



User Manual

[Product Name: DrNoon]

[Model Name: DN-FSCVD]

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[Revision history]

Version	Date	Description
0	2023-12-28	Creation
1	2025-05-14	Revise to add detailed information Delete a product name, Reti-Eye Reti-CVD
2	2026-08-13	Software version correction

1. Introduction

Thank you for your purchase of **DrNoon**. Please use the product following its purpose of use.

2. Device description

2.1. Description

This medical image detection assistant software receives and stores and manages medical image and blood vessel information data of patients. It provides, stores, and manages the results of artificial intelligence(AI) analysis on medical image data, and if necessary, medical image data of specific patients can be inquired. Additionally, artificial intelligence results are presented on the patient's retina, glaucoma and cataract diseases about medical image data. It also predicts cardiovascular risk by identifying the structure of the retina and changes in the blood vessels in the retina (the retinal artery, the retinal vein, and the intraretinal microvascular) within the fundus image with artificial intelligence.

2.2. Intended Use / Purpose

DrNoon is an artificial intelligence-based software that assists medical personnel by analyzing a patient's retinal image to detect eye diseases and estimate cardiovascular risk. Through retinal image analysis, it aids diagnosis by identifying conditions such as glaucoma, cataracts, and retinal diseases (including diabetic retinopathy, age-related macular degeneration and epiretinal membrane), while also assessing the risk of future cardiovascular events.

2.3. Intended user

This medical device should be used by the qualified doctor and/or optometrist

2.4. Intended medical conditions

Eye diseases (glaucoma, cataracts, and retinal diseases (including diabetic retinopathy, age-related macular degeneration and epiretinal membrane) and risk of future cardiovascular events.

2.5. Intended environment

Hospital or Clinic or Optometrist Office or Medical examination/ checkup center

2.6. Principle of operation

This computer-aided detection software stores and manages medical images of patients uploaded. This software provides/stores/and manages AI analysis result about the medical images. This software looks up medical image data of the particular patient in case of necessity. This software provides AI-analyzed result about the site of the lesion, retinal abnormality, glaucoma possession, and cataract possession in order to

provide support on the convenience of healthcare provider making a medical decision.

Overall operation process is as below.

- a. Upload medical image data of patients sent to the client.
- b. Analyze medical image data of patients uploaded by user using AI and save the result.
- c. Look up medical image data of patients and its AI analysis result sent.
- d. Confirm AI analysis result.

3. Technical Specification

Category	Contents	Information
Software operating environment	Applicable image	Fundus image
	Image Format	DICOM, JPG, PNG, TIFF format
	Operating environment	Operating system including Window, Mac, or Linux installed. Higher than the following versions; - For Cloud: Windows 7, OS X Yosemite 10.10(Mac), Ubuntu 14.04 (Linux), Debian 8, opebSUSE 13.3 and Fedora Linux 24 - For On-premise: Windows 10, OS X Yosemite 10.14(Mac), Ubuntu 24.04 (Linux), Debian 10, opebSUSE 15 and Fedora Linux 30
		Latest web browser complying web standard available.
		Server access through network available.
	Communication environment	Internet access based on Ethernet.
		Microsoft Edge or Chrome or Safari or Firefox (Higher than the following versions; Internet Edge 84, Chrome 84, Safari 12 and Firefox 78)
	Security	Network security and encryption based on TLS/SSL Firewall network security and endpoint security(Anti-Virus).
	Image Resolution	Recommended to be 1280 X 960px or higher.

User PC Specification	CPU	Intel Core i3 Processors or higher
	RAM Memory	4G or higher
	Storage	50GB or higher
On-premise Workstation Specification	CPU	Intel Core i5 Processors or higher (4-core)
	RAM Memory	8G or higher
	Storage	256GB or higher

4. Performance Summary

Contents	Information
Target populations	- Age: Adult (19 years or older) - Weight: Not relevant - Gender: Not relevant - Nationality: Multiple
Key performance	1) For eye disease) Sensitivity and Specificity over 0.8 2) For CVD) Cardiovascular disease risk prediction C-index over 0.7
Performance characteristics	1) For eye disease The sensitivity and specificity were analyzed by comparing the results of readings for the presence or absence of eye disease and the diagnosis results made by independent evaluators composed of ophthalmologists, and 95% CIs were presented. The sensitivity was 95.51% (95% CI: 91.34% to 98.04%), and the specificity was 92.35% (95% CI: 87.5% to 95.75%). 2) For CVD The final model had a Harrell's C-index value of 0.7518, therefore indicating good performance in risk prediction.
Clinical Benefit	It can manage patient health by predicting symptoms of eye disease (cataract, glaucoma, retinal disease and etc) or cardiovascular risk and assisting medical personnel.
Clinical Reference	[1] Deep-learning-based cardiovascular risk stratification using coronary artery calcium scores predicted from retinal photographs, 3: e306–16, Lancet Digit Health 2021

	[2] Pivotal trial of a deep-learning-based retinal biomarker (Reti-CVD) in the prediction of cardiovascular disease: data from CMERC-HI, 2023, 1–9
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4.1. Major function

- ◆ Artificial intelligence analysis of structure of the retina and changes in the blood vessels in the retina
- ◆ Fundus abnormality suspicion detection
- ◆ Cardiovascular risk prediction result
- ◆ Key Element
 - Image transmission
 - Analysis of input (Input information: Fundus photography image, Patient information, Health information)
 - Patient information management
 - Result management
 - Report print
 - Account management

4.2. Training data

- ◆ Type of training data: Fundus photography image
- ◆ Number of training data: About 100,000 photographs (single institution)
- ◆ Training data update period: yearly update by manufacturer

4.3. Clinical performance

4.3.1. Overview

DrNoon is intended for routine clinical use, and the tests present a validation of the following aspects using clinical data from Ophthalmology.

- ◆ The accuracy of **DrNoon** is defined as the agreement with an established reference. Established reference in this case is the reading results
- ◆ For eye disease prediction, the effectiveness is defined as the average difference between DrNoon and skilled ophthalmologists.
- ◆ For CVD risk prediction, the effectiveness is defined as future risk prediction metric for future CVD event with retrospective dataset.

The performance evaluation is presented with sensitivity and specificity for eye diseases and C-index for cvd risk prediction by comparing the performance of **DrNoon**.

4.3.2. Methods

For eye diseases, sampled 4 retinal images open dataset and retina images from Korean client who is using our software is labeled by skilled ophthalmologists. All images were labeled as 3 category diseases (retina disorder, glaucoma, media opacity) normal or abnormal. And tester compared the **DrNoon** prediction and ophthalmologists's label and check for 5 datasets's 3 disease prediction performance is over sensitivity 0.8 and specificity 0.8.

For CVD risk prediction, 3 retrospective datasets were used for validation. All datasets has and retinal images and cvd events tracking records after capturing the retinal images. And tester validated our risk score's prediction performance for future cvd events as defined and check for 3 dataset's C-index for future cvd events.

- ◆ Dataset (Validation dataset : CMERC-HI, SEED, UK Biobank)

5. Safety Caution and Warning

Residual risks associated with the use of this device include:

- ◆ Misinterpretation of results due to incorrect analysis
- ◆ Incorrect clinical decision-making if results are solely relied upon
- ◆ Data security and privacy concerns related to patient information

These risks are mitigated through verification and validation including clinical evidence, and compliance with data protection regulations.

 The results provided by this software are not a definitive diagnosis and should not be used as the sole basis for clinical decision-making. Healthcare professionals must confirm findings through additional medical tests, laboratory analysis, and patient history evaluation.

Before using DrNoon, read and understand all the safety cautions and warnings listed below. The device may be at increased risk if used in an environment other than the specifications claimed in chapter 3.

5.1. Warning (Danger)

- ◆ Final clinical diagnosis decision and treatment should be made by a person who is medically trained.
- ◆ Patient data for image analysis should be clearly recognized.
- ◆ This product only provides indications similar to the clinically classified eye diseases (such as glaucoma, cataracts, and retinal diseases (including diabetic retinopathy, age-related macular

degeneration and epiretinal membrane), while also assessing the risk of future cardiovascular events for medical personnel and optometrist.

- ◆ Do not use the device out of intended use.
- ◆ Users must ensure that their passwords are not disclosed to anyone and that their account information is not shared with any third parties.
- ◆ Do not upload user information other than age, gender, and fundus images.

5.2. Contraindications

- ◆ Do not use for patient with known white dense cataract.
- ◆ Do not use the images which are not fundus image.
- ◆ Diagnosis or treatment cannot be based solely on this software.
- ◆ Restrict to use with other device out of specification referred in Chap 3. Technical Specification.
- ◆ Do not upload with extension files other than the suggested image format.
- ◆ Do not use in any environments or devices other than those recommended.
 - Without operating system of Window, Mac, or Linux.
 - Without network security and encryption based on TLS/SSL
 - Without server access through network available

5.3. Caution

- ◆ Ignorance of this sign and following mishandle of the product may result in injury of a person or property damage.
- ◆ It should be used by medically well-trained users only. The 'well-trained user' means medical level of knowledge or education is an expert and licensed person.
- ◆ For accurate diagnosis, it must be a safe image with a clear blood vessel in the safe house. In particular, the diagnostic results for opacity may be affected by the image condition or quality.
- ◆ The measured results are based on medical opinion and the healthcare professional makes the final judgement.
- ◆ Before reviewing and analyzing images, check the patient ID to prevent the use of images of other patients.
- ◆ Before upload a fundus image, check acceptable image quality. (Refer to 3. Technical specifications)
- ◆ Check if the image you are uploading is inappropriate (images that are not fundus images, images that are partially obscured by light interference and light shadows, etc.).
- ◆ This product is used for a patient population who want to predict eye disease and cardiovascular disease by using a fundus image, and analysis performance is not guaranteed for fundus images under the age of 19 and over the age of 80.
- ◆ Check if the patient data images are in a format (DICOM, JPG, PNG, TIFF).

- ♦ The analysis results may vary depending on the format or resolution of the image and the filming environment.
- ♦ Install security controls on the PC that you want to access this software to periodically inspect the PC to prevent it from being infected with malicious code.
- ♦ Do not shut down the software or turn off the PC when storing or loading data.
- ♦ If you don't use the software over 30 minutes, it will be automatically logged out. When you upload a patient's image, do not leave your seat for more than 30 minutes.
- ♦ After finished or using the software, should log out to ensure account security.
- ♦ It may be made wrong results if used out of recommended environments/purposes.
- ♦ Please ensure that the PACS server does not transmit a large volume of images in a short period of time, as this may affect system performance or result in data processing delays.

5.4. Precautions

- ♦ Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the you are established.
- ♦ After logging in for the first time, should change your temporary password.
- ♦ Passwords should be updated periodically or whenever a password breach is suspected.

6. Indication and Safety

6.1. Indications

The product is recommended for those who need to annually check/screen their eye condition.

- ♦ The patients who have symptoms of chronic diseases.
- ♦ The patients who are afflicted with diabetes
- ♦ People with known or unknown eye diseases status who wants to perform regular eye screening.
- ♦ A person who has high blood pressure or hyperlipidemia due to a underlying disease.
- ♦ A person who has never been tested for cardiovascular disease
- ♦ A person who simply wants to know his current cardiovascular risk.

6.2. Safety function

- 1) Web service information security: TLS/SSL encryption.
- 2) User certification: Authorization of user ID and PW or API key
- 3) Data encryption and decryption: Security protocol HTTPS used when web service interlocked with data
- 4) Stop to offer service by one month after that the user is notified of the decision to no longer provide post-service including software updates.
- 5) Account information updates can only be made through a verified email.

- 6) Database and storage are regularly backed up through the cloud.
- 7) Cloud servers and on-premise servers must be secured with SSH.

6.3. Personal Information Security

- 1) The minimum information (patient ID, examination date, gender, date of birth) is saved in database without recognizing the patient information by partial deletion of identifier and deletion of record.
- 2) Data saved apart is controlled by strong security system of Amazon Web Service, for which data encryption is operated through SQL Server RDS method. Encrypted data is administered by the hospital directly and never is used or lost for any purpose except the update of trained AI model.
- 3) On-premise servers are isolated from external networks to reduce the risk of data leakage
- 4) You should login the authenticated privileged account or use API key to access the product.

7. IT security summary

7.1. Ensure integrity/validation of software updates and security patches

Ensuring the integrity and validation of software updates and security patches is critical to maintaining the security and reliability of our web service and SaMD. This section outlines the processes and mechanisms we have implemented to achieve this objective.

- Source Code Management
- Integration and Continuous Deployment (CI/CD)
- Software Update Process
- Security Patches
- Monitoring

7.2. Security options

7.2.1. Security configuration options

- 1) **Identity and Access Management (IAM):** Utilize IAM to manage access to AWS services and resources securely. Implement least privilege principles to ensure users and services have only the necessary permissions.
- 2) **Virtual Private Cloud (VPC):** Deploy services within a VPC to isolate resources and control network traffic.
- 3) **AWS Shield and AWS WAF:** Protect against DDoS attacks using AWS Shield and filter malicious web traffic using AWS Web Application Firewall (WAF).
- 4) **SSH Configuration:** Secure servers using SSH to prevent unauthorized access.
- 5) **Firewall Configuration:** Configure the Uncomplicated Firewall (UFW) to control incoming and outgoing traffic.
- 6) **Reverse Proxy Configuration:** Use Nginx as a reverse proxy to manage and direct incoming traffic to backend services securely.

- 7) **SSL/TLS Configuration:** Ensure strong SSL/TLS configuration to protect data in transit.
- 8) **Access Controls:** Restrict access to Nginx and backend services.
- 9) **Monitoring and Logging:** Enable detailed logging and monitoring to detect and respond to potential security incidents.

7.2.2. Security-by-default principle

- 1) **Default Security Settings:** Ensure that all deployments use secure default settings to minimize the risk of misconfiguration.
 - IAM Policies
 - VPC Configurations
 - SSH Key Management
- 2) **Hardened Server Configurations:** Deploy servers with hardened configurations out of the box.
 - Disable Unnecessary Services
 - Secure Default User Permissions

7.3. Product installation

7.3.1. Cloud Server Installation

- 1) Users must be familiar with AWS services and have basic IT skills.
- 2) Ensure sufficient storage for logs in AWS CloudWatch.
- 3) Regularly back up logs to AWS S3.
- 4) Recommendations for using AWS CloudWatch logs for monitoring and troubleshooting.

7.3.2. On-premise Server Installation

- 1) Users must have basic IT skills, including knowledge of Ubuntu OS, SSH configuration, Docker, and Nginx.
- 2) Ensure sufficient log storage capacity to maintain detailed logs of all system activities.
- 3) Implement regular log backups to prevent data loss.
- 4) Provide recommendations on how to use logs for monitoring and troubleshooting.

7.3.3. PACS Integration and DICOM Communication

This product is designed to interface with the hospital's PACS system using the DICOM standard. Configuration of the PACS connection, including the AE Title, IP address, and port number, is performed by an authorized installation technician during product setup. This software is not intended to be installed or configured by the end user.

7.4. Procedures for using the medical device in failsafe mode

7.4.1. Detection of Anomalies or Malfunctions

- Continuously monitor the device for signs of malfunctions, anomalies, or security threats.

7.4.2. Deactivating User Access

- To prevent unauthorized access or usage, affected user accounts are temporarily deactivated.
- Users are notified of the deactivation and given instructions on how to proceed.
- Deactivated accounts can be reactivated once the issue is resolved and security is verified.

7.4.3. Data Backup

- Ensure that regular backups of all critical data are performed.

7.4.4. Investigation and Resolution

- Engage technical support teams to investigate and resolve the underlying issue.
- Detailed Logging: Maintain detailed logs of the events leading up to and during the incident to aid in troubleshooting and resolution.

7.4.5. Restoring Normal Operations

- Once the issue is resolved, restore the system using the latest secure backup.
- Reactivating Users: Reactivate user accounts after verifying that the system is secure and fully operational.
- Perform thorough checks to ensure that the system operates correctly and safely before resuming normal operations.

7.5. When the device's cybersecurity has been compromised**7.5.1. Cloud server****1) Initiate AWS Backup**

- Immediately start the backup process using AWS Backup to create a secure copy of all critical data.
- Ensure that the backup is stored in a secure, isolated environment to prevent further access by unauthorized entities.

2) Assess and Mitigate

- Assess the extent of the compromise and identify the affected components.
- Implement mitigation measures to contain and eliminate the threat, leveraging AWS security tools and services.

3) Restore Data and System

- Once the threat is contained, use the secure backup to restore data and system configurations.

- Verify the integrity and functionality of the restored system before resuming normal operations.

7.5.2. On-premise server

1) Network Isolation:

- Immediately isolate the affected systems by disconnecting them from the network to prevent further compromise.
- Ensure that no unauthorized access is possible during the isolation period.

2) Data Backup

- Perform a full backup of all critical data to a secure, isolated storage medium.
- Ensure the backup is comprehensive and includes all necessary data for system restoration.

3) Assess and Mitigate

- Assess the scope of the cybersecurity compromise and identify the affected components.
- Implement measures to contain and resolve the threat, ensuring that no residual vulnerabilities remain.

4) Restore Data and System

- Use the secure backup to restore the data and system configurations.
- Verify the integrity and functionality of the restored system before reconnecting to the network and resuming normal operations

7.5.3. Cloud Server

- Use security groups to control inbound and outbound traffic, allowing only necessary ports and IP addresses.
- Use key pairs for SSH access, disabling password-based logins to enhance security.
- Monitoring and Alerts: Enable AWS CloudWatch and AWS Config to monitor EC2 instances for compliance and security issues, and set up alerts for any suspicious activities.
- Enable automated backups and snapshots to ensure data recovery in case of an incident.
- Use security groups and IAM database authentication to control access to RDS instances.
- Apply bucket policies to control access to S3 buckets, ensuring that only authorized users and services can access the data.
- Enable S3 access logging and use AWS CloudTrail to monitor API calls made to S3 buckets.

7.5.4. On-premise Server

- Ensure physical access controls are in place to prevent unauthorized access to on-premise servers and network equipment.

- Implement robust firewall rules to control traffic between segments, allowing only necessary communication.
- Use key-based SSH authentication, change the default SSH port, and implement tools like Fail2Ban to protect against brute-force attacks.

7.6. When anomalous conditions are detected

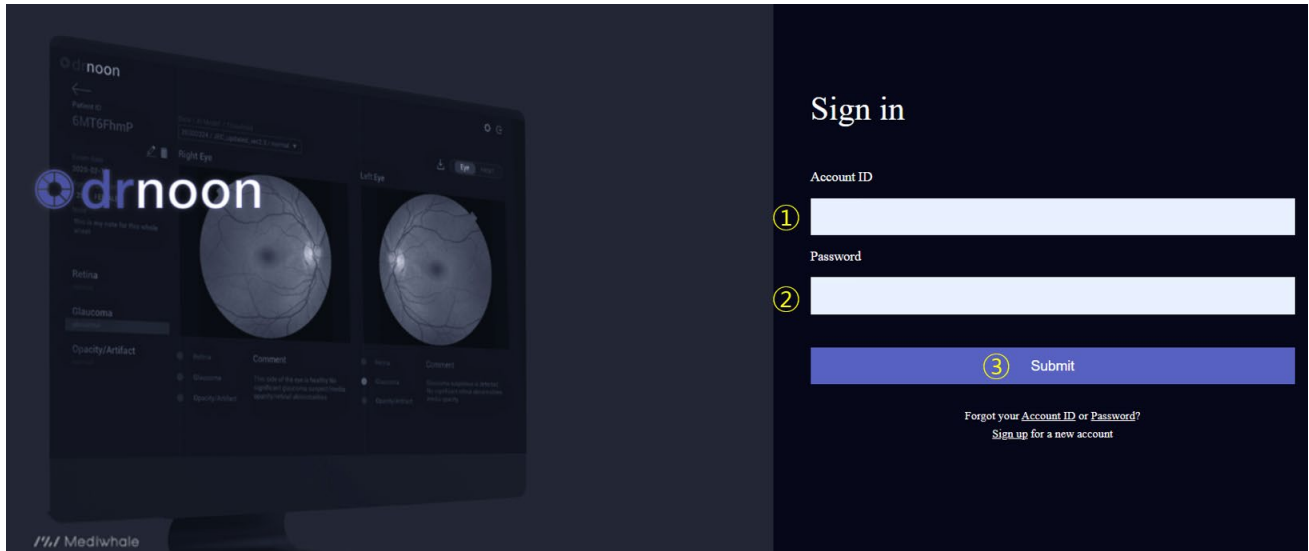
- When system error and malfunction occur, the system send email and slack message to the Product team.
- In case of using On-premise server, User should report to manufacturer

7.7. Methods for retention and recovery of device configuration

An ticated person accesses the server via SSH, rebuilds the Docker containers, and resauthentarts Nginx.

