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& IMPACT

FUNDUS ON PHONE (FOP)

Recent Advances — Evidence-Based & Source-Verified Edition

All statistics traceable to PubMed-indexed publications | PG Ophthalmology 2026

1. DEVICE OVERVIEW — WHAT IS FOP?

Manufacturer: Remidio Innovative Solutions Pvt. Ltd., Bengaluru, India. FOP is a portable smartphone-coupled fundus camera using an **annular illumination optical design** that eliminates corneal reflection. It mates with any commercially available smartphone. It is **FDA 510(k)-registered and CE-marked**. Both **mydriatic and non-mydriatic** versions exist (NM-FOP for non-dilated; FOP-NM 10 for dilated 3-field).

Fields captured: Macula-centred, disc-centred, nasal, superior-temporal, inferior-temporal (4-field protocol used in Rajalakshmi et al., 2015 PLOS ONE validation study).

Source: Rajalakshmi R et al. PLOS ONE 2015;10(9):e0138285 — original validation study (n=301 diabetics, Chennai, vs Zeiss FF450 Plus 7-field gold standard).

1A. Validated Clinical Performance of FOP — DR Detection (Peer-Reviewed Data)

Study	Journal / Year	n	Endpoint	Sensitivity	Specificity
Rajalakshmi et al.	PLOS ONE, 2015	301	Any DR	92.7%	98.4%
Rajalakshmi et al.	PLOS ONE, 2015	301	STDR	87.9%	94.9%
Rajalakshmi + EyeArt AI	Eye (Nature), 2018	296	Any DR (AI)	95.8%	80.2%
Rajalakshmi + EyeArt AI	Eye (Nature), 2018	296	STDR (AI)	99.1%	80.4%
SMART Study (Sosale et al.)	BMJ Open Diabetes, 2020	900	Referable DR	93.0%	92.5%
SMART Study (Sosale et al.)	BMJ Open Diabetes, 2020	900	Any DR	83.3%	95.5%
Sengupta et al.	Ophthalmol Retina, 2019	277	Referable DR	92%	88%

Sources: Rajalakshmi R et al. PLOS ONE 2015; Rajalakshmi R et al. Eye (Nature) 2018;32:1138–44; Sosale B et al. BMJ Open Diabetes Res Care 2020;8:e000892; Sengupta S et al. Ophthalmol Retina 2019;3:146–53.

2. AI-INTEGRATED FOP — KEY ADVANCES

2A. FOP + EyeArt AI (Rajalakshmi et al., Eye 2018)

First landmark study demonstrating automated AI grading on FOP images. **EyeArt** (Eyenuk Inc.) algorithm applied to 296 patients at Madras Diabetes Research Foundation (MDRF), Chennai. AI achieved **95.8% sensitivity for any DR** and **99.1% sensitivity for STDR** — critically important as STDR sensitivity is prioritised in mass screening to prevent blindness. Kappa agreement: k=0.78 for DR; k=0.75 for STDR (both p<0.001).

2B. FOP + Medios AI — SMART Study (Sosale et al., BMJ Open Diabetes 2020)

The **SMART (Simple Mobile-based Artificial Intelligence Algorithm in the detection of DR)** study is the landmark validation of **offline AI on FOP**. Medios AI (Medios Technologies, Singapore) — the **first offline AI algorithm** integrated with a smartphone fundus camera. No internet required; grading in **<10 seconds**. n=922 enrolled; 900 analysed. Referable DR sensitivity **93%**, specificity **92.5%**. STDR sensitivity **98.7%**. Ground truth: majority diagnosis of 5 retina specialists.

■ **Exam Pearl: 'Offline AI on FOP' = the SMART study. The key innovation is no internet needed — grading happens on the smartphone itself, making it viable in areas with no connectivity.**

2C. Device-Agnostic AI — External Validation (Medios, PMC 2022)

Vajpayee et al. (PMC 2022) externally validated Medios AI on Remidio FOP vs Topcon camera images. Found **100% sensitivity for referable DR and STDR** when compared to clinical examination — demonstrating that AI trained on FOP images generalises across devices.

Source: Vajpayee et al. PMC9393096. External validation of device-agnostic AI for DR screening.

2D. AI for ROP Detection — KIDROP Dataset (Frontiers Pediatrics, 2023)

Remidio AI team + KIDROP collaboration: deep learning (DL) algorithm trained on **227,326 images from 5,944 premature infants** over 11 years (2011–2022). Multiple camera systems used (RetCam III, RetCam Shuttle, Forus 3Nethra NEO). Binary classification: ROP present/absent. Key design feature: **edge-deployable offline model** — paves way for on-device ROP screening without connectivity.

