

RSPlus software

Software Manual



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Follow
instructions
for use



Complies with
the
requirements
of EU MDR
2017/745.



This is a medical
device

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1. Purpose of use and usage of software

This document covers the RSPlus software. This software is a class I device following MDCG 2021-24 Guidance on classification of medical devices and EU MDR Annex VIII Classification rules according to rule 11, since the software is not intended to take decisions with diagnosis or therapeutic purposes and is not intended to monitor physiological processes.

- The software is designed to be compatible with the fundus imaging camera WFC-01 for use within the medical environment.
- RSPlus software is designed to be used as a user interface between the WFC-01 device and the user.
- By using the RSPlus software the user can view the retinal image, view examination results from patients and export images from the device to the user's chosen location.

1.1. Intended Use of the device as presented in the Instructions for Use

The RSPlus software is intended to make images of the retina for later diagnosis.

1.2. Intended User and User profile

It is intended that this device is used by a medical professional. This can include but is not limited to the following professions:

- Ophthalmologists
- General Practitioners
- Pharmaceutical staff
- Nursing staff

1.3. Intended Use environment

Practice environment of intended users.

1.4. Intended sample type

The device will be used to take non-mydratic images of a patient fundus for use by a medical professional.

1.5. Clinical Benefit

This will have clinical benefits due to creating an easier, handheld solution for medical professionals to use than what is currently available at a significantly reduced cost/quality when compared to comparable equipment. This will allow for the point of care to move from tertiary care for many conditions to primary/secondary care, reducing pressure on high level health services and creating a solution where screening can be accessed by patients at an area closer to home lessening travelling times and increasing patient access to care.

2. Installation Instructions

2.1. Requirements

In order to successfully use the RSPlus Software the user must have access to the following:

- Software compatible Android device (as supplied with the device)
- A WFC-01 Device

Go to www.retinascope.eu/download and follow the instructions there. No training is required.

2.2. Pre-requisites to install

2.2.1. Allow Unknown sources Install.

Before installation of the software the following actions need to be performed:

1. Navigate to settings on the smartphone.
2. Select Security and Privacy
3. Select "install Unknown Apps."
4. Allow the application "Drive" to install unknown applications using the slider.

2.2.2. Download software

To access the software download site the user must do the following:

1. Navigate to www.RetinaScope.eu/download
2. Follow the on-screen instructions

2.2.3. Google Files (optional)

Since the settings of the phone can prevent you from seeing certain files we recommend you to install Google Files on the phone.

- a. Install 'Google Files' that indexes all pictures recently taken (in descending order) in the images section.
- b. In the 'Google Files App' -> ☰ menu -> Settings -> switch 'show hidden files' on.
- c. Depending on the phone's settings, there could be a hidden file called '.nomedia' which would prevent to index/show media files from any other app. If this is the case, you have 2 options: you find and erase that hidden file, or force the gallery app to ignore hidden elements.

2.2.4. Close every other App that can use the device.

Close every other App that can use the device.

2.2.5. Uninstall previous versions of the RSPlus app

Uninstall previous versions of the RSPlus app via options.


2.3. Install process

To install the software the user should navigate to the following address via the web browser on the smartphone www.retinascope.eu/download

retinascope.eu/download

Download

RS PLUS ANDROID SOFTWARE INSTALL (.APK FILE)




RS Plus Android software install (.apk file)