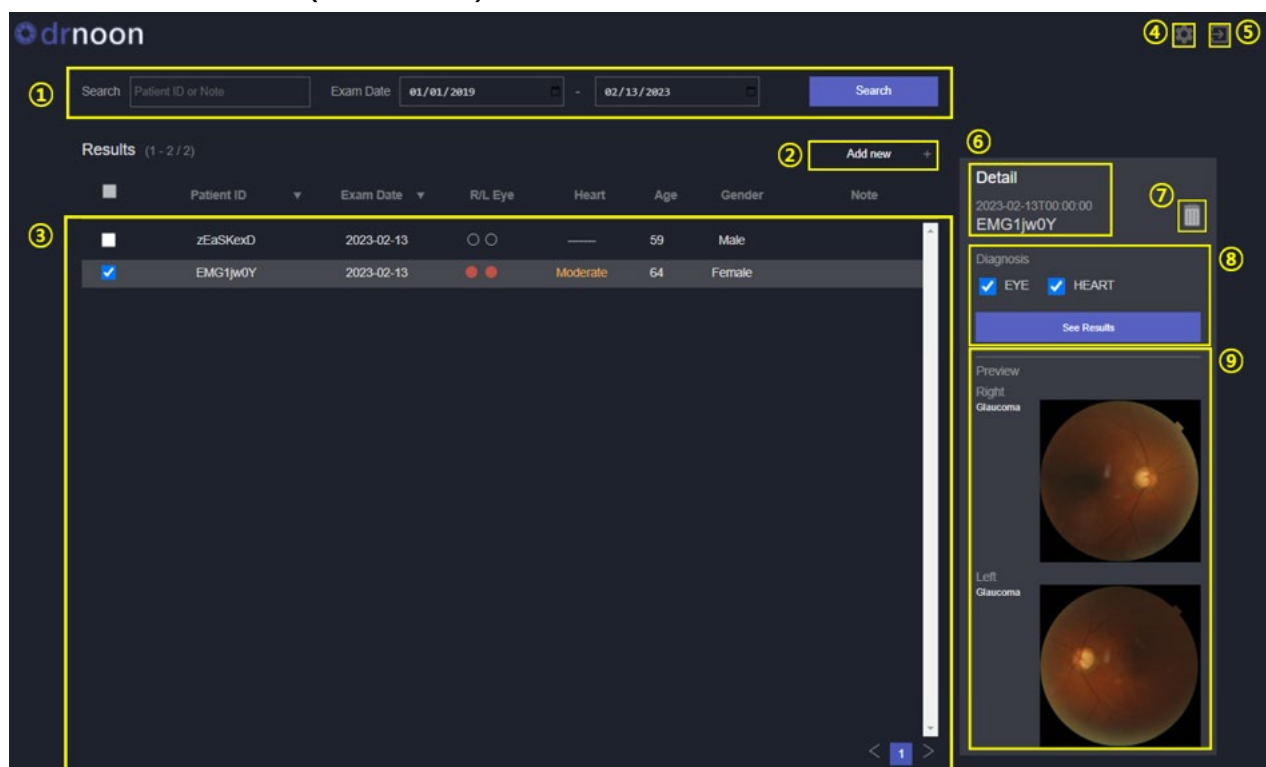
8. Screen Explanation

8.1. Login screen



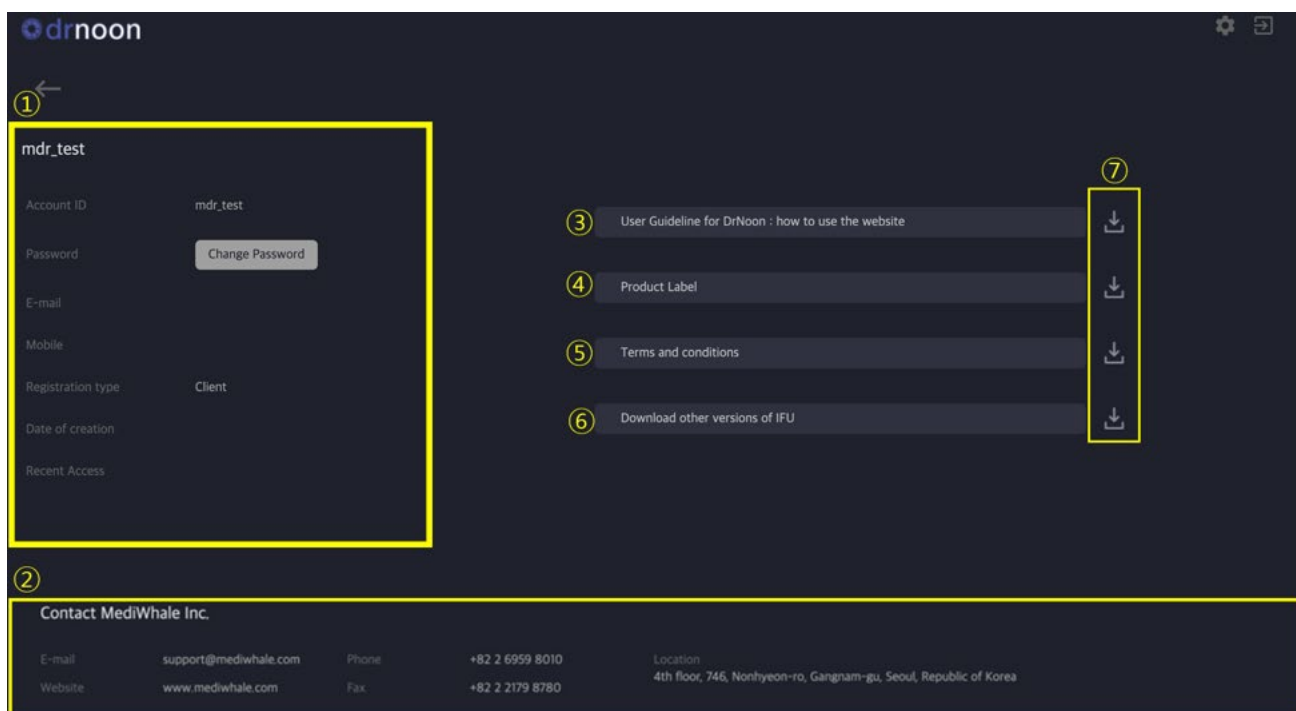
No.	Name	Description
1	Account ID	Enter account ID
2	Password	Enter password of the account
3	Submit	Log in after entering ID and password

8.2. Patient List Screen(Main Screen)



No.	Name	Description
1	Filters	Retrieve information about uploaded patients (Patient ID, Exam data)
2	Add new	Use for uploading new fundus images
3	Results	For each patient, display the Fundus image a summary of eye disease detection and cardiovascular risk prediction results.
4	Setting	View information about the account you are logged in and company and product information
5	Log-out	Logout of logged-in account information
6	Patient Information	Shows selected patient information (patient ID, exam data).
7	Delete	Delete selected patient data
8	Diagnosis	Check box check (EYE, HEART) allows you to selectively view detection and prediction results.
9	Preview	View uploaded fundus images of selected patients

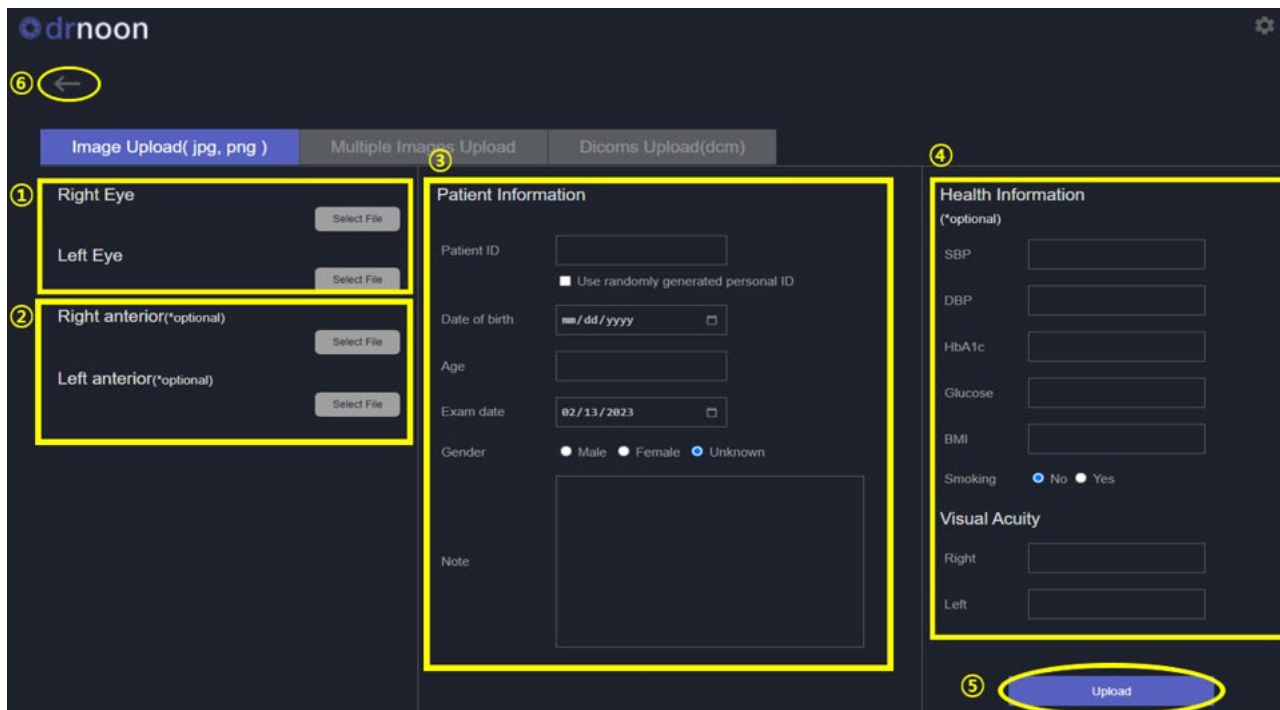
8.3. Account Information Screen



No.	Name	Description
1	USER ID	Information about the account you are logged in to
2	Contact	Contactable Company Contact
3	Product User's Guide	Product Manual
4	Product Label	Product Indications
5	Terms and Conditions	Terms and Conditions of Use of Software
6	Other versions of IFU	Download IFUs (Full versions or other Languages)
7	Download	Download for each asset

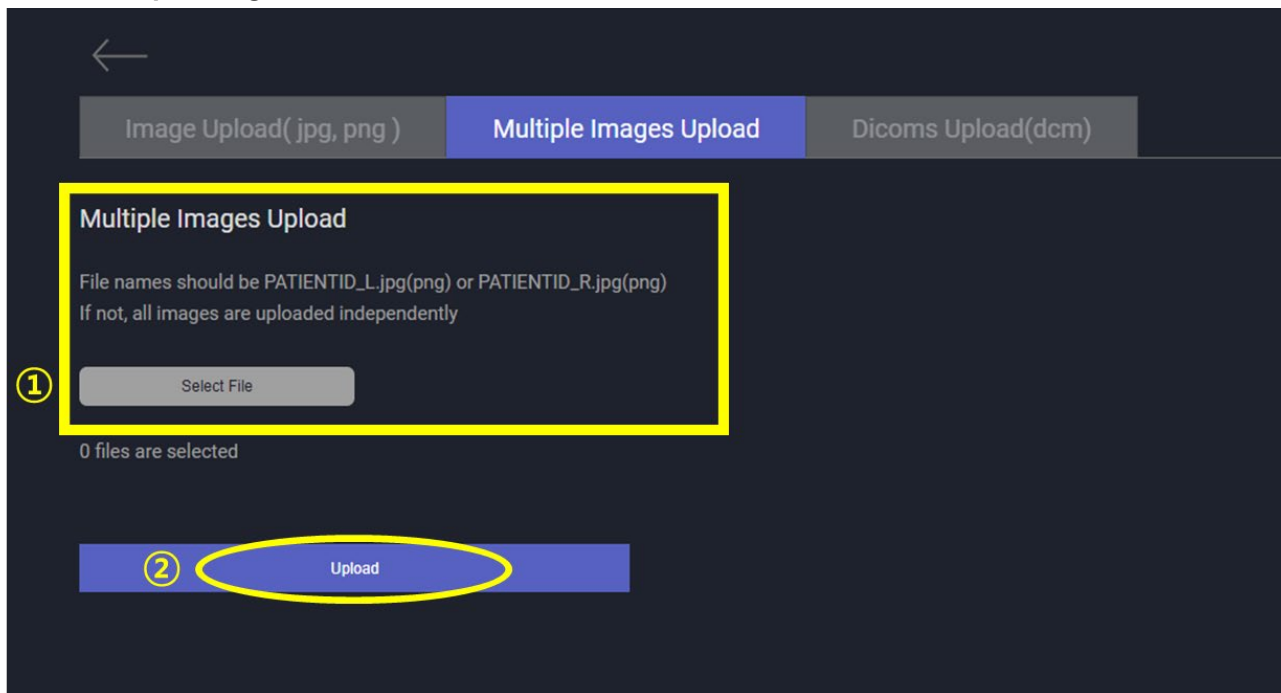
8.4. Upload Screen

8.4.1. Single Image File(JPG, PNG, TIFF)



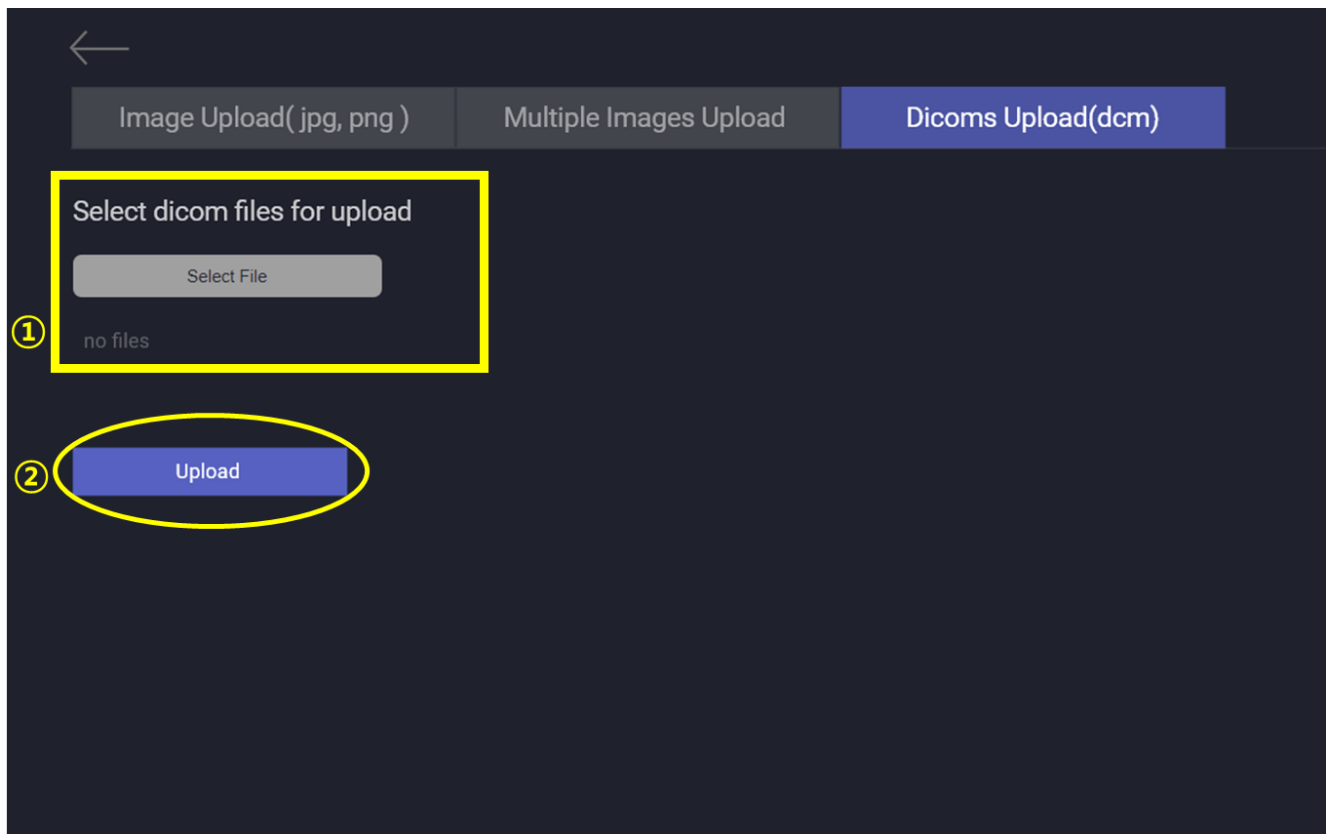
No.	Name	Description
1	Select Fundus image file	Select a single Fundus image to detect.
2	Select Anterior Image File	Optionally, anterior images can be uploaded as a single.)
3	Patient Information	Enter patient information (patient ID, date of birth, age, gender, date of examination, note). It must be entered for detection.
4	Health Information	Optionally, enter vessel information for the patient (SBP, DBP, HbA1c, Glucose, BMI, Smoking , Visual Acuity)
5	Upload	Upload the patient's data and selected images.
6	Backward movement	Show previous screen.

8.4.2. Multiple Image File(JPG, PNG, TIFF)



No.	Name	Description
1	Select File	Select multiple image files to upload.
2	Upload	Upload the selected image.

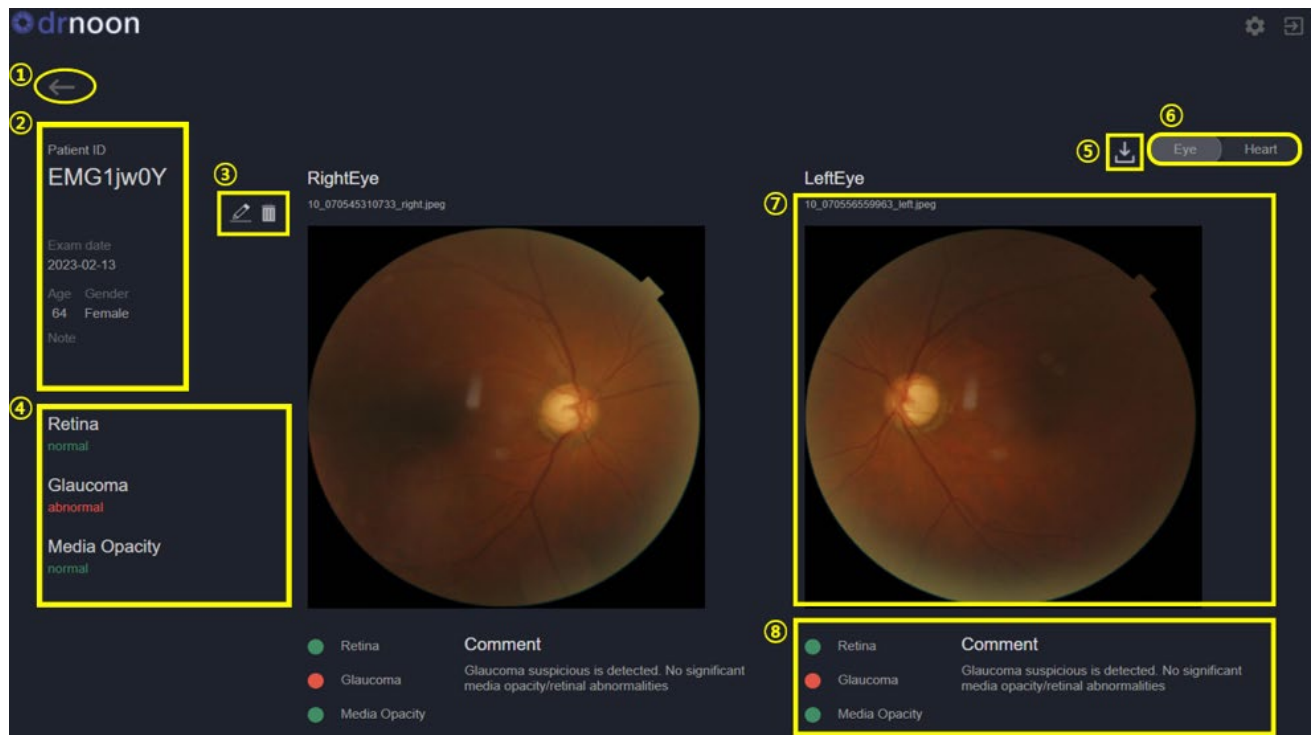
8.4.3. DICOM file



No.	Name	Description
1	Select File	Select DICOM files to upload.
2	Upload	Upload the selected image.

