

# Performance of an Artificial Intelligence Automated System for Diabetic Eye Screening in a Large English Population

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# Why we need more eye screening?



Eye diseases lead to serious visual impairment or blindness



Global costs of vision loss is estimated to be nearly \$3 trillion



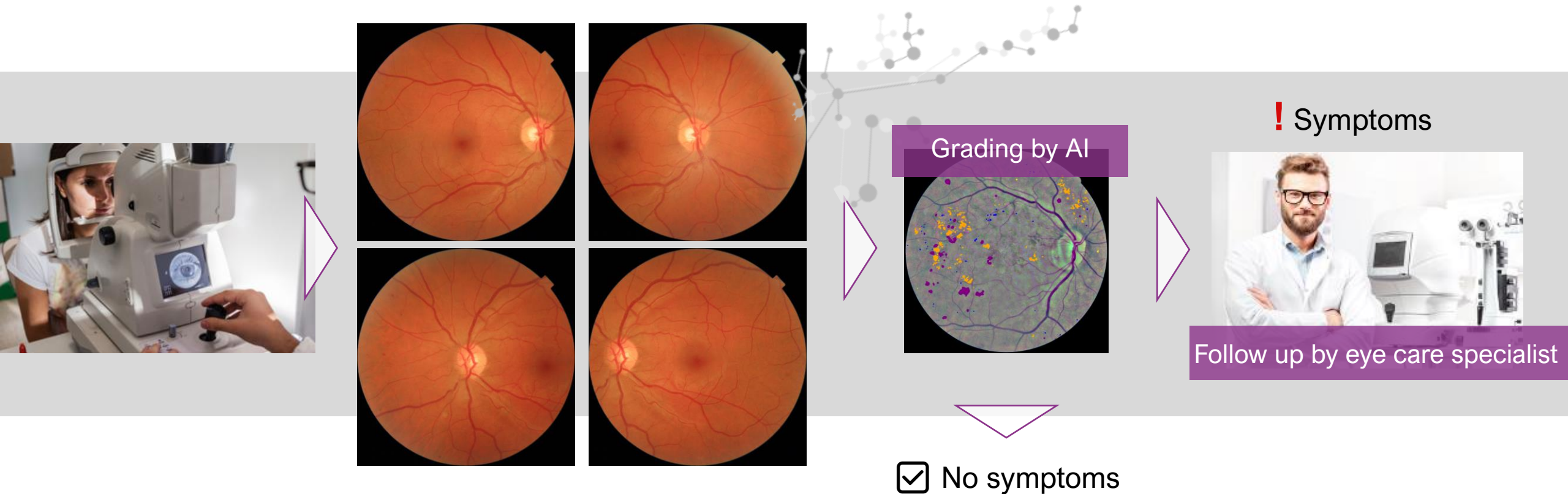
In 80% of these cases we can prevent blindness if detected timely

