

# RETINARISK

## IFU-RetinaRisk DR

Written by / Date: *Ægir Þór Steinarsson* 2025-12-05

Reviewed by / Date: *Stefán Einarsson* 2025-12-05

Approved by / Date: *Stefán Einarsson* 2025-12-05





## TABLE OF CONTENTS

<b>1 OVERVIEW</b>	<b>4</b>
<b>2 NAME AND MANUFACTURER INFORMATION</b>	<b>4</b>
<b>3 INTENDED PURPOSE</b>	<b>4</b>
<b>4 SPECIFICATIONS</b>	<b>5</b>
<b>5 TECHNICAL SPECIFICATION</b>	<b>6</b>
<b>6 PERFORMANCE CHARACTERISTICS</b>	<b>7</b>
Predictive Model	7
Performance Validation	7
<b>7 PATIENT FLOW IN CLINICAL USE</b>	<b>8</b>
<b>8 RISK COMMUNICATION</b>	<b>8</b>
<b>9 ACCESS AND INSTRUCTIONS FOR USE</b>	<b>9</b>
<b>10 ARTWORK</b>	<b>15</b>
Risk scores	15
HbA1c	15
Blood pressure	16
<b>11 MAINTENANCE AND UPDATES</b>	<b>16</b>
<b>12 VERIFY OUTPUTS</b>	<b>16</b>
DefaultsResults	16
MediumResults	17
DR Mild&Moderate non-proliferative	17
<b>13 DATA PRIVACY AND SECURITY</b>	<b>17</b>
<b>14 STORAGE, HANDLING, AND LIFECYCLE</b>	<b>18</b>
<b>15 TROUBLESHOOTING</b>	<b>18</b>
<b>16 REPORTING OF SERIOUS INCIDENTS</b>	<b>18</b>
<b>17 GLOSSARY AND SYMBOLS</b>	<b>18</b>
<b>18 VERSION HISTORY</b>	<b>18</b>

## 1 OVERVIEW

RetinaRisk DR was created based on epidemiological data on risk factors for diabetic retinopathy. RetinaRisk DR is fed clinical data, including type and duration of diabetes, HbA1c, gender, systolic blood pressure and the presence and grade of retinopathy. These data are used to calculate risk for sight-threatening retinopathy for each individual's worse eye over time. A risk margin is defined and the RetinaRisk DR recommends the screening interval for each patient with standardized risk of developing sight-threatening retinopathy (STR) within the screening interval. We set the risk margin so that the same number of patients develop STR within the screening interval with either fixed annual screening or our individualized screening system.

This document shares instructions for the Graphical User Interface (GUI) and the API.

## 2 NAME AND MANUFACTURER INFORMATION

**Device Name:** RetinaRisk DR

**Software Model / Version:** 1.8.1

**UDI-DI (GTIN):** 05694110101006

**UDI-PI:** RR-DR-v1.8.1

**UDI (Full Barcode):** (01)05694110101006(21)RR-DR-v1.8.1

**Issuing Agency:** GS1

**Date of Manufacture:** 2025-06

**Manufacturer:** Risk ehf.

**Manufacturer address:** Grandagarður 16, 101 Reykjavík, Iceland



## 3 INTENDED PURPOSE

**Medical Purpose:** RetinaRisk DR is a decision support tool that calculates the individual risk of sight-threatening diabetic retinopathy (STR) to recommend personalized screening intervals.

**Indications:** For patients with Type 1 or Type 2 diabetes to determine the appropriate eye-screening interval.

**Contraindications:** Should not replace a medical doctor's judgment or clinical decisions. Not for patients with severe non-proliferative or proliferative retinopathy; these patients should be under the care of an ophthalmologist.

**Intended User Group(s):** Healthcare professionals, primarily physicians managing diabetic patients.

**Target Patient Population:** Adult (18+) individuals diagnosed with either Type 1 or Type 2 diabetes.

**Expected Clinical Benefits:** Reduced screening burden, timely identification of high-risk individuals, and optimized resource use.

## 4 SPECIFICATIONS

RetinaRisk DR clinical performance has been demonstrated through six peer-reviewed validation studies summarized below.