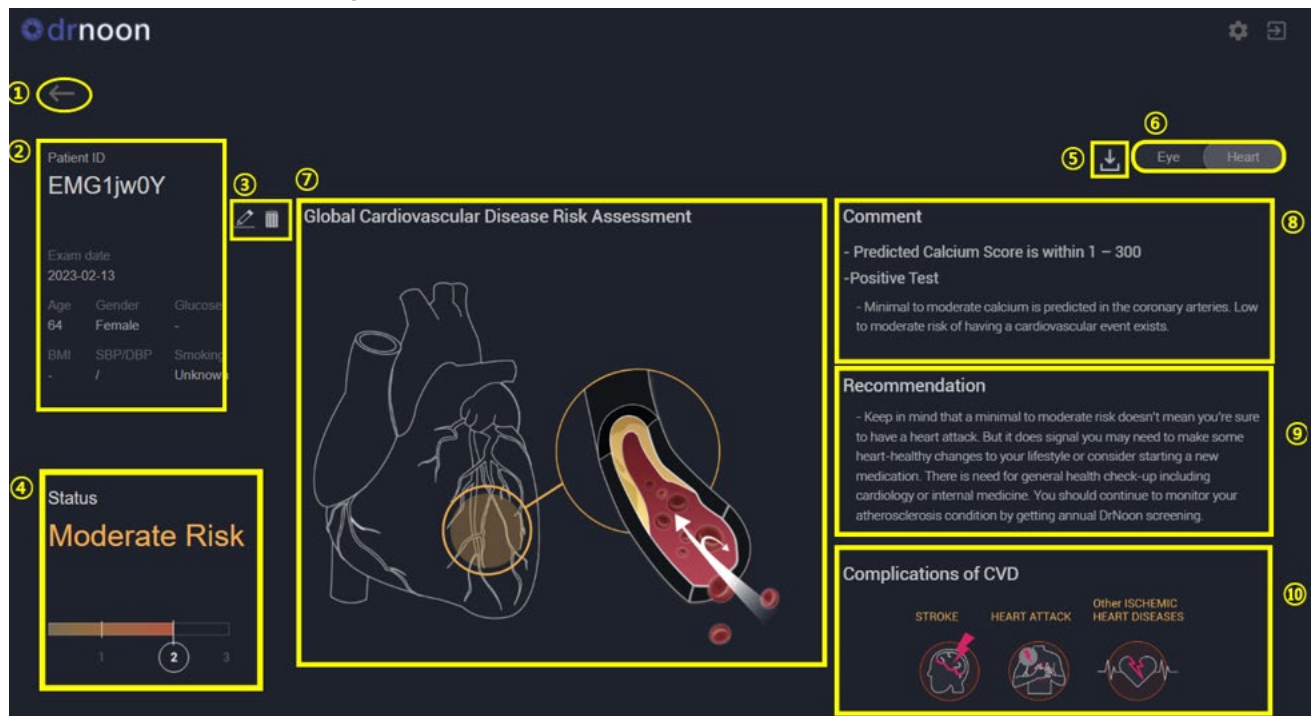
8.5. Result screen

8.5.1. Fundus disease detection result



No.	Name	Description
1	Backward movement	Show previous screen.
2	Patient ID	Information about the selected patient (Patient ID, Exam date, age, Gender, Note)
3	Modification ()	Change information for the selected patient
	Delete()	Delete the selected patient detection results
4	Composite detection result	Disease-specific detection results for the fundus image of the selected patient
5	Download Detect Image Report	Download Detections Report for Selected Patients
6	Toggle	Detection and prediction results (EYE/ HEART) screen movement switch for selected patient
7	Detection data image	Shows uploaded data images, showing abnormal areas in light green
8	Detection result	Circular display of AI detection results for left-eye (or right-eye) images (Displayed in green for normal and red for abnormal), and view of detection results.

8.5.2. cardiovascular-risk prediction result



No.	Name	Description
1	Backward movement	Show previous screen.
2	Patient ID	Display information (Patient ID, Exam date, age, Gender, Note) and health information (SBP, DBP, Glucose, BMI, Smoking) for the selected patient
3	Modification ()	Change information for the selected patient
	Delete()	Delete the selected patient prediction results
4	Status	Display the cardiovascular risk prediction status of the selected patient in three stages (green (normal)/ orange(Moderate Risk)/ red(High Risk)
5	Download prediction Image Report	Download prediction report for selected patients
6	Toggle	Detection and prediction results (EYE/ HEART) screen movement switch for selected patient
7	Blood vessel image	Display of vascular image for cardiovascular risk prediction with fundus image
8	Comment	Display Comments for Predictive Results
9	Recommendation	Display Recommendation for Predictive results
10	Complication of CVD	Show Complications Based on Predictions

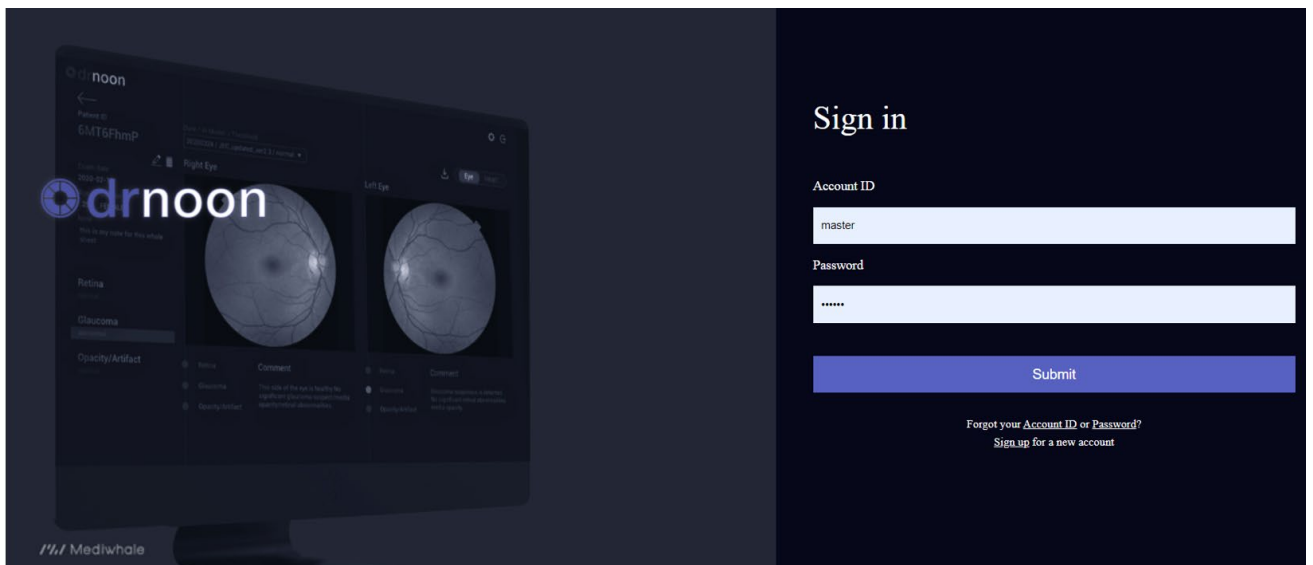
9. Method of Use

9.1. Preparation before use

- 1) Read and understand the user manual before operating the product.
- 2) Access the software using authorized account information (MEMBER ID, Password).

9.2. Software Access and Login

- 1) Access the cloud address (<https://cvd.eyexam.ai/>) provided.



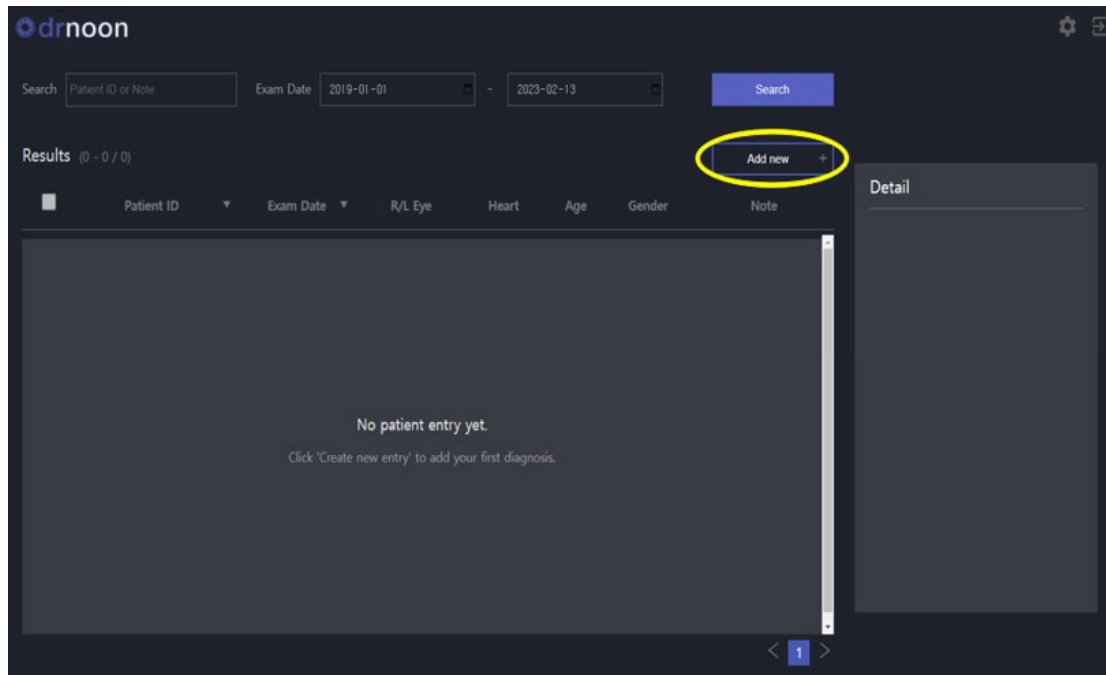
9.3. Image Upload



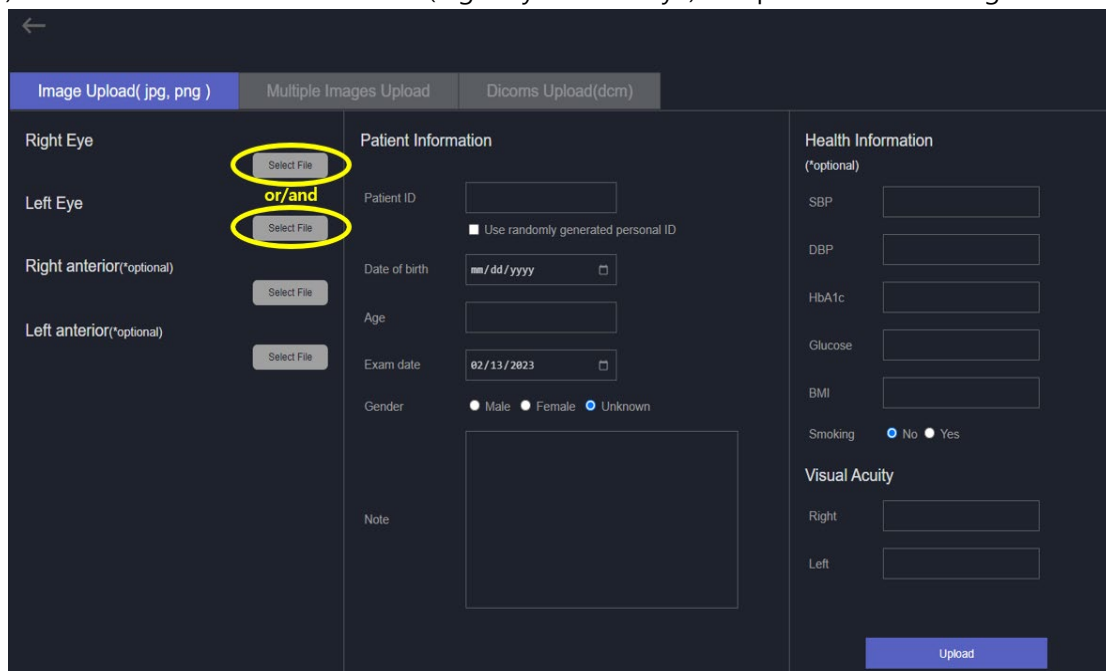
For inappropriate fundus images, the quality of the image is evaluated through the Quality module and a warning message is displayed.

9.3.1 Single Upload (JPG, PNG files)

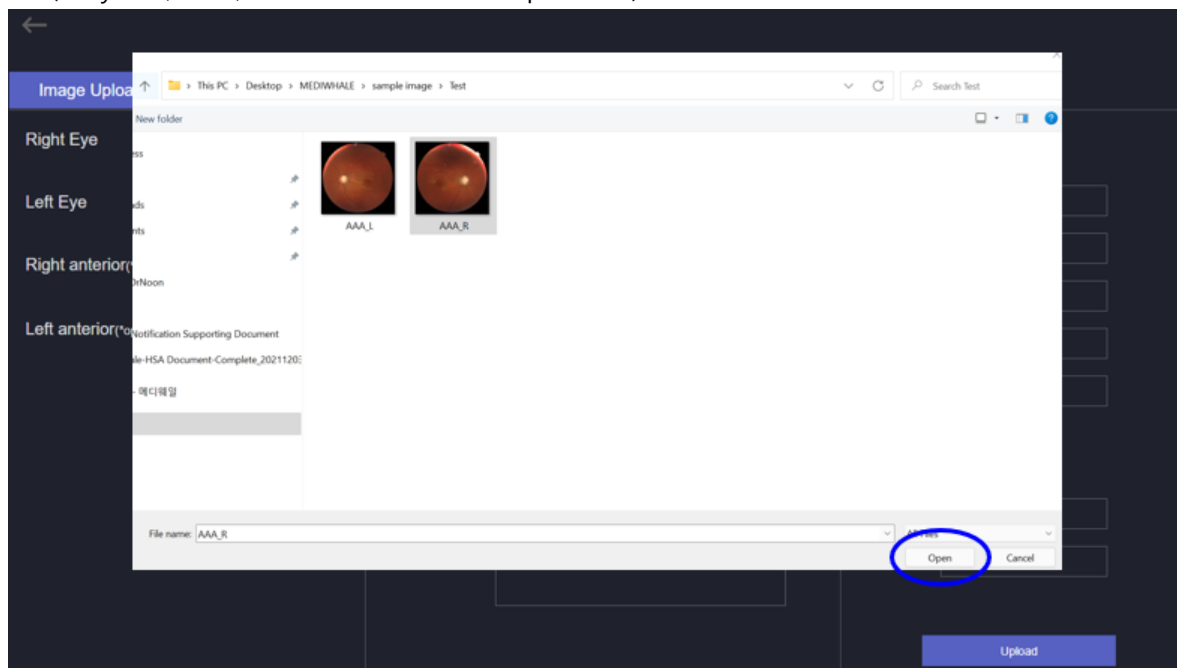
- 1) Click "Add new".



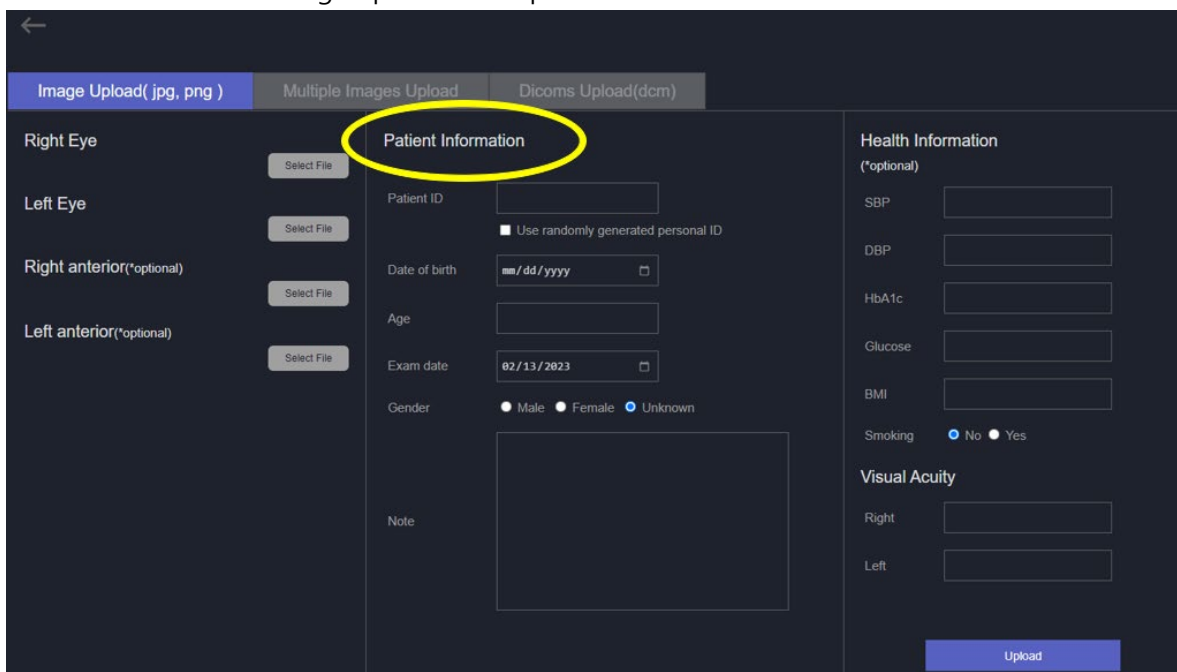
- 2) Select "Select File" of the item (Right Eye or Left Eye) to upload the safe image.



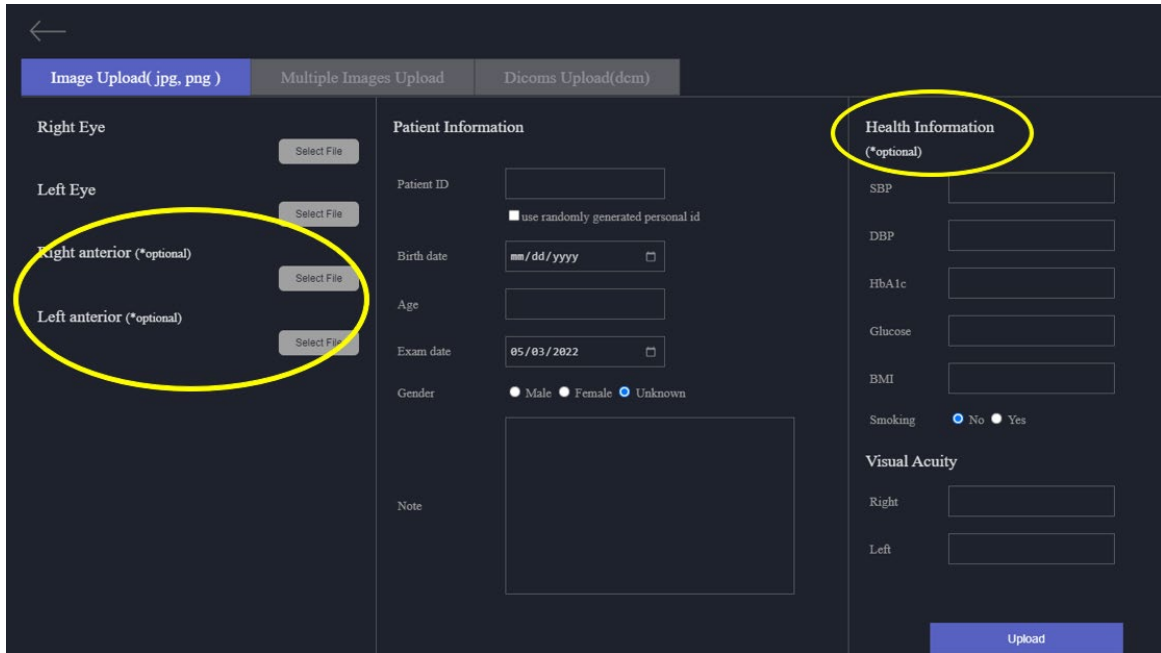
- 3) Locate and select the file that matches the selected item, then click "Open".
(Only JPG, PNG, and TIFF files can be uploaded.)



- 4) When the upload is complete, the uploaded image is shown as shown below.
Enter patient ID, date of birth, age, date of imaging, and gender as required in "Patient Information" after image upload is completed.

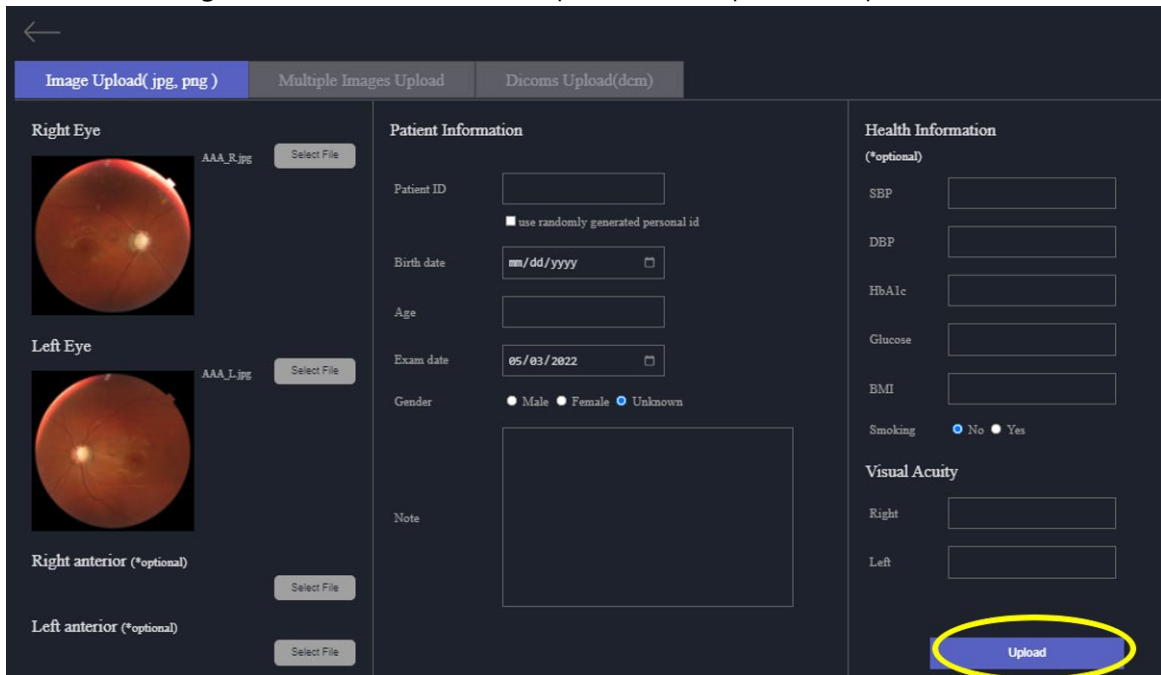


- 5) You can enter anterior or health information (SBP, DBP, HbA1c, Glucose, BMI, smoking, visual acuity) as necessary.



