

# The Diagnostic Accuracy of Diabetic Retinopathy Screening using Handheld Digital Retinal Imaging Devices in real-world settings: A Systematic Review and Meta-Analysis

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## INTRODUCTION

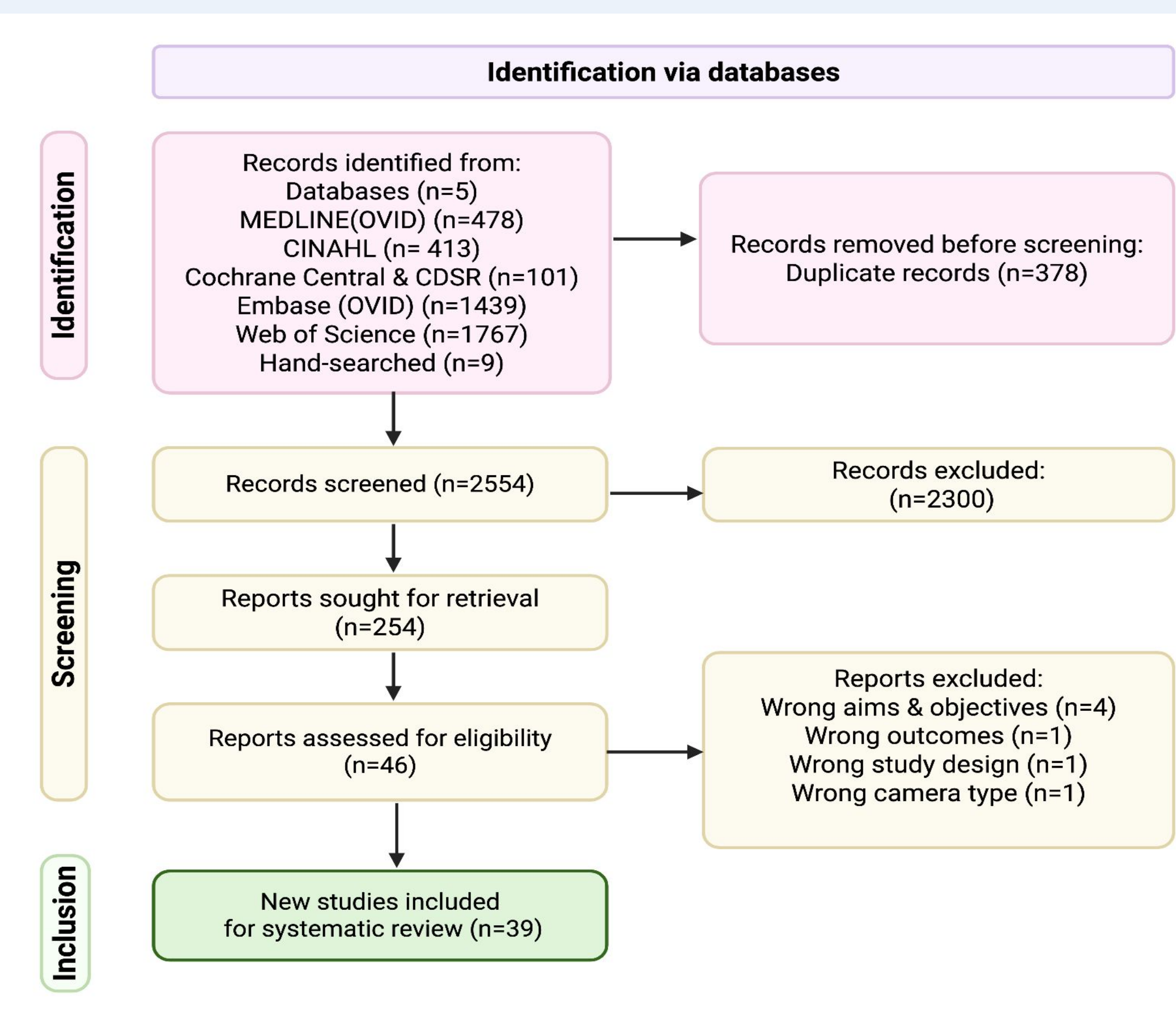
Diabetic retinopathy (**DR**) is a common complication of Diabetes Mellitus (**DM**) and a leading cause of sight loss among economically working age adults (1). Studies have demonstrated that early diabetic retinopathy screening (**DRS**) and treatment is pivotal in preventing blindness (2). The advent of **handheld devices** for DRS compared to conventional tabletop cameras could relieve the burden of care and optimise patient uptake (3). Recent evolution in artificial intelligence (**AI**) systems may enhance the detection of sight-threatening DR (4). This poster summarises a systematic review and meta-analysis, assessing the **diagnostic test accuracy (DTA)** of handheld devices that use human graders, as well as AI algorithms.

