

vx610

User manual

FC001315-REV00_EN/2024-08-01



Contents

I - Introduction	4
II - Definitions	6
II.1 - Graphic symbols	7
II.2 - Indication for use and use condition	9
III - Safety requirements	11
III.1 - Contraindications	12
III.2 - Warnings	12
III.3 - Precautions	14
III.4 - Special patient populations	14
III.5 - Adverse reactions	14
III.6 - Prescription devices	14
III.7 - Disclaimer of liability	14
IV - Transport, handling and unpacking	15
IV.1 - Packaging and transport	16
IV.2 - Package contents	16
IV.3 - Unpacking and storage	18
V - Assembly and powering on	19
VI - Technical features	22
VI.1 - Plate data	23
VI.2 - Labelling	23
VI.3 - Parts and components	24
VII - Use of the device	27
VII.1 - Initial powering on	28
VII.2 - First Login - Password change	28
VII.3 - Turn on, turn on and off the tablet	30
VII.4 - Test execution	34
VII.5 - Data analysis and image printing	37
VII.6 - Applicable features	38
6.a) Comparison of images and filters	38
6.b) Mosaic	43
6.c) Image tool	50
6.d) Processing of VX610 retinal images through artificial intelligence (AI)	51
6.e) Cup To Disk Feature (CDR)	54
6.f) Shared Folder	64
6.g) DICOM Setting	73
6.h) Optional Functionality Of TeamViewer For Remote Support	76
VIII - Change APP language	77
IX - Change system language	79
X - Change password	81

XI - Recover your lost password through the PUK code	83
XII - Problems - causes - solutions - alarms	86
XIII - Maintenance	89
XIII.1 - Cleaning.....	90
XIII.2 - Cleaning the lens	90
XIII.3 - Cleaning the cheekbone and forehead rests.....	90
XIII.4 - Periodic checks.....	90
XIV - Appendices	91
XIV.1 - Assistance	92
XIV.2 - Notifications - Alert	92
XIV.3 - Manufacturer's declaration of electromagnetic emissions	92
XV - Contact information.....	93

I - Introduction

This usage and maintenance manual, together with the instructions on the label, reflects the information supplied by the manufacturer in accordance with Regulation (EU) 2017/745 on medical devices to ensure that it is used safely, taking the training and knowledge of potential users into account.

The manual is an integral part of the device, and therefore must be maintained with extreme care and always attached, in the event the product is transferred of to third parties. It is addressed to operators, the owner, users, and maintenance technicians.

The manual provides guidance on the technical characteristics, proper use of the device, transportation, storage, maintenance, disposal, and security precautions.

Any changes to the manufacturer's instructions that prove relevant for patient and/or operator safety will be promptly communicated to the owners/users of the product through all channels useful for these purposes.

Any other changes and/or additions are excluded from the manufacturer's notification obligation.

Any accident malfunction and/or dysfunction, deterioration in the characteristics and performance of the device that has caused or may potentially be liable to cause harmful events for the operator/patient must be promptly reported by contacting the manufacturer, in order to take all appropriate measures, including recalls.

Legal manufacturer :



Luneau Technology Operations SAS

2 rue Roger Bonnet

27340 Pont-de-l'Arche, FRANCE

For the digital version of the user manual and current service contacts please visit:

<http://academy.visionix.com/>

II - Definitions

The terms referred to in this manual shall have the meaning given below:

Medical device: Device intended by the manufacturer to be used on human beings for care, diagnosis, or the alleviation of disease.

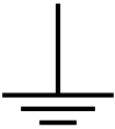
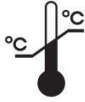
Patient: The exam can be performed on all patients seeking eye care or undergoing routine eye examination who are capable of following instructions including pregnant; breastfeeding women and pediatric population and able to complete eye examination in sitting position.

Operator: The device can be used by medical personnel, healthcare professionals, optometry professionals or any appropriately trained person. The operator must possess the qualifications required by law.

II.1 - Graphic symbols

The use of graphic symbols is seen in this manual and on the device, whose meaning is described in the following table.

Symbol	Meaning	Note
	Mark of conformity with European laws. CE marking of conformity with identification number of the notified body.	Located on the device
	Disposal of electrical and electronic equipment by return to the manufacturer. (in accordance with WEEE Directive 2012/19/EC)	Located on the device
	Manufacturing date	Located on the device
	Manufacturer	Located on the device
	Medical Device	Located on the device
	Unique Device Identification	Located on the device
	Serial Number	Located on the device
	Device Catalogue number	Located on the device
	B type applied part - Symbol IEC 60417-5840	Located on the device
	Refer to the instruction for use (manual / user manual)	Located on the device. Follow the instructions for use

Symbol	Meaning	Note
	Functional ground (IEC 60417-5017)	Located on the device
	General warning signal	Located on the device and AC/DC adaptor. Pay attention if this signal is shown
	Warning: Dangerous voltage	Located on the AC/DC adaptor. Pay attention if this signal is shown
Rx only	Symbol for Professional only : prescription only. U.S. Federal law restricts this device to be used by or on the order of a physician or properly licensed practitioner.	Located on the device
	General prohibition signal	Located on this manual, Pay attention if this signal is shown
	General mandatory behavior	Mandatory behavior
	Keep upright	Located on Packaging
	Fragile	Located on Packaging
	Keep dry	Located on Packaging
	Indicate the thermal limits to which the medical device can be exposed un the complete safety.	Located on Packaging
	Indicate the humidity limits to which the medical device can be exposed in complete safety.	Located on Packaging
	Indicate the limits of atmospheric pressure to which the medical device can be exposed in complete safety.	Located on Packaging

II.2 - Indication for use and use condition

INDICATIONS FOR USE (IFU)

VX610 device is an automatic eye-fundus camera and software intended for photographing, displaying and storing images of the retina without the use of a mydriatic agent.

Use Condition:

This manual has been drawn up taking the operator characteristics, knowledge, education level and training into account.



Operators using VX610 must:

- Be adequately trained in the use of the device,
- Be informed about the risks and side effects.
- Be in possession of the qualifications required by law.
- Read and understand every part of the user manual accompanying the device itself.
- Carefully evaluate any contraindications before performing an exam.



CHECK THE SUITABILITY OF THE ENVIRONMENT PRIOR TO EACH USE!!

The Operator is always entirely responsible for compliance and compatibility of the premises in which the product is used.

Like all electromedical devices, VX610 requires special precautions as regards electromagnetic compatibility. The environment in which the device is used must comply with the characteristics set forth in the electromagnetic compatibility tables in Section 15 and must also be connected to a compliant electrical system.

The VX610 medical device takes color photographs of the bottom of the retina with a retinal field of 45°. By means of the tablet, the doctor begins the automatic exam that results in a photo of the patient's retina, saved in the internal database of the device in JPEG format. VX610 is able to store acquired images and patient data in a local or remote database, through a secure data encryption system that complies with current privacy regulations.

The exam can be performed on all patients. The successful outcome of the exam (image quality of the retina) depends on the transparency of the optical channel that spans from the cornea to the retina (for example, this may be reduced in subjects with cataracts or crystalline lens with low transparency).

The use of this electromedical device on children and minors is prohibited without the assistance of adults.

VX610 is comprised by a movable head equipped with optics, powered at 24 Vdc by means of an AC/DC adaptor (provided). To initiate the exam and view the image of the retina, a user interface is provided by a tablet (also included).

The device is only intended for exam of the retina as indicated herein.



It must be used within the limits and according to the procedures explicitly described by the manufacturer in this manual. The manufacturer is therefore deemed to be held harmless for all liability for damages resulting from misuse of the product by untrained persons, as well as any unauthorized modifications or interventions, including the

use of parts other than those supplied directly by Visionix (or its authorized parties), exceptional events and the total or partial non-observance of the instructions in this manual.

The expected life of the device and its components are 4 years.

Where the device can be used:

The device can be used in hospitals, public and private health clinics and all establishments other than domestic where eye or systemic and/or vision tests are carried out. The device can be used by medical personnel in collaboration with healthcare professionals and/or optometry professionals. The device can be used remotely. Users must be adequately trained in the use of the device and informed about the risks and side effects and possess the qualifications required by law. The device, for the sole function of image acquisition and excluding the reporting (and clinical interpretation) part, can be used in self-acquisition mode by an appropriately trained person or assisted by appropriately trained personnel. The clinical interpretation of the images acquired by the retinal camera is restricted to licensed eye care practitioners. The process of making a diagnosis using the camera results is the responsibility of the eye care practitioner.

III - Safety requirements

III.1 - Contraindications

No Contraindications.

III.2 - Warnings

This device is to be used for its intended use, according to the indicated instructions and directions for use. Visionix does not assume responsibility for damage to persons or property caused by improper use and/or misuse of the device, or for its use other than the function for which it was intended by its manufacturer.

The use of VX610 assumes that the operator has knowledge of this manual and its user guide, as well as awareness of the risks related to improper use and misuse.

Therefore, it must not be used by persons who do not have adequate knowledge of the device and its methods/features of use, with the caveat that in the event of any questions and/or uncertainties about its operation and use, the operator will contact the authorized dealer and/or the manufacturer directly in order to acquire any clarifications and/or explanations, or, where necessary and expressly requested, specific assistance in the terms and procedures provided for in the receipts of purchase.



CAREFULLY READ THIS MANUAL AND WARNINGS BEFORE USE OF THE DEVICE

The following must not be carried out, as they may compromise the compliance and/or the characteristics of the device:

- Incorrect installation
- Improper use
- Use of parts and/or third-party accessories that are not approved by the manufacturer.
- Interventions and/or tampering by unauthorized personnel.
- Lack of or improper maintenance



The warnings to be observed during installation, operation and maintenance of the device are contained below, in order to ensure the fulfilment of the requirements for operator and end-user safety as well as the proper functioning of the device.

- Any manipulation, replacement or operation performed on the device that is not carried out by Visionix personnel authorized shall void the warranty and exempt the manufacturer from any liability for direct and/or indirect damages that might be caused to persons or property.
- Use the power cord supplied with the product. Periodically check the integrity of the cable. Fully insert the plug into the mains socket on the rear side of the device.
- Use a power supply voltage between 220-230Vac 50/60Hz (not different from that listed on the plate).
- To avoid danger to persons or property, observe all nominal data and markings on the product. Consult the manual before making connections to the device.

- Avoid exposed circuitry. Do not touch exposed connections or components connected to power supply.
- Do not operate in the event of suspected fault or if cracks are present on the casing.
- If you suspect that the device is faulty and/or damaged, have it checked by specialized and approved personnel of the manufacturer.
- Avoid contact or penetration of liquids or powders into the device.
- Do not operate in a potentially explosive atmosphere and/or in the presence of flammable mixtures.
- Avoid exposure to excessive heat. The temperature of use must be between 10 and 40° C, maximum humidity is 90%, without condensation, at an atmospheric pressure of between 800 and 1060 hPa.
- Do not use VX610 outdoors. It was designed and built for use in areas that are closed and protected from the elements.
- Use the device only with the original spare parts supplied by the manufacturer.
- Make sure that the features of the electric network comply with the power requirements of the device as indicated on its label and in this manual.
- Do not use devices other than VX610 simultaneously on the patient.
- Do not use the device in environments with high electromagnetic fields that could cause VX610 and other equipment in the surrounding area to malfunction. Do not keep mobile phones in the treatment area.
- The appliance must be installed and commissioned according to the EMC information contained in this manual.
- Portable and mobile radiocommunications equipment can affect the operation of the device.
- Do not operate near (within 1 m) of a DEVICE for short wave or microwave therapy.
- The use of accessories other than those supplied may adversely affect the electromagnetic compatibility performance of VX610;
- Do not simultaneously connect the patient to a high frequency electrosurgical device.
- Caution - the use of controls and adjustments or the performance of procedures other than those specified herein may result in injury to the patient and the operator.

The minimum Wi-Fi protocol requirements should be WPA-PSK or WPA2. It is excluded free network (without password) or WEP protocol because that are not safe against unauthorized access, malicious intent, and cyber-security threats.

The tablet is compatible with 2.4 GHz Wi-Fi.

The tablet is in normal condition using the TCP protocol on port 443; if the shared folder function or the Fundus Adapter is used, port 445 is also used (always with TCP protocol).

III.3 - Precautions

VX610 may only be used by personnel trained to operate the device, and it is essential to carefully consider the following precautions:



- The device must only be operated and used by personnel trained on its usage techniques.
- To prevent misuse by unauthorized personnel, the operator must log out of the management app at the end of each exam.
- Remember to never use the device on patients who have a pacemaker or other devices whose operation will interfere with electromagnetic fields and electrostatic discharge (for example, insulin infusers). If in doubt, consult a doctor.
- Perform cleaning and maintenance only after disconnecting the device from the mains and switching it off.
- Perform maintenance of the device according to that indicated by the manufacturer.

III.4 - Special patient populations

The use of this electromedical device on children and minors is prohibited without the assistance of adults.

III.5 - Adverse reactions

None known.

III.6 - Prescription devices



Caution: Federal (USA) laws restrict this device to be used by or on the order of a physician or a properly licensed practitioner

The clinical interpretation of the images acquired by the VX610 is restricted to licensed eye care practitioners. The process of making a diagnosis using VX610 results is the responsibility of the eye care practitioner. A device specific training is required for any operator to become able to use the system.

III.7 - Disclaimer of liability

The manufacturer assumes no liability for damages, accidents or injuries caused by failure to follow the requirements, directions and safety guidelines provided for in this manual.

Visionix will not cover any damages that may result from improper use and/or misuse of the product, nor will it respond in any way for any damage that may result from wear and tear, negligence, neglect, manipulation, incorrect/improper installation and/or connection of the products, or by improper use and/or misuse by the operator/end user of any third parties not authorized to use the device.

IV - Transport, handling and unpacking.

IV.1 - Packaging and transport

The device is contained in a cardboard box and adequately protected against vibration arising from a regular transport by means of specially shaped polyethylene foam. The box must be transported while maintaining it in the vertical position and avoiding bumps or jerks, and according to the environmental conditions of transport contained on the packaging:

Temperature: [-40°C ; 70°C]

Maximum humidity: [10%; 95% without condensation]

Atmospheric pressure: [500 ; 1060 hPa]

Verify the integrity of the packaging upon receipt. If any damage to the packaging is noted, the operator who carried out the shipment must be immediately notified.



Before operating a device whose packaging shows signs of damage, the device itself must be checked by Technical Assistance or personnel approved by Visionix.

- If damage caused by transport is noted upon receipt of the device, the device must not be used, and technical assistance must be contacted for an audit and revision of the device itself.
- The user must be fully aware of the contents of the manual and symbols.

IV.2 - Package contents

VX610 package contains the following items:

- VX610 device (1)



- **Mean Well AC/DC adaptor GSM60A24 model (2).**



- **Detachable power cord (3).**



- **Lenovo Tab P11 tablet (4) with charger and micro-USB cable.**
- **Flathead Screwdriver.**



- **Lens cap (5).**



- **Flyer QrCode for the user manual.**

IV.3 - Unpacking and storage



It is necessary that the person unpacking the box has been trained as regards the risks of such operations.

To properly lift the box without jeopardizing the spine:

- Keep the back straight.
- Keep the trunk upright.
- Assume a squat position.
- The weight lifted should be kept as close to the body as possible.



Do not store the products above shoulder height.

The device must be stored in an area that complies with the environmental conditions for storage, as displayed on its packaging:

- Temperature: [0°C ; 60°C]
- Maximum humidity: [10% ; 90% without condensation]
- Atmospheric pressure: [700 ; 1060 hPa]

THE DEVICE DOES NOT MEET THE TEMPERATURE REQUIREMENTS OF ISO 15004-1 FOR STORAGE. DO NOT STORE THE DEVICE IN CONDITIONS WHERE THE TEMPERATURE MAY EXCEED 60° C OR DROP LOWER THAN 0° C

Bring the box to an area that is suitable for the extraction and installation of the machine's parts. Open the package without the use of sharp objects that can damage its content.

Retain the packaging for reuse in the event of that the device needs to be shipped (such as for technical assistance), as the original packaging provides safe transportation.

To ship the device, you place it in the shipping position.