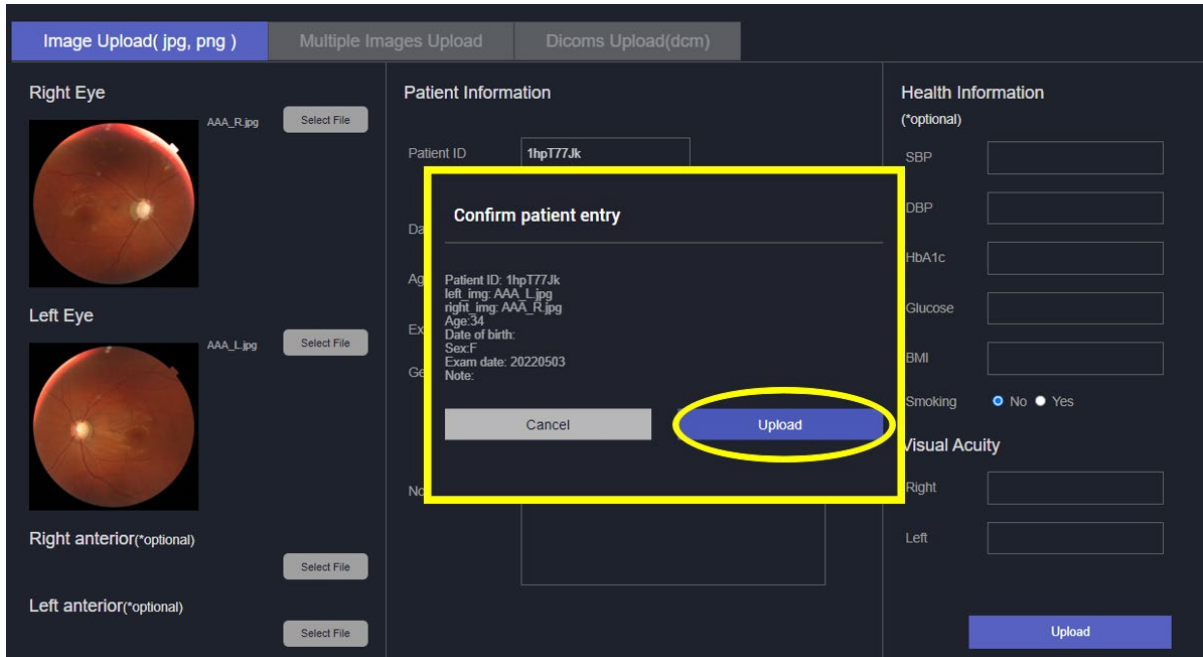
The screenshot shows the 'Image Upload (jpg, png)' tab selected. The form is divided into three main sections: Image Upload, Patient Information, and Health Information. The 'Health Information' section is highlighted with a yellow circle. It includes fields for SBP, DBP, HbA1c, Glucose, BMI, Smoking (No/Yes), and Visual Acuity (Right/Left). The 'Patient Information' section includes fields for Patient ID, Birth date, Age, Exam date, and Gender. The 'Image Upload' section includes fields for Right Eye, Left Eye, Right anterior (*optional), and Left anterior (*optional), each with a 'Select File' button. A blue 'Upload' button is located at the bottom right.

- 6) After entering all the information, click "Upload" to complete the upload.



The screenshot shows the same form as before, but now with sample images uploaded for the Right Eye and Left Eye. The 'Upload' button at the bottom right is highlighted with a yellow circle. The 'Health Information' section remains highlighted with a yellow circle. The 'Patient Information' section includes fields for Patient ID, Birth date, Age, Exam date, and Gender. The 'Image Upload' section includes fields for Right Eye, Left Eye, Right anterior (*optional), and Left anterior (*optional), each with a 'Select File' button.

- 7) A confirm patient entry window appears to check whether the information to be uploaded is correct, and click "Upload" to finally upload.

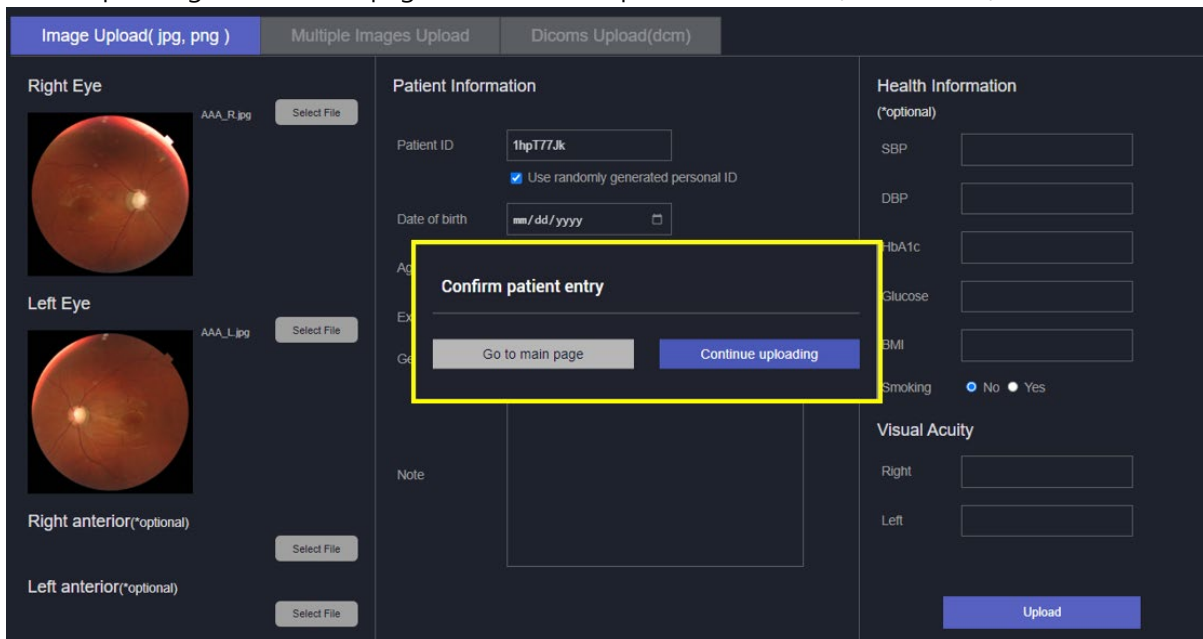


The screenshot shows the 'Image Upload' section with tabs for 'Image Upload(jpg, png)', 'Multiple Images Upload', and 'Dicom Upload(dcm)'. The 'Image Upload' tab is active, showing 'Right Eye' and 'Left Eye' sections with image thumbnails and 'Select File' buttons. The 'Patient Information' section is partially visible, showing 'Patient ID: 1hpT77Jk'. A 'Confirm patient entry' dialog box is overlaid, displaying the following information:

- Patient ID: 1hpT77Jk
- left_img: AAA_L.jpg
- right_img: AAA_R.jpg
- Age: 34
- Sex: F
- Date of birth: 20220503
- Exam date: 20220503
- Note:

The dialog box has two buttons: 'Cancel' and 'Upload'. The 'Upload' button is highlighted with a yellow circle.

- 8) A confirm patient entry window appears to check "Continue uploading" or "Go to main page", and pressing "Go to main page" moves to the patient list screen(main screen).



The screenshot shows the 'Image Upload' section with tabs for 'Image Upload(jpg, png)', 'Multiple Images Upload', and 'Dicom Upload(dcm)'. The 'Image Upload' tab is active, showing 'Right Eye' and 'Left Eye' sections with image thumbnails and 'Select File' buttons. The 'Patient Information' section is partially visible, showing 'Patient ID: 1hpT77Jk' and a checked checkbox for 'Use randomly generated personal ID'. A 'Confirm patient entry' dialog box is overlaid, displaying the following information:

- Patient ID: 1hpT77Jk
- Use randomly generated personal ID (checked)
- Date of birth: mm/dd/yyyy

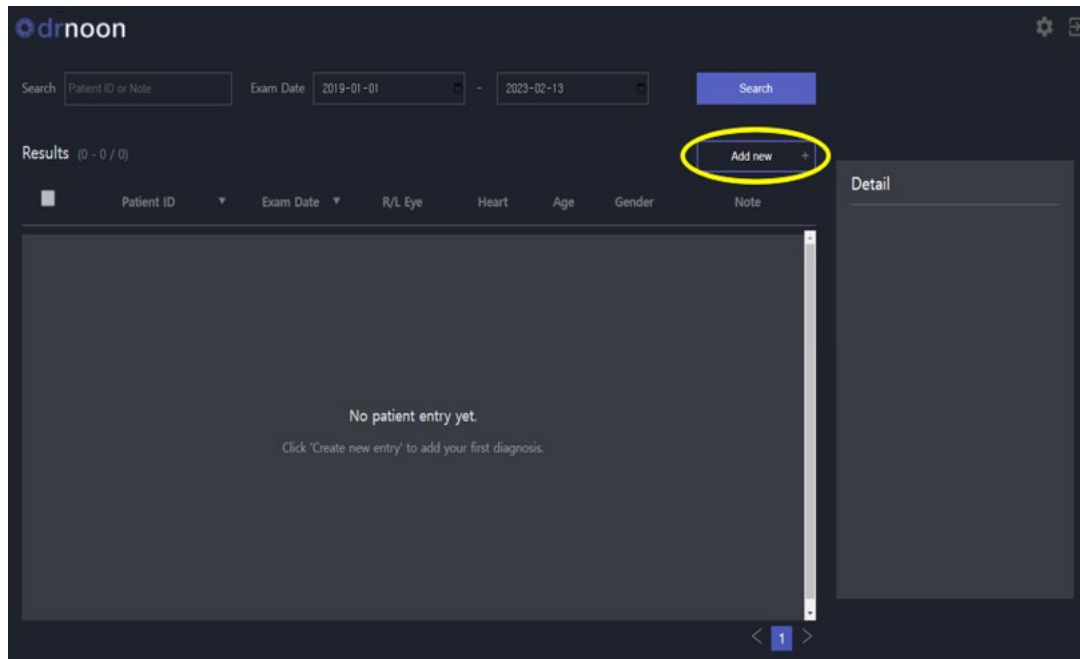
The dialog box has two buttons: 'Go to main page' and 'Continue uploading'. The 'Go to main page' button is highlighted with a yellow circle.

9.4. Multiple Upload

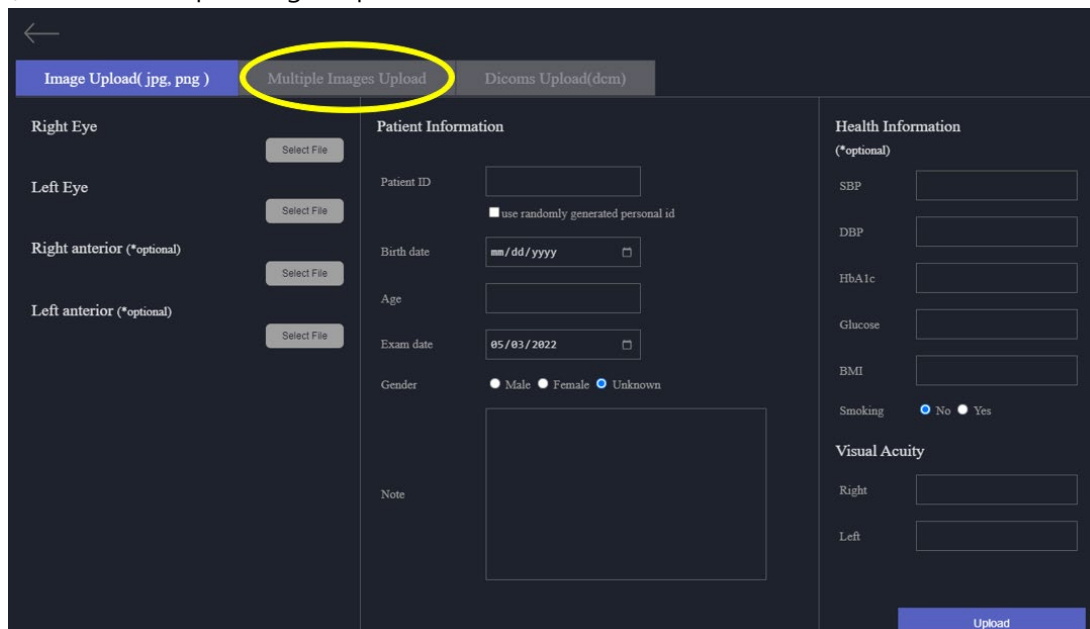
※ Save file name as "Patient ID_L or Patient ID_R" before multiple uploads

※ For image file multiple uploads, patient information must be entered on the detection result screen.

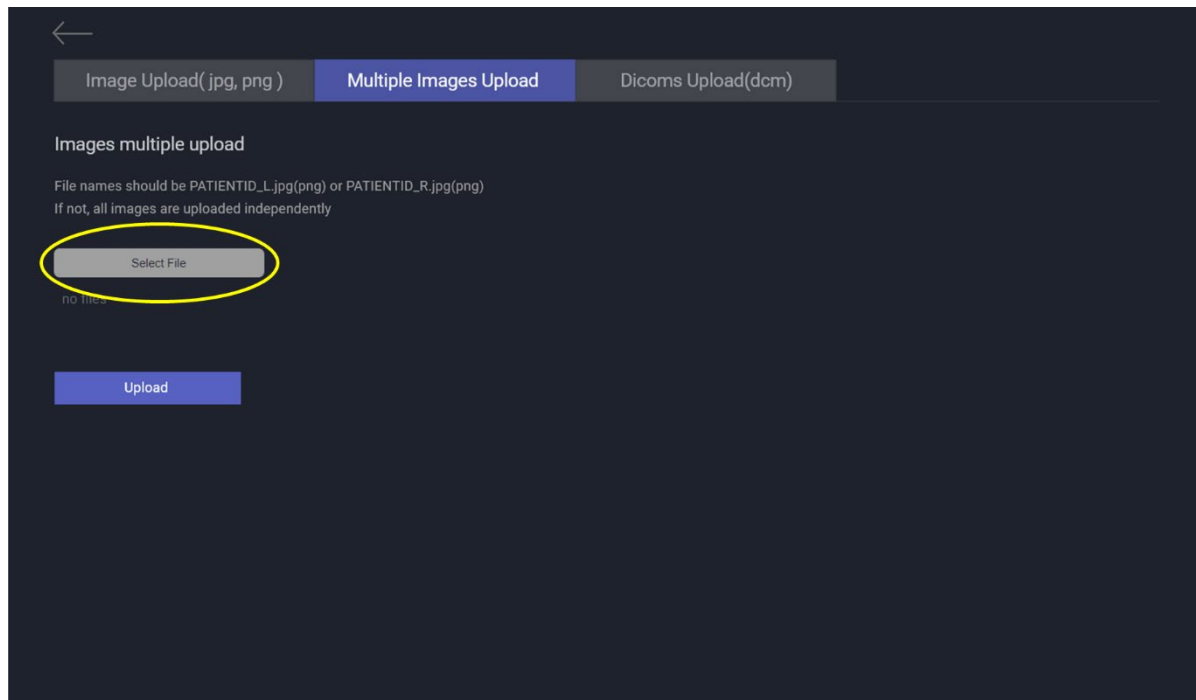
1) Click "Add new"



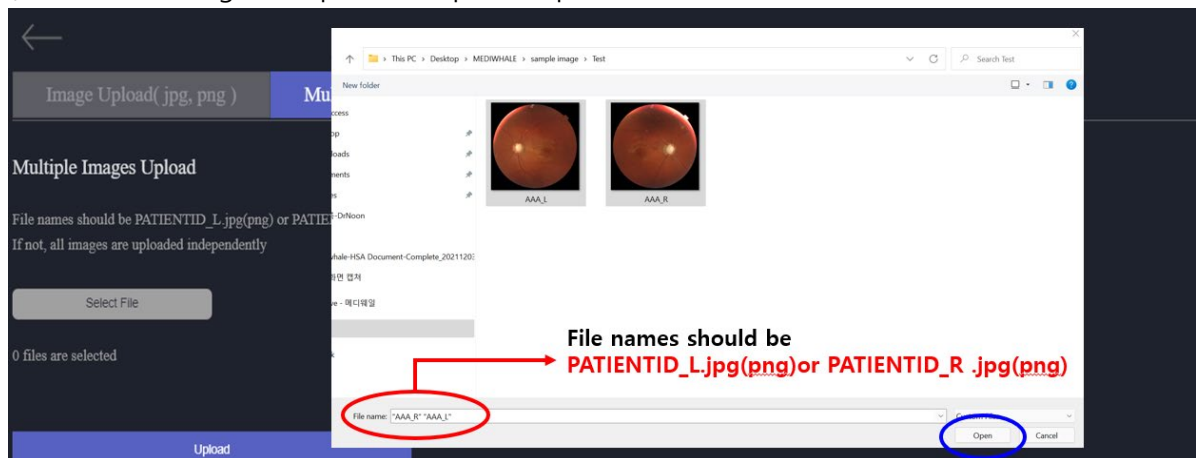
2) Click "Multiple Images Upload"



3) Click "Select File"

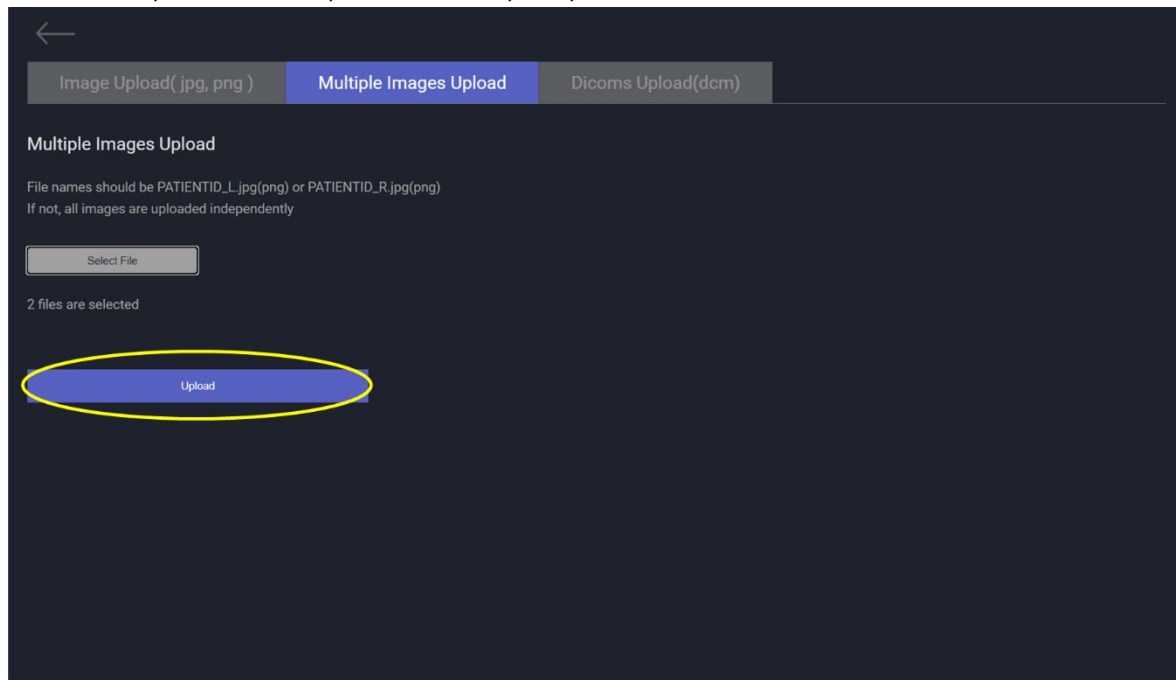


4) Select all images to upload and press "Open".