# Why we need Artificial Intelligence?

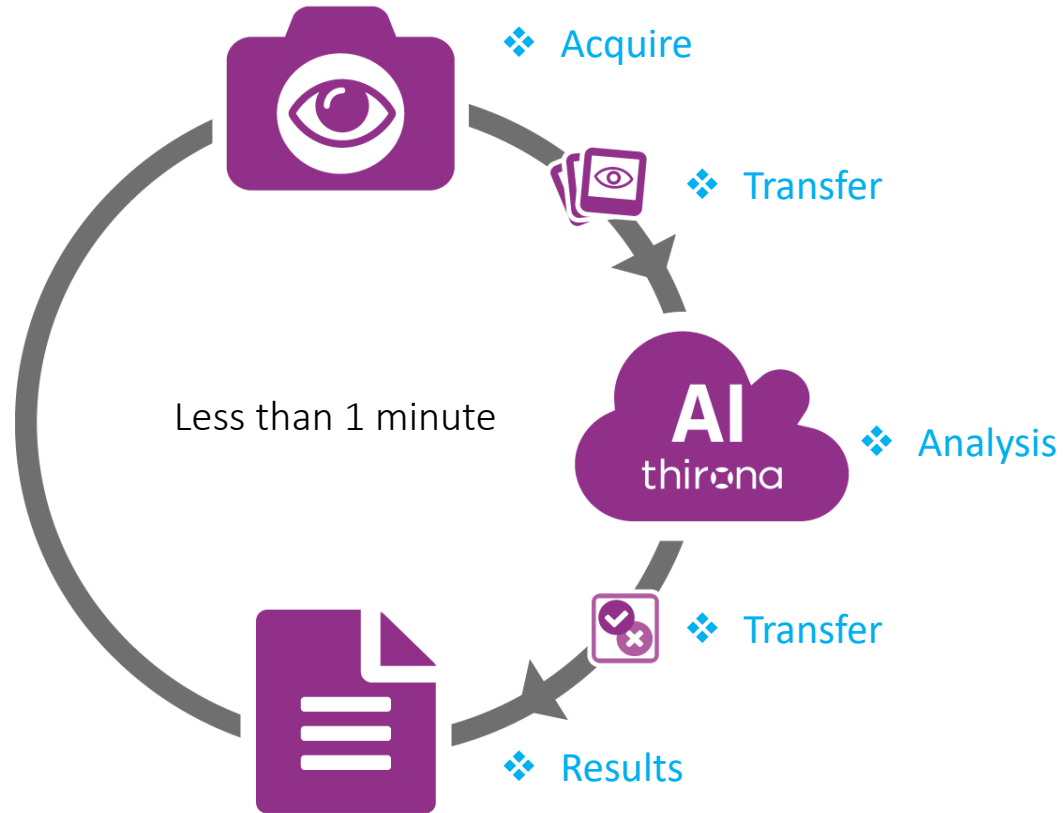


Using AI we can screen many more people faster with even higher accuracy and timely help patients who need it.

# Highly effective triaging process with AI-based screening



# RetCAD™



- **Severity** of Age-related Macular Degeneration (AMD)
- **Severity** of Diabetic Retinopathy (DR)
- **Suspicion** of Glaucoma
- Processing in the cloud or on-premise