V - Assembly and powering on

Check VX610 device for damage or dents that may have occurred during transport; if in doubt, contact your dealer or the manufacturer

- a) Place the contents of the box on a flat surface and check that all of the components are present and in good condition.**



- b) Place the device in a room with dim lightening.**
- c) Before the first switching on, unlock the device by using the flat screwdriver, and unscrew the locking screw.**



- d) Connect the plug of the AC/DC adaptor into the socket on the base of VX610 device.**



- e) Turn on the tablet. If it does not turn on, use the special charger and microUSB cable provided in its box.**



- f) **Connect the AC/DC adaptor plug to a 230 Vac, 50 Hz power supply, or that appropriate for the power requirements specified on the nameplate.**



- g) **Press the power button (for about 3 seconds) until the corresponding green light comes on.**



VI - Technical features

VI.1 - Plate data

Supply voltage: 100-240 VAC

Rated frequency: 50/60 Hz

Internal voltage: 24 VDC - 12 VDC - 5 VDC

Maximum absorbed power: 54 VA

Max absorbed current: 400 mA

Safety class: 1

Applied part: type B (Body)

Vx610 dimensions: 270x445x480 mm

Weight: 14.7 kg

Sensor resolution 2.1 mpixel

VI.2 - Labelling



Fig. 1 Device manufacturer label



Refer to user Manual



Part type B (Body)



Warning



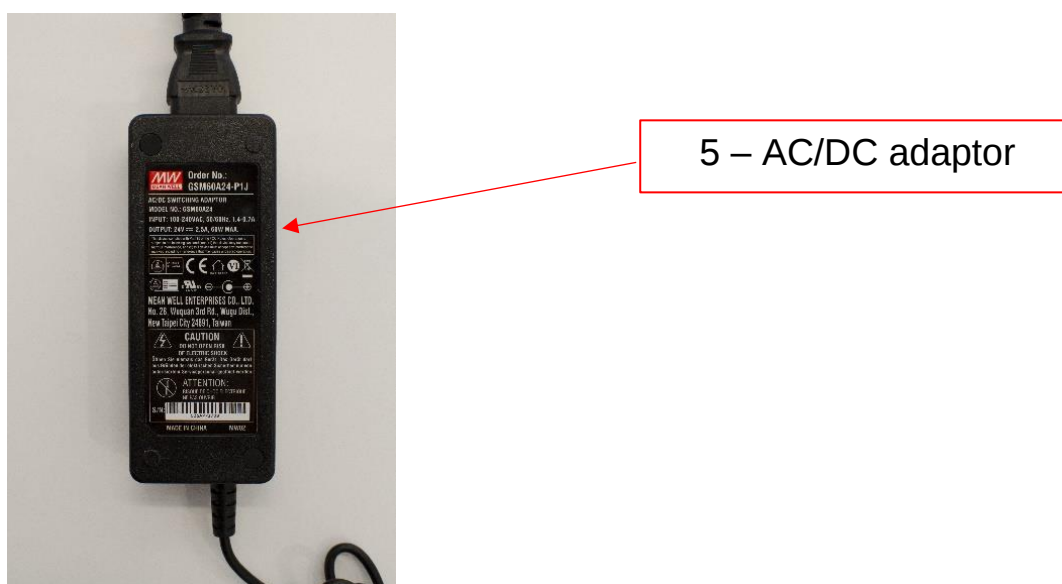
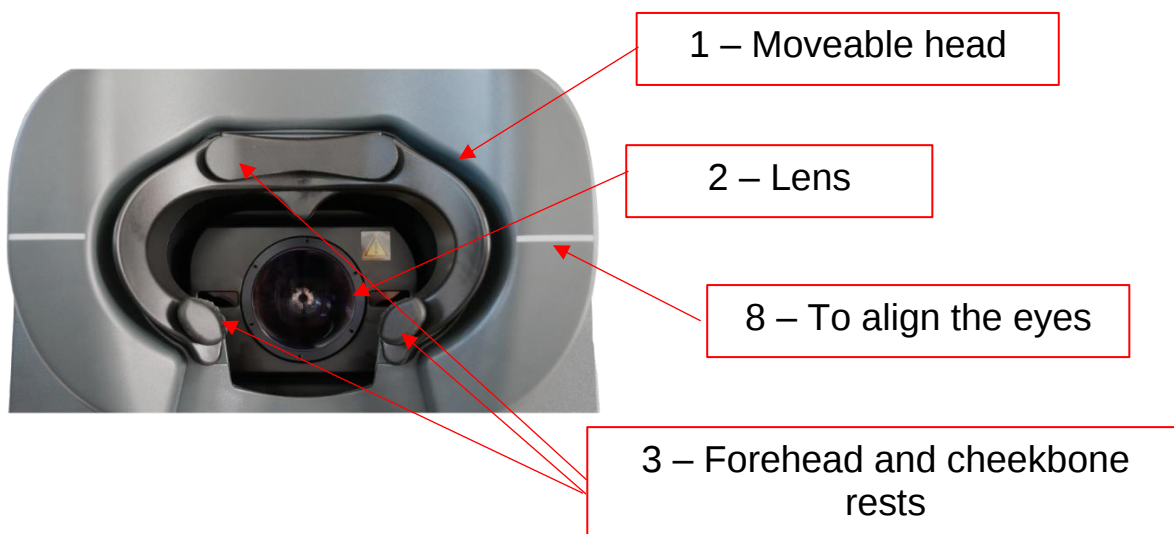
Fig. 2 AC/DC switching adaptor identifying label.

The meaning of the symbols used on the labels is provided in graphic symbols section.

VI.3 - Parts and components

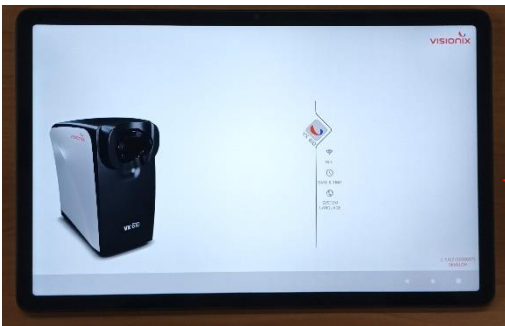
The parts and components of VX610 device are shown below:

1	Moveable head
2	Lens
3	Forehead and cheekbone rests
4	Socket panel
5	AC/DC adaptor
6	Power cord
7	Tablet
8	Screwdriver





6 – Power cable



7 – Tablet

VII - Use of the device

VII.1 - Initial powering on

Ensure that VX610 is correctly mounted: see Section V for more details on proper installation procedures.



When powering on for the first time, perform a device configuration. If there is a wireless network, enter the SSID and password.

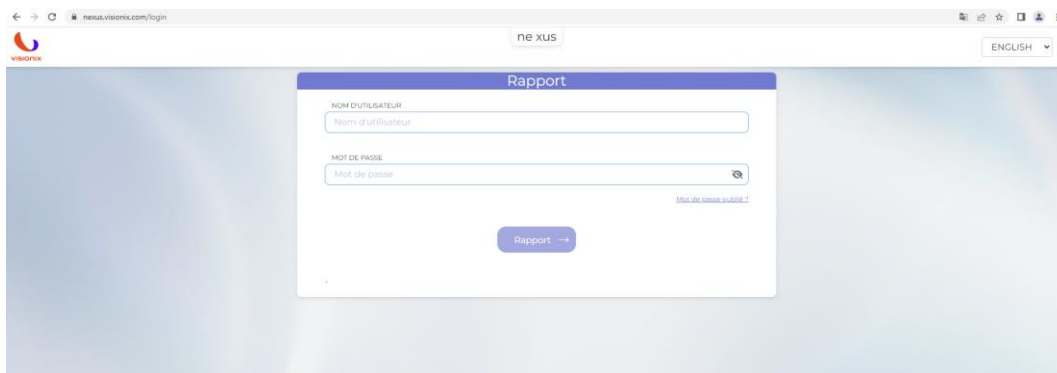


Safety and patient well-being are the top priority during the use of VX610. Follow the safety indications at the beginning of this manual, as well as all recommendations provided during the description of the device.

VII.2 - First Login - Password change

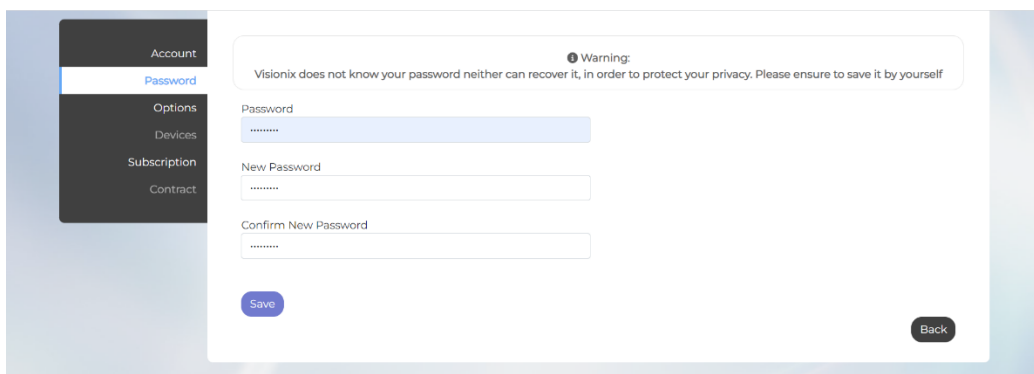
First of all, it is mandatory that the user performs the first login and the mandatory password change through the reserved area of Visionix website.

- 1) Go on the “reserved area” at the web site <https://nexus.visionix.com/login> and insert the credentials:
 - **USERNAME:** insert the username of your account
 - **PASSWORD:** insert the temporary password of your account.



Then Click on “Report”.

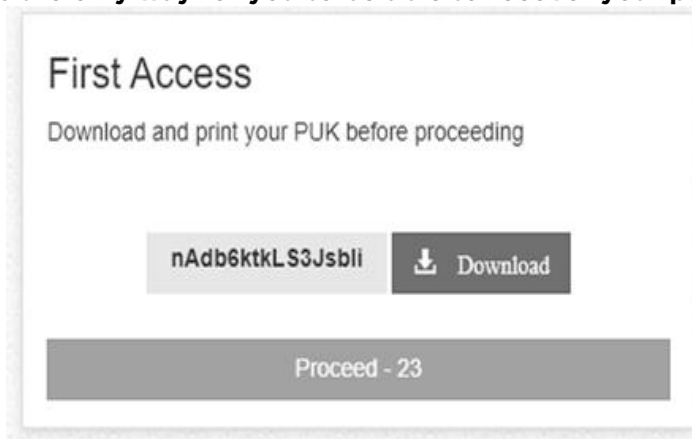
- 2) The image below appears requesting to insert and confirm the new password chosen by the user and click on “Continue”



NOTE: Do not share your password, keep it carefully; the password allows you to log in to your account and see patients and exams performed.

3) Download and keep the PUK code carefully.

NOTE: PUK code is the only way for you to be able to recover your password.

A screenshot of a web interface titled "First Access". Below the title, it says "Download and print your PUK before proceeding". There is a grey box containing the PUK code "nAdb6ktkLS3Jsbli" and a dark grey button with a download icon and the text "Download". At the bottom, there is a wide grey button labeled "Proceed - 23".

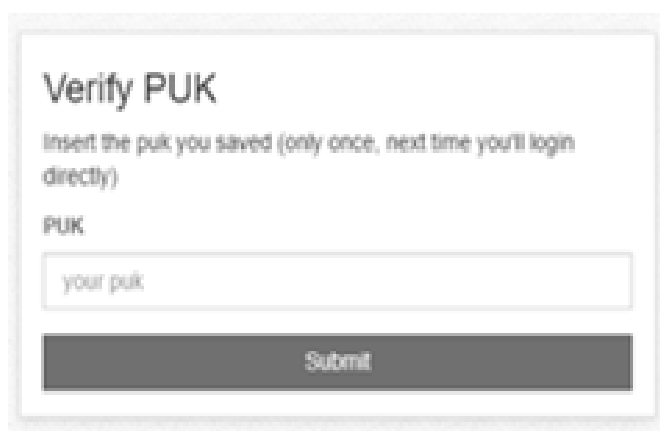
First Access

Download and print your PUK before proceeding

nAdb6ktkLS3Jsbli Download

Proceed - 23

Then, insert the PUK code just downloaded and then click “Continue”

A screenshot of a web interface titled "Verify PUK". Below the title, it says "Insert the puk you saved (only once, next time you'll login directly)". There is a label "PUK:" followed by a text input field containing the placeholder text "your puk". At the bottom, there is a dark grey button labeled "Submit".

Verify PUK

Insert the puk you saved (only once, next time you'll login directly)

PUK:

your puk

Submit

Now you are logged in your reserved area.

VII.3 - Turn on, turn on and off the tablet

Switching on the tablet and activating the app

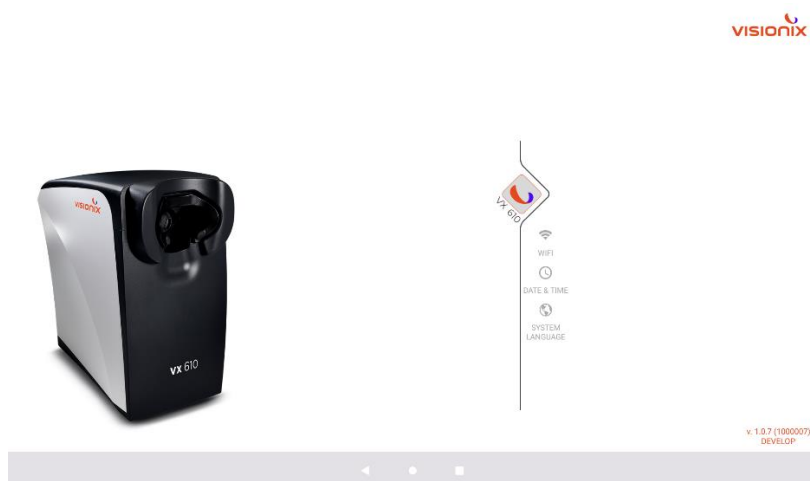
The VX610 user interface consists of the appropriate APP pre-installed in the supplied tablet, the various screens of the APP are shown below.

From each of the main screens you can immediately access all the other main screens using the menu on the left. From all the screens you can access the shutdown / log out feature using the round button at the top right.

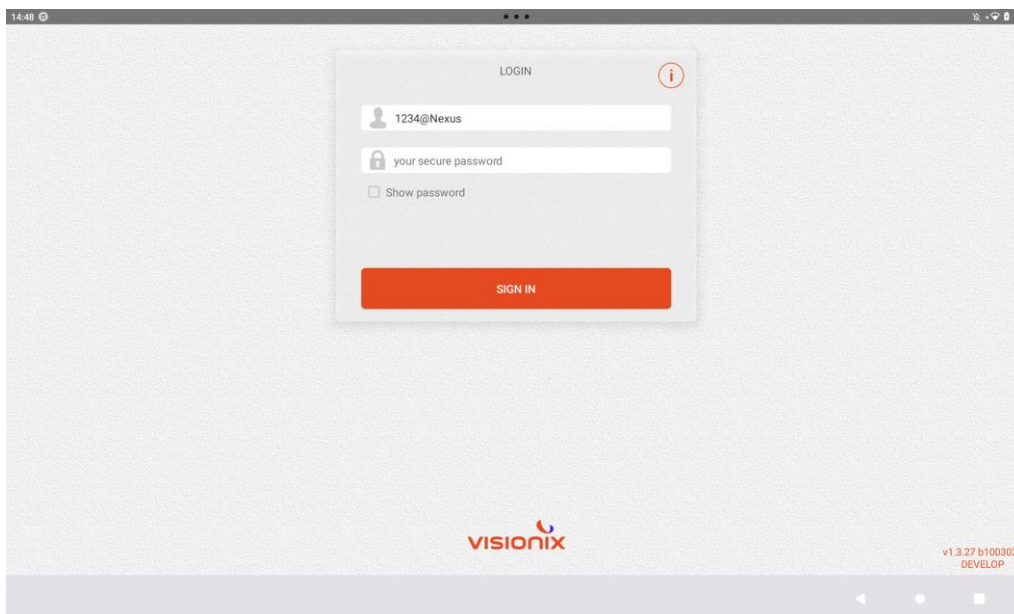
Remove the tablet from the packaging and switch it on with the power button located at the bottom left.



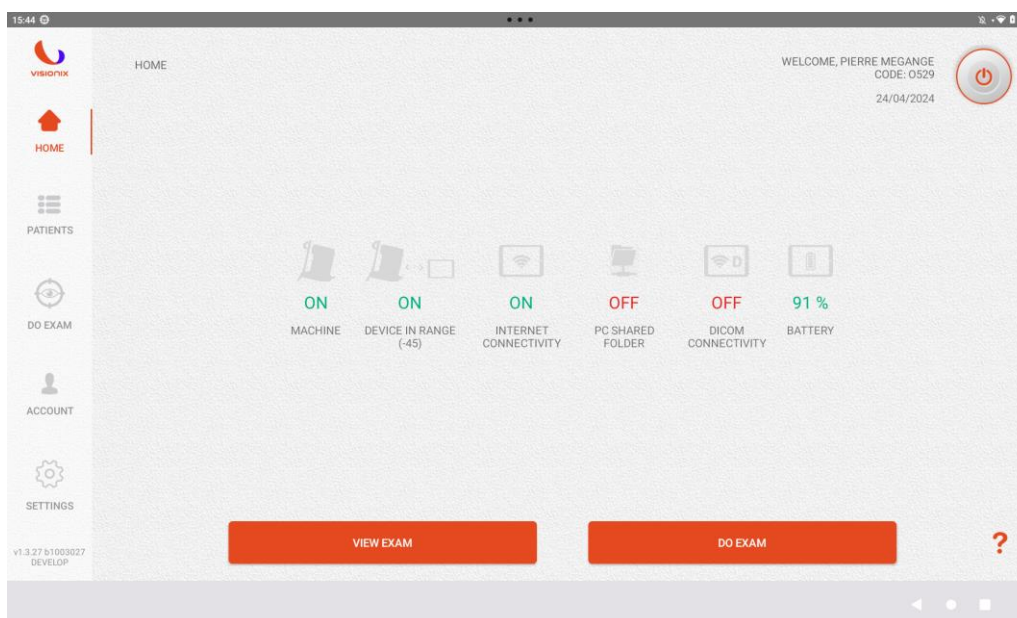
After switching on, a screen like the one below will appear.