Size: 236.53 MB
Date added: 2023-11-02

Download

RSPLUS SOFTWARE INSTRUCTIONS FOR USE PDF



RSPlus software instructions for use

Size: 611.98 KB
Date added: 2023-11-02

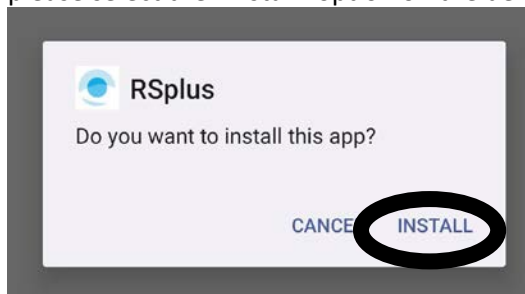
Download

Open

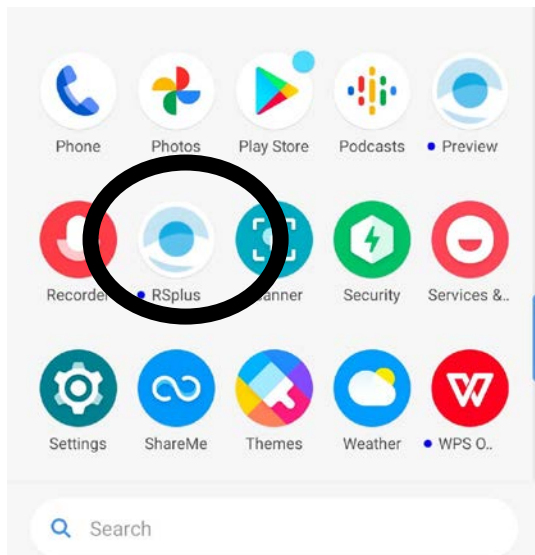
If you see the download web page with the link to the software package please select the apk file.

If you see a message saying “installation from unknown sources is not allowed on this application” then please refer to section 2.2.1 of the software manual and try again.

Otherwise, if the software has finished downloading a pop-up should appear, at this time please select the “install” option on the device as shown below:



When the installation is completed and all steps followed you should now have access to the RSPlus software package and it should appear in your app library as shown below:



If the installation was not successful, then please refer back to the start of section 2.2 and ensure that all specifications are followed.

2.4. Software update

Once you have registered your device at www.retinascope.eu you will receive an email as soon as a new software version has become available. Or check back at www.retinascope.eu to see if there is a software update available for downloading.

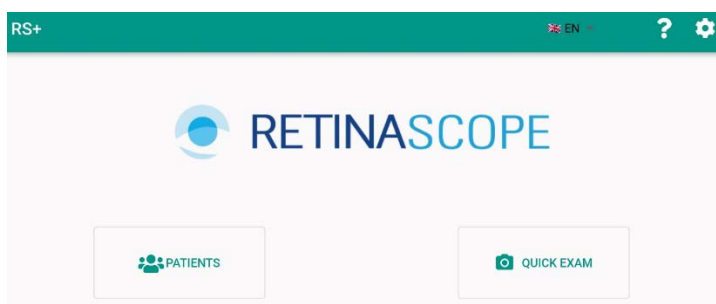
The software does not check for updates. The manufacturer will notify users of new versions, and the user is responsible for downloading the latest version.

2.5. Optional Set-up

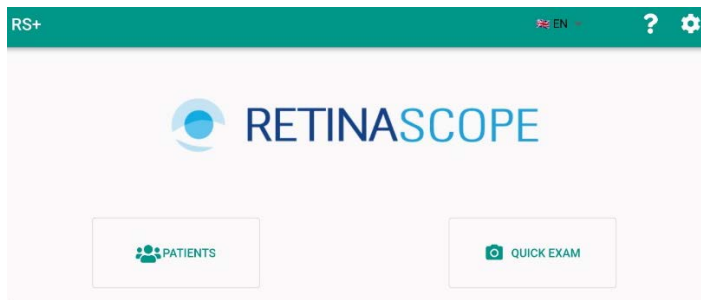
2.5.1. Language options

By default, the application language will be set to English. If you wish to change this to one of the other pre-registered languages, then refer to this section of the guide.

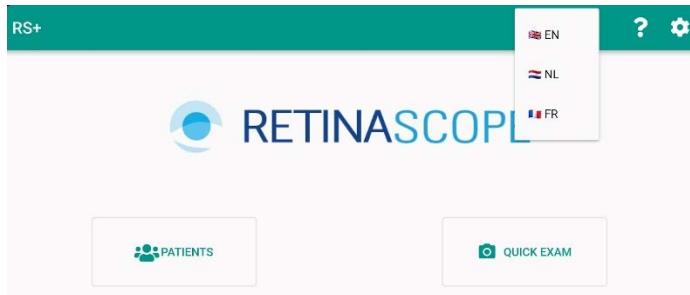
Open the RSPlus software application by selecting it from the home screen. By default, you will be greeted with the home page as shown below:



To change the language please select the drop-down menu on the top-right of the screen labelled with the letters "EN":



This will then expand the menu to allow for one of the other language options to be selected as shown below:



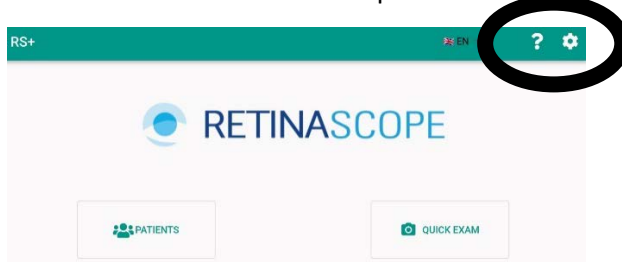
To change language please select one of the options from this menu. If you wish to keep the application at its default setting, please select “EN” from the list to keep the language as English.

If the language is required to be changed from the currently set language, please follow the steps from the start of 2.4.1 with the letters shown in the top right signifying the current selected language

2.5.2.Quick exam only mode

By default, the application will have two examination modes, “quick exam” and “patient.” The application also has the option to remove the “patient” option for users only looking to examine quickly without the need for inputting user information. If you wish to enable this option, please follow this guide. Note: Depending on the way your device was supplied, a different workflow may be implemented in the software as default. Please refer to your supplier for further information.

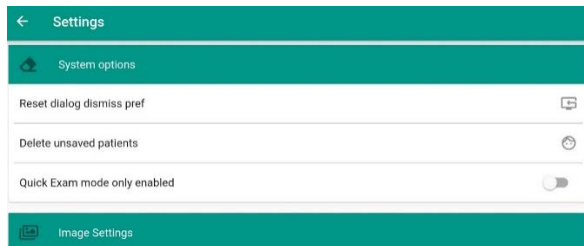
From the default home screen please select the settings cog, as shown in the image below:



You will then have opened the settings menu, as shown below:



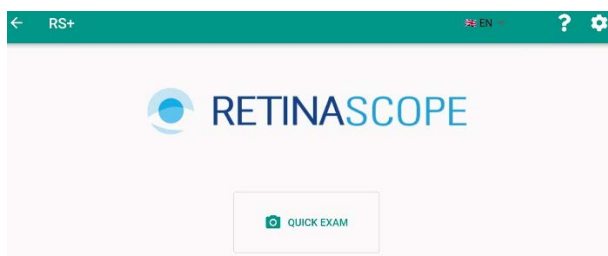
From here scroll to the bottom of the settings area where you will see under the “system options” section the option to “Quick Exam mode only Enabled” as shown below:



Turn this to enabled by tapping on the right-hand-side dot until it is as shown below:



This will now turn on “Quick exam mode” and the default home screen will now look as is shown below:

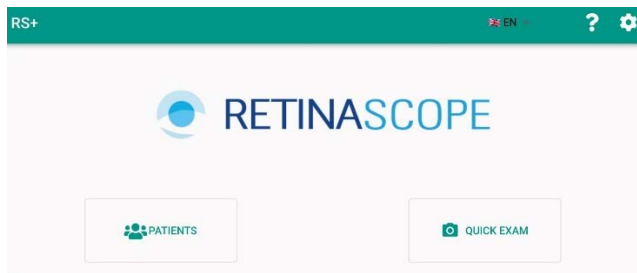


To turn Quick exam mode off return this slider to the original position.

2.5.3. Image storage options

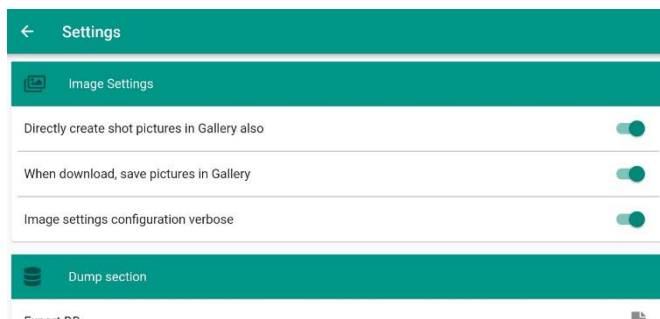
This section explains how to automatically create the shot pictures in the "Pictures folder" of the phone, in addition to the ones stored in the DCIM structured folder, to allow easy access with file navigation.

