1)

MYOPIA, DEFINITION 2 (SER WORSE THAN -1.0 D)

Technology	Eccentric Photorefraction	Wavefront Aberrometer	Badal Optometer	Shack-Hartmann Wavefront Sensing	SynchroScan Technology	Auto Fogging
Sensitivity (95% CI)	78.1 (71.6 -83.8)	66.8 (60.1 - 72.3)	18.2 (12.9 - 24.5)	78.3 (63.6 - 89.0)	76.3 (68.7 - 82.8)	64.5 (57.1 - 71.4)
Specificity (95% CI)	79.6 (74.1 - 84.4)	90.3 (84.7 - 94.4)	93.4 (89.0 - 96.5)	96.8 (94.3 - 98.4)	95.2 (91.7 - 97.5)	95.4 (91.7 - 97.8)
PPV (95% CI)	74.6 (68.0 - 80.5)	92.0 (87.4 - 95.4)	72.3 (57.4 - 84.4)	76.6 (62.0 - 87.7)	90.6 (84.2 - 95.1)	92.2 (86.1 - 96.2)
NPV (95% CI)	82.6 (77.2 - 87.1)	61.8 (55.4 - 68.0)	54.7 (49.3 - 60.1)	98.0 (94.6 -98.6)	86.8 (82.1 - 90.6)	76.1 (70.6 - 81.0)

HYPEROPIA, DEFINITION 1 (SER GREATER THAN +0.50 D)

Technology	Eccentric Photorefraction	Wavefront Aberrometer	Badal Optometer	Shack-Hartmann Wavefront Sensing	SynchroScan Technology	Auto Fogging
Sensitivity (95% CI)	23.3 (15.5 - 32.7)	50.0 (33.8 - 66.2)	51.2 (42.0 - 60.4)	50.5 (40.2 - 60.8)	72.6 (63.1 - 80.8)	64.0 (53.8 - 73.4)
Specificity (95% CI)	98.2 (96.2 - 99.3)	97.5 (95.5 - 98.8)	88.6 (84.2 - 92.2)	85.1 (80.4 - 89.0)	97.6 (95.2 - 99.0)	93.3 (89.9 - 95.9)
PPV (95% CI)	80.0 (61.4 - 92.3)	66.7 (47.2 - 82.7)	67.4 (56.8 - 76.8)	53.3 (42.6 - 63.7)	91.7 (83.6 - 96.6)	76.2 (65.6 - 84.9)
NPV (95% CI)	80.8 (76.7 - 84.5)	95.2 (92.6 - 97.0)	79.9 (74.8 - 84.3)	83.6 (78.9 - 87.7)	90.8 (87.1 - 93.8)	88.6 (84.6 - 91.9)

HYPEROPIA, DEFINITION 2 (SER GREATER THAN +1.0 D)

Technology	Eccentric Photorefraction	Wavefront Aberrometer	Badal Optometer	Shack-Hartmann Wavefront Sensing	SynchroScan Technology	Auto Fogging
Sensitivity (95% CI)	16.5 (9.1 - 26.5)	36.7 (19.9 - 56.1)	34.2 (23.5 - 46.3)	51.2 (35.5 - 66.7)	75.3 (63.9 - 84.7)	66.1 (53.2 - 77.3)
Specificity (95% CI)	99.2 (97.6 - 99.8)	98.8 (97.2 - 99.6)	96.5 (93.8 - 98.2)	95.9 (93.2 - 97.7)	98.8 (96.9 - 99.8)	95.2 (92.4 - 97.2)
PPV (95% CI)	81.2 (54.3 - 96.0)	68.7 (41.3 - 89.0)	69.4 (51.9 - 83.6)	61.1 (43.5 - 76.9)	93.2 (83.5 - 98.1)	72.9 (59.7 - 83.6)
NPV (95% CI)	84.5 (80.7 - 97.8)	95.5 (93.1 - 97.3)	86.2 (82.2 - 89.7)	94.0 (91.0 - 96.2)	94.7 (91.8 - 96.8)	93.6 (90.4 - 95.9)

*Sensitivity measures a test's ability to identify positive cases, while specificity measures its ability to identify negative cases.

**Positive Predictive Value (PPV) is the probability that a positive test result is accurate.

***Negative Predictive Value (NPV) is the probability that a negative test result is accurate.

Table 10: Performance of Handheld Autorefractors (HHAs) in Myopia and Hyperopia

MYOPIA REFRACTIVE ERROR (BASED ON GOLD-STANDARD SER) (WORSE THAN -0.50 D)