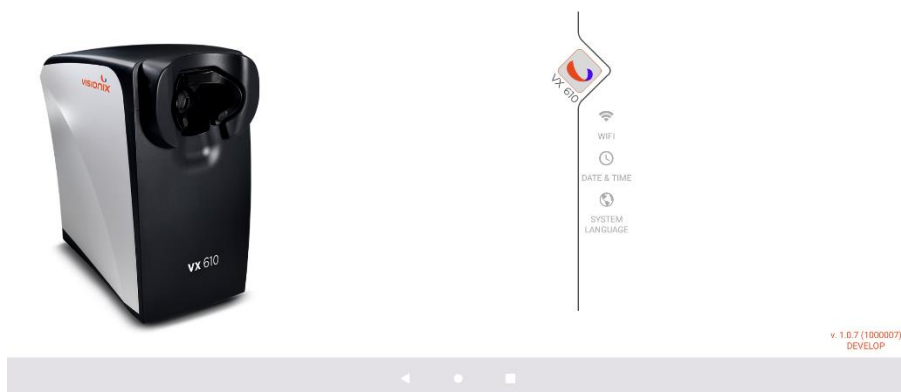
Click on the icon VX610 and enter your login and password in the screen below.



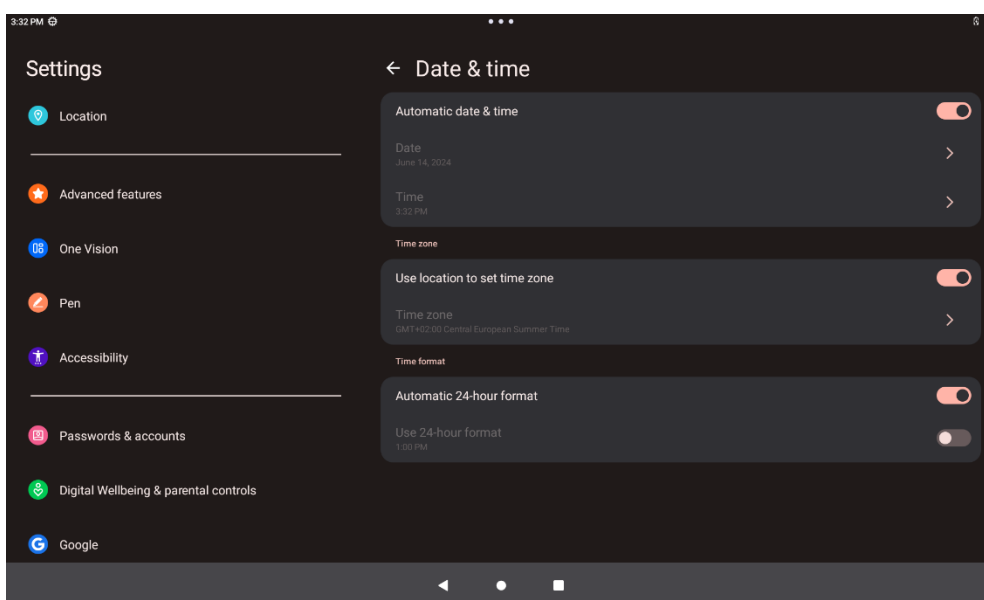
After logging in with login and password, the home screen will appear:



- **Machine:** indicates whether VX610 is on or off.
- **Device in range:** indicates whether Bluetooth communication between the tablet and the device is on or off (if OFF, switch ON the Bluetooth communication of the tablet and/or bring the tablet closer to the device).
- **Internet connectivity:** indicates the tablet wi-fi status.
- **PC Shared Folder :** indicate the communication is ON or OFF to share patient retina on a local folder.
- **Dicom connectivity:** indicates if the connection with the DICOM interface is enabled /disable.
- **Battery:** indicates the charge level of the tablet battery

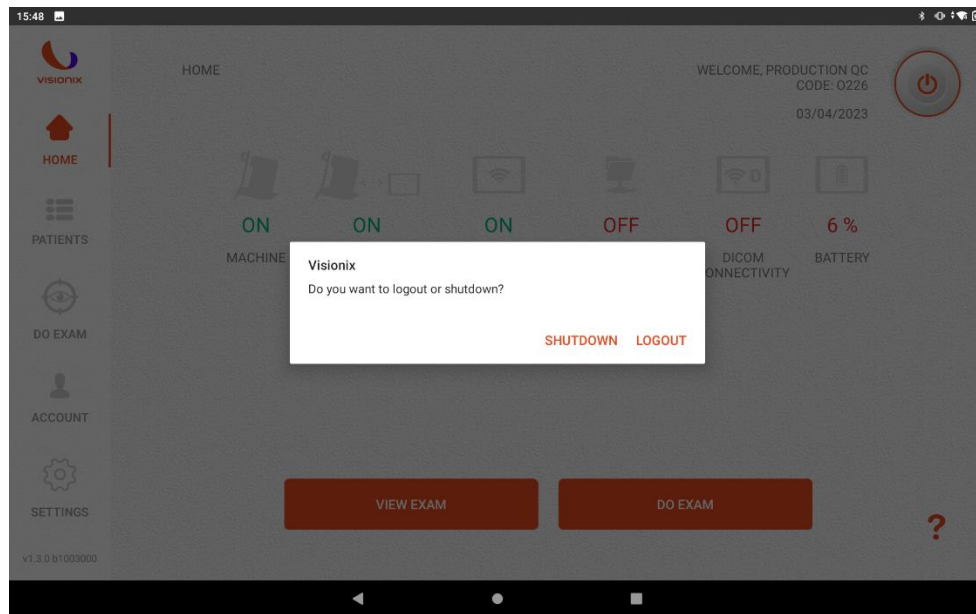


By clicking on the DATE AND TIME icon on the start page, the user can set the date and time of the tablet, as shown in the figure below.



Switching off

Select the OFF button in the upper right. Press the “Shutdown” button.



Switch off VX610 pressing the green button and replace the cap on the front lens.

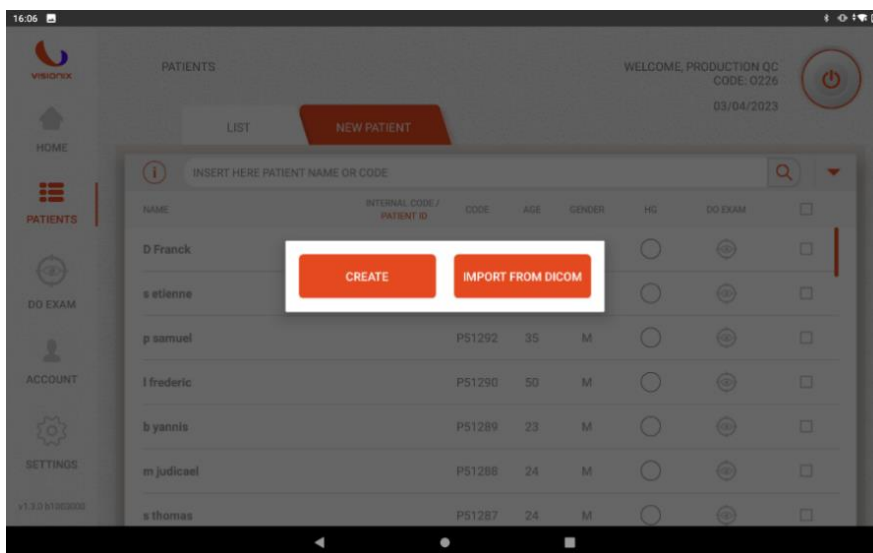


Leave the tablet under charge.

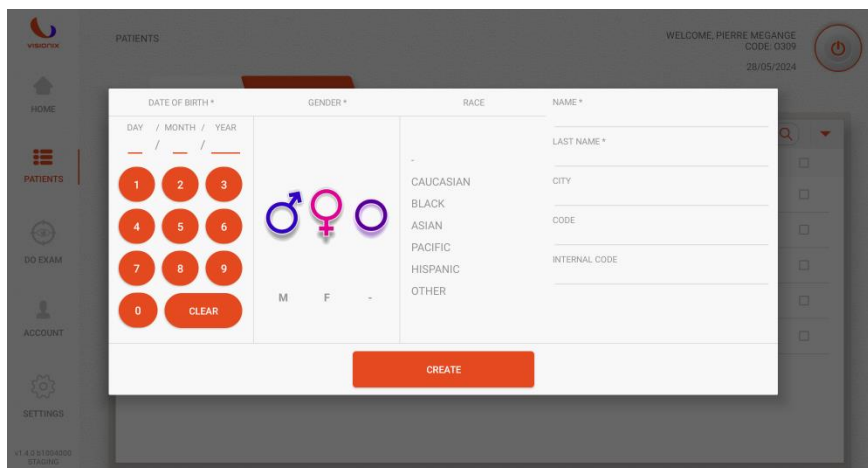
VII.4 - Test execution

Entering patient

To enter a patient click on “PATIENTS”.
Then select “NEW PATIENT” and “CREATE”.



Fill in all the patient's information. And then click on “Create”.



You can either to choose to start an exam by clicking on “Yes”, or click “No” to go to patients menu.

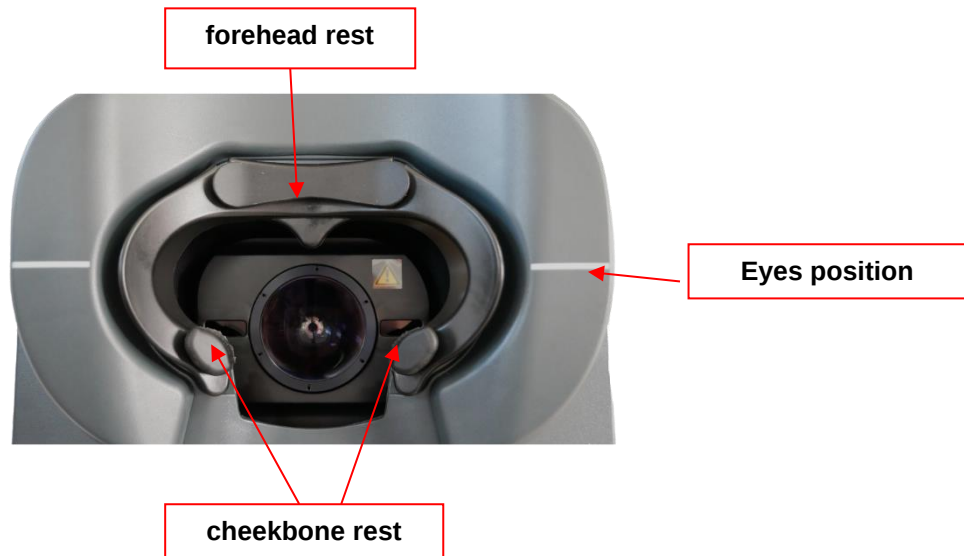
Visionix

Do you want to make an exam with the new patient?

NO YES

Performing an exam

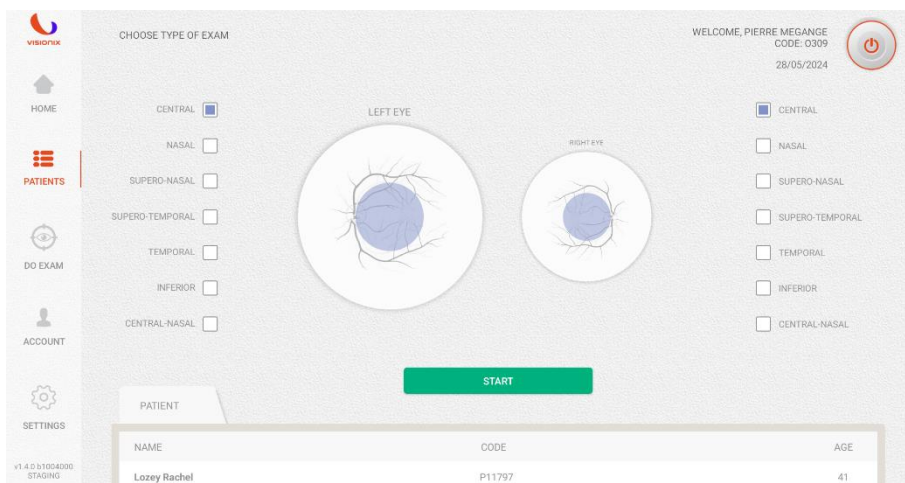
Verify that the VX610 is positioned in a dim place and make sure that the front lens cap has been removed. The patient will position the head as shown, with forehead and cheekbones resting on the black silicon parts:



The patient's eye must be positioned in the center of the black cheekbone rest at the height of the white line.

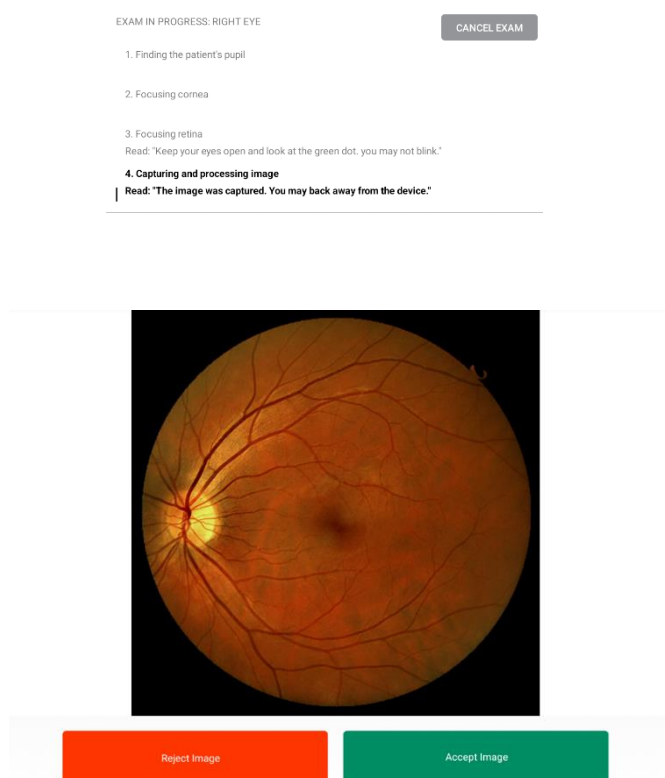


Click on the **START EXAM** button and select the eye (left and/or right) and the type of fixation that you want to examine as shown in the figure below.



Click on the **START** button. The machine will move by itself. You will be guided through each step of the process.

When the exam is completed (after about 20 seconds), it will show the first image of the retina.

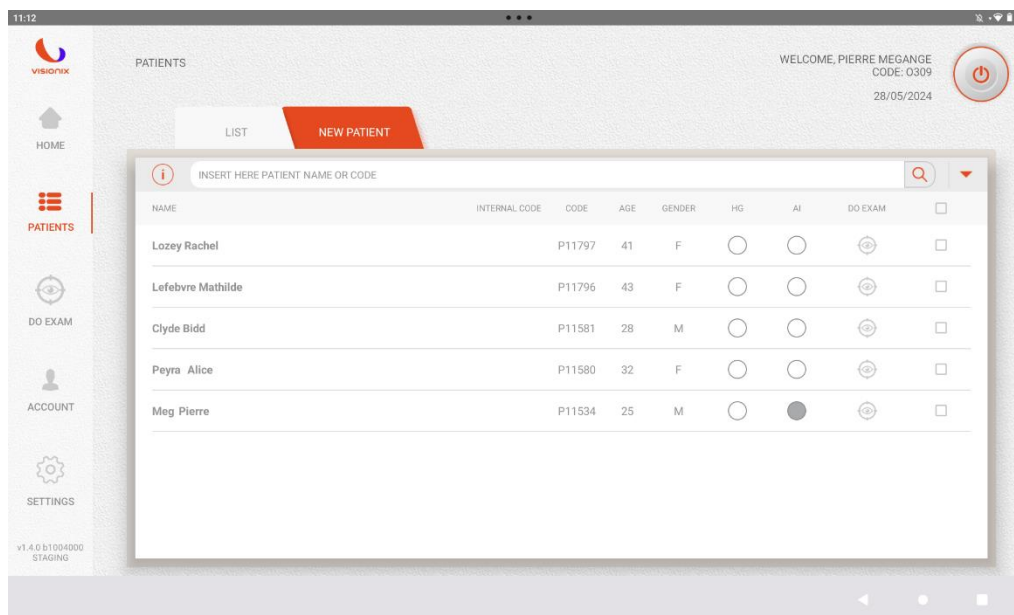


You will be asked to confirm the image which, if confirmed, will be saved in the tablet's memory. After confirmation, the machine will automatically move to the right eye to capture the image of the retina.

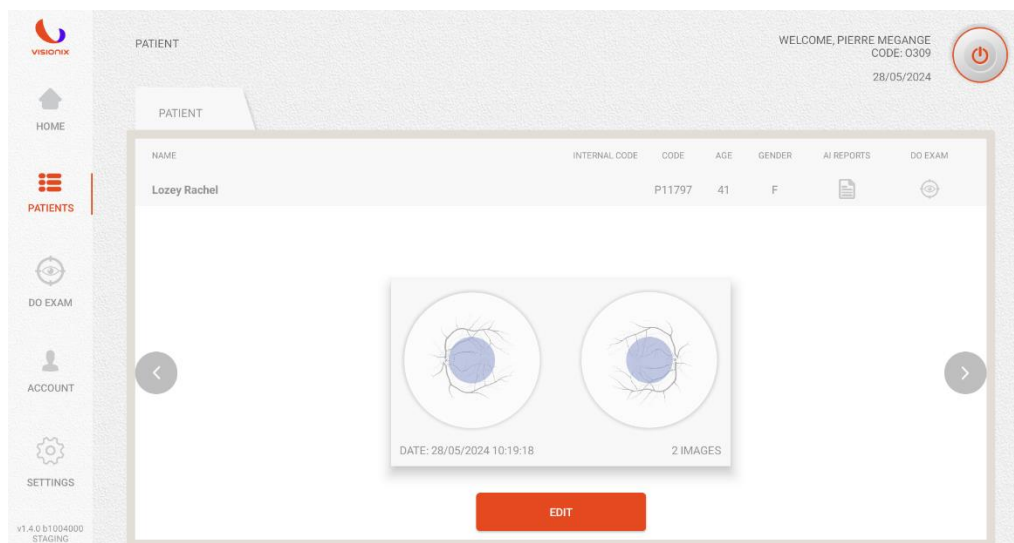
VII.5 - Data analysis and image printing

Consulting patient records

To consult the records of a patient, click on the patient's name from the patient list:



At this point, a screen like this one will appear, where in the lower section all the exams carried out can be scrolled using the grey arrows:



To enter an individual exam, click on it: the images concerning that exam will appear.