#	Study & Setting	Cohort (n) / Diabetes Type	ROC AUC (95 % CI)	Screening-Visit Reduction
1	<b>Denmark (2011, <i>Diabetologia</i>)</b> - Prospective evaluation using national diabetes registry	n = 5 199 / <b>T1 &amp; T2</b>	0.76(0.74 - 0.78)	59 % fewer visits vs annual
2	<b>Netherlands (2014, <i>Diabetologia</i>)</b> - External validation in DCS West-Friesland cohort	n = 3 319 / <b>T2</b>	0.83(0.74 - 0.92)	61 % fewer visits vs annual
3	<b>Spain (2015, <i>J Diabetes &amp; Complications</i>)</b> - Clinic-based validation study	n = 508 / <b>T1 &amp; T2</b>	0.74(0.62 - 0.85)	40 % fewer exams vs annual
4	<b>United Kingdom (2016, <i>Br J Ophthalmology</i>)</b> - External validation in NHS screening programme	n = 9 690 / <b>T1 &amp; T2</b>	0.80(0.78 - 0.81)	40 % fewer visits vs annual
5	<b>Netherlands (2019, <i>Br J Ophthalmology</i>)</b> - Academic hospital validation (Type 1 DM)	n = 268 / <b>T1</b>	0.82(0.74 - 0.90)	61 % fewer visits vs annual
6	<b>Norway (2020, <i>Acta Ophthalmologica</i>)</b> - Real-world implementation in ophthalmology clinic.	n = 843 / <b>T1 &amp; T2</b>	n/a (RetinaRisk DR applied in routine care)	Mean interval 23 months vs 14 month (fixed)

External, peer-reviewed validation studies across Europe—including Denmark, the Netherlands, Spain, the United Kingdom, and Norway—have confirmed that RetinaRisk DR provides accurate and reliable individualized risk predictions for both Type 1 and Type 2 diabetes. Across six independent cohorts, including Denmark, the Netherlands, Spain, the United Kingdom, and Norway reported ROC AUC values ranged from 0.74 to 0.83, demonstrating consistently good discrimination for sight-threatening diabetic retinopathy (STR).

These studies collectively showed screening-visit reductions between 40 % and 61 % compared with fixed annual schedules, without compromising detection safety or increasing missed STR cases. A dedicated Type 1 diabetes validation (Netherlands 2019, *Br J Ophthalmol*) and real-world implementation data (Norway 2020, *Acta Ophthalmologica*) confirmed that extended, risk-based screening intervals are clinically safe and operationally feasible in routine ophthalmic care.

Together, this evidence supports the clinical performance, safety, and intended purpose of RetinaRisk DR as a medical device software (SaMD) for guiding personalized screening intervals based on individual STR risk.

Please follow the link below to access our full list of peer-reviewed publications, comprising six scientific manuscripts listed in the table above: <https://www.retinarisk.com/research/>

### Reference to supporting documentation

The summarized performance data presented above are derived from independent, peer-reviewed validation studies that collectively demonstrate the clinical safety and predictive performance of RetinaRisk DR. Detailed descriptions of study methodologies, inclusion criteria, statistical analyses, and post-market clinical follow-up are provided in the Clinical Evaluation Report (REC-760) and in Sections 3.2 and 3.3 of the Technical Documentation, maintained by the Legal Manufacturer (Risk ehf, Reykjavík, Iceland). These documents form the official evidence base supporting the intended purpose and regulatory classification of the device.

## 5 TECHNICAL SPECIFICATION

Item	Specification
<b>Device Features</b>	Individualized STR risk prediction, screening interval recommendation, REST API + GUI access, multi-language support
<b>Dimensions</b>	Not applicable – software-only device
<b>Performance Attributes</b>	Outputs: 0–30% risk estimate; Screening interval: 6–24 months; Response time: <2 seconds
<b>Output</b>	Percentage risk score, screening interval in months, downloadable PDF report or API JSON output
<b>Voltages</b>	Not applicable – software-only device
<b>Temperatures</b>	Not applicable – software-only device
<b>Flows</b>	Not applicable – software-only device
<b>Weight</b>	Not applicable – software-only device
<b>Speed</b>	Average GUI/API response time under 2 second
<b>Other Specifications</b>	<b>Browser compatibility:</b> Chrome, MS Edge, Safari, Firefox; <b>Device support:</b> desktop, tablet, mobile; Platform-independent API connection;



## 6 PERFORMANCE CHARACTERISTICS

RetinaRisk DR is a clinically validated risk stratification tool designed to estimate an individual's likelihood of developing sight-threatening diabetic retinopathy (STR). It functions as a decision support system based on established epidemiological and clinical data but does not measure physiological parameters directly. Its outputs are designed to guide personalized screening intervals and complement clinical decision-making, while the final decision is made by the healthcare professional.

