Market insights and product offerings in low- and middle-income countries for digital assistive technology, eyeglasses, hearing aids, prostheses, and wheelchairs.

ASSISTIVE PRODUCTS MARKET REPORT 2024

CLINTON HEALTH ACCESS INITIATIVE

ATscale
GLOBAL PARTNERSHIP FOR ASSISTIVE TECHNOLOGY
Hosted by UNOPS

Foreword

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Assistive Technology (AT) enables millions of people to live healthier, more independent, productive, and dignified lives. And by empowering persons with disabilities, the ageing population, and those with chronic conditions, it fosters inclusion and engagement in our societies and economies.

Despite Assistive Technology's obvious value, however, not nearly enough people have access to the AT that they need. Some 2.5 billion people need one or more assistive products, for example, but in low-income countries, just 10 percent of people can access the AT that they need. In some cases, this figure falls to just 3 percent. In contrast, in high-income countries, the average is closer to 90 percent.

So why does this inequity exist? And what can we do about it? One answer is that market failures are an important part of the problem, and correcting these failures will be vital to any sustainable solutions.

Figuring out how to correct these failures has occupied ATscale since its inception and a large part of our time is devoted to figuring out pragmatic answers and finding scalable solutions. With that in mind, we commissioned the Clinton Health Access Initiative to look at individual AT markets in more detail, peeling back the layers to give us a more granular view on pricing, market segmentation, quality issues, and the different companies involved.

We have long known about market failures such as monopoly market power, trade barriers, technological barriers, and asymmetric information, for example. But this report, the first of its kind, expands and deepens that knowledge. It provides us with actionable insights on the most dynamic AT markets.

This report aims to address at least some of those market failures, consolidating a significant amount of market information in one single and easily accessible location. This information will soon also be available online where it will remain easily accessible to government officials, businesses, organizations involved with service provision, AT users and all those at the sharp end of AT supply. Procurement teams can use the information to procure quality items at the most reasonable possible prices. In future iterations, we will expand its scope and depth, building upon this first report to make the available information even more comprehensive.

This is not the first time that such an approach has been tried. In Indonesia, reducing information asymmetries enabled an 85 percent price drop on treatment for Hepatitis C, for example. But this is the first time that such an approach has been tried for assistive technology.

This report represents a most welcome collaboration therefore, drawing on the expertise and contributions of a very diverse set of stakeholders, including policymakers and development practitioners to innovators and entrepreneurs.

At its core, this report is a call to action – a call to leverage the power of market transparency in shaping a more inclusive and sustainable future. By equipping stakeholders with the knowledge and insights needed to navigate the complexities of the market, we can unlock the full potential of assistive technology as a catalyst for positive change.

For those supplying and procuring assistive products directly, please do keep us in mind. We will always welcome your news and updates on products and prices, and will be glad to include this in our database - when ready - and future reports.

Our hope is that the comprehensive market intelligence in this report is a stepping stone towards enhancing the much needed availability of affordable, high-quality assistive products in LMICs.

Acknowledgements

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We would also like to express our gratitude to:

- Our public and private partners across low- and middle-income countries (LMICs),
- Manufacturers and suppliers of eyeglasses, digital assistive technology (augmentative and alternative communication, smartphones, screen readers), hearing aids, prostheses and wheelchairs for their valuable input that forms the foundation of this report.

Thanks to the dedicated efforts of all involved, we are collectively working to increase the accessibility of assistive technology for more people in need.

Acronyms

AAC	augmentative and alternative communication
APS	Assistive Product Specifications
ARIA	Accessible Rich Internet Applications
AT	assistive technology
BTE	Behind-The-Ear
CE	European conformity (for Conformité Européenne in French)
CHAI	Clinton Health Access Initiative
CLASP	Consolidating Logistics for Assistive Technology Supply and Provision
DAISY	Digital Accessible Information System
EU MDR	The European Union Medical Device Regulation
FDA	Food and Drug Administration (United States)
GSMA	Global System for Mobile Communications Association
HI	Humanity & Inclusion
HICs	high-income countries
ICRC	International Committee of the Red Cross
IEC	International Electrotechnical Commission
IHHAPP	International Humanitarian Hearing Aid Purchasing Program
ISO	International Organization for Standardization
ISPO	International Society for Prosthetics and Orthotics
ISWP	International Society of Wheelchair Professionals
JAWS	Job Access With Speech
LMICs	low-income and middle-income countries
MSVI	moderate and severe vision impairment
NGO	non-governmental organization
NHS	National Health Service (United Kingdom)
NVDA	NonVisual Desktop Access
NVG	New Vision Generation
ODM	original design manufacturer
OEM	original equipment manufacturer
OS	operating system
OTC	over the counter
P&O	prosthetic & orthotic

SACH	solid ankle cushion heel
SGD	speech-generating devices
UNICEF	United Nations International Children's Emergency Fund
USAID	United States Agency for International Development
WCAG	Web Content Accessibility Guidelines
WHO	World Health Organization

Executive summary

Assistive Products Market Report

Scope: This report attempts to address the lack of visibility of supplier and product information by creating a one-stop product catalogue for potential buyers including NGOs and governments across low- and middle-income countries. This report acknowledges the criticality of services along with assistive products for comprehensive care. The current scope of the report is limited to assistive products.

This report focuses on five assistive products (in alphabetical order): digital assistive technology (including augmentative and alternative communication, screen readers, and smartphones), eyeglasses, hearing aids, prostheses, and wheelchairs. These products were selected for their high-impact opportunity in low- and middle-income countries.

Report structure: Developed through a combination of desk research, interviews with selected suppliers, and consultations with industry experts and organizations, the report is organized into seven sections. Each section focuses on one assistive product, providing an overview of the market, recommended technical specifications and quality certification, supplier landscape, and indicative pricing. Additionally, the Annex features a product catalogue, highlighting representative companies and products available in low- and middle-income countries.

Upcoming updates:

Update 1: Online product catalogue: The report acknowledges the need of a comprehensive product catalogue and envisions a digital platform that would enhance accessibility and dynamic interaction. Periodic updates would keep the listings relevant.

Update 2: The next edition of the market report, set for release by the end of 2024, aims to enhance the report's scope with key additions likely to include:

- *In-depth regional market research:* A more granular analysis of specific low- and middle-income country markets, including detailed case studies, to better understand localized needs and challenges.
- *Innovation:* A focus on innovative assistive product design and technology, tailored to the unique requirements of low- and middle-income country environments.
- *Comprehensive pricing analysis:* A thorough assessment of all-inclusive pricing factors such as fitting, maintenance, and service costs.
- *Price markup exploration:* Various elements contributing to in-country price mark-ups.

Key insights: Key market overview highlighting need, current access, supplier landscape, and pricing is provided below.

Assistive technology

- More than 2.5 billion people require one or more assistive products, and this number is expected to grow to over 3.5 billion by 2050.
- According to the 2022 Global Report on Assistive Technology published by World Health Organization, the assistive technology global market is expected to be valued at between 26 billion to 31 billion United States dollars by 2024.
- The projected increase in need is explained by:
  - An ageing population: The global population aged 60 years and older is projected to reach 2.1 billion dollars by 2050, doubling the number recorded in 2020.
  - A shifting global burden of disease: Fewer infectious diseases and more non-communicable diseases (e.g. Alzheimer's disease, and diabetes and stroke).
- Nearly one billion people are unable to access assistive technology, particularly in low- and middle-income countries where access is as low as 3 per cent of the population in need.

Digital assistive technology: Augmentative and alternative communication

Market overview

- Access to augmentative and alternative communication is low and has unique challenges.
- Market segmented by technology level (low, medium, high), and differentiated by level of technological complexity and pricing.
- Access to high-tech solutions is particularly limited, with access to communication aids being among the lowest. Only 1.75 per cent of people surveyed have access to communication boards, books, and cards.

Supplier landscape

- 12 major global companies and suppliers identified.
- Europe and China are the primary manufacturing locations.
- Independent developers in the mobile phone space are emerging as players in augmentative and alternative communication.

Pricing

- Mid-tech pricing ranges from 50 to 300 dollars; high-tech ranges from 100 to 20,000 dollars depending on the level of sophistication.
- Price disparities exist due to augmentative and alternative communication still being an emerging specialist field.

Digital assistive technology: Screen readers

Market overview

- Roughly 43.3 million people were blind in 2020, and approximately 295 million people had moderate and severe vision impairment.
- Globally, 92 per cent of people who are blind and 88 per cent of those with moderate and severe vision impairment live in low- and middle-income countries.
- Estimating the market size for screen readers or even the number of devices and users in circulation is a challenge due to – (a) Screen reader use for convenience vs disability driven, (b) in-built and open-source software as 'licensed' user base, (c) lack of standardized tracking measures of screen reader-based access of web content.

Supplier landscape

- The market is divided into open-source offerings, commercial offerings, and in-built screen readers (for devices or browsers) with a few major offerings/ products across each category.
- In recent years, the market has consolidated, with many previously popular screen reader offerings becoming defunct/obsolete or inactive.
- The United States, United Kingdom and Australia are the primary manufacturing/ development locations.

Pricing

- Commercial offerings range from 1,000–1,200 dollars for lifetime licenses, but yearly licenses are available for 85-90 dollars.
- Open-source offerings are available for free, alongside built-in offerings, which are also free and included with the procurement of devices.

Digital assistive technology: Smartphones

Market overview

- At least 4.3 billion people use or own a smartphone, and 57 per cent of the world's population uses mobile internet.
- Growth in smartphone ownership across low- and middle-income countries lags significantly behind high-income countries. For example, as of 2022, smartphone ownership is at 21 per cent in Sub-Saharan Africa and 35 per cent in South Asia compared to 76 per cent in high-income countries.
- People with disabilities in low- and middle-income countries are significantly less likely to own a smartphone compared to people without disabilities.

Supplier landscape

- A fairly consolidated market, with 6 to 10 major global companies.
- The United States, China, and Japan are the primary manufacturing locations.
- Local developers in South Asia and Africa are emerging to provide low-cost/ budget alternatives.

Pricing

- Premium smartphones range from 700 to 2,000 dollars, with mid-range options available from 400 to 700 dollars, and budget options available for less than 100 dollars.
- Ultra-low-cost smartphones from local manufacturers may be available for as little as 50 dollars but provide limited functionalities.

Eyeglasses

Market overview

- Large need: myopia and presbyopia affect 2.6 billion and 1.8 billion people respectively globally.
- Only 36 per cent globally have access to appropriate spectacles.
- Market segmented by type (prescription glasses and reading glasses) and by component (frames, lenses and ready-made reading glasses).

Supplier landscape

- A global market led by companies such as EssilorLuxottica, Carl Zeiss and Hoya.
- China is the primary manufacturing location.
- Rise of local manufacturing in emerging markets like India.

Pricing

- Prescription glasses in high-income countries range between 240 and 1,000 dollars.
- Price disparities in low- and middle-income countries due to import duties, logistics, and distribution costs.
- Manufacturing cost is 1-1.20 dollars for lenses and frames, and 0.4-0.5 dollars for reading glasses.

Hearing aids

Market overview

- Globally, 1.6 billion people have hearing loss of which 430 million have moderate to severe loss.
- 80 per cent of those with moderate to severe hearing loss reside in low- and-middle-income countries.
- Less than 20 per cent of people needing hearing aids have access.
- Market segmented by type (behind-the-ear, receiver-in-canal, in-the-ear, and completely-in-canal), technology (analogue and digital), and distribution channels (independent hearing clinics, hospitals, online retailers, optical chains and over-the-counter).

Supplier landscape

- Global market led by five companies that have over 90 per cent of market share.
- Local manufacturers exist in middle income countries like China and India.

Pricing

- Price range in high-income countries between 500 and 4,000 dollars.
- Low- and-middle-income countries can purchase hearing aids at 60 to 175 dollars through international organization procurement.
- Additional costs include batteries, and earmould costs.

Prostheses

Market overview

- 65 million people worldwide have had limb amputations.
- 64 per cent of them live in low- and-middle-income countries.
- Only 20 per cent have access to prostheses.
- Market segmented by type (lower-limb: above-knee, below-knee, partial foot; upper-limb: shoulders, above-elbow, and below-elbow) and by technology mechanically controlled and microprocessor controlled.

Supplier landscape

- Market led by a few companies with a focus on high- and upper-middle income countries.
- Suppliers have emerged in low or middle-income countries like China, Türkiye, and Russia, providing more affordable solutions for low- and middle-income markets.

Pricing

- In high-income countries, prostheses leg prices range from 3,500 to over 70,000 dollars for advanced control.
- In low- and middle-income countries, costs for basic component kits are 77 to 450 dollars for transtibial and 188 to 540 dollars for transfemoral.
- Prices are largely influenced by functionality, material, and manufacturing origin.

Wheelchairs

Market overview

- 80 million people need wheelchairs globally.
- 65 million people in need live in low- and middle-income countries.
- Globally, 65 to 95 per cent of people in need do not have access.
- Market segmented by user (adult and children); technology (manual, powered/electric); and terrain functionality (indoor and urban settings, outdoor/rural/rough terrain, and dual-terrain).

Supplier landscape

- Fragmented market: five established leading global companies have less than 50 per cent market share.
- NGOs address low- and middle-income countries' needs with appropriate designs for low-resource settings.

Pricing

- In high-income countries, wheelchairs for rough terrains could cost 900 to 1,700 dollars.
- International organizations like UNICEF offer affordable options for rough terrain at around 350 dollars in low- and middle-income countries.
- Prices in low- and middle-income countries are influenced by procurement channels, volumes, and product choices.

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Introduction

Assistive technology (AT) encompasses assistive products and the accompanying systems and services designed to aid individuals facing permanent or temporary functional challenges. AT is vital for enabling and empowering persons with disabilities, the ageing population, and those with chronic conditions. It plays a crucial role in fostering inclusion and engagement in all aspects of society. Assistive products come in various forms, including physical items like wheelchairs, glasses, hearing aids, prosthetic limbs, walking aids, and incontinence pads, as well as digital tools like software and applications that facilitate interpersonal communication, access to information, daily time management, rehabilitation, education, and training. These technologies are essential across all life stages, aiding children with disabilities in education and activities and supporting adults, particularly as they age.[1]

Globally, more than 2.5 billion people need one or more assistive products.[2] With an ageing global population and a rise in noncommunicable diseases, more than 3.5 billion people will need at least one assistive product by 2050, with many older people needing two or more.[3]

Despite the necessity of AT, access is a challenge. Nearly one billion people are unable to access such technology, particularly in low- and middle-income countries (LMICs), where access can be as low as 3 per cent of those in need of these products.[4] In LMICs, market inefficiencies, such as limited awareness about AT products and suppliers, high costs, workforce capacity gaps, and a weak supportive environment, hinder AT access. Among these barriers, the lack of essential market information on pricing, manufacturers, and product offerings is a key challenge across LMICs. Due to limited visibility and information, buyers face challenges in accessing affordable, quality products that meet their needs.

There is a pressing need to mitigate market shortcomings, specifically addressing the lack of visibility regarding supplier and product information by creating a one-stop product catalogue guide for potential buyers including NGOs and governments across low- and middle-income countries.

This report is the first attempt towards such a solution. The aim is to feed this information into a web-based product catalogue that can be exhaustive and

1 Global report on assistive technology. Geneva: World Health Organization and the United Nations Children's Fund (UNICEF), 2022. https://www.unicef.org/reports/global-report-assistive-technology.

2 Ibid.

3 Ibid.

4 Ibid.

periodically updated. This report focuses on five assistive products: wheelchairs, prostheses, eyeglasses, hearing aids, and digital AT (including augmentative and alternative communication, screen readers, and smartphones), selected for their high demand in LMICs. The report is organized into seven sections focusing on these product categories. Each section provides an overview of the market, recommended technical specifications and quality certifications, the supplier landscape, and pricing. Additionally, the appendices feature a product catalogue highlighting representative companies and products available in LMICs. This provides reference points for individuals or organizations influencing or planning for improved provision processes and provides information for those in need of AT, helping them to understand more about the providers and products available in their region.

The report serves multiple purposes: 1) to guide AT buyers in LMICs to better understand available suppliers and products, aiding direct procurement, 2) to inform AT donors and funding agencies, allowing them to strategize their investment in the AT sector, and 3) to assist policymakers in identifying market needs and shaping policies to bridge the demand gap. Overall, the report aims to offer key market insights and visibility into the supplier landscape and product offerings for five assistive products.

Methodology

This report has been developed through a combination of desk research, interviews with suppliers, and consultations with industry experts and organizations. For a detailed breakdown of the suppliers interviewed and the esteemed experts and organizations consulted during the research process, please refer to Appendices A and B, respectively.

Limitations

Importance of services: This report acknowledges the criticality of services along with assistive products for comprehensive care. However, the scope of the report is limited to assistive products.

Importance of other assistive products: The authors also acknowledge the need for other assistive products, especially for children, in addition to those included in the report. Products such as standing frames, night-time positioners, height adjustable tables and chairs for schools, bathing equipment, hoists, grab rails, and ramps are not included in the current scope.

No comprehensive supplier listing: AT markets in LMICs are fragmented, therefore the list of suppliers and products featured in this report is not to be considered comprehensive. The report is structured for a general audience, and as such, may not fully cater to the specific needs and challenges of one country or buyer. Information

about local innovations, which are often tailored to specific needs, may not be widely documented or easily accessible through desk research.

Interpreting findings: The authors advise to exercise caution when interpreting the findings of this report, given that the research depending largely on desk research, which heavily relies on the accessibility and quality of existing data, leaving room for the potential inclusion of outdated, biased, or incomplete information, all of which may impact overall findings and recommendations. ATscale and CHAI have taken precautions to verify the information shared in the report, however, the analysis is not exhaustive, and the responsibility for the interpretation and use of the material lies with the reader.

The information about suppliers primarily comes from public resources, and mention of specific companies or products does not imply that ATscale or CHAI is endorsing or recommending them. The purpose of featuring certain suppliers and products is to demonstrate the variety of options available within LMICs, thereby aiding connections between suppliers and buyers who are seeking products to meet specific national or individual requirements.

We encourage suppliers to share product information available in LMICs that can be highlighted through these reports. We are committed to continually enhancing these reports. Your contributions, in the form of sharing products and insights, will be invaluable for inclusion in future editions, thus enriching this resource for all stakeholders.

Digital assistive technology: Augmentative and alternative communication

Market overview

Augmentative and Alternative Communication (AAC) are a set of strategies and tools that can be used to support individuals with communication impairments, irrespective of their physical or cognitive abilities. This includes individuals with conditions such as autism, cerebral palsy, and Down syndrome, as well as those who experienced brain injuries or strokes. AAC is designed to help people with communication challenges to express themselves more effectively and includes low-tech methods such as gestures, symbols, and images, as well as high-tech solutions requiring digital devices. AAC can allow users to develop social skills and academic competence through their support of everyday function and reasoning, as well to improve the ability to express oneself.

Market size

Although no specific estimates exist on the need for AAC solutions, many people worldwide experience communication impairments due to developmental disorders, injuries, and age-related issues. The World Health Organization's global report on assistive technology[5] provides some insights into the unmet need for AT for communication, with communication aids such as boards, books and cards achieving the lowest median access percentage of 1.75 per cent. This indicates a significant gap between the need for these communication aids and their actual usage. In the United States, it is estimated that five million people (or 1.5 per cent of the population) have conditions that prevent them from relying solely on speech for communication. In Germany, 46 per cent of adults with ALS indicated a need for AAC, but 39 per cent were unable to obtain a device.

5 Ibid.

Even fewer data exist on low- and middle-income countries (LMICs), but we understand that access to AAC is low and comes with unique challenges.[6] Purchasing high-tech AAC devices can be cost-prohibitive and reliant on internet connectivity, which is not always available. The diversity of languages also provides a barrier, as many LMICs use many domestic languages. Additionally, negative societal attitudes and stigmas surrounding disabilities can hinder the acceptance of AAC users and there may be a shortage of professionals such as speech-language pathologists, who are trained in AAC provision. Moreover, some LMICs may lack specific policies or guidelines addressing the needs of individuals with communication impairments and the provision of AAC services. Efforts are underway to address some of these challenges, including the development of culturally relevant and affordable AAC, training programmes for professionals, and advocacy for inclusive policies. As access to technology and connectivity improves globally, it is anticipated that the demand for AACs will also grow.

Market growth drivers

The global market for AACs has grown over the years, driven by advancements in technology, decreasing costs of devices, increasing awareness of communication disorders, and a growing emphasis on inclusivity.

Market segmentation

The market is comprised of a wide range of products and services. AAC can be segmented by the need for supportive tools:

- *Unaided*: Do not require a physical tool. Examples include facial expressions, sign language, body language or gestures.
- *Aided*: Require tools such as symbols and boards as well as speech-generating devices.

Aided AAC can be further segmented by the level of technical sophistication of the products:

- *Low-tech:* Simple and cost-effective solutions like communication boards, picture cards, and manual communication aids that are basic and analogue in nature.
- *Mid-tech:* Solutions that may involve electronic components and voice output, such as basic speech-generating devices (SGDs). These have digital features with limited functionality.

6 Janice Light, et al. (2019). Challenges and opportunities in augmentative and alternative communication: Research and technology development to enhance communication and participation for individuals with complex communication needs, *Augmentative and Alternative Communication*, 35:1, 1-12, DOI: 10.1080/07434618.2018.1556732.

- *High-tech:* Complex solutions rich in functionality such as advanced electronic devices, including tablets, smartphones, and dedicated speech-generating devices, often equipped with sophisticated software for comprehensive communication support. Other high-tech solutions with sensors or eye-tracking devices can enable individuals with motor impairments to communicate using gestures or eye movement.

This report focuses on Aided AAC, specifically, mid-tech to high-tech digital tools (see table 1).

Table 1: Low-tech vs high-tech augmentative and alternative communication

Low-tech augmentative and alternative communication	Mid-tech and high-tech augmentative and alternative communication
Communication board 	**Dedicated dynamic screen devices** 
Communication books 	**Advanced SGD** 
Basic SGD 	**Eye gazing device** 
Voice output switches 	**Smartphone applications** 

Quality

Quality standards and frameworks for AACs are limited due to the diverse and complex nature of AAC needs, the interdisciplinary nature of AAC provision, and the relatively recent evolution of high-tech AAC provision. High-tech AAC devices are governed by quality standards depending on the type of device, such as mobile phone accessibility standards for mobile-phone-based AAC solutions. Despite the complexity of communication standards, core vocabulary has played a crucial role in enhancing AAC solutions. Core vocabulary consists of essential words that are central to language use and applicable across various contexts. Examples include pronouns and verbs. Efficiently incorporating core vocabulary into AAC systems is recommended to benefit users.[7]

Supplier landscape

Several companies manufacture and supply AAC devices globally. These companies operate in various regions around the world, with the majority able to provide products and services across different geographic areas and meet diverse needs. Currently, product differentiation is centred around complexity and level of product sophistication, which also affect pricing. More active players producing AAC products and services are presented here. This report focuses on Aided AAC, specifically, mid-tech to high-tech digital tools (see table 2).

Table 2: Augmentative and alternative communication suppliers focused on the global market

Organization (country)	Description	Presence	Products
7ivensun *(China)*	Supplier of high-tech AAC, diagnostics, and communication-aiding devices and software	China (primarily)	High tech: Eye-tracking devices, software, and accessories
AssistiveWare B.V. *(Netherlands)*	Known for its AAC app designed for iOS devices (for iPads and iPhones). Provides a customizable communication solution for individuals with speech impairments.	Global	Develops iOS and MacOS AAC apps

7 https://link.springer.com/article/10.1007/s40489-023-00399-x.

Organization (country)	Description	Presence	Products
Attainment Company *(USA)*	Provides AAC solutions, including devices and software, with a focus on accessibility and inclusivity.	Global	AAC devices and communication software focusing on accessibility and inclusivity
Dynavox Mayer-Johnson *(Sweden)*	Offers a variety of AAC solutions, including communication devices and software, to support individuals with speech and language challenges.	Global	Communication devices and communication software
Honeycomb *(China)*	Supplier of AAC solutions, including low- and high-tech devices with a focus on aiding communication	Global, 40+ countries	Low-tech: Voice output devices High-tech: Communication aid software
Jabbla *(UK)*	Provides AAC solutions, including devices and software, with a focus on aiding communication for individuals with disabilities	Global	AAC devices, communication software focusing on aiding communication for people with disabilities
Liberator Ltd *(USA)*	Offers AAC solutions, including communication devices, language software, and accessories	Global	Communication devices, language software, accessories
Prentke Romich Company *(USA)*	Specializes in AAC, offering a range of communication devices, language systems, and software	Global	Communication devices, language systems, software
Saltillo Corporation *(USA)*	Provides AAC devices, including touch-based communication devices and software designed to assist individuals with communication disorders	Global	AAC devices, touch-based communication devices, communication software
Sense *(Chinese Taipei)*	Supplier of communication-aiding software	Chinese Taipei (primarily)	High-tech: Eye-tracking software and accessories

Organization (country)	Description	Presence	Products
Smartbox Assistive Technology *(UK)*	Specializes in communication aids and software, offering a range of AAC solutions for individuals with different communication needs.	Global	Communication aids, software, various AAC solutions
Tobii Dynavox *(Sweden)*	Well-known provider of AAC, including speech-generating devices with eye-tracking technology.	Global	AAC devices, speech-generating devices with eye-tracking technology

Pricing overview

AAC product prices are based on factors such as device type, technological complexity, features offered, as well as licensing and maintenance costs. Mid-tech AAC, such as basic speech-generating devices can range in price from under a hundred to a few thousand dollars, once again depending on the technology, software licensing costs as well as maintenance. AAC applications for smartphones are available for a one-time fee or annual purchase, from fifty to a few thousand dollars. Speech-generating devices tend to be less complex, offer limited voice outputs and have a limited number of functionalities.

High-tech AAC, such as advanced dedicated speech generating devices, can range from several thousands to tens of thousands of dollars. These devices are versatile, often having multiple access methods, advanced communication software, and the latest technological innovations such as eye-tracking technology.

Table 3: Different augmentative and alternative communication categories

	Low-tech	Mid-tech	High-tech
Characteristics	Basic and analogue in nature	Digital features with limited functionality	Versatile solutions rich in functionality
Cost *(in United States dollars)*	20 to 100	50 to 3,000	100 to 20,000
Availability *(ease of supply)*	High	Medium	Low

Global leading augmentative and alternative communication devices

Table 4: Global leading augmentative and alternative communication devices

Brand	Access method	Price range *(in United States dollars)*
Tobii Dynavox	Eye gaze, touch, and switch	3,000 to 20,000
AssistiveWare	Touch	99 to 299
Lingraphica	Touch and scanning	7,000 to 10,000

Augmentative and alternative communication devices for low- and middle-income countries

Although not directly involved in the manufacturing of AACs, there are several organizations that champion and support the provision, availability, and use of AACs in LMICs:

Table 5: Organizations focusing on augmentative and alternative communication devices availability in low- to middle-income countries

Organization	Description	Presence	Area of focus
Bridge to Asia Foundation	Works to improve the quality of life for individuals with disabilities in Asia. Collaborates with local partners to implement sustainable AAC solutions.	Asia	AAC devices and services for individuals with disabilities
Project Vive	A social enterprise focusing on creating affordable and customizable AAC solutions. Works on projects in various countries, including those with limited resources.	Global	Affordable and customizable AAC solutions

Conclusion

The future of AAC appears promising thanks to ongoing technological advancements, increasing availability and accessibility of smart devices in LMICs, and sustained advocacy efforts aimed at fostering inclusivity for individuals with speech impairments.

Whilst high-tech AAC continues to develop rapidly, tailoring to local contexts as well as access challenges need to be addressed.

Potential opportunities for mid- to high-tech AAC continue to emerge, such as modifications to fit an individual's unique needs and abilities more precisely. This adaptability allows for a wide range of communication options, from simple pre-recorded messages to more sophisticated, eye-controlled systems.[8] Furthermore, rapid advancements in technology, including in speech recognition, natural language processing, eye-tracking, and mobile devices, have improved the capabilities and accessibility of AAC devices. This means that more people who need AAC can have access to them.[9]

The advent of app development presents a significant opportunity in digital AAC. As machine learning and natural-language processing come to the forefront, further research is essential to optimize AAC solutions, leveraging cutting-edge technology to improve user experience, affordability, and portability. Addressing the unmet global need for AAC requires a multi-faceted approach that includes raising awareness, improving accessibility, reducing costs, enhancing education and training, fostering research and development, and considering cultural and linguistic diversity in the provision of AAC. Collaborative efforts between governments, healthcare professionals, educators, technology developers, and advocacy groups are crucial to making meaningful progress in meeting the communication needs of individuals with speech and language disorders worldwide.

8 https://www.communicationcommunity.com/aacfileshightech/.

9 https://financialpost.com/pmn/business-wire-news-releases-pmn/global-augmentative-and-alternative-communication-devices-low-tech-aac-mid-tech-aac-high-tech-aac-market-report-2023-2029-researchandmarkets-com.

Digital assistive technology: Screen readers

Market overview

Screen readers are designed to assist people with visual impairments, particularly those who are blind or have limited vision, in accessing and interacting with digital content such as websites, applications, and eBooks. Functionally, a screen reader is any software application that converts digital text and visual information into synthesized speech or braille output by connecting to a braille hardware device for some advanced devices. Users have the flexibility to customize various aspects, such as adjusting the speech speed or changing the language.

Market size

The Lancet Global Health Commission on Global Eye Health estimates that approximately 43.3 million people were blind in 2020, and nearly 295 million people had moderate and severe vision impairment (MSVI).[10] Nearly 55 per cent were women, and 70 per cent were older than 50 years.

There are also significant regional variations in prevalence. Globally, 92 per cent of people who are blind and 88 per cent of those with MSVI live in LMICs. Western sub-Saharan Africa has the highest age-standardized prevalence of blindness (1.1 per cent), and North America the lowest (0.1 per cent). South Asia has the highest age-standardized prevalence of MSVI (6.4 per cent). Because of large regional populations, the highest number of blind people live in South Asia (11.9 million) and East Asia (9.1 million). MSVI follows a similar pattern.

While estimates exist of those who may require screen readers, it is challenging to estimate the market size for screen readers or even the number of devices and users in circulation. Even when using tracking measures like cookies, or self-reported surveys, it is still difficult to distinguish between those who use screen readers for convenience (i.e. when driving, multi-tasking, or senior citizens with decreasing vision proficiency) as opposed to disability. Further, individuals may have multiple disabilities complicating the analysis. Additionally, the utilization and popularity of built-in and open-source software contribute to the lack of certainty, as these have no 'licensed' user base that may be leveraged. Further, the lack of tracking of or reporting on web

10 Moderate and severe vision impairment is defined as visual acuity worse than 6/18, but equal to or better than 3/60. Blindness is defined as visual acuity worse than 3/60.

pages accessed through screen readers through standard web-tracking measures (cookies, Google Analytics etc.) is an added complexity.

Market trends

COVID-19 led to a growing recognition worldwide about the importance of making digital content accessible to all. The market for screen readers is poised for growth due to:

- *Enabling country policies:* Several countries and regional entities (e.g., Argentina, Australia, Brazil, the European Union, India, Japan, Kenya, South Africa, the United Kingdom, and the United States of America) have enacted accessibility laws to ensure that people with disabilities have equal access to digital content and services or included this within their disability or anti-discrimination regulations.
- *Growing need:* The high prevalence of vision loss blindness is a significant factor driving market growth. Additionally, the expanding ageing populations, associated with various vision-related disorders, contributes to the demand for screen readers.
- *Artificial intelligence (AI):* Advances in machine learning and AI have enhanced screen reader capabilities, improving accuracy and flexibility in response to evolving digital content forms. There may be increased demand for screen readers with AI capabilities that allow users to customize their experience.
- *Increased multi-modal communication:* One report indicates that screen-reader manufacturers are becoming more interested in multimodal interaction and haptic feedback (also called kinaesthetic communication or 3D-touch) technology.[11] Improving the user experience can entail combining several sensory inputs such as haptic feedback, touch gestures, and voice commands.
- *Seamless integration:* There is likely to be significant gain from screen readers to seamlessly integrate with different smart devices (wearables, home systems etc.) along with each other as many users report using multiple screen reader software across different devices (laptops, tablets, mobile phones) or applications (digital documents, e-books, web browsing, financial services etc.).

11 Verified Reports, Screen Readers, 2019-2024.

Market segmentation

The market for screen readers is diverse and can be segmented:

- *By desktop versus mobile platform:* Some screen readers are designed for computers and laptops. Mobile Screen Readers are tailored for smartphones and tablets, like VoiceOver for iOS and TalkBack for Android devices.
- *By built-in versus standalone*: Some screen readers are built into digital devices providing seamless accessibility without additional tools. Other screen readers are available as standalone software for laptops, tablets, and smartphones, offering flexibility for users to choose the screen reader that best suits their needs. Selecting a screen reader depends on various factors, including the type of device in use, preferred browsers, and specific applications. There are few standalone screen readers designed specifically for mobiles.
- *By commercial versus open source:* Some screen readers are commercially available, with the software being proprietary and available for a fee or yearly licenses. These provide advanced features, dedicated support, and are often used in professional settings. Other screen readers are available for free as open-source software.[12] These rely on community contributions, fostering collaboration, customization, and affordability for users. Both are widely used. Major open-source software like NVDA have a large active community supporting feature revisions, yet the additional feature availability with built-in software and comfort of existing user base may inhibit further uptake of open-source software.
- *By operating system (OS):* Screen Readers are typically built to be compatible with one operating system. Most people prefer Windows as the main OS for their primary screen reader, yet Apple systems (iOS) are more commonly used. Based on self-reported screen-reader proficiency, Apple OS might be considered too advanced for less proficient screen reader users.[13]

Compatibility between the screen reader and the device/browser combination is crucial for optimal performance. Some screen readers can be scripted to work seamlessly with applications, expanding their utility for users with diverse needs.

This report explores the screen-reader market, with a focus on software offerings, and does not evaluate standalone devices visual assistance devices with screen reading capabilities.

12 Denoting software for which the original source code is made freely available and may be redistributed and modified.

13 WebAIM User Survey 2021.

Key features

While there are no minimum technical and functional standards for screen readers, we outline applicable sections from: (1) The WHO-UNICEF Assistive Product Specifications (APS) for audio book players (see table 6);[14] (2) Web Content Accessibility Guidelines (WCAG) that govern accessibility of web content (see table 7); and (3) Accessible Rich Internet Applications (ARIA), geared to enhance the accessibility of web content for people with disabilities (see table 8).