Technology	Eccentric Photorefraction	Wavefront Aberrometer	Badal Optometer	Shack-Hartmann Wavefront Sensing	SynchroScan Technology	Auto Fogging
Number examined	220	252	77	77	166	166
Mean SER difference between gold standard & HHA	0.42 (0.97)	0.64 (0.80)	-0.41 (3.60)	-0.53 (2.76)	0.19 (1.23)	0.52 (2.50)
Statistical significance (p-value)	<0.01	<0.01	0.32	0.10	0.06	<0.01
Bland-Altman limits of agreement in myopia	−1.48 to 2.31	−0.94 to 2.22	−6.69 to 7.51	−4.87 to 5.94	−2.24 to 2.60	−4.36 to 5.41

HYPEROPIA (BASED ON GOLD-STANDARD SER) (MORE THAN +0.50 D)

Technology	Eccentric Photorefraction	Wavefront Aberrometer	Badal Optometer	Shack-Hartmann Wavefront Sensing	SynchroScan Technology	Auto Fogging
Number examined	20	26	92	92	84	84
Mean SER difference between gold standard & HHA	0.49 (2.03)	0.25 (1.20)	0.57 (3.30)	0.32 (1.21)	0.11 (1.34)	0.50 (2.43)

Technology	Eccentric Photorefraction	Wavefront Aberrometer	Badal Optometer	Shack-Hartmann Wavefront Sensing	SynchroScan Technology	Auto Fogging
Statistical significance (p-value)	0.30	0.30	0.10	0.01	0.45	0.03
Bland-Altman limits of agreement in hyperopia	−3.50 to 4.47	−2.10 to 2.60	−5.91 to 7.05	−2.06 to 2.71	−2.52 to 2.74	−4.19 to 5.37

Table 11: Performance of HHAs in Severity Grades of Myopia and Hyperopia

LOW MYOPIA (<-0.50 TO <-3.0 D)

Technology	Eccentric Photorefraction	Wavefront Aberrometer	Badal Optometer	Shack-Hartmann Wavefront Sensing	SynchroScan Technology	Auto Fogging
Number examined	189	190	54	54	109	109
Mean SER difference between gold standard & HHA	-0.40 (0.92)	0.65 (0.80)	0.73 (2.05)	-0.20 (0.90)	0.07 (0.80)	0.57 (1.50)
Statistical significance (p-value)	<0.01	<0.01	0.01	0.13	0.39	<0.01

MODERATE MYOPIA (>-3.00 D)

Technology	Eccentric Photorefraction	Wavefront Aberrometer	Badal Optometer	Shack-Hartmann Wavefront Sensing	SynchroScan Technology	Auto Fogging
Number examined	31	62	23	23	57	57
Mean SER difference between gold standard & HHA	0.53 (1.12)	0.60 (0.86)	-3.10 (4.94)	-1.33 (4.83)	0.40 (1.78)	0.44 (3.75)
Statistical significance (p-value)	0.03	<0.01	<0.01	0.20	0.09	0.37

LOW HYPEROPIA (>+0.50 TO <-3.0 DS)

Technology	Eccentric Photorefraction	Wavefront Aberrometer	Badal Optometer	Shack-Hartmann Wavefront Sensing	SynchroScan Technology	Auto Fogging
Number examined	17	20	87	87	55	55
Mean SER difference between gold standard & HHA	-0.24 (0.80)	0.39 (1.18)	0.33 (2.98)	0.27 (1.04)	-0.02 (1.39)	0.41 (2.08)
Statistical significance (p-value)	0.25	0.15	0.30	0.19	0.92	0.15

HIGH HYPEROPIA (>+3.00 D)

Technology	Eccentric Photorefraction	Wavefront Aberrometer	Badal Optometer	Shack-Hartmann Wavefront Sensing	SynchroScan Technology	Auto Fogging
Number examined	3	6	5	5	29	29
Mean SER difference between gold standard & HHA	4.6 (2.13)	-0.23 (1.25)	4.68 (5.95)	1.30 (2.99)	0.36 (1.23)	0.94 (3.00)
Statistical significance (p-value)	0.15	0.67	0.15	0.39	0.13	0.10

Table 12: Performance of HHAs across Different Age Groups

AGE GROUP (5-16 YEARS)

Technology	Eccentric Photorefraction	Wavefront Aberrometer	Badal Optometer	Shack-Hartmann Wavefront Sensing	SynchroScan Technology	Auto Fogging
Number examined	100	114	104	104	99	99
Mean SER difference between gold standard & HHA	0.40 (1.20)	0.60 (0.90)	2.50 (4.20)	0.02 (1.74)	0.26 (1.42)	0.73 (2.78)
Statistical significance (p-value)	<0.01	<0.01	<0.01	0.92	0.07	0.01
Bland-Altman limits of agreement	-1.92 to 2.71	-1.16 to 2.37	-5.76 to 10.78	-3.40 to 3.43	-2.52 to 3.04	-4.72 to 6.18

AGE GROUP (17-28 YEARS)