### *Predictive Model*

Based on a **Weibull proportional hazards model** incorporating the following inputs:

- Type of diabetes
- Duration of diabetes
- HbA1c
- Systolic blood pressure
- Gender
- Retinopathy presence and grade (worse eye only)

### **Output:**

- Percentage risk of developing STR over time
- Recommended screening interval (range: 6 to 24 months)
- Key risk factors are displayed based on the patient's risk profile with incentives on how much the patient can improve with lowering key factors

### *Performance Validation*

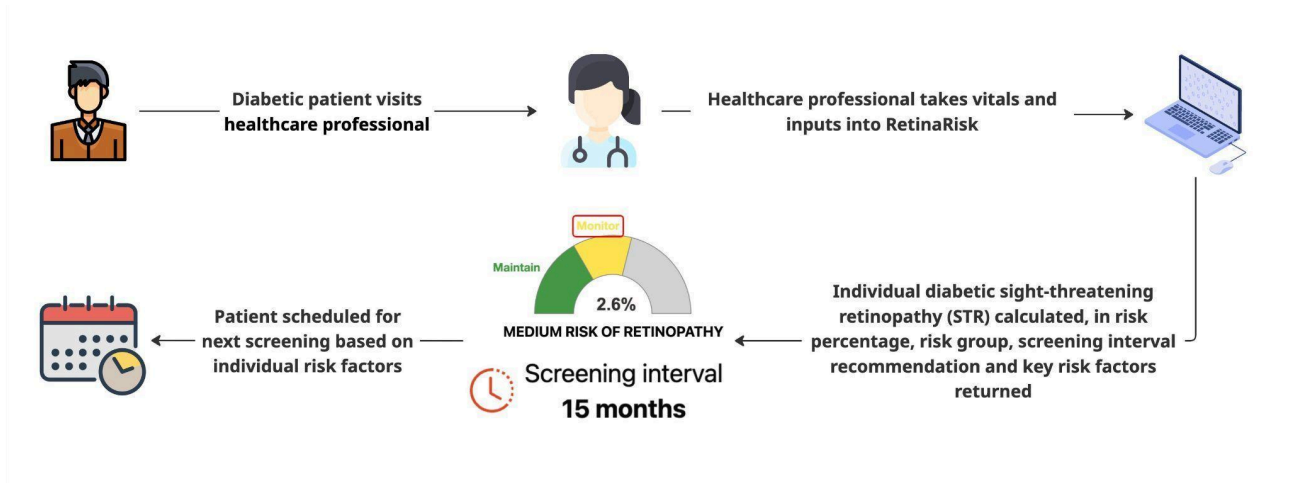
The model has been validated across six independent cohorts (Icelandic, Swedish, Dutch, UK, Spanish, and Norwegian), demonstrating:

- **Area Under the ROC Curve (AUC):** 0.74–0.83, indicating consistently good discriminatory performance.
- **Reduction in screening frequency:** Up to **59%** compared to fixed annual screening schedules
- **Preservation of safety:** Validations confirmed that reduced screening frequency did not lead to increased rates of missed STR cases.
- **Alignment with clinical standards:** Model-driven recommendations matched or improved upon outcomes from conventional fixed-interval screening protocols.

**Note:** RetinaRisk DR performance is dependent on the quality and accuracy of input data. Clinical parameters such as HbA1c and blood pressure should be up-to-date and laboratory-confirmed. RetinaRisk DR is not a diagnostic device and must not replace ophthalmologic evaluation in patients with symptoms or known advanced diabetic retinopathy.

## 7 PATIENT FLOW IN CLINICAL USE

RetinaRisk DR integrates into routine diabetic care by calculating individualized risk of sight-threatening retinopathy, providing a personalized screening interval, and supporting clinicians in scheduling follow-up.



Integrated with the EHR system, RetinaRisk DR provides individualized risk scores that enables the EHR to flag those with significant increases in risk of sight-threatening retinopathy.



## 8 RISK COMMUNICATION

**Warnings:** The tool is not intended to substitute clinical decision-making. Patients with advanced DR must be referred to ophthalmologists.

**Precautions:** Ensure accurate and up-to-date input of clinical parameters.

**Limitations:** Tool accuracy depends on completeness and correctness of input. Outputs are probabilistic estimates. In particular, HbA1c and blood pressure values should be clinically current (ideally within the last 3–6 months) to ensure accurate risk calculation.