VII.6 - Applicable features

6.a) Comparison of images and filters

Retinal images can be filtered in different ways depending on what needs to be highlighted most. A more complete and detailed vision will thus allow to deepen the sections of the retina that are being examined.

In the image view section, the following features can be selected at the bottom left:

- **COMPARE IMAGES:** allows comparisons of retinal images of the same patient. After pressing the COMPARE IMAGE button, simply select the second image to be compared among those that appear on the right side of the screen.
- **FILTERS:**
 - **NONE:** original image acquired by the device without any filter - the image is displayed as it was captured by the device
 - **VASCULAR:** allows user to view images using a green filter - this filter highlights the blood vessels
 - **CHOROIDAL:** allows user to view images using a red filter - this filter highlights the choroid (lamina of the eyeball that, together with the iris and the ciliary body, forms the vascular tunic of the eye)
 - **NERVE FIBRE:** allows user to view images using a blue filter - this filter highlights the nerve fibers.
 - **RED FREE:** allows user to view images using a 50% blue and 50% green filter - this filter highlights both blood vessels and nerve fibers.
 - **INVERT:** allows the user to view images using the inverted filter - this reverses the colors of the image
 - **DEBLURRING:** allows user to view images with sharpness improvement - This filter improve images quality on blurry images.

Image without filters

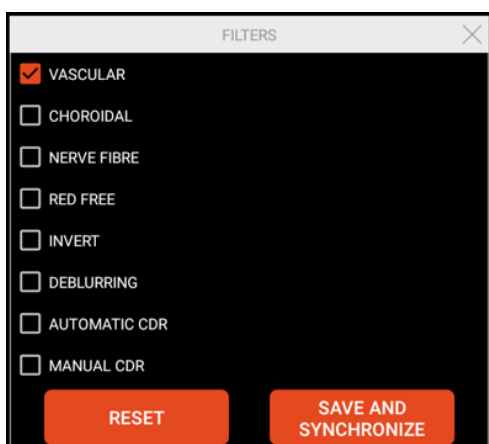
None filter:

The image is shown without any filters.



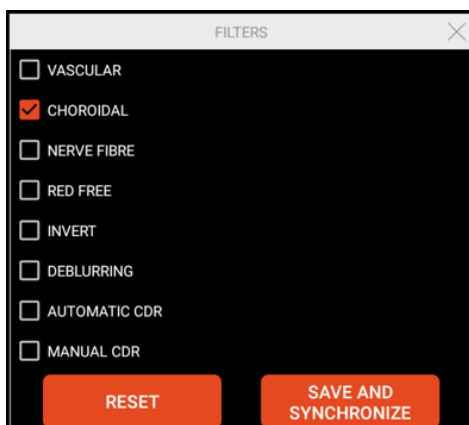
Vascular filter:

Click on "FILTRES" in the image below, then select "VASCULAR"



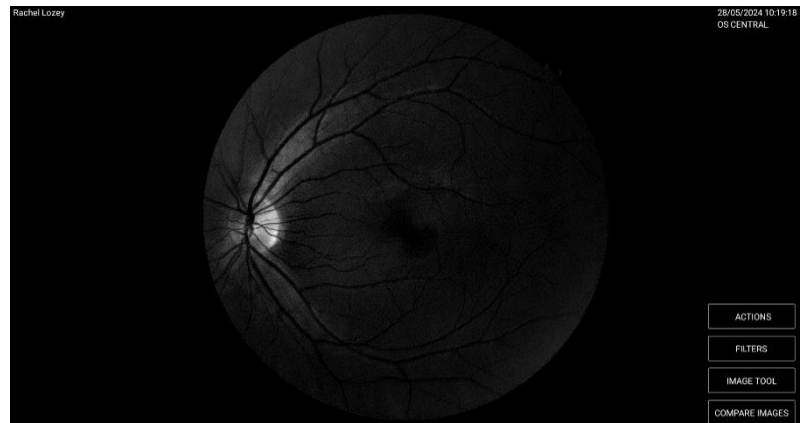
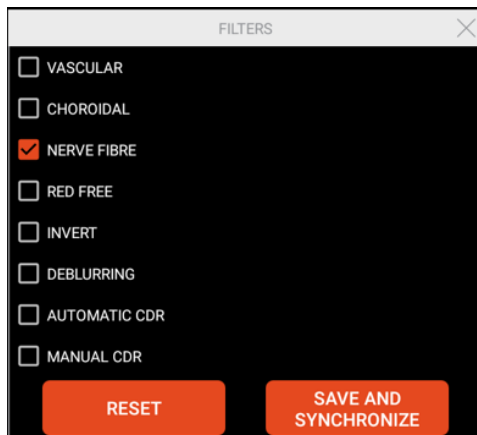
Choroidal filter:

Click on "FILTRES" in the image above, then select "CHOROIDAL"



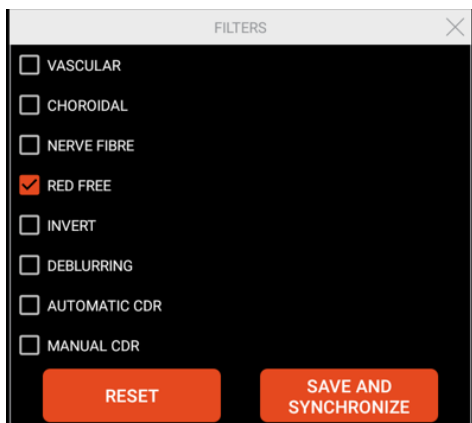
Nerve fibre filter:

Click on "FILTERS" in the image above, then select "NERVE FIBRE"



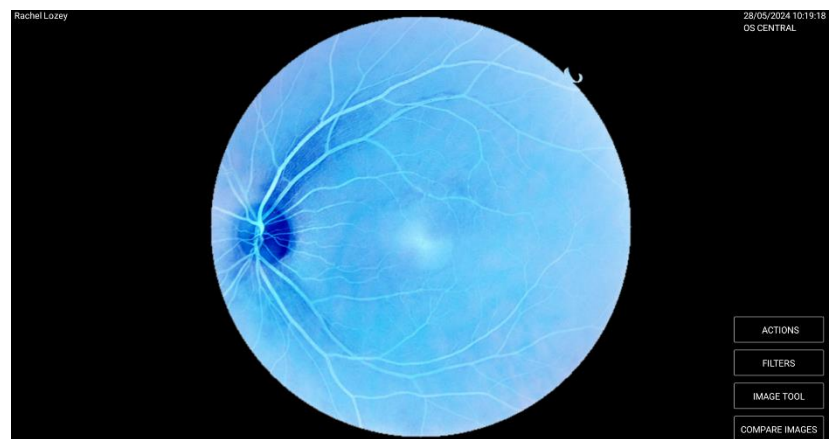
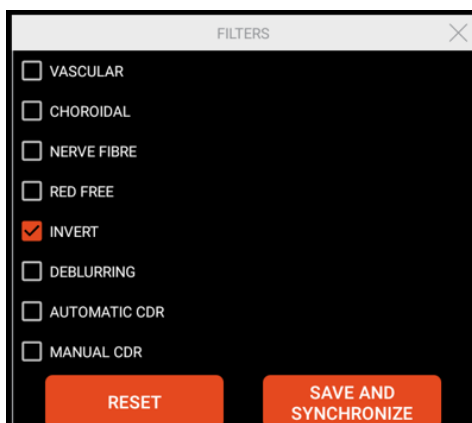
Red free filter:

Click on "FILTERS" in the image above, then select "RED FREE"



Invert filter:

Click on "FILTERS" in the image above, then select "INVERT"

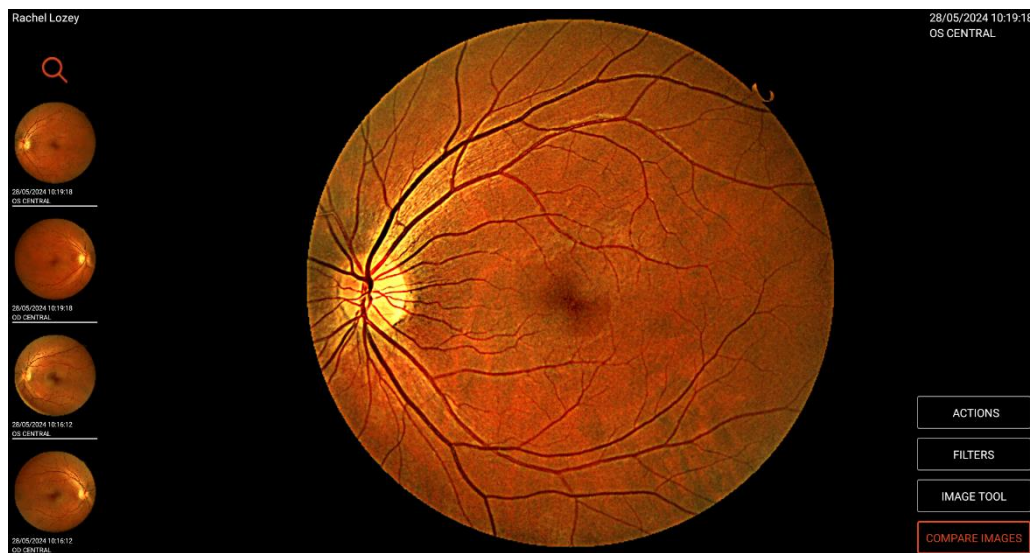


Deblurring filter:

Click on "FILTERS" in the image above, then select "DEBLURRING"



To compare two images, check the option "COMPARE IMAGES" as shown in the figure below and then select the image to be compared by choosing between the images on the right:



The comparison of images will therefore result as follows:

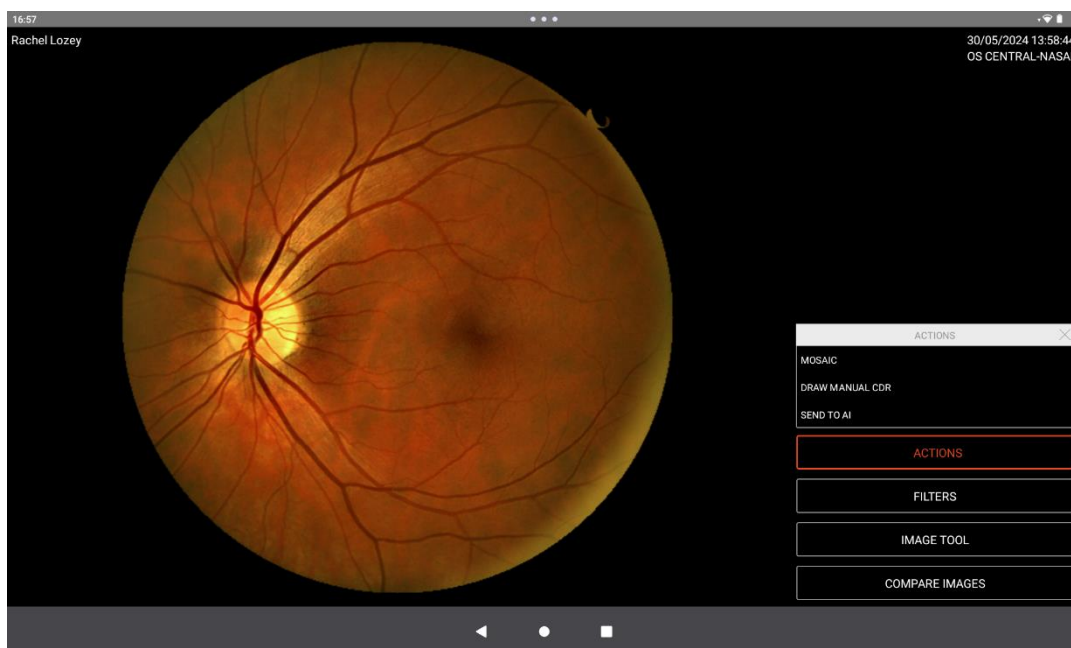


It is also possible to combine the two functions shown above (comparison of images and filters applicable clicking on “FILTERS”).

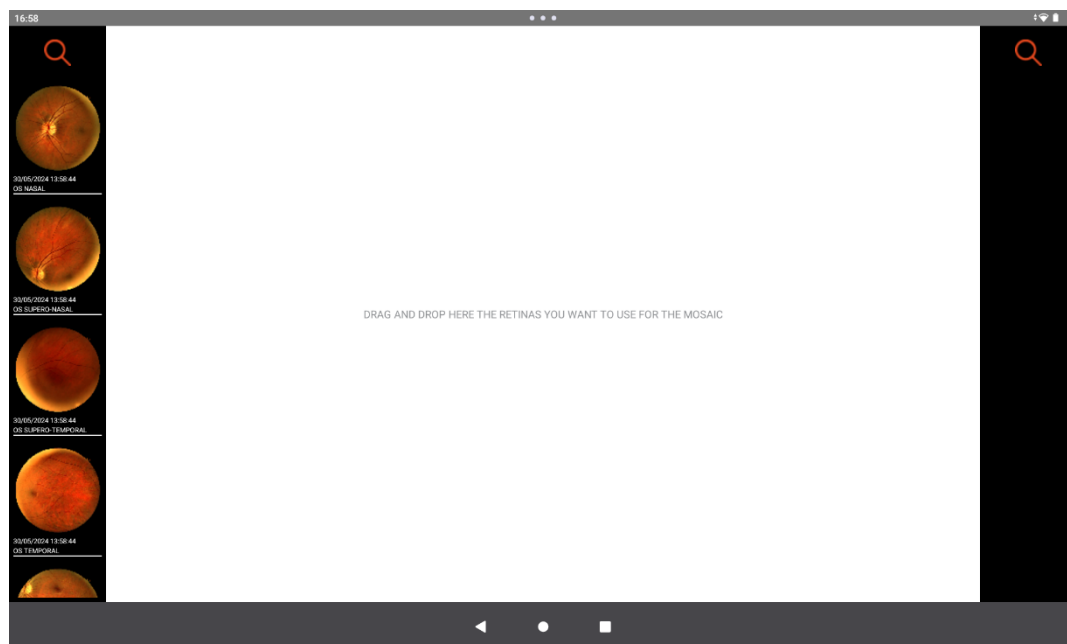
6.b) Mosaic

The mosaic functionality is used to merge together from a minimum of 2 to a maximum of 7 images of the different fixations previously acquired.

To enable the mosaic functionality, select "MOSAIC" from the action's menu at the bottom left.

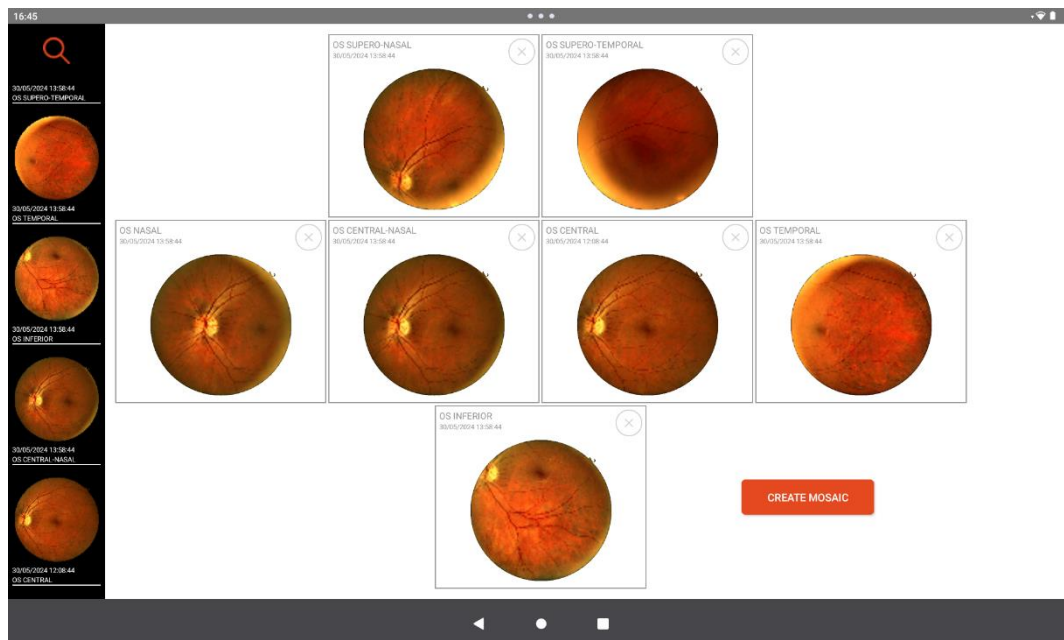


Then select the images acquired previously to create the mosaic and drag them onto the white screen.