Table 6: WHO-UNICEF Assistive Product Specifications: Selected functional requirements for audio book players

Feature	Standalone/Tabletop Audio DAISY Player
Audio formats	AAC (audio), AMR-WB+, FLAC, MP3, Ogg Vorbis, Speex, WAV
Digital document formats	• DAISY 3.0 and EPUB 3 text-only books • DAISY 2.02 TOC only audiobooks • DAISY 2.02 and DAISY 3.0 full-text full audio synchronized books • docx, doc, html, and txt files
Text-to-speech function	Built-in text-to-speech function with preferred languages
Variable speed playback	• Slow down to 75 per cent or less • Speed up to 200 per cent or more
Additional features	• Internet connectivity for content transfer and firmware update • Optional: Built-in camera or compatible with external camera and built-in optical character recognition

Note: Standalone/Tabletop Audio DAISY Player apply to audio players with Digital Accessible Information System (DAISY) capability. Advanced audio coding (AAC); Extended Adaptive Multi-Rate – Wideband (AMR-WB+); Free Lossless Audio Codec (FLAC), MPEG Audio Layer III (MP3); Waveform Audio File Format (WAV).

Available guidelines, research, and evidence around screen-reader user needs and preferences can be used to define a set of key features that would characterize a user-friendly screen reader interface.

14 Specifically, those that apply to Audio players with Digital Accessible Information System (DAISY) capability.

Table 7: Selected technical and functional features for screen readers

Key features	Description
Text-to-speech conversion	Allow users to adjust speech rate, volume, and preferences.
Navigation commands	Provide keyboard commands for efficient element navigation.
Braille output	Support refreshable Braille displays for tactile feedback.
Annotations and descriptions	Include descriptive information for non-text elements.
Compatibility with AT	Ensure integration with other assistive tools.
Customization	Allow users to customize settings for a personalized experience.
HTML mark-up	Use semantic HTML for better screen reader interpretation.
Alternative text	Provide descriptive alternative text for non-text content.
Keyboard compatibility	Ensure keyboard navigation for users relying on-screen readers.
Visually led content	Make web content understandable without visual cues.
Dynamic content	Avoid automatic carousels. Allow user-controlled interactions.
Accessibility overlays	Test overlays for compatibility with screen readers.

Table 8: Screen reader-friendly interfaces

Key features	Description
Large touch targets	Design touch targets to be easily accessible on mobile devices.
Limited links	Minimize links in banners to enhance navigation efficiency.
Skip links	Provide skip links for quick access to essential page sections.
Short paragraphs	Use short paragraphs to aid screen reader users in content comprehension.
Adequate (sub-)headings	Structure content with clear headings for easy navigation.
Coded headings	Follow HTML specifications; use correct heading levels.
Alt-text for images	Provide descriptive alt-texts for images for accessibility.
Careful with modals	Ensure modals receive focus for accessibility. Test thoroughly.
Avoid CAPTCHAs	Avoid using CAPTCHAs. Consider alternative security measures.
Follow coding standards	Use standard components. Adhere to coding standards for accessibility.
Test with a screen reader	Familiarize yourself with screen-reader usage for effective testing.

Important parameters in the quality of screen readers include the number of tasks that can be performed and user-friendliness of the software. Examples include user-friendliness to install and navigate the software; multiple language support; voice recognition; integration with Braille displays; ability to perform tasks in word processing, spreadsheets, and presentations, e-mail, web-browsing, videoconferencing, or PDF applications. Multiple language support is still limited across many technologies, and language-coverage gaps remain for specific functionalities such as text-to-speech (TTS).

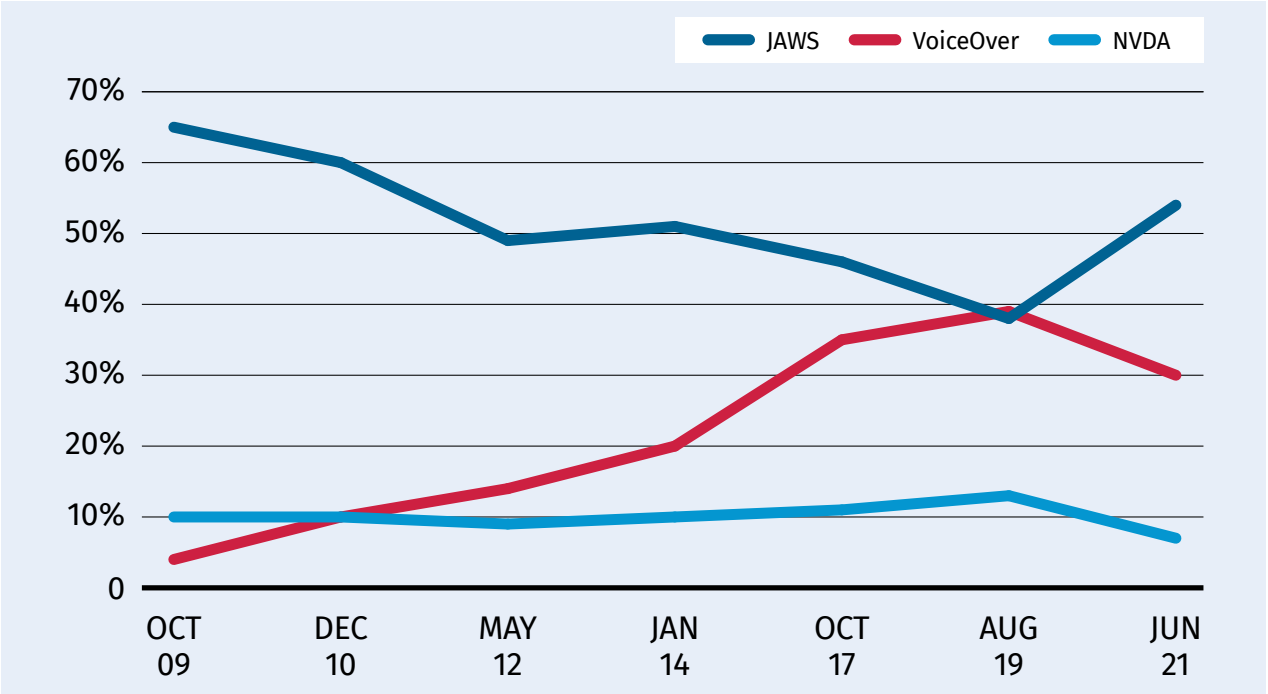
Supplier landscape

The screen-reader market is characterized by multiple commercial and open-source offerings. Many major device or operating-system manufacturers also offer built-in screen-reader software. In recent years, the market has consolidated, with many previously popular screen-reader offerings becoming defunct, obsolete, or inactive. Each screen reader has differentiating features. No all-in-one solution exists. Many users have more than one screen reader. Nearly 40 per cent use three or more.

It is difficult to estimate the comparative uptake between open source and commercial solutions, due to challenges in market-size estimation. According to the user surveys conducted by WebAIM (for 'Web Accessibility in Mind", a non-profit organization based in the United States) the three preferred desktop-based screen readers are: Job Access with Speech (JAWS), NonVisual Desktop Access (NVDA), and VoiceOver. JAWS is a leading commercial screen reader for Windows. NVDA is the leading open-source software. VoiceOver is an integral part of the iOS and macOS ecosystem, and a popular choice for its integration across Apple devices.

According to the same survey, JAWS reported usage had been declining since 2009 and in 2019, NVDA took over as the most popular choice. However, since then, JAWS seems to have regained their lead. Primary usage varied greatly by region. JAWS usage was much higher than NVDA in Australia and North America. NVDA usage was higher in Europe, Africa/Middle East, and Asia (see figure I).

Figure I: Historical trends in primary screen reader usage



Source: WebAIM User Survey (2021)

Commercial solutions often ensure compatibility with a wide array of software, have frequent updates for optimal performance and are backed by dedicated development teams that ensure regular support. Further, commercial solutions offer advanced functionalities, including support for complex applications and superior customization options.

Open-source solutions rely on community contributions, potentially leading to varied update frequencies. A stable and active community is thus a critical factor. Some screen-reader and assistive-technology communities[15] have noted that certain open-source offerings like NVDA, backed by a strong community, are just as robust as commercial products like JAWS (Job Access with Speech). Open-source alternatives might have customization limitations since they focus on simple and essential functions, but they offer greater transparency and community-driven improvements. Users of both commercial and open-source solutions are dependent on regular updates and maintenance to ensure their ongoing compatibility with the latest systems, creating a notable sustainability risk, even when manufacturers provide 'lifetime' offerings. The consequences are varied but involve an increase in health inequity, accentuated by pre-existing disparities in technological readiness, such as those reflected in the digital divide experienced in various LMICs. Major manufacturers have broad screen-reader offerings for desktops and mobile phones, with commercial and open-source offerings (see table 9).

15 https://blog.equally.ai/disability-guide/jaws-vs-nvda/ ; https://www.techassistantforblind.com/blog/nvda-vs-jaws-a-comprehensive-comparison-of-screen-reader-softwares-features-accessibility-ease-of-use-and-customization/ ; https://medevel.com/os-screen-readers-for-visually-impaired-users/.

Table 9: Leading commercial screen-reader manufacturers

Manufacturer	Product	Compatibility	Key features	Indicative price *(in United States dollars)*
Freedom Scientific *(USA)*	JAWS	Computer only Windows	Primarily screen reader with Text to Speech and Braille output, Built-in DAISY player; skim reader; text analyser; pearl camera (print-to speech add on)	90 / year 1,475 (lifetime)
	ZoomText	Computer only Windows	Primarily screen Magnifier for computer screen (focused on low vision as opposed to blind users), echoes your typing and essential programme activity, and automatically reads documents, web pages, email.	85 / year 800 (lifetime)
	ZoomText Fusion	Computer only Windows	Combines JAWS with ZoomText, offering a dual solution with both screen reading and magnification. Integrated solution, screen reading, and magnification	Available, 170 / year 1,540 (lifetime)

Manufacturer	Product	Compatibility	Key features	Indicative price *(in United States dollars)*
Dolphin Computer Access *(UK)*	Dolphin ScreenReader	Computer only Windows	Screen reading, Windows compatibility; customized speech settings; Scan & Read printed text; navigate with a keyboard or braille display; natural voice reading	Lifetime: 1,105 to 1,200
	Supernova	Computer only Windows	Screen reading, magnification, Windows compatibility; intelligent reader and magnifier; scan and read paper (print to-speech); natural voice reading	Lifetime: 1,195 to 1,435
Cambium Learning Group *(USA)*	Kurzweil 3000 (+Read the Web extension)	Computer only Windows and MacOS	Educational software with text-to-speech support, aiding students with various learning needs. Educational software, text-to-speech; customized reading rate; Natural Text-to-Speech voices in 13 languages; OpenDyslexic font, text magnification; OCR capability.	Single-user license 1,065 to 1,200 (Bulk-purchase tiered pricing available)

Manufacturer	Product	Compatibility	Key features	Indicative price *(in United States dollars)*
VisioBraille GmbH (BAUM Retec) *(Germany)*	COBRA	Computer Only Windows	Screen reader (voice and braille) Magnification up to 32x Edge Smoothing and extra-large mouse pointer	Obsolete[i] 849
Serotek	System Access	Computer Only Windows	Speech and Braille output, accessibility features	Obsolete Trial download available
Upward Spiral Software	TalkButton	Computer Only Microsoft Word on Windows and Mac	Primarily geared towards individuals with speech difficulties TalkButton works together with Microsoft Word to create an extensive text-to-speech environment, highlighting of spoken text and keyboard echo.	Obsolete Trial download available

i Listed as obsolete if company is defunct or listed website is unavailable, or no pay links are currently available. However, the software was reportedly in use as of 2021.

Note: Listed by popularity if known.

Table 10: Leading open-source and in-built screen readers

Manufacturer	Product	Compatibility	Key features	Type
NV Access *(Australia)*	NVDA	Computer Only Windows	Speech synthesizer in 50 languages; textual formatting report; Braille-display enabled; optional audible mouse tracker	Open source

Manufacturer	Product	Compatibility	Key features	Type
BRLTTY team *(Online collective)*	BRLTTY	Computer Only Linux/Unix	Basic text to speech support; support for multiple braille codes; can integrate with other braille displays and speech synthesizers;	Open source
GNOME project[i] *(USA)*	Orca	Computer Only Linux	Screen reader (braille/ speech); magnifier with auto-focus; different voice types	Open-Source
Microsoft *(USA)*	Narrator	Computer Only Windows	Text-to-speech, Braille output; pick and read sentence; verbosity level adjustment; scan mode; narrator key	Built-in
Apple *(USA)*	VoiceOver	Computer and Mobile iOS + macOS	Text-to-speech, Braille support. Audio screen reader; swipe and flick-through; double-tap; select icon and buttons with voice commands	Built-in
Google *(USA)*	TalkBack	Mobile only Android	Android compatibility, spoken feedback, navigation support; swipe and flick-through; double-tap; select icon and buttons with voice command; activate with different gestures	Built-in / Free (Built into Android)
	ChromeVox	Computer and Mobile ChromeOS	Web-based extension for Chrome – audio screen reader for content displayed on the web (HTML5; CSS; JavaScript)	Open source / Free (Web based, built into Google Chrome)

i Initially offered by Sun Microsystems. After the Oracle acquisition, the software became community driven.

Notes: Listed by popularity if known. Cascading Style Sheets (CSS) and HyperText Markup Language (HTML) are coding languages.

Product catalogue

All products generally offer the following features:

- *Text-to-speech conversion:* Screen readers use synthesized speech to read aloud text displayed on a screen. Users can customize speech settings such as rate, volume, and voice.
- *Navigation commands:* Screen readers provide keyboard commands to navigate through different elements on a screen, facilitating efficient interaction with websites and applications.
- *Braille output:* Many screen readers support refreshable Braille displays, offering tactile feedback to users who read Braille.
- *Annotations and descriptions:* Screen readers include features providing additional information about images, buttons, and non-text elements, enhancing context and comprehension.
- *Compatibility with assistive technologies:* Integration with other assistive technologies, such as screen magnifiers and voice recognition software, ensures a comprehensive solution for diverse user needs.
- *Customization*: Users can personalize screen-reader settings, adjusting preferences for speech, shortcut keys, and Braille display settings.
- *Keyboard compatibility:* Navigability using keyboard-only commands facilitates accessibility for users who rely on keyboards rather than mouse input.

A detailed table comparing key screen-reader features based on information provided by manufacturers or public sources is available in the Product Catalogue Annex to this document. The list is not exhaustive but is indicative for providing visibility to buyers on potential screen-reader product options.

User preferences

Understanding user needs and preferences is critical to underline what works and what could be improved. Some commonly reported challenges according to a study of blind participants by Lazar et al. are: 1) page layouts causing confusing screen-reader feedback; 2) conflict between screen reader and application; 3) poorly designed or unlabelled forms; 4) no alternative text for pictures or poor image-recognition capabilities; and 5) three-way tie between misleading links, inaccessible documents (such as portable document files or PDFs), and screen-reader crashes.[16]

16 Jonathan Lazar, Aaron Allen, Jason Kleinman, & Chris Malarkey (2007). What Frustrates Screen Reader Users on the Web: A Study of 100 Blind Users, *International Journal of Human–Computer Interaction,* 22:3, 247-269, DOI: 10.1080/10447310709336964.

Screen-reader user preferences are described in the WebAIM annual user surveys, which are often used as a source of information. The most recent iteration from 2021 is based on 1,568 responses from participants from North America (57.7 per cent), Europe (23.5 per cent) and Asia (8.2 per cent). A few key insights are noted below:

- *No 'one size fits all':* There has been an increasing trend among users reporting using multiple screen readers. This might indicate that there may be distinct utility to different screen readers (some might work better for web vs eBooks vs documents etc.) and no single screen reader currently on the market is able to meet all their needs/requirements.
    - *Multiple screen readers:* Most respondents (71.3 per cent) use more than one desktop/laptop screen reader. This was up from 53 per cent in July 2015 and 68 per cent in 2017; 39 per cent use three or more, and 15.9 per cent use four or more different screen readers.
- *Accessibility remains heterogenous:* Content is not uniformly accessible using screen readers. While the Internet of Things is critical that content accessibility guidelines be customized across content type (web content, eBooks, digital documents) there is also a need for screen reader software to improve capability to deal with a wider array of content types, especially among different digital documents.
    - *Increased accessibility of web content:* 39.3 per cent of participants feel that web content has become more accessible in the past year. However, 42.3 per cent say there have been no changes made to web content accessibility. 18.5 per cent of screen reader users state web content has become less accessible since 2020.
- *Mobile vs. desktop:* While desktops remain the primary way people use screen readers, they are increasingly being used on mobile devices. Further, for many common tasks (banking, shopping etc.) , mobile apps may be preferred over websites. This highlights the need for device specific screen reader customization/software, as well as the need for better integration between different software and devices across a user.
    - 90 per cent of surveyed screen reader users use screen readers on their mobile devices. WebAIM also notes this number has increased over the last 12 years. They also note that participants with disabilities (91.6 per cent) are more likely to use a mobile screen reader compared to individuals surveyed without disabilities (71.4 per cent).
- Respondents indicated that they are slightly more likely to use a mobile app than a web site for common online tasks. The preference for mobile app usage increased to 51.8 per cent in 2021, up from 50.8 per cent in 2019 and 46 per cent in 2017.

Conclusion

The future of screen readers holds immense promise as technology advances to address accessibility concerns and diverse user requirements. The integration of artificial intelligence and machine learning is anticipated to enhance screen-reader accuracy, adaptability, and the overall user experience.

Despite progress, challenges persist in achieving seamless integration across platforms and devices. While built-in screen readers in mobile operating systems have improved, there is a need for greater collaboration between assistive technology providers and mainstream developers to ensure consistent accessibility features.

Accessibility standards for digital content, including WCAG and ARIA, have gained traction, yet implementation gaps persist as they are not enforced by legislation in most geographies. Industry stakeholders must prioritize universal design and usability testing to bridge these divides, and governments should focus on creating enforceable digital accessibility standards to create truly inclusive digital environments.

Finally, specific concerns around local languages, user awareness and training, higher illiteracy rates etc. will have to be addressed to live up to the potential for wider uptake in LMICs. The industry should continue refining these interfaces to cater to a broader spectrum of user needs. Most critically, ensuring financial accessibility to these technologies for those most disadvantaged will require specific financial schemes, as well as a concerted effort to make open-source software as feature-rich as possible.

Digital assistive technology: Smartphones

Market overview

Mobile phones are ubiquitous in today's world. Smartphones can act as assistive devices in addition to their primary function as telecommunication devices. Smartphones cluster multiple accessibility features, such as screen readers, voice control or captioning, and facilitate access to apps and other content for people with disabilities.

Market size

Over 5.4 billion people worldwide have at least one mobile subscription and approximately 4.3 billion people use or own a smartphone.[17] Due to the rapid proliferation of smartphones and mobile devices, over 57 per cent of the world is using mobile internet, with most growth in mobile internet and smartphone adoption in 2022 coming from low- and middle-income countries (LMICs). The smartphone industry is one of the fastest growing in the world, with projections indicating an increase from 485 billion dollars in 2022 to 793 billion dollars by 2029.[18] Smartphones are available through three major channels. In 2021, nearly half of global smartphones were sold through e-commerce, followed by one third in retailers and branded stores.[19]

The rapid increase in smartphone ownership has not been homogenous, with 76 per cent of inhabitants of high-income countries owning smartphones compared to 45 per cent in emerging markets.[20] These numbers drop further when considering low-income countries. For example, as of 2022, smartphone ownership is merely at 21 per cent in sub-Saharan Africa and 35 per cent in South Asia. Furthermore, there are regional disparities in mobile connectivity with nearly 70 per cent of sub-Saharan Africa still using 3G, unlike the rest of the world where a majority use 4G.

Despite the potential for smartphones to act as assistive devices, people with disabilities in LMICs are significantly less likely to own a smartphone compared to people without disabilities. A GSMA study in seven countries found that the disability

17 GSMA The-State-of-Mobile-Internet-Connectivity-Report-2023.

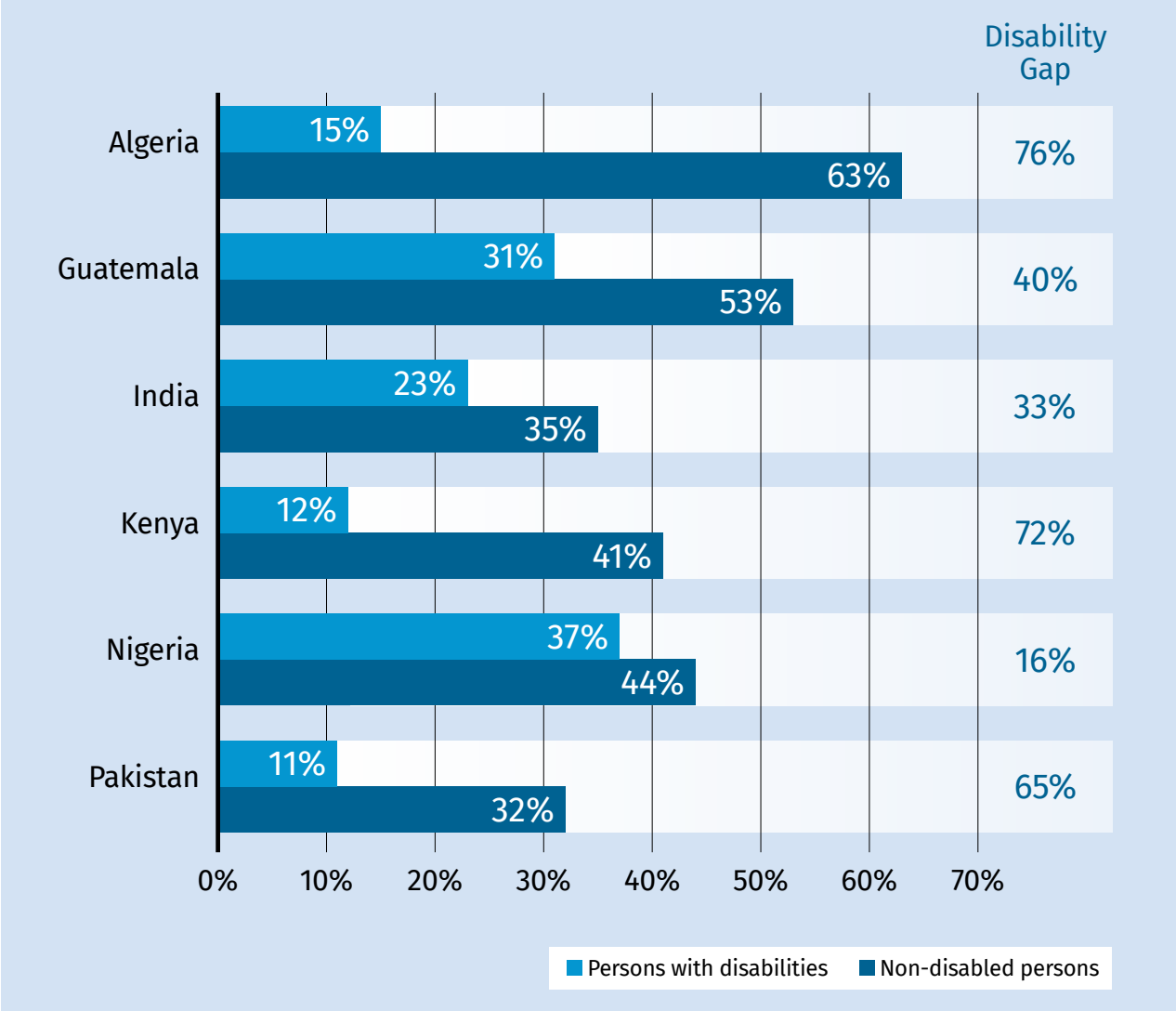
18 https://www.fortunebusinessinsights.com/industry-reports/smartphone-market-100308.

19 Ibid.

20 https://www.pewresearch.org/global/2019/02/05/smartphone-ownership-is-growing-rapidly-around-the-world-but-not-always-equally/.

gap ranged from 16 per cent in Nigeria to 76 per cent in Algeria (see figure II). Bridging this gap is vital to digital inclusion.

Figure II: Disability Gap in smartphone ownership



Source: GSMA State of Mobile Disability Gap Report 2021

This report explores the smartphone market and products with a focus on accessibility features.

Market growth drivers

Several factors contribute to the growth trend of the smartphone market, including increased disposable income, improved telecom infrastructure, the availability of affordable handsets, and frequent product launches. Rising consumer interest in 5G devices is motivating manufacturers to incorporate 5G chips into their smartphones. Lower prices, the emergence of 4G and 5G network technologies[21] and network development

21 https://www.mordorintelligence.com/industry-reports/smartphones-market.

and expansion, as seen with the launch of Super TimeFreq Folding, a new innovative 5G-Advanced technology by China Telecom and Huawei, contribute to market growth.

Additionally, the market experiences growth through key players engaging in strategic partnerships to enhance services. Notable collaborations include Samsung Electronics expanding its agreement with Google to advance smart home interoperability (2022).

Market growth rate is expected to be the highest for the Asia-Pacific region, followed by Latin America and Africa.

Accessibility trends

The recent surge in accessibility features is driven by an increasing commitment to inclusion and universal design. As societal awareness of diverse user needs grows, smartphone manufacturers are intensifying their focus on accessibility. An ageing population and an increased understanding of diverse disabilities are propelling this trend.

In response to growing momentum around accessibility, smartphones are incorporating features that cater to users with visual, auditory, and motor impairments. Apple first launched VoiceOver in 2009, marking a turning point for visually impaired users, with Android soon following with TalkBack. Haptic feedback, customizable gestures, and voice assistants became integral components, with significant improvements in 2016 and 2017.

Government regulations and industry standards further incentivize smartphone manufacturers to prioritize accessibility. In 2008 and 2013, global standards like Web Content Accessibility Guidelines (WCAG) and Global Public Inclusive Infrastructure (GPII) set the stage for a more comprehensive approach to accessibility providing benchmarks for creating accessible digital interfaces and prompting companies to integrate such features. The adoption of digital content access for people with disability in legal frameworks like the Americans with Disabilities Act (ADA), the European Accessibility Act (EAA), and The Rights of Persons with Disabilities Act 2016 in India, to name a few, has further fuelled this trend.

Market segmentation

Smartphones with accessibility features are typically segmented by operating system. The market is categorized into Android (Google), iOS (Apple) and others (HarmonyOS, KaiOS, etc.). Android is the market leader, with a roughly 70 per cent share as of 2021 while Apple's iOS has a market share of 25 per cent.[22] Huawei's HarmonyOS has captured a 3 per cent share.[23]

22 Ibid.

23 https://www.counterpointresearch.com/insights/global-smartphone-os-market-share/.

Accessibility standards and guidelines for smartphones

Existing international standards

There is no harmonized international standard or certification for mobile phone accessibility. There are, however, international accessibility guidelines and best practices that offer recommendations for creating accessible digital content, products, and services. These guidelines are intended to ensure that web content technology is accessible for people with diverse abilities. Two prominent international accessibility guidelines are:

- *Web Content Accessibility Guidelines (WCAG):* Developed by the World Wide Web Consortium, WCAG 2.0 is a set of guidelines and technical specifications for making web content accessible to people with disabilities. WCAG covers recommendations for designing, developing, and testing web content to enhance its usability for people with disabilities. WCAG is organized around four core principles of being perceivable, operable, understandable, and robust (POUR) (see table 11).

Table 11: Web Content Accessibility Guidelines 2.0 accessibility principles

Principle	Description
Perceivable	Information and user-interface components must be presented in a way that users can perceive them.
Operable	User-interface components and navigation must be operable.
Understandable	Information and operation of the user interface must be understandable.
Robust	Content must be robust enough that it can be reliably interpreted by a wide variety of user agents, including assistive technologies

- *ISO/IEC 40500:2012 – Information technology:* Developed by the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC), this international standard, often referred to simply as ISO/IEC 40500, aligns with WCAG 2.0. It provides the adoption of WCAG 2.0 as an international standard, supporting the creation of accessible digital content and documents.

WCAG 2.0 acts as the foundation for many organizations and countries looking to develop their own digital accessibility standards. India and Kenya have both recently released digital accessibility standards that conform with WCAG 2.0.

Considerations from international standards for mobile accessibility

Examples of widely used considerations, techniques and technical properties that determine accessibility of web content on smartphones and mobile content are listed here (see table 12).

Table 12: Web Content Accessibility Guidelines 2.0 considerations and techniques for mobile content

Principle	Consideration	Description
Perceivable	Small screen size	Make it easy to optimize content for small screens.
	Zoom/magnification	Methods for users to control text size on mobile devices.
	Contrast	Contrast for varied environments, especially outdoors.
Operable	Keyboard control	Support external keyboards for various disabilities.
	Touch Target Size and Spacing	Make interactive elements touch-accessible with sufficient size.
	Touchscreen gestures	Design for ease of use, considering screen reader users.
	Device manipulation gestures	Provide alternatives for device manipulation gestures.
	Placing buttons where easy to access	Consider ease of access for different user preferences and needs.

Principle	Consideration	Description
Understandable	Changing screen orientation	Support both orientations and notify users of changes programmatically (Portrait/Landscape).
	Consistent layout	Maintain consistent layouts across pages / screen sizes.
	Positioning page elements before scroll	Ensure vital information is visible without scrolling (for users with low vision).
	Grouping operable elements	Improve touch target size and reduce redundancy for better usability.
	Provide indication on actionable elements	Visually distinguish actionable elements for all users, especially those with vision impairments.
	Provide instructions for touchscreen and device manipulation	Offer clear instructions for gestures, aiding discoverability, and usability.
Robust	Virtual keyboard for the type of data entry required	Setting the type of keyboard helps prevent errors and ensures formats are correct but they can be confusing for people who are using a screen reader.
	Easy data entry methods	Users can enter information on mobile devices in multiple ways such as on-screen keyboard, Bluetooth keyboard, touch, and speech. Minimize text entry.
	Support the properties of the platform	Examine internal and external (with apps) consistency of mobile device features especially with Android OS as it allows external apps through Play Store.

Accessibility features of major operating systems

There is alignment between mobile operating system accessibility features and WCAG 2.0 principles. Mobile platforms often go beyond these guidelines to address broader device-usage scenarios. As such, there are smartphone-specific accessibility guidelines provided by the operating system developers that leverage the WCAG 2.0 principles.

Both Apple (iOS) and Google (Android) have established accessibility guidelines and best practices to ensure that their mobile operating systems are accessible. These guidelines offer recommendations for app developers.

Accessibility features across iOS and Android support different types of disabilities.

- *Vision*: Both iOS and Android offer screen readers (VoiceOver and TalkBack, respectively). iOS's Magnifier and Android's Magnification gestures assist in zooming and exploring the screen.
- *Hearing*: iOS includes Live Listen, which amplifies nearby sounds, while Android offers Live Transcribe for real-time text conversion.
- *Motor*: Features like iOS's Switch Control and AssistiveTouch enable control through adaptive switches and on-screen touch gestures. Android's Switch Access and Voice Access serve a similar purpose.
- *Cognitive*: iOS's Guided Access and Speak Selection provide focused app use and text-to-speech functionality. On Android, Google Assistant, and features like Live Transcribe offer voice command support and real-time text conversion.
- *Speech*: Both iOS and Android incorporate TTS and voice-recognition features. Predictive typing and word suggestion are available on both platforms, aiding users with speech challenges.

Apple encourages app developers to adhere to accessibility guidelines, contributing to a more consistent experience. Android's open-source nature has led to diverse devices and user interfaces, providing users with options to choose devices that align with their preferences. While the core functionalities are comparable, users may find variations in feature availability or performance based on individual needs and preferences. Ultimately, the 'better' choice depends on the user's familiarity, comfort, and specific requirements. Users may find that certain features or aspects of one operating system better suit their needs.

Some of the basic accessibility features offered by Android (see table 13) and iOS (see table 14) accessibility suites are highlighted below. Specific features may differ from device to device and operating system version or require that you enable accessibility shortcuts in the device and/or download additional apps. The table in the Product Catalogue Annex provides a sample comparative of accessibility features of both operating systems across a range of smartphone-specific accessibility requirements, with a table comparing operating systems available in Appendix E.

Table 13: Sample of Android accessibility suite

Category	Android feature	Description
Screen Reader	TalkBack	Uses audio feedback and vibration to help users who have vision impairments interact with their devices.
	Braille keyboard	Supports Unified English Braille and enables users to enter 6-dot Braille on the screen.
	Select to Speak	Provides users with spoken feedback when manually selected to be read aloud.
Display changes	Display size	Users have the option to change the font size and display size.
	Magnification	Helps users temporarily magnify or zoom the screen when required.
	Color and contrast	Android offers alternative views for users with low vision and those who are color blind.
Interaction controls	Lookout	Google app that uses the camera to help users with vision impairment obtain information related to their surroundings.
	Voice access	Users can control their Android device using spoken commands with this feature.
	Switch access	Allows users to interact with their devices without using the touchscreen.
Audio and text	Live caption	Provide automatic captioning for content viewed on a mobile device that does not require wi-fi or a mobile network. On Pixel phones, this is also available for calls.
	Live transcribe	Provides users who are deaf or hard of hearing the ability to turn their phone into a live transcription service. Can interpret sounds and words in over 70 languages.
	Sound notifications	Keeps users informed about the sounds in their homes. Allows users to connect sounds in their homes, such as fire alarms and doorbells, to automatic notifications on their screens.
	Real-time text	With RTT, users can make use of text during a phone call for more effective communication.

Table 14: Sample of iOS accessibility suite

Category	iOS Feature	Description
Vision	VoiceOver	Describes what is happening on the screen and helps users navigate content from battery level to text blocks.
	VoiceOver + Braille	Allows users to connect Bluetooth Braille devices for VoiceOver output.
	Speak screen	Even with VoiceOver off, users can have messages, emails, Safari, and almost any other text read aloud.
	Magnifier	Operates like a digital magnifying glass to help users increase the size of any physical object using their camera.
Mobility	Voice Control	Navigate their iPhone, iPad, iPod touch, or Mac using only voice commands and interact with any iOS apps. Voice control requires iOS 13 or later.
	Switch Control	Users can control their iOS device with just a single tap using a range of adaptive switch hardware.
	AssistiveTouch	This feature lets users adapt their touchscreen to suit specific physical needs. If tap or pinch or another gesture doesn't work, users may swap it with a customized gesture.
	Touch Accommodations	Users can adjust the response of their screen to touch with this feature on iPhone, iPad, iPod touch, or Apple Watch.
Hearing	Sound Recognition	This feature uses on-device intelligence to recognize and inform users when a specific sound is detected.
	Headphone accommodations	Users can customize their listening experience while watching a movie, listening to music, or speaking to someone by adjusting sound frequencies according to their specific needs
	Live Listen	This assistive audio feature allows users to have clearer conversations in loud places by turning iPad and iPhone into a remote microphone that transmits sound back to Made for iPhone hearing aids.
	Made for iPhone Hearing Aids	Made for iPhone hearing aids connect directly into Apple's iOS and provide users the ability to stream audio from their phone, to answer phone calls, and to communicate with others by using iPad and iPhone microphones to improve sound quality.