## AIMS & OBJECTIVES

- To determine the **DTA of handheld imaging devices** for detecting the Referable level of DR (**RDR**), compared to a reference standard.
- To compare the **DTA** of handheld imaging devices for detecting RDR, **between AI and Human graders**.

## METHODS

- 5 Databases searched.
- Inclusion: Adults ( $\geq 18$  years) with diagnosed type 1 or type 2 diabetes mellitus at a clinic, community or programme setting. Peer reviewed literature from 2004-2025.
- PRISMA and Cochrane guidelines used to conduct and report the review (**Fig. 1**).
- Meta-analysis performed using STATA IC Version 14.2 (StataCorp, 2025) (**Fig. 3**).



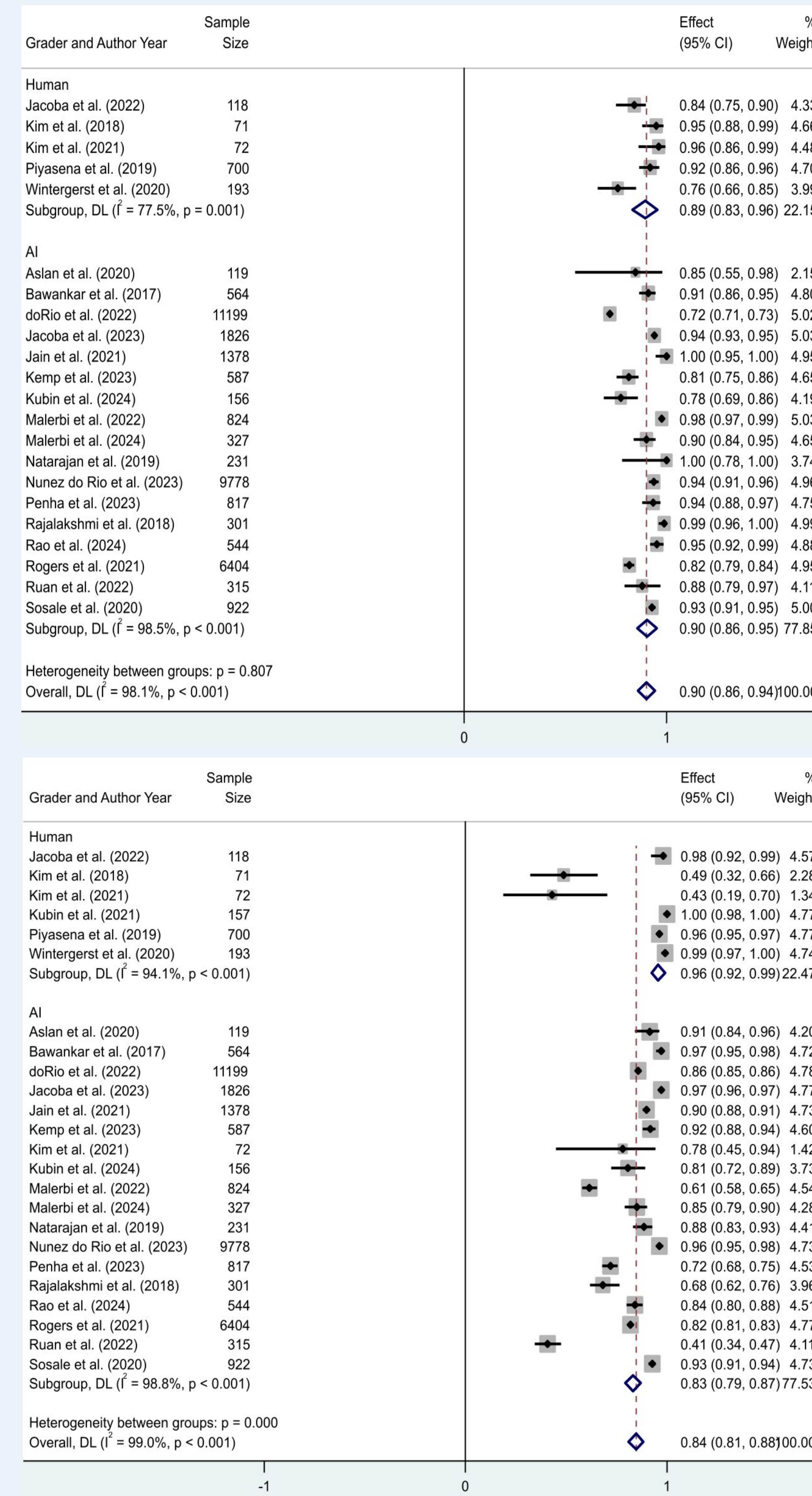
**Figure 1.** PRISMA flow diagram detailing search and selection process applied during the systematic review (5).