From the default home screen please select the settings icon, as shown in the image below:



You will now have opened the settings menu. From this page scroll down until you see the “Image settings” sub-category. Within this there are two options:

1. “Directly create shot pictures in gallery also”: This setting will automatically create the images in the "Pictures folder" of the phone in addition to the one stored in the DCIM structured folder, to allow easy access with file navigation.
2. “When download, save pictures in gallery.”: when the download button is selected in the exam details section (refer to section 3.2.4 for further information on exam details), usually the picture is copied from the DCIM Library to the "**Download folder**". If this



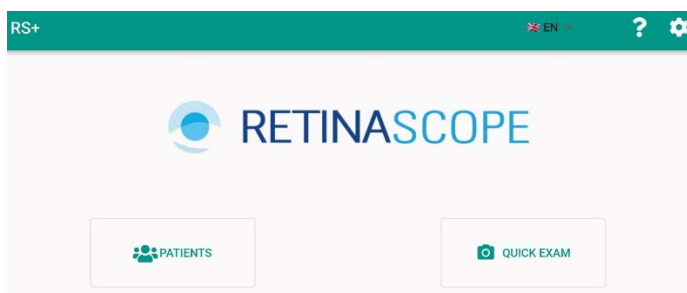
option is enabled, the picture is copied from the DCIM Library to the "**Picture folder**", so you can see it in film roll. To enable either option please slide the dot on screen beside the desired option to turn the slider green, as shown below:

2.5.4. Log-on set-up

CAUTION: IF A USER ACCOUNT IS SET-UP, YOU WILL NOT HAVE ACCESS TO THE APPLICATION WITHOUT THIS LOG-IN

If you wish to set up a log-in for the software, then refer to this section of the guide.

Open the RSPlus software application by selecting it from the home screen. By default, you will be greeted with the home page. To set up an account select the settings cog in the top right of the screen as highlighted by the circle below:



This will open the settings menu, as shown below:



Under the Login Options section of the settings, you will find the “Login active” slider. Turn this to enabled by tapping on the right-hand-side dot until it is as shown below:



Swipe the App out from background applications (or close all background applications, or restart the phone).

Following this, launch the RSPlus software application where you will be greeted by a screen enabling you to set-up log in information as shown:



In the textbox labelled “Username” insert the desired log-on username. In the textbox labelled “Password” please insert the desired log-on password. When this is complete, please tap the “sign up” box to set the username and password of the device application.

This will replace the default home screen with the Log-in page as shown below in which the user-set username and password will be required to be entered before accessing the application:

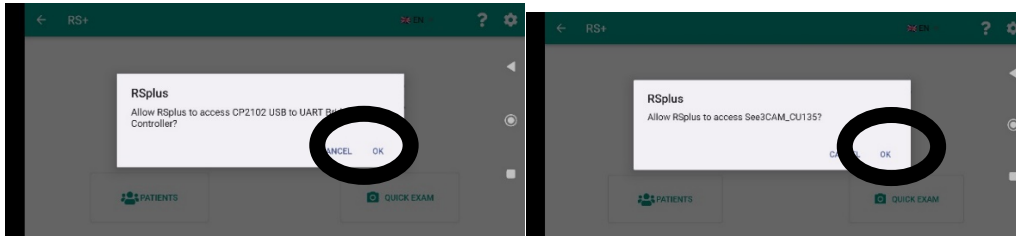


You have now set the username and password for this device. If unsuccessful, please try again from the start of 2.2.2.

3. Usage Instructions

3.1. Permissions

On initial connection of the device the following two prompts will appear that need to be accepted in order to allow connection between the mobile device and the WFC-01. These prompts are as shown below, and without allowing access image acquisition will not be possible.



3.2. Use Guide

Upon application launch you will be given two options, depending on the exam type that you wish to conduct depends on the option selected.