Source: Frontiers in Pediatrics 2023;11:1197237. doi:10.3389/fped.2023.1197237 — KIDROP AI validation.

3. FOP IN ROP SCREENING — EVIDENCE REVIEW

KIDROP Programme — Vinekar et al. (Indian J Ophthalmol 2014; Semin Fetal Neonatal Med 2015)

KIDROP (Karnataka Internet Diagnosis of ROP) — founded by **Dr. Anand Vinekar, Narayana Nethralaya, Bangalore**. Initially used **RetCam Shuttle** (portable wide-field contact camera), not FOP. Covered **81+ neonatal units in Karnataka** with non-physician trained technician graders. By 2015, reported **20,214 imaging sessions** in rural outreach. The KIDROP model demonstrated that telemedicine + non-physician graders + wide-field imaging can scale ROP screening effectively. Later iterations incorporated smartphone-based imaging and Forus 3Nethra NEO camera.

■ **CORRECTION FROM EARLIER VERSION: KIDROP originally used RetCam Shuttle, NOT the Remidio FOP device. The KIDROP AI validation (Frontiers 2023) used RetCam/Forus images. FOP-specific ROP studies are separate.**

Smartphone Fundus Imaging vs RetCam for ROP (Scientific Reports, 2019)

Non-contact smartphone-based fundus imaging (SBFI) vs conventional contact fundus imaging (CFI) in 26 eyes. Field of view ratio SBFI:CFI = **1:2.5** (smaller with smartphone). Sensitivity/specificity for **plus disease**: SBFI 90%/100% vs CFI 80%/100%. For **ROP stage**: SBFI 88%/93% vs CFI 100%/96%. Examination time: SBFI **109 sec** vs CFI 76 sec (longer with smartphone). Conclusion: SBFI is a viable low-cost alternative for ROP documentation in resource-limited settings.

Source: Lorenz B et al. Scientific Reports 2019;9:19220. doi:10.1038/s41598-019-56155-x

AI-Enabled ROP Screening (JAMA Ophthalmology, 2025 — Mexico/Argentina)

ML algorithms on smartphone-collected fundus **videos** (not still images) from 512 neonates. Cost of setup **~USD 1,000** (~1/100th of wide-angle contact imaging systems). Patient-level ROP classifier sensitivity: **93.3%** (95% CI 86.4–100%). Algorithm exceeded sensitivity of a panel of 3 paediatric ophthalmologists. Specificity and accuracy were higher for ophthalmologist classification.

Source: PMC12042057. AI-Enabled Screening for ROP in Low-Resource Settings. JAMA Ophthalmol 2025.

4. SMARTPHONE FUNDUS CAMERAS — COMPARISON TABLE

Multiple validated smartphone-based systems exist. Key devices referenced in peer-reviewed literature:

Device	Manufacturer	FOV	Mydriasis	AI Integration	Key Publication
Remidio FOP / NM-FOP	Remidio, Bangalore	45°–60°	Optional (NM version)	EyeArt, Medios (offline)	Eye 2018; BMJ Diabetes 2020
Volk iNview / Vistaview	Volk Optical, USA	~40°	Required	Limited	Surv Ophthalmol 2024
Forus 3Nethra NEO	Forus Health, Bangalore	55°–130°	Required	KIDROP AI (2023)	Frontiers Pediatr 2023
3D-Printed Adapter (DIY)	Various / Open-source	~30°–45°	Required	Research phase	Am J Trop Med 2023; Phil J Ophth 2024
GSoP (Glaucoma on Phone)	Academic prototype	Optic disc focus	Required	Research prototype	medRxiv preprint 2025

Sources: Vaughan N. *Surv Ophthalmol* 2024;69:279–286 (review); *Frontiers Pediatrics* 2023; Varo et al. *Am J Trop Med Hyg* 2023;109:1192.

5. TELEMEDICINE INTEGRATION — STORE-AND-FORWARD MODEL

The **'store-and-forward'** telemedicine model — images captured offline, uploaded when connectivity available, auto-graded by AI, reviewed asynchronously by specialists — is the central use-case for FOP in low-resource settings. This is evidenced across multiple programmes:

Programme / Study	Country	Disease	Model	Outcome / Reference
KIDROP (Vinekar)	India (Karnataka)	ROP	Store-and-forward + Non-physician graders	20,214 sessions; 81 NICUs covered — <i>Semin Fetal Neonatal Med</i> 2015
MDRF + EyeArt (Rajalakshmi)	India (Chennai)	DR	FOP + cloud AI grading	STDR sensitivity 99.1% — <i>Eye</i> 2018
SMART Study (Sosale)	India (Bangalore)	DR	FOP + offline Medios AI	RDR sensitivity 93% without internet — <i>BMJ Diabetes</i> 2020
Amazon Forest Programme	Brazil	DR/General	Smartphone + telemedicine	Feasibility in extreme remote access — <i>MDPI Ophthalmol</i> 2025
Pakistan NICU Study	Pakistan (Karachi)	ROP	Smartphone BIO + remote expert review	Validated vs BIO (Pak AKU, Jan–Apr 2022) — PMC10214799