RetCAD™

Next level  
eye care diagnostics

MDR class IIa approved

CE (0344) certified

ISO 13485 certified

**TGA** Health Safety  
Regulation

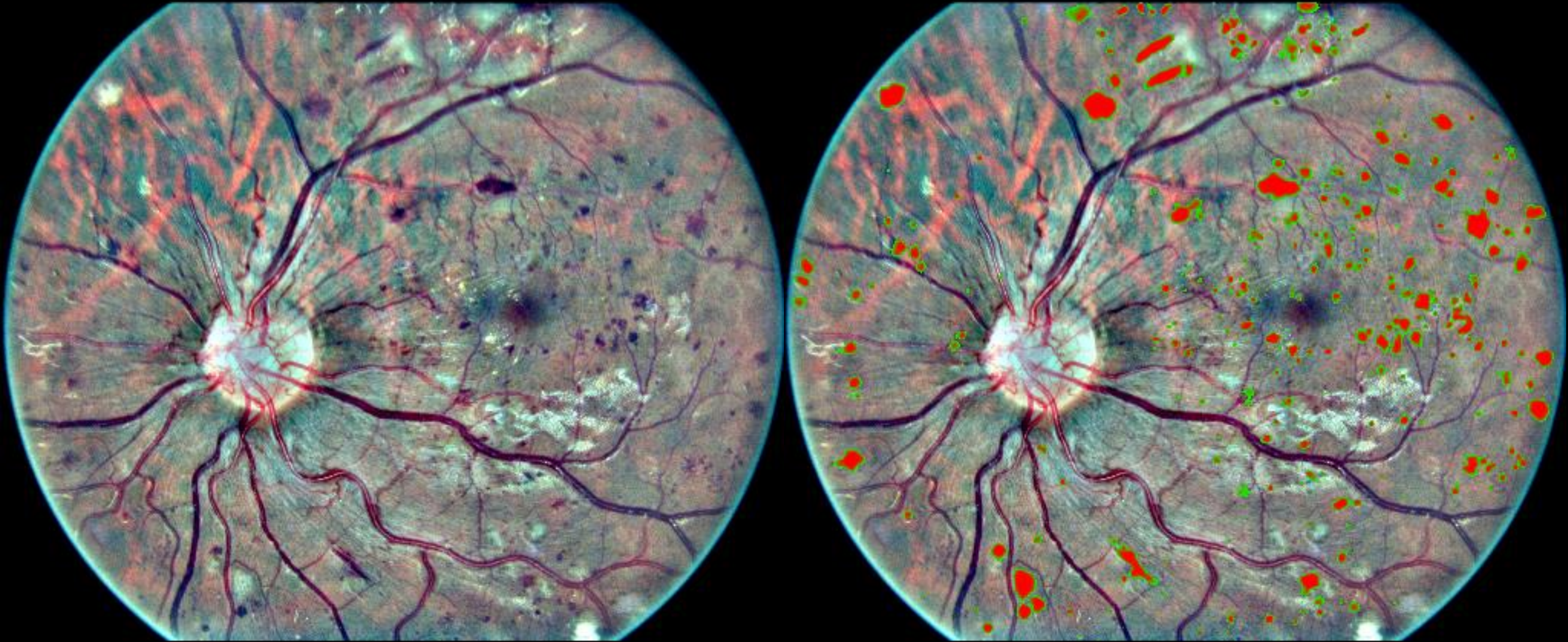
 **MHRA**

 **EU GDPR**  
COMPLIANT

**thirona**  
retina



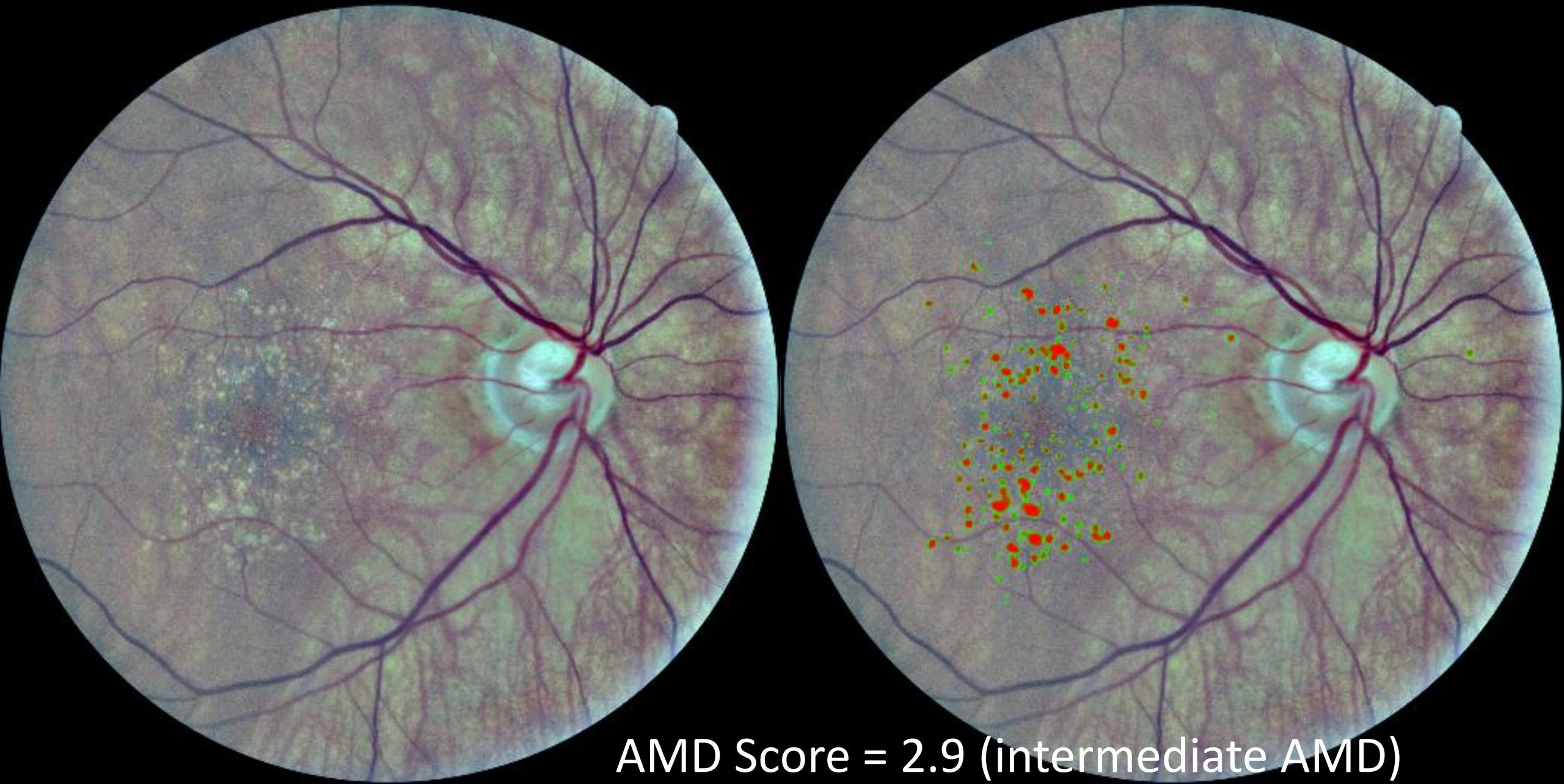
# Example output for DR



DR Score = 4.6 (proliferative DR)



# Example output for AMD





# Example output for GLC



GLC Score = 0.89 (Suspicion of glaucoma)

# RetCAD report: Standardised 4-image report

RetCAD™ Screening Report RetCAD™

**Patient information**

Patient ID	000001	Examination date	22-02-2023
Patient Name	example example	Processing date	02-05-2023
Accession No.	-		

**Patient recommendation**

RetCAD™ outcome: **No abnormalities are detected.**  
 Recommendation: **No follow-up action is advised.**

**OD**

RetCAD™ DR assessment: **No DR detected**

RetCAD™ AMD assessment: **No AMD detected**

RetCAD™ GLC assessment: **Not suspicious of Glaucoma**

Exam quality: **good**

**OS**

RetCAD™ DR assessment: **No DR detected**

RetCAD™ AMD assessment: **No AMD detected**

RetCAD™ GLC assessment: **Not suspicious of Glaucoma**

Exam quality: **good**