1. Patient Exam: Please follow instructions in 3.2.1 of the instructions for use on conducting a specific patient exam along with patient details and examination tracking.
2. Quick Exam: Please follow instructions in 3.2.2 of the instructions for use on conducting a quick exam without inputting patient details.

3.2.1. Patient mode

For a patient exam, patient details will have to be inserted for an exam to take place. These details include the following:

- Forename
- Surname
- Gender
- Date of Birth
- ID number (If applicable)
- Phone number
- E-mail
- Company (if applicable)
- Patient Number (If applicable)

On top of this, the patient will be required to accept the GDPR policy for the examination to take place, which should be shown to the participant and ensured that it is fully understood before acceptance. When the patient information has been completed, please select the exam "New Exam" button and follow the steps in section 3.2.3 detailing the examination process.

3.2.2. Quick mode

For a quick examination, the user will be taken directly to an examination and the images acquired will not be linked to any patient data. Please note the images acquired can still be exported from the application, however, patient data will not be associated with it. 'Quick exam mode' removes pictures in the DCIM folder when the App is restarted, but does not remove those pictures you saved/copied in Gallery when option 'save in gallery' is active.

3.2.3.Exam process

The following is the default workflow for an examination following selection of exam type:

Device Set-up

1. Please make sure the device is on and the battery is charged.
2. Make sure the smartphone is plugged in to the WFC-01 Device.
3. Make sure focus wheel on front of device is in the center (white line).

Right eye examination

4. Ask the patient to hold the hand over the Left eye.
5. Hold device with one hand and steady the front area with the other hand.
6. Slowly move the device forward, always keeping the pupil in the center of the image.
7. Keeping the pupil in the center, place the eyecup of the device on the eye socket of the patient.
8. Ask the patient if they see a green dot, if they do not, ensure fixation target is on.
9. Move the focus wheel on the front of the device right and left until a clear image is seen.
10. When the image is in focus use the rectangular trigger on the front of the device or the image capture button on the screen to capture an image.
11. If you are happy with the image quality, select "next eye" otherwise if the image is not of the desired quality please select "another picture" and repeat steps 4-11 until the desired image is taken and then select "next eye."

Left eye examination

12. Ask the patient to hold the hand over the right eye.
13. Hold device with one hand and steady the front area with the other hand.
14. Slowly move the device forward while always keeping the pupil in the center of the image.
15. Keeping the pupil in the center place the eyecup of the device on the eye socket of the patient.
16. Ask the patient if they see a green dot, if they do not, ensure fixation target is on.
17. Move the focus wheel on the front of the device right and left until a clear image is seen.
18. When the image is in focus use the rectangular trigger on the front of the device or the image capture button on the screen to capture an image.
19. If you are happy with the image quality, select "next eye" otherwise if the image is not of the desired quality please select "another picture" and repeat steps 12-19 until the desired image is taken and then select "Exit examination."

The examination is now complete. Please refer to section 3.2.4 Examination results for information on the viewing and exporting of the examination results.

3.2.4.Viewing examination results

Following the examination, the user will be presented with an exam details page with data from the examination and giving the user input options:

- Examination Date and time
- Location (optional)
- Examination notes

Followed by the images acquired during the examination process in 3.2.3.

If a user wishes to close inspect the images, each image can be individually expanded using the three lines next to the picture and the image inspected closer from this point as well as an optional description can be added.

3.2.5.Exporting examination results

To export any exam information, either through quick examination or patient examination, the user will first have to navigate to the examination details page. This is automatic through a quick examination in which the final page following examination exit will display exam details.

If tracing an older exam via the patient examination option from the home page navigate as follows: Patients →select" Patient Name" → Select the three lines shown in the top right corner of the patient details page (shown below) →select date and time of desired examination.

This will now show details of that specific exam and you can either:

Exporting Images only

To export the images from that specific examination, select "Download images" and the pictures taken during the exam will be individually exported to the mobile device's picture library with labelling of examination date and time but no patient identifiers.