Table 15: Mapping of Android and iOS accessibility features

Feature	iOS (iPhone/iPad)	Android	Accessibility type(s)
Screen Reader	VoiceOver	TalkBack	Vision
Magnification	Magnifier	Magnification Gestures	Vision
Switch Control	Switch Control	Switch Access	Motor
Voice Assistant	Siri	Google Assistant (Voice Access)	Cognitive, Motor
Speech-to-Text	Dictation	Google Keyboard with Voice Typing	Hearing, Cognitive
Captioning and Subtitles	Closed Captions	Live Transcribe	Hearing
Voice Commands	Voice Control	Voice Access	Motor
Sound Amplification	Sound Recognition	Sound Amplifier	Hearing
Hearing Aid Compatibility	MFi Hearing Devices Support	Compatibility with Hearing Aid Streaming	Hearing
Customizable Text Size	Dynamic text	Font Size and Display Size settings	Vision
Color Inversion	Smart Invert Colours	Color Inversion	Vision
Mono Audio	Mono Audio	Mono Audio	Hearing
Guided Access	Guided Access	Screen Pinning (similar functionality)	Cognitive, Motor
Closed System for Sensory Issues	Guided Access	None specified, but third-party apps exist	Cognitive, Sensory
Live Transcribe	Not inbuilt, third-party apps available	Live Transcribe	Hearing

In the absence of a harmonized international standard, it is challenging to evaluate the utility and comprehensiveness of guidelines developed by OS developers, as well as many third-party app developers. For a comprehensive understanding of accessibility compliance, the creation of additional evaluation based on platform-specific guidelines and standards is recommended.

Supplier landscape

Global suppliers

The smartphone market is concentrated, with six leading companies collectively having a 70–85 per cent market share by volume in 2022:[24,25]

- Samsung, a global tech giant with a presence in 180 countries, is renowned for its wide range of smartphones from flagship to budget-friendly models. Samsung is the global market leader (28 per cent market share in 2022) and leads in all regions except North America and Europe.
- Apple is synonymous with premium smartphones like the iPhones that use iOS and is a closed ecosystem. Apple is tied with Samsung, with 2022 global market share at nearly 27.8 per cent, and dominates the European and North American markets.
- Xiaomi, a Chinese tech innovator, has gained international acclaim for delivering feature-rich smartphones at competitive prices. Xiaomi has significant presence in Brazil, China, India, Singapore, Türkiye, and certain other Asian countries. Its subsidiary POCO also manufactures smartphones (now as an independent company). Xiaomi holds nearly 13 per cent of the global market, and ranks just behind Samsung in Asia, and was third in South America and Europe.
- Oppo is recognized for its emphasis on camera technology. Its subsidiary OnePlus also manufactures smartphones. It held nearly 7 per cent of the global market (including OnePlus) and is in the top five suppliers in Asia and Europe, seventh in Africa and with just a small presence in American markets.
- Huawei, a global technology giant, has made a mark with its innovative smartphones, and is now in the process of releasing their own HarmonyOS. It accounted for nearly 6 per cent of the global market and ranked just behind Samsung and Apple in Africa. The company is also among the top five brands in Europe and South America.
- Vivo offers smartphones with advanced features and an emphasis on photography capabilities. It held roughly 4 per cent of the global market, but has significant presence in China, India and Southeast Asia (approximately 9 per cent Asian market share).

Other notable suppliers include: Google, Honor, Infinix, Motorola Mobility (Lenovo), Nokia, Realme and Tecno (see table 16).

24 StatCounter reports.

25 CounterPoint research reports.

Table 16: Leading smartphone brands

Manufacturer *(country)*	Operating system	Geographical presence	Major Smartphone Lines	Reference Pricing *(in United States dollars)*
Samsung *(South Korea)*	Android (OneUI)	180+ countries	Flagship (Premium): Samsung Galaxy, Note series	700 and above
			Mid-range: Galaxy A	300 to 700
			Budget: Galaxy M	Up to 300
Apple *(USA)*	iOS	180+ countries	Premium: iPhone	700 and above
			Mid-range: iPhone SE	400 to 500
Xiaomi Inc *(China)*	Android (to be replaced by HyperOS)	100+ countries	Flagship: Redmi, Mi	200 to 700
Oppo /BBK Electronics *(China)*	Android (Realme UI, ColorOS)	60+ countries	Flagship: FindX series	600 and above
			Mid-range: Reno series	200 to 500
			Budget: Oppo A series	Up to 200
Huawei *(China)*	Android HarmonyOS	170+ countries	Premium: Huawei P Series, Mate Series	500 and above
			Mid-range: Nova Series	200 to 500

Manufacturer *(country)*	Operating system	Geographical presence	Major Smartphone Lines	Reference Pricing *(in United States dollars)*
Vivo / BBK Electronics *(China)*	Android (Funtouch OS)	60+ countries	Premium: X series	500 and above
			Mid-range: V series	200 to 500
			Budget: Y series	Up to 200
Realme /BBK Electronics *(China)*	Android (Realme UI)	27 countries (regional)	Realme 8 Series, Narzo Series	150 to 400
Motorola Mobility/ Lenovo *(USA)*	Android 11.0	Global	Mid-range/ Budget: Moto G, Moto One Series, Moto Razr, Moto Edge	100 to 700
Transsion *(China)*	Android (HiOS)	Global – High in Africa	Tecno, Itel, Infinix	100 to 800 (and above)
Google *(USA)*	Android	Global	Pixel	700 and above
HMD Global *(Finland)*	Android	Global	Nokia 8 Series, Nokia 7 Series	200 to 700
Sony *(Japan)*	Android	Mostly Japan and Europe	Xperia 1 Series, Xperia 5 Series	600 and above
Honor *(China)*	Android (MagicOS)	100+ countries	Flagship smartphones: Honor 10X Lite, Honor X30, Foldable Honor Magic V	200 to 500

Note: Reference pricing range based on prices across vendor websites and e-commerce platforms.

Local manufacturers

In addition to these global players, locally manufactured smartphones are also available, particularly in India and China. These local offerings contribute to market diversity, providing alternatives and meeting the specific needs of regional demographics (see table 17).

Table 17: Some local smartphone manufacturers

Manufacturer	Headquarters	Brands	Operating Systems	Reference Pricing *(in United States dollars)*
MicroMax	India	In Note Series, In Series	Stock Android	50 to 150
Lava	India	Z Series, BeFIT Series	Android	50 to 200
Karbonn	India	Aura Series, Frames Series	Android	50 to 200
Jio	India	JioPhone Series	KaiOS	20 to 100
IKALL	India	IK Series, K Series	Android	50 to 150
iBall	India	Andi Series, Slide Series	Android (Remix OS)	50 to 200
Xolo	India	Era Series, ZX Series	Android	50 to 150
ZTE	China	Axon Series, Blade Series	Android	200 to 700
Meizu	China	Meizu 18 Series, Note Series	Android (Flyme OS)	300 to 800

Product catalogue

For both Android and iOS, most accessibility features are available across standard devices and rarely impact product pricing of the same brand or manufacturer. However, ultra-budget smartphones might face some constraints across features that depend on new functions, are tied to specific hardware, or require higher performance (camera, RAM etc.). For some major brands, we compared 133 accessibility features (see the Product Catalogue Annex and Appendix F)[26] across a sample of smartphones within each brand to provide a representative sense of accessibility feature differences by smartphones, and their relationship with pricing.

A table in the Product Catalogue Annex lists major global manufacturers, their product lines in budget and mid categories and prices[27] based on information provided by manufacturers or publicly available information. This list is not exhaustive but is indicative for providing visibility to buyers on potential smartphone product options. Despite minor device-by-device differences, most accessibility features are determined by the operating system.

Conclusion

As technology evolves, special attention must be paid to ensuring that access is not only enhanced but is also equitable. Smartphones with built-in features increasingly have the potential to serve as digital AT. Most smartphones have extensive accessibility features although there appear some limitations for basic models, and models capable of using only older versions of an operating system. As smartphone-market penetration grows, it is critical that manufacturers harmonize core accessibility features across all offerings, offer OS updates on all models, and where not possible, finance incentives for model switches to ensure equitable access for people with fewer resources. When operating in open systems (like Android), manufacturers and app developers are not held to common standards. This leads to variations in both physical devices and software experiences.

Whilst global guidelines like Web Content Accessibility Guidelines (WCAG) and Accessible Rich Internet Applications (ARIA), (see appendices C and D) provide benchmarks for accessibility, they are not legally enforceable unless backed by local laws. Further, they typically deal with digital content, and not specific digital devices. While both Android and iOS have developed their own accessibility guidelines, the features offered are not regularly benchmarked against prevailing standards, if and where they exist. There is no external international, or local accessibility certification that manufacturers and software developers can access to certify their product and assist consumers looking for inclusive

26 https://www.gari.info.

27 Based on pricing available on Indian e-commerce websites.

products and in making informed decisions. It is critical that enforceable and localized accessibility standards be developed and incorporated into national legal frameworks for both digital content, and digital devices.

Similarly, app developers should also be incentivized to pursue inclusive design, and app certification programmes can be established to set standards and encourage developers to adopt best practices. Certified apps could then be easily identifiable to users seeking inclusive solutions.

Another key concern will be localization of accessibility features. Recognizing diverse linguistic and cultural needs, future smartphones should emphasize the localization of accessibility features. Tailoring solutions to specific regions and languages can significantly enhance the usability of smartphones for people with varying abilities.

Currently, all accessibility feature updates on the two major operating systems are likely driven by technology updates, bug reports by users, community feedback, or internal market research. There is a paucity of large-scale, representative research focusing on user preferences and feedback by disability type across core mobile accessibility features. Collaborations between manufacturers, accessibility experts, and advocacy groups can lead to more user-centric research. Understanding the unique needs and stated preferences of individuals with disabilities is crucial for developing effective and universally accessible features. Further, it is critical to facilitate dialogue between smartphone manufacturers and users with disabilities. Collecting feedback and insights directly from the community can guide the development of features that truly address the challenges faced by users with diverse abilities.

Eyeglasses

Market overview

Eyeglasses compensate for refractive error (RE). Four common types of RE are myopia (near-sightedness), hyperopia (far-sightedness), astigmatism (combined near- and far-sightedness) and presbyopia (age-related far-sightedness). Presbyopia has a different root cause and as such is often considered a separate category (it is due to the hardening of lenses as a natural part of ageing which results in people losing their ability to accommodate or to change focus from far to near).

Refractive error can be corrected by eyeglasses, contact lenses, and/or laser surgery. Prescription glasses generally involve customized lenses that are mounted into frames to correct the individual aspects of each eye's vision. These are typically worn continuously. The corrective power of lenses is indicated by dioptres ("D"). Ready-made reading glasses, on the other hand, only serve people with presbyopia, typically involving lower corrective powers. These are used for near-vision tasks only.

Market size

Refractive error is highly and increasingly prevalent in LMICs. Reliable population-based data are scarce and the current global estimates are based on systematic reviews and meta-analyses:

- Myopia is the most common form of refractive error, usually developing in childhood and adolescence. The 2019 World Report on Vision reported 2.6 billon people of all ages with myopia in 2020 (34 per cent of the global population uncertainty interval 1.97–3.43 billion),[28] which is based on a 2016 systematic review and meta-analysis by Holden et al. The authors also report regional differences, with the highest prevalence in Asia, where rates can be up to 90 per cent among young adults.[29,30]
- Presbyopia affects 1.8 billion people worldwide according to the same WHO report based on a systematic review and meta-analysis by Fricke et al in 2016.

28 WHO, World report on vision, 2019, https://www.who.int/publications/i/item/9789241516570.

29 Holden, B.A., Wilson, D.A., Jong, M., Sankaridurg, P., Fricke, T.R., Smith EL III, Resnikoff S. Myopia: a growing global problem with sight-threatening complications. *Community Eye Health*. 2015;28(90):35. PMID: 26692649; PMCID: PMC4675264.

30 Ian G. Morgan, Amanda N. French, Regan S. Ashby, Xinxing Guo, Xiaohu Ding, Mingguang He, Kathryn A. Rose, The epidemics of myopia: Aetiology and prevention, *Progress in Retinal and Eye Research*, 62, 2018, 134-149, https://doi.org/10.1016/j.preteyeres.2017.09.004. https://www.sciencedirect.com/science/article/pii/S1350946217300393.

However, globally, it is estimated that only 36 per cent of people with a distance vision impairment due to refractive error have received access to an appropriate pair of spectacles.[31] Approximately 90 per cent of people with unaddressed vision impairment or blindness live in LMICs.[32] But the coverage of essential eye care interventions in LICs is up to six times lower than that in HICs.

- Distance vision loss in many LMICs is estimated to be four times more prevalent than in HICs.[33]
- East Asia, South Asia and Southeast Asia account for 62 per cent of the moderate and severe distance vision impairment cases[34] (while representing 51 per cent of the world's population).
- Rates of unaddressed near vision impairment are greater than 80 per cent in West Africa, East Africa, and central sub-Saharan Africa, while comparative rates in many high-income regions are lower than 10 per cent.[35]
- India and China account for approximately 50 per cent of global vision impairment and blindness due to uncorrected RE.[36,37,38]

The global prescription frames and sunglasses retail market is valued at approximately 54 billion dollars[39] in 2021 with prescription frames accounting for 61 per cent. The global lenses market is valued at 50 to 60 billion dollars in 2023.[40,41] Across all segments of eyewear, the market is focused on high-value segments. These segments

31 WHO Consultation on Uncorrected Refractive Errors, International Council of Ophthalmology https://icoph.org/who-consultation-on-uncorrected-refractive-errors/.

32 Increasing eye care interventions to address vision impairment, 2023, WHO, https://www.who.int/publications/m/item/increasing-eye-care-interventions-to-address-vision-impairment.

33 WHO Key Facts on Blindness and Vision https://www.who.int/news-room/fact-sheets/detail/blindness-and-visual-impairment.

34 Bourne RRA, Flaxman SR, Braithwaite T, Cicinelli MV, Das A, Jonas JB, et al. Magnitude, temporal trends, and projections of the global prevalence of blindness and distance and near vision impairment: a systematic review and meta-analysis. The Lancet Global Health. 2017;5(9):e888-e97.

35 WHO Key Facts on Blindness and Vision https://www.who.int/news-room/fact-sheets/detail/blindness-and-visual-impairment.

36 Lou L, Yao C, Jin Y, Perez V, Ye J. Global patterns in health burden of uncorrected refractive error. Invest Ophthalmol Vis Sci 2016;57:6271-7.

37 Flaxman SR, Bourne RRA, Resnikoff S, Ackland P, Braithwaite T, Cicinelli MV, et al. Vision Loss Expert Group of the Global Burden of Disease Study. Global causes of blindness and distance vision impairment 1990-2020: A systematic review and meta-analysis. Lancet Glob Health 2017;5:e1221-34.

38 Naidoo KS, Leasher J, Bourne RR, Flaxman SR, Jonas JB, Keeffe J, et al. Global vision impairment and blindness due to uncorrected refractive error, 1990-2010. Optom Vis Sci 2016;93:227-34.

39 Safilo Group Analysis, https://assets.ctfassets.net/cmstik7jzbvm/4W6anAsxW4ixZYYE8YSADg/caa24136281215979766c635b26893ce/Eyewear_market.pdf.

40 Spectacle Lens Market Size & Share Analysis - Growth Trends & Forecasts (2023 - 2028), GlobeNewswire, https://www.globenewswire.com/news-release/2023/08/16/2726745/0/en/Spectacle-Lens-Market-Size-Share-Analysis-Growth-Trends-Forecasts-2023-2028.html.

41 Spectacle Lens Market Size & Share Analysis - Growth Trends & Forecasts (2024 - 2029), Mordor Intelligence, https://www.mordorintelligence.com/industry-reports/spectacle-lens-market.

typically target affluent, predominantly urban populations with a preference for more expensive prescription glasses.

Market growth drivers

Continued growth is projected for the global eyeglasses market, attributed to:

- *Demographic shift:* Nearly everyone will experience presbyopia as they age. WHO predicts that 1 in 6 people in the world will be over 60 years of age by 2030. Ageing has become more pronounced in LMICs and the WHO projects that by 2050, two thirds of the global population aged 60 and above will reside in LMICs.[42]
- *Lifestyle changes:* A combination of genetic and environmental factors can cause myopia. Lifestyle changes, for example, reduced time spent outdoors, increased screen time, and increased near work, among other factors, contribute to more myopia cases. According to estimates, the global myopia burden will increase to 4.8 billion in 2050 (affecting approximately 50 per cent of the global population).[43]
- *Growing policy focus:* WHO member states have adopted a resolution in 2021 that aims to achieve a 40-percentage point increase in effective coverage of RE by 2030.[44] Increased public awareness about eye health, fuelled in part by government and NGO initiatives, is propelling the demand for eyewear. For example, the President of Nigeria announced a national initiative in 2023 to provide eyeglasses to 5 million Nigerians.[45]

Market segmentation

- *By type:* The eyeglasses market is segmented into prescription glasses and reading glasses. Prescription glasses can be single focus (e.g. for myopia, hyperopia, or astigmatism) or multifocal (e.g. for astigmatism or combined myopia, hyperopia, and presbyopia). Multifocal lenses can be further segmented into bifocal lenses that are split into an upper part for distance vision and a lower part for near vision; and progressive lenses that contain three main fields of vision including near, intermediate and distance. Reading glasses are ready-made magnifiers that have the same corrective power on both lenses.

42 WHO factsheet on ageing and health, 2022, https://www.who.int/news-room/fact-sheets/detail/ageing-and-health.

43 Holden BA, Fricke TR, Wilson DA, Jong M, Naidoo KS, Sankaridurg P, Wong TY, Naduvilath TJ, Resnikoff S. Global Prevalence of Myopia and High Myopia and Temporal Trends from 2000 through 2050. Ophthalmology. 2016 May;123(5):1036-42.

44 SPECS 2030, WHO, https://www.who.int/initiatives/specs-2030.

45 President Tinubu Approves Initiative to Provide 5 Million Eyeglasses to Nigerians with Sight Impediments, 2023, https://statehouse.gov.ng/news/president-tinubu-approves-initiative-to-provide-5-million-eyeglasses-to-nigerians-with-sight-impediments/.

- *By component:* Frames and lenses from prescription glasses are commonly procured separately so consumers have more control over the style, comfort, functionality, and price. Ready-made reading glasses, however, are sold as finished goods.

Component can be further segmented as follows:

- Eyeglass lenses:
    - Lens material:
        - Glass or plastic are the main materials for making glass lenses. Glass lenses have a higher refractive index, giving them a thinner and more attractive appearance, but their low impact resistance makes them prone to breakage and unsafe for wearing. Today, most eyeglass lenses are plastic. Resin is the most used material in current plastic lens production. For example, the proportion of resin lenses in the production volume of spectacle lenses in China is around 95 per cent.[46] Resin lenses can be half the weight of traditional glass lenses while offering higher impact resistance.
        - Lenses can have various coatings for scratch resistance, anti-glare, ultraviolet protection, and anti-reflective properties.
        - Lenses are further categorized as standardized or customized lenses.
            - Standardized ('finished') lenses are most common in the market. These lenses are mass-produced with certain standardized refractive indices, designs, and functionalities. They are then edged and assembled onto frames for end users. They are designed to fit a broad range of prescriptions and may be readily available in optical stores without the need for customization.
            - Customized lenses are tailored to the specific needs of an individual's prescription, eye shape, and lifestyle. Customization may involve factors such as lens power, lens material, coating options, and additional features based on the wearer's requirements.
        - Lenses are available cut or uncut.
            - Cut lenses are fitted to specific frame designs.
            - Uncut lenses are sized to the prescription. These are edged and mounted onto the frame in a local optical assembly lab. Having the option to finish uncut lenses in-house can better fit user preferences on frame designs.

46 Independent Study on Spectacle Lens Manufacturing Market, 2021, Frost & Sullivan https://www1.hkexnews.hk/listedco/listconews/sehk/2021/1130/10029386/2021113000224.pdf.

- Lens production:
  - Plastic lenses are typically mass-produced via a precise injection mould, which is inexpensive and rapid.
  - Glass lenses are more complex to produce, involving additional steps such as polishing.[47]
- Lens market structure:
  - Mass production of plastic lenses is concentrated in China where around 560 Chinese manufacturers make resin lenses.[48] Globally, a little less than 30 per cent of the lens market is held by small to medium-sized manufacturers.[49]
- Lens delivery:
  - Users acquire lenses from hospitals, clinics, or retailers, usually along with frames following an eye examination for a prescription.

- Eyeglass frames:
  - Frame materials:
    - Typically made from metal (e.g., aluminium, silver, stainless steel, or titanium), plastic or wood. Metal frames are more durable but also more expensive. Plastic frames are the most affordable. Two commonly used plastic frame materials are Zyl and propionate.
  - Frame-production processes:
    - Injection moulding for plastic or metal forging and bending.
    - Computer Numerical Control machines to cut acetate or plastic blanks to produce glasses.
  - Frame market structure:
    - Because eyeglass production is simpler than lens production, and because frames serve as fashion accessories rather than a medical product, there are many smaller manufacturers with the capability of producing frames.

47 Ibid.

48 Minyue Lens Research Report, 2022, https://xueqiu.com/9508834377/220468333.

49 Life Care Business, Hoya https://www.hoya.com/ir/2023/en/review/lifecare.html.

- Frame delivery:
  - Consumers acquire frames from hospitals, clinics, or retailers, usually along with lenses following an eye examination for a prescription.

- Reading glasses: Reading glasses typically have power ranging from +0.75D to + 4D with 0.25D intervals. Reading glasses can be categorized by frame type: full-frame, half-frame, and rimless glasses, while full-frame glasses have the largest market share.[50]
  - Reading glasses materials:
    - Typically made from plastic lenses and frames.
  - Reading glasses production processes:
    - Lenses of specific powers are edged and assembled onto the frame and sold as ready-made products in the market.
  - Reading glasses market structure:
    - Reading glasses are mass-produced with standardized magnification strengths. They typically have a simple design with the same magnification power in both lenses. Simplicity and lack of customization not only contribute to lower production costs but also attract many smaller companies to manufacture. Compared to optical lenses, the reading glass market is much more crowded with many smaller companies such as those in China manufacturing them at low prices. Reading glasses face significant demand across many countries. Large companies on this market, such as FGX, an EssilorLuxottica subsidiary, focus on the design, manufacture and distribution of non-prescription glasses including reading glasses.
  - Reading glasses delivery:
    - Ready-made readers are generally available as consumer products in LMICs; thus, consumers can acquire readers in different places such as optical shops, retails, pharmacies, and e-commerce platforms.

Essential features of LMIC markets

Ready-made reading glasses are included in the WHO-UNICEF Assistive Product Specifications (APS) which describe the minimum requirements related to technical performance and function for safe and effective assistive technology use.

50 Non-prescription Reading Glasses Market Report, Fortune Business Insights, https://www.fortunebusinessinsights.com/non-prescription-reading-glasses-market-106233.

Table 18: World Health Organization Assistive Product Specifications for reading glasses

Quality standard
ISO 16034:2002: This international standard specifies the minimum requirements for complete single-vision ready-to-wear near-vision spectacles. These spectacles are not intended for regular use without the approval of an eyecare professional.
EN 14139:2002: This European standard specifies the minimum requirements for complete ready-to-wear spectacles. These are not intended for regular use without the approval of an eyecare professional.
US ANSI standard: Z80.31–2017: This American national standard created by the American National Standards Institute specifies the minimum requirements for complete ready-to-wear near-vision spectacles with positive power available directly to the public without the prescription of a licensed professional.
Lens
Power range: +0.75D to +4D with 0.25D intervals (The power should be labelled on each pair of glasses)
Material: Plastic/Glass
Solar ultraviolet radiation transmittance: ultraviolet radiation absorption >95 per cent close to 400nm
Resistance: Impact- and scratch-resistant
Lens diameter should depend on the lens design and frame size
Frames
Design: Full-field and half-eye frames
Weight: Light
Durability: Long
Other
Individual box, case or pouch should be provided for each pair
Cleaning cloth should be provided for each pair

Table 19: WHO Assistive Product Specifications – Essential information required for reading glasses

Product
Overall weight
Lens
Lens type
Lens material
Lens coating
Optical centration distance
Power range
Solar ultraviolet radiation transmittance
Frame
Frame dimensions: (Lens width x Bridge width x Temple width and Lens height)
Frame material
Frame colour

Quality

An appropriate pair of eyeglasses matches the person's prescription for each eye and is comfortable, durable, fits the face of the user, and acceptable in terms of style. For example, eyeglass lenses can vary in terms of materials used, manufacturing processes, coatings, and design features, which can significantly impact their quality and performance.[51]

At a minimum, eyeglasses should meet ISO quality standards or their equivalent. ISO quality standards exist for frames, uncut lenses, and mounted lenses (see table 20).

51 Cheap vs. Expensive Glasses Lenses: What Are You Paying For? 2023, Eyewellness, https://myeyewellness.com/cheap-vs-expensive-glasses-lenses-what-are-you-paying-for/.

Table 20: ISO standards for eyeglass products

Standard	Products	Description
ISO 12870: 2016	Frames	Applicable to all frame types at the point of sale by the manufacturer or supplier to the retailer.
ISO 16034: 2002	Reading Glasses (Ready-Made)	Specifies the minimum requirements for complete single-vision ready-to-wear near-vision spectacles. These spectacles are not intended for regular use without the approval of an eyecare professional.
ISO 13666: 2019	Lenses	Defines terms relating to ophthalmic optics, specifically to blanks, finished spectacle lenses and fitting purposes.
ISO 8980: 2017	Lenses	Specifies requirements and verification methods for the optical and geometrical properties for uncut finished single-vision and multifocal spectacle lenses.
ISO 8902: 2022	Lenses	Defines terms relating to raw optical glass and related manufacturing processes.

Many LMICs do not have national regulations for eyeglasses and their sale. Quality standards for glasses are often missing or not properly structured, causing disparities in the quality of eyewear sold in these markets. For example, the quality of reading glasses sold in small street optical shops remains an issue in Southeast Asia[52] where poor frame quality causes easy breakage and tiny bubbles in lenses cause vision distortion.

Product defects can compromise not only the durability of glasses but also pose potential harm to users. For instance, frames that easily break under normal usage conditions could lead to lenses dislodging and potentially injuring the wearer's eyes or face.[53] Moreover, the use of substandard materials in eyeglass frames can cause harm such as skin irritation.[54] Such quality issues may result in product recalls and damage the supplier's reputation and sales. Therefore, some manufacturers and suppliers proactively implement quality control and assurance measures to meet international quality standards. These measures focus on strength, durability, and impact resistance, even though regulations in many LMICs may be inadequate.

52 Product Narrative: Eyeglasses, 2020, ATscale, https://at2030.org/static/at2030_core/outputs/Product_Narrative-Eyeglasses_final.pdf.

53 Clear Vision, Safe Glasses: Understanding the Importance of Eyewear Testing, QIMA, 2023 https://at2030.org/static/at2030_core/outputs/Product_Narrative-Eyeglasses_final.pdf.

54 Prescription glasses and sunglasses: Problems with cheap quality, All About Vision, https://at2030.org/static/at2030_core/outputs/Product_Narrative-Eyeglasses_final.pdf.

Supplier landscape

The global eyewear market is characterized by a select number of global companies that have strong market positions in high-value markets and a very large number of manufacturers of different eyewear, mainly located in China.

Global leading suppliers

EssilorLuxottica is the world's leading eyewear company, established in 2018 with the merger of Essilor and Luxottica, respectively the leading global suppliers of lenses and frames. Other leading global manufacturers are Hoya, Carl Zeiss and Safilo.

- EssilorLuxottica (France) reported approximately 26.9 billion dollars revenues for the group in 2022.[55] Over 80 per cent of the revenues are from North America and Europe.[56] Known for several luxury brands, the company owns manufacturing sites in more than 10 countries and generates half of its revenues from direct-to-consumer sales, maintaining strong integration across the value chain.[57]
- Hoya (Japan) is the second largest global eyeglass lenses supplier. Its life-care unit's revenue in 2022 was 407,549-million-yen (approximately 2.8 billion dollars). The sales of lenses for eyeglasses make up approximately 50 per cent of the revenue at 1.4 billion dollars. North America and Europe account for around 70 per cent of the eyeglass lenses sales at Hoya.[58,59]
- Zeiss Group (Germany) reported revenue of 1.624 billion euros (approximately 1.744 billion dollars) in 2022–2023[60] from its consumer markets segment (including vision care, film, hunting and nature observation). It is the largest supplier in the China eyeglass lenses market, and accounts for close to 25 per cent of sales in China.[61]
- Safilo generated net sales 1.1 billion euros in 2022 (approximately 1.2 billion dollars) and 86 per cent of Safilo's eyewear sales are in North America and Europe.[62]

Companies such as EssilorLuxottica and Safilo have their own factories in Europe but also source products from original equipment manufacturers (OEMs), including those from China. OEMs manufacture products for other businesses. Carl Zeiss and

55 FY 2022 Results, 2023, EssilorLuxottica, https://www.essilorluxottica.com/en/newsroom/press-releases/fy-2022-results/.

56 Financial report 2022, EssilorLuxottica, https://www.essilorluxottica.com/en/cap/content/106494/.

57 Our Global Footprint, EssilorLuxottica, https://www.essilorluxottica.com/en/group/global-footprint/.

58 Life Care Business, Hoya, https://www.hoya.com/ir/2023/en/review/lifecare.html.

59 Highlights of Fiscal 2021, Hoya, https://www.hoya.com/ir/2022/en/highlight/#top.

60 Zeiss Group annual report 2022/23, 2023 , https://www.zeiss.com/annual-report/home.html.

61 German optical giant sets sights on tackling myopia, 2023, China Daily, https://www.chinadaily.com.cn/a/202310/27/WS653b1931a31090682a5eb0a1.html.

62 Financial Highlights, Safilo, https://www.safilogroup.com/en/investors/financial-highlights.

Hoya manufacture their high-end products in-house in their respective headquarters countries, Germany and Japan. They have also established their own plants in LMICs; Carl Zeiss owns a factory in China for optical lenses and has recently invested in a new factory in India. Hoya has opened factories in Thailand and Viet Nam.

By region:

- Leading global suppliers focus on high-income markets. For example, EssilorLuxottica generates around 47 per cent of its sales from North America.[63]

By segment:

- *Lenses*: EssilorLuxottica had an estimated 45 per cent market share in 2018, ahead of Hoya and Carl Zeiss, with roughly 10 per cent of market share each.[64] Together these companies thus have approximately 65 per cent of the market. The remainder is held by numerous small to medium-sized manufacturers.[65]
- *Frames*: EssilorLuxottica is also the leading global supplier of frames with an estimated 25 per cent global market share in 2018.[66] Other major suppliers, such as Safilo, were reported to have less than 10 per cent market share.
- *Ready-made reading glasses:* Most large global suppliers appear reluctant to engage in the manufacturing or sale of low-margin products such as reading glasses. EssilorLuxottica sells and produces reading glasses through FGX, a North American market leader in the design and sale of non-prescription reading glasses, which it acquired in 2010.

Leading global suppliers have begun to establish inclusive business segments specifically targeting LMIC markets to address issues of product accessibility. Two notable examples are EssilorLuxottica's inclusive business division, 2.5 New Vision Generation (2.5 NVG) and Warby Parker's donation programme titled 'Buy a Pair, Give a Pair'.

EssilorLuxottica established 2.5 NVG to provide affordable, high-quality vision products to underserved populations in LMICs who lack access to traditional distribution channels. Business solutions include a network of small vision entrepreneurs, and product innovations to make provision simpler in low-resource settings. A notable innovation is Ready2Clip™, a system combining frames with ready-to-mount lenses, allowing for the quick preparation directly on-site of customized glasses according to an individual's prescription. The 2.5 NVG line is purchased by governments, NGOs, and

63 Financial report 2022, EssilorLuxottica, https://www.essilorluxottica.com/en/cap/content/106494/.

64 Product Narrative: Eyeglasses, 2020, ATscale, https://at2030.org/static/at2030_core/outputs/Product_Narrative-Eyeglasses_final.pdf.

65 Life Care Business, Hoya, https://at2030.org/static/at2030_core/outputs/Product_Narrative-Eyeglasses_final.pdf.

66 Product narrative: Eyeglasses, 2020, ATscale, https://at2030.org/static/at2030_core/outputs/PN-Eyeglasses_final.pdf.

private sector providers, such as pharmacies and Essilor's own Eye Mitra and Eye Rafiki which are small retail entrepreneurs. 2.5 NVG currently distributes products across 50 countries in Asia, Latin America, and Africa.

Warby Parker is an American retailer of prescription glasses, contact lenses, and sunglasses. It has developed a donation programme titled 'Buy a Pair, Give a Pair,' through which over 15 million pairs of glasses have been distributed in more than 75 countries. The programme works with a handful of partners worldwide to ensure that for every pair of Warby Parker glasses purchased, a pair is distributed to someone in need. Key partners include VisionSpring, RestoringVision, and the LV Prasad Eye Institute in India.

Table 21: Global leading suppliers with multiple products (lenses, frames, reading glasses)

Name *(Headquarters location)*	**Revenue** *(in United States dollars)*	**Product (s)**	**Manufacturing sites**	**LMIC Markets served**
EssilorLuxottica *(France)*	26.9 billion	• Lenses • Frames • Reading glasses	Mostly in China, but 50 manufacturing plants in over 10 countries including Brazil, India, Laos, Thailand, and Viet Nam[i]	More than 50 countries in Asia, Latin America, and Africa.[ii]
Nikon Lenses *(Japan)*	Information not available	• Lenses • Reading glasses	Japan	Asia and Africa[iii]

i Our Global Footprint, EssilorLuxottica. See Change official website, https://www.essilorseechange.com/what-we-do/2-5-new-vision-generation/.

ii Essilor See Change official website, https://www.essilorseechange.com/what-we-do/2-5-new-vision-generation/.

iii Global Network, Nikon, https://www.nikonlenswear.cn/about_us/global_network.