**RetCAD™ score explanation**

<p><b>Diabetic Retinopathy (DR)</b> Relates to the ICDR* severity classification</p> <p>0: No DR detected 1: Mild DR detected 2: Moderate DR detected 3: Severe DR detected 4: Proliferative DR detected</p> <p>* International Clinical Diabetic Retinopathy</p>	<p><b>Age-related Macular Degeneration (AMD)</b> Relates to the AREDS* severity classification</p> <p>0: No AMD detected 1: Early AMD detected 2: Intermediate AMD detected 3: Advanced AMD detected**</p> <p>* Age-Related Eye Disease Study ** Advanced AMD includes both the wet and dry form</p>	<p><b>Glaucoma (GLC)</b> Indicates the likelihood for Glaucoma</p> <p>0: Not suspicious of glaucoma 1: Very suspicious of glaucoma</p>
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Disclaimers  
 When more than mild Diabetic Retinopathy (DR ≥ 2) or more than Early Age-related Macular Degeneration (AMD ≥ 2) or suspicion of Glaucoma (GLC > 0.5) is detected, it is recommended to see an eye-care specialist for follow-up diagnosis. The RetCAD™ software is approved for clinical use and is CE (0344) certified as a Class IIa medical device. The analysis using RetCAD™ does not replace an eye-health check-up.

This report was generated using RetCAD™ v2.0.1, CE (0344), Thirona Retina 1.