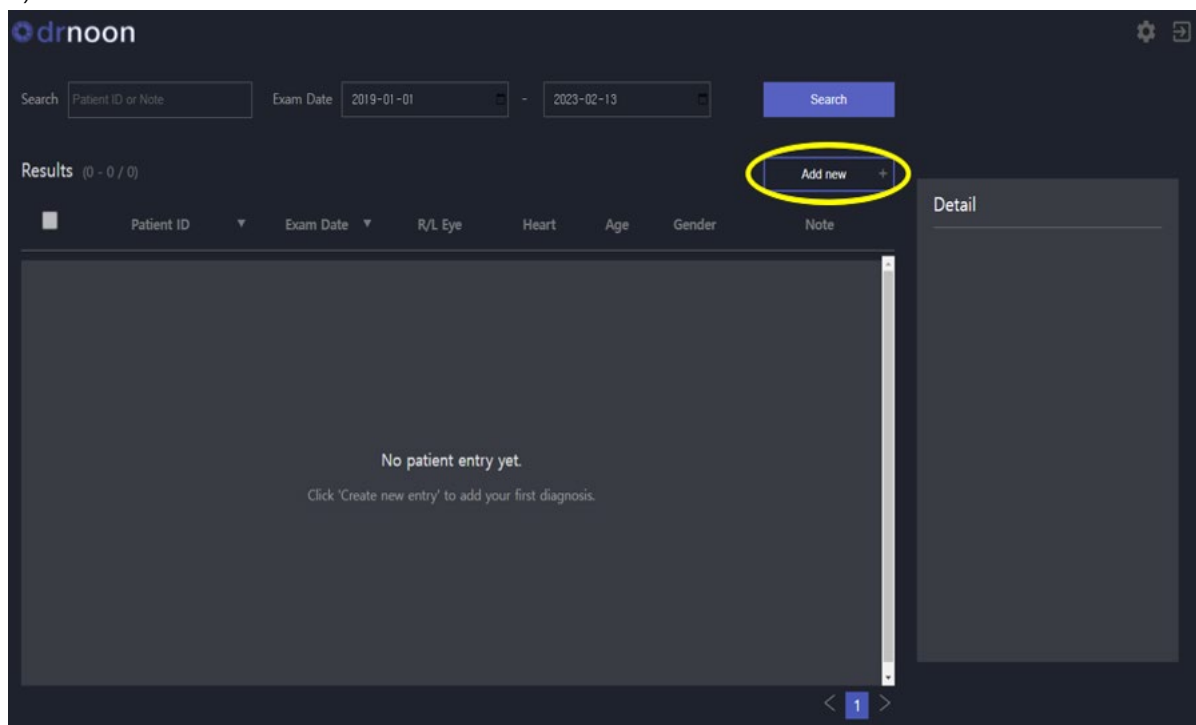
Do not upload different image except fundus image.

- 5) Click "Upload" to complete the multiple uploads.

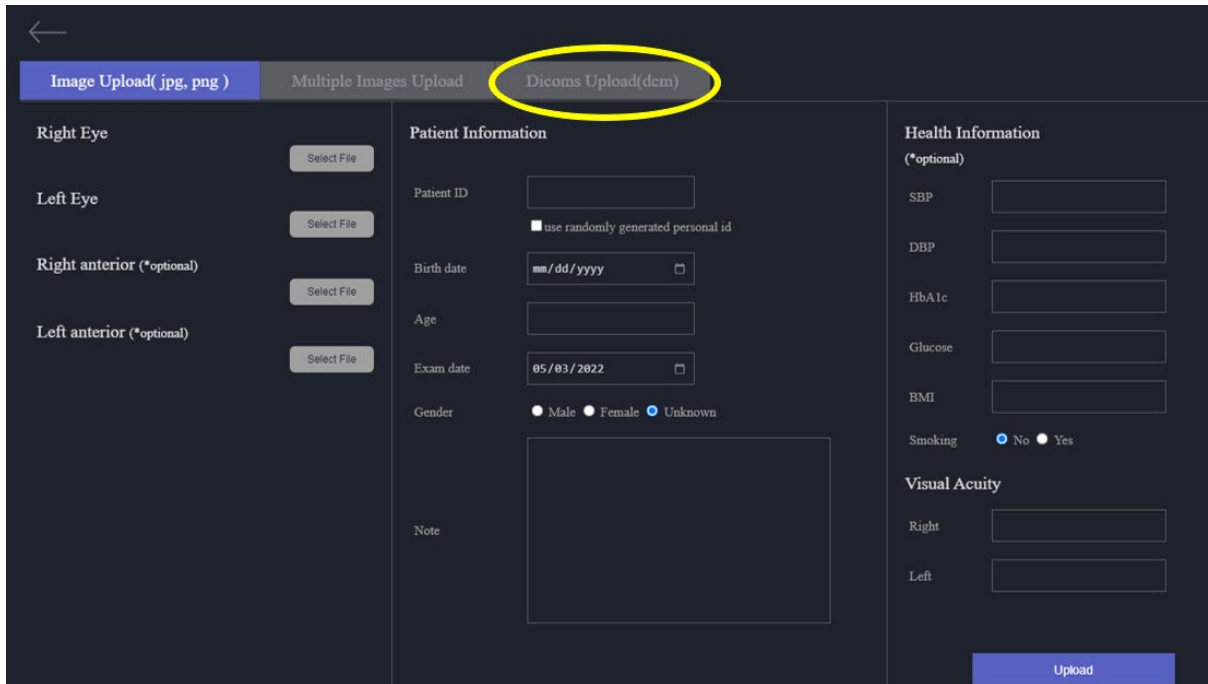


9.5. DICOM Upload

- 1) Click "Add new"



2) Click "Dicoms Upload(dcm)"

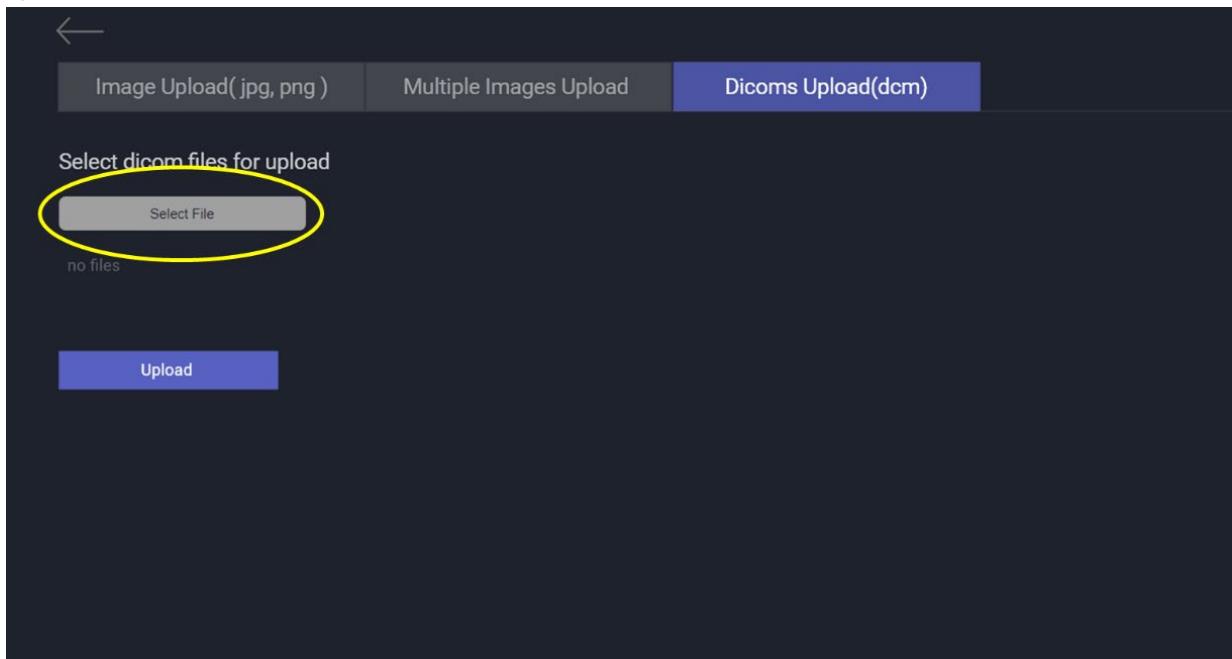


The screenshot shows the 'Dicoms Upload(dcm)' tab selected in the top navigation bar. The interface is divided into several sections:

- Image Upload (jpg, png):** Contains four 'Select File' buttons for 'Right Eye', 'Left Eye', 'Right anterior (*optional)', and 'Left anterior (*optional)'.
- Patient Information:** Includes fields for 'Patient ID' (with a checkbox for 'use randomly generated personal id'), 'Birth date' (with a date picker), 'Age', 'Exam date' (with a date picker), and 'Gender' (with radio buttons for 'Male', 'Female', and 'Unknown'). There is also a 'Note' text area.
- Health Information (*optional):** Includes input fields for 'SBP', 'DBP', 'HbA1c', 'Glucose', 'BMI', and 'Smoking' (with radio buttons for 'No' and 'Yes').
- Visual Acuity:** Includes input fields for 'Right' and 'Left'.

An 'Upload' button is located at the bottom right of the form.

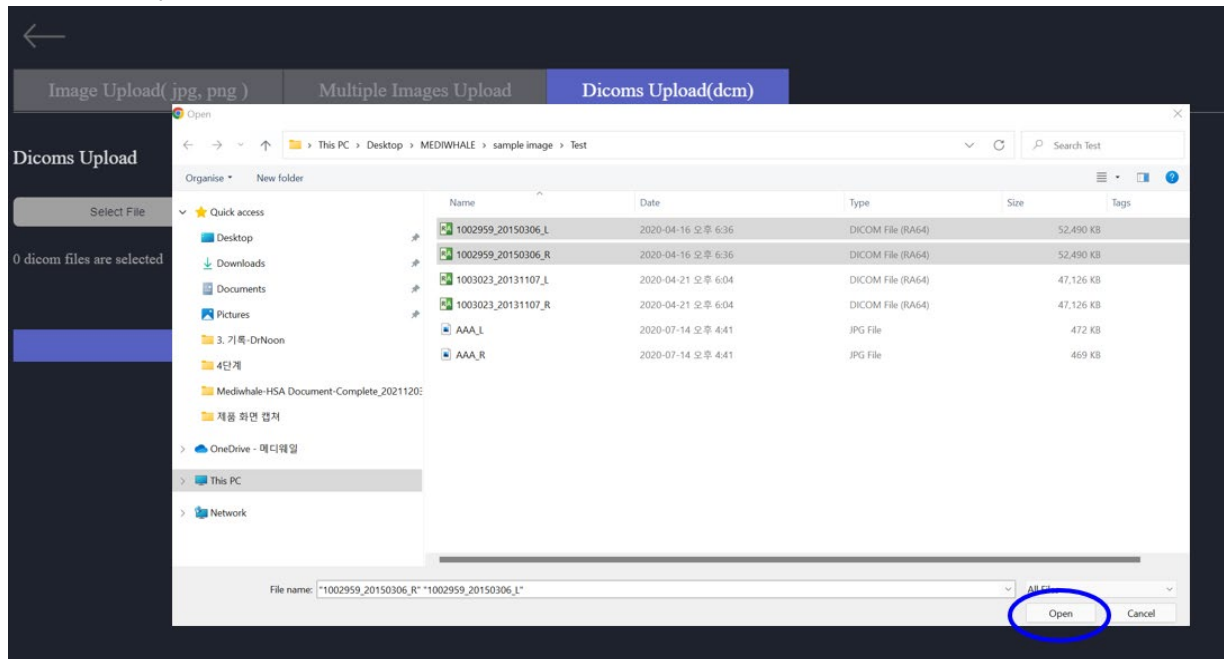
3) Click "Select File"



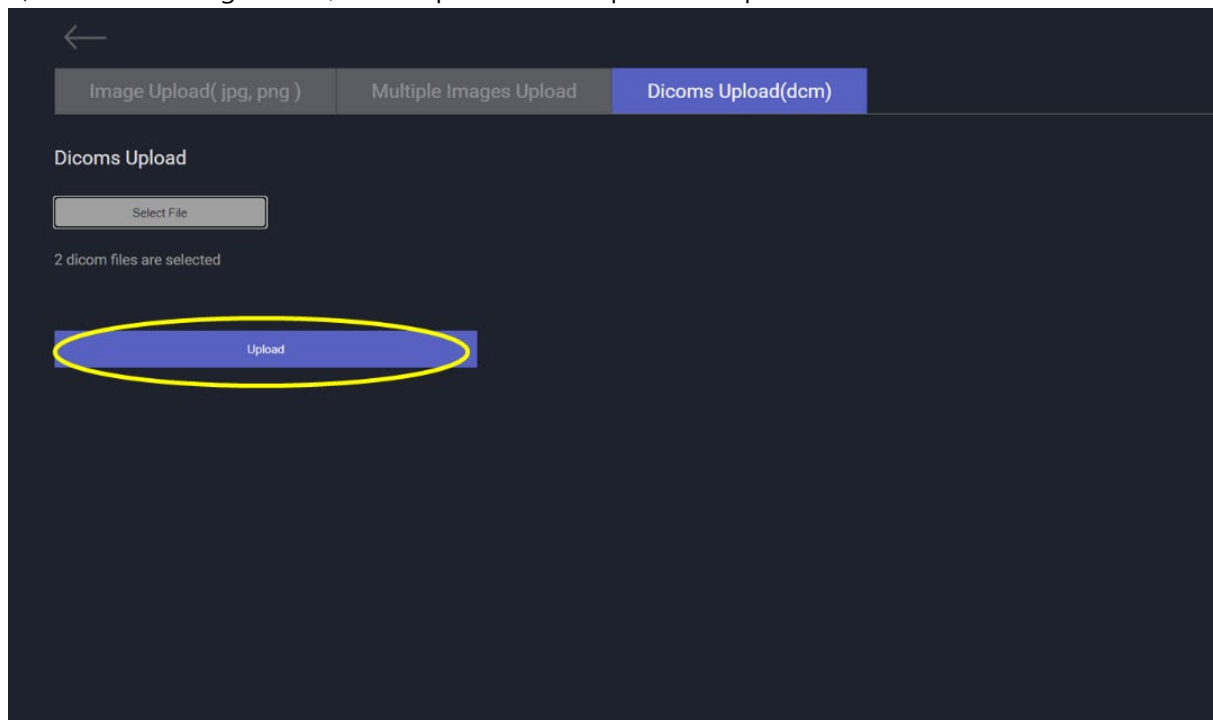
The screenshot shows the 'Dicoms Upload(dcm)' tab selected in the top navigation bar. The interface is divided into several sections:

- Select dicom files for upload:** This section is highlighted with a yellow circle. It contains a 'Select File' button and a list of files. Below the list, it says 'no files'.
- Upload:** A blue button at the bottom of the section.

- 4) Select DICOM file (extended dcm) and click "Open". DICOM uploads can be uploaded by single or multiple selection.



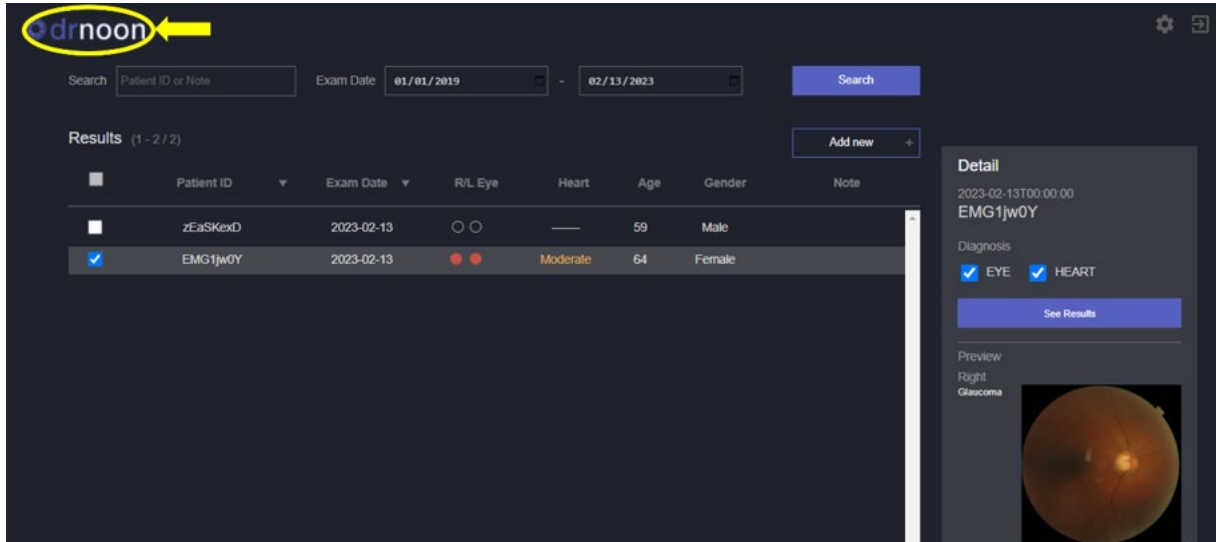
- 5) After selecting the file, click "Upload" to complete the upload.



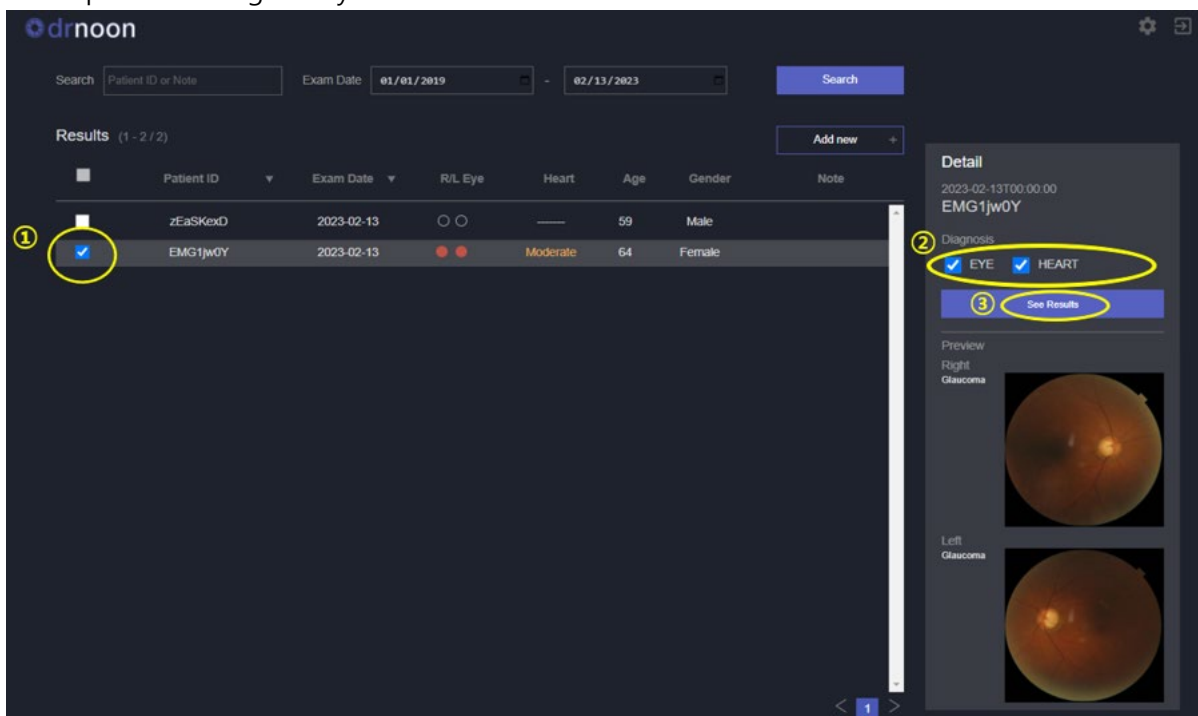
9.6. Main Function

9.6.1. Image Detection

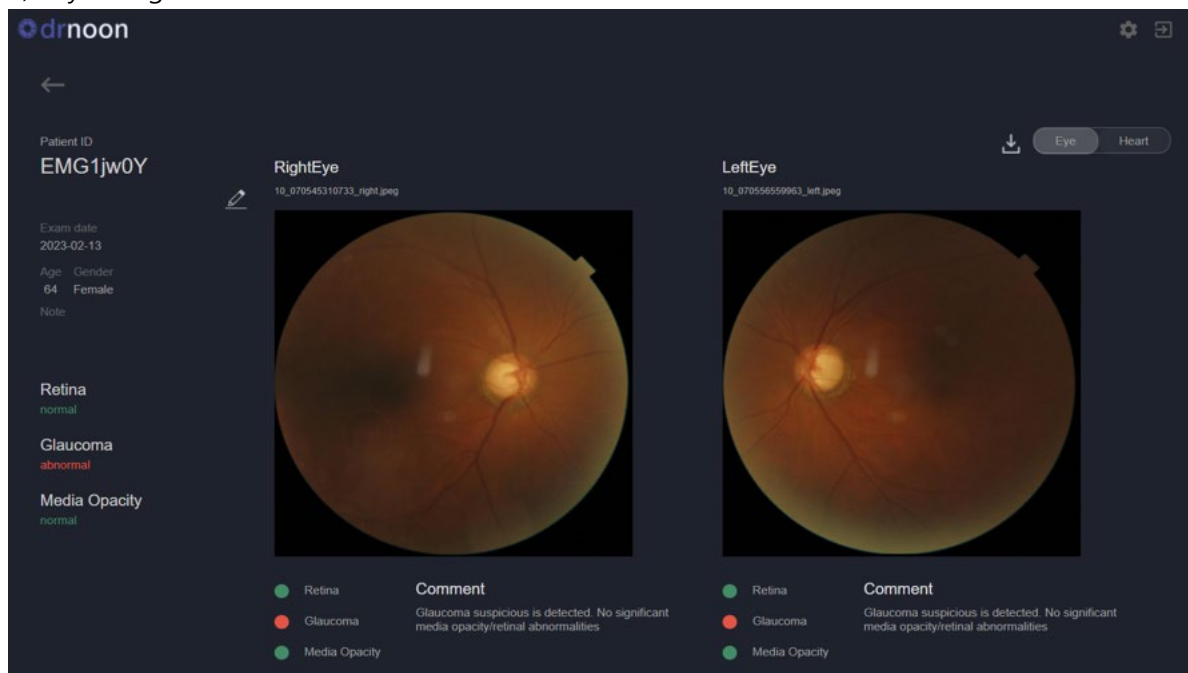
- 1) Enter the Patient List screen (main screen). If connected to a different screen, click on the top of product name (ex. DrNoon) logo as shown in the figure below to display the patient list screen.