Table 22: Global leading suppliers with single product focus (lenses or frames)

Company *(Headquarters location)*	Revenue	Main Product	Manufacturing Sites	Markets Served
Carl Zeiss *(Germany)*	1.6 billion euros (approximately 1.7 billion dollars) in 2022-2023 from its Consumer Market business unit	Lenses	Germany, China, and US[i]	50 countries[ii]
ChemiLens[iii] *(Korea)*	Information not available	Lenses	Korea	Mainly China followed by Viet Nam
De Rigo *(Italy)*	452.7 million euros in 2022 (approximately 500 million dollars)[iv]	Frames	Information not available	80 countries[v] including Middle East, Asia
Hoya *(Japan)*	407,549 million yen (2.8 billion dollars) revenue in 2022 life care unit, eyeglasses lenses account for around 50 per cent[vi]	Lenses	Thailand, Viet Nam	Africa, Middle East, Asia[vii]
Kering Eyewear *(Italy)*	1.1 billion euros in 2022 (approximately 1.2 billion dollars)[viii]	Frames	Information not available	Information not available
Marcolin *(Italy)*	547.4 million euros (approximately 600 million dollars)[ix]	Frames	Italy	125 countries[x], such as Brazil, China, Mexico and Russia as well as the Middle East

Company *(Headquarters location)*	Revenue	Main Product	Manufacturing Sites	Markets Served
Safilo *(Italy)*	1.1 billion euros in 2022 (approximately 1.2 billion dollars)[xi]	Frames	Italy, US, China, and Slovenia[xii]	40 countries directly served[xiii] in regions including Latin America, Middle East, Africa, Asia Pacific
Thelios *(France)*	Information not available	Frames	Italy[xiv]	Information not available

i Carl Zeiss to create 600 jobs with $270m lens factory in India, 2023, Investment Monitor, https://www.investmentmonitor.ai/news/carl-zeiss-to-create-600-jobs-with-270m-lens-factory-in-bangalore-india/.
ii Annual Report 2022/23, Zeiss Group, https://mamcache.zeiss.com/616_1702972605705.original.html.
iii Chemilens, About us, http://www.chemilens.co.kr/eng/html/chemilens/about.php.
iv Directors' Report, De Rigo, https://www.derigo.com/en/media/2023/09/management_report_2022_1208.pdf.
v 2022 Full-Year Results, Kering, https://www.kering.com/api/download-file/?path=Presentation_FY_22_VDEF_d9d384ac97.pdf.
vi Life Care Business, Hoya, https://www.hoya.com/ir/2023/en/review/lifecare.html.
vii Hoya company official website, https://hoyafilter.com/support/distributors/.
viii Kering 2022 Full-Year Results, https://www.kering.com/api/download-file/?path=Presentation_FY_22_VDEF_d9d384ac97.pdf.
ix Marcolin 2022 Report, https://www.marcolin.com/wp-content/uploads/2023/03/Press-release_Marcolin_FY22-Results_final_EN.pdf.
x Marcolin company official website, https://www.marcolin.com/en/group/about-us/.
xi Net sales of Safilo Group from 2010 to 2022, 2023, Statista, https://www.statista.com/statistics/617602/net-sales-of-safilo-group-in-italy-timeline/.
xii Safilo Group SpA – Company Profile, Global Data, https://www.globaldata.com/company-profile/safilo-group-spa/.
xiii Safilo company official website, https://www.safilogroup.com/en/investors/glance.
xiv LVMH 2018 Annual Report, https://www.lvmh.com/2018interactiveannualreport/en/104-Thelios.html#/page/104.

Note: List categorized by product type and listed alphabetically by producers.

Chinese eyewear manufacturers

Global eyewear production is concentrated in China. Other LMICs such as Brazil and India also produce frames and spectacles, but most markets import their products from China.[67] Chinese manufacturers, once primarily production partners to large global eyewear companies, have become market contenders, actively promoting their

67 IAPB, Glasses for All Report, 2024, https://www.iapb.org/learn/resources/glasses-for-all/.

own brands with in-house research and development. In 2022, the total export of eyewear from China was valued at 7.4 billion dollars.[68]

By region:

China is the largest exporter of eyewear to LMIC markets.[69] For instance, 78 per cent of India's eyewear imports come from China.[70] Nigeria relies significantly on imports, with over 90 per cent from China. Even though countries like Brazil and Mexico have local eyewear-manufacturing capabilities, Chinese manufacturers are still important for their eyeglasses markets.[71]

Table 23: China eyeglasses exports (2022)

Segment	Value *(in United States dollars)*	Compound annual growth rate	Volume (millions)	Compound annual growth rate	Percentage of China export in world export value
Spectacles	4.0 billion	+19%	2,427	+18%	50%[i]
Frames	1.8 billion	+11%	397	-1%	53%[ii]
Lenses	1.4 billion	-5%	1,614	+15%	40%[iii]
Total	7.4 billion	+11%	Information not available	Information not available	Information not available

i Spectacles, goggles and the like, World Bank, https://wits.worldbank.org/trade/comtrade/en/country/ALL/year/2022/tradeflow/Exports/partner/WLD/product/900490

ii Frames and mountings, World Bank, https://wits.worldbank.org/trade/comtrade/en/country/ALL/year/2022/tradeflow/Exports/partner/WLD/product/900390

iii Lenses, spectacle, World Bank, https://wits.worldbank.org/trade/comtrade/en/country/ALL/year/2021/tradeflow/Exports/partner/WLD/product/900140

Source: 2022 China's eyewear industry import and export brief, 2023, China Optometric and Optical Association http://www.chinaoptics.com/policy/details215_4577.html

68 Briefing on the Import and Export Status of China's Optical Industry in 2022, 2023, China Optometric and Optical Association, http://www.chinaoptics.com/policy/details215_4577.html.

69 Center for Collective Learning company official website, https://oec.world/en/profile/hs/eyewear-frames#market-dynamics.

70 Eyewear market in India, 2018, Deloitte, https://www2.deloitte.com/content/dam/Deloitte/in/Documents/consumer-business/immersion/Eyewear market in India.pdf.

71 IAPB, Glasses for All Report, 2024, https://www.iapb.org/learn/resources/glasses-for-all/.

There are over 3,000 Chinese manufacturers involved in the manufacturing of eyeglasses and related products.[72] Of those, approximately 400 have annual sales of over RMB 20 million (approximately 2.8 million dollars), which classifies these companies as 'enterprises above designated size' by the Chinese National Bureau of Statistics. [73,74] Production of eyewear is in four city clusters. Each cluster has a group of related eyewear manufacturing companies and suppliers located close to each other to improve efficiency and collaboration. Danyang and Wenzhou clusters produce more affordable products, and Wenzhou focuses on export. Danyang is China's main production base, the city hosts nearly 600 eyewear manufacturers, accounting for roughly one third of China's total production of frames. [75]

Table 24: Geographical clusters of eyeglasses manufacturers in China

Cluster	Main products	Value *(in United States dollars)*	Price segment[i]	Description
Danyang, Jiangsu Province[ii]	• Lenses: 75 per cent of Chinese market production volume and 50 per cent of global market • Frames: 1/3 of Chinese market	660 million in exports in 2022[iii]	Low-to mid-end	~400 million pieces of lenses and 100 to 200 million pairs of frames are produced annually ~600 eyewear manufacturers in total
Wenzhou, Zhejiang Province	• Frames • Reading glasses	1.4 billion in exports in 2022[iv]	Low-to mid-end	80 per cent of production is exported to over 150 countries[v] ~700 eyewear companies[vi]

72 Product narrative: Eyeglasses, 2020, ATscale, https://at2030.org/static/at2030_core/outputs/PN-Eyeglasses_final.pdf.

73 Economic Overview of the Eyewear Industry in 2021, 2022, China Optometric and Optical Association, http://www.chinaoptics.com/policy/details215_4446.html.

74 Must large and medium-sized enterprises be enterprises above designated size, 2021, National Bureau of Statistics https://www.stats.gov.cn/zt_18555/zthd/sjtjr/d12kfr/tjzsqzs/202302/t20230216_1908942.html.

75 Danyang city remains world's top glasses manufacturing hub, accounting for half of global industrial outcome, 2023, Global Times https://www.globaltimes.cn/page/202303/1288291.shtml.

Cluster	Main products	Value *(in United States dollars)*	Price segment[i]	Description
Shenzhen, Guangdong Province[vii]	• Branded Eyewear: 50 per cent of the global mid-to-high-end eyewear production	1.4 billion produced annually. (80 per cent of them are exports)	Mid- to high-end	125 million eyeglasses produced annually ~800 eyewear companies
Xiamen, Fujian Province[viii]	• Sunglasses: 80 per cent of Chinese market production and over 50 per cent of global market	1.6 billion produced annually	Mid- to high-end	~200 eyewear companies

i White Paper on China's eyewear industry, 2022, https://pdf.dfcfw.com/pdf/H3_AP202211241580537853_1.pdf?1669309701000.pdf.

ii Jiangsu Danyang's annual output of lenses exceeds 400 million pairs, accounting for half of the world's total - the county-level city has become the world's "glasses capital", 2023, OurJiangsu, [Link]

iii How did a county-level city with a population of less than one million become the world's top seller of glasses? A direct look at the transformation of Jiangsu Danyang's industry, 2023, Xinhua, http://www.news.cn/fortune/20231226/f18958596b834cb181549d3e8fa7d86f/c.html

iv Wenzhou Eye Valley Industry Decoding Healthy Appearance Level Economy, 2023, Wenzhou News, https://finance.66wz.com/system/2023/09/11/105599348.shtml

v Eyeglasses Industry, 2018, The Government of Wenzhou, https://www.wenzhou.gov.cn/art/2018/4/24/art_1475545_17575567.html.

vi Industrial Cluster Development – China's Eyewear Production Base, Wenzhou, 2020, China Optometric and Optical Association, http://chinaoptics.com/news/details230_4350.html.

vii Annual output of more than 125 million pairs, accounting for more than 50% of the world's high-end glasses production Shenzhen glasses why let the world "light up," 2022, Shenzhen News, https://www.sznews.com/news/content/2022-12/01/content_25492574.htm.

viii Xiamen's eyeglasses industry is booming: there are 120 manufacturing companies, accounting for more than 80% of the domestic mid-to-high-end sunglasses market, 2020, Tencent [Link]

The five largest lens companies in China are Wanxin (15 per cent of the Chinese market volume), Vivo Optics/Mingyue (10 per cent), Hongchen (9 per cent), Huiding (8 per cent), and Yoli (7 per cent). The 10 largest suppliers account for 65 per cent share of the China's lenses market.[76] Wanxin stands out with a production capacity of 100 million lenses per year, and roughly 8 per cent of the world's total lens shipments.[77] Mingyue (Vivo Optics) and Conant are the sole publicly listed companies. Mingyue focuses on the domestic market, while Conant products are sold to more than 80 countries. The frame market is more fragmented.

76 White Paper on China's eyewear industry, 2022, https://pdf.dfcfw.com/pdf/H3_AP202211241580537853_1.pdf?1669309701000.pdf.

77 Wanxin company official website, http://www.wx-china.com/en/AboutTheBusiness/index.aspx.

Table 25: Leading eyeglasses suppliers in China by product category and capacity

Company	Capacity	Quality	International sales
Lenses and frames			
Hongchen Optical	Daily: 300,000 pieces of resin lenses	CE, ISO	More than 50 countries
Frames and reading glasses			
Ouhai Glasses	*Annual:* 24.7 million pairs[i]	CE, ISO	Experience in Southeast Asia, Europe, and the United States.[ii]
Wenzhou Readsun Glasses	*Monthly:* 500,000 pairs[iii]	CE, FDA	International customers include Disney, Sisley, and Hello Kitty.[iv]
Wenzhou Matt (Weilan) Optical	*Annual:* 30 million pieces, including 10 million reading glasses	EU-MDR[v]	OEM for Walmart, Costco, BOOTs, M&S, etc.[vi]
Wenzhou Zhantai Optical	*Monthly:* Plastic frames 1 million pieces Metal Frames 800,000 pieces[vii]	CE, FDA, ISO	Europe, the United States, Southeast Asia, Japan, India, Brazil, OEM for Safilo, MUJI, Walmart etc.[viii]
Pilot Optics	*Monthly:* 1 million pairs	CE, FDA, ISO	International customers incl. Essilor, Costco, ALDI, Watsons etc.[ix]
Wenzhou Mike Optical	*Annual:* 1.8 million pairs	CE, FDA, ISO	Global experiences with LMICs such as Zimbabwe, Cameroon, Mexico, Indonesia etc.[x]
Wenzhou Hengbo International Trade	Information not available	CE, FDA, ISO	The United States, Europe, Southeast Asia, Middle East, Africa, Asia etc.[xi]
Lenses and frames			
Wanxin Optical	*Annual:* 100 million pieces of lenses	CE, FDA	More than 40 countries[xii]

Company	Capacity	Quality	International sales
Yoli Optical	*Daily:* 250,000 pieces[xiii]	CE, ISO 9001	The United States, Africa, Asia and Europe. Joint venture with Essilor since 2011.
Select Optical	*Daily:* 15,000 pieces	CE	20 countries[xiv]
Wenzhou Sense Optical	*Annual sales:* 2 million frames	Information not available	OEM/ODM and international sales: 65 per cent Europe, 20 per cent America Continent[xv]
Conant Optical	Information not available	CE, FDA, ISO	80+ countries, including Australia, Brazil, Germany, India, Japan, Thailand and the United States.[xvi]
Huiding Optical	Information not available	CE, ISO	Mainly domestic; limited exports
New Tianhong Optical	Information not available	CE, ISO	Mainly domestic; limited exports
See World Optical	Information not available	CE, FDA	60+ countries, OEM for international brands including EssilorLuxottica[xvii]
Vivo Optics (Mingyue Optical)	Information not available	CE, FDA	Asia Pacific, Europe, and South America[xviii]

i Information provided by Ouhai Glasses.
ii Ouhai company official website, http://www.ouhaiglasses.com/yy/aboutus/aboutus/index.html.
iii Information provided by Readsun.
iv Readsun company official website, http://www.readsunoptical.com/.
v The European Medical Device Regulation (EU MDR) is a new set of regulations that governs the production and distribution of medical devices in Europe, and compliance with the regulation is mandatory for medical device companies that want to sell their products in the European marketplace. It has gradually been required in Assistive technology procurement.
vi Information provided by Matt Optical.
vii Information provided by Zhantai Optical.
viii Zhantai company official website, https://www.zhantaiworld.com/about/about-us.
ix Pilot Optics company official website, https://www.pilot-eyewear.com/about-us.html.
x Information provided by Wenzhou Mike Optical.
xi Wenzhou Hengbo official Alibaba website, https://wzhengbo.en.alibaba.com/company_profile.html?spm=a2700.shop_index.88.70.
xii Wanxin company official website, http://www.wx-china.com/en/AboutTheBusiness/index.aspx.
xiii Yoli Optical company official website, https://www.youlilens.com/about-us/.
xiv Select Optical company official website, http://www.select-optical.com/Aboutus.asp.
xv Sense Optical company official website, https://senseoptical.com/.
xvi Conant Optical company official website, https://www.conantoptical.com/about.
xvii See World Optical company official website, http://www.swoptical.com/swoptical/en/gywm.asp.
xviiii Vivo optics company official website, http://www.vivooptics.com/.

Manufacturers in other emerging markets

India is emerging as a manufacturing location. For example, Zeiss Group is setting up a manufacturing unit in India.[78] In 2022, the social enterprise VisionSpring (see next section for more details) has also moved its sourcing from China to partnering with a subcontractor or OEM manufacturer based in India. LensKart, the largest optical retailer in India that sells multiple global brands along with its in-house brand, has vertically integrated its manufacturing in India. Carl Zeiss also plans to open its biggest lens factory in India for Rs 2,500 crore (approximately 300 million dollars) in 2023.[79] India itself has a strong demand for eyewear. Moving manufacturing to India could address costs related to imports—both financial (such as import duties, taxes, and transportation) and non-financial (such as customs clearance time)—and potentially make eyewear more affordable for local Indian customers.

Manufacturing in Africa is nascent with small-scale businesses such as Wazi Vision distinguishing itself by creating high-quality, fashionable frames designed and manufactured in Uganda using sustainable materials. Despite the successes of these smaller-scale businesses, there remains a pressing need for them to expand their efforts.[80]

Table 26: Illustrative manufacturers in other emerging countries – listed alphabetically

Company	Product	Manufacturing Sites	Presence
LensKart *(India)*	Prescription Glasses	India and China	Asia, including India, Singapore, Thailand, Chinese Taipei, the Philippines, Indonesia, Malaysia, and Japan.[i]
Wazi Vision *(Uganda)*	Prescription Glasses	Frames locally manufactured from acetate and sustainable materials	Uganda

i Lenskart may shift SE Asia manufacturing to India plant, 2022, mint, https://www.livemint.com/industry/manufacturing/lenskart-may-shift-se-asia--to-india-plant-11661706547231.html.

78 Zeiss Group to invest Rs 2,500 cr on new plant in India, 2023, The Economic Times, https://economictimes.indiatimes.com/industry/cons-products/fashion-/-cosmetics-/-jewellery/zeiss-group-to-invest-rs-2500-cr-on-new-plant-in-india/articleshow/101797316.cms.

79 Ibid.

80 Eliminating poor vision in a generation, 2020, Essilor, https://www.essilorseechange.com/wp-content/uploads/2020/02/Eliminating-Poor-Vision-in-a-Generation-Report.pdf.

Social enterprises

Several social enterprises, NGOs, and major corporations aim to meet the demand for lower-cost products in emerging economies. Organizations such as VisionSpring, DOT, and GV2020 offer readers and ready-to-clip models to NGOs and private sector buyers, including pharmacy chains. Organizations like Lapaire and RestoringVision are focusing on providing affordable, quality eyewear in LMIC markets by distributing products through their retail shops and programmes respectively.

VisionSpring is a social enterprise established in 2001 with a mission focused on expanding the use of eyeglasses in emerging and frontier markets. It aims to enhance lifelong learning, safety, and well-being through eyeglasses, particularly for people vulnerable to poverty, defined as those living on less than 4 dollars per day. VisionSpring delivers quality reading glasses and frames to low-income underserved customers for as close to a dollar as possible. Key activities include delivering optical products and services, developing markets for eyeglasses, catalysing collective action, and influencing systemic change in the sector. Since 2001, VisionSpring has distributed over 8.7 million pairs of eyeglasses in more than 20 countries.

DOT Glasses is deploying an innovative supply chain solution aimed at providing affordable prescription lenses for LMIC markets. Founded in 2014, DOT Glasses offer one-size-fits-all eyeglasses. The Good Enough Vision Approach is assuming that 90 per cent correction is close to perfect with a maximum variance of ±0.75 dioptre. This approach enhances access to better vision in LMICs while reducing dependency on expensive equipment and highly trained eyecare professionals for addressing basic refractive errors and decreasing expenses for individuals seeking vision care. Using DOT Glasses' testing process, snap-together frames and pre-cut lenses, individuals can receive corrected vision in just minutes, without repeat visits that are a feature of traditional optometry in LMIC markets. However, the benefits and costs of this 'imperfect' fitting model are still debated within the industry and it has not yet become mainstream.

Global Vision 2020 was established to address the lack of eyeglasses distribution in LMICs, primarily in Africa, South America, and parts of Asia. Its main product, the USee Vision Kit™, is aimed at partner organizations such as hospitals, clinics, NGOs, and faith-based organizations. The kit includes products needed for these organizations to perform basic vision screenings (refraction) and provide eyeglasses.[81] (See the Product Catalogue Annex.)

Lapaire Glasses was founded in 2018 and now operates 40 optical shops across Africa with over 200 employees. The company offers free vision tests and aims to provide quality, affordable eyeglasses across major African cities and then in rural

81 Global Vision 2020 official website, https://gv2020.org/partner/.

areas. Eyeglasses prices range from around 30 dollars (standard lenses) to 90 dollars (progressive photochromic).[82]

RestoringVision is a 20-year-old non-profit organization focused on providing people who live on less than 2 dollars a day with the vision services and eyeglasses they need to see clearly. In 2022 alone, they empowered 3.3 million people with eyeglasses and vision services, 3 million of whom received reading glasses.[83]

Table 27: Social enterprises and NGOs focusing on emerging markets

Company	Product	Manufacturing Sites	Presence
DOT Glasses *(Kenya)*	• Frames (custom-fit/ adjustable) • Lenses (With positive and negative dioptres, ultraviolet radiation-blocking sunglass, and photochromic lenses)	• Lenses are imported from Lanson & Essilor • Frames co-designed by a subsidiary of Mercedes Benz, are imported from their partner	Presence in six countries– Ethiopia, Kenya, Nepal, Nigeria, Uganda and South Africa[i] with distribution to the United States and Zimbabwe.
GV 2020 *(USA)*	A kit with different eyewear products: • Frames • Lenses (snap-in lenses) • Reading glasses • Vision screening products	Information not available	Has delivered glasses in 65 countries
Lapaire[ii] *(Kenya)*	• Frames • Lenses	Information not available	Côte d'Ivoire, Benin, Burkina Faso, Kenya, Mali, Togo and Uganda.

82 Lapaire online shop, https://lapaire.africa/products/khartoum?variant=43801310429397.

83 RestoringVision 2022 Annual Report, https://restoringvision.org/wp-content/uploads/2023/05/FINAL-FOR-RELEASE-RestoringVision_AnnualReport_2022_5.3.2023-2.pdf.

Company	Product	Manufacturing Sites	Presence
Restoring Vision[iii] **(USA)**	• Reading glasses (90 per cent of total volume) • Myopia glasses (5 per cent of total volume) • Sunglasses (5 per cent of total volume)	Information not available	90 countries served in 2022. 147 countries have been served since its establishment.
VisionSpring (USA)	• Reading glasses • Prescription glasses • Frames	India, China, Bangladesh, Viet Nam[iv]	Focus on LMICs; distributed products in over 20 countries in Africa, Asia, Central and South America.[v] In 2022, 75 per cent of sales were in the Indian subcontinent and 17 per cent in Africa.[vi] Offices in Bangladesh, Ghana, India, Kenya, Nigeria, Uganda, Viet Nam, Zambia, and China.

i Dot Glasses company official website, https://www.dotglasses.org/home/.
ii Lapaire company official website, https://lapaire.africa/pages/about-us.
iii RestoringVIsion official website, https://restoringvision.org/about/.
iv VisionSpring Moves Manufacturing from China to India to Create a Clear Vision India, https://visionspring.org/Files/Images/about-us/Media-Room/VisionSpring-Moves-Manufacturing-from-China-to-India-to-Create-a-Clear-Vision-India.pdf.
v VisionSpring Annual Report 2022, https://visionspring.org/Files/Images/Financials/VS-AnnualReport-2022_VS4237A.pdf.
vi Ibid.

Product catalogue

Please refer to the Product Catalogue Annex for major manufacturers, their brands and product line.

Pricing overview

Pricing structure

The combined average manufacturing cost of uncut lenses and frames for prescription glasses is 1 to 1.20 dollars.[84] The manufacturing cost for reading glasses is typically 0.4 to 0.5 dollars. Final landed cost includes international and domestic freight, customs, and import duties and averages between 30 and 50 dollars but can reach 300 dollars and above. There may be additional margins if sold through a distributor in-country which are typically higher in retail sales as compared to government tenders. In high-income countries (HICs) such as Canada, the average prescription eyeglasses can range from 240 to almost 1,000 Canadian dollars.[85] Spectacles are not a 'one-off' intervention. Most users need to update their prescription and, thus, their eyeglasses periodically. This is especially applicable for children, who typically need to update their prescription every one to two years.

Inefficiencies in LMIC supply chains and added costs make glasses prohibitively expensive for the consumer, including inefficient international shipping, high import taxes, costly inventory management, and costly in-country logistics. Due to a lack of competition, retailers charge high margins on optical products, including reading glasses, this drives up the final landed cost in most settings. Due to the impact of duties and taxes, international players are considering local manufacturing options. Trial partnerships are being initiated in regions where local production costs align closely with those of major production hubs such as China. It is argued that international importing introduces not only tariff barriers but also non-tariff barriers, such as delays at the border for customs clearance and additional quality checks.

Among the various supply chain inefficiencies, import tariffs currently represent one of the major additional costs for eyeglasses (see table 28). The International Agency for the Prevention of Blindness (IAPB) published research in 2024 on import duties for eyewear in several LMICs, showing that tariffs for both lenses and glasses are generally higher than those for compared to vaccines, for example. On average, LMICs impose tariffs that are 3.3 per cent higher for lenses compared to other medical products such as vaccines. However, in some countries, the difference is even more pronounced. For

84 Independent Study on Spectacle Lens Manufacturing Market, 2021, Frost & Sullivan, https://www1.hkexnews.hk/listedco/listconews/sehk/2021/1130/10029386/2021113000224.pdf.

85 Eye Wellness company official website, https://myeyewellness.com/cheap-vs-expensive-glasses-lenses-what-are-you-paying-for/.

example, Zambia and Sri Lanka have a tariff gap exceeding 15 per cent between lenses and vaccines. While 84 per cent of LMICs offer duty-free allowances for vaccines, only 41 per cent extend these allowances to lenses and 31 per cent to glasses. Advocating for the classification of eyeglasses as medical products in LMICs could potentially help facilitate lower import tariffs.

Table 28: Illustrative import duties for reading glasses, frames, and lenses

Country	Reading Glasses	Frames	Lenses
Bangladesh	25%	25%	10%
Cambodia	7%	15%	7%
Kenya	0%	10%	0%
Nigeria	1%	7.5%[i]	0%
India	0%	0%	0%
Indonesia	10%	10%	5%
South Africa	0%	0%	0%

i EYElliance internal analysis

Cost difference between reading glasses and prescription lenses

Reading glasses or 'readers' are cheaper than prescription glasses for the following reasons:

- *Mass production:* Readers come with standardized magnification levels, typically ranging from +1D to +3D in increments of 0.25D or 0.50D. Since they are not custom-made, they can be produced in bulk, which reduces manufacturing costs. Economies of scale allow for manufacturers to spread the costs of production, materials, and design over many units, making each pair more affordable.
- *Simplified design and options:* The design of reading glasses is simpler compared to prescription glasses. Prescription glasses must be tailored to an individual's unique prescription, which involves additional manufacturing processes and quality-control measures. Readers typically come in a limited range of styles, materials, and sizes. This simplifies the manufacturing process and reduces costs compared to the customization required for prescription glasses.

Conclusion

The eyeglasses gap is concentrated in LMICs where the need is rapidly growing. A new focus from global policymakers on reducing the global burden of vision loss due to refractive error suggests that the optical sector may see rapid developments in the coming years.

Regarding supply, the international eyewear market is dominated by a handful of multinational corporations with robust positions in high-income markets, while a substantial number of eyewear manufacturers are based in China. There's an increasing interest in bolstering domestic eyewear production in countries like India, yet African countries continue to depend heavily on imports.

Domestic prices for both reading and prescription eyeglasses remain inflated due to inefficiencies in the supply chain. This situation is further aggravated by a lack of regulation on the quality and sale of eyeglasses in many countries, leading to exorbitant costs for consumers. It is essential to ensure that eyeglasses meet, at the very least, ISO quality standards or their equivalent. Moving forward, it is crucial to tackle the issues of quality control and domestic price surges to guarantee universal access to vision correction and to address the unsatisfied demand for eyecare in LMICs. An industry regulatory reform would be beneficial across many LMICs.

Hearing aids

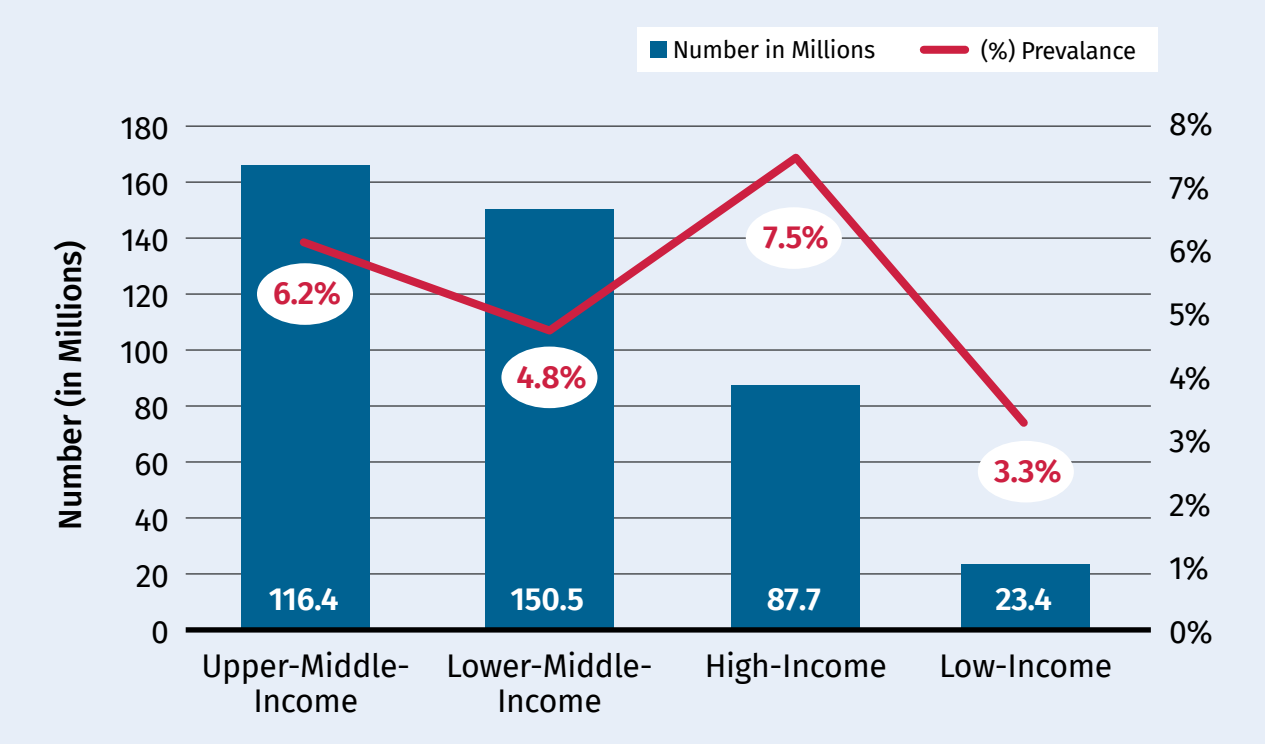
Market overview

A hearing aid is a small electronic device that can be worn in or behind the ear. It helps individuals with hearing loss to listen, communicate, and participate more fully in daily activities.[86]

Market size

Latest estimates reveal that hearing loss affects 1.6 billion people worldwide (approximately 1 in 5 members of the global population), of whom 430 million (5.5 per cent of the global population) have moderate or higher severity hearing loss.[87] By 2050, the number of people with hearing loss is projected to reach nearly 2.5 billion, of whom 700 million will have moderate or higher severity of hearing loss.[88] Prevalence of hearing loss varies across regions, with 80 per cent living in LMICs.[89]

Figure III. Prevalence of hearing loss (of moderate or higher grade) by income group



86 https://www.nidcd.nih.gov/health/hearing-aids#hearingaid_01.

87 World Report on Hearing, https://www.who.int/publications/i/item/9789240020481.

88 Ibid.

89 Ibid.

As of the latest available data in 2022, approximately 20 million units[90] are sold annually and the global hearing-aid market boasted a valuation of approximately 11 billion dollars.[91] Forecasts indicate a robust year-on-year growth of +8 per cent over the next 8 years, underscoring the sustained expansion of this market. The need is significantly under-tapped despite this growth: fewer than 20 per cent of people who need hearing solutions currently utilize them, presenting a significant growth opportunity.[92]

Key markets

The largest hearing-aid markets currently include Canada, China, France, Germany, Japan, the United Kingdom, and the United States, with distinct usage patterns influenced by economic and cultural factors. European and North American markets together account for a market share of close to 75 per cent of the hearing aids market.[93] This trend is visible in the revenue distribution of major hearing-aid manufacturers.

Market growth drivers

The following factors are driving market growth:

- *Ageing population:* The global population is ageing, and this is the most important growth driver. Age-related hearing loss is known as presbycusis. In most cases, hearing loss affects both ears and can begin when someone is as young as 30 or 40 years old and worsens gradually over time. In the United States, approximately 15 per cent of adults aged 18 and over report some trouble hearing, and nearly half of those older than 75 years of age have difficulty hearing.[94] The WHO projects that by the year 2030, one sixth of the global population will be aged 60 years or older or 1.4 billion people.[95] Population ageing initially emerged in high-income countries. For instance, in Japan, 30 per cent of the population is already aged 60 or older. However, the most significant shifts are now occurring in LMICs. It is projected that by 2050, two thirds of the global population aged 60 and above will reside in LMICs.[96]

90 Sales reported by European Hearing Instrument Manufacturers Association (EHIMA), https://www.ehima.com/about-ehima/hearing-aid-sales/.

91 Hearing Aids Market Size, Fortune Business Insights, https://www.fortunebusinessinsights.com/industry-reports/hearing-aids-market-101573; WS Audiology Annual Report 2021/22, https://www.wsa.com/en/investor-relations/annual-report/.

92 https://pubmed.ncbi.nlm.nih.gov/32011190/.

93 Fortune market insights report, https://www.futuremarketinsights.com/reports/hearing-aids-market.

94 National Institute on Deafness and other Communication Disorders, https://www.nidcd.nih.gov/health/age-related-hearing-loss.

