Prototype

Digital microscope*

Country of origin | United Republic of Tanzania
Primary use | Diagnosis/measurement/monitoring
Category | Medical device (including in vitro diagnostics)

Commercial information

List price (USD): 600

Expected year of commercialization: 2025

Number of existing prototypes in use/trials/tests: 100

Currently used in: Cameroon, Rwanda, United Kingdom, United Republic of Tanzania and USA

Model: OpenFlexure Microscope v7

Product description

The OpenFlexure Microscope is a fully motorized digital microscope capable of scanning and tiling samples automatically. It has primarily been developed for use with 100x oil immersion objective lenses for malaria diagnostics. However, it can also be configured for a wide variety of other conditions, including other parasitic diseases and oncology.

Product details

Accessories: Standard ancillary equipment is required for staining and preparing samples. Computers are required for the operation and read-out of scanned samples.

Consumables: Lubrication oil, lead screws (replacement annually), reagents for staining (Giemsa stain, distilled water, microscope slides, etc.), immersion oil if required.

Warranty duration: 1 year (dependent on manufacturer: this design will be available from a range of manufacturers).

Lifetime: 5 years (if maintained correctly).

Energy requirements: Intermittent electrical power (can run for ~1 day on battery power from a standard 20Ah 5V battery pack).

Facility requirements: For standard optical microscopy: requires a laboratory bench, sink, drying facilities, and reagents for sample preparation.

Contact: Richard Bowman | Phone: +44 7751627671 | Web: https://bit.ly/3xA9nk1

*** Information reported by manufacturer, October 2023**

WHO assessment**

Clinical

Clinical → Recommended

The technology is a digital microscope that uses a digital sensor instead of eyepieces. It is equipped with three motors to translate the sample and focus the microscope. It is accompanied by software capable of automatically focusing and acquiring images over a wide region of the sample and stitching the images acquired into a single digital representation of the slide. It has primarily been developed for use with 100x oil immersion objective lenses for malaria diagnostics. However, it can also be configured for a wide variety of other conditions, such as other parasitic diseases and oncology.

Overall, this technology is very useful as it makes it more accessible to low-resource settings that currently have only manual microscopes, enhancing technician training, record-keeping, and quality assurance.

**** This assessment was initiated November 2023**

Comparison with WHO technical specifications

Cannot be verified.

WHO has a technical specifications document available, dated 2014 (last modification), referring to a basic binocular microscope. This WHO technical document would not be fully appropriate the specifications of the technology proposed since the manufacturer does not provide any supporting and/or technical documentation, such as a user manual. It has not been possible to verify what was claimed in the submission form or retrieve the missing technical information.

The main requirements that cannot be verified are the following: objectives shall be held on a rotating changer with a ribbed grip for easy rotation and click stops, accommodating at least three at once; eyepiece interpupillary distance adjustable with a minimum range of 54–74 mm; the sub-stage condenser shall be fitted with an aspherical lens and an iris diaphragm; the slide holder shall have spring-loaded side clamps; the slide stage shall have a Vernier gauge rule in at least one dimension, with movement possible in both X and Y directions with a range not smaller than 60 mm for the x-direction and 40 mm for the y-direction; wide-field eyepieces at least 10x and 15x; at least the following plan achromatic objectives are provided: 4x, 10x, 40x, and 100x (oil immersion) with numerical aperture; anti-fungus-treated observation tubes, eyepieces, and objectives.

Regulatory

Pre-market assessment	N/A Not available
Post-market assessment	N/A Not available
Quality system assessment	N/A Not available
Security	N/A Not available

Pre-market: The product is in the early prototype stage and needs to undergo preclinical testing and clinical evaluations before regulatory approval. The premarket documentation is not complete.

Post-market: The manufacturer did not submit surveillance and vigilance documentation to monitor the safety and effectiveness of the product after placement in the market.

Quality management system (QMS): The manufacturer site is not certified to the ISO13485:2016 quality management system and is unable to demonstrate that the product is safe and effective.

Security: The manufacturer did not submit risk management documentation, risk analysis, risk management plan, risk control, post-production information, or other hazard reports.

Health technology assessment

Indicators	Evidence assessment	Innovation
Medical	→	
Safety	!	
Economy	!	
Organizational	→	
Legal	!	
Social	!	
Ethical	!	
Green environment	→	

The OpenFlexure Microscope shows its potential in resource-limited health-care settings. Supported by evidence demonstrating affordability, customization, and accessibility, it offers remote diagnosis and digital archiving, presenting significant advantages over the standard of care. The ability of the company to manufacture medical devices on-site or locally through 3D printing can reduce the need for long-distance transport of products, thereby lowering the carbon footprint associated with shipping. Error detection mechanisms render safety concerns comparatively insignificant. Although a detailed budget impact analysis was absent, the economic feasibility seemed promising. Although organizational changes may be required, the documentation was insufficient. Caution is advised when making recommendations regarding legal, social, ethical, and environmental factors due to the scarcity of corresponding information. Further assessment of safety, ethical, and social aspects is crucial for a comprehensive evaluation and endorsement.

Technology readiness level 6

Technology evidence assessment Recommended

Health technology management

- Durability
- Ease of Use
- Ease of maintenance
- Environmental conditions
- Affordability
- Local access to technical support
- Ease of cleaning
- Infrastructure requirements

Health-care delivery platform

The digital microscope is an open-source project in which the aim is to provide several manufacturers with designs to locally produce devices in LMICs. This device is used in conjunction with software to control and obtain the images that are also part of the project, but it is installed on a computer supplied by the end user. It is based on a conventional bright-field optical microscope with the improvement of motorized adjustments and image sensors but maintaining standard parts such as the 100X oil immersion objective or LED light source.

The digital microscope is unique because mechanical parts are 3D printed; this allows resolution of supply chain issues. The rated duration is 5 years if correctly maintained. The advantage is that the open source project allows production of the microscopes in the same countries in which they are used, facilitating procurement of the devices, technical support, and availability of parts. The cost will be similar to that of microscopes imported from manufacturers in other countries, owing to the documentation capabilities of its software and the advantage of receiving local technical support.

Intellectual property and local production

- Technology transferability
- Open source/ access
- Local production (N/A)

Intellectual property: Open-Source Technology. Technical details for commercialization or further development of the technology are available in the public domain. The use of patented, compatible third-party products may require clearance.

Local production: No evidence was provided of a systematic product development approach. It is in an early prototype phase and it is not ready for local production.

WHO guidance

- Malaria Microscopy Quality Assurance Manual – Version 2. (2016). https://www.who.int/docs/default-source/documents/publications/gmp/malaria-microscopy-quality-assurance-manual.pdf
- Basic Malaria Microscopy – 2nd edition. (2010). https://iris.who.int/bitstream/handle/10665/44208/9789241547826_eng.pdf?sequence=1