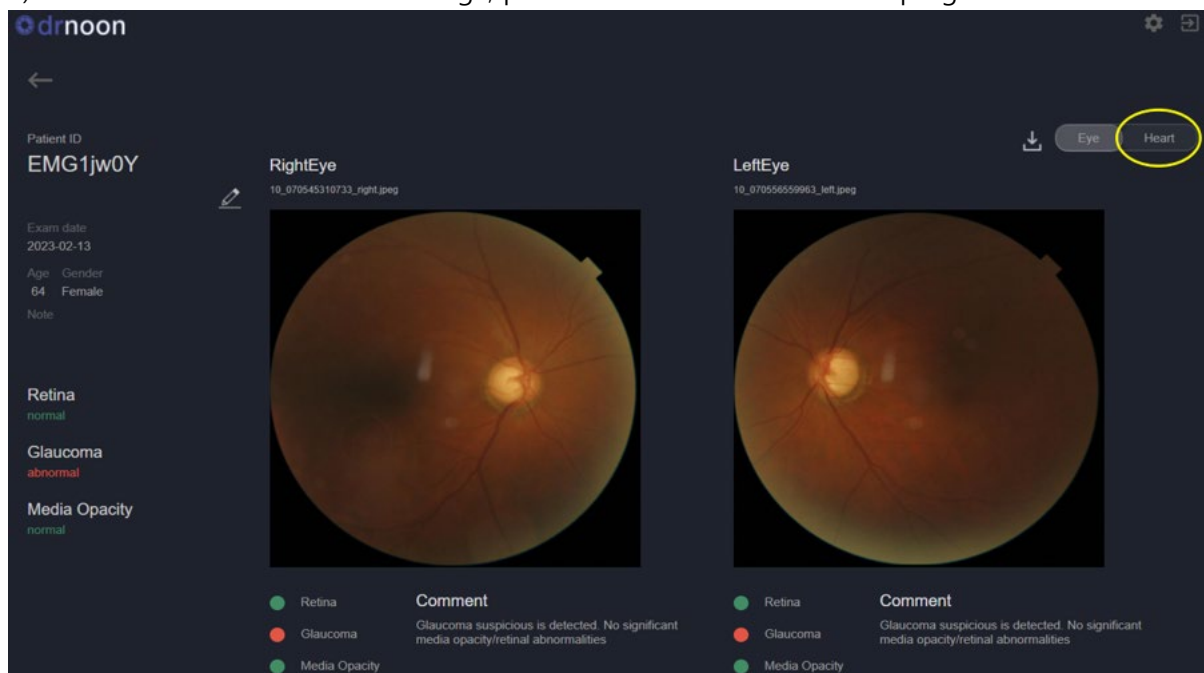
- 2) First, check the left checkbox for the patient who wants to check the detection results. Then, after checking the result information (EYE, HEART) you want to see, click "See Results" and the AI performs image analysis.



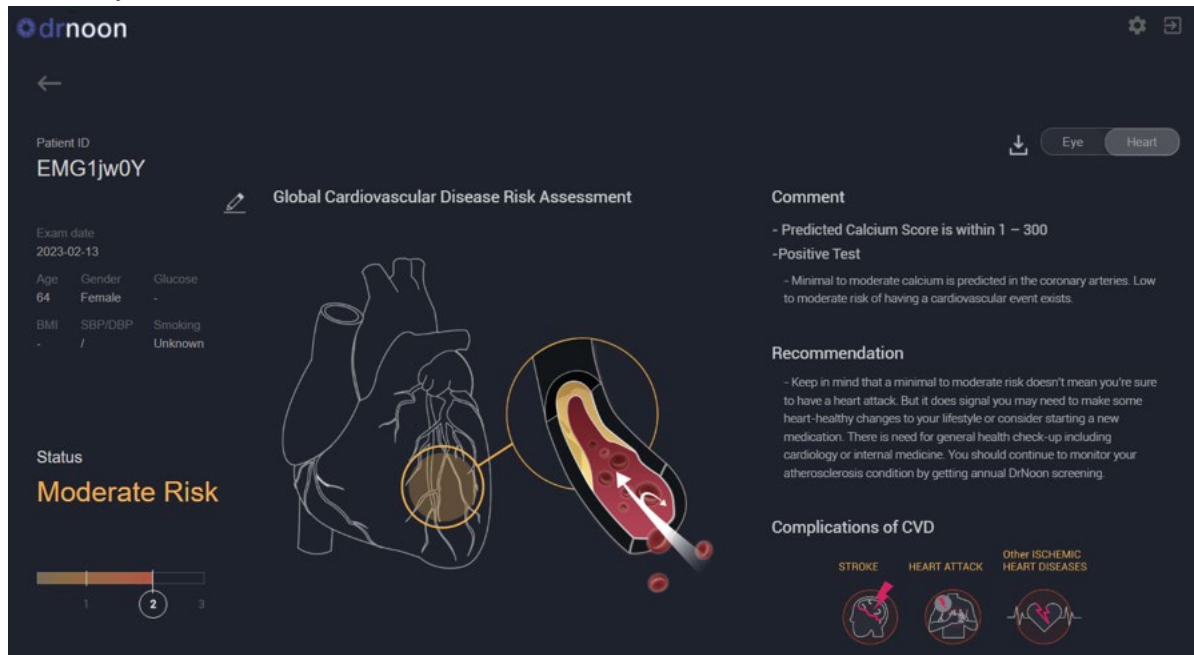
3) Eye image detection result can be checked.



4) To check the heart detection image, press the heart button on the top right.

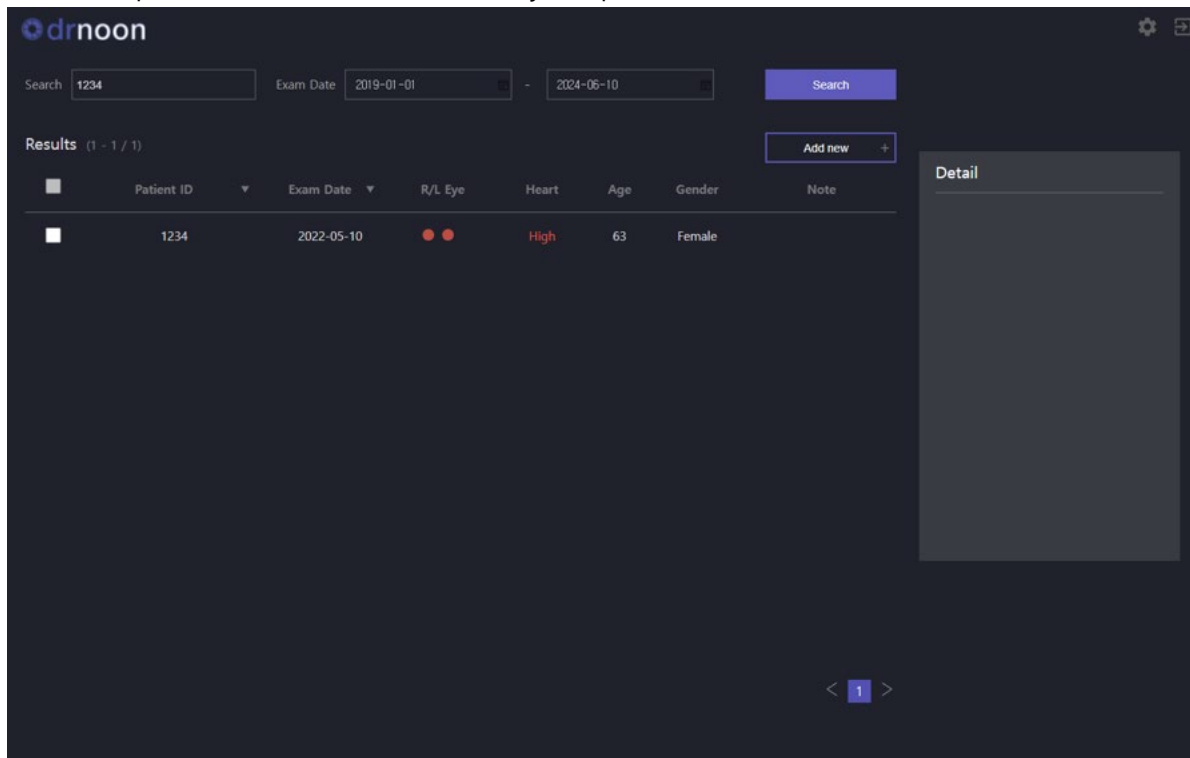


- 5) It shows the detection results of an analysis of cardiovascular risk based on the image base of the eye.



9.6.2. Search for Patient ID

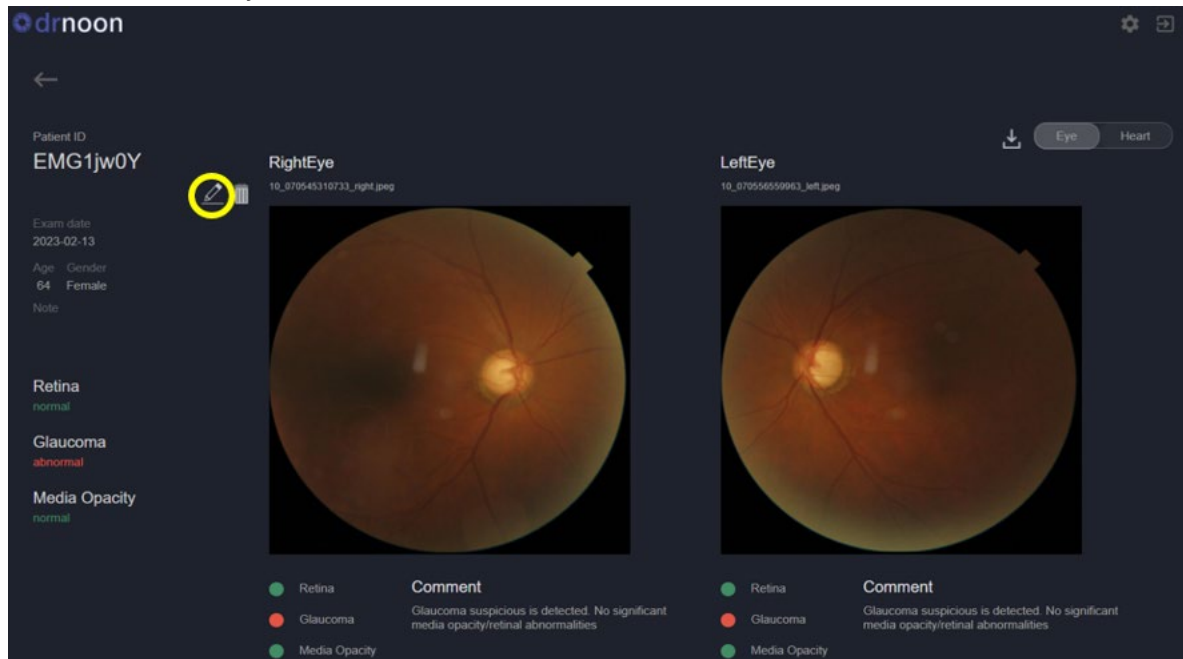
- 1) In the search bar at the top of the patient list screen, enter the patient ID you wish to check and press enter.
- 2) The patient list will filter to show only the patient with the entered ID.



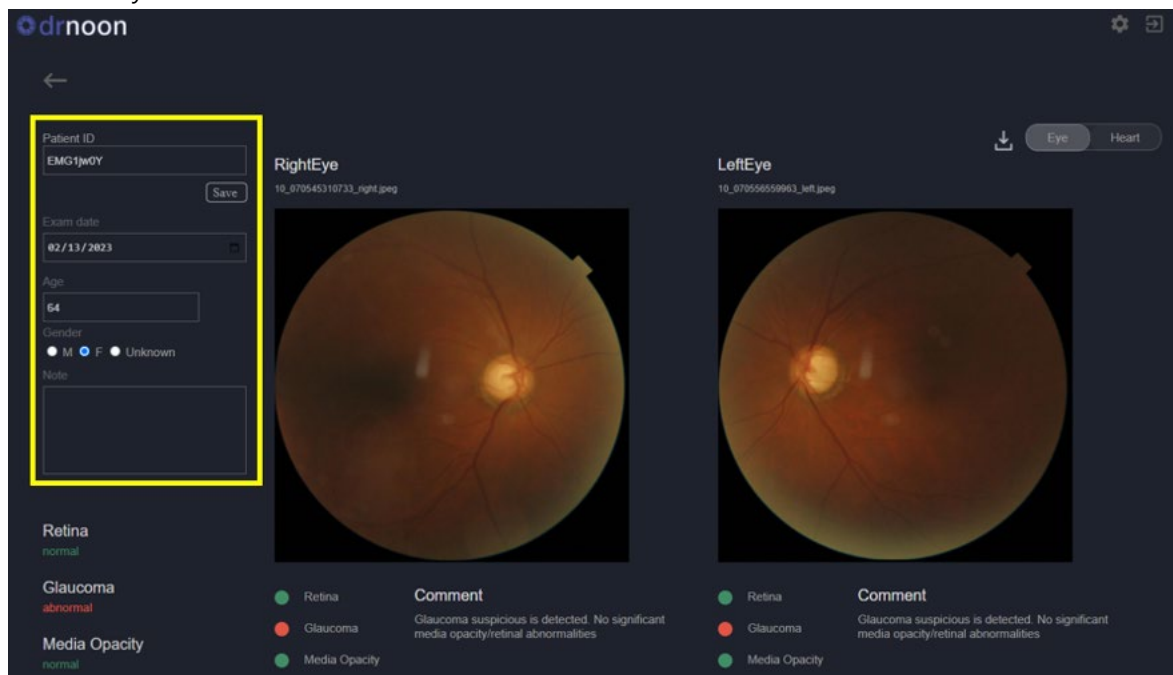
※ 9.6.3 "Modify patient information" through 9.6.5 "Report Output" first proceed with 9.6.1 "image Detection" of the patient data to be modified.

9.6.3. Modify patient information

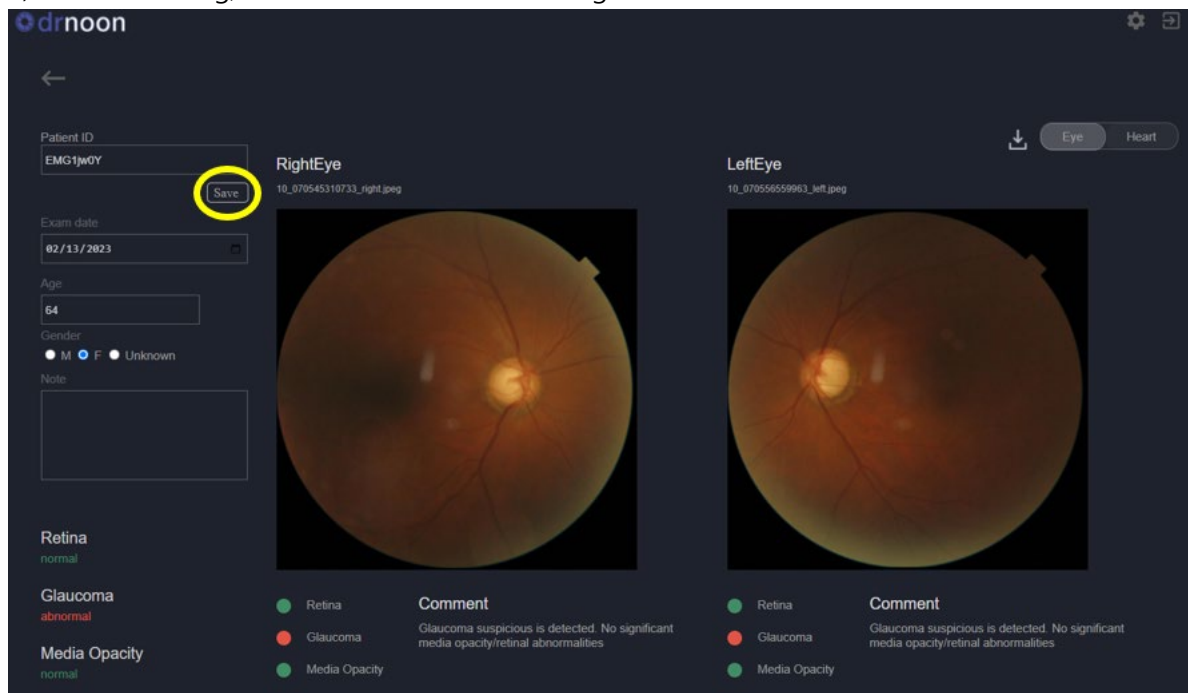
- 1) Click the Modify icon.



- 2) Enter the patient information (patient ID, date of shooting, age, gender, note) you wish to modify.



3) After entering, click "save" to save the changes.

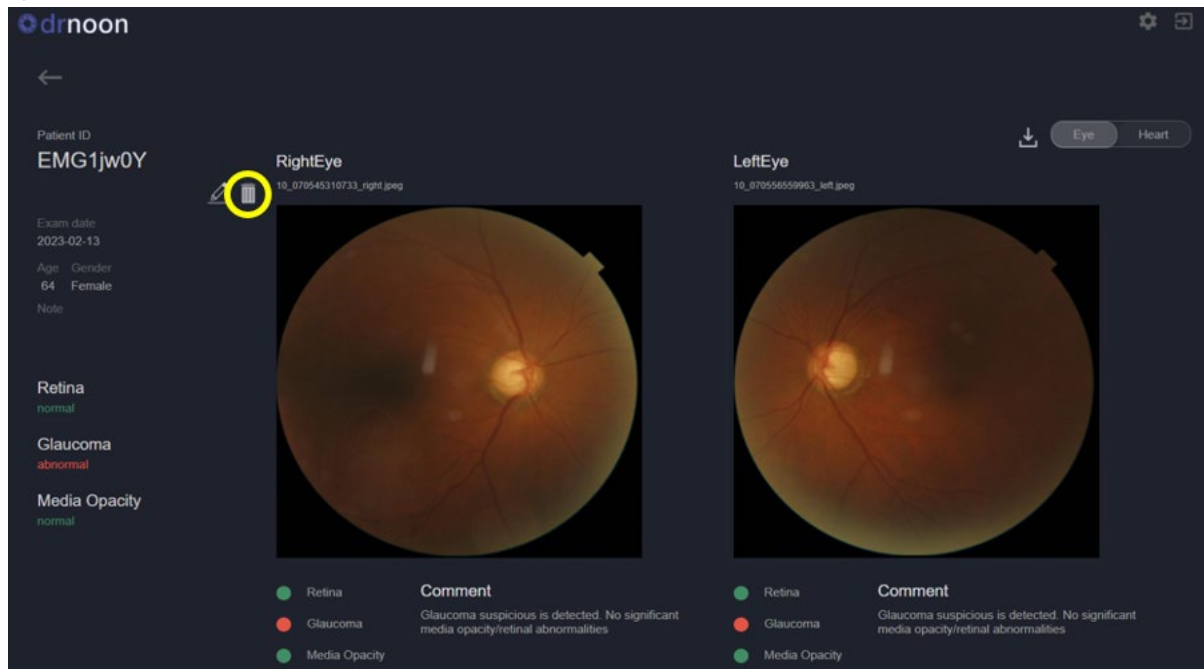


The screenshot displays the drnoon interface for a patient's eye examination. On the left, a sidebar contains patient information: Patient ID (EMG1w0Y), Exam date (02/13/2023), Age (64), Gender (M, F, Unknown), and a Note field. A yellow circle highlights the 'Save' button next to the Patient ID. The main area shows two eye images: 'RightEye' and 'LeftEye'. Below each image, there are analysis results for Retina, Glaucoma, and Media Opacity, along with a comment. The Retina status is 'normal' for both eyes. The Glaucoma status is 'abnormal' for both eyes, with a comment: 'Glaucoma suspicious is detected. No significant media opacity/retinal abnormalities'. The Media Opacity status is 'normal' for both eyes.