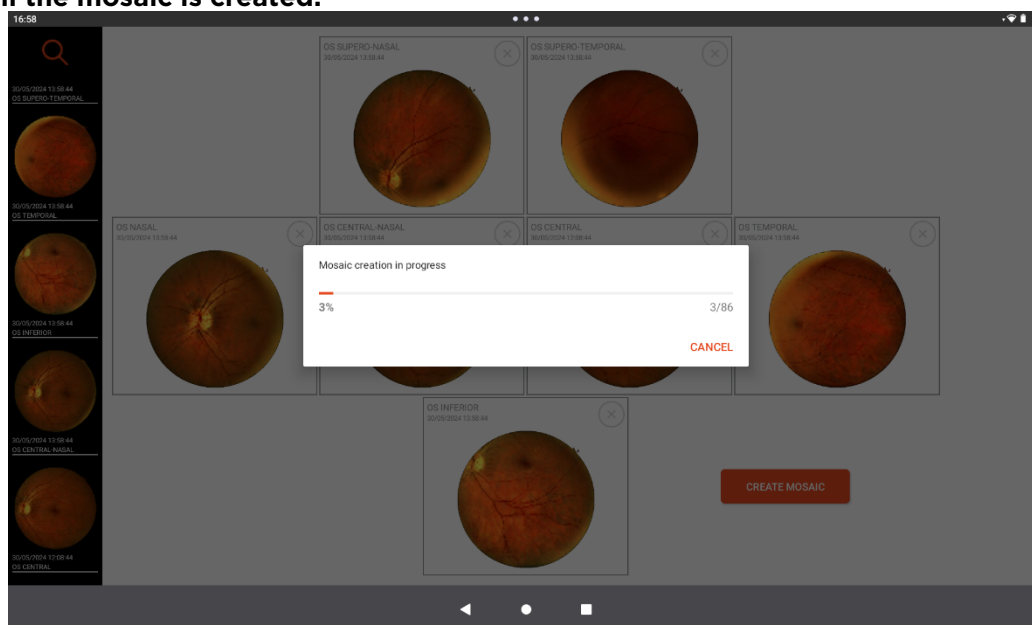


The mosaic can be created from a minimum of 2 images to a maximum of 7.

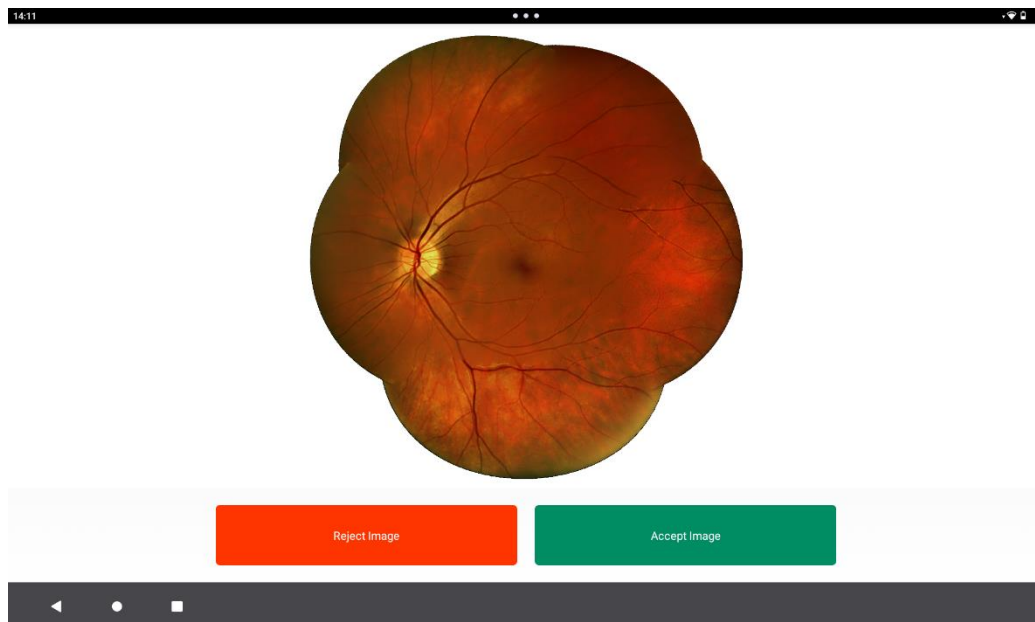
Once you have chosen the images with which you want to make the mosaic, click on "CREATE MOSAIC".



Wait until the mosaic is created:

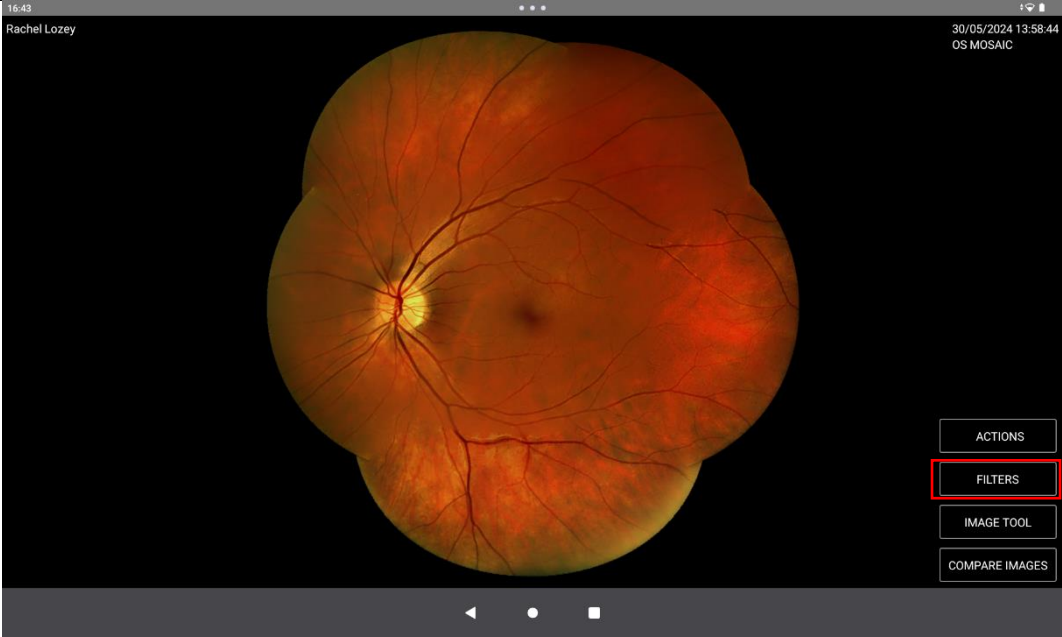


The image of the mosaic creation is shown below, the user chooses whether to accept or reject the image.

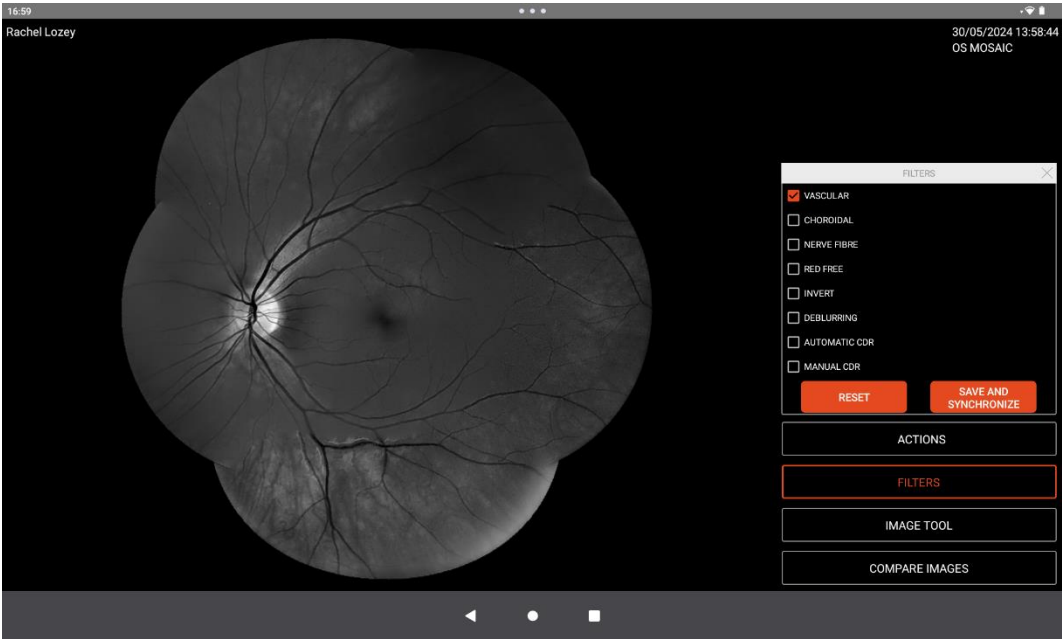


On the resulting image it is possible to apply the functions described above (application of filters and image comparison), shown in the following figures.

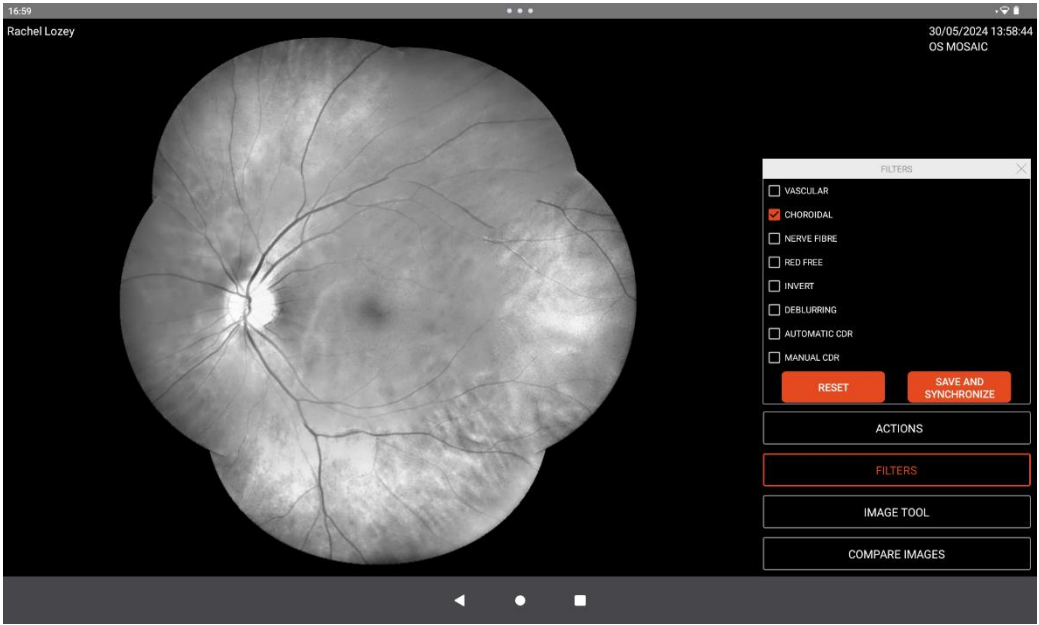
Image of the mosaic without applying filters:



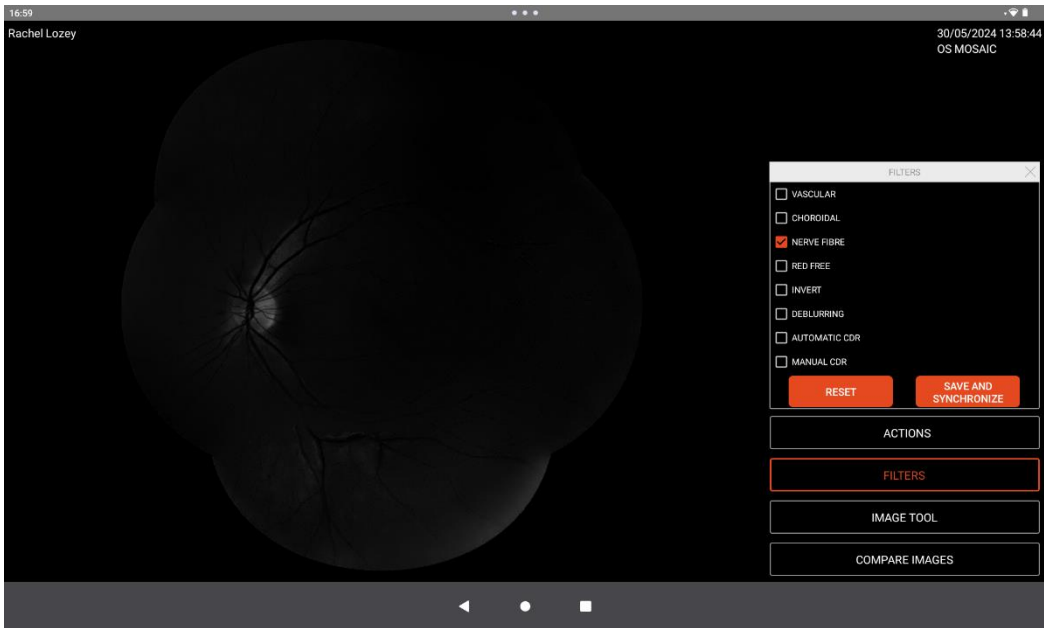
Mosaic image with VASCULAR filter:



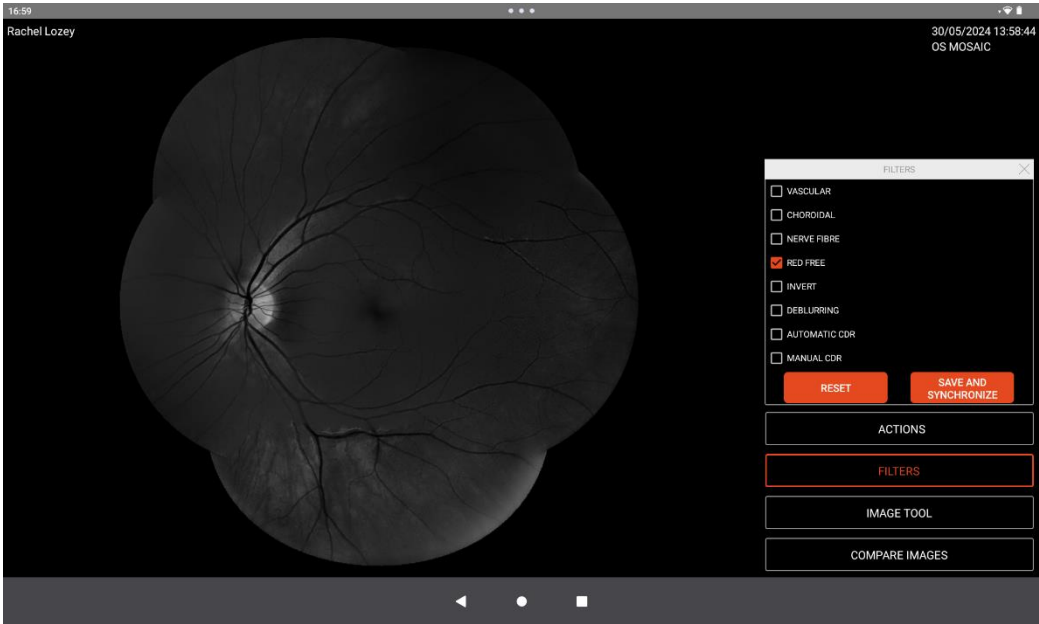
Mosaic image with CHOROIDAL filter:



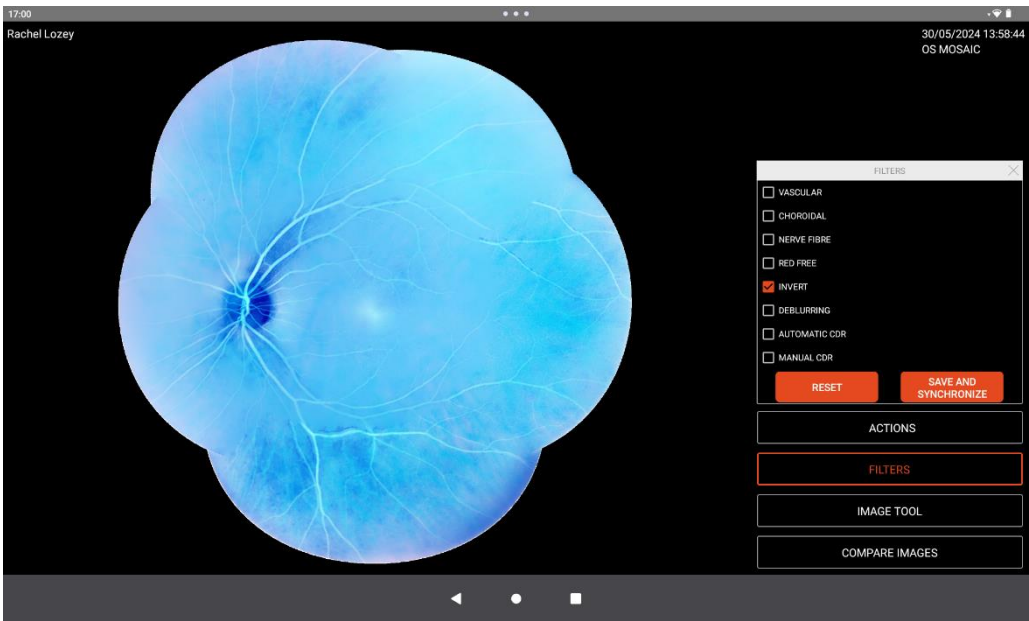
Mosaic image with NERVE FIBRE:



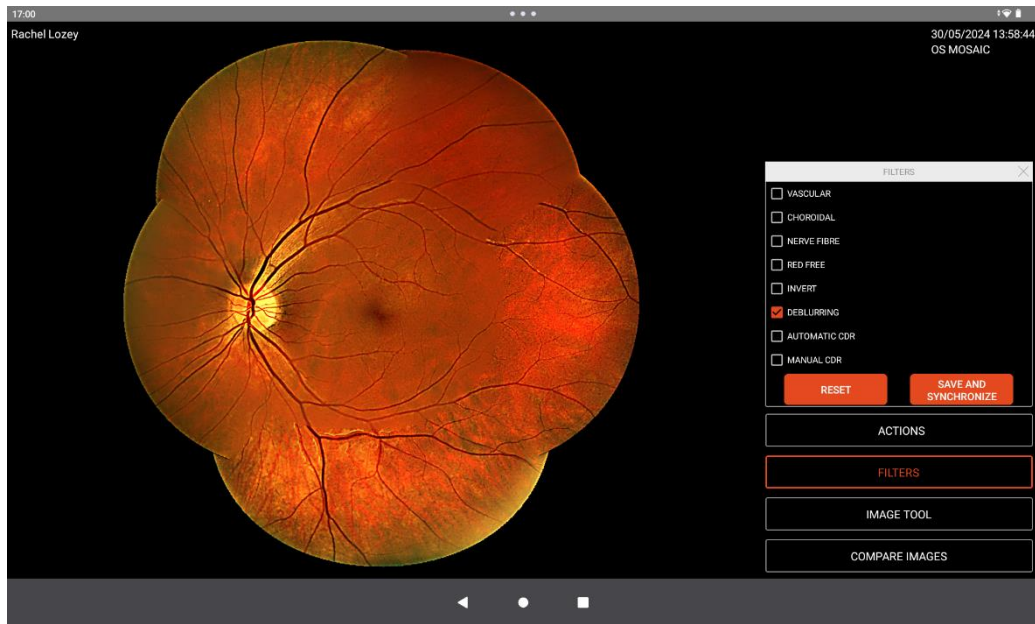
Mosaic image with RED FREE:



Mosaic image with INVERT:



Mosaic image with DEBLURRING:

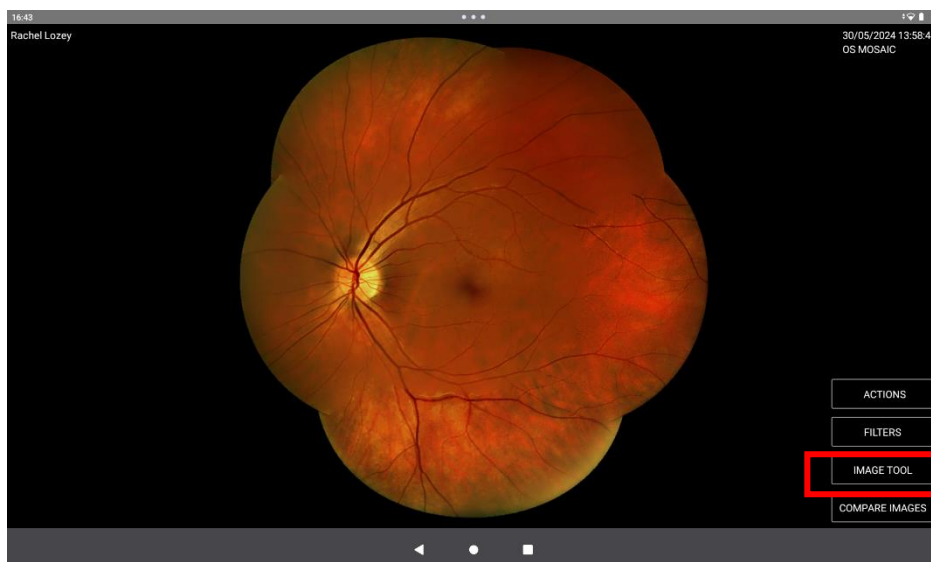


Mosaic picture can be compared to single picture as displayed below.
Image comparison:



It is also possible to combine the two functions shown above (comparison of images and filters applicable, clicking on FILTERS).

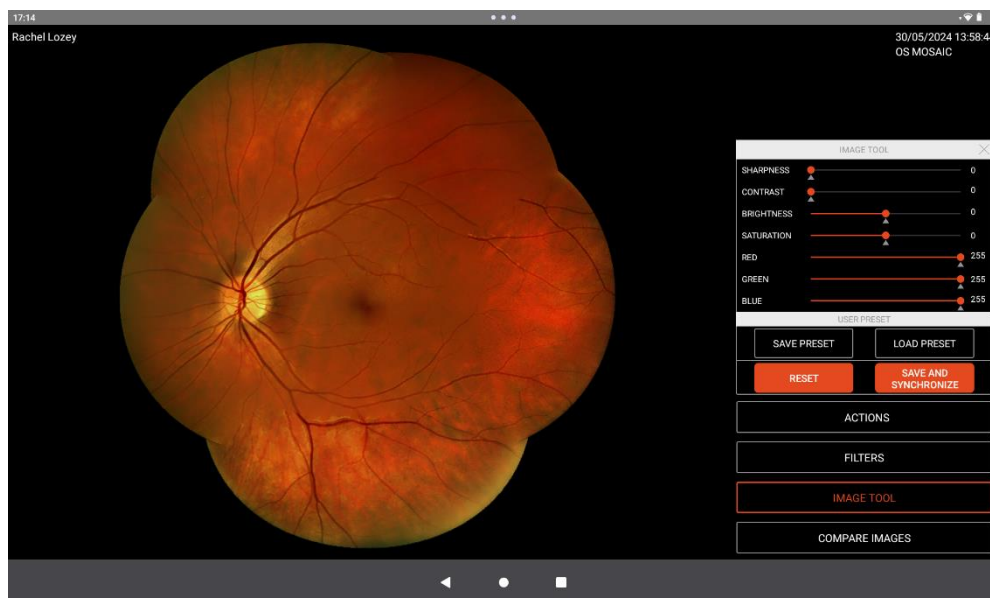
6.c) Image tool



The image tool section allows the user to create his own filter. The images settings can be saved as preset and reused in the future.

The user can adjust:

- **Sharpness:** sharpness is the level of clarity of detail and is the tool for highlighting textures
- **Contrast:** It indicates the difference in density between the lightest and darkest tones in an image
- **Brightness:** is the amount of light in an image (which varies from pixel to pixel) or emitted by a light source, such as a screen.
- **Saturation:** Saturation defines the intensity of a color
- **Red:** adjust the red level of the image
- **Green:** adjust the level of green in the image
- **Blue:** adjust the level of blue in the image

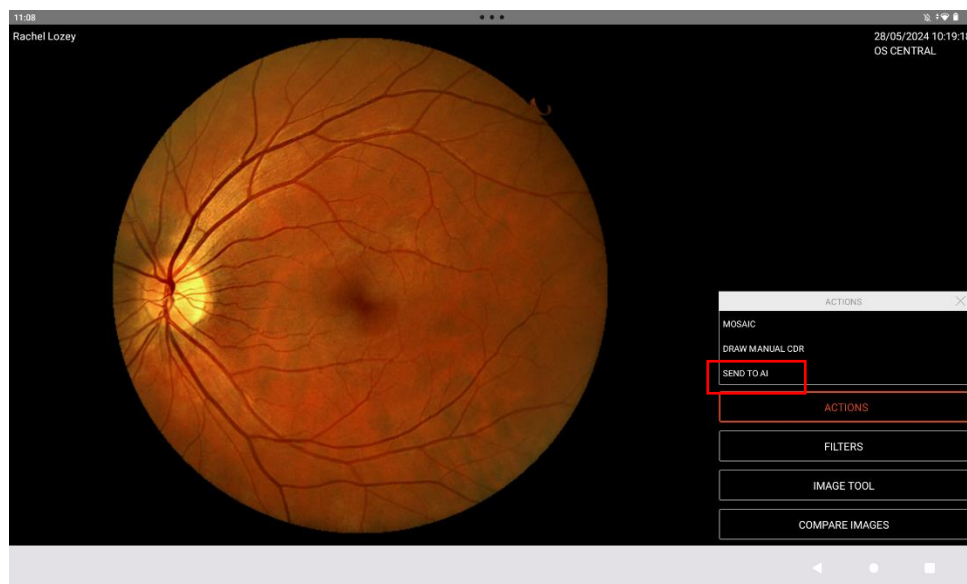


6.d) Processing of VX610 retinal images through artificial intelligence (AI)

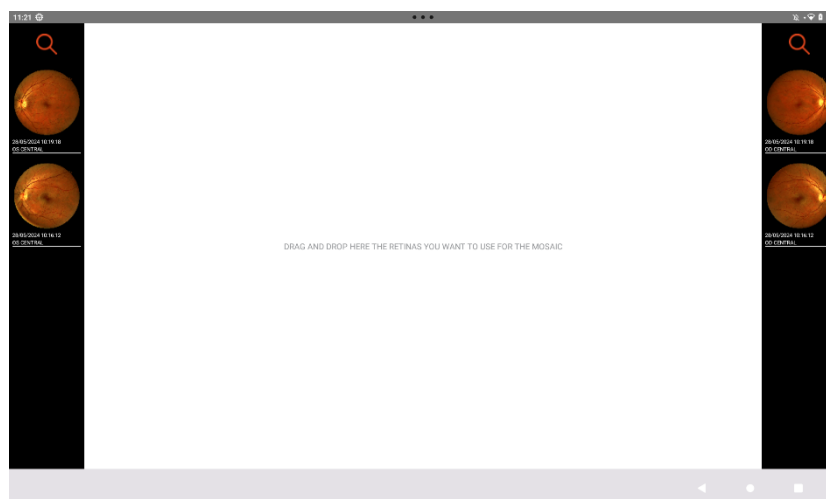
Using the AI depends of your Nexus subscription and your country.

To perform the AI on the images, please follow the instructions below:

- 1) Open the desired retinal image of the patient and click on **ACTIONS** and select **SEND TO AI** from the menu.

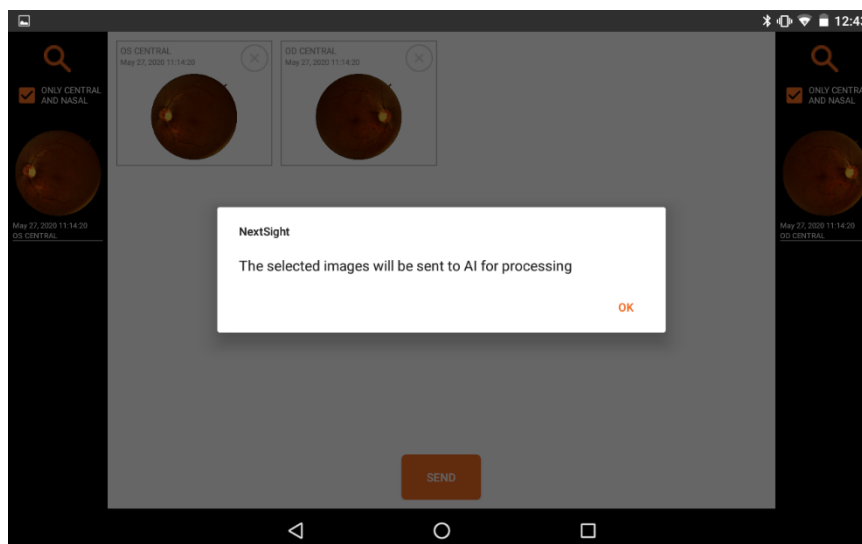


- 2) Selecting the **SEND TO AI** option the user enters the AI processing section.



- 3) Since the AI evaluation is done only on central images, an automatic filter on “fixation type” limits the displayed images to the ones that can be sent to AI for processing. In case of more than one central image available, each central images available is displayed with its acquisition date for an easy selection.

4) Drag and drop the desired images into the white area

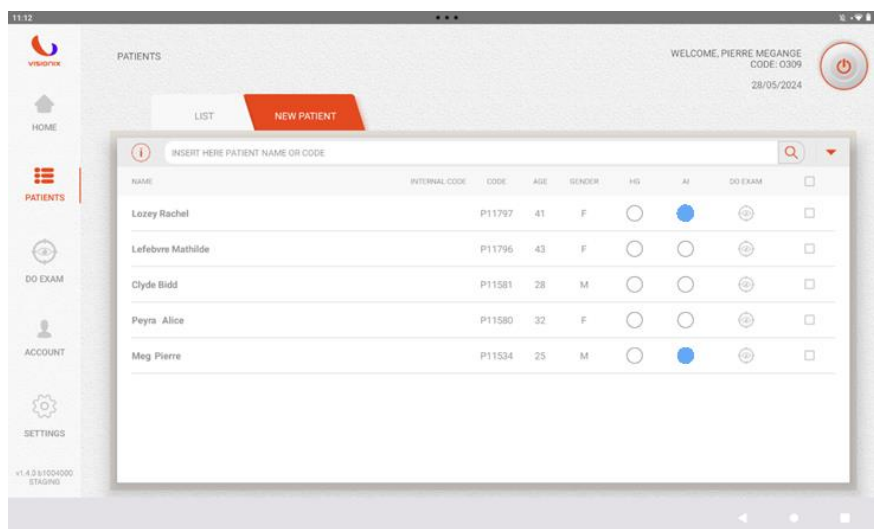


An image quality assessment of the images is performed directly on the tablet to evaluate the quality before sending the images to AI. If the image quality is not sufficient, a warning message will inform the user that the AI can't be performed. If the image quality is acceptable, but not optimal to guarantee the standard performance of AI, the user is asked to confirm or not the processing of those images.

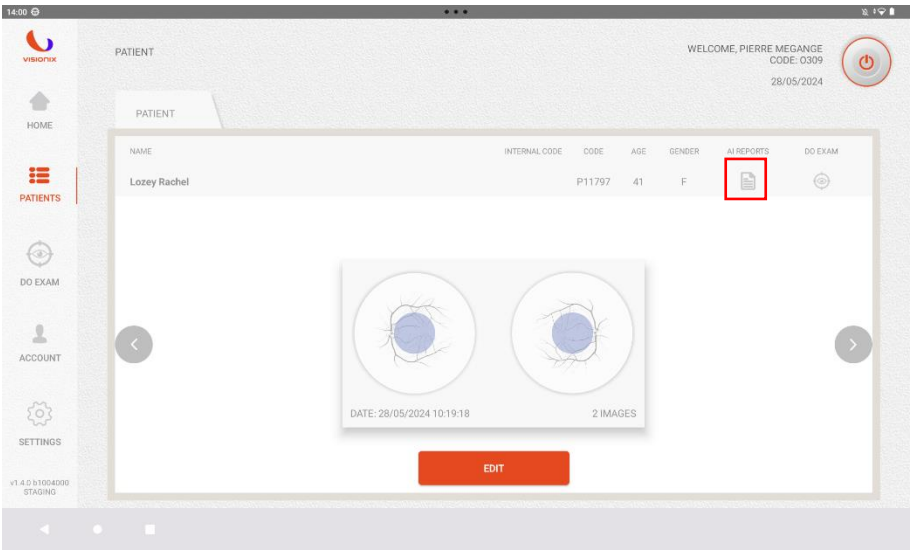
5) To send the images to AI select SEND.

6) Soon after submitting images, the AI report is sent back on the tablet.

7) The notification of AI report reception will appear as a dot on the AI column in correspondence of the patient's row.



8) Click on the patient’s name. The AI report can be opened by clicking on the “file”.

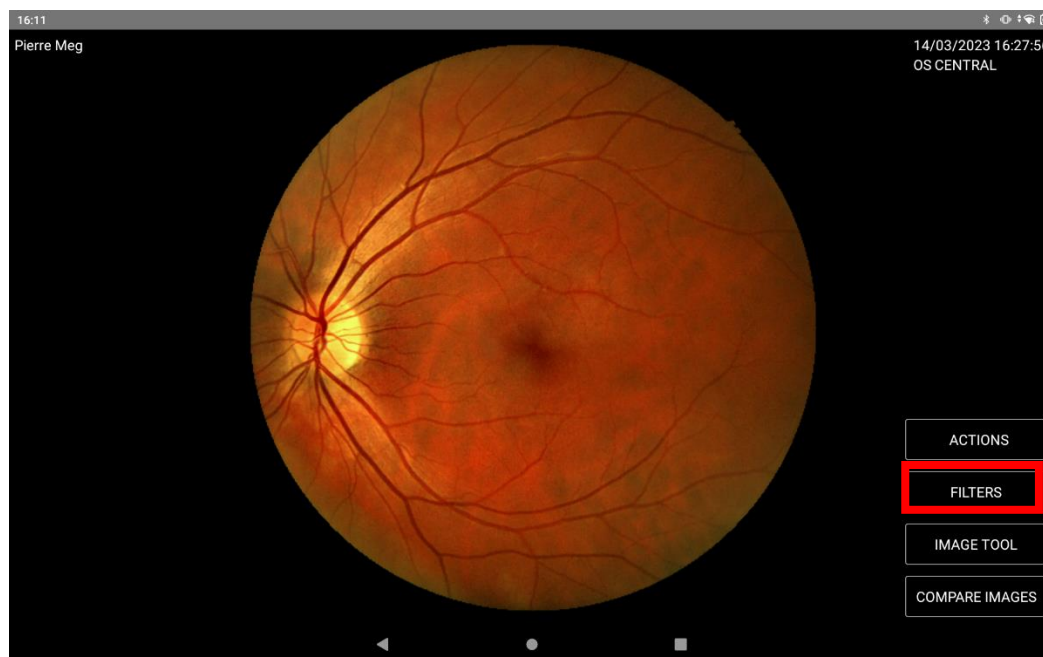


6.e) Cup To Disk Feature (CDR)

The functionality of the cup to disk allows to evaluate the excavation of the optic nerve, allowing the doctor to estimate the possible presence of glaucoma.

Through VX610 APP interface, the user can select the "Manual CDR" function in isolation or in combination with the applicable filters. In the case of manual mode it is the user himself who performs the sizing of the two ellipses (cup and disc).