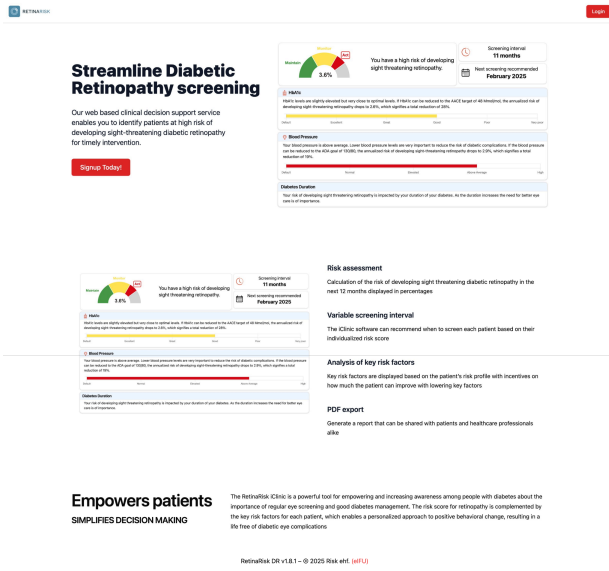
## 9 ACCESS AND INSTRUCTIONS FOR USE

**How to Access:** Access via secure login at <https://portal.retinarisk.com/> or via [API access](#).

**Licensing and Subscription:** Use of RetinaRisk DR is subject to a license agreement between the user organization and the manufacturer. Subscriptions may be time-limited depending on contract terms.

To renew or modify a license, contact RetinaRisk support at [support@retinarisk.com](mailto:support@retinarisk.com). Access credentials and usage permissions are managed centrally by the licensed institution’s administrator.

If license expiration occurs, system access may be suspended until renewal is confirmed.

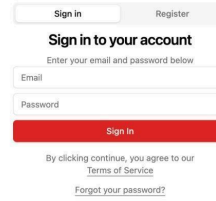
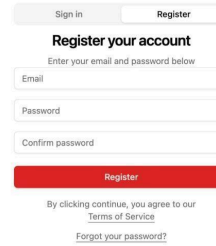
Instruction steps	Figures
<p>Go to the RetinaRisk Portal:  <a href="https://portal.retinarisk.com">https://portal.retinarisk.com</a></p> <p>Click the Login or Signup Today! buttons</p>	 <p>The screenshot shows the RetinaRisk portal interface. At the top, there's a navigation bar with the RetinaRisk logo and a 'Login' button. The main content area features a large banner titled 'Streamline Diabetic Retinopathy screening' with a 'Sign Up Today!' button. Below the banner, there are several sections: 'Risk assessment' with a calculator showing a 3.6% risk and a 11-month screening interval, 'Diabetes Decision' tool, and 'Empowers patients SIMPLIFIES DECISION MAKING' section. A 'PDF export' button is also visible.</p>

### Sign In / Register

When entering the login page, you automatically enter the Sign In tab. New users need to click the Register tab to create an account.

Enter email and password, please note when registering a confirmation email will be sent to the email address registered. It is required to click the confirmation link to activate the account.

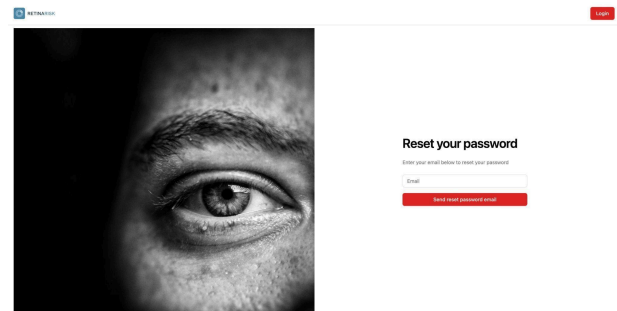
Before logging in for the first time, please review the Terms of Service.

### Forgot Password?

Click 'Forgot your password?' on the login page and submit your email to receive a reset password email.

Please click the reset password link in the email and you will be taken to a page where you input your new password.



**Instructions RetinaRisk DR page**

**Using the Risk Calculator**

Once logged in, you are taken to the RetinaRisk DR page:

**Initial View**

You will see prompts: 'Risk factors needed' and 'Measurement needed' for the 6 risk factors required. These are:

- Gender
- Type of diabetes
- Diabetes diagnosis year
- Previous diagnosis of diabetic retinopathy
- HbA1c
- Systolic blood pressure

**Input Risk Data**

Enter the 6 risk factors listed above. Input constraints will automatically be displayed in a red banner below the input if they are out of range.

**Default Values**

If any of the risk factors are missing, it is optional to 'Use default values' for educational purposes. Please note that using default values will lower the accuracy of the diabetic retinopathy estimations.