RetCAD™ Screening Report RetCAD™

**Detailed RetCAD™ analysis results**

Original image	Bright lesions	Red lesions	Scores
OD			
			DR: 0.12 AMD: 0.07 GLC: 0.13 QA: 100.00
			DR: 0.03 AMD: 0.07 GLC: 0.07 QA: 100.00
OS			
			DR: 0.17 AMD: 0.09 GLC: 0.04 QA: 100.00
			DR: 0.10 AMD: 0.07 GLC: 0.03 QA: 100.00

The highest score per disease is taken as the overall eye / patient disease score. Images with a quality assessment (QA) score below 25.00% are deemed insufficient quality and are not taken into consideration for the overall eye / patient assessment. When both images of an eye are deemed insufficient quality, no score is reported for that eye. When an eye is deemed insufficient image quality, no patient score is reported.

This report was generated using RetCAD™ v2.0.1, CE (0344), Thirona Retina 2.



# Interpreting the AI output

## RetCAD™ Patient Report

### AMD score (range: 0 - 4)

- 0.00 - 0.99: No AMD
- 1.00 - 1.99: Early AMD
- 2.00 - 2.99: Intermediate AMD
- 3.00 - 3.99: Advanced AMD

\* (AREDS classification)

### DR score (range: 0 - 5)

- 0.00 - 0.99: No DR
- 1.00 - 1.99: Mild DR
- 2.00 - 2.99: Moderate DR
- 3.00 - 3.99: Severe DR
- 4.00 - 4.99: Proliferative DR

\* (ICDR classification)

### GLC score (range: 0 - 1)

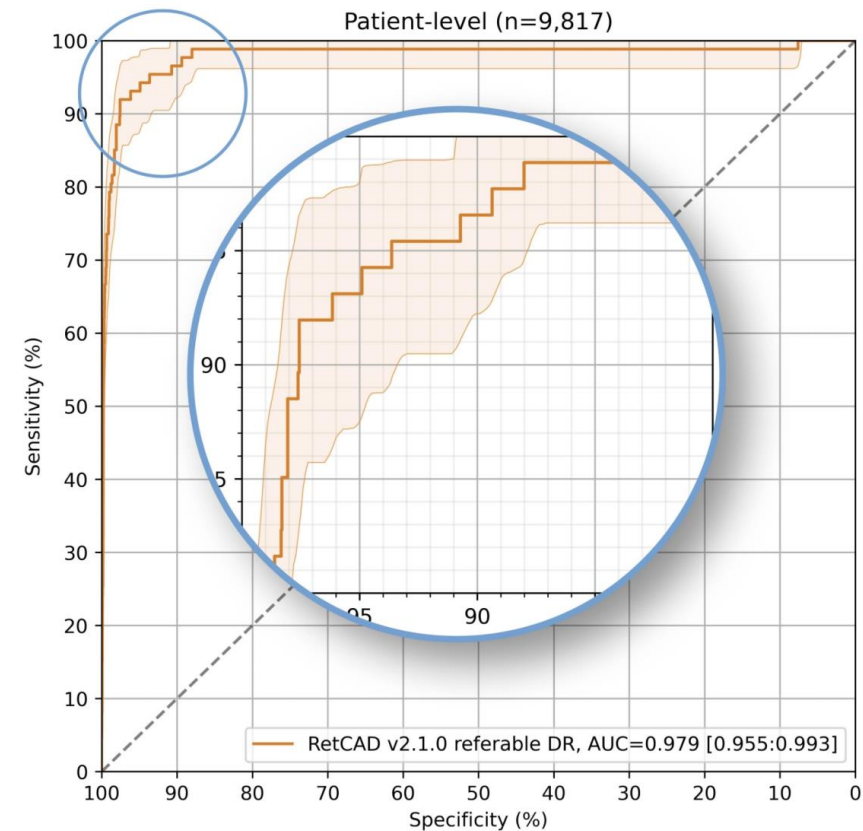
- 0.00 – 0.49: No suspicion
- 0.50 – 1.00: Suspicion

\*Output scores can be mapped to other (inter)national classifications

# RetCAD as reliable as human graders

**95.4% sensitivity**  
**92.0% specificity**  
performance in detecting  
referable DR


- ✓ Validated on a multi-ethnic NHS population
- ✓ 10 000 patients
- ✓ 40 000 fundus images





RESEARCH ARTICLE

# Performance of an artificial intelligence automated system for diabetic eye screening in a large English population

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## Correspondence

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## Abstract

**Aims:** A diabetic eye screening programme has huge value in reducing avoidable sight loss by identifying diabetic retinopathy at a stage when it can be treated. Artificial intelligence automated systems can be used for diabetic eye screening but are not employed in the national English Diabetic Eye Screening Programme. The aim was to report the performance of a commercially available deep-learning artificial intelligence software in a large English population.