95 WHO factsheet on ageing and health, https://www.who.int/news-room/fact-sheets/detail/ageing-and-health.

96 Ibid.

- *Increased awareness and acceptance:* Initiatives that address stigma and raise awareness on hearing loss are driving demand for hearing aids.[97] People are becoming more cognizant of the impact of untreated hearing impairment on overall well-being.
- *Technological advancements:* Innovations such as Bluetooth connectivity and improved noise cancellation enhance the appeal and effectiveness of these devices to beneficiaries. In a survey conducted by the Hearing Industries Association (HIA), hearing aid performance in terms of sound quality is stated as the primary driver for hearing aid satisfaction.[98] This technological progress not only meets the evolving expectations of consumers but also attracts new users.
- *Rising disposable income*: Studies have shown that hearing-aid demand increases in flourishing economies and decreases during recessions.[99] As more individuals can invest in their health and well-being, the affordability of hearing aids becomes a less prohibitive factor.
- *Government initiatives*: In South Korea, a government subsidy was launched in 2015 and in 2016, 85.3 per cent of individuals with newly registered hearing disabilities received hearing aid subsidies.[100] In France, hearing aids are covered by Social Security and complementary health insurance.[101] By recognizing the importance of addressing hearing loss at a public health level, governments are actively taking steps to make hearing aids more available and affordable. These initiatives not only benefit individuals with hearing impairments but also contribute to the overall growth of the hearing-aid market.
- *Provision for over-the-counter (OTC) sales*: In 2022, the United States Food & Drug Administration (FDA) published the final rule for the over-the-counter sales of hearing aids, allowing people with mild to moderate hearing loss to buy hearing aids online and in retail stores without a need for prescription.[102] OTC sales of hearing aids is further expected to increase accessibility and competition and subsequently, demand.[103]

97 Fortune market insights report, https://www.futuremarketinsights.com/reports/hearing-aids-market.

98 HIA (2019). Base Report - MarkeTrak 10. Hearing Industry Association, https://www.betterhearing.org/HIA/assets/File/public/marketrak/MT10 Hearing Review Article.pdf.

99 Amlani AM, De Silva DG. Effects of economy and FDA intervention on the hearing aid industry. Am J Audiol. 2005 Jun;14(1):71-9. doi: 10.1044/1059-0889(2005/006). PMID: 16180970.

100 Byun, H., Kim, E.M., Kim, I. et al. The trend in adoption of hearing aids following changes in provision policy in South Korea. *Sci Rep* 12, 13389 (2022). https://doi.org/10.1038/s41598-022-17459-7.

101 100% Health: care for all, 100% covered, https://www.securite-sociale.fr/home/dossiers/galerie-dossiers/tous-les-dossiers/100-sante--des-soins-pour-tous-1.html.

102 Christina Jewett, FDA Clears Path for Hearing Aids to Be Sold Over the Counter, *New York Times*, 16 August 2022, https://www.nytimes.com/2022/08/16/health/fda-hearing-aids.html.

103 https://hearingreview.com/hearing-products/hearing-aids/otc/hia-assesses-the-state-of-the-otc-hearing-aid-market.

These factors position the hearing-aid industry for sustained future growth. As technology continues to advance and public awareness expands, the global hearing-aid market is poised to play a pivotal role in enhancing the quality of life for people with hearing loss.

Market segmentation

By type: The hearing-aid market is segmented into Behind-the-ear (BTE), Receiver-in-canal (RIC), In-the-ear (ITE), and Completely-in-canal (CIC) devices, each catering to diverse user preferences and needs.

Table 29: Types of hearing aids

Behind-the-ear (BTE) *Recommended by WHO as preferred hearing aid for low- and middle-income countries*	**Receiver-in-canal (RIC)**	**In-the-ear (ITE)**	**Completely-in-the-canal/ Invisible-in-"the-canal**
			
The technology is housed in a casing that rests behind the ear and a plastic, acoustical tube directs sounds into an earbud or custom earmould.	RICs are a subset of BTE hearing aids where the receiver of the hearing aid is inside the ear canal.	Smaller than BTE hearing aids, ITE hearing aids sit inside the ear itself.	Custom made to fit completely in the ear canal with only a small plastic 'handle' on the outside for removing it when not in use.

By technology: Analog hearing aids pick up sound energy and change it to electrical signals which are then amplified and delivered through the ear canal to the eardrum. Digital hearing aids perform the same key function as analogue hearing aids but can be programmed to suit individual audiological needs. They commonly allow for many additional features and are generally the preferred option.[104] Digital hearing aids dominate the market due to their superior performance and the greater ease with which their amplification can be tailored to suit the needs and preferences of the user.

104 WHO, World Report on Hearing, https://www.who.int/publications/i/item/9789240020481.

Digital hearing aids are pre-programmed or programmable. Pre-programmed hearing aids come with settings that are configured by the manufacturer based on a typical range of hearing loss profiles and are designed to accommodate average hearing loss patterns. The customization options are generally limited to these pre-set configurations. Programmable hearing aids offer a higher level of customization. These are fitted by an audiologist or a hearing specialist who uses specialized software to adjust the settings based on the hearing loss profile of the user. Programmable hearing aids can be fine-tuned to address specific frequencies and types of hearing loss, and adjustments can be made over time as the user's hearing condition changes or as they adapt to the hearing aid.

The WHO preferred product profile for hearing-aid technology suitable for LMICs recommends the use of pre-programmed or similarly easy-to-fit hearing aids that maintain high quality standards.[105]

By distribution channels: Hearing aids are available through various channels, including independent hearing clinics, hospitals, online retailers, optical chains, and OTC options.[106]

Essential hearing aids features for LMICs

The WHO profile lists features for high-quality digital hearing aids in LMICs, emphasizing behind-the-ear hearing aids with earmoulds. This preference stems from their ease of fit, decreased susceptibility to malfunctioning due to ear-canal debris, and their cost-effectiveness, especially as earmoulds can be replaced individually as the ear canal grows. These features can be categorized across product design as well as suitability in LMICs (including cost and serviceability) which is equally critical.[107]

105 WHO, Preferred profile for hearing-aid technology suitable for low- and middle-income countries, 2017, https://www.who.int/publications/i/item/preferred-profile-for-hearing-aid-technology-suitable-for-low--and-middle-income-countries.

106 Depends on country regulations, some countries such as the United States allows certain types of hearing aids to be made available over the counter for mild to moderate hearing loss.

107 WHO, Preferred profile for hearing-aid technology suitable for low- and middle-income countries, op. cit.

Table 30: Summary of essential product design features for LMICs as defined by WHO

Feature	Rationale
Behind-the-ear	Behind-the-ear hearing aids with earmoulds enable easy fit and lower risk of earwax-related malfunctions. In growing ear canals, only the earmould needs to be replaced, saving costs.
Digital	Digital hearing aids offer increased adaptability in moulding the output signal to suit a broad spectrum of devices with a limited range; superior performance is achieved by allowing the utilization of an individual's remaining hearing capabilities.
Robust design	Hearing aids should endure mild impact shocks, light rain, and dust, and should aim for a minimum of five years of continuous usage to be suitable for use in LMICs where access to professionals for repair is limited.
Compression	Compression in hearing aids reduces the range of sound level in the environment to match the restricted hearing range. It enhances comfort for loud sounds, reduces distortion, and improves soft speech clarity. Proper management prevents amplification-induced hearing loss. Compression can be implemented as signal enters the device (input) or after the device amplifies the signal (output).
Feedback management	Effective feedback management in hearing aids is vital to prevent acoustic loops that degrade the listening experience and drain the battery excessively. Common causes include loose earmoulds, prevalent in LMICs, and difficulties faced by new and elderly users during insertion. The effectiveness is measured by added stable gain (ASG), with a recommended ASG of 10 dB or more.
On–off switch	Hearing aids must feature a dedicated on-off switch or a straightforward alternative for powering down, enabling user-friendly management and battery conservation.
Volume control	A volume control, a prevalent user-directed feature, is crucial for wearer comfort, particularly when the amplified signal is too intense.

Proper validation of hearing-aid performance is vital to avoid insufficient amplification or over-amplification in all users, especially in children with small ear canals.

Table 31: Preferred technical properties of the World Health Organization

Parameter	Minimum requirement

Maximum Output Sound Pressure Level (OSPL) (90)	100-130 dB SPL +/- 4 dB
Maximum Output Sound Pressure Level (OSPL) (90) at 1 kHz	90-124 dB SPL +/- 4 dB
Maximum full-on acoustic gain	45-67 dB SPL +5/-0 dB
Full-on acoustic gain at 1 kHz	42-70 dB SPL +5/-0 dB
Basic frequency response	200-4,500 Hz 200-2,000 Hz +/- 4 dB SPL 2000-4,500 Hz +/- 6 dB SPL
Total harmonic distortion at 70 dB SPL input	500 Hz <8% 800 Hz <8% 1,500 Hz <2%
Equivalent input noise @ 1kHz	≤30 dB SPL @ 1 kHz
Battery current drain	≤1 mA
Battery life	2-3 weeks
Telecoil sensitivity	≥75 dB at 10 mA/m

Table 32: Summary of essential product design features for LMICs

Feature	Rationale
Affordability	Cost is a key barrier to hearing-aid uptake in LMICs. Hearing aids should be affordable for the majority of those in need in each community.
Labelling	Hearing aids must bear permanent markings indicating the manufacturer or distributor's name, model name, serial number, and year of manufacture.
Robust packaging	Packaging and labelling must endure exposure to high moisture levels and withstand impacts throughout the extended distribution chain common in LMICs. Additionally, the packaging should guarantee the safe storage of the hearing aid.
Technical data	The hearing aid should be accompanied by technical specifications outlining electronic and acoustic performance expectations, including parameters detailed (see table 31).

Feature	Rationale
Contraindications	Package covers must feature an advisory statement for hearing-aid dispensers. It should instruct dispensers to recommend that potential recipients seek clearance from healthcare personnel if any of the specified conditions, such as visible ear deformity or acute dizziness, are present.
User guide	Every hearing aid should include clear usage instructions, featuring an illustration of the device, operational controls, user adjustments, and battery compartment. The guide should also cover accessory descriptions, maintenance procedures, and care instructions in the national language(s) of the purchase country, supported by easily comprehensible diagrams. Maintenance advice should consider local factors, like cost-effective dehumidification methods.
Obtainable power cells	The hearing aid should be designed to accommodate a battery type readily available in the local region. This may include conventional hearing aid batteries, watch batteries (particularly accessible in some LMICs), or rechargeable cells.
Safe packaging of batteries	Hearing aid batteries pose a danger, and ingestion may result in fatal consequences (Litovitz, Whitaker & Clark, 2010). Battery packaging must be explicitly labelled, emphasizing that batteries should be kept out of the reach of children and small animals. The design should make it challenging for a young child to open.
Appropriate earmoulds	Earmoulds should align with the hearing aid type, device gain/output, and user preferences. Suitable options include stock earmoulds (pre-configured), custom earmoulds, instant earmould products, and disposable standard flexible dome moulds.
Sustainable production facilities for earmoulds	If earmold production facilities are established, they should be designed to be sustainable within a local or regional context.
Hearing aid housing	Design of the hearing aid should facilitate the opening of the housing for maintenance purposes and adjustment of pre-set controls (if provided) without risking damage to the housing or internal components.

Feature	Rationale
Post-fitting service	As all hearing aids are prone to malfunction, service support from hearing-aid suppliers in LMICs is crucial. The nature and scope of service activities will vary based on the type of hearing aid. Facilities should be accessible for minor repairs, including device cleaning, ear hook replacement, battery contact adjustments, switch changes, and trimmer and volume control adjustments.

As the global hearing aid market continues to expand, understanding the nuanced dynamics of adoption, segmentation, and essential features becomes imperative for stakeholders shaping the future of hearing health. Along with access to hearing aids, implementation of appropriate service delivery approaches for the provision and maintenance of hearing aids is critical. WHO hearing-aid service-delivery approaches for LMIC settings provides guidance to develop and implement a national or subnational community-level programme for the delivery of hearing aid services.[108]

Quality

The WHO preferred product profile provides guidance on quality but is not designed to be a rigorous quality standard. Many products match the WHO preferred product profile on paper, but in practice have poorer sound quality, are not durable, or are difficult to programme by the provider. There are no existing or planned standards for hearing aids that provide an objective measure of quality to inform procurement for low- resource settings. According to experts, the US FDA and CE marks are not able to differentiate quality from non-quality products on the measure of hearing quality, and there is no globally recognized quality-testing programme. The FDA requires certification of gains and output of hearing aids through a third-party agency to ensure they match specifications, but this process is not a quality certification. Hearing aids are tested for quality at four levels but clinical tests for quality are not conducted at a global level, which deters transparency on product quality.

108 Hearing aid service delivery approaches, https://www.who.int/publications/i/item/9789240087927.

Table 33: Existing quality standards and gaps at the global level

Test type	What does it test for?	Testing organization	Information available publicly
Manufacturing plant tests	ISO 13845: Whether plant follows manufacturing standards and protocols.	United States FDA	Yes
Engineering tests	Whether hearing aids can perform acoustically according to their specifications. For example: can it amplify sounds higher than 80dB? Can it reduce background noise effectively?	United States FDA, European Union CE (Conformité européenne), and National Health Service United Kingdom (NHS UK)	Yes
Durability tests	Whether the product is durable. For example, drop test, climate test (moisture/dust/heat), etc.	United States FDA, European Union CE (Conformité européenne), and National Health Service United Kingdom (NHS UK)	Yes
Clinical tests	Test user experience of sound quality; provider experience with fitting and provision; longer-term performance and reliability	Independent procurers such as the United Kingdom National Health Service, International Humanitarian Hearing Aid Purchasing Programme (IHHAPP); independent audiologists conducting field testing	No

There is a need to establish quality testing derived from high-income countries' public procurer models, mirroring product selection approaches from other product areas.

Supplier landscape

Leading global hearing-aid companies

The hearing-aid market is characterized by a high level of concentration, with five established companies leading the industry. These manufacturers, Demant Holding A/S, GN Store Nord A/S, Starkey Hearing Technologies, Sonova Holding AG, and WS Audiology collectively control over 90 per cent of the market.[109] Other notable global suppliers include Aurica, IntriCon, and Sound World Solutions.

Table 34: Leading global hearing-aid manufacturers

Manufacturer *(Headquarters location)*	Country presence	Main production sites	Hearing-aid brand	Quality
Aurica *(Russia)*	Information not available	Information not available	Aurica	ISO 13845, CE[i]
Demant A/S *(Denmark)*	Subsidiaries in more than 30 countries and sells products in more than 130 countries	Mexico, Poland, China	Oticon PHILIPS Bernafon SONIC	ISO 13485, US FDA, European Union Medical Device Regulation (EU MDR)
GN Store Nord *(Denmark)*	Sold in around 100 countries. GN has its own organization in more than 30 countries and operates via partners and distributors in another 70 countries	Denmark, China, Malaysia, United States and Spain	ReSound	ISO 13485, US FDA, EU MDR

109 European Hearing Instrument Manufacturers Association, https://www.ehima.com/about-ehima/.

Manufacturer *(Headquarters location)*	Country presence	Main production sites	Hearing-aid brand	Quality
IntriCon *(United States)*	Primarily ships within United States of America[ii]	Three facilities in the Asia Pacific and the United States	Hearing Health Express[iii]	ISO 13485, All Minnesota- and Singapore-based facilities FDA registered[iv]
Sonova *(Switzerland)*	Presence in 100+ countries through subsidiaries in 30+ countries and a network of independent distributors in more than 100 countries through subsidiaries in over 30 countries and a network of independent distributors	China, Switzerland, Viet Nam	Phonak Unitron Hansaton	ISO 13485, FDA, EU MDR, the Medical Device Directive 93/42/EEC
Starkey Hearing Technologies	100+ independent partners and 28 facilities globally	US, China, and Mexico	Starkey Audibel Nuear Microtech	ISO 13485, US FDA, EU MDR, MDD CE, ISO 10993, IED 60601-1, ISO 14971, ANVISA, TGA, INVIMA, COFEPRIS, MHLW
WS Audiology *(Denmark and Singapore)*	Global office in 45 countries. 45 offices globally Sold in 130 countries through distributors	China, Denmark, Mexico the Philippines, Poland and Singapore	Signia Widex A&M Hearing Coselgi	ISO 13485, FDA, EU MDR

Manufacturer *(Headquarters location)*	Country presence	Main production sites	Hearing-aid brand	Quality
Sound World Solutions *(United States)*	Product available in LMICs through partnership with hospitals and charities	United States	HD100 HD75	United States FDA

i https://www.aurica.ru/en/sertifikaty-i-litsenzii/.
ii https://hearinghelpexpress.com/shipping-info.
iii https://hearinghelpexpress.com/categories/otc-digital-hearing-aids.html.
iv https://intricon.com/services/#manufacturing-and-tech-transfers.

Note: In alphabetical order by manufacturer

Emerging manufacturers

The market is diversified by locally manufactured hearing aids in China and India.

China:

- Global export leader:
  - China has established itself as a major global producer and exporter of hearing aids. In 2022, China exported almost 14 million units to over 110 countries.[110]
  - The United States accounted for more than 21 per cent of China's hearing aid exports. The Netherlands and the United Kingdom were other top export destinations.
- Large and efficient manufacturing capabilities:
  - China's manufacturing capabilities in the hearing-aid sector reflect its prowess in producing hearing aids at scale and with cost-effectiveness.
- Diverse product range:
  - Chinese manufacturers contribute to a diverse range of hearing aid products, offering options that cater to various user needs and preferences.

India:

- Growing Market Presence:

110 Research report on China hearing aids industry, https://www.globenewswire.com/en/news-release/2023/02/02/2600779/28124/en/Research-Report-on-China-s-Hearing-Aid-Export-Industry-2023-2032.html.

- Number of hearing Aids manufacturer based in India are serving domestic and export market.
- Local manufacturers in India are playing a role in expanding access to hearing aids, addressing the needs of the country's substantial population with hearing impairments.

- Accessible Solutions:
  - Locally manufactured hearing aids in India often focus on affordability and accessibility, making them more attainable for a broader segment of the population.

Table 35: Hearing aid manufacturers in China and India

Manufacturer	Country Presence	Brands	Quality
AcoSound[i] *(China)*	Operates in 68 countries across regions such as Africa, the Middle East, and Southeast Asia. Notable countries include Bangladesh, Cambodia, Egypt, Malaysia, and Türkiye.	AcoSound	EU CE, ISO, US FDA CFDA
ALIMCO *(India)*	Exports to Afghanistan, Angola, Bangladesh, Cambodia, Iraq, Jordan, Nepal, Sri Lanka, United Arab Emirates, Uzbekistan etc.	ALIMCO	Information not available
Alps *(India)*	Africa, India, South America and the United States	Alps	ISO 13485. IEC 60118, FDA
Austar[ii] *(China)*	Present in Asia, Europe, the Middle East, and the United States	Austar	CE, ISO 13485, ISO 9001, FDA
Cofoe[iii] *(China)*	Exports to over 46 countries including Germany, Italy, Spain, Türkiye, and the United States, and others in Asia and the Middle East	Cofoe	CE, ISO 13485, FDA
Jieyuda[iv] *(China)*	International sales experience	Jieyuda	CE
Jinghao[v] *(China)*	Top public-listed hearing-aid manufacturer in China. Exports to 90+ countries in Asia and the Middle East	Jinghao	CE, ISO 13485, ISO 9001, FDA

Manufacturer	Country Presence	Brands	Quality
Kunvmed *(China)*	International sales experience	Kunvmed	FDA
Li Sound *(China)*	Exports in Canada, Chile, France, India, Italy, etc.[vi]	Li Sound	ISO 13485, ISO 13488, ISO 9001, ISO 9002, MDD93/42 1EEC
MicroDSP *(China)*	Retail networks in Canada and the United States and Europe	Weidi Digital	CE, ISO 13485
New Sound[vii] *(China)*	20 distribution centres including Brazil, France, Iran, Kuwait, Malaysia, Türkiye, the United States. Across 110 countries in all.	New Sound	CE, FDA, ISO[viii]
Shenrui *(China)*	Products are sold in more than 100 countries in regions such as Asia, Central, South America, Middle East, and Africa.	Shenrui	CE, FDA

i https://www.acosound.net/
ii https://www.austar-hearing.net/
iii https://www.cofoe.com/
iv http://m.jieyuda18.com/about_mobile/gywm1a5.html
v https://www.jhhearingaids.com/
vi https://www.exporthub.com/lisound-hearing-aid-fuzhou/
vii https://www.usnewsound.com/pages/solution
viii https://www.hear-better.com/new-sound-digital-hearing-aids.html

Note: Listed in alphabetical order by manufacturer. MDD93/42 1EEC is the medical Device Directive — Council Directive 93/42/EEC of 14 June 1993.

Product catalogue

Please refer to the Product Catalogue Annex for major manufacturers, their brands and product lines.

Pricing overview

High-income countries

In the United States, people have access to hearing aids at 4,000 dollars and over-the-counter hearing aids at 500 to 1,000 dollars.[111] In the United Kingdom, the pricing for these hearing aids ranges from 875 to 2,387 dollars,[112] encompassing comprehensive services such as hearing tests, audiologist examinations, fitting and programming of the devices, and lifelong aftercare and fine-tuning.

Global procurement options for LMICs: UNICEF and International Humanitarian Hearing Aid Purchasing Programme (IHHAPP)

International organizations offer procurement services for hearing aids. UNICEF, for instance, offers pre-programmed behind-the-ear hearing aids at 61.69 dollars, while six programmable behind-the-ear hearing aids are available from three different brands between 55.43 and 162.13 dollars.

Similarly, the IHHAPP offers digital behind-the-ear hearing aids ranging from 85 to 175 dollars.[113] Countries ranked as low, medium, and high on the United Nations Human Development Index are eligible for participation in the IHHAPP programme. IHHAPP members include Brazil, Cambodia, Dominican Republic, Guatemala, Malawi, Mexico, Nicaragua, Papua New Guinea, Peru, the Philippines, Romania, Tanzania, Uzbekistan, and Zimbabwe.

111 https://www.health.harvard.edu/diseases-and-conditions/over-the-counter-hearing-aids-what-we-know-so-far.

112 https://www.hearingaid.org.uk/hearing-aids?price_from=695&price_to=1895&style=1&brand_id=0&page=1&limit=0&display=grid

113 https://www.ihhapp.org/products.

Table 36: International Humanitarian Hearing Aid Purchasing Programme offered hearing aids

Manufacturer	Model	Fitting range	Unit cost *(in United States dollars)*	Minimum order quantity	Other features
Alps	Erika I	Mild up to 95db loss	87	25	Pre-programmed
	Erika ND BTE	Mild up to 95db loss	85		
	Erika Power	Mild up to 105db loss	97		
	Erika ND Powe	Mild up to 105db loss	95		
Starkey	Livio 1000 BTE 13 model	Severe hearing losses; matrices: 130/70	133	10	Wirelessly programmed
	Livio AI 1000 BTE 13 model	Severe hearing losses; matrices: 130/70	135		
	Evolv AI 1000 BTE 13 PWRPLS	Severe hearing losses; matrices: 140/80	175		
Sound World Solutions	HD 75 RIC Hearing Aid	Moderately severe hearing loss	115	10	Pre-programmed

Total cost of ownership

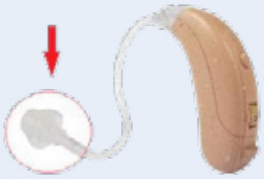
Buyers should not only focus on the initial product prices but should also consider the costs associated with repairs, battery replacements, ear dome or earmould replacements, and other post-fitting services. The total cost of ownership approach allows for a well-informed procurement preference.

Ear domes and/or Earmoulds

Ear domes (also known as ear tips or ear cushions): These are small, bell-shaped silicone pieces that connect to the end of the hearing-aid tubing. It rests deep inside the ear canal. They are available in many different shapes and sizes to fit just about anyone's ears. These small attachments are often soft and pliable and serve a crucial role in ensuring comfort and effective sound transmission for the wearer. They play a vital role in sealing the ear canal, which helps to improve sound quality, reduce background noise, and prevent feedback in hearing aids or earphones, ultimately enhancing the overall listening experience for users.

Earmoulds: Usually made of medical-grade plastic or silicone, these are custom-made so that they sit comfortably within the user's ear canal, preventing a feedback loop, which is a high-pitched whistling that is caused when the amplified sound leaks out and is re-amplified. The process to develop custom-made earmoulds requires specialized equipment and materials, adding to the supply-chain complexity of hearing aids and time required for service provision and fitting. In most places, earmould impressions are sent to a lab where a trained technician develops the mould. This can add additional waiting time and requires follow-up visits to the clinic, which may limit access. Furthermore, earmoulds typically last 2 to 3 years for adults and 6 to 12 months for children. These earmoulds need to be made consistently available to ensure long-term usage. The medical-grade silicone or plastic is often unavailable locally and must be imported.

Table 37: Difference between earmoulds and ear domes

	Ear domes	Earmoulds
		
Function	Small, soft attachments at the end of the hearing aid's sound tube	Custom-made or semi-custom earpieces
Customization	Available in various standard sizes and shapes	Custom-made based on ear impressions

	Ear domes	Earmoulds
Application	Mild to moderate hearing loss Harnesses low frequencies and allows the hearing aid to amplify higher frequencies to be heard more clearly	Severe or profound hearing loss Close fit stops amplified noises from moving back out of the canal and producing the high-pitched whistling noise created from loud sounds that leak out and become reamplified. This is known as a feedback loop
Comfort and Aesthetics	Available in various standard sizes and shapes	High level of comfort, secure fit
Cost	< 1 dollar	18 – 19 dollars

i https://www.hearingaidaccessory.com/shop/domes/oticon-minifit-hearing-aid-domes-x2-sample-domes/
ii https://www.ihear.in/wp-content/uploads/2023/05/Resound-Pricelist-March-2023.pdf

Although ear domes provide less customization, which can potentially lead to comfort issues or reduced sound quality, they are advantageous in resource-limited settings. The trade-off between customization and cost becomes particularly relevant when considering the unique needs and constraints present in LMICs. With technological advancements, good quality hearing-aid models now offer suitable feedback cancellation, and hence the need for using earmoulds is reduced. They are thus required only for those with higher grades of hearing loss where greater amplification is needed and hence, they have a greater chance of feedback.

Batteries

Hearing aids either use a replaceable zinc-air battery or a rechargeable lithium-ion battery. When using a disposable battery, users would need to replace the battery every 135 – 540 hours of usage, depending on the processing power and features of the hearing aid. The size of the battery used in a specific hearing aid is also developed for and unique to hearing aids. Hence, local availability of a specific battery size is a key consideration. Hearing-aid batteries cost between 0.35 and 0.70 dollar per battery across LMIC markets, which translates to about 12 –50 dollars per year in battery costs depending on the depletion rate. When using a rechargeable battery, hearing aids need to be charged every day and batteries need to be replaced in 2 to 3 years. Rechargeable batteries typically cost above 30 dollars, translating into a yearly cost of 10 to 15 dollars along with a charger cost of 100 dollars which translates to 33 –50 yearly cost.

Rechargeable batteries have higher upfront costs making them more cost-prohibitive. Rechargeable batteries are better than zinc-air batteries when it comes to pollution levels of the environment. Most of the leading companies offer rechargeable hearing aids.

Table 38: Indicative price of hearing aids accessories

Accessories	Indicative Price *(in United States dollars)*
Zinc-air batteries	0.35 – 0.70
Rechargeable battery[i]	31
Charger	100 – 130
Hard BTE earmould	19
Soft BTE earmould	18

i https://www.ihear.in/wp-content/uploads/2023/08/OTICON-Hearing-Aid-Price-in-Kolkata.pdf

Conclusion

The global hearing aid market remains poised for sustained growth, fuelled by an ageing global population, increased awareness, technological advancements, rising disposable incomes, and government initiatives. However, stark disparities exist in hearing-aid-adoption rates between mature and emerging markets. The industry is led by five global companies, including Demant Holding A/S, GN Store Nord A/S, Sonova Holding AG, Starkey Hearing Technologies, and WS Audiology.

Quality assurance remains a pivotal consideration, with the WHO emphasizing the need for high-quality hearing aids in LMICs. The lack of globally recognized quality-testing programmes and standards raises challenges, necessitating a concerted effort to establish frameworks derived from successful public-procurer models in high-income countries or through WHO Prequalification. Given the significant need and growing demand in LMICs, there is a requirement for a global effort that strengthens supply in LMICs to ensure sustainability and affordability, while maintaining good quality in line with global quality criteria still to be defined.

As the market unfolds, the concluding insights underscore the imperative of continued innovation, global collaboration, and inclusive design to meet the diverse needs of users worldwide.

While providing affordable hearing aids is a crucial step towards mitigating hearing loss in LMICs, it is equally important to integrate comprehensive service delivery by trained professionals with the distribution of these devices along with follow-up support and maintenance. Through comprehensive service provision, health systems can ensure that these devices are effectively used to improve hearing and quality of life for individuals. This holistic approach is essential for maximizing the impact of hearing aid programmes, especially in resource-limited settings.

Prostheses

Market overview

A prosthesis is an externally applied device designed to wholly or partially replace a missing or deficient limb segment such as an arm or leg.[114] This technology supports individuals who have experienced limb loss or difference as of their birth, or later in life from amputation, or other causes. Prostheses enhance overall physical functionality, alleviate pain, restore cosmetic appearance, protect joints, correct deformities, and prevent secondary impairments.[115]

Market size

No reliable and robust estimates exist on the global need for prostheses and existing studies report wide ranges. A 2021 study by MacDonald et al. estimated that there were 57.7 million people living with limb amputation due to traumatic causes worldwide in 2017.[116] India and China have the highest prevalence of traumatic amputations.[117] Leading traumatic causes were falls (36 per cent), road injuries (16 per cent), other transportation injuries (11 per cent) and mechanical forces (10 per cent). However, traumatic amputations are not the only cause for prostheses around the world, amputations due to non-communicable diseases like diabetes are rapidly rising and 25 per cent of the diabetic population are at risk of losing some part of their foot. Diabetes is one of the leading causes of amputation in high-income countries.[118],[119]

Globally, an estimated 65 million people live with limb amputations, and approximately 1.5 million people undergo amputations annually.[120] Of global amputees, 64 per cent

114 WHO Standards for Prosthetics and Orthotics, Part 1: Standards, 2017, https://iris.who.int/bitstream/handle/10665/259209/9789241512480-part1-eng.pdf?sequence=1.

115 Advanced Prosthetics company official website, https://www.advancedpro.biz/.

116 McDonald CL, Westcott-McCoy S, Weaver MR, Haagsma J, Kartin D. Global prevalence of traumatic non-fatal limb amputation. Prosthet Orthot Int. 2021 Apr 1;45(2):105-114. doi: 10.1177/0309364620972258. PMID: 33274665.

117 Yuan B, Hu D, Gu S, Xiao S, Song F. The global burden of traumatic amputation in 204 countries and territories. Front Public Health. 2023 Oct 20;11:1258853. doi: 10.3389/fpubh.2023.1258853. PMID: 37927851; PMCID: PMC10622756.

118 Ahmad, N, Thomas, GN, Gill, P, Chan, C, and Torella, F. Lower limb amputation in England: prevalence, regional variation and relationship with revascularisation, deprivation and risk factors. A retrospective review of hospital data. J R Soc Med. (2014) 107:483–9. doi: 10.1177/0141076814557301.

119 Behrendt, CA, Sigvant, B, Szeberin, Z, Beiles, B, Eldrup, N, Thomson, IA, et al. International variations in amputation practice: A VASCUNET report. Eur J Vasc Endovasc Surg. (2018) 56:391–9. doi: 10.1016/j.ejvs.2018.04.017.

120 Product Narrative: Prostheses, 2020, ATscale, https://at2030.org/product-narrative-prostheses/.

live in LMICs.[121] Overall, fewer than 20 per cent of the people in need of prostheses have access to them.[122]

As of 2022, the global prostheses market was valued at 1.4 to 1.7 billion dollars, projected to grow at 3–6 per cent annually.[123],[124]

- Most revenues for prostheses manufacturers are generated in high-income countries. Germany and the United States are the largest markets in the world by value.
- China is the largest market by volume, followed by India and the United States.[125]
- Regarding component type, microprocessor joints are estimated to account for more than 50 per cent of global market value, while mechanical feet account for 60 per cent of global volume.[126] The reason that high-end segments account for a larger market value is mainly due to the cost of the components used in these types of devices.
- Lower limbs make up significantly more of the prostheses market due to a higher prevalence of lower limb amputations.[127] It is estimated that more than 60 per cent of limb amputations every year are lower limb.[128]

Market growth drivers

Demand for prostheses is expected to double by 2050,[129] particularly in LMICs:

- *Increase in trauma incidence:* Trauma is a major cause of limb amputation, accounting for around 50 per cent of amputations, and up to 80 per cent of amputations are in LMICs.[130,131,132] Globally, the prevalence of traumatic

121 Prostheses for people: matching the person and their new limb, 2022, Futurum Careers, https://futurumcareers.com/prostheses-for-people-matching-the-person-and-their-new-limb.

122 UNDP Rwanda launches 3D Computer-Aided Orthotics and Prosethetic, 2022, https://www.undp.org/rwanda/blog/undp-rwanda-launches-3d-computer-aided-orthotics-and-prosthetics#:~:text=Globally%2C%20access%20to%20prosthetic%20care,prosthetic%20and%20orthotic%20training%20program%5D,

123 Limb Market Prosthetics Report 2023-2030, Fortune Business Insights, https://www.fortunebusinessinsights.com/limb-prosthetics-market-106893.

124 Our Business, Ossur, https://www.ossur.com/an-as/our-business.

125 Product Narrative: Prostheses, 2020, ATscale, https://at2030.org/product-narrative-prostheses/.

126 Ibid.

127 Lower Extremity Devices Market: Global Industry Analysis and Forecast (2023-2029), Maximize Market Research https://www.maximizemarketresearch.com/market-report/lower-extremity-devices-market/167120/.

128 Product Narrative: Prostheses, 2020, ATscale, https://at2030.org/product-narrative-prostheses/.

129 WHO Standards for Prosthetics and Orthotics, 2017, https://www.who.int/publications/i/item/9789241512480.

130 Chui, K.C., Yen, S.-C., Jorge, M. and Lusardi, M.M. (2019b). *Orthotics and prosthetics in rehabilitation*. 4th ed. Philadelphia: Saunders, pp.784-797.

131 Quality of life and complications in lower limb amputees in Tanzania: results from a pilot study, The Lancet Global Health, ISSN: 2214-109X, Vol: 6, Page: S18.

132 Equenazi A, & Flack M, & Yoo S (2019). Basic principles in the rehabilitation of persons with limb amputation. Mitra R(Ed.), Principles of Rehabilitation Medicine. McGraw Hill, https://accessmedicine.mhmedical.com/content.aspx?bookid=2550&sectionid=206763723.

amputations increased by 49 per cent between 1990 and 2019.[133] Risk factors for traumatic amputations in LMICs are especially common among older adults, as well as in unsafe working environments leading to crush injuries or electrical burns, and traffic accidents.