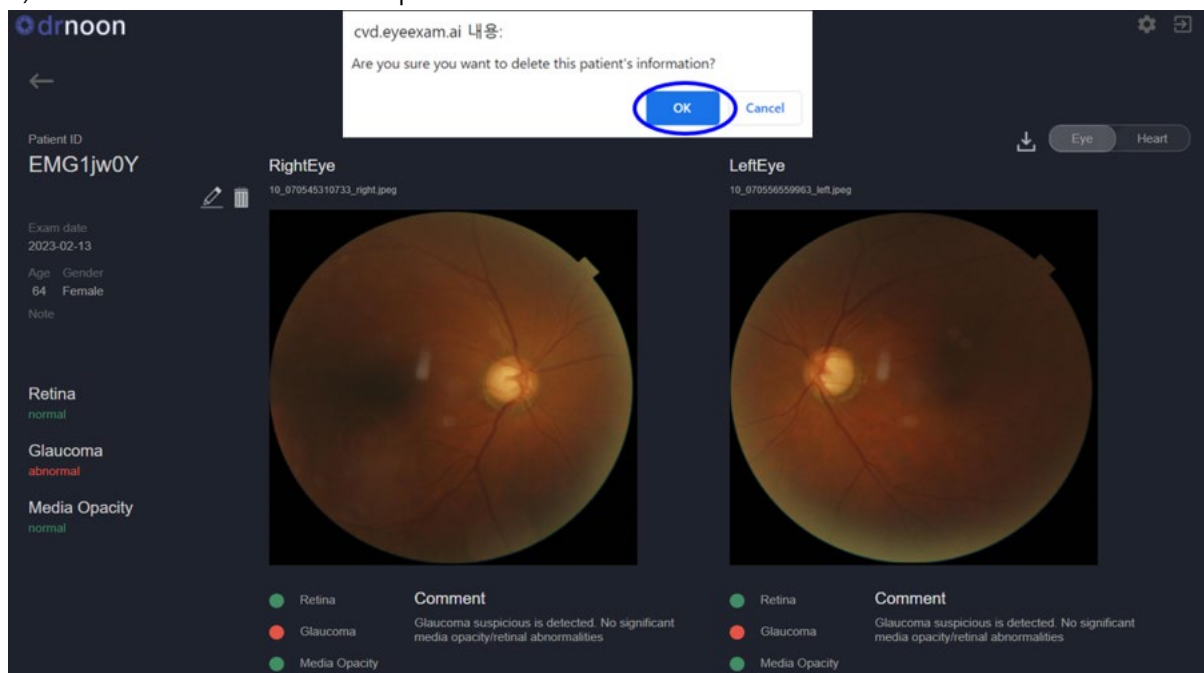
Parameter	RightEye	LeftEye
Retina	normal	normal
Glaucoma	abnormal	abnormal
Media Opacity	normal	normal
Comment	Glaucoma suspicious is detected. No significant media opacity/retinal abnormalities	Glaucoma suspicious is detected. No significant media opacity/retinal abnormalities

9.6.4. Delete Detections Results

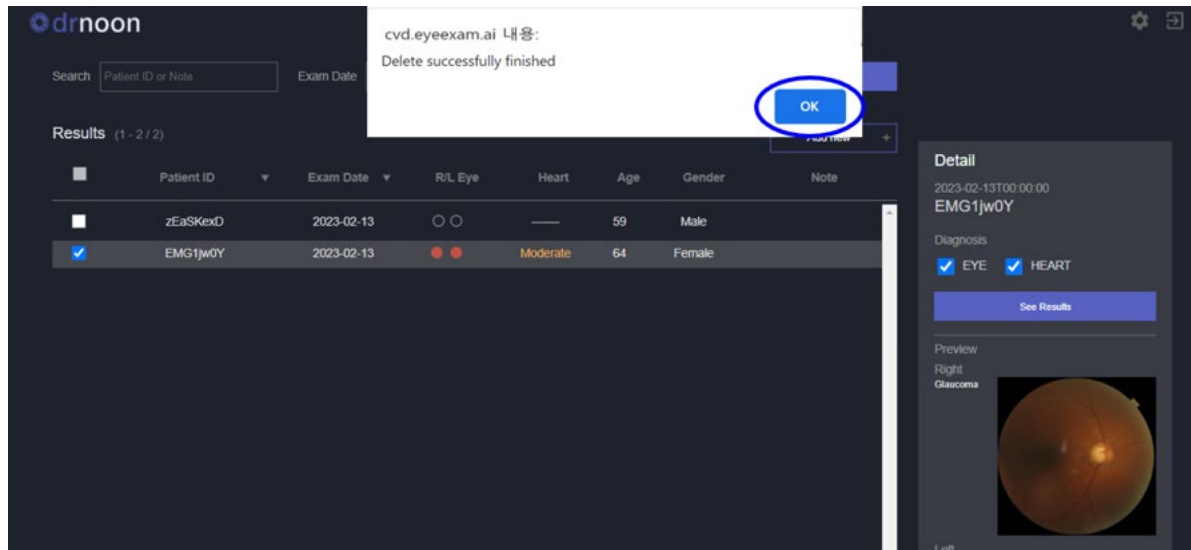
1) Click the Delete icon.



2) Click the OK button to complete the deletion.

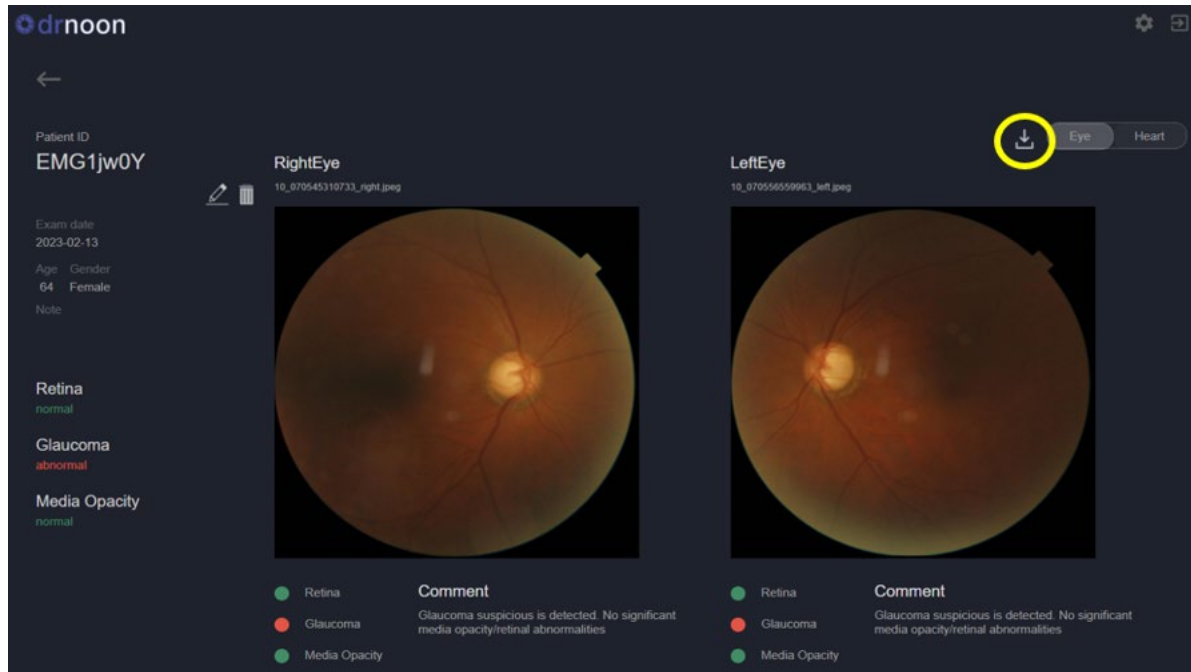


3) Click the OK button.

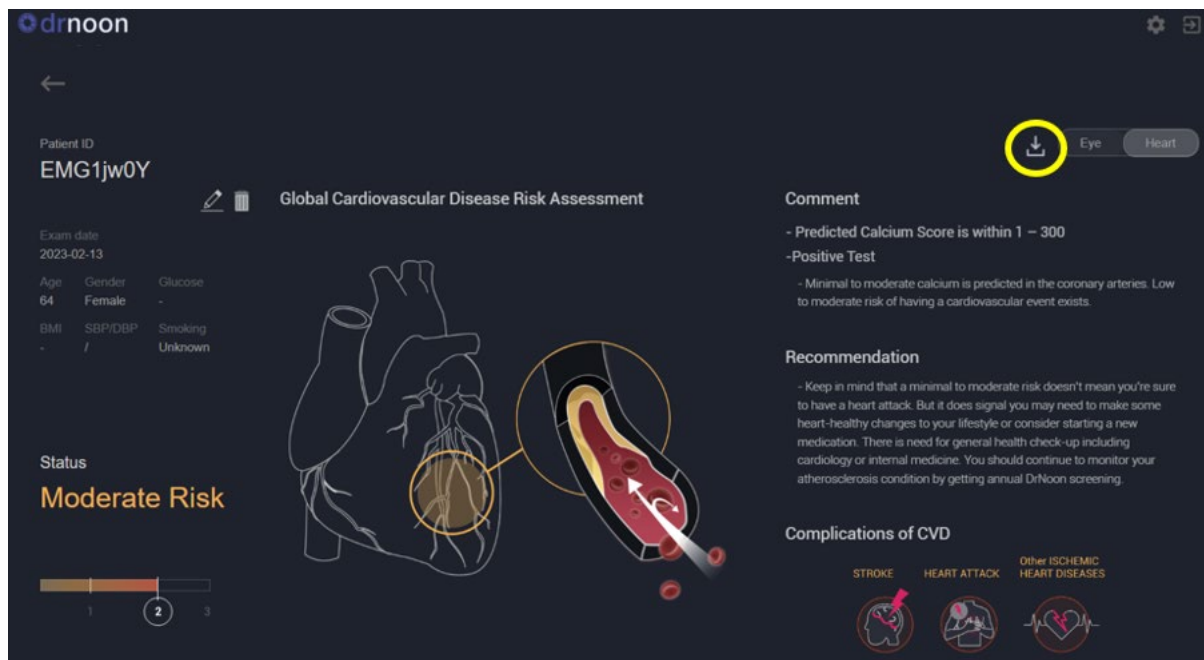


9.6.5. Report Output

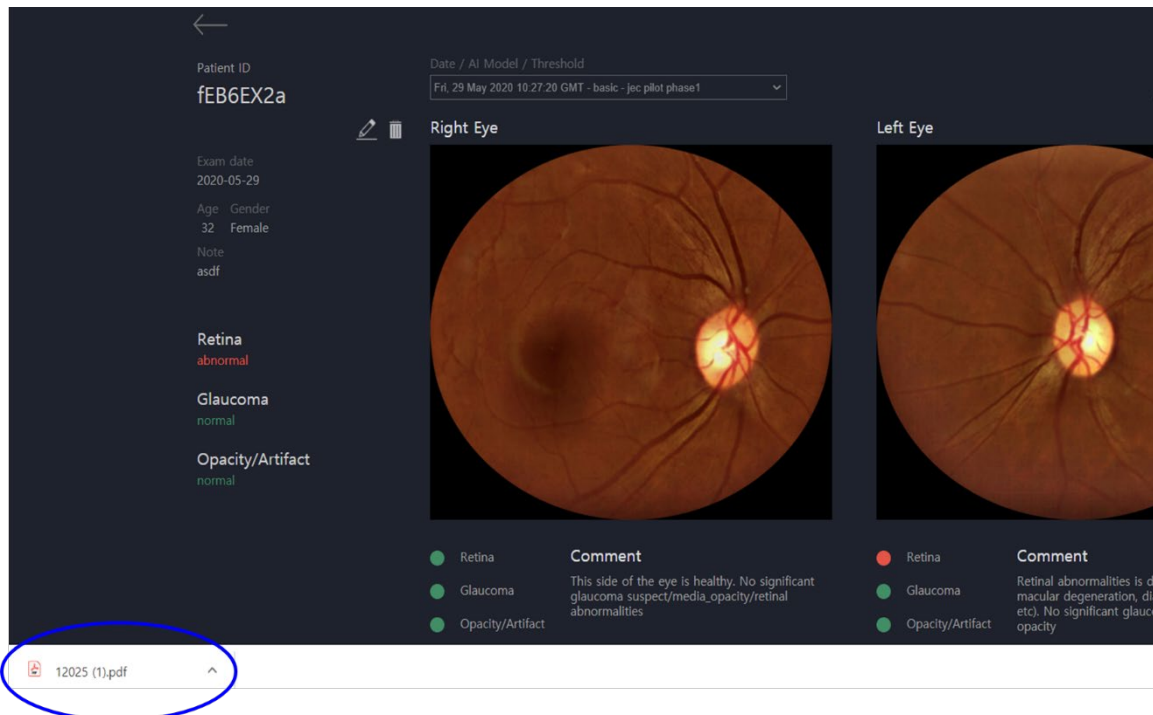
- 1) Enter the detection result (Eye or Heart) you want to print out.
- 2) Click the report down icon.
 - ♦ For Fundus detection results:



- ♦ For cardiovascular risk detection results:



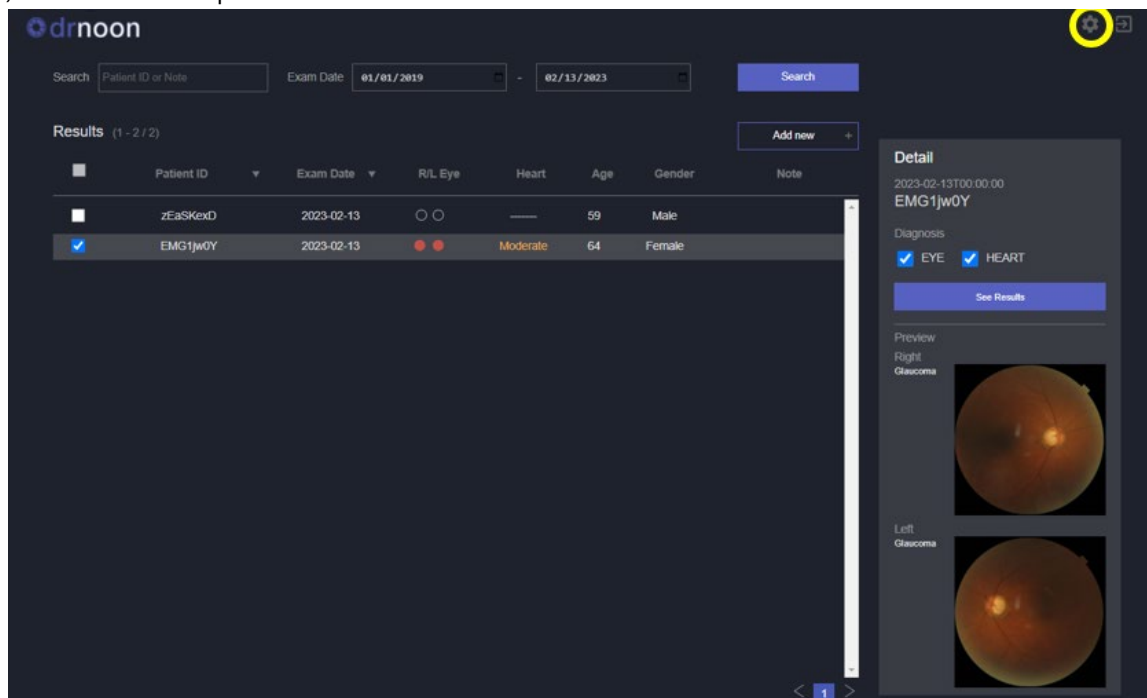
- 3) Click on the file that has been downloaded.



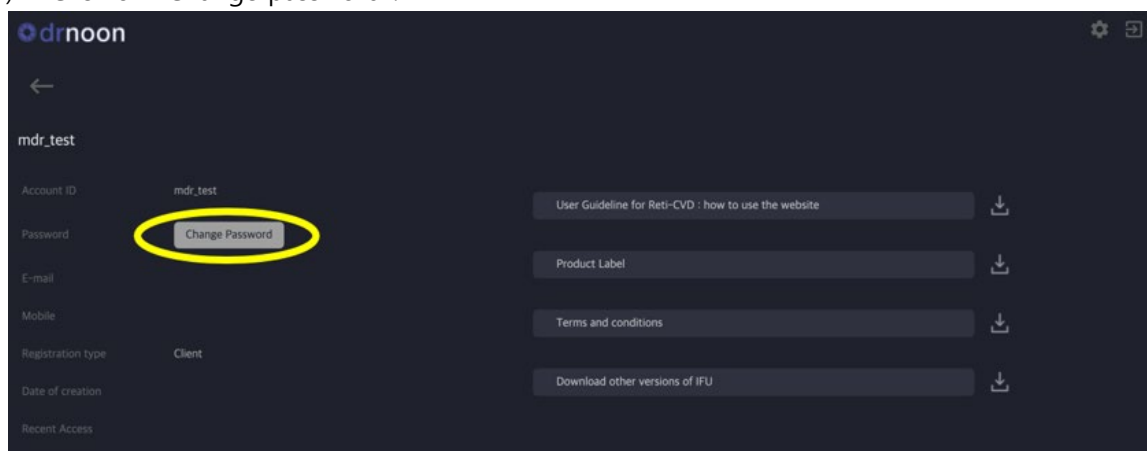
- 4) Print a report

9.6.6. Change account password settings

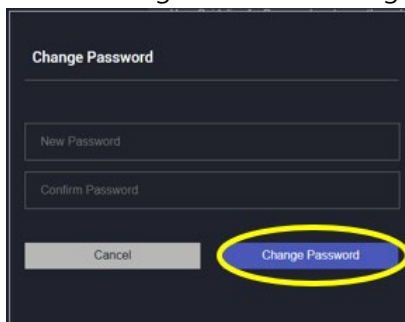
- 1) Click the Setup icon.



- 2) Click on "Change password".

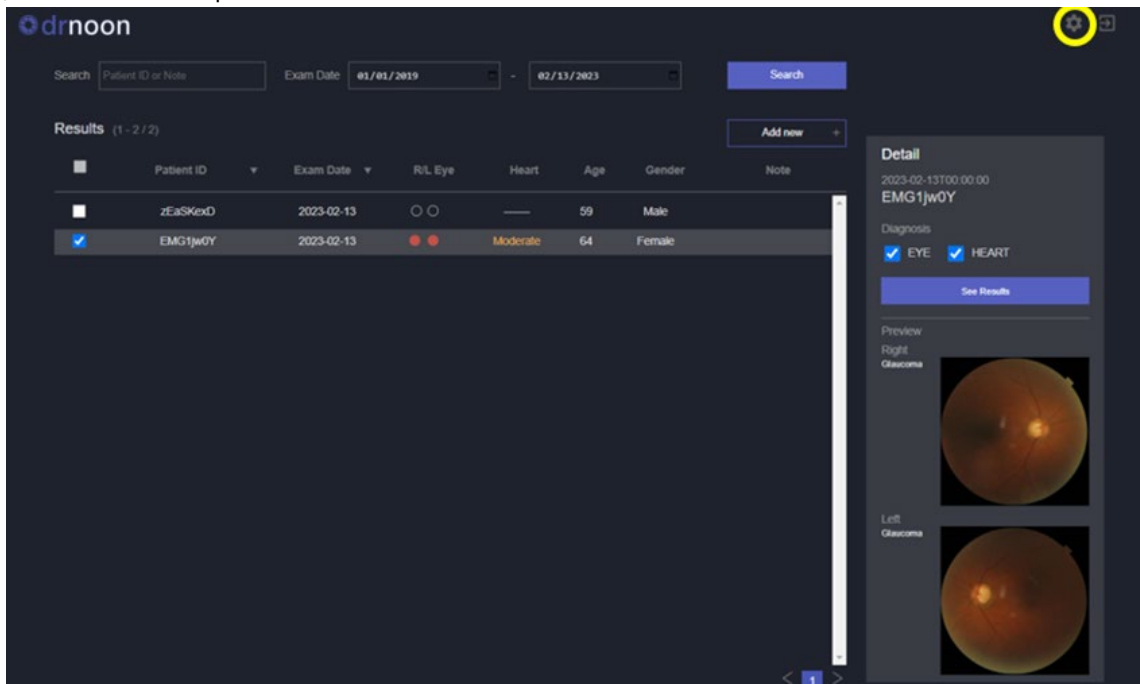


- 3) Enter the new password you want to change and click "Change Password".