**Methods:** 9817 anonymised image sets from 10,000 consecutive diabetic eye

# Methods & Data

RetCAD AI score	ICDR level	DESP grade
Stage 0: 0-0.5	Stage 0: No DR	R0: No retinopathy
Stage 1: 0.5-1.5	Stage 1: Mild DR	R1: Background retinopathy
Stage 2: 1.5-2.5	Stage 2: Moderate DR	R2: Pre-proliferative retinopathy
Stage 3: 2.5-3.5	Stage 3: Severe DR	
Stage 4: 3.5-4.0	Stage 4: Proliferative DR	R3(a/s): Proliferative retinopathy

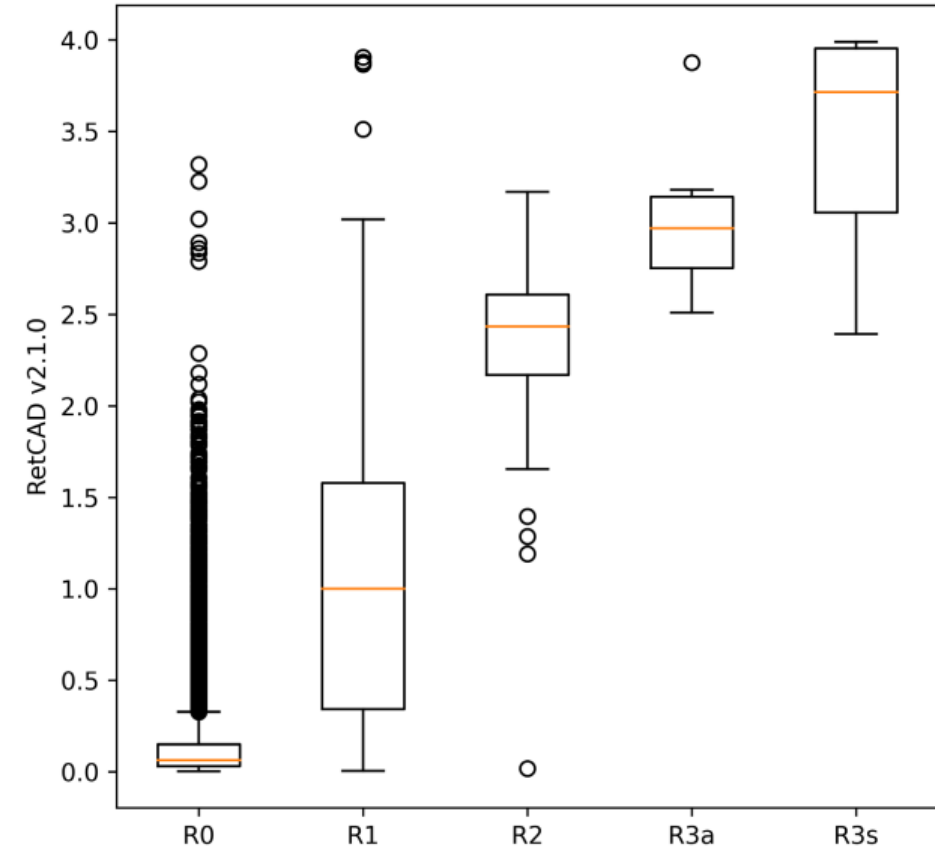
Referable DR

Final human grade in worst affected eye	Number of people	Percentage
R0	7156	72.89
R1	2574	26.22
R2	72	0.73
R3 (active)	6	0.06
R3 (stable)	9	0.09
Total	9817	100.00