- *Increase in non-communicable diseases:* Patients with diabetes have a 30 times greater lifetime risk of undergoing an amputation: 80 per cent of all lower extremity non-traumatic amputations in the United States are caused by diabetes. [134],[135]. In the United States, the number of amputations caused by diabetes is estimated to have increased by 24 per cent from 1988 to 2009.[136] Furthermore, three out of four people in the diabetic population reside in LMICs. The number of diabetic cases worldwide is expected to grow globally from an estimated 537 million (with approximately 400 million in LMICs) in 2021 to 783 million in 2045.[137]

Market segmentation

By type: The prostheses market is segmented based on the type of limb that it replaces.

- Lower-limb prostheses, sub-divided into:
    - Transfemoral (TF) or above-knee prostheses
    - Transtibial (TT) or below-knee prostheses
    - Symes, partial foot, and toe prostheses
- Upper-limb prostheses, sub-divided into:
    - Shoulders
    - Transhumeral (TH) or above-elbow prostheses
    - Transradial (TR) or below-elbow for the wrist and hand

133 Yuan B, Hu D, Gu S, Xiao S, Song F. The global burden of traumatic amputation in 204 countries and territories. Front Public Health. 2023 Oct 20;11:1258853. doi: 10.3389/fpubh.2023.1258853. PMID: 37927851; PMCID: PMC10622756.

134 Molina CS, Faulk J. Lower Extremity Amputation. 2022 Aug 22. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2023 Jan–. PMID: 31536201.

135 Preventing Diabetes- Related Amputations, CDC, https://www.cdc.gov/diabetes/diabetes-complications/preventing-diabetes-related-amputations.html?CDC_AAref_Val=https://www.cdc.gov/diabetes/library/features/amputations.html.

136 15 Limb Loss Statistics that May Surprise You, 2017, Access Prosthetics, https://accessprosthetics.com/15-limb-loss-statistics-may-surprise/.

137 Facts and Figures, International Diabetes Federation official website, https://idf.org/about-diabetes/diabetes-facts-figures/.

Table 39: Examples of limb-replacement products

Upper-Limb			Lower-Limb		
Shoulder	Elbow	Hand	Above-knee	Below-knee	Foot
					

By technology: Prostheses can be purely cosmetic restoration, body-powered/mechanically controlled or externally powered.

- *Mechanically controlled:* Prostheses can function with mechanical hinges or locks. Control is manual and relies on body movements, harness systems, or residual limb muscle contractions. These are simpler in design, lighter, more durable, and cost-effective as compared to microprocessor prostheses.
- *Microprocessor controlled:* Such prostheses use sensors, software, and a built-in computer to adjust fluid-based resistance to control movement. These devices leverage sensors to detect muscle signals, movement, load, and terrain, providing a higher level of control and precision, allowing users to manipulate their prosthetic limbs more intuitively.

Prostheses components

Prostheses are typically modular, assembled from individual components rather than purchased as complete units. These components can be selected, assembled, and adjusted to adapt to a user's environmental and lifestyle factors, such as professional activity, temperature, humidity, culture (being able to sit cross-legged or to squat; limb covering colour or cosmesis), and affordability. Components from different suppliers are mostly interchangeable and compatible. Key components of lower limb prostheses are summarized in the below Table.

Table 40: Summary of lower-limb prostheses components

Component type and materials	Component descriptions and varieties
Component type: **Socket** *Materials:* Polypropylene, thermoplastic elastomer (TPE), wood, aluminium, glass-reinforced plastic (GRP), resin, carbon fibre	Interface between the residual limb and the prosthesis. Must be individually moulded and meticulously fitted to ensure pressure is distributed and to avoid damage to skin and tissue. 

Component type and materials	Component descriptions and varieties
Component type: **Liner, sleeves, socks** *Materials:* Ethylene-vinyl acetate (EVA) foam, silicone, gel, urethane, thermoplastic elastomer (TPE), Pe-Lite, wool, cotton	Soft interface materials that ensure fit, comfort, and that the prostheses stays attached to residual limb. Certain suspension systems require liners. When used properly, they provide a cushioning effect within the socket, help to minimize friction forces, and provide even pressure distribution. Socks can be used to adapt to changes in the volume of the residual limb. 
Component type: **Foot prostheses** *Materials:* Polypropylene, polyurethane, wood, rubber, carbon fibre. *Description:* Point of contact between prosthesis and contact surface, with different designs optimized for different functions or terrains. The foot can be differentiated by age group, gender, and weight. By its functionality, foot prostheses can be subcategorized into the following types:	**SACH (solid ankle cushion heel) Foot:** Rigid foot without ankle articulation. 
	Single Axis Foot contains an ankle joint that allows the foot to move up and down, enhancing knee stability. The SACH foot and the single axis foot are the most used in LMICs currently. 
	Multi-Axis Foot: More advanced than s ingle-axis foot which allows a rocking motion of the foot from heel to toe as well as from side to side. 
	Carbon Fibre Prosthetic Foot: More advanced prosthetic foot, are lighter and provide users the maximum energy storage and return. 
	Pirogoff Foot: A half foot for patients that have experienced diabetic foot amputation. 

Component type and materials	Component descriptions and varieties
	Energy Storing and Return Foot: Designed to store energy when weight is applied (during the stance phase) and release it as the foot lifts off the ground. This makes walking more efficient and reduces the energy needed from the user. 
	Microprocessor-Controlled Foot incorporate computer chips that adjust the stiffness and angle of the foot in real-time. They respond to changes in terrain and walking speed, providing a more natural gait and increased stability. 
Component type: **Knee Joint** Prosthetic knees can be mechanical or pneumatic. All prosthetic knees require some stability mechanism, this can be manual or a weight-activated auto locking system. Knee joints mimic the function of a natural knee by providing safety, symmetry, and smooth movement while walking. High variations exist in activity level, functionality, technology, and materials. *Materials:* Stainless steel, titanium, aluminium, polypropylene, nylon, wood	**Mechanical Knee Joint (Single-axis**  **Mechanical Knee Joint (Multi-axis)**  **Mechanical knees** use a mechanical hinge to replace the knee joint. Mechanical knees could be further subdivided into single-axis (monocentric) or multi-axis (polycentric knees). Polycentric knees have multiple axes of rotation that help mimic the natural movement of the human knee, providing a more stable walk, especially for those who need enhanced stability.
	Pneumatic knees utilize air to adapt their behaviour to different walking speeds as the wearer swings the leg forward and backward. 
	Hydraulic knees use fluid dynamics to control the swing and stance phases of walking, offering a smooth and natural gait at various walking speeds. 

Component type and materials	Component descriptions and varieties
	Microprocessor-Controlled knees (MPKs) incorporate sensors and computer technology to adjust the knee's response in real-time, improving stability and efficiency. They are particularly useful for navigating slopes, sitting down, and standing up. 
Component type: **Pylon** *Materials:* Wood, titanium, aluminium, steel, carbon fibre, glass-reinforced plastic (GRP), polypropylene	A **pylon** connects the socket to the foot it is lightweight it absorbs shocks. 
Component type: **Adapters** *Materials:* Mainly metals such as stainless steel, titanium, aluminium	A wide range of **adapters** is used to connect different parts of the prosthetics components. For example, there are adapter for the foot, adapter for pylon, adapter between knee joints and socket etc. 
Component type: **Cosmesis** *Materials:* Silicone, local fabrics, ethylene-vinyl acetate (EVA) foam	**Limb covering** to mimic appearance of real limb. Can be readymade or custom-designed or made from locally sourced materials 

The report will primarily focus on the key components of lower limb prostheses, such as knee joints and foot, as these are more standardized and in greater demand for large-scale procurement.

Essential Features for LMICs

In 2017, the World Health Organization (WHO) in collaboration with the International Society for Prosthetics and Orthotics (ISPO) published the WHO standards for prosthetics and orthotics (P&O) for countries to use in developing or strengthening high-quality, affordable P&O services.[138] The report recommends the evaluation of suitability from three key aspects: 1) user acceptance, 2) economic viability, and 3) technical adequacy.

138 WHO Standards for Prosthetics and Orthotics , 2017, https://iris.who.int/bitstream/handle/10665/259209/9789241512480-part1-eng.pdf?sequence=1.

Table 41: WHO standards for prosthetics and orthotics (P&O): recommendation on prosthetics technology selection

Criteria for determining the appropriateness of prosthetic and orthotic technologies, components, materials and working methods
1. User-related criteria – Products should:

• Be comfortable, with a well-adapted interface between the body segment and the device
• Be functional
• Be easy to put on and remove
• Not endanger user safety
• Be durable
• Have the best possible cosmetic appearance (e.g. Shape, finish, colour)
• Be biocompatible (for example, not provoke allergic reactions)
• Not be too heavy (in most cases, they should be light)
• Be acceptable by and adaptable to most users, i.e., they should also:
  ◦ Suit the user's needs
  ◦ Be culturally appropriate, and thus respecting the culture and lifestyle of individuals, which may include such aspects as walking barefoot, squatting and sitting cross-legged
  ◦ Suit the climate (and, if necessary, be resistant to humid, wet conditions)
  ◦ Suit the local terrain, and
  ◦ Suit local working conditions

2. Economic criteria
Products should be affordable by the system and/or the individual. • Technologies should be cost-effective and they should be: • Clinically effective • Allow for rationalization of production methods and swift fabrication • Not require many tools and machines or very advanced, expensive equipment • Require low service maintenance • Generate minimum waste, and • Made of readily available components and materials (on the local market and imported). Technologies should promote sustainable development by enhancing local entrepreneurship and making use of local markets, such as locally produced components or materials.

Criteria for determining the appropriateness of prosthetic and orthotic technologies, components, materials and working methods

3. Technical criteria

- Technologies and working methods should be of proven, documented efficacy and safety.
- Technologies and working methods should adhere to international standards.
- Technologies should ensure biomechanically correct products that can be given proper alignment.
- Products should be durable and have a long lifespan.
- Products should be easily adjusted, maintained, and repaired (as far as possible by the users themselves).
- Prosthetists and orthotists should have sufficient skill and knowledge to apply technologies and working methods; if this is not the case, training must be practically feasible and affordable.
- Working methods should not be hazardous to personnel.
- Materials should be easy to store.

Note: The priority of these criteria may vary according to the setting, but all should be considered.

Source: WHO Standards for Prosthetics and Orthotics, Part 2: Implementation Manual, 2017, https://iris.who.int/bitstream/handle/10665/259209/9789241512480-part2-eng.pdf?sequence=2&isAllowed=y

Quality

Categorization

Prostheses are categorized as medical devices by the United States Food and Drug Administration (US FDA) and the European Commission (CE marking). The US FDA exempts suppliers of prostheses from pre-market notification [510(k)] but requires them to follow a Quality System Regulation (QSR) [or the Current Good Manufacturing Practice (CGMP), or a section of the United States Code of Federal Regulations (CFR) (21 CFR 820)].[139]

139 Class I and Class II Device Exemptions, FDA, https://www.fda.gov/medical-devices/classify-your-medical-device/class-i-and-class-ii-device-exemptions.

Manufacturing standards

Several ISO standards apply to prosthetic components, including standards for ensuring quality of the design and manufacturing process and others that are specific to structural testing of components in a laboratory environment. Conformity with these standards should therefore be evaluated.

ISO 9001:2015 and ISO 13485:2016 on manufacturing standards are the most acquired ISO certifications (see table 42). ISO 9001 provides specifications for a quality management system that can be applied at any organization regardless of company size, industry, product, or service. ISO 13485 is a comprehensive management system for medical devices. ISO 13485 appears more commonly required for international procurement as it has more specific requirements. For example, it includes medical device terminology, requirements for clinical and performance evaluations and a fundamental framework infused with risk management to ensure patient safety.[140]

Table 42: ISO manufacturing standards

ISO 9001: 2015	Global standard for quality management. Helps organizations of all sizes and sectors to demonstrate their commitment to quality. Its requirements define how to establish, implement, maintain, and continually improve a quality management system. It is the most used quality management standard in the world.[i]
ISO 13485: 2016	Specifies quality management system for suppliers of medical devices and related services. Organizations can be involved in one or more stages of the life cycle, including design and development, production, storage and distribution, installation, or servicing of a medical device and design and development or provision of associated activities (e.g. technical support).[ii]

i ISO 9001:2015 - Quality management systems — Requirements [https://www.iso.org/standard/62085.html]
ii ISO 13485:2016 - Medical devices — Quality management systems — Requirements for regulatory purposes [https://www.iso.org/standard/59752.html]

140 Differences between ISO13485 and ISO9001: When do I need each?, 2023, Scilife, https://www.fda.gov/medical-devices/classify-your-medical-device/class-i-and-class-ii-device-exemptions.

Testing Standards

Various ISO quality standards exist for the structural testing of prosthetic components in laboratory settings (see table 43). These standards focus on the durability of the components.

Table 43: ISO standards for structural testing for Prostheses.

ISO 10328:2016	Specifies procedures for static and cyclic strength tests on lower-limb prostheses which typically produce compound loadings by the application of a single test force. Suitable for the assessment of the conformity of lower limb prosthetic devices/structures with the strength requirements specified in 4.4 of ISO 22523:2006.[i]
ISO 22523:2006	Covers strength, materials, restrictions on use, risk and the provision of information associated with the normal conditions of use of both components and assemblies of components. Specifies requirements and test methods for external limb prostheses and external orthoses, including the following classifications from ISO 9999: 06 03 – 06 15 Orthoses and 06 18 – 06 27 Limb prostheses.[ii]

i ISO 10328:2016 – Prosthetics --- Structural testing of lower-limb prostheses — Requirements and test methods, https://www.iso.org/standard/70205.html.

ii ISO 22523:2006 – External limb prostheses and external orthoses — Requirements and test methods, https://www.iso.org/standard/37546.html.

The following are limitations to the current ISO system:

- *No standards for sockets:* No ISO standards exist for the strength of sockets and socket materials, particularly at the interface where the leg component connects to the socket. Ongoing research and efforts to develop standards in this area are needed as new materials and processes, such as 3D printing, emerge.
- *ISO 9002 certification is often confused for ISO compliance:* ISO 9002 is a broad management standard and not an 'engineering' standard. Hence, confusion occurs when manufacturers claim ISO compliance but only have ISO 9002 certifications. This gives purchasers a false sense of security with respect to product quality.

Field testing

Clinical testing of components in a field setting is not often undertaken, which is a major gap. As recommended in the 2017 WHO Standards for Prosthetics and Orthotics, field testing should complement structural testing to determine the strength, durability, functionality, safety, and effectiveness of components in normal use. The lack of a standardized approach to field testing makes it challenging to make an objective comparison of performance. A standard protocol is needed based on a set of unified

outcome measures, pertaining to 'wear and tear' or durability. However, many small companies do not have the resources or network to conduct such field evaluations.

ISPO has developed two tools to address the lack of standardized data and information about outcomes in the prosthetics sector:[141]

- The Lower Extremity Amputation Data Set (LEAD) is a core data set of information that can be collected in a registry or database. Use of a core data set allows standardization of data items across data-collection efforts to facilitate comparison and aggregation of data to answer real-world questions for users of rehabilitation services, clinicians, managers, and policymakers.
- Consensus Outcome Measures for Prosthetic and Amputation Services (COMPASS) is a list of standardized outcome measures for routine clinical practice. By collecting outcome-measurement data before and after an intervention the effect of the rehabilitation interventions can be determined.

Supplier landscape

Rapid developments in technology present new opportunities for the leading global suppliers to create market value while improving user experience. These companies therefore tend to focus on high-income markets with their products and solutions becoming increasingly more sophisticated. However, most companies have also designed solutions for low-resource settings. In LMICs, much of the service capacity has been developed through humanitarian responses to war and natural disasters. International organizations like the International Committee of the Red Cross (ICRC) have played a vital role in establishing and expanding prosthetic services in many LMICs. As a result, many of the solutions commonly found are designed and/or supplied via these organizations. Over the past decades, suppliers have emerged in emerging economies like China, India, Russia, and Türkiye. These companies supply a range of solutions inspired by basic modular components of the leading companies that have gone off-patent and develop a range of their own products. These companies cater to different price ranges. According to current best estimates, there are likely more than 80 suppliers across these emerging markets. Many companies are based in China and supported by a government focus to strengthen rehabilitation services over the past few decades.

141 LEAD and COMPASS: Defining Outcome Measures and a Core Dataset for the Lower Limb Prosthetics Sector, 2021, ATscale, https://www.ispoint.org/wp-content/uploads/2022/03/ispo_lead__compass_project_r.pdf.

Leading global prostheses companies

The global market is dominated by a few companies that are largely focused on Europe and North America (see table 44). The majority of the prostheses market is made up of products from companies including Ottobock, Ossur, Blatchford, and Proteor.

- Ottobock (Germany) started in the aftermath of World War I and has been a leading global innovator in the design and manufacturing of prostheses and other mobility solutions like wheelchairs. Ottobock reported a revenue increase of +12 per cent to 1.3 billion euros (approximately 1.4 billion dollars) in 2022. Prosthetic segments account for 750 million euros (approximately 800 million dollars), including products and services. Ottobock is present in LMICs, mainly through distributors and service providers, as well as through acquisitions or technology transfer partnerships. Ottobock market share is estimated to be around 40–50 per cent in the prostheses market.
- Össur (Iceland) is the second-largest company operating in prostheses with a market share estimated at 23–24 per cent. The company total sales in 2023 was 786 million dollars, of which prostheses account for 46 per cent (around 362 million dollars).[142] The company has a regional presence in the Middle East and Southern Africa, with sales growing fastest in the Asia-Pacific region.
- Blatchford (UK) was founded in 1890, with 1,000 employees and focuses on prosthetic devices. Endolite is part of Blatchford and mainly operates in India.
- Proteor (France) specializes in prosthetic and orthotic solutions with three strategic pillars: software, components, and custom-made devices. In 2019, the company successfully completed its acquisition of Freedom Innovations (US) to expand into the United States market.

These companies have all developed more affordable solutions for LMIC markets. For example, Blatchford has formed the Endolite subsidiary and line of prostheses, which targets LMIC markets such as China and India. Ottobock has similarly acquired a Brazilian company, Polior, to enter the basic component segment and has also partnered with ALIMCO (India) to jointly make quality components in India. Proteor components are commonly found in Francophone Africa, partially through partnerships with Humanity & Inclusion, with whom they have developed an emergency prosthetic kit.

142 Ossur Annual Report 2023, Ossur, https://media.ossur.com/image/upload/documents/corporate/Quarterly Reports/2023/2023_Ossur_Annual_Report.pdf.

Table 44: Leading global prostheses manufacturers

Company	Product types	LMIC Presence	Manufacturing Sites	Quality
Becker *(USA)*[i]	• Lower limb	Africa, Middle East, Latin America, Asia. Countries include Brazil, Egypt, India, South Africa, Thailand, Türkiye, and Venezuela.	United States	ISO 13485
Blatchford *(UK)*	• Lower limb	Africa, Middle East, Asia. Countries include Pakistan, India, Bangladesh, Myanmar, Tunisia, Algeria, Malaysia etc.	United States, United Kingdom	CE, ISO
Fillauer *(USA)*	• Lower limb • Upper limb	Asia, Africa. Sales across the world	Information not available	ISO 22675, ISO 9001
Ottobock *(Germany)*	• Lower limb • Upper limb	Asia, Africa	North America, Europe, China	CE, US FDA, ISO
Össur *(Iceland)*	• Lower limb	Africa, Asia, America, Middle East	Iceland, Scotland, Mexico, China, US, France	CE, US FDA, ISO, MDSAP[ii], EU MDR
Proteor *(France)*	• Lower limb • Upper limb	Africa, Asia, Middle East	France (22,000 pcs/year), United States	CE, ISO
WillowWood[iii] *(USA)*	• Lower limb • Upper limb	Asia, Africa, South America, Oceania. Has 20 distributors across five continents	Information not available	ISO 13485

i Becker company official website, https://www.beckerorthopedic.com/.

ii According to FDA, The Medical Device Single Audit Program (MDSAP) allows the conduct of a single regulatory audit of a medical device manufacturer's quality management system that satisfies the requirements of multiple regulatory jurisdictions. https://www.fda.gov/media/90179/download.

iii WillowWood company official website, https://willowwood.com/about-willowwood/.

Products developed for humanitarian response in LMICs

The International Committee of the Red Cross (ICRC) has been considered the largest driving force in the development of more affordable and appropriate solutions for LMIC contexts. ICRC works with national partners to provide Prosthetic & Orthotic (P&O) services in many LMICs. In response to the need for a more affordable, robust, and easier to fit solution to support its operations, ICRC established Rehab Impulse in 2011, targeting patients with limited resources. Rehab Impulse works in close collaboration with Foundation Alfaset, a non-profit organization, providing evolutionary, appropriate, and high-quality components for mobility-enabling assistive technology.[143] Rehab Impulse's lower limb products are offered at competitive prices, meeting the needs of both service users and providers in LMICs, thereby facilitating a first step towards social inclusion (see table 45).

Table 45: Rehab Impulse - prosthetics and orthotics manufacturer focused on LMICs

Manufacturer	Description	LMIC Presence	Manufacturing Sites	Products	Quality
Rehab Impulse *(Switzerland)*	Owned by ICRC, provides products with competitive prices that meet the needs of service users and providers in LMICs	Central Asia, Sub-Saharan Africa, Middle East	Information not available	• Components • Fabrication Materials • Machinery and Equipment	ISO 9001

143 Rehab Impulse company official website, https://www.rehabimpulse.org/index.php/en/about-us.

Emerging suppliers

Manufacturers have emerged, mainly in Mexico, Türkiye, China, and India (see table 46). They offered lower-priced options suited for LMICs contexts. Many of these suppliers have obtained internationally recognized certificates of quality, including ISO conformity, approved by the US FDA and the European Commission (CE marking). Small companies like Camfore and Aosuo concentrate on LMIC markets by producing generics (i.e. copies of components developed decades ago, now free from IP protection), or strive to develop innovative products and services with competitive pricing for the broader market, exemplified by companies like ST&G.

Emerging manufacturers make products classified into three categories:

- *Components*: The individual parts that assemble a limb prostheses, each playing a specific role in the functionality and structure of the prosthetic.
- *Fabrication materials*: A variety of substances used to construct artificial limbs and body parts. These materials are chosen for their strength, flexibility, weight, and compatibility with the human body.
- *Machinery and equipment*: Specialized machinery and equipment used for fabrication and fitting of prostheses in prosthetics centres. They are designed to meet the unique needs of creating and customizing artificial limbs and other body parts, ensuring precision and customization in the manufacturing process.

Table 46: Emerging prostheses suppliers

Supplier *(Country)*	Description	LMIC Presence	Manufacturing Sites	Products	Quality
ALIMCO[i] *(India)*	NGO under the Ministry of Social Justice and Empowerment. It has helped establish 170 Limb Fitting Centres in India	India and export experience in Afghanistan, Angola, Bangladesh, Cambodia, Nepal, Jordan, Iraq, Sri Lanka, United Arab Emirates, Uzbekistan etc.	India	• Components • Machinery and Equipment	ISO 9001
Beijing Jingbo *(China)*	Leading prostheses supplier in China	40+ countries globally, including Africa and Asia	China Annual capacity: - 100,000 prosthetic parts - 20,000 prosthetic joints[ii]	• Components • Fabrication Materials • Machinery and Equipment	CE, ISO10328, ISO9001
Camfore *(China)*[iii]	Manufacturer of prostheses, focus on export	Mainly Asia	China	• Components • Fabrication Materials	CE, FDA, ISO
Center for Assistive Technology *(India)*	Manufacturer of P&O products, tools & machineries	India and other emerging countries	Bangalore, India	• Components • Fabrication Materials • Machinery and Equipment	Information not available
Circleg *(Switzerland)*[iv]	Supplier of polycentric knee, dynamic foot, pylon and cover for LMICs market	Supply across LMICs. Kenya is the hub for supplying African continent	Nairobi Kenya and Zurich Switzerland	• Components	CE, ISO 10328, EU MDR
College Park *(USA)*	Prostheses supplier since 1988, acquired by Ossur in 2020	50+ countries including countries in Asia, Africa, Middle East[v]	USA	• Components	ISO 13485

Supplier *(Country)*	Description	LMIC Presence	Manufacturing Sites	Products	Quality
DOI ortho-innovativ *(Germany)*	Manufacturer of prosthetic products	Asia, Africa, Middle East, South America	Germany	• Components	ISO 13485[vi]
e-life International *(Chinese Taipei)*	Prostheses component supplier	Asia, Africa, Middle East[vii]	China	• Components	ISO 13485, FDA, EU MDR[viii]
EXONEO[ix] *(France)*	Innovative start-up	South America, Asia and Africa etc. Countries include Algeria, Egypt, Ghana, India, Iraq, Jordan, Lebanon, Morocco, Myanmar, Nigeria, Pakistan, Palestine, Togo, Tunisia, Viet Nam, and Zimbabwe.	Parts of the products are manufactured in Tunisia, Austria and France and assemble or pre-assemble in France	• Components	ISO 10328, CE
Fujian Guozi FPC *(China)*	Leading Chinese prosthetic exporter	Asia, Africa, Middle East	Fujian, China	• Components	CE, FDA, ISO 9001[x]
GO Assistive Technology *(UK)*	Innovative start-up	Tanzania, Rwanda, South Africa, Cambodia, Nepal. More distributors in pipeline for Africa and Asia.	South Africa, Switzerland	• Components	CE (In progress, planned for June 2024)
Hua Kang Pros *(Hong Kong SAR)*	Component manufacturer	Eastern Asia, Southeast Asia, Middle East, Africa, South America	Information not available	• Components • Fabrication Materials	CE, ISO 13485

Supplier *(Country)*	Description	LMIC Presence	Manufacturing Sites	Products	Quality
IB-ER Prosthetics *(Türkiye)*	Manufacturer of lower-limb components	Asia, Africa, South America. Countries include Syria, Iraq etc. Sales in 40+ countries	Manisa City, Türkiye	• Components • Fabrication Materials	CE, FDA, ISO 13485, ISO 9001, fulfilled Medical Device Regulation 2017/745
Limbtex *(UK)*	Manufacturer of prostheses materials	Worldwide distributor network	South Wigston, Leicestershire, East Midland, UK	• Components • Fabrication Materials	UK NHS supplier
Medex[xi] *(USA)*	Prostheses supplier with a focus on lower-limb	Information not available	Information not available	• Components	CE
Metiz[xii] *(Russia)*	Prostheses manufacturer	Asia, Africa, Middle East, South America. Countries include Iran, Sri Lanka, Mexico etc. Export to 24 countries		• Components • Machinery and Equipment	ISO 9001, ISO 13485
MTO[xiii] *(Italy)*	Produces and distributes semi-finished components for orthopaedics	Worldwide distributor network	Information not available	• Components	ISO 9001
Mobility India (MI) *(India)*	Designed and developed modular components in below knee prosthesis	India and other emerging countries	India	• Components • Fabrication Materials • Machinery and Equipment	Information not available
Ortho-Europe *(UK)*	Manufacturer of limb prostheses	Information not available	7 manufacturing facilities across Europe	• Components • Fabrication Materials	ISO 13485

Supplier *(Country)*	Description	LMIC Presence	Manufacturing Sites	Products	Quality
Ortotek[xiv] *(Türkiye)*	Manufacturer and distributor of prosthetic products	Africa, Middle East. Export in 55 countries	Ankara	• Components • Fabrication Materials • Machinery and Equipment	ISO 9001, ISO 13485, TS 12426, TS 13181
Ortpar[xv] *(Türkiye)*	Manufacturer of over 30 different prosthetic parts and devices	Africa, Asia, Middle East. Countries include India, Lebanon etc.	Türkiye	• Components	ISO 13485, ISO 9001
Proted *(Türkiye)*	Prosthetic component supplier	80+ countries via global distributor network		• Components • Machinery and Equipment	Information not available
Proactive Technical Orthopaedics[xvi] *(India)*	Manufacturer of P&O products	Distributor network and export to 30 countries	Pune	• Components • Fabrication Materials	CE, ISO 10328, ISO 9001
Regal Prostheses[xvii] *(Hong Kong SAR)*	Manufacturer of a range of prostheses products	Asia, Africa, South America	Information not available	• Components • Fabrication Materials	ISO 13485, ISO 9001
Roadrunnerfoot[xviii] *(Italy)*	Manufacturer of prostheses	Africa, Southeast Asia	Information not available	• Components • Fabrication Materials • Machinery and Equipment	ISO 9001, ISO 13485, EU MDR

Supplier *(Country)*	Description	LMIC Presence	Manufacturing Sites	Products	Quality
Re-life *(Canada)*	The company covers prosthetic products including lower limb and upper limb components, joint bar systems components, raw material, machinery and equipment	Middle East such as Iraq, Lebanon, Syria	USA, Canada, China, Korea, Germany etc.	• Components • Fabrication Materials • Machinery and Equipment	Information not available
Shijiazhuang New Ausuo[xix,xx] *(China)*	Prostheses ODM and OEM. 'Ausuo' is its own brand as well	Targets LMICs (Asia, Africa, Middle East)	Shijiazhuang, China	• Components • Fabrication Materials • Machinery and Equipment	CE, ISO 13485, ISO 9001
Shijiazhuang Perfect[xxi] **(***China***)**	Mainly lower limb components	Sales in more than 50 countries in Southeast Asia, South America	Shijiazhuang, China	• Components	CE, FDA, ISO
Shijiazhuang Wonderfu[xxii] *(China)*	OEM/ODM for international brands; 15 years' experience	Southeast Asia, Africa, Middle East	Shijiazhuang, China	• Components • Machinery and Equipment	ISO 13485, CE
ST&G *(USA)*	Lower limb prostheses company	Distributors in 25+ countries: Asia, South America, Middle East	Southern California	• Components • Fabrication Materials	ISO 9001; experience with NGOs and government
Streifeneder[xxiii] *(Germany)*	Supplier of prostheses components	Asia, South America	Germany	• Components • Fabrication Materials • Machinery and Equipment	ISO 13485

Supplier *(Country)*	Description	LMIC Presence	Manufacturing Sites	Products	Quality
Teh Lin *(Chinese Taipei)*	Customized solutions for all levels of amputation with 50+ years' experience	Asia, South America. Globally serves 50+ countries	Chinese Taipei	• Components	CE, FDA, ISO 9001, ISO 13485, EN 46001
Tehsen *(Chinese Taipei)*	Manufacturer of prosthetic products	Asia	Information not available	• Components	ISO 13485
Win Walker[xxiv] *(Chinese Taipei)*	Prostheses manufacturer with office in China	Information not available	Information not available	• Components	CE, ISO 13485, ISO 9001

i Punarbhava official website, https://punarbhava.in/index.php/resources/institutions/ministry-of-social-justice-and-empowerment/alimco.
ii Production R&D, 2018, Beijing Jingbo, http://www.jingbo-po.com/index.php/Article/detail?id=9.
iii Information provided by Camfore.
iv Information provided by Circleg.
v College Park official website, https://www.college-park.com/resources/international/.
vi DOI ortho-innovativ GmbH official website, https://www.ortho-innovativ.de/en-gb/home.
vii e-life distributors, https://www.e-lifebracing.com/distributors.php.
viii e-life history, https://www.e-lifebracing.com/about-history.php
ix Information provided by EXONEO.
x Fujian Guozi Rehabilitation Medical company official website, http://www.fpcfoot.com/article/about/gsgk.shtml.
xi Medex company official website, https://www.medexinternational.com/about.cfm.
xii Metiz company official website, https://metiz-ltd.com/.
xiii M.T.O S.p.A official website, https://www.mto.it/.
xiv Ortotek company official website, https://www.ortotek.com/en.
xv Ortpar Orthopedics company official website, https://www.ortpar.com/contact.html.
xvi Proactive Technical Orthopaedics company official website, https://www.protechortho.com/.
xvii Regal prosthesis official company website, https://regalprosthesis.com/web/.
xviii Roadrunnerfoot Engineering company official website, https://www.roadrunnerfoot.com/about-us/.
xix Aosuo company official website, https://m.as-health.cn/intro/About-us-1.html.
xx Information provided by Aosuo.
xxi Shijiazhuang Perfect Prosthetic Manufacture company official website, https://www.sjzpfc.com/.
xxii Shijiazhuang Wonderfu Alibaba official website, https://wonderful-reha.en.alibaba.com/company_profile.html?spm=a2700.shop_index.88.34.
xiii Streifeneder ortho.production GmbH company official website, https://www.streifeneder.com/op/company/profile.
xxiv Win Walker company official website, http://www.win-walker.com/.

Product catalogue

Please refer to the Product Catalogue Annex for major manufacturers, their brands and product lines.

Pricing overview

Pricing structure

The cost of prosthesis components is influenced by:

- *Technological advancements:* Prices vary depending on the level of technology used in the prostheses, which can be categorized as basic, intermediate, or advanced. The level of technology directly influences the cost of the prostheses. In high-income countries (HICs), the prosthetic leg price could range from 3,500 to over 70,000 dollars for advanced control.[144],[145] Advanced technology, such as myoelectric control systems or artificial intelligence integration, predominantly used in HICs, is more expensive compared to the basic technology, like the polypropylene method, which is common in LMICs.
- *Materials*: The choice of materials plays a crucial role in pricing. Lightweight, and durable materials are often more costly.
- *Manufacturing origin:* Prostheses imported from high-income regions, such as Europe or North America, are more expensive compared to those sourced from emerging markets like Türkiye or China.

Pricing range

Based on the survey and prices for basic modular components, components for below-knee and above-knee prostheses in LMICs cost between 77 to 450 dollars and 188 to 540 dollars respectively. Please note that the price excludes the sockets and their production, which require further in-house customized production by prosthetic centres.

144 Price listed in OPC company official website, 2022, https://opcenters.com/.

145 CHAI Analysis

Table 47: Lower limb prostheses component indicative price

Component	Component price range *(in United States dollars)*			Suppliers reporting *(N)*
	Average	Minimum	Maximum	
Below-knee set *(SACH foot with no ankle articulation)*	137	77	450	11
Above-knee set *(SACH foot, no ankle articulation, free knee; hand operated knee lock)*	284	188	540	11
SACH/ Rubber foot	40	22	110	15
Foot – single axis	56	16	190	12
Foot – multi axis	160	18	292	6
Knee joint	147	48	173	12
Pylon/ shank	24	11	50	10
Adapter	32	15	53	12
Rotator	233	150	420	6
Pelvic belt	30	10	45	5
Liners	177	120	220	9

Note: Based on interviews with 17 suppliers in 2021. The table above encompasses a range of prices provided by suppliers for different products in their catalogues. During the COVID-19 pandemic, the cost of raw materials for prostheses increased. As a result, the current price range for these products is likely to be reasonably higher than it was two years ago.