**Calculate**

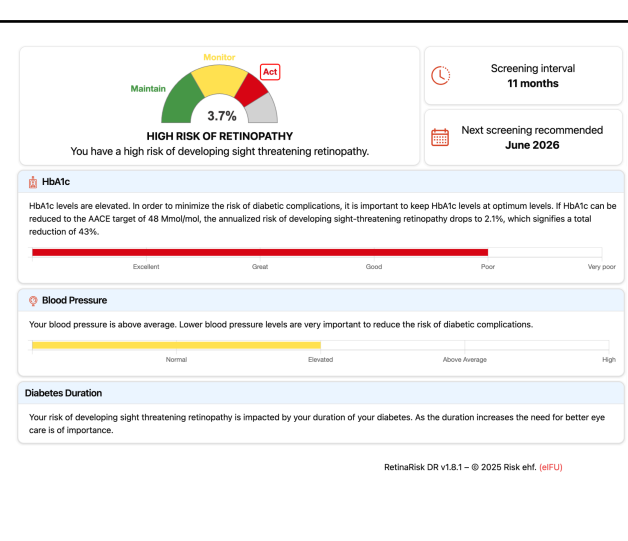
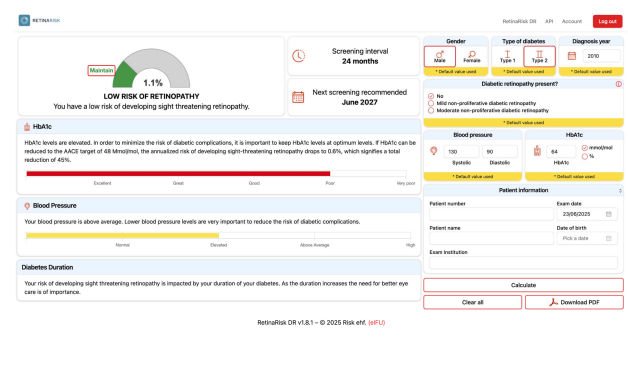
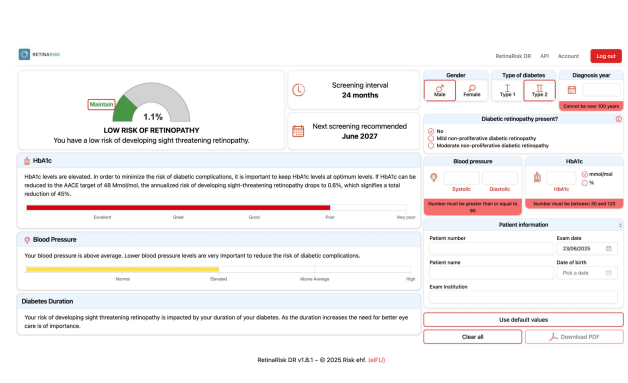
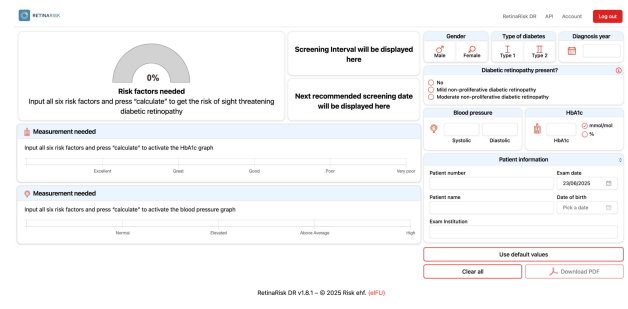
When all input values have been filled, click the 'Calculate' button to calculate the risk of diabetic retinopathy.

**Results**

The outputs consists of three different pieces of information:

- Calculation of the risk of developing sight threatening diabetic retinopathy in the next 12 months displayed in percentages.
- Recommendation of appropriate eye Screening Interval, given in months.
- The maximum recommended interval given is 24 months.
- Analysis of the risk factors most affecting each risk calculation.


**Figures**

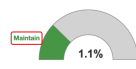


**PDF report**

A PDF report can be generated by clicking the 'Download PDF' button after a calculation has taken place.


Optionally described below, the patient information can be added to the PDF.

 RETINARISK
Exam date:30/07/2025




**LOW RISK OF RETINOPATHY**  
You have a low risk of developing sight threatening retinopathy.

**HbA1c**  
HbA1c levels are elevated. In order to minimize the risk of diabetic complications, it is important to keep HbA1c levels at optimum levels. If HbA1c can be reduced to the AACE target of 48 Mmol/mol, the annualized risk of developing sight-threatening retinopathy drops to 0.6%, which signifies a total reduction of 45%.



**Blood Pressure**  
Your blood pressure is above average. Lower blood pressure levels are very important to reduce the risk of diabetic complications.



**Diabetes Duration**  
Your risk of developing sight threatening retinopathy is impacted by your duration of your diabetes. As the duration increases the need for better eye care is of importance.

**Screening Interval**  
24 months

**Next screening**  
07-2027

**Gender**  
Male

**Type of diabetes**  
Type 2

**Diagnosis year**  
2010

**Diabetic retinopathy present?**  
No

**Blood pressure**  
130/90

**HbA1c**  
64 Mmol/mol

Mathematical modelling using common risk factors for Diabetic Retinopathy is used to assess risk of progression and to estimate the time for next retinal screening. Kindly follow the advice of your physician and ophthalmologist. RetinaRisk DR v1.8.1 - © 2025 Risk-ent.