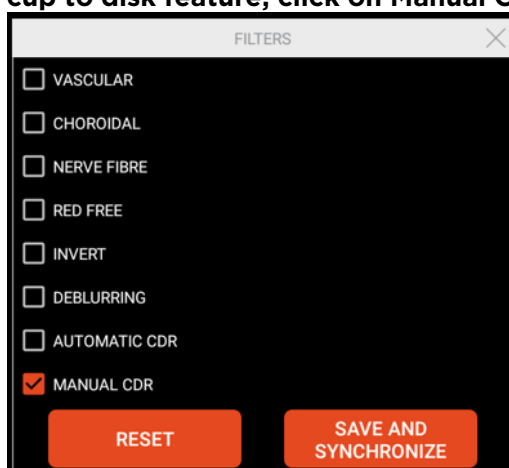
To use the cup to disk feature (CDR), go on the selected image clicking on Patient List and then on the selected patient.



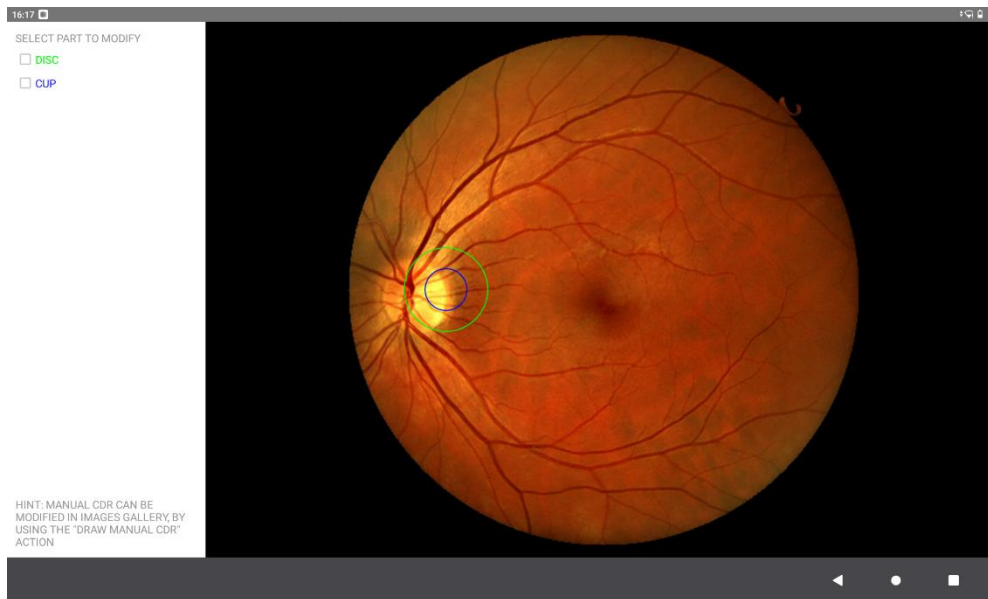
Then, click on "FILTERS" to select the manual CDR.

MANUAL CDR:

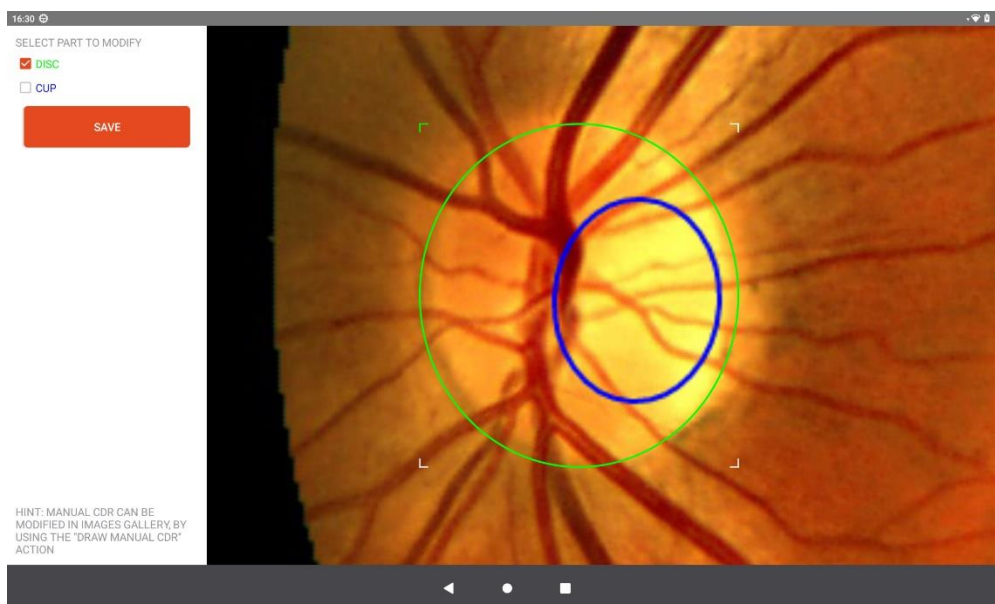
To perform the manual CDR cup to disk feature, click on Manual CDR.



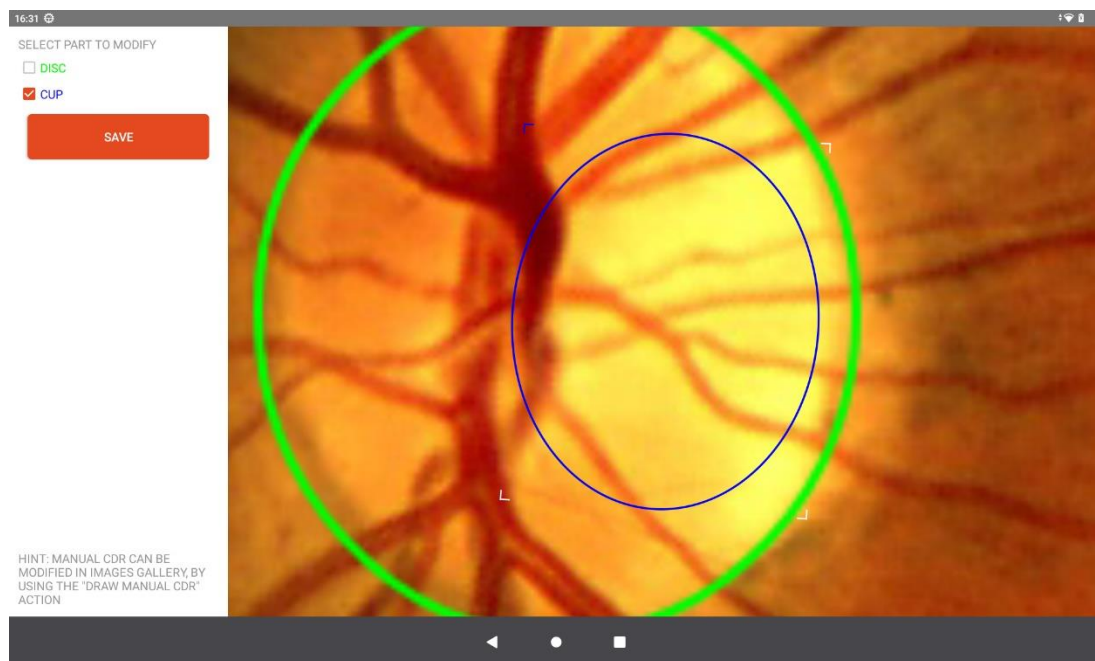
Then, the following screen appears:



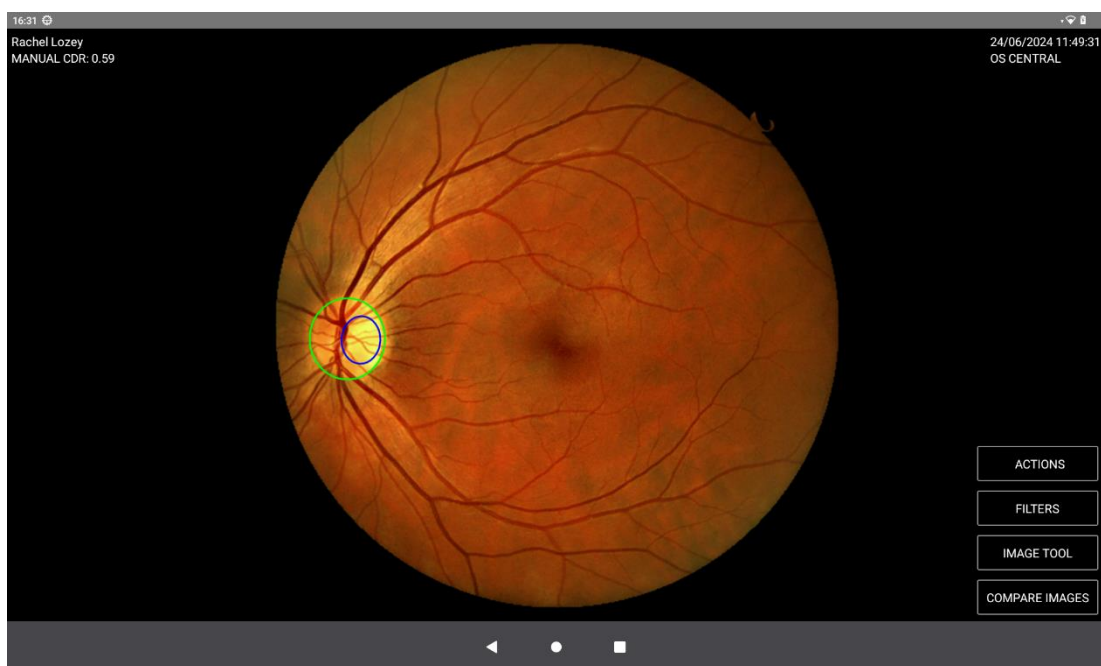
Selecting “DISC” is possible to modify the dimensions and perform the rotation of the DISC ellipse (circled in green)



Selecting “CUP” is possible to modify the dimensions and perform the rotation of the CUP ellipse (circled in blue)



Then, the image will result as shown below:

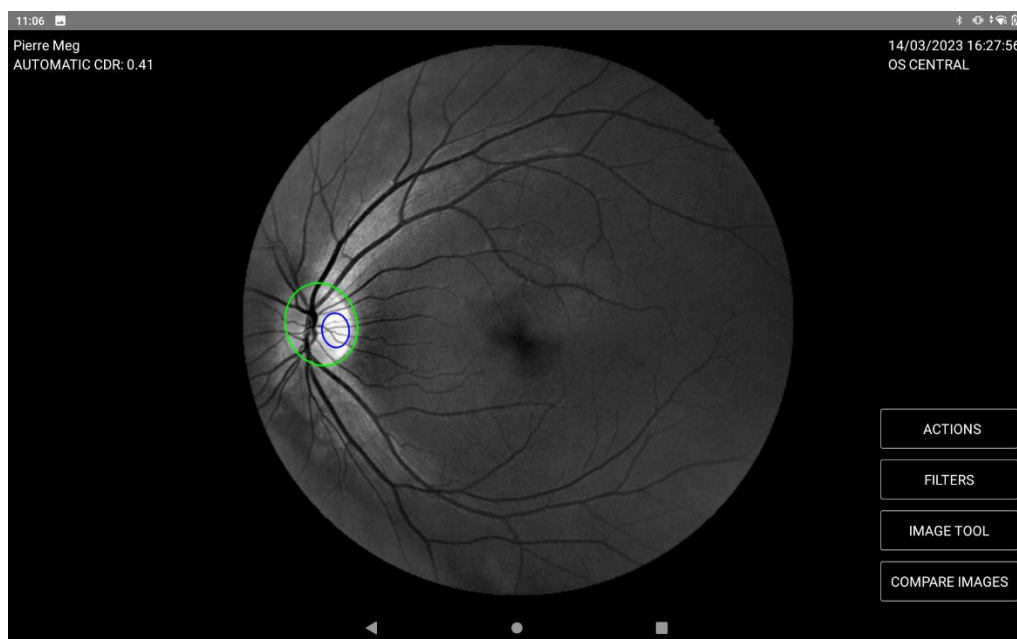
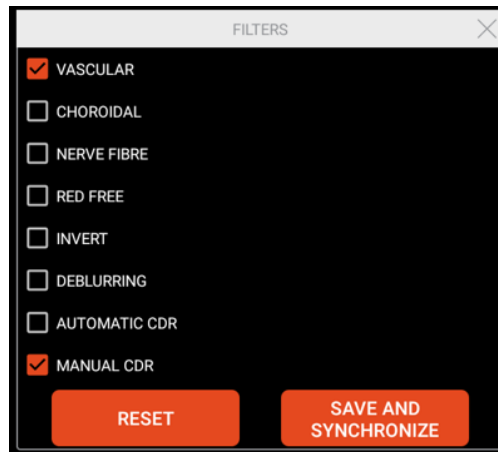


FILTERS ON CUP TO DISK FEATURE

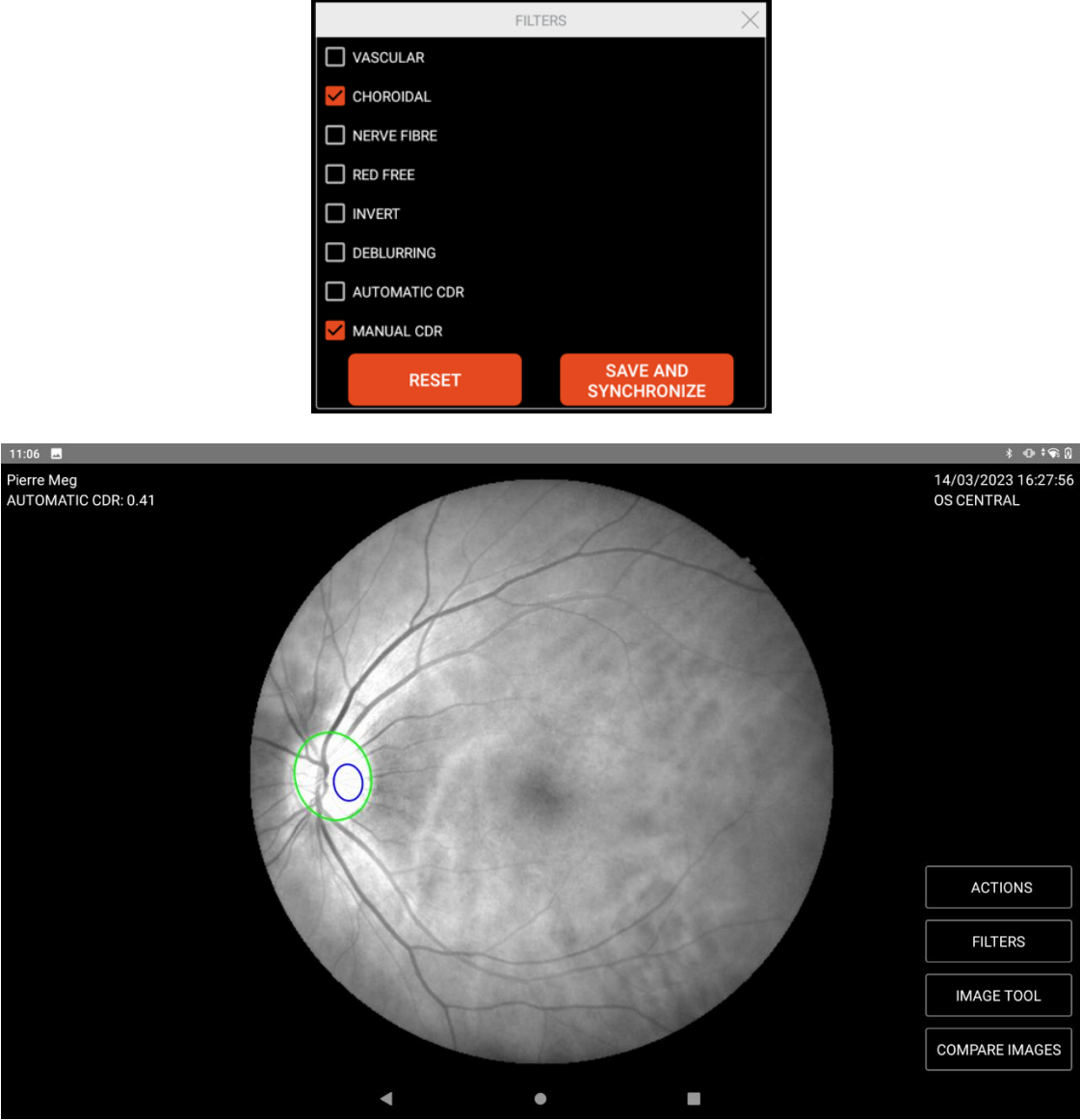
It is possible to combine cup to disc feature with the other image filter and also to compare images with cup to disc and filters.

As described above, clicking on filters, it is requested to insert the possible filters.

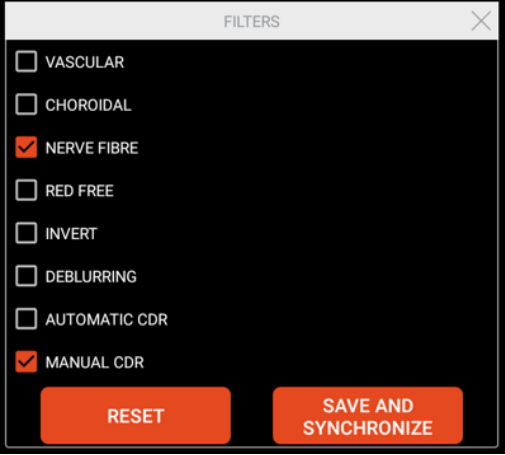
If the user selects "VASCULAR" the image will appear as shown below.