6. VALIDATED LIMITATIONS (EVIDENCE-BASED)

Limitation	Evidence / Source	Potential Solution
Smaller FOV vs RetCam	SBFI:CFI FOV ratio = 1:2.5 (Lorenz, <i>Sci Rep</i> 2019)	UWF adapters; video-based capture (<i>JAMA</i> 2025)
Longer exam time	SBFI: 109s vs CFI: 76s (Lorenz, <i>Sci Rep</i> 2019)	Operator training; AI-automated frame selection
Lower specificity with AI	EyeArt specificity for any DR: 80.2% (<i>Eye</i> 2018)	Higher specificity offline AI: Medios 95.5% for any DR

No OCT capability	Cannot image retinal layers (all FOP studies)	Handheld SS-OCTA emerging (IJO 2023 review)
Image quality variability	Artefacts: glare/noise noted (GSoP preprint 2025)	Automated quality scoring in AI pipeline
Diagnostic only — no treatment	All ROP/DR FOP studies — device does not treat	Still requires BIO-guided laser or IVI anti-VEGF

7. MCQ TRAPS & VIVA PEARLS — EVIDENCE ANCHORED

◆ MCQ TRAP 1: FOP uses which condensing lens?

→ Answer: +20D condensing lens with annular illumination design. Trap: +78D/+90D are slit-lamp non-contact lenses; +20D is used for both FOP and BIO. Source: Rajalakshmi PLOS ONE 2015 — annular illumination eliminates corneal reflex.

◆ MCQ TRAP 2: KIDROP originally used which device for ROP screening?

→ Answer: RetCam Shuttle (portable contact wide-field camera) + Forus 3Nethra NEO — NOT Remidio FOP. The KIDROP AI validation (Frontiers 2023) used 227,326 RetCam/Forus images. FOP is validated separately for DR.

◆ MCQ TRAP 3: FOP can treat ROP — True/False?

→ FALSE. FOP is DIAGNOSTIC ONLY. All published studies use FOP for screening/documentation. Treatment requires BIO-guided diode laser or intravitreal anti-VEGF. No exceptions.

◆ MCQ TRAP 4: In the SMART study, what was the key advance of Medios AI over EyeArt AI?

→ OFFLINE operation — no internet needed. EyeArt requires cloud upload; Medios AI processes images on-device. Result in <10 seconds. This is the critical advantage for rural/field deployment. Source: Sosale et al. BMJ Open Diabetes 2020;8:e000892.

◆ VIVA PEARL: What does the 1:2.5 FOV ratio of SBFi vs RetCam mean clinically?

→ Smartphone-based fundus imaging captures a field ~2.5x smaller than RetCam. This means peripheral ROP lesions (Zone I anterior, Zone II posterior) may be missed. This is the primary validated limitation for ROP vs DR, where peripheral field matters less. Source: Lorenz et al. Scientific Reports 2019.

◆ VIVA PEARL: What is the significance of 99.1% STDR sensitivity in the EyeArt study?

→ In mass screening, FALSE NEGATIVES (missed STDR) cause blindness. Even if specificity is 80% (20% false positives), the near-perfect sensitivity ensures no sight-threatening case is missed. The tradeoff is more false referrals — acceptable in a screening programme. This is the WTO/IAPB-recommended priority metric. Source: Eye 2018.

■ CONSULTANT-LEVEL EXTENSION QUESTION

"Critically compare the sensitivity and specificity profiles of EyeArt AI (Eye 2018) vs Medios offline AI (BMJ Diabetes 2020) when integrated with FOP. Which metric — sensitivity or specificity — should be prioritised in a national DR screening programme, and why? How does this influence the threshold design of the AI algorithm, and what are the economic implications of a lower specificity in a resource-limited health system where follow-up capacity is limited?"

Discussion framework: EyeArt: any DR sens 95.8%, spec 80.2% (high sens, lower spec = more referrals). Medios: RDR sens 93%, spec 92.5% (balanced; offline advantage). National programme priority = sensitivity (miss no STDR = blindness). But low specificity → false referral burden → overwhelms overburdened retina services. Ideal threshold: maximise STDR/RDR sensitivity (>95%) while keeping specificity >85% for any DR. Algorithm threshold is a policy decision balancing epidemiology, workforce, and healthcare economics.



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