**Patient information**

Optionally patient information can be inputted. This information is only used for PDF report generation and at no point is the patient information stored.

All the input fields in the patient information box are optional.

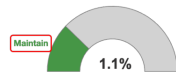
**Patient information**

Patient number 1012715599	Exam date 01/07/2025
Patient name John Smith	Date of birth 10/12/1971
Exam Institution	

**RETINARISK**

Patient number: 1012715599  
Patient name: John Smith  
Date of birth: 10/12/1971

Exam date: 30/07/2025




1.1%

**LOW RISK OF RETINOPATHY**

You have a low risk of developing sight threatening retinopathy.


**HbA1c**

HbA1c levels are elevated. In order to minimize the risk of diabetic complications, it is important to keep HbA1c levels at optimum levels. If HbA1c can be reduced to the ACE target of 48 Mmol/mol, the annualized risk of developing sight-threatening retinopathy drops to 0.6%, which signifies a total reduction of 45%.



**Blood Pressure**

Your blood pressure is above average. Lower blood pressure levels are very important to reduce the risk of diabetic complications.



**Diabetes Duration**

Your risk of developing sight threatening retinopathy is impacted by your duration of your diabetes. As the duration increases the need for better eye care is of importance.

Mathematical modelling using common risk factors for Diabetic Retinopathy is used to assess risk of progression and to estimate the time for next retinal screening. Kindly follow the advice of your physician and ophthalmologist. RetinaRisk DR v1.8.1 – © 2025 Risk ehf.

**Screening interval**  
24 months

**Next screening**  
07-2027

**Gender**  
Male

**Type of diabetes**  
Type 2

**Diagnosis year**  
2010

**Diabetic retinopathy present?**  
No

**Blood pressure**  
130/90

**HbA1c**  
64 Mmol/mol

**Instructions Accounts page**

In the accounts page you can hide the display of the screening interval, change the maximum screening interval and change the displayed language.

Subscription information is displayed as 'Credit based' by default and when entering a subscription service with RetinaRisk, one would have a monthly or yearly subscription.

**Figures**

**Account settings**

**Screening interval**  
Display screening interval on iClinic page and in PDF?

**Maximum screening interval**  
Set the maximum screening interval displayed in months. 24 months

**Language:**  
Set the language for iClinic and PDF report.

English

English

Spanish

Norwegian

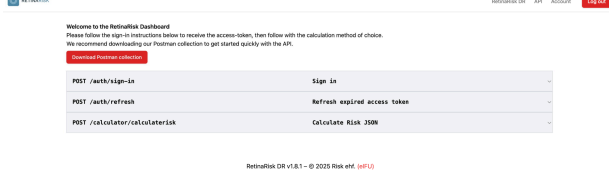
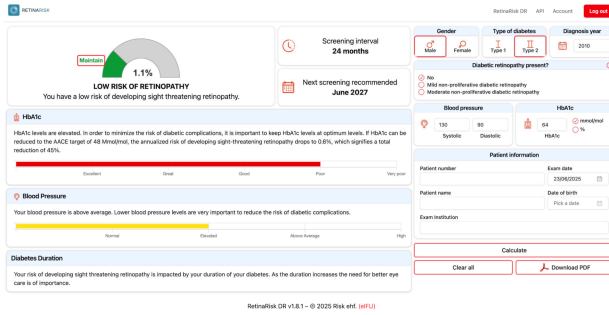
Finnish

Icelandic

German

**Subscription**  
Subscription status:

RetinaRisk DR v1.8.1 – © 2025 Risk ehf. (aIFU)

Instructions API page	Figures
<p>API instructions intended for developers. The API can be used standalone.</p> <p>The instructions show how to connect to the RetinaRisk API in a dropdown list.</p> <p>For ease of use a Postman collection is available for download by clicking the red button labeled “Download Postman collection”.</p> <p>Extended and detailed instructions are listed in the following link:  <a href="#">Postman collection documentation</a></p>	 <p>RetinaRisk DR v1.8.1 – © 2025 Risk ehf. (eIFU)</p>
eIFU	Figures
<p>The eIFU is downloadable by clicking the red (eIFU) link in the footer of every page.</p>	 <p>RetinaRisk DR v1.8.1 – © 2025 Risk ehf. (eIFU)</p> <p style="text-align: center;"><b>RetinaRisk DR v1.8.1 – © 2025 Risk ehf. (eIFU)</b></p>

## 10 ARTWORK

General records for artwork used by RetinaRisk DR. All following artwork is for RetinaRisk DR version 1.8.1.