## RESULTS

- 31/39 (79.5%) studies included in the meta-analysis.
- 30/39 (76.9%) studies conducted in lower and middle income countries (**LMICs**).
- 21 handheld cameras were utilised, a representative example is shown in (**Fig. 2**).
- Handheld retinal imaging achieved a pooled estimates of **90%/ 84%** (**Sensitivity/Specificity**) when compared to gold-standard tabletop cameras (**Fig. 3**).
- AI grading showed **similar sensitivity** to Human grading (**90%/89%**) (**Fig. 3**).
- AI grading showed **lower specificity** to Human grading (**83%/96%**) (**Fig. 3**).



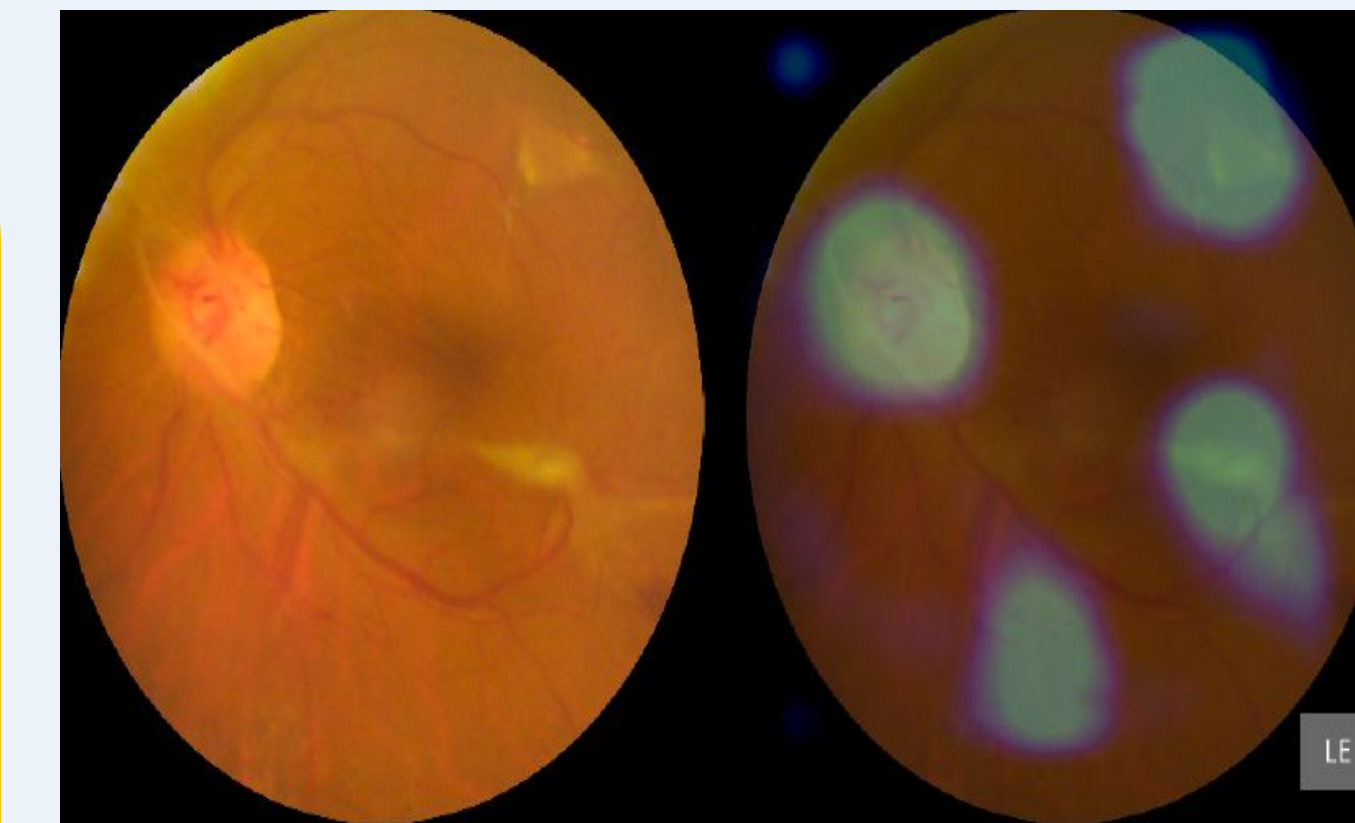
**Figure 2.** Picture of Remedio Fundus-on-Phone camera (6)



**Figure 3.** Forest plots displaying the **Meta-Analysis** of the **Sensitivity** (top) and **Specificity** (bottom) of handheld imaging devices used to detect RDR compared to a reference standard. Stratified into Human and AI graders.

## DISCUSSION

The UK Diabetic Eye Screening Programme requires 80% sensitivity and 95% specificity for viable DRS (7). Our findings demonstrate **AI algorithms met the sensitivity threshold (90%), but not the required specificity standard (83%)**, increasing potential referral burden and cost in real-world programmes. As illustrated in (**Fig. 4**), handheld devices capture sufficient image quality for AI detection of sight-threatening DR, supporting their potential clinical utility. **76.9% of included studies were from LMICs**, where the portability and lower cost of handheld cameras offer a compelling advantage. The clinical case for handheld imaging is therefore strongest where the research base is the largest (8). Significant **heterogeneity in outcomes**, driven by **variation in the RDR cut-off point** and grading classification systems used, limits direct cross-study comparability. Additionally, AI algorithms likely trained on high-income datasets raise concerns about **generalisation across diverse populations**. Standardisation of grading criteria and population-diverse AI training datasets are critical before handheld AI based screening can be deployed in national programmes.



**Figure 4.** Retinal images captured using a handheld camera with signs of sight threatening diabetic retinopathy detected using an AI Algorithm) [Image copyrights - Dr Mapa Prabhath Piyasena] (9).

## CONCLUSION

- Handheld retinal imaging offers DTA sufficient for real-world DRS**, particularly in LMICs.
- AI matches human sensitivity for RDR detection**, but falls below national specificity standards. Further validation is needed before deployment.
- Standardised grading criteria and diverse AI training datasets** are essential for equitable DRS globally.

We declare that this work is our own and all references cited have been seen by us.