Many emerging suppliers sell basic prosthesis components online where the price is publicly available. Using China supplier export prices on Alibaba (see table 48):

- Below-knee set (excluding socket) prices range from 50 to 60 dollars. Some suppliers suggest that for larger orders, the unit price could drop below 40 dollars for basic sets, offering significant savings on bulk purchases.
- Above-knee set (excluding socket) price starting at around 90 dollars, with higher-end options reaching up to 300 dollars.

Table 48: Basic below-knee prosthetic kits from Chinese suppliers

Company	Product	Specifications	Price *(in United States dollars)*	Lead time
Beijing Golden Star		Lifetime warranty Online technical support	50 (<100 pcs) 47 (>500 pcs)	7 days (<100 pcs) 15 days (<500 pcs) Negotiable if more
Ningbo Xinyu		1 year warranty Online technical support Plastic and nylon	60 (<50 pcs) 45 (>1,000 pcs)	10 days (<10 pcs) Negotiable if more
Shijiazhuang Wonderful		1 year warranty Return and Replacement Stainless steel	49(<100 pcs) 45 (>1,000 pcs)	15 days (<15 pcs) 20 days (<200 pcs) Negotiable if more

Source: Retrieved in November 2023 from Alibaba.com

Conclusion

While high-end companies like Ottobock and Ossur along with other listed global leading manufacturers are lauded for their innovative technology, most of their products have steep prices which limit access in LMIC. A recent shift has seen emerging companies in countries like China, India and Türkiye producing quality components for basic modular prostheses at more affordable prices. However, the ambiguous definition of 'quality' and the absence of widespread structural testing as well as field/clinical trials raise concerns about substandard, less durable products entering the market. Addressing these quality-control issues is crucial for providing durable, effective prostheses that are both innovative and accessible to those in LMICs, ensuring a balance between innovation, affordability, accessibility and sustainability.

Wheelchairs

Market overview

Wheelchairs enhance personal mobility. They are designed for people who cannot walk or have difficulty walking, enabling them to move around and participate in everyday activities.[146] Wheelchairs are recognized as clinical tools that improve health outcomes and improve function, emotional wellbeing, physical independence, thereby enabling learning and financial independence. Wheelchairs are not simply form of transport and mobility. Appropriate wheelchairs prevent the development of secondary complications that may occur from incorrect device provision, incorrect fitting, and poor positioning, such as pressure injuries and fixed postural deformities and loss of function.

Market size

According to the WHO, approximately 1 per cent of the global population, or 80 million people, require a wheelchair.[147] A significant proportion, around 65 million individuals, is concentrated in LMICs. According to the WHO and UNICEF Global Report on Assistive Technology, between 65 and 95 per cent of those who need a wheelchair do not have access to one.[148]

Market growth drivers

The global demand for wheelchairs is anticipated to witness a sustained rise, driven by:

- *Ageing Populations:* With the global population steadily ageing, there is a consequential increase in the prevalence of conditions such as arthritis, leading to pain, and stiffness in the knee, hip, ankle, or foot. This demographic shift contributes to the growing demand for long-term use wheelchairs.
- *Injuries*: The surge in injuries, whether resulting from accidents or other incidents such as conflicts between countries, has become a significant driver for wheelchair market growth. People facing temporary or long-term mobility

146 https://www.who.int/teams/health-product-policy-and-standards/assistive-and-medical-technology/assistive-technology/wheelchair-services.

147 WHO report on wheelchair provision, https://iris.who.int/bitstream/handle/10665/368493/9789240074521-eng.pdf?sequence=1.

148 Global report on assistive technology, World Health Organization and the United Nations Children's Fund (UNICEF); 2022, https://www.who.int/publications/i/item/9789240049451.

challenges due to injuries find wheelchairs indispensable in maintaining their mobility and independence during the recovery process.

- *Increase in non-communicable diseases (NCD)*: People with chronic health conditions are a major group of wheelchair users. Non-communicable diseases disproportionately affect people in low- and middle-income countries, where more than three quarters of global NCD deaths (31.4 million) occur.[149]
- *Innovation in wheelchair design and functionality*: Innovations enhance the overall user experience, making wheelchairs more adaptable, comfortable, and user-friendly. These advancements lead to more users opting for wheelchairs.

Market segmentation

The wheelchair market is segmented based on usage duration and postural support. Categories include temporary use, long-term use, and those designed for specific postural support needs. Further differentiation arises in reference to technology and terrain.

By users: Wheelchairs specifically designed for children are different from those for adults, wheelchairs for children accounted for over 31 per cent of the revenue share in 2022.[150] The adaptability of wheelchairs to accommodate the changing needs of children with disabilities is crucial for long-term usability and effectiveness. Understanding these variations and providing flexibility in wheelchair design, particularly in terms of adjustable width and length, significantly enhance the wheelchair's utility and lifespan. For children with conditions like cerebral palsy, who often exhibit greater growth in height, extending the wheelchair's length becomes a primary concern to ensure continued comfort and support. Conditions such as spina bifida, on the other hand, may lead to increased width and weight over time, necessitating adaptability in those dimensions.[151] Flexibility allows the wheelchair to be useful to the child for a longer period. Adjustability is also vital for children who have conditions that may change over time, such as muscular dystrophy, where a wheelchair could be adapted to provide more posture support at the trunk. Besides adjustability, appropriate selection of materials is essential and depends on specific needs for back support (solid back system vs. sling back system), seat (solid vs. sling), and various head-support features and types.

By technology: Wheelchairs are technologically classified into manual and powered variants, with the latter also known as motorized or electric-powered wheelchairs. Manual wheelchairs may be propelled by the attendant or self-propelled by the user.

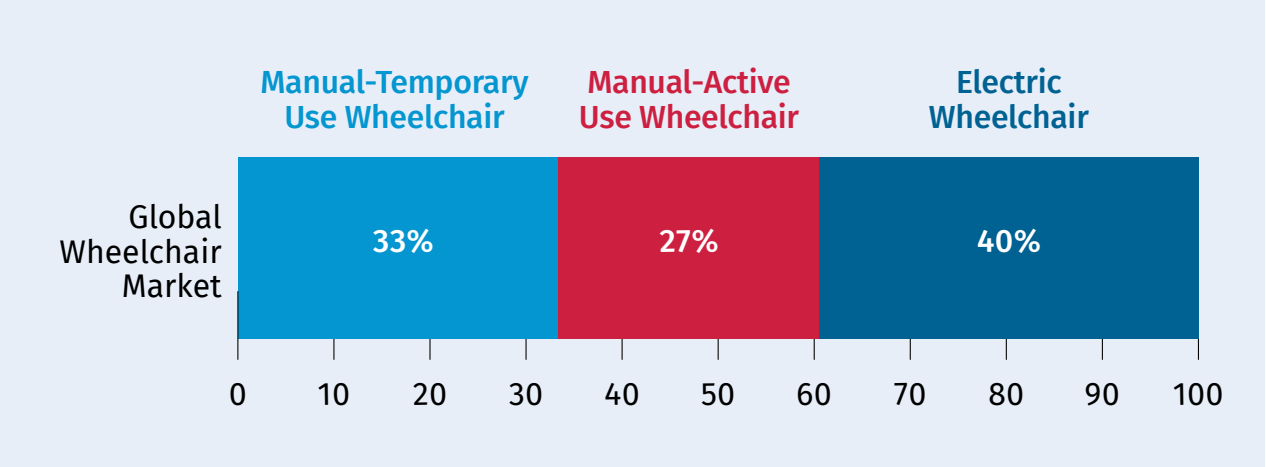
149 WHO Factsheet on noncommunicable diseases, https://www.who.int/news-room/fact-sheets/detail/noncommunicable-diseases.

150 Report by Grand View Research, https://www.grandviewresearch.com/industry-analysis/wheelchair-market.

151 ISWP: Design considerations for wheelchairs used in adverse conditions, https://wheelchairnetwork.org/wp-content/uploads/2019/08/DesignConsiderations_WheelchairsAC_12142017.pdf.

In addition, manual wheelchairs can be modular and have features such as recline or tilt in space to allow for accommodations for people with complex disabilities. Based on published market reports, manual wheelchairs account for over 60 per cent revenue share in 2022 due to their extended durability and comparatively lower cost.[152] Absence of batteries and motors along with less moving parts results in extended durability and comparatively lower cost of manual wheelchairs as compared to electric wheelchairs.[153] Notably, electric wheelchairs garnered a larger customer base in high-and-upper-middle-income countries, particularly in high-income countries such as the United States, where the availability of advanced healthcare facilities has influenced consumer preferences.

Figure IV: Wheelchair market value in 2022



Source: (as per published global market reports on wheelchair by Grand View Research)

By terrain functionality: Further categorization is based on terrain functionality, distinguishing between wheelchairs designed for indoor and urban settings, those suitable for outdoor/rural/rough terrain, and those with dual functionality catering to both indoor and outdoor environments.

152 Report by Grand View Research, op. cit.

153 https://penn-yorkmedical.com/2023/07/electric-wheelchairs-vs-manual-wheelchairs-pros-and-cons/.

Table 49: Different wheelchair types for different usage durations and terrains

Temporary Use	Long-term or Active use			Postural Support
	Indoor/urban/ even surface	Outdoor/ rural/ rough-terrain	Dual use/ indoor-outdoor	
Depot, transport, orthopaedic or 'hospital' chairs Does not provide the user with additional fitting, postural support or pressure relief Often pushed by attendant or carer	Adjustable for proper fit, provides pressure relief, and basic postural support mode, postural support devices may be added to fit user needs Divided into manual and powered wheelchairs			Designed for users requiring a higher degree of postural support Highly adjustable Has additional postural support systems for back and head support and a positioning cushion Can be active users or attendant-propelled, manual or motorised
	Lightweight Has a fixed/ rigid or foldable frame Transportable Easy to manoeuvre in small spaces 	Designed to be robust and stable Easier to propel over uneven ground Often three-wheel with longer wheelbase 	Have level of compromise for both environments E.g., robust wheelchair with large castor wheels but with a short wheelbase 	

This segmentation provides a nuanced understanding of the diverse needs and preferences within the wheelchair market, reflecting the dynamic nature of the assistive device landscape.

Essential wheelchair features for LMICs

An 'appropriate wheelchair' as defined by WHO is a wheelchair that:

- Meets the user's needs and environmental conditions
- Provides proper fit and postural support
- Is safe and durable
- Is available in the country
- Can be obtained, maintained, and serviced in country at the most economical and affordable price.

WHO emphasizes that inappropriate wheelchairs can lead to poor outcomes for wheelchair users, including decreased health and mobility participation barriers, wheelchair breakdown resulting in disruption in use, and/or development of secondary complications – which in cases of people with spinal cord injuries and similar conditions can cause premature death.

WHO guidance on manual wheelchairs design for low-resourced settings[154] emphasizes the following:

- User's health and safety
- Strength and durability – Wheelchairs used outdoors in low-resource settings often encounter rough terrain and are subject to greater wear and tear.
- Suitability for use – One wheelchair design will not suit all, and a wheelchair design needs to account for the environment and the way the wheelchair would be used.

Table 50: WHO assistive product specification for manual active-use wheelchair

	Active Urban Wheelchair	Active Dual-Terrain Wheelchair	Active Rough Terrain Wheelchair
User	Child or adult with basic, intermediate or advanced posture support needs Primarily for people who self-propel, but also for people who need assistance	Child or adult with basic, intermediate or advanced posture support needs Primarily for users who self-propel, but also for users who need assistance	Child or adult with basic, intermediate and advanced posture support needs to self-propel in rough outdoor terrain

154 WHO guidelines on the provision of manual wheelchair in low-resourced settings, https://iris.who.int/bitstream/handle/10665/43960/9789241547482_eng.pdf?sequence=1.

	Active Urban Wheelchair	Active Dual-Terrain Wheelchair	Active Rough Terrain Wheelchair
User *(continued)*	For use in urban, indoor and outdoor environments People with advanced mobility skills may also use this wheelchair for short distances on uneven terrain	For use in indoor and outdoor uneven urban, peri-urban and rural environments Offers better outdoor mobility for users who do not have advanced wheelchair mobility skills	Also users who need assistance (excluding lever-propelled wheelchairs)
Specific Characteristic	Wheelchair with folding or rigid frame, three or four wheels with large rear wheels, seat and backrest, armrests and footrests Overall length and wheelbase are similar to or shorter than transport wheelchair with large rear wheels Rear wheels and front castors appropriate for urban indoor and outdoor use	Wheelchair with folding or rigid frame, three or four wheels with large rear wheels, seat and backrest, armrests and footrests Footrests positioned in line or behind front castors Longer wheelbase and shorter or similar overall length than transport wheelchair with large rear wheels Rear wheels and front castors appropriate for indoor and outdoor mixed terrain	Wheelchair with folding or rigid frame; three, four or more wheels, with two larger drive wheels; seat and backrest; and footrests behind front castors May be lever-propelled Similar or longer wheelbase than dual-terrain wheelchair; larger overall length than transport wheelchair with large rear wheels Low centre of gravity to ensure stability Rear wheels and castors appropriate for outdoor rough terrain

	Active Urban Wheelchair	Active Dual-Terrain Wheelchair	Active Rough Terrain Wheelchair
Requirements for standard configuration			
Frame	• Frame with mechanism(s) to fold or dismantle • Push-handles can be integrated into frame, supplied as add-on components, or omitted if not required • Backrest or back posts with adjustable height or supplied with range of back posts with fixed height • Backrest contouring options, such as tension-adjustable backrest or rigid backrest that can be adjusted independently from back posts or with forward and backward and angle adjustment, including separate padded cover; can be mounted at different heights on back posts; quick-release mechanism to allow folding	• Frame with mechanism(s) to fold or dismantle • Push-handles can be integrated into frame, supplied as add-on component, or omitted if not required • Backrest or back-posts with adjustable height or supplied with range of back-posts with fixed height • Backrest contouring options, such as tension-adjustable backrest or rigid backrest that can be adjusted independently from back-posts or with forward and backward and angle adjustment, including separate padded cover; can be mounted at different heights on back posts; quick-release mechanism to allow folding	• Frame with mechanism(s) to fold or dismantle • Push-handles can be integrated into frame, supplied as an add-on component or omitted • Integrated stability options for feet • Backrest or back-posts with adjustable height or supplied with range of back-posts with fixed height • Backrest contouring options, such as tension-adjustable backrest or rigid backrest that can be adjusted independently from back-posts or with forward and backward and angle adjustment, including separate padded cover; can be mounted at different heights on back- posts; quick-release mechanism to be removed to allow folding

	Active Urban Wheelchair	Active Dual-Terrain Wheelchair	Active Rough Terrain Wheelchair
Frame *(continued)*	• Footrests with adjustable height available in at least two adjustment ranges on all sizes of wheelchair to accommodate people with shorter and longer legs • Two flip-up, swing-away or removable footrests on folding frame • Optional – armrests and clothing guards with minimal profile	• Footrests with adjustable height; available in at least two adjustment ranges on all sizes of wheelchair to accommodate people with shorter and longer legs • Two flip-up, swing-away or removable footrests on folding frames • Optional: armrests and clothing guards with minimal profile	• Footrests with adjustable height; available in at least two adjustment ranges on all sizes of wheelchair to accommodate people with shorter and longer legs • Two flip-up, swing-away or removable footrests on folding frames • Optional: armrests and clothing guards with minimal profile
Frame Size Range	• Seat width appropriate for profile of users; includes child, adult and bariatric sizes with 25–50 mm increments • Seat depth adjustable or with option for seat extension or supplied with range of seat frame depth options	• Seat width appropriate for profile of users; includes child, adult and bariatric sizes with 25–50 mm increments • Seat depth adjustable or with option for seat extension or supplied with range of seat depth options	• Seat width appropriate for profile of users; includes child, adult and bariatric sizes with 25–50 mm increments • Seat depth adjustable or with option for seat extension or supplied with range of frame seat depth options

	Active Urban Wheelchair	Active Dual-Terrain Wheelchair	Active Rough Terrain Wheelchair
Rear Wheels	• Quick-release or removable without tools • Optional camber with maximum 3 ° (off from vertical) • diameter e.g. 508–660 mm • Width e.g. 25–35 mm Puncture-proof or pneumatic rear tyres	• Quick-release or removable without tools for rigid frames • Quick-release or removable without tools for folding frames is optional • Camber ranges from 0 ° (rear wheel perpendicular to ground) to 1–3 ° (off from vertical) • Diameter, appropriate for size of wheelchair, e.g. 508–660 mm • Width e.g. 35–44 mm Puncture-proof or pneumatic rear tyres	• With push-rims or lever-propelled • Quick-release or removable without tools for rigid frames for transport; optional for wheelchairs with folding frame • Camber minimum 3 ° (off from vertical) for stability • Diameter, appropriate for size and design of wheelchair, e.g. 610–711 mm • Width e.g. 35–44 mm • Wider or larger-tread tyres Puncture-proof or pneumatic rear tyres
Front Castors	• Diameter e.g. 127–203 mm • Width e.g. 13–50 mm Puncture-proof or pneumatic front castors	• Diameter and width variable: e.g. 203 x 50 mm, 102 x 76 mm Puncture-proof or pneumatic front castors	• Diameter e.g. Over 203 mm • Width e.g. Over 50 mm Puncture-proof or pneumatic front castors

	Active Urban Wheelchair	Active Dual-Terrain Wheelchair	Active Rough Terrain Wheelchair
Frame and Wheel Adjustments	• Rear wheel or seat unit relative to wheelbase can be horizontally adjusted using tools • Front and rear seat-to-floor heights can be adjusted through wheel or frame adjustments or through range of different fixed-frame seat heights to optimize fit for foot propelling on folding-frame wheelchairs	• Rear wheel or seat unit relative to wheelbase can be adjusted horizontally using tools • Front and rear seat-to-floor heights can be adjusted through wheel or frame adjustments or supplied through range of different fixed-frame seat heights	• Rear wheel axle or seat unit relative to wheelbase can be horizontally adjusted using tools • Front and rear seat-to-floor heights can be adjusted through wheel or frame adjustments or supplied through range of different fixed-frame seat heights
Rear and front wheels *(lever propelling)*	Information not available	Information not available	• Size and width of front and rear wheels appropriate for rough terrain and wheelchair design • Three or multiple wheels • Puncture-proof or pneumatic wheels
Postural Support for intermediate- and advanced-level services	• Wheel or frame adjustments using tools to change seat angle; minimum adjustment range 10–15 degrees; if seat angle is independently adjustable, seat-to- backrest angle must also be adjustable • Backrest to seat angle (recline) adjustments with or without use of tools; minimum adjustment range 10–15 degrees • Mechanism or adjustment options are available to maintain backwards stability with maximum combined seat and backrest configuration adjustments Additional requirements on adjustability for postural support for intermediate- and advanced-level services: • Removable backrest upholstery with back-post capabilities to accept third- party backrests • Armrests with adjustable height, and short and full-length arm pads; design and function of armrests should not restrict fitting of third-party backrests		

Source: WHO Assistive Product Specification https://www.who.int/publications-detail-redirect/9789240020283

Table 51: WHO general seating and postural support guidelines

WHO general seating and postural support guidelines	
All wheelchairs provide seating and postural support as well as mobility. Good postural support is critical especially for users who have an unstable spine or are likely to develop secondary deformities. A wheelchair and cushion should meet the seating and postural support requirements of the user(s). This includes the size of the wheelchair, the type of cushion, and the adjustability and ergonomic factors of the wheelchair • All wheelchairs should be provided with a cushion that is appropriate to manage the user's risk of developing pressure sores. • A wheelchair should be evaluated based on the seating and postural support measures, and the results should be available to the users and purchasers. • Cushions should be evaluated and rated based on their ability to provide comfort, pressure relief and postural support, and the results should be available to the users and purchasers. A higher level of adjustability or custom adaptations may be needed for users who require more complex postural support. Overall, WHO recommends that wheelchairs and cushions be evaluated based on the seating and postural support performance measures, and the results be available to the users and purchasers. The areas in which a wheelchair and cushion should be evaluated or reported on are 1. seating dimensions and adjustability, and 2. cushion types and characteristics. Seating dimensions and cushion characteristics tests and reporting techniques are covered in ISO standards 7176-7 and 16840-2.	
Seating and Postural Support Elements	
Seat bases	• Wheelchair seats should have a continuous surface with no breaks that might cut or pinch the user's skin. • The angle of the seat, in relation to the horizontal, should be between 0 and 12 degrees (with the front portion of the seat higher than the rear portion of the seat) • The seat must be level from side to side • A range of seat sizes should be available to fit a range of body sizes • Sling seats should be designed with materials that do not stretch over time from the weight of the user • Sling seats and solid seats should be used with cushions designed or modified for use on a sling seat and solid seat, respectively

WHO general seating and postural support guidelines	
Cushions	• The cushion should be removable from the wheelchair. • The cushion should be easy to clean using basic materials such as soap and water. • The cushion should be an appropriate size to fit on the seat base. • Correct cushion use and the way in which it should be placed on the wheelchair seat (which side is up, and which is the front of the seat) should be clearly indicated. • Information on how the cushion should be used and maintained should be available. Pressure relief cushions: • A pressure relief cushion should reduce pressures at the high-risk areas for pressure sore development (commonly at ischial tuberosities and sacrum) • A pressure relief cushion should minimize the build-up of moisture between the cushion and the user's skin • Information should be available on how to use the cushion, how to maintain it, the expected life of the cushion, when to replace the cushion or parts of it, and any particular risks when using the cushion • The cushion and cushion cover material should not cause high pressures, thereby reducing the effectiveness of the cushion in distributing pressure over the seat surface • Pressure relief cushions should maintain their pressure relief properties in the climates where the cushion is expected to be used
Backrests	• The angle between the seat and the backrest (seat to back angle) should be between 80 and 100 degrees • Different backrest heights should be available • The backrest should support the normal curvature of the spine. The middle of the back should be able to rest further back than the back of the pelvis
Footrests	• Sufficient ground clearance needs to be maintained to prevent the footrest hitting obstacles or catching and tipping the wheelchair on uneven ground • The height of the footrest should be adjustable • Footrests need to be long or wide enough to support the foot but, at the same time, should not create difficulty while folding or moving around
Armrests	• Armrests should be removable, folding or low-profile for easy transferral in and out of the wheelchair

WHO general seating and postural support guidelines	
Rear Wheels	• The position of the rear wheel should allow the user to have a good push stroke and provide the necessary stability

Source: WHO Guidelines on the provision of manual wheelchairs in less resourced settings (2008) https://iris.who.int/bitstream/handle/10665/43960/9789241547482_eng.pdf?sequence=1

Many international organizations such as the International Society of Wheelchair Professionals (ISWP)[155], a global, multidisciplinary, nongovernmental organization aiming to improve the quality of life for people who may benefit from mobility devices, serve as global resources to coordinate and improve wheelchair service standards and provision. ISWP has published design considerations for wheelchairs used in adverse conditions.

Per ISWP guidance, "a wheelchair interacts with and is affected by both the environment and the user." Hence a wheelchair design needs to consider both the user and its environment.

Design considerations should consider the user: A wheelchair design needs to account for who they are designing the wheelchair for. Wheelchairs for permanent use are not generic devices that can be utilized by anyone needing a wheelchair. Wheelchair users vary by:

- Size
- Age
- Postural requirements and the need for Postural Support Devices (PSDs)
- Functional, educational, and social needs
- Ability to propel the wheelchair independently
- Geographical or home environment (the environments in which the person needs to use the wheelchair)
- Changing needs (e.g., children who are growing) or fluctuating medical needs such as people with progressive deteriorating conditions.

Design choices should also consider users' environment and transportation.

- The usability of the wheelchair in different environments
- Rough terrain can affect the usability of the wheelchair for users with weak upper extremities.
- Tight or small living spaces can affect the manoeuvrability of the wheelchair.

Implications on reliability related to the environment:

- Cold weather can cause plastic parts to fracture prematurely.

155 https://iswp.org/

- Rough, uneven terrain accelerates breakage.
- Heat and light can fade colours and break down fabrics and rubber.
- Moisture can corrode parts quickly and speed up the decay of tires and castors, as well as foam and upholstery.
- Constraints to access to replacement parts (wheels, tires, castors, upholstery, etc.) in the area.

How will the wheelchair be transported:

- Can the person transfer out of the wheelchair?
- Does the person need to be seated in the wheelchair during transportation?
- Has the wheelchair been crash tested?
- What sort of transport tie-down systems are required in the vehicles?

In the rehabilitation of individuals with walking limitations, it is crucial to provide a wheelchair that not only fits correctly but also aligns with the user's physical, functional, and environmental needs. This requires an approach that responds to individual's unique requirements and promotes the provision of wheelchairs through service provision that assesses individual user needs, assist in selecting an appropriate wheelchair, train users and caregivers, and provide ongoing support and referral to other services where appropriate.

In terms of service delivery, WHO recommends wheelchair provision through a service model, which provides, at a minimum: individual assessment and selection; preparation and fitting of the wheelchair for the wheelchair user; information and training for wheelchair users to maximize their safe and efficient use and care of the product; and follow-up to ensure the wheelchair continues to meet the user's needs.

Figure V: Summary of wheelchair service steps recommended by WHO

1. Select	2. Fit	3. Train	4. Follow up
			
The wheelchair user's specific needs and preferences are defined through an individual assessment, to select the most appropriate wheelchair(s) for them.	The wheelchair, wheelchair cushion, postural support devices and any other accessories are prepared and fitted for the wheelchair user.	The wheelchair user, along with those who will assist them, takes part in task-specific training in how to use and care for their wheelchair.	Follow up is offered to all users, for as long as they require a wheelchair, with the frequency based on their individual needs.

Quality

WHO guidelines refer to ISO standards for quality. The ISO has developed a series of standards for wheelchairs (Series 7176), wheelchair cushions (ISO 16840 Part 2), and postural support devices (ISO 16840 Part 3). ISO 7176 series tests for stability, performance, wheelchair dimensions, and durability along with strength, impact, and fatigue. ISO 16840 tests for wheelchair seating systems and postural support devices. All requirements in the ISO 7176 series may not reflect typical conditions in less-resourced settings, as some of the requirements were designed to simulate the conditions in city environments with smooth roads.

WHO recommends countries use ISO 7176 as baseline standards and develop additional quality testing standards based on local conditions.

WHO assistive product specifications recommend that manual wheelchairs must meet ISO 7176 series, EN 12183, or equivalent standards for stability, brakes, dimensions, and impact and fatigue strength. And, to confirm adherence to standards ensuring quality and safety, a dated and signed report from a third-party test lab is required.

In LMICs, wheelchairs face a wide variety of environmental conditions, such as uneven terrains, high temperatures and humidity that can affect the durability of the wheelchair such that its components can fail prematurely. In fact, castors are one component that commonly fails in such conditions. Additionally, wheelchair parts are not particularly easy to repair or replace in less-resourced environments even though ISO 7176 section 8 refers to wheelchair testing including static, impact and fatigue, only a subset of field castor failures is covered. ISWP Standards Working Group proposed castor durability testing to meet the need to improve design and products. A team of ISWP staff designed, implemented, and is currently using a Castor Testing Machine to test castors as part of ISWP projects at the University of Pittsburgh.[156]

ISWP Wiki is a collaborative resource to support wheelchair and wheelchair component product evaluation. The Wiki includes best-practice recommendations, test methods, test equipment designs, and information about wheelchair testing centres, among other information. The content and its resources are based on publicly available material, research literature, and recommendations from experienced wheelchair testers around the world.

156 https://wheelchairnetwork.org/kb/caster-testing/.

Supplier landscape

Leading global wheelchair companies

Five established global suppliers – Invacare, Sunrise Medical, Ottobock, Pride Mobility Products Corp (electric wheelchairs) and Permobil – control less than 50 per cent of the global mobility market.[157] These large global manufacturers are focused on high-income countries and have limited presence in LMICs where they operate through distributors. For instance, Europe and North America comprised more than 96 per cent of net sales of Invacare in 2021.[158] The production of active wheelchairs for high-income countries is highly customized and localized, which limits the product range that could be provided cost-effectively in LMICs.[159] Thus, most existing wheelchair designs are not suitable for use in rural and peri-urban areas where ground is uneven, local transport is not wheelchair accessible and local repair and maintenance is not available.

Table 52: Leading global wheelchair manufacturers

Company *(Head-quarters location)*	**Description**	**Regional Presence**	**Manufacturing Sites**	**Products**
Invacare *(United States)*	Leading global supplier of mobility aids, respiratory products and hospital furniture; publicly listed	Europe, North America, Africa, Middle East, Asia	North America, Europe, China	• Manual: active, postural support, sports • Powered
Medline *(United States)*	Manufacturer and distributor of more than 80K healthcare products for surgery and lab supplies; privately owned	Europe, North America, Asia, Latin America, Africa etc.	Australia, France, Japan, Mexico, Poland, Slovakia, U.S.	• Manual: active, postural support, standard/ transport

157 AT 2030 Product Narrative Wheelchairs.

158 https://global.invacare.com/investor-relations/annual-report-and-proxy-materials.

159 https://discovery.ucl.ac.uk/id/eprint/10084646/1/Applying-Market-Shaping-Approaches-to-Increase-Access-to-Assistive-Technology-Summary-of-the-Wheelchair-Product-Narrative.pdf.

Company *(Head-quarters location)*	Description	Regional Presence	Manufacturing Sites	Products
Ottobock *(Germany)*	Global manufacturer with focus on prosthetics and orthotics; privately owned	Europe, North America, Australia, Africa, Asia. LMICs such as Algeria, Kenya, Morocco etc.	Germany[i]	• Manual: active, postural support, sports • Powered
Permobil *(Sweden)*	Global supplier of wheelchairs with primary focus on powered wheelchairs; privately owned	Europe, North America, Australia, Asia, South Africa (50 countries worldwide)	China, Italy, Netherlands, Sweden, UK, USA	• Manual: active • Powered
Sunrise Medical *(Germany)*	Leading global suppliers of wheelchairs and mobility products; privately owned	Europe, North America, Asia Pacific Distribution across 130 countries	UK, Mexico, Germany, USA, Spain, Netherlands, Poland, China[ii]	• Manual: active, postural support, sports • Powered

i https://corporate.ottobock.com/en/company/about-ottobock
ii https://www.sunrisemedical.com/

Note: Listed in alphabetical order by manufacturer.

Manufacturers and social enterprises supplying to LMICs

Various emerging manufacturers and social enterprises, supplying to LMICs, fill the gap and deliver low-cost, manual wheelchairs that are specifically designed for LMIC environments.

Table 53: Emerging manufacturers

Company *(Headquarters location)*	Description	Regional presence	Manufacturing sites	Products
ALIMCO *(India)*	Public enterprise that manufacturers various assistive products; fully owned by the Government of India	India	India	• Manual: active, postural support
CE Mobility *(South Africa)*	Started in 1949; largest wheelchair manufacturer and distributor in South Africa	Southern Africa	South Africa	• Manual: active, postural support, sports, standard
Colors *(United States)*	Part of Nissin Group, Custom wheelchair manufacturer OEM for Latter-day Saint Charities, Momentum Wheels for Humanity, and Participant Assistive Products	Around 60 countries	China, Viet Nam, United States, Japan, South Korea Manufacturing for LMICs in China and Viet Nam	• Active wheelchair (Rigid and Folding), Standard (Rigid and Folding), Light weight chair, Reclining, Paediatric, Module, Postural support
Comfort Mobility *(Chinese Taipei)*	OEM/ODM enterprise for wheelchair companies in Europe/ US; have own brands	Europe (70 per cent of sales)	Chinese Taipei	• Manual: active, postural support, sports • Powered

Company *(Headquarters location)*	Description	Regional presence	Manufacturing sites	Products
Foshan Wheelchair *(China)*	One of the top exporters of wheelchairs in China with 60 per cent of its exports being made to LMICS	Middle East Latin America Southeast Asia: Cambodia, Laos, Viet Nam Africa: North and central Africa	China	• Active outdoor/ rough-terrain • Postural support
Heartway Medical *(Chinese Taipei)*	Primarily a producer of powered mobility products	Europe, North America, Asia	Chinese Taipei	• Manual: active, postural support, sports • Powered
INTCO *(China)*	Specializes in the production of metal-related medical equipment (e.g. wheelchairs). Public listed company. OEM for Latter-day Saint Charities	Europe, North America, Asia-Pacific	China	• Manual: active, standard, all-terrain, cross-terrain • Paediatric
Karma Medical *(Chinese Taipei)*	One of Asia largest wheelchair manufacturers	India (25 per cent market share) + 40 countries	China, Thailand, Taipei	• Manual: active, postural support, sports Powered
Kien Tuong *(Viet Nam)*	Manufacturer of various hospital equipment OEM for RoughRider	Europe, North America, Asia	Viet Nam	• Manual: active, postural support, standard

Company *(Headquarters location)*	Description	Regional presence	Manufacturing sites	Products
Merits Healthcare *(Chinese Taipei)*	Specialized in scooters, wheelchairs, home care bed, accessibility, patient aids OEM (China) for Motivation, DDO	Europe, Japan, America	Chinese Taipei, China	• Manual: active, postural support, sports Powered
Nissin *(Japan)*	Leading developer and manufacturer of wheelchairs and welfare equipment in Japan	Japan (60 per cent market share), United States, Asia, such as China, Mexico, Brazil, India, Viet Nam, Indonesia, Cambodia, Philippines, Thailand)160	China, Viet Nam, USA, Japan, South Korea	• Manual: active, postural support, sports • Powered • Standard
Rehasense *(Hong Kong SAR)*	Manufacturer of mobility products (e.g. wheelchairs)	Europe, Asia	China and Poland	• Manual: active, postural support
Taiwan Armada *(Chinese Taipei)*	Primarily a producer of powered mobility products	Chinese Taipei, US	Chinese Taipei	• Manual: active, postural support, sports Powered

Note: Listed in alphabetical order by manufacturer.

160 https://nissin.com/en_jp/network/.