### Risk scores

<p>We group risk scores into 3 groups: <b>Low/Medium/High.</b></p> <p><b>Low risk</b> Low risk is represented in green and is displayed when the risk factor is 1.5% or less.</p> <p><b>Medium risk</b> Medium risk is represented in yellow and is displayed when the risk factor is greater than 1.5% or less than 3%.</p> <p><b>High risk</b> High risk is represented in red and is displayed when the risk factor is 3.0% or more.</p>	<p>The figure shows three semi-circular gauges representing risk levels. Each gauge is divided into segments: green for 'Maintain', yellow for 'Monitor', and red for 'Act'. The gauges are labeled with their respective risk percentages: 1.5% (Low risk), 2.8% (Medium risk), and 4% (High risk). The 'Maintain' segment is green, 'Monitor' is yellow, and 'Act' is red. The gauges are arranged vertically, with 'Low risk' at the top, 'Medium risk' in the middle, and 'High risk' at the bottom.</p>
---	--

### HbA1c

HbA1c stages go from Excellent/Great/Good/Poor and Very poor.

**Excellent** is represented in green. Excellent is with lower than 50 mmol/mol.

**Great** is represented in green and is displayed when HbA1c is between 50 and 55 mmol/mol.

**Good** is represented as yellow and is displayed if HbA1c is between 56 and 60 mmol/mol.

**Poor** is represented as red and is displayed if HbA1c is between 61 and 70 mmol/mol.

**Very poor** is represented as red and is displayed if HbA1c is more than 70 mmol/mol.



### Blood pressure

Systolic blood pressure stages go from Normal/Elevate/Above Average and High.

**Normal** is represented in green. Excellent is with lower than 120 mmHg.

**Elevated** is represented in yellow. Elevated is equal or lower than 130 mmHg.

**Above average** is represented in red. Above average is equal or lower than 139 mmHg.

**High** is represented in red. High is equal or higher than 140 mmHg.

Note: The terminology “Normal,” “Elevate,” “Above Average,” and “High” correspond respectively to the “Normal,” “Elevated,” “High-Normal,” and “Hypertension” categories defined in the 2021 European Society of Cardiology (ESC) and European Society of Hypertension (ESH) Guidelines for the management of arterial hypertension (Williams B et al., Eur Heart J 2021; 42: 3227–3337). RetinaRisk DR uses these simplified labels for user clarity; the underlying systolic thresholds and clinical rationale remain consistent with the ESC/ESH definitions.



## 11 MAINTENANCE AND UPDATES

Major updates are version-controlled and documented in the official changelog. Previous major versions remain accessible to ensure continuity and compatibility for users.

## 12 VERIFY OUTPUTS

### DefaultsResults

Input	Expected results
<ul style="list-style-type: none"> <li>● <b>Gendar:</b> Male</li> <li>● <b>Diabetes type:</b> Type 2</li> <li>● <b>Diagnosis year:</b> Current year-15</li> <li>● <b>Diabetic retinopathy:</b> 0</li> <li>● <b>Systolic blood pressure:</b> 130 mmHg</li> <li>● <b>HbA1c:</b> 64 mmol/mol or 8.0 %</li> </ul>	<ul style="list-style-type: none"> <li>● <b>Risk Score:</b> 1.1%</li> <li>● <b>Screening Interval:</b> 24 months</li> </ul>



**MediumResults**

Input	Expected results
<ul style="list-style-type: none"> <li>● <b>Gendar:</b> Male</li> <li>● <b>Diabetes type:</b> Type 2</li> <li>● <b>Diagnosis year:</b> Current year-15</li> <li>● <b>Diabetic retinopathy:</b> 0</li> <li>● <b>Systolic blood pressure:</b> 144 mmHg</li> <li>● <b>HbA1c:</b> 66 mmol/mol or 8.1 %</li> </ul>	<ul style="list-style-type: none"> <li>● <b>Risk Score:</b> 2.1%</li> <li>● <b>Screening Interval:</b> 19 months</li> </ul>

**DR Mild&Moderate non-proliferative**

Input	Expected results
<ul style="list-style-type: none"> <li>● <b>Gendar:</b> Male</li> <li>● <b>Diabetes type:</b> Type 2</li> <li>● <b>Diagnosis year:</b> Current year-15</li> <li>● <b>Diabetic retinopathy:</b> 1</li> <li>● <b>Systolic blood pressure:</b> 130 mmHg</li> <li>● <b>HbA1c:</b> 64 mmol/mol or 8.0%</li> </ul>	<ul style="list-style-type: none"> <li>● <b>Risk Score:</b> 3.7%</li> <li>● <b>Screening Interval:</b> 11 months</li> </ul>