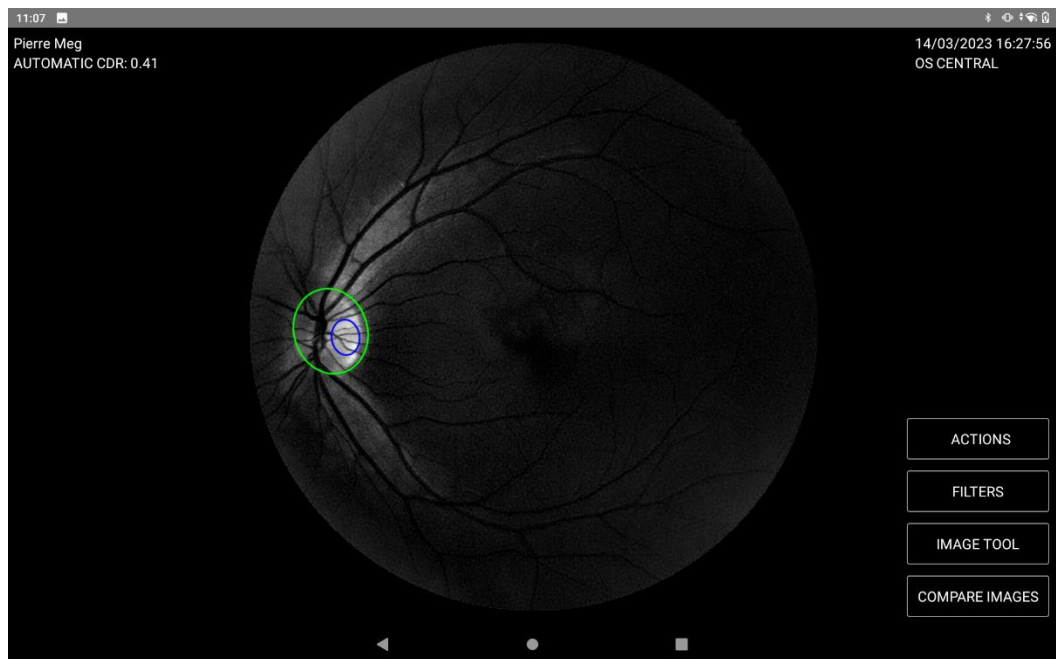


If the user selects "CHOROIDAL" the image will appear as shown below.

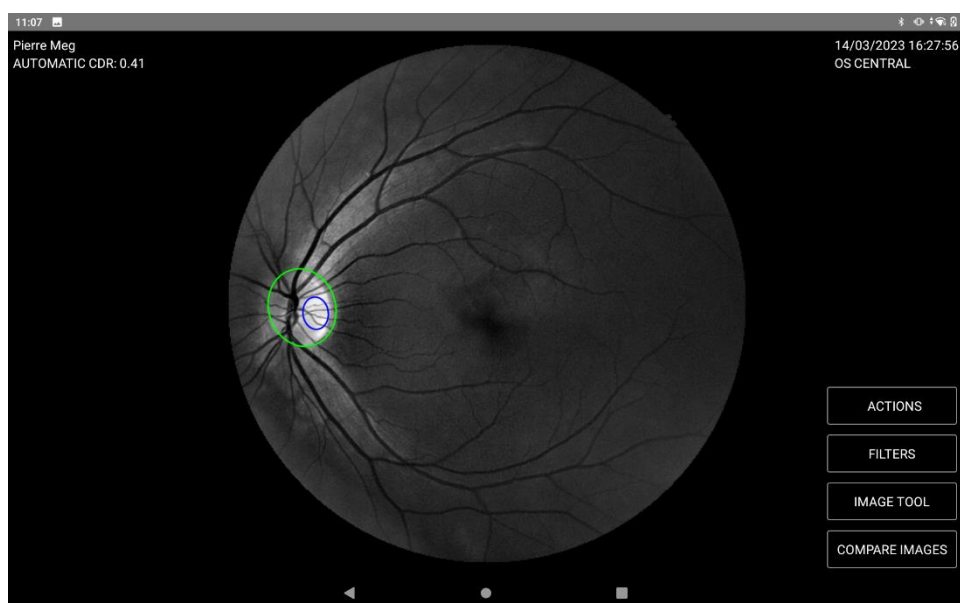
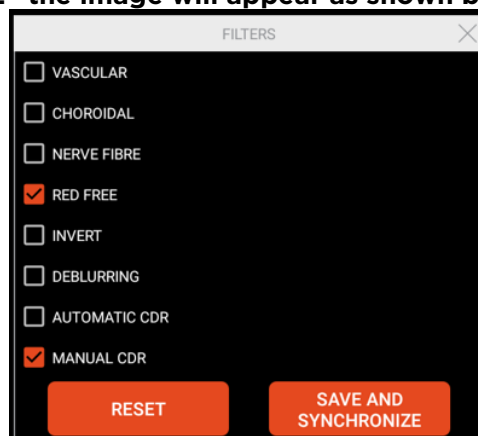


If the user selects "NERVE FIBRE " the image will appear as shown below.

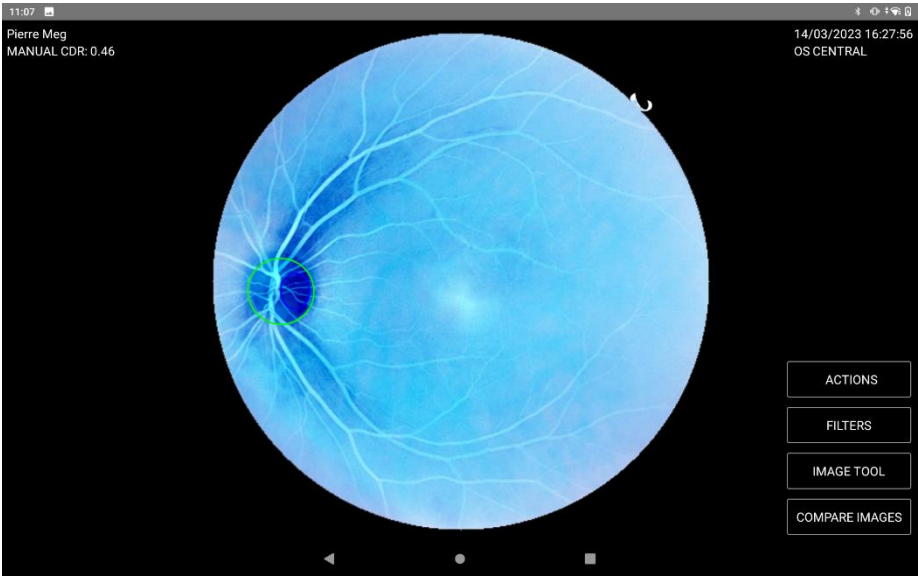
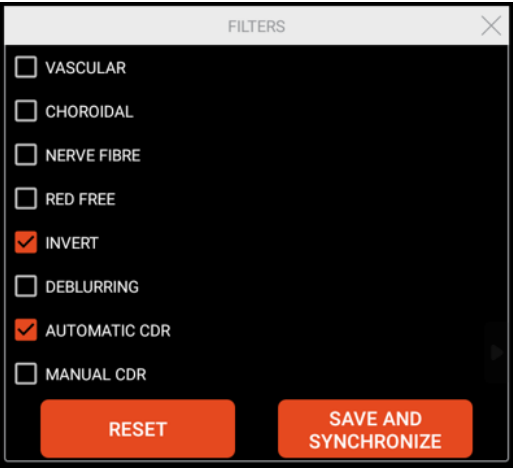




If the user selects "RED FREE" the image will appear as shown below.

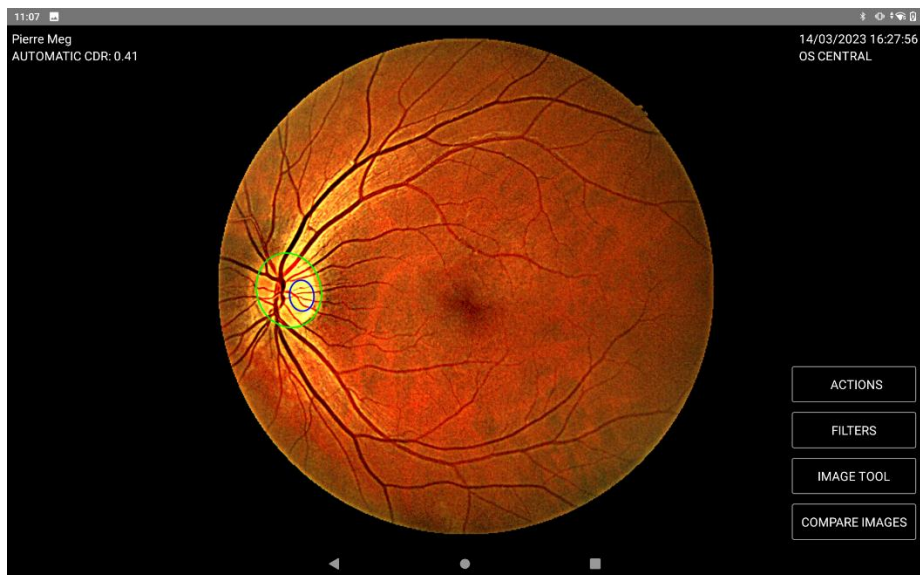


If the user selects "INVERT" the image will appear as shown below.



If the user selects "DEBLURRING" the image will appear as shown below.

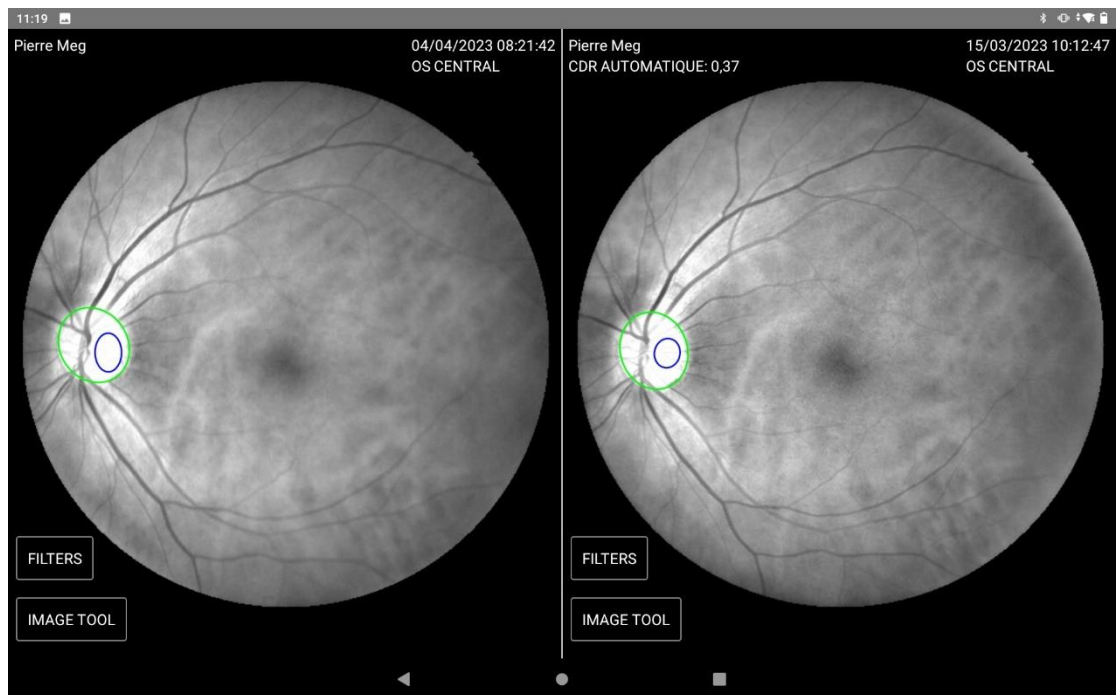




Clicking on “COMPARE IMAGES” and “FILTERS”, it is possible to combine cup to disk and filters as shown on the figures below.

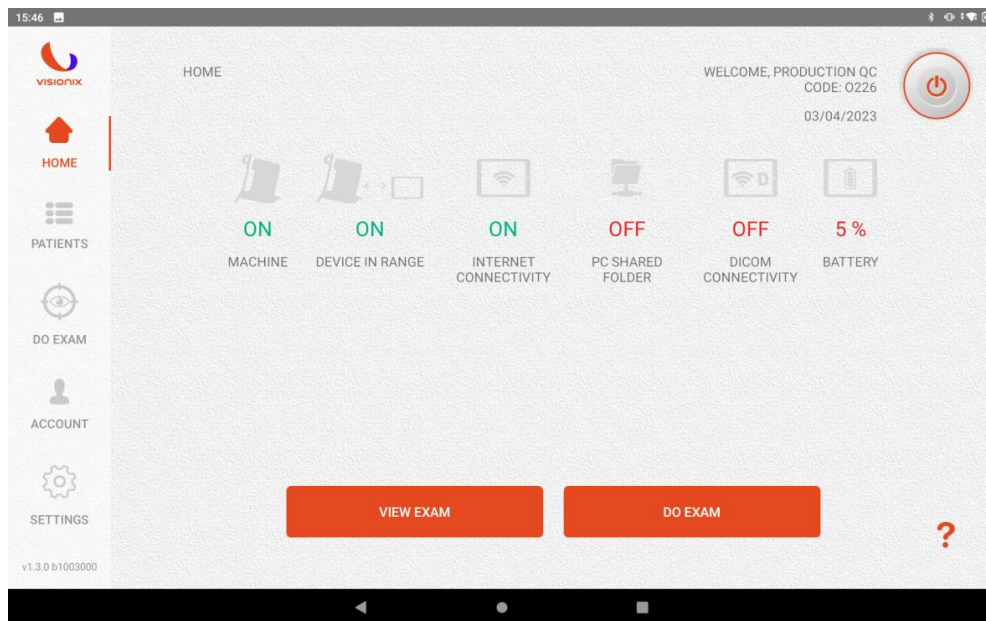






6.f) Shared Folder

If Shared folder is available (but not yet configured) on your account, the dedicated icon “PC Shared Folder” is visible on the VX610 home page of the APP.

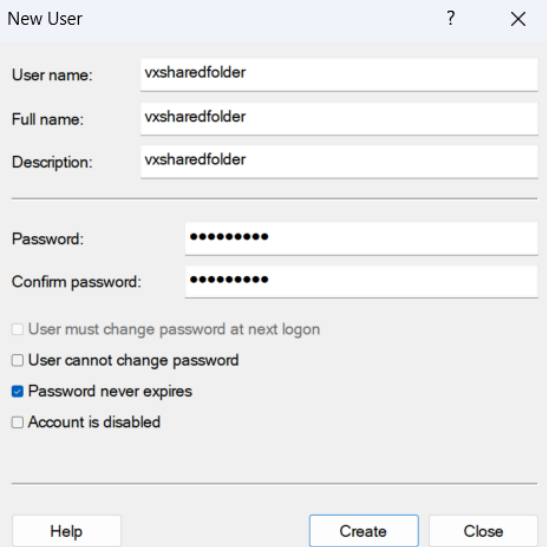
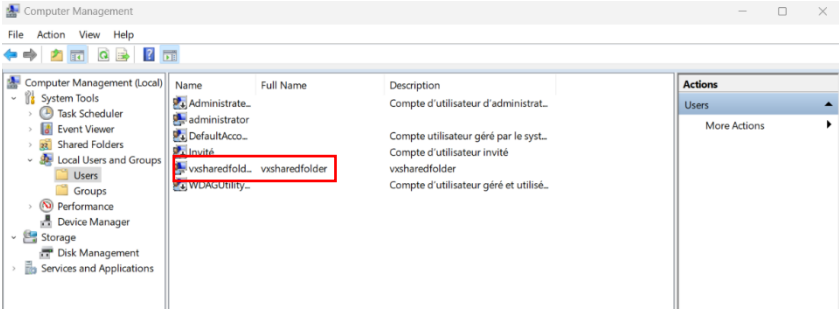
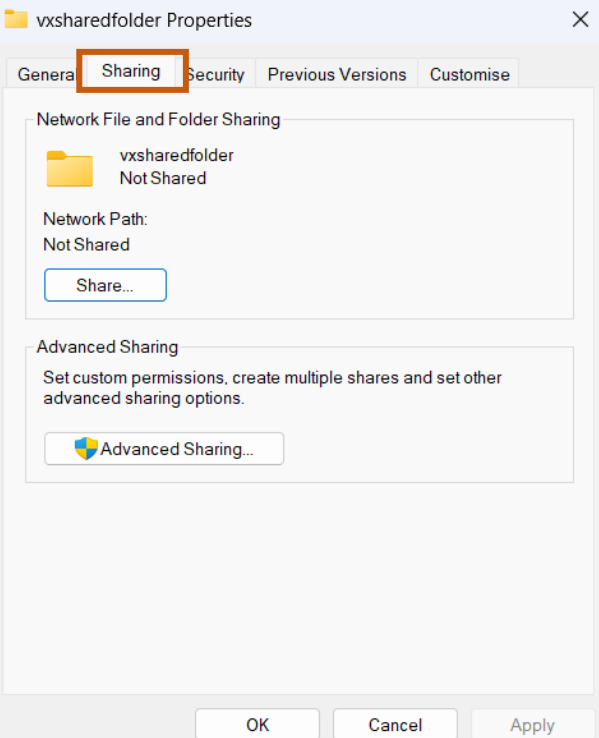


SETUP INSTRUCTIONS