# Results

RetCAD Reference	No diabetic retinopathy	Mild	Moderate	Severe	Proliferative
R0	6600	495	54	7	0
R1	806	1046	709	9	4
R2	1	3	39	29	0
R3active	0	0	0	5	1
R3stable	0	0	1	2	6



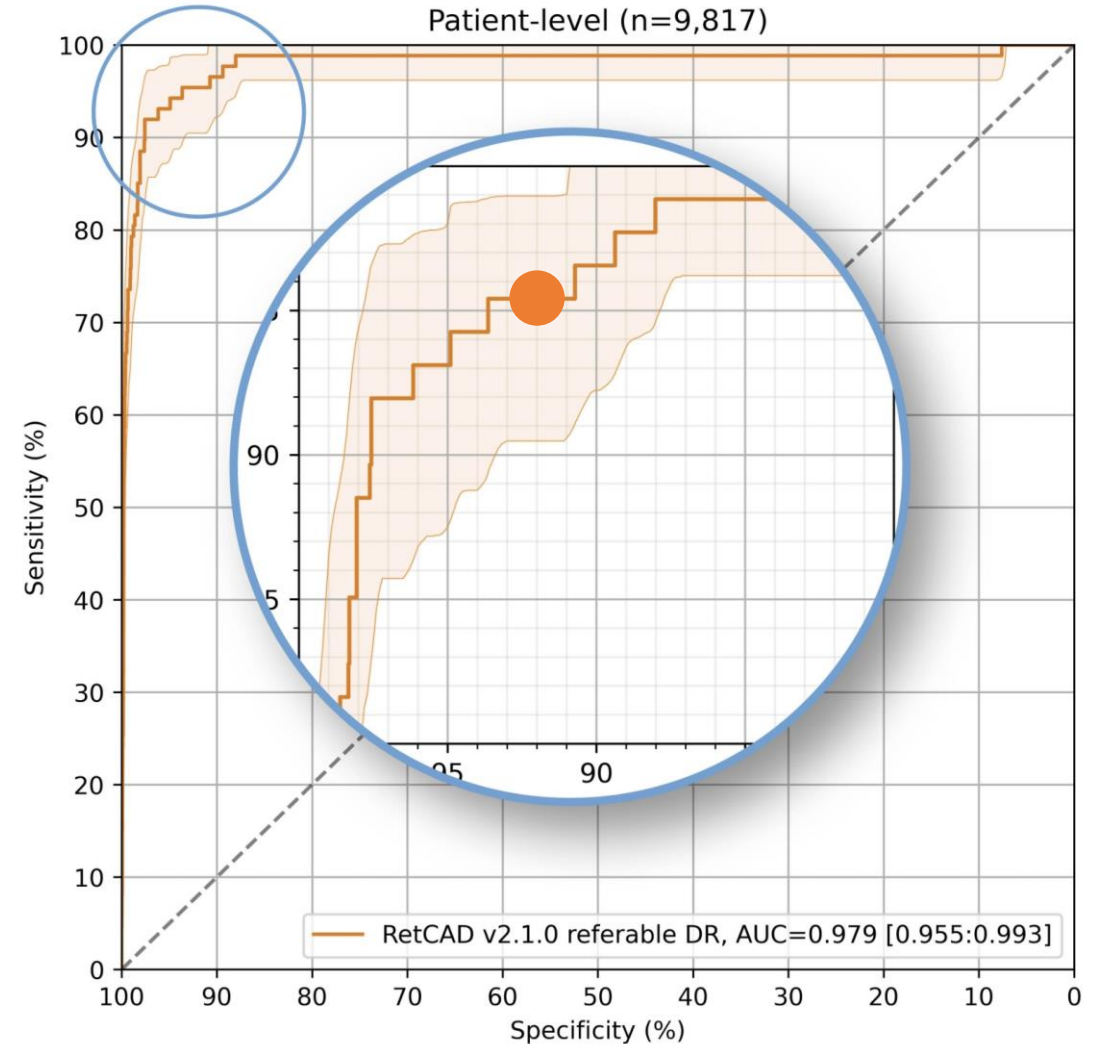
# Results

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R3active	0	0	0	5	1
R3stable	0	0	1	2	6