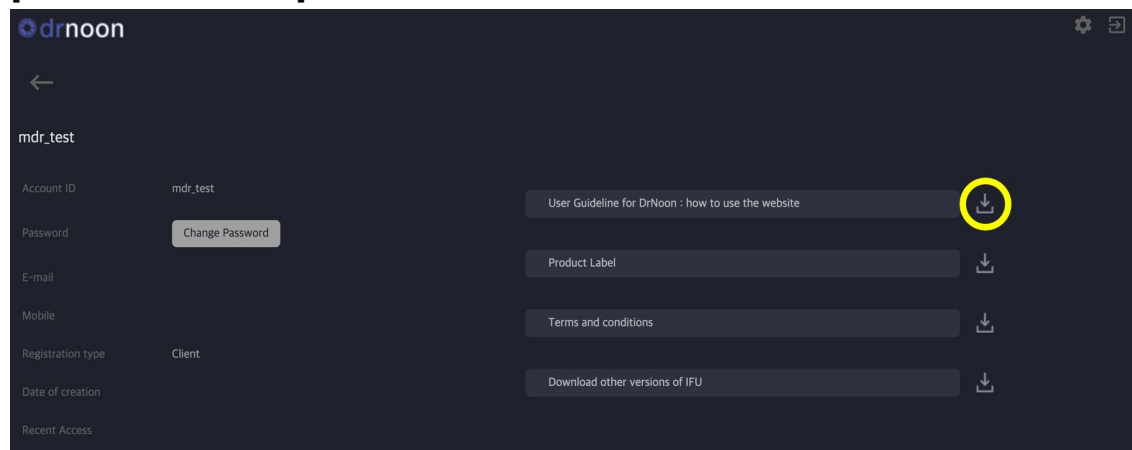
9.6.7. Download a user manual and label

- 1) Click the Setup icon.

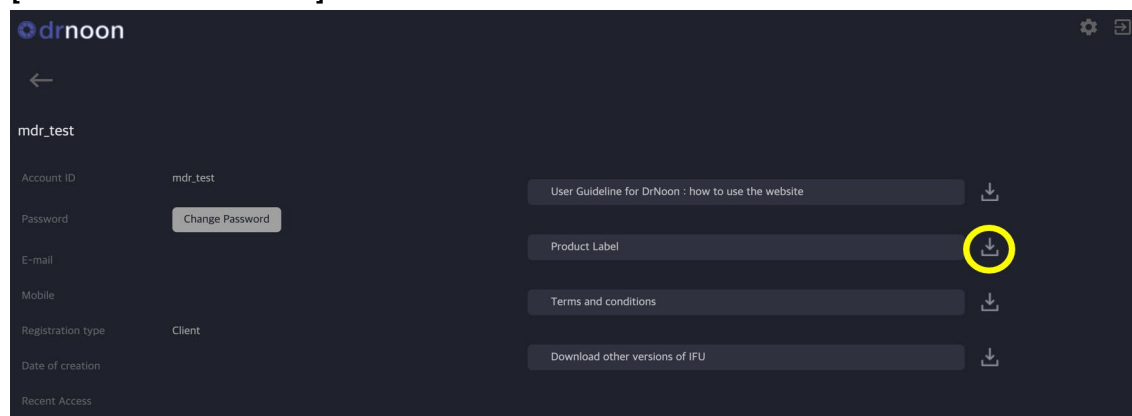


- 2) Click the download button.

[The latest version IFU]

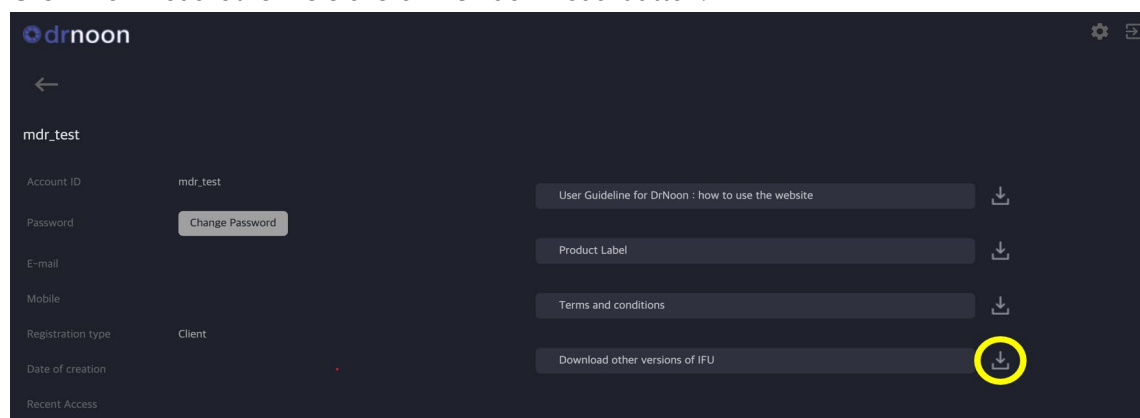


[The latest version label]



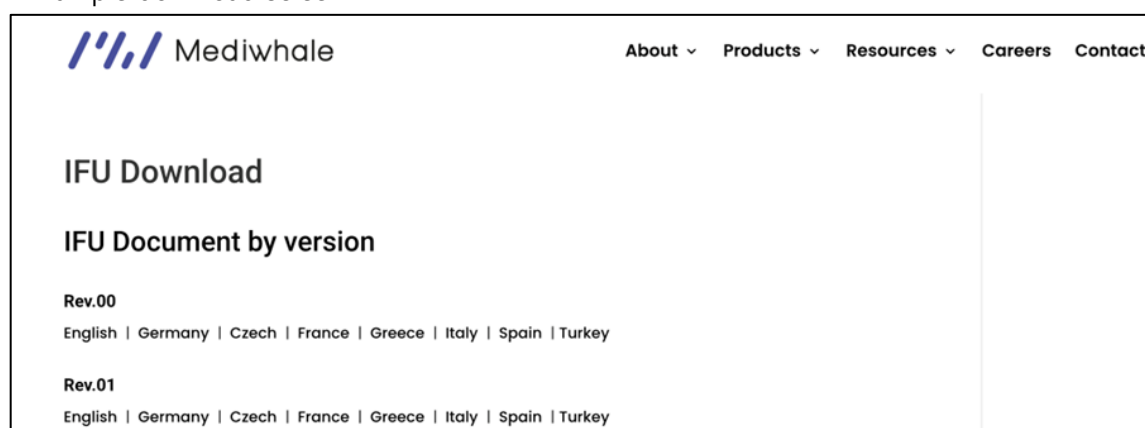
[All versions of IFUs]

- ① Click "Download other versions of IFU" download button.



- ② Download the full version of the IFU and translations in your preferred language.

* Example download screen



※ If you would like to download the previous version user manual or there is a software failure to limit your download access, you can enter this web address(<https://mediwhale.com/ifu-download/>).

※ Users should have basic knowledge of operating a computer or mobile device and using a web browser(ex. HTML) or PDF reader to access the e-IFU. If assistance is required, a paper IFU can be requested from the distributor or Mediwhale, Inc

10. Solution for problem

If there happens any problem while using the product, carefully check the solution below and take necessary actions as needed for your situation.

If the failure occurs again, contact Mediwhale Inc.

Problem	Cause	Solution
Access failure	Wrong address	Check the web address
	Cloud server invalid	Check internet connection and reconnect to the server.
Login failure	Wrong account ID or password	Check account ID and password. Use "search ID" or "search password" if you forgot account information.
Image upload failure	Wrong format	Convert the image into DICOM, JPG, PNG, or TIFF format and retry.
	Bad internet connection	Check internet connection and reconnect to the server.
Keyboard control failure	Browser focusing failure	Click any blank spot of the browser screen to adjust the focus.
Image loading failure	Bad internet connection	Check internet connection and reconnect to the server.
	Low quality or Wrong image	Check the resolution or name of image. Re-upload the image at the recommended resolution or higher.



This product of Mediwhale Inc. is a medical device. In case of the no working or a security risk, it is recommended to stop using the product and and contact the manufacturer.

10.1. Regarding of serious incidents

If you are aware of a serious incident involving the product, you must communicate this with your contact company or manufacturer as quickly.

10.2. When an accident occurs

We report a serious incident before the corrective action to eliminate the risk is taken, except in an emergency, in which case we immediately carry out a field safety corrective action. And the accident is reported to the authorities until the set deadlines in accordance with the MDR (EU) 2017/745.

- ♦ No later than within 15 calendar days after you have been informed of a serious incident.

- ♦ No later than within 2 calendar days after you have been informed of a serious incident which implies a serious threat to public health.
- ♦ No later than within 10 calendar days after you have been informed of a serious incident which has led to a death, or a serious deterioration in someone's state of health.

11. Account deactivation and Safe data disposal procedure

This product does not generate physical waste. However, upon the termination or deactivation of a user account, the following procedures are applied to ensure the safe disposal of data:

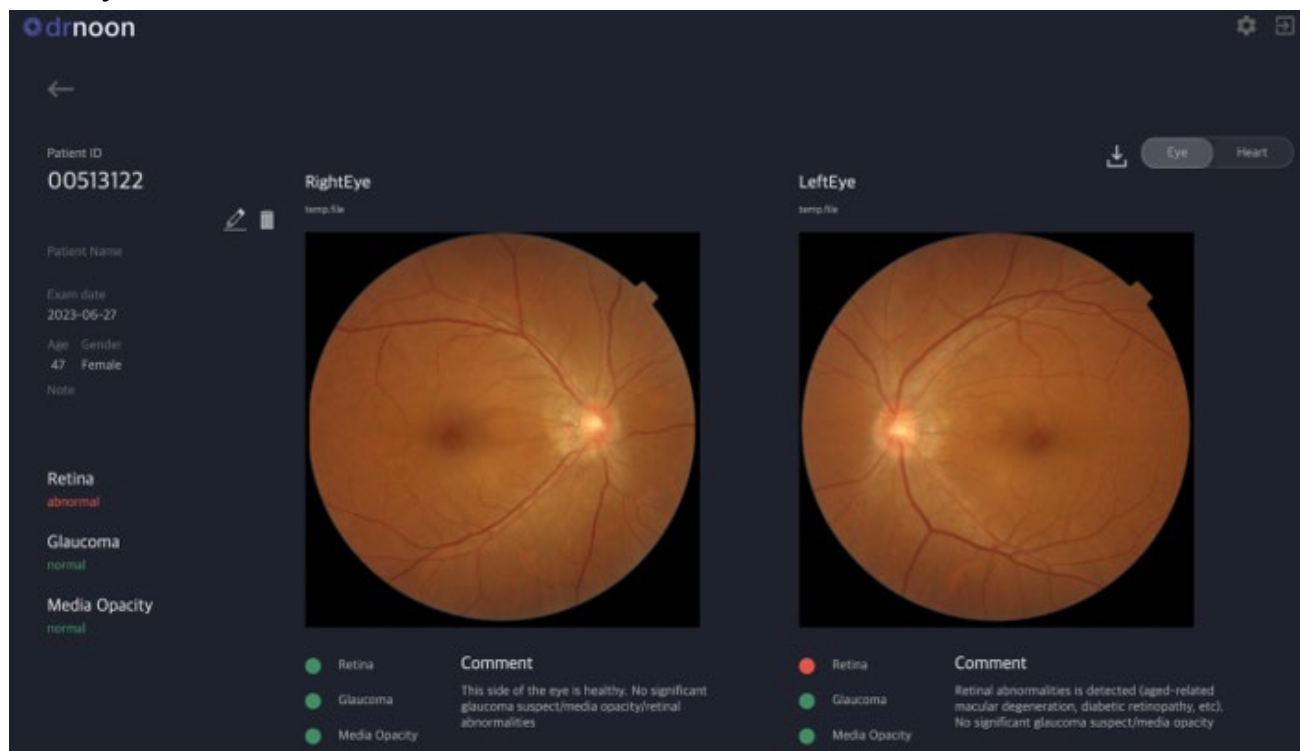
1. User accounts can be deactivated by an authorized system administrator.
2. Upon deactivation, all personal and patient-related data associated with the account are securely anonymized.
3. Log files and system usage records are retained only for the minimum period required by applicable regulations and are then securely purged.
4. The data disposal follows compliant processes(ex. ISO 27001) for data wiping and access control.

* User data is retained for 10 years in accordance with applicable regulations, unless otherwise requested by the user (Regardless of account status). The service period for on-premise servers is limited to two years.

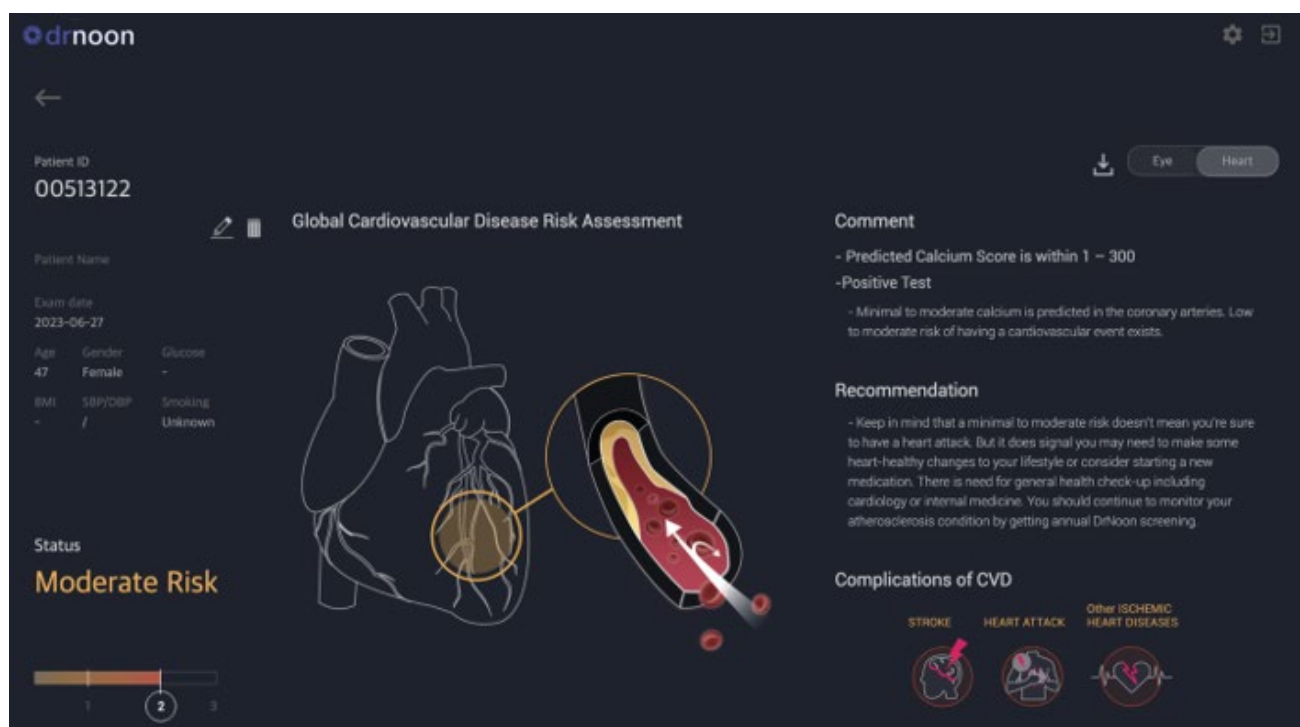
12. Example of result

12.1. Normal result

12.1.1. Eye

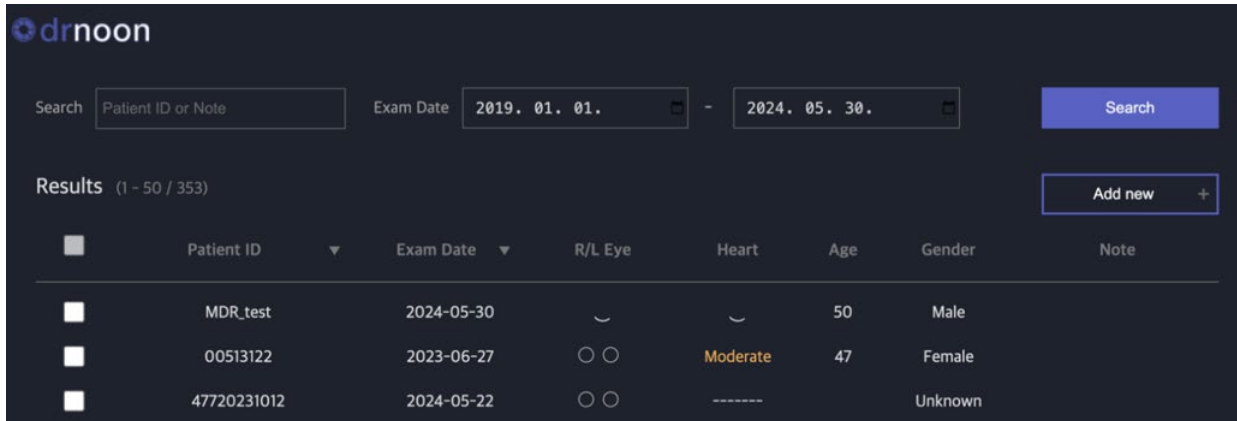


12.1.2. CVD



12.2. Abnormal result

12.2.1. System malfunction

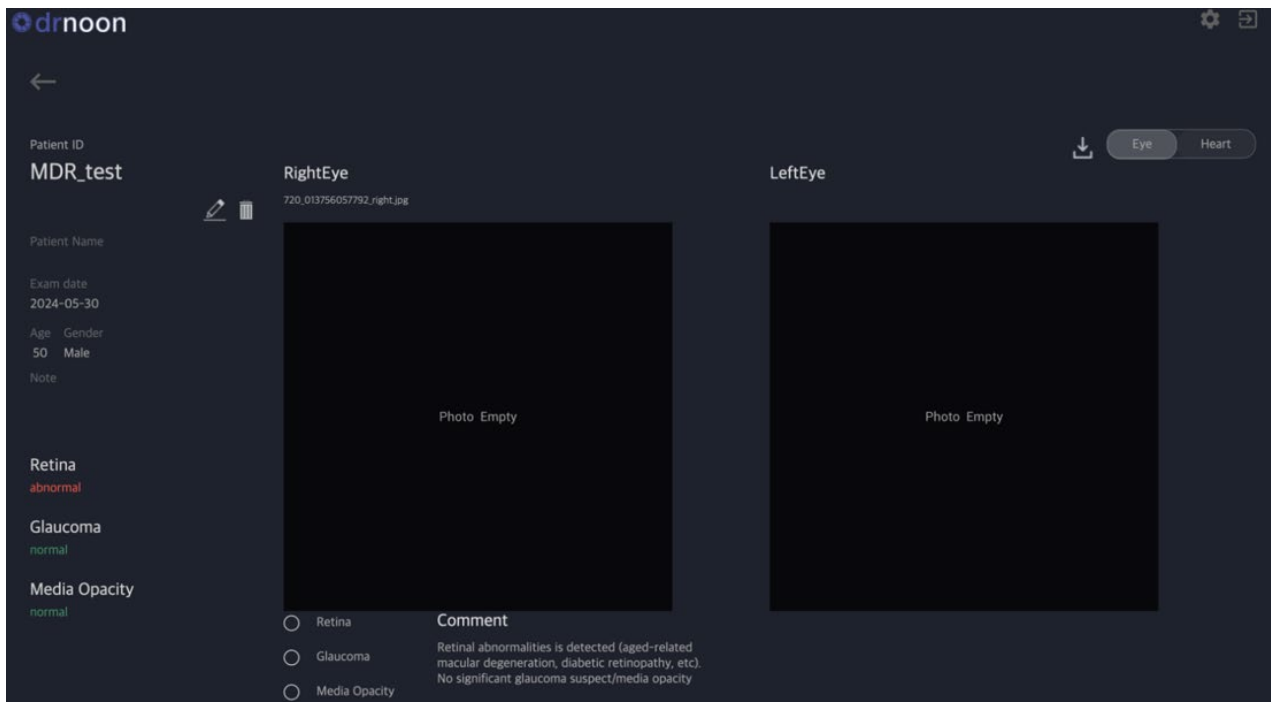


- Users can not open result after 3 minutes uploading images. Users cannot download pdf report files.

When using an API, issues in the system may result in API responses such as 404 or 500 errors.

12.2.2. Network malfunction

- System browsers cannot show fundus images or users cannot download report images.
- When using an API, issues in the system may result in API responses such as 502 errors or invoke timeout errors.



13. Symbol

Symbol	Description
	Manufacturer
	Date of manufacture
	Authorized Representative in the European Community
	Consult instructions for use
 https://mediwhale.com/ifu-download/	Electronic instruction for use (e-IFU)
	Model number
	Country of manufacture
	Unique device identifier
	Serial Number
	Medical device
	Caution
	CE mark

14. Stated Matter

14.1. Product Information

Item	Content
Model Name	DrNoon
Item Name	Computer-aided Processing software
Manufacturer (Manufacturer address)	Mediwhale Inc. 4th floor, 746, Nonhyeon-ro, Gangnam-gu, Seoul, Republic of Korea 06049
Software version	2.0.4
Manufacturing No.	DN-FSCVD-261007
Software Classification	Class B according to IEC/EN 62304
Basic UDI	88001180RetiAI68 <i>* A product UDI-DI/PI is referred to the product's label.</i>

14.2. DICOM Conformity Statement

This software uses DICOM format images either transmitted from the hospital PACS or directly generated by other medical imaging equipment in a specific DICOM modality.

Therefore, the software is DICOM compliant, and this compliance has been verified and validated through the DICOM Conformity Statement.

15. Manufacturer information



Manufacturer

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