Exporting Examination PDF

To export a full report of the examination in question, including any notes taken and exam location, please use the export examination PDF setting. This will export a report (example report provided below) to the mobile devices "downloads" folder where the user can process it as necessary.

To export the examination images that were taken, either through quick examination or patient examination, the user will first have to navigate to the examination details page. This is automatic through a quick examination in which the final page following examination exit will display exam details.

If tracing an older exam via the patient examination option from the home page navigate as follows: Patients → select "Patient Name" → Select the three lines shown in the top right corner of the patient details page (shown below) → select date and time of desired examination.

RetinaScope screening Report

- patient Unsaved
Gender:
ID Number: null

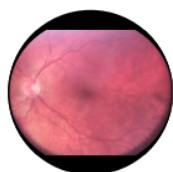
Date
2023/04/20 16:05

Updated
2023/04/20 16:05

Anamnesis:
-

Notes:
-

RIGHT EYE



3.3. Additional Help

If you require any additional help please navigate via web browser to:

www.retinascope.eu/contact

and fill out the contact form and we will get back to you as soon as possible.

3.4. Risks, warnings, precautions, instructions

After conducting risk management activities, there are the following residual risks.



- The RSPlus software is intended to make images of the retina for later diagnosis. The device does not provide a diagnosis. the device does not provide image enhancement. A professional grader would have to interpret the image to determine whether further examination is needed. The intended user is a medical professional, this can include but is not limited to: Ophthalmologists, General Practitioners, Pharmaceutical staff and Nursing staff. The RSPlus software is intended to make images of the retina. The intended patient population consists of people that are eligible for regular retina screening. The device does not have contra-indications. The device does not sustain or support life. No special intervention is necessary in the case of failure of the medical device. If a security breach would prevent access to the software there would be loss of availability to generate an image, but this unauthorized access or loss of data would not affect the medical device safety.
- The RSPlus software is designed to be compatible with the fundus imaging camera WFC-01 for use within the medical environment. Performance issues may occur if legacy hardware is used. RSPlus software is designed to be used as a user interface between the WFC-01 device and the user. The software does not use image enhancement. When the user uses the latest version of the software as instructed on the website of the manufacturer, we do not foresee issues that impact the performance of the WFC-01. The RSPlus software uses default image settings which minimize performance issues when the instructions are not followed well, but the instructions on the device need to be followed to get a clear image.
- The software is only compatible on the phone that is recommended by the manufacturer as per the website.
- If the user uses the software on a different phone than the one that has been delivered with the hardware, then the software may not work. The software only works with compatible devices. Usability has only been tested with the related phones. The related smart phone has an electronic display; usability verification revealed sufficient legibility (Google Usability Guidelines).
- Old versions of the software may not result in optimal image quality. The registered user receives a notice when a new software release is available. The latest software version is available for registered users on the website of the manufacturer. The user needs to install the software himself.
- The RSPlus software contains software that should be installed by the user. The user does not have to verify, modify or exchange it. Only registered users can download the software from the website of the manufacturer. User registration is required to ensure authentic Installation instructions and software use.
- It allows access to information through a USB port (controlled through a standard interface, libUSB). Video is controlled through the lib UVC interface (a cross-platform

library for USB video devices, built atop libUSB). The data stored in a local db file are encrypted.

- New hardware functionality may require new software support.
- Successful use is dependent on the usability of the user interface.
- The default settings should provide a good image, but focus precision varies and auto capturing success is driven by flickering, positioning and sensibility. Image definition and faded borders vary for different subjects.
- An internet connection is required. The user may not be able to transfer images when no internet connection is available. The device is installed on an Android phone connected to a WFC-01 camera. An internet connection can be used for exporting images.
- The default settings should be good, but the user can opt for an alternative mode in the menu.
- It displays a retinal image. The user should take another image if the first one is not clear.
- If an unauthorized person gets access to the smartphone with the RSPlus software on it he can make a picture but not manipulate the settings.
- If an image is not clear, than a professional grader would have to request an alternative image.
- Due to GDPR compliance: Images will be removed unless user consent is given for storing patient information after restart. This results in image loss if the user does not store the image.

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 user and/or patient is established.



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requirements
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This is a
medical
device