- Predefined cutoff point
- **Sens/spec: 95.4% / 92.0%**

**Negative Predicted Value (NPV): 99.96%\***

\*4 cases were missed by the software, but these turned out to be non-referable DR after regrading





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R2	1	3	39	29	0
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R3stable	0	0	1	2	6

AI Grade: Severe DR

Original Grade: ROM0

Urgent Non DR

Regrade: ROM0

Urgent Non DR





RetCAD Reference	No diabetic retinopathy	Mild	Moderate	Severe	Proliferative
R0	6600	495	54	7	0
R1	806	1046	709	9	4
R2	1	3	39	29	0
R3active	0	0	0	5	1
R3stable	0	0	1	2	6

AI Grade: Severe DR

Original Grade: R0M0  
Urgent Non DR: CRVO

Regrade: R0M0  
Urgent Non DR: CRVO



RetCAD Reference	No diabetic retinopathy	Mild	Moderate	Severe	Proliferative
R0	6600	495	54	7	0
R1	806	1046	709	9	4
R2	1	3	39	29	0
R3active	0	0	0	5	1
R3stable	0	0	1	2	6

AI Grade: Severe DR

Original Grade: R1M0

Regrade: R2M0

Agree with AI Grade

# What about the referable cases?

- Data from 1 DESP from 1 year:
  - 1<sup>st</sup> Aug 2022 – 31<sup>st</sup> July 2023
  - 202.874 patient total
- 1664 eyes had final grade of R2 or R3
- All referable eyes analysed using RetCAD

	Nr of patients	Nr of eyes
<b>Both eyes referable DR</b>	822	1664*
One eye referable DR	????	????
Both eyes non-referable DR	???.???	???.???
<b>Total</b>	202.874	~405.748

\*12 patients with two screenings in the time period; 4 patients with only 1 eye



# Initial results

RetCAD	No diabetic retinopathy	Mild	Moderate	Severe	Proliferative
Reference	R0	R1	R2		R3
<b>R2</b>	7	13	644		12
<b>R3</b>	27	32	599		330

RetCAD	No diabetic retinopathy	Mild
Reference	R0	R1
<b>Non-DR disease</b>	10	5
<b>R0</b>	6	1
<b>R1</b>	2	14
<b>R2</b>	2	7
<b>R3</b>	12	18

RetCAD undergraded 15 eyes since their complications are not due to DR

RetCAD correctly graded 23 eyes as being below referable (R2 or R3) level

RetCAD undergraded 39 eyes



RetCAD	No diabetic retinopathy	Mild
Reference	R0	R1
Non-DR disease	10	5
R0	6	1
R1	2	14
R2	2	7
R3	12	18

AI Grade: No DR

Original Grade: R3

Regrade: R3

Pre-retinal haemorrhage. No other DR, likely non-DR related.



RetCAD	No diabetic retinopathy	Mild
Reference	R0	R1
Non-DR disease	10	5
R0	6	1
R1	2	14
R2	2	7
R3	12	18

AI Grade: No DR

Original Grade: R3

Regrade: R3

Pre-retinal haemorrhage noted.  
Could be non-DR related.



# Discussion & Conclusions



1. Further analysis is pending on the single eye referable patients
2. Quality assurance done by RetCAD:
  - ~50%-60% of patients currently only seen by 1<sup>st</sup> grader\*
  - RetCAD serves as tool running the background
3. RetCAD as 1<sup>st</sup> grader in DESP system
  - If RetCAD indicated DR-negative, it was correct in 99.96% of the cases → no DR patients would be missed
  - Additional analysis showed that 2.34% of referable eyes were missed by RetCAD\*\*

\*60%-70% patients is DR-negative. These are only graded by 1<sup>st</sup> grader and 10% is randomly graded by 2<sup>nd</sup> grader for quality assurance, resulting in about 50%-60% of patients seen only by 1 grader

\*\* On patient level, the miss-rate will likely be lower as the AI needs to detect referable DR in at least one eye.

# Contact



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