Technology	Eccentric Photorefraction	Wavefront Aberrometer	Badal Optometer	Shack-Hartmann Wavefront Sensing	SynchroScan Technology	Auto Fogging
Number examined	106	116	107	107	103	103
Mean SER difference between gold standard & HHA	0.45 (0.96)	0.78 (0.82)	1.50 (2.64)	-0.28 (2.00)	0.27 (0.14)	0.63 (2.80)
Statistical significance (p-value)	<0.01	<0.01	<0.01	0.15	0.14	0.03
Bland-Altman limits of agreement	-1.43 to 2.34	-0.83 to 2.39	-3.67 to 6.67	-4.18 to 3.61	-3.39 to 3.93	-4.85 to 6.11

AGE GROUP (29-39 YEARS)

Technology	Eccentric Photorefraction	Wavefront Aberrometer	Badal Optometer	Shack-Hartmann Wavefront Sensing	SynchroScan Technology	Auto Fogging
Number examined	82	96	67	67	92	92
Mean SER difference between gold standard & HHA	0.90 (0.73)	0.57 (0.76)	0.98 (2.50)	0.01 (0.90)	0.27 (1.28)	0.60 (1.76)
Statistical significance (p-value)	0.27	<0.01	<0.01	0.93	0.05	<0.01
Bland-Altman limits of agreement	-1.34 to 1.52	-0.92 to 2.05	-3.94 to 5.90	-1.72 to 1.74	-2.25 to 2.79	-2.84 to 4.05

AGE GROUP (40 YEARS AND OLDER)

Technology	Eccentric Photorefraction	Wavefront Aberrometer	Badal Optometer	Shack-Hartmann Wavefront Sensing	SynchroScan Technology	Auto Fogging
Number examined	95	98	107	107	103	103
Mean SER difference between gold standard & HHA	-0.13 (0.81)	0.30 (0.81)	-0.87 (1.58)	0.04 (0.84)	0.12 (0.81)	0.25 (1.21)
Statistical significance (p-value)	0.13	<0.01	<0.01	0.57	0.13	0.03
Bland-Altman limits of agreement	-1.72 to 1.47	-1.29 to 1.90	-3.98 to 2.23	-1.60 to 1.69	-1.47 to 1.71	-2.13 to 2.64

Table 13: Overall Performance of HHAs

Technology	Eccentric Photorefraction	Wavefront Aberrometer	Badal Optometer	Shack-Hartmann Wavefront Sensing	SynchroScan Technology	Auto Fogging
Number examined	383	424	385	385	397	397
Mean difference in SER compared to the gold standard	0.22 (0.97)	0.60 (0.84)	1.02 (3.20)	-0.06 (1.50)	0.23 (1.40)	0.56 (2.25)
Statistical significance (p-value)	<0.01	<0.01	<0.01	0.44	<0.01	<0.01
Bland-Altman limits of agreement	−1.69 to 2.13	−1.08 to 2.23	−5.22 to 7.27	−3.00 to 2.88	−2.50 to 1.39	−3.85 to 4.96

Annex 4: Universe of technologies reviewed

The table below provides an overview of the handheld autorefractor technologies reviewed as part of the landscaping study. The market landscape and secondary review supported shortlisting of the six technologies that were studied.

Table 14: Overview of Universe of Handheld Autorefractor Technologies

S. No.	Product name	Company	Price (USD)
1.	FOFO	LVPEI, India	18
2.	Self-adjustable	Adspecs, Oxford, UK	18
3.	ClickCheck	Essilor, France	55
4.	Smartscope	Optomed, Finland	822
5.	Netra G	EyeNetra, USA	1290
6.	USEE	GV2020, USA	2040
7.	Instaref R20	Remidio, India	2650
8.	E-see	Aurolab, India	2772
9.	EasyRef	Moptim, China	3100
10.	3nethra aberro	Forus Health, India	3696
11.	HAR 680	Redsun, China	3900
12.	Eyenetra	Netra	3980
13.	HAR 800/880	Moptim, China	4300
14.	Souer SW 800 vision screener	Optohellas, Greece	4900
15.	PlusoptiX A12R/ A12C	PlusoptiX, Germany	4924
16.	PlusoptiX S12R/ S12C	PlusoptiX, Germany	4924

S. No.	Product name	Company	Price (USD)
17.	Welch Allyn SureSight	Hillrom, China	4995
18.	Welch Allyn spot vision screener	Hillrom, China	5645
19.	Vision Screener EVS-1800	US ophthalmic, US	5890
20.	QuickSee Flip	PlenOptika, USA	5900
21.	Kaledos	Adaptica, Italy	6595
22.	Pictor	Volk Optical Inc, USA	6991
23.	SVOne	Smart Vision labs, USA	7000
24.	2Win	Adaptica, Italy	9000
25.	Vision R800	Esillor, France	10,892
26.	Retinomax K-3	Righton Ophthalmic Instruments, Japan	11,187
27.	HandyRef- K	Nidek, Japan	14,112
28.	i.profiler	Zeiss, Malaysia	30,000
29.	VARS	Vmax vision, USA	NA

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