Table 54: Social enterprises that design and manufacturer wheelchairs (listed in alphabetical order)

Company *(Headquarters location)*	Description	Regional Presence	Manufacturing Sites	Products
Association for the Physically Disabled of Kenya *(Kenya)*	NGO that produces wheelchairs and provides wheelchair services in Kenya	Information not available	Kenya	• Active • Postural support • Standard
Beeline Wheelchair *(Guatemala)*	Non-profit that designs, produces and provides wheelchairs; spin off from Hope Haven	Latin America, Middle East, Africa, Asia	Guatemala	• Active outdoor/ rough-terrain • Postural support
Diversability Development Organization *(Canada)*	Non-profit that designs and supplies innovative mobility and positioning solutions	Information not available	Contract manufacturing (by Meritis in China)	• Active folding and rigid frame wheelchair • light and ultra-light wheelchairs • Sports wheelchairs • Postural support wheelchairs, • Wheelchair postural support unit • Power add-on motorized drive for wheelchairs

Company *(Headquarters location)*	Description	Regional Presence	Manufacturing Sites	Products
Momentum Wheels for Humanity *(United States)*	Non-profit that implements projects globally to strengthen rehabilitation services and increase access to AT, including the USAID-funded CLASP project	Asia, Africa, Middle East, Latin America	Contract Manufacturing: • Colors Through CLASP, carries a diverse range of products from several suppliers	• Active urban/ even-surface • All-terrain\ Postural support • Sports • Transport
Motivation *(United Kingdom)*	Social enterprise focusing on appropriate wheelchair provision	Asia, Africa	Contract Manufacturing: China	• Active rigid/ folding • Rough-terrain • Postural support • Sports • Paediatric
Participant Assistive Products *(United States, Kenya, Nigeria, Zambia)*	Benefit corporation that is looking at cross subsidization model for both HIC and LMIC	20 countries worldwide	China	• Active Dual Terrain • Active urban • Transport • Postural support
RoughRider America *(United States)*	Previous Enterprise arm of Whirlwind Wheelchairs International (WWI); just recently began to operate independently	Information not available	Contract manufacturing: - Kien Tuong-Viet Nam - INTCO – China	• Active outdoor/ rough-terrain

Company *(Headquarters location)*	Description	Regional Presence	Manufacturing Sites	Products
ShonaquipSE *(South Africa)*	A Hybrid Social Enterprise that designs, manufactures and sells products and provides training and services through both a company and non-profit organization that supports the inclusion of children with mobility disabilities in Africa	Africa	South Africa	• Postural support buggies, active and attendant propelled manual and electric powered wheelchairs; • Paediatric and adult; • Complete devices and Postural Support Devices, and components (back systems, laterals, cushions, head supports and 24 hour posture support equipment – standing and lying). • Rural, peri-urban and urban focus

Charities donating wheelchairs in LMICs

Most wheelchairs in LMICs are donor-funded with delivery models ranging from organizations distributing refurbished wheelchairs with limited services to mass distribution campaigns to organizations providing quality appropriate wheelchairs with services that meet WHO Guidelines. Regardless of the model, almost all chairs are delivered at little or no cost to the user.

Table 55: Charities providing wheelchairs in LMICs

Company *(Headquarters location)*	Description	Regional presence	Product	Manufacturing sites
Free Wheelchair Mission *(United States)*	Established in 2001; provides wheelchairs at no cost to people with disabilities in developing nations; has donated more than 1 million wheelchairs	94 countries (active in 34), with top-5: Viet Nam, India, China, Peru, Philippines	• Standard • Urban/Semi Urban	Contract manufacturing: • Jam Metal Manufacturing • Krypton, India
Hope Haven *(United States)*	Established in 1994; work with international ministries to donate refurbished wheelchairs; has donated 126,000 wheelchairs	108 Countries	• Refurbished wheelchair in various types	
The Church of Jesus Christ of Latter-day Saints (Latter-day Saints Charities) *(United States)*	Started Wheelchair Initiative in 2001; has donated over 700,000 wheelchairs	134 countries including the top five of China, Brazil, Türkiye, Viet Nam, Mexico	• Active urban/ even-surface • Outdoor/ rough-terrain • Postural support • Standard	Contract manufacturing: • Colors Wheelchairs • INTCO Medical
Wheelchairs for Kids *(Australia)*	Started in 1988; manufacture and distribute paediatric wheelchairs; run by volunteers	Distributed in over 80 countries in Asia, Africa and elsewhere	• Postural support (paediatric)	Local workshop in Australia

Product catalogue

Refer to the Product Catalogue Annex for major manufacturers, their brands and product lines.

Pricing overview

High-income countries

The pricing landscape for wheelchairs exhibit notable variations across different regions and income levels. In high-income countries, such as the United States, manual all-terrain wheelchairs are available at a range of 895 to 1,695 dollars [161] with the higher end products typically associated with folding X-brace aluminium frame wheelchairs designed for active use on rough terrains.

Global procurement options for LMICs: UNICEF

International organizations like UNICEF play a pivotal role in providing affordable options for LMICs, offering rim-propelled wheelchairs for rural settings at 372.51 dollars [162] and rigid frame dual-terrain wheelchairs for diverse settings at 330 dollars,[163] pricing for different wheelchairs available through UNICEF (see table 56).

Table 56: Prices for wheelchairs available through UNICEF

Wheelchair type	UNICEF price *(in United States dollars)*
Active rough terrain, child	251
Active rough terrain, adult	358
Active dual terrain, folding	250
Active urban, rigid	335–385
Active urban, folding	385–500
Postural support	375–474
Active dual terrain, rigid	275–330
Active urban, folding, more support	385

161 https://roughrideramerica.com/.

162 https://supply.unicef.org/catalogsearch/result/index/?q=wheelchair.

163 https://supply.unicef.org/s0004009.html.

Global procurement options for LMICs: Consolidating Logistics for Assistive Technology Supply and Provision

Consolidating Logistics for Assistive Technology Supply and Provision (CLASP), a USAID-funded project implemented by Momentum Wheels for Humanity, is another global procurement option for LMICs with competitive prices. CLASP has been operational since 2014 and serves buyers, NGOs, and governments in LMICs. Through a consolidation hub in China, CLASP enables buyers to make large or small orders of mixed products and sizes, delivering mobility devices that best suit users' individual needs faster and more efficiently. CLASP stocks and ships a range of wheelchairs, postural support devices, walking aids, cushions, parts kits, and more from suppliers including Diversability Development Organization (DDO), INTCO, Jarik Medical, Momentum Wheels for Humanity, Motivation, RoughRider America, Sunshine Tech, Participant Assistive Products, and Zhongshan Kangdebao Rehabilitation Equipment Co., Ltd.

LMICs challenges and diverse pricing scenarios

In LMICs, there are no standardized public-provision frameworks. As a result, available wheelchairs vary in quality and price, influenced by procurement channels, volumes, and product choices. In the subsequent version of the report, a thorough analysis of wheelchair prices across LMICs would be documented.

Conclusion

The global wheelchair market exhibits robust growth, with manual wheelchairs contributing over 60 per cent of the total revenue share. Factors driving market growth include the ageing population, a surge in injuries, and an increase in non-communicable diseases.

A growing number of countries are implementing assistive product lists and associated assistive product specifications. This could lead to a better standardization of specifications across LMIC markets and improved quality. WHO has launched new guidelines and is driving this adoption. This is expected to improve considerations of product specifications.

Quality standards are guided by ISO, with WHO recommending countries to use ISO 7176 as baseline standards and develop additional testing standards based on local conditions. In LMICs, environmental challenges such as uneven terrains and high temperatures, impact wheelchair quality, with castors being a commonly affected component. Efforts to address this include the ISWP proposal for castor durability testing using the Castor Testing Machine.

The market is fragmented, with five key players controlling less than 50 per cent, including Invacare, Sunrise Medical, Ottobock, Pride Mobility Products Corp, and

Permobil. The large global manufacturers are focused on high-income countries, have limited presence in LMICs and a limited cost-effective product range, and operate through distributors which further increases costs. Manufacturers in low- and middle-income countries and social enterprises have filled the gap and are delivering low-cost, manual wheelchairs that are specifically designed for LMIC environments.

Absence of public-provision frameworks in LMICs resulting in variable-quality wheelchairs at different prices. International organizations like UNICEF provide options for LMICs, such as active rough terrain wheelchairs for adults at 358 dollars and rigid frame dual-terrain wheelchairs at 275 to 330 dollars.

In conclusion, while the global wheelchair market is witnessing growth and technological advancements, challenges persist, particularly in LMICs. Addressing these challenges requires a concerted effort involving adherence to international standards, empowering local production and assembly, and implementing transparent pricing models. Besides, it is critical that LMICs implement a service delivery approach that responds to individual's unique requirements and promotes the provision of appropriate wheelchairs that not only fit correctly but also align with the user's physical, functional, and environmental needs.

Looking forward

The Assistive Products Market Report covers market insights, supplier landscape, and product offerings for various assistive devices like eyeglasses, digital devices, hearing aids, prostheses, and wheelchairs.

Looking ahead, the next edition of the ATscale Market Report set for release by the end of 2024, aims to significantly enhance its scope and depth. Key additions include:

- *In-depth regional market research:* A more granular analysis of specific LMIC markets, including detailed case studies, to better understand localized needs and challenges.
- *Innovation*: A focus on innovative AT design and technology, tailored to the unique requirements of LMIC environments.
- *Updated data and trends*: Featuring the latest data and insights, reflecting the evolving landscape of assistive technology.
- *Comprehensive pricing analysis*: A thorough assessment of all-inclusive pricing factors such as fitting, maintenance, and service costs.
- *Price markup exploration:* Various elements contributing to in-country price mark-ups.

The goal is to make these reports a comprehensive resource for stakeholders in the assistive technology sector. Additionally, the integration of these reports into a digital platform is envisioned, enhancing accessibility and dynamic interaction with the report's content, thereby making it a more impactful tool for advancing assistive technology in LMICs.

We encourage manufacturers and suppliers to share assistive product information available in LMICs that can be highlighted through these reports. We are committed to continually enhancing the breadth and depth of these reports. Your contributions, in the form of sharing products and insights, will be invaluable for inclusion in future editions, thus enriching this resource for all stakeholders.

Appendices

Appendix A: List of suppliers, social enterprises, and charities interviewed

#	Product category	Company/organization name
1	**Eyeglasses**	DOT Glasses
2		OneSight EssilorLuxottica Foundation
3		Ouhai Glasses
4		Pilot Optics
5		VisionSpring
6		Wenzhou Matt (Weilan) Optical
7		Wenzhou Mike Optical
8		Wenzhou ReadSun Glasses
9		Wenzhou Zhantai Optical
10	**Prostheses**	ALIMCO
11		Beijing Jingbo
12		Camfore
13		Circleg
14		EXONEO
15		Fuyu Tiancheng
16		GO Assistive Technology
17		Mobility India
18		Shijiazhuang New Aosuo
19		Shijiazhuang Wonderfu Prosthetics
20		ST&G

#	Product category	Company/organization name
21	**Hearing Aids**	AcoSound
22		Alps
23		Demant
24		GN Group
25		Sonova
26		Starkey
27		Tech for Good
28		WS Audiology
29	**Wheelchairs**	CE Mobility
30		Colours ‘n Motion
31		Diversability Development Organization (DDO)
32		Foshan Wheelchair
33		Free Wheelchair Mission
34		INTCO
35		LDS Charities
36		Momentum Wheels for Humanity
37		Motivation
38		Participant Assistive Product
39		ShonaquipSE

Note: Listed in alphabetical order by supplier name.

Appendix B: List of experts consulted

#	Organization	Name
1	**Christian Blind Mission**	Diego Santana
2	**Christian Blind Mission**	Fabian Schindler
3	**Christian Blind Mission**	Michael Schwinger
4	**Christian Blind Mission**	Michiel Steenbeek
5	**Coalition for the Future of Hearing Healthcare, Denmark**	Bo Bredsgaard Lund
6	**EYElliance**	Maggie Savage
7	**Former ISPO, UNHCR, ICRC Prosthetics Expert**	Greg Halford
8	**Humanity & Inclusion**	Christophe Van Geel
9	**HumanWare**	Pedro Polson
10	**ISPO**	David Constantine
11	**ISWP**	Alex Kamadu
12	**National Research Center for Audiology and Hearing Rehabilitation Russia**	Prof George Tavartkiladze
13	**Rwanda Assistive Technology Access (RATA)**	Rene William Ngabo
14	**UNICEF**	Dennis Soendergaard
15	**UNOPS**	Matias Jorge Gomez Raffo
16	**University of Pittsburgh, Department of Rehab Science & Technology**	Dr. Jon Pearlman
17	**USAID**	Michael Allen
18	**WHO**	Shelly Chadha
19	**WHO**	Stuart Keel

Note: Listed in alphabetical order by organization name.

Appendix C: Web Content Accessibility Guidelines and Accessible Rich Internet Applications guidelines to make digital content accessible for screen readers

WCAG Guideline	ARIA Guideline	Description
Perceivable (Guideline 1-4)		
1.1 Text Alternatives	aria-label, aria-labelledby, aria-describedby	Provide text alternatives for non-text content. ARIA attributes like aria-label help associate labels with elements for screen reader users.
1.2 Time-based Media	aria-live, aria-relevant	Provide alternatives and controls for time-based media. ARIA live regions notify screen reader users of dynamically changing content.
1.3 Adaptable	role="presentation," role="img," aria-hidden	Ensure content can be presented in different ways. Use ARIA roles and attributes to convey semantic meaning and control what is presented to screen readers.
1.4 Distinguishable	aria-labelledby, aria-describedby, role="img"	Make content visually and auditorily distinguishable. Use ARIA attributes to associate labels with elements and provide context for screen reader users.
Operable (Guideline 5-8)	**aria-disabled, aria-haspopup, tabindex**	
2.1 Keyboard Accessible	tabindex, focus management, aria-haspopup	Ensure all functionality is operable via a keyboard. ARIA attributes help manage focus and indicate elements with pop-up menus or sub-levels.
2.2 Enough Time	aria-live, aria-relevant, timeouts, focus control	Provide users enough time to read and interact with content. ARIA live regions and timeout management assist in conveying timely information to screen reader users.

WCAG Guideline	ARIA Guideline	Description
2.3 Seizures and Physical Reactions	N/A	Avoid content that may cause seizures or physical discomfort. This guideline primarily pertains to visual content but can impact screen reader users indirectly.
2.4 Navigable	tabindex, skip links, headings, ARIA landmarks	Make navigation and operation predictable and consistent. Use semantic HTML elements, ARIA landmarks, and skip links for efficient screen reader navigation.
Understandable (Guideline 9-10)	**aria-label, aria-labelledby, role="alert"**	
3.1 Readable	text alternatives, language attributes	Make text content readable and understandable. Provide language information and ensure that screen reader users receive accurate and meaningful text alternatives.
3.2 Predictable	role="alert," ARIA live, aria-relevant	Make web pages appear and operate in predictable ways. Use ARIA live regions and relevant settings to notify screen reader users of dynamic content changes.
Robust (Guideline 11)	**role="presentation," role="img"**	
4.1 Compatible	role="presentation," role="img"	Maximize compatibility with current and future technologies. Use ARIA roles appropriately to enhance compatibility with assistive technologies like screen readers.

Note: Web Content Accessibility Guidelines (WCAG) and Accessible Rich Internet Applications (ARIA).

Appendix D: Web Content Accessibility Guidelines success criteria and best practices

Consideration	Description	Related WCAG success criteria/ best practice
Perceivable principle		
Small screen size	Optimize content for small screens, consider mobile versions or responsive design.	1.4.4 Resize text (Level AA) – Text must be resizable without assistive technology up to 200 percent. Ensure content does not prevent text magnification by the user.
Zoom/ Magnification	Provide methods for users to control text size on mobile devices.	1.4.4 Resize text (Level AA) – Text must be resizable without assistive technology up to 200 percent. Implement features like browser pinch zoom without blocking to meet this criterion. Support system fonts following platform-level user preferences.
Contrast	Ensure good contrast for varied environments, especially outdoors.	1.4.3 Contrast (Minimum) (Level AA) – Requires a contrast of at least 4.5:1 (or 3:1 for large-scale text). 1.4.6 Contrast (Enhanced) (Level AAA) – Requires a contrast of at least 7:1 (or 4.5:1 for large-scale text).
Operable principle		

Consideration	Description	Related WCAG success criteria/ best practice
Keyboard control for touchscreen devices	Support external keyboards for various disabilities.	2.1.1 Keyboard (Level A) – All functionality is available from a keyboard. 2.1.2 No Keyboard Trap (Level A) – Keyboard focus can be moved away from components that are not user input fields. 2.4.3 Focus Order (Level A) – Logical navigation sequence is present. 2.4.7 Focus Visible (Level AA) – Keyboard focus is visible and indicates the component currently in focus.
Touch Target Size and Spacing	Ensure interactive elements are touch-accessible with sufficient size.	Best practice is to ensure touch targets are at least 9 mm high by 9 mm wide.
Touchscreen Gestures	Design gestures for ease of use, considering screen reader users.	Follow design alternatives for complex gestures to accommodate screen reader users and those with motor or dexterity impairments.
Device Manipulation Gestures	Provide alternatives for device manipulation gestures.	Implement touch and keyboard operable alternative control options for device manipulation gestures.

Consideration	Description	Related WCAG success criteria/ best practice
Placing buttons where they are easy to access	Consider ease of access for different user preferences and needs.	2.4.4 Link Purpose (In Context) (Level A) – The purpose of each link can be determined from the link text alone or from the link text together with its programmatically determined link context. 2.4.9 Link Purpose (Link Only) (Level AA) – A mechanism is available to allow the purpose of each link to be identified from link text alone.
Understandable principle		
Changing screen orientation (portrait/ landscape)	Support both orientations and notify users of changes programmatically.	Best practice is to support both orientations or ensure easy orientation change.
Consistent layout	Maintain consistent layouts across pages and screen sizes.	3.2.3 Consistent Navigation (Level AA) – Navigational mechanisms that are repeated on multiple Web pages within a set of Web pages occur in the same relative order each time they are repeated. 3.2.4 Consistent Identification (Level AA) – Components that have the same functionality within a set of Web pages are identified consistently.
Positioning important page elements before scroll	Ensure vital information is visible without scrolling for users with low vision.	Best practice is to place important elements before the page scroll to assist users with low vision, cognitive impairments, and improve consistency.

Consideration	Description	Related WCAG success criteria/ best practice
Grouping operable elements that perform the same action	Improve touch target size and reduce redundancy for better usability.	2.4.4 Link Purpose (In Context) (Level A) – The purpose of each link can be determined from the link text alone or from the link text together with its programmatically determined link context. 2.4.9 Link Purpose (Link Only) (Level AA) – A mechanism is available to allow the purpose of each link to be identified from link text alone.
Provide clear indication that elements are actionable	Visually distinguish actionable elements for all users, especially those with vision impairments.	Best practice is to use conventional visual features such as shape, colour, style, positioning, text label, or iconography to indicate actionable elements.
Provide instructions for custom touchscreen and device manipulation gestures	Offer clear instructions for gestures, aiding discoverability and usability.	3.3.2 Labels or Instructions (Level A) – Labels or instructions are provided
Robust principle		
Virtual keyboard for the type of data entry required	Setting the type of keyboard helps prevent errors and ensures formats are correct but can be confusing for people who are using a screen reader when there are subtle changes in the keyboard.	N/A

Consideration	Description	Related WCAG success criteria/ best practice
Easy data entry methods	Users can enter information on mobile devices in multiple ways such as on-screen keyboard, Bluetooth keyboard, touch, and speech. Text entry can be time-consuming and difficult in certain circumstances. Reduce the amount of text entry needed by providing select menus, radio buttons, check boxes or by automatically entering known information (e.g. date, time, location).	N/A
Support the characteristic properties of the platform	Mobile devices provide many features to help users with disabilities interact with content. These include platform characteristics such as zoom, larger fonts, and captions. The features and functions available differ depending on the device and operating system version. For example, most platforms can set large fonts, but not all applications honour it for all text. Also, some applications might increase font size but not wrap text, causing horizontal scrolling.	N/A

Appendix E: Feature evaluations of Android and iOS accessibility settings

Feature	Android Accessibility Feature	iOS Accessibility Feature
Hearing/Speech Features		
Broadcast Streaming (Auracast)	N/A	N/A
Hearing Aid Profile (Bluetooth)	Android supports Bluetooth Hearing Aid Profile	iOS supports Made for iPhone (MFi) hearing aids
Closed captions adjustable	Live Caption	Live Caption
HD Audio	High-quality audio settings	HD Audio (various settings in Accessibility)
Recognition of atypical speech patterns	N/A	N/A
Total conversation capability	Real-Time-Text	Real-Time-Text
Safe audio	Volume settings with safety features	Headphone Accommodations with warnings
Sound quality adjustable	Equalizer settings	Sound Recognition and Audio/Visual Settings
Live transcription / captions	Live Transcribe	Live Listen
Audio Streaming to Hearing-Aid (ASHA)	N/A	Audio Sharing (for supported hearing aids)
Configurable Audio	Equalizer settings	Sound Recognition and Audio/Visual Settings
Visual Display of Volume with Warning	Volume controls with visual feedback	Hearing devices settings with warnings
Connection available for Induction Loop	N/A	Hearing devices settings

Feature	Android Accessibility Feature	iOS Accessibility Feature
Allows for sign language communication	No specific feature	FaceTime with Sign Language detection
Flashlight notifications	Flash alerts	LED Flash for alerts
Adjustable Vibrating Alerts	Vibration settings	Custom Vibrations for alerts
Supports Closed Captioning for Web Video	Accessibility settings for captions	Closed Captions and SDH in Video settings
Front Facing Camera	Front camera settings	FaceTime with Video and Zoom settings
Adjustable Maximum Volume Control	Volume controls with limit settings	Hearing devices settings with volume limits
Mono Audio	Accessibility settings for mono audio	Mono Audio
Two-way Video Communications – using wire...	Video call settings	FaceTime and Video call settings
Two-way Video Communications – using mobility features	Video call settings	FaceTime and Video call settings
Visual Alerts – Electronic Message	Notification settings with visual alerts	LED Flash for Alerts and Notification settings
Text to telephone (TTY) compatibility	N/A	TTY settings
Call Logs	Call history settings	Recent Calls
Ringer Volume Adjustable	Volume controls	Ring/Silent Switch and volume controls
Key Feedback – Displayed	Key press feedback settings	Keyboard settings with key previews
Hearing Aid T-coil Coupling	N/A	Hearing devices settings
Video conferencing	Video call settings	FaceTime and Video call settings

Feature	Android Accessibility Feature	iOS Accessibility Feature
SMS Personalisation and Reuse	SMS settings with templates	Text Replacement
Messaging Options – Predictive Text	Keyboard settings with predictive text	Predictive Text settings
Messaging Options – MMS	Messaging settings with MMS	Messaging settings with MMS
Messaging Options – IM	Messaging settings with instant messaging	iMessage settings
Messaging Options – Email	Email settings	Mail settings
Messaging Options – Text Messaging /SMS	Messaging settings with text messaging	Messaging settings with text messaging
Visual Indicators on Display – Enhancements	Notification settings with visual alerts	LED Flash for Alerts and Notification settings
Visual Indicators on Display – Line Status	Status bar indicators	Cellular settings
Visual indicators on Display – Voice Mail	Visual voicemail settings	Voicemail settings
Visual Indicators on Display – Volume Control	Volume controls with visual feedback	Hearing devices settings with volume controls
Visual indicators on Display – Network	Status bar indicators	Cellular settings
Visual Indicators on Display – Battery	Battery status settings	Battery settings
Visual Alerts – Incoming Calls	Notification settings with visual alerts	LED Flash for Alerts and Call settings
Visual Alerts – Other	Notification settings with visual alerts	LED Flash for Alerts and Notification settings
Visual Alerts – Battery	Battery status settings	Battery settings
Visual Alerts – Power	Power settings with visual alerts	Power settings with Low Power Mode

Feature	Android Accessibility Feature	iOS Accessibility Feature
Vibrating alert	Vibration settings	Vibration settings
Improved Call Quality	Accessibility settings for improved call quality	Phone settings with Noise Cancellation
Vision Features		
Display Characteristics – Enhance screen magnification	Accessibility settings for display enhancement	Display & Text Size settings
Screen refresh rate adjustable	Android doesn't have a specific feature	iOS doesn't have a specific feature
Display Characteristic – Colour Inversion	Accessibility settings for colour inversion	Display & Text Size settings
Light/Dark Theme	Dark mode settings	Dark Mode settings
Text-to-Speech (TTS)	Text-to-Speech settings	VoiceOver settings
Haptic Feedback	Vibration settings	Haptic Touch settings
Audible Cues – Enhancements	Auditory feedback settings	Sound Recognition and Audio/Visual Settings
Audible Cues – Charging	Auditory feedback settings	Charging Sound settings
Screen Reader	TalkBack	VoiceOver
Screen Magnifier	Magnification gestures	Magnifier settings
Braille Display Support	Braille settings	VoiceOver settings
Web Browser Zoom	Zoom gestures	Zoom settings
Speed Dial	Contacts settings with speed dial	Touch settings with Shake to Undo
Supports Accessibility application programming interfaces	Accessibility settings for app integration	Accessibility settings for app integration
High Contrast Mode	High contrast text and theme settings	Invert Colours settings

Feature	Android Accessibility Feature	iOS Accessibility Feature
Display Characteristics – Symbols/Icons	Accessibility settings for symbols/icons display	Display settings with Reduce Motion
Display characteristics – Colour differentiation	Accessibility settings for color differentiation	Display & Text Size settings
Display characteristics – Backlight for display	Screen brightness settings	Display & Text Size settings
Display characteristics – Adjustable brightness	Brightness settings	Display & Text Size settings
Voice output of caller ID from contacts list	Auditory feedback settings	VoiceOver settings with Caller ID
Voice output of SMS: inbuilt	Text-to-Speech settings	VoiceOver settings with SMS reading
Display Characteristics – Adjustable contrast	Contrast settings	Display & Text Size settings
Voiced Menus	Auditory feedback settings	VoiceOver settings
Ring Tone Variations	Sound settings with ring tone variations	Sound settings with ring tone variations
Voice Recognition for Dialling or Accessing functions	Voice recognition settings	Siri settings with voice commands
Personalized shortcuts	Customizable gestures and shortcuts settings	Accessibility settings with custom gestures and shortcuts
Automatic Features – Automatic Answer	Accessibility settings for automatic answering	Accessibility settings for automatic answering
Adjustable font – Size	Font size settings	Display & Text Size settings
Adjustable font – Style	Font style settings	Font settings
Audible cues – Volume	Auditory feedback settings	Sound Recognition and Audio/Visual Settings
Audible cues – Calls	Auditory feedback settings	Sound Recognition and Audio/Visual Settings

Feature	Android Accessibility Feature	iOS Accessibility Feature
Audible cues – Power	Auditory feedback settings	Sound Recognition and Audio/Visual Settings
Audible cues – Battery	Auditory feedback settings	Sound Recognition and Audio/Visual Settings
Audible Identification of keys – Functions	Auditory feedback settings	Sound Recognition and Audio/Visual Settings
Audible Identification of keys – Spoken	Auditory feedback settings	Sound Recognition and Audio/Visual Settings
Key feedback – Audible	Auditory feedback settings	Sound Recognition and Audio/Visual Settings
Key feedback – Tactile	Haptic feedback settings	Haptic Touch settings
Standard number key layout	Accessibility settings for keyboard layout	Keyboard settings
Tactile key marker – '5'	Haptic feedback settings	Haptic Touch settings
Tactile key markers – 'F' & 'J'	Haptic feedback settings	Haptic Touch settings
Mobility/Dexterity Features		
Eye tracking	N/A	N/A
Facial gestures to control the device	Face gestures settings	Face ID and Gestures settings
Air gestures to control the device	Motion gestures settings	N/A
Customizable Touch Gestures	Customizable gestures settings	Custom gestures settings
Device Coupling – Near Field Communications	NFC settings	N/A
Physical keyboard	External keyboard settings	External keyboard settings
Device Coupling – USB	USB settings	N/A

Feature	Android Accessibility Feature	iOS Accessibility Feature
Speech-to-Text / Dictation	Voice input settings	Dictation settings
Personal Assistant / Voice Control	Google Assistant or Voice Access settings	Siri settings
Supports Gesture Based Navigation	Gesture navigation settings	N/A
Stylus or Prosthetic Device support	Stylus or input device settings	Apple Pencil settings
External Switch / Pointer Support	Switch control and pointer settings	Switch Control and AssistiveTouch settings
Visible Focus Indicators	Focus indicators settings	Focus indicators settings
Voice recognition for accessing features	Voice recognition settings	Siri settings with voice commands
Hand movement	Motion gestures settings	iOS doesn't have a specific feature.
Voice recognition for dialling	Voice recognition settings	Siri settings with voice commands
Any Key Answering	Accessibility settings for answering calls	Accessibility settings for answering calls
Automatic Redial	Accessibility settings for redialling calls	Accessibility settings for redialling calls
Automatic Answer	Accessibility settings for automatic answering	Accessibility settings for automatic answering
Flat Back for Table Top Operation	Device design	Device design
Device coupling – Other	Various connectivity settings	Various connectivity settings
Device coupling – Bluetooth/WLAN	Bluetooth and Wi-Fi settings	Bluetooth and Wi-Fi settings
Device coupling – Infrared	Infrared settings	N/A

Feature	Android Accessibility Feature	iOS Accessibility Feature
Device coupling – Cable	USB and cable settings	N/A
Guarded/Recessed Keys	Physical design	Physical design
Predictive Text Input	Keyboard settings with predictive text input	Keyboard settings with predictive text input
Text Messaging Service Capable	Messaging settings with text messaging	Messaging settings with text messaging
Speakerphone capable	Speakerphone settings	Speakerphone settings
Cognition Features		
Focus mode	Focus mode settings	Focus mode settings
AssistiveTouch	AssistiveTouch settings	AssistiveTouch settings
Highlight content as it is spoken	Accessibility settings for spoken content highlights	Accessibility settings for spoken content highlights
Intelligent Personal Assistant	Google Assistant settings	Siri settings
Voice Notes	Voice recording settings	Voice Memos settings
Simplify display	Simplification settings	N/A
GPS capability	Location settings	Location settings
Copy and paste	Copy and paste settings	Copy and paste settings
Simple Instructions	Simplification settings	N/A
Photo associated telephone book	Contacts settings with photo association	Contacts settings with photo association
Assistance instructions	Instructions and assistance settings	Instructions and assistance settings
Simple reminders	Reminder settings	Reminder settings
No screen timeout	Screen timeout settings	Screen timeout settings

Appendix F: Available accessibility features across a range of Android and iOS smartphones

S.N.	Feature
Accessibility Support Type: Mobility/Dexterity Features	
1	Eye tracking
2	Facial gestures to control the device
3	Air gestures to control the device
4	Customizable Touch Gestures
5	Device Coupling – Near field communications (NFC)
6	Physical keyboard
7	Device coupling – USB
8	Speech-to-text / Dictation
9	Personal Assistant / Voice Control
10	Supports gesture-based navigation
11	Stylus or prosthetic device support
12	External switch / pointer support
13	Visible focus indicators
14	Voice recognition for accessing features
15	Hand movement
16	Voice recognition for dialling
17	Any key answering
18	Automatic redial
19	Automatic answer
20	Flat back for table-top operation
21	Device coupling – Other
22	Device coupling – Bluetooth/WLAN

S.N.	Feature
23	Device coupling – Infrared
24	Device coupling – Cable
25	Guarded/recessed keys
26	Predictive text input
27	Text-messaging service capable
28	Speaker-phone capable
Accessibility support type: Vision Features	
29	Display characteristics – Enhance screen color
30	Screen refresh rate adjustable
31	Display characteristic – Color Inversion
32	Light/dark theme
33	Text-to-speech (TTS)
34	Haptic feedback
35	Audible cues – Enhancements
36	Audible cues – Charging
37	Screen reader
38	Screen magnifier
39	Braille display support
40	Web browser zoom
41	Speed dial
42	Supports accessibility application programming interfaces (APIs)
43	High contrast mode
44	Display characteristics – Symbols/Icons
45	Display characteristics – Colour differentiation
46	Display characteristics – Backlight for display

S.N.	Feature
47	Display characteristics – Adjustable brightness control
48	Voice output of caller ID from contacts list
49	Voice output of SMS: inbuilt
50	Display characteristics – Adjustable contrast control
51	Voiced menus
52	Ring tone variations
53	Voice recognition for dialling or accessing features
54	Personalized shortcuts
55	Automatic features – Automatic answer
56	Adjustable font – Size
57	Adjustable font – Style
58	Audible cues – Volume
59	Audible cues – Calls
60	Audible cues – Power
61	Audible cues – Battery
62	Audible identification of keys – Functions
63	Audible identification of keys – Spoken
64	Key feedback – Audible
65	Key feedback – Tactile
66	Standard number key layout
67	Tactile key marker – '5'
68	Tactile key markers – 'F' & 'J'
Accessibility support type: Hearing/Speech Features	
69	Broadcast streaming (Auracast)
70	Hearing aid profile (Bluetooth HAP)

S.N.	Feature
71	Closed captions adjustable
72	HD audio
73	Recognition of atypical speech patterns
74	Total conversation capability
75	Safe audio
76	Sound quality adjustable
77	Live transcription / captions
78	Audio streaming to hearing-aid (ASHA)
79	Configurable audio
80	Visual display of volume with warning
81	Connection available for induction loop
82	Allows for sign-language communication
83	Flashlight notifications
84	Real-time-text capability
85	Hearing aid or 'HAC' setting
86	Adjustable vibrating alerts
87	Supports closed captioning for web video or streaming
88	Front-facing camera
89	Adjustable maximum volume control
90	Mono audio
91	Two-way video communications – using wireless LAN networks
92	Two-way video communications – using mobile networks
93	Visual alerts – Electronic message
94	HAC rating
95	Text to telephone (TTY) compatibility

S.N.	Feature
96	Call logs
97	Ringer volume adjustable
98	Key feedback – Displayed
99	Hearing aid T-coil coupling
100	Video conferencing
101	SMS personalisation and reuse
102	Messaging options – Predictive Text
103	Messaging options – MMS
104	Messaging options – IM
105	Messaging options – E-mail
106	Messaging options – Text messaging/SMS
107	Visual indicators on display – Enhancements
108	Visual indicators on display – Line Status
109	Visual indicators on display – Voice Mail
110	Visual indicators on display – Volume Control
111	Visual indicators on display – Network
112	Visual indicators on display – Battery
113	Visual alerts – Incoming Calls
114	Visual alerts – Other
115	Visual alerts – Battery
116	Visual alerts – Power
117	Vibrating alert
118	Improved Call Quality

S.N.	Feature
Accessibility support type: Cognition Features	
119	Focus mode
120	Assistive touch
121	Highlight content as it is spoken
122	Intelligent personal assistant
123	Voice notes
124	Simplify display
125	GPS capability
126	Copy and paste
127	Simple instructions
128	Photo-associated telephone book
129	Assistance instructions
130	Simple reminders
131	No screen timeout
132	Alternative format user manual
Accessibility support type: Optional Accessories	
133	Related accessories that may also benefit people with disabilities