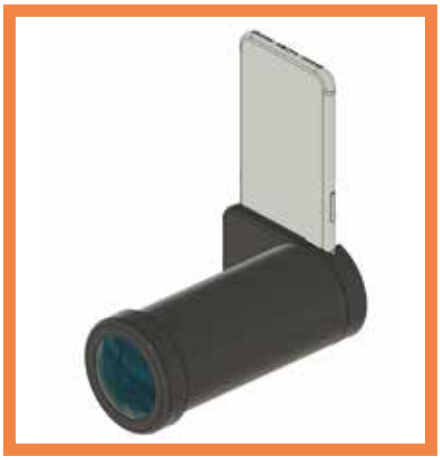
Prototype

Smart eye camera fundas model*

Country of origin | Japan

Primary use | Diagnosis/measurement/monitoring

Category | Medical device (including in vitro diagnostics)



Commercial information

List price (USD): 5000

Expected year of commercialization: 2024

Number of existing prototypes in use/trials/tests: 15

Currently used in: Tested for trials in Indonesia, Japan, Mozambique

Model: Software Version (as of 31 Oct 2023)

Product description

Smartphone attachment medical device which utilizes the camera and light source of the smartphone to observe the posterior segment without mydriation. The price is 5~10 USD per patient for single use. The detailed price will be set with the existing cognitive assessment and the national health insurance reimbursement policy in individual countries.

Product details

Accessories: The device is applicable to iPhone 7/8/SE2/SE3. The device is delivered with the applicable phones with the software (SEC App) installed and the charger of the iPhone as well as the hard-case for the device.

Consumables: Not applicable

Warranty duration: 2 years

Lifetime: 5 years

Energy requirements: Not necessary

Facility requirements: Please store in the attached case at the stable place. Carry by putting it in the attached case. Store under the following environment - Temperature: 4-35°C; Humidity, 30–80% (no condensation of moisture); Atmospheric pressure: 800–1060 hPa; Avoid direct sunlight, store away from any liquid. Store at the place away from flammable fumes/liquid.

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

WHO assessment**

Clinical

Clinical — Recommended with caution

Preventable blindness is one of the major public health challenges faced today. In low-resource settings, access to adequate ophthalmic care is hindered by the low availability of adequate equipment and trained professionals, delaying diagnosis and referral. Fundoscopy is an essential part of ophthalmic examination. However, use of an ophthalmoscope requires use of mydriatic drugs, as well as extensive training. Moreover, most ophthalmoscopes cannot acquire images (photography or video).

This technology simplifies several aspects of the fundoscopic examination. It is a compact device that transforms a smartphone into a device capable of performing a comprehensive examination of the posterior structures of the eye, without the need for mydriatic drugs. Through the smartphone's capabilities, it is also possible to record and transmit videos to other health-care professionals at different locations.

The device is currently undergoing several trials, with good preliminary results.

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

Comparison with WHO technical specifications

Cannot be verified.

This medical device is an ophthalmic camera that can be used on mobile phones to diagnose specific ophthalmic clinical issues. Similar medical equipment to compare technical requirements is a slit lamp which is not detailed in any technical requirements document in WHO or the UNICEF catalogue. Consequently, at the time of this report creation, WHO and/or UNICEF technical specifications were not available to compare this type of technology.

Regulatory

Pre-market assessment	N/A Not available	**Pre-market:** This is a prototype, therefore, the premarket documentation is not complete.
Post-market assessment	N/A Not available	**Post-market:** The manufacturer did not submit post-market surveillance and vigilance documentation.
Quality system assessment	Proceed with caution	**Quality management system (QMS):** Based on the certification and standards, the manufacture of the product conforms to ISO13485:2016.
Security	Proceed with caution	**Security:** The introduction of this technology does not lead to biosecurity or cybersecurity risk. 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 technology (Smart Eye Camera) is non-invasive and uses the light source and the camera of a smartphone to deliver ophthalmic diagnosis, while not introducing any additional safety risk. The technology is very safe especially since it does not require any external power supply. The associated risks are low, acceptable, and highly predictable. The expected clinical benefits are very high since it will enable non-ophthalmologists, nurses, and other health-care workers with no specific experience in ophthalmology to take good-quality ophthalmic images that can satisfy professional ophthalmologists, only after a short (<10 minutes) tutorial session. It is expected to play a critical role in improving the standard quality of ophthalmic services. The device is 80-90% less expensive than a conventional slit-lamp microscope (5000-8000 USD) and can extend the reach of accessible eyecare tremendously. The technology will allow delivery of eyecare to millions of patients (22 million blind and 1.1 billion visually impaired). It would broaden the possibility and capacity of local health-care workers in the rural areas and would save economic loss due to preventable blindness and visual impairment of the population greatly.

Technology readiness level 9

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 Smart Eye Camera Fundas model is designed as an alternative to the traditional portable fundas. The device consists of an app that is pre-installed on an iPhone with an included lens attachment that enables ophthalmological examinations in low-resource settings. The app is easy to use by health-care workers, including non-ophthalmologists. It promises to be more cost-effective than the current standard of care due to the lower cost of the device and the possibility of task shifting to any health-care worker.

Maintenance of the lens attachment is minimal, but the durability of the phone is dependent on careful handling according to the manufacturer's instructions. Currently, the app and attachment are only compatible with iPhones, which generally are more expensive to repair in LMICs.

Intellectual property and local production

- Technology transferability
- Open source/ access
- Local production

Intellectual property: This technology is protected by copyrights, patents, and registered trademarks. Some patents are pending, and trade secrets are likely to exist. The use of all intellectual property will require clearance.

Local production: Only the SEC Fundas model is considered (the mobile phone is excluded from the scope of evaluation for local production).

Currently, the product is in the prototype/clinical trial phase, hence cannot be considered for local production . The product is likely to evolve further.