**13 DATA PRIVACY AND SECURITY**

RetinaRisk DR has been designed to protect patient confidentiality and ensure secure data handling in compliance with international privacy standards:

- **Non-Identifiable Data Only:** The API processes only six clinical parameters (type of diabetes, duration of diabetes, gender, previous DR grade, systolic blood pressure, and HbA1c). These parameters are not traceable to any individual and do not include personal identifiers.
- **Anonymized Clinical Data Retention Only:** Clinical data is processed transiently by the API and web interface. No traceable patient information is retained, logged, or stored on the servers.
- **Secure Communication:** All data exchanges use encrypted HTTPS (TLS 1.2 or higher). SSL certificates are regularly updated, and no insecure channels are permitted.
- **Cloud Security:** The platform is hosted in AWS serverless architecture using VPC segmentation, IAM policies, and secure-by-default configurations (see SOP-706 Production). Environments are logically separated and protected.
- **User Authentication:** Access requires licensed credentials and token-based authentication.
- **Compliance:** The platform complies with the General Data Protection Regulation (GDPR) and follows privacy-by-design principles. Any integration with hospital or clinic IT infrastructure is performed under data processing agreements with local controls.



## 14 STORAGE, HANDLING, AND LIFECYCLE

### Storage and Handling

No physical or environmental storage requirements apply. RetinaRisk DR is accessed via a secure online platform or API and does not require local installation unless explicitly specified.

No safety or handling symbols are used in this software or associated materials. In accordance with ISO 15223-1 and SFDA Annex 10, symbols will be introduced if applied in future physical or digital labeling.

### Service Termination and Removal

RetinaRisk DR operates as a Software as a Service (SaaS), it does not maintain a footprint on the user's local infrastructure. Consequently, a traditional uninstallation process is not applicable. For systems integrating RetinaRisk DR via API, "uninstallation" is achieved by ceasing all API requests and removing the integration logic from the host system code.

### Expected Lifetime and Updates

RetinaRisk DR is a software-only medical device. It does not expire or degrade over time like physical devices; therefore, no use-by date applies. The software is considered valid for clinical use as long as it is actively supported and maintained by the manufacturer.

RetinaRisk DR (v1.8.1) remains valid for use while it is maintained by the manufacturer. Users will be notified in writing of any critical changes, version deprecations, or updates that may affect clinical performance, regulatory compliance, or safe operation.

## 15 TROUBLESHOOTING

If risk outputs do not appear or the result seems implausible, please verify output values from section 8.

Contact support: [support@retinarisk.com](mailto:support@retinarisk.com)

## 16 REPORTING OF SERIOUS INCIDENTS

If any serious incident related to this software occurs, it should be reported to the manufacturer immediately at [support@retinarisk.com](mailto:support@retinarisk.com).

## 17 GLOSSARY AND SYMBOLS

**STR:** Sight-threatening retinopathy

**DR:** Diabetic Retinopathy

**HbA1c:** Glycated hemoglobin, used to estimate blood glucose levels



## 18 VERSION HISTORY

Version	Description of changes	Date of approval	Author
1.0	New document	2025-05-15	Stefan Einarsson
2.0	Added section 8 Verify	2025-06-17	Stefan Einarsson
3.0	Added step by step visual instructions. Added to NAME AND MANUFACTURER INFORMATION, STORAGE, HANDLING, AND LIFECYCLE, PERFORMANCE CHARACTERISTICS, SPECIFICATIONS and DATA PRIVACY AND SECURITY sections.  Added ARTWORK section.	2025-07-31	Stefan Einarsson
4.0	Added section 7 (PATIENT FLOW IN CLINICAL USE).	2025-10-13	Stefan Einarsson
5.0	Expanded section 4. Added uninstall instructions	2025-11-13	Ægir Þór Steinarsson

# Audit trail

## Details

FILE NAME IFU-RetinaRisk DR.docx - 12/5/25, 6:30 PM

STATUS ● Signed

STATUS TIMESTAMP 2025/12/05  
20:50:33 UTC

## Activity



SENT

stefan@retinarisk.com **sent** a signature request to:

- Stefán Einarsson (stefan@retinarisk.com)
- Ægir Þór Steinarsson (aegirthorst@retinarisk.com)

2025/12/05  
18:30:40 UTC



SIGNED

**Signed** by Stefán Einarsson (stefan@retinarisk.com)

2025/12/05  
20:50:33 UTC



SIGNED

**Signed** by Ægir Þór Steinarsson (aegirthorst@retinarisk.com)

2025/12/05  
18:51:14 UTC



COMPLETED

This document has been signed by all signers and is **complete**

2025/12/05  
20:50:33 UTC

The email address indicated above for each signer may be associated with a Google account, and may either be the primary email address or secondary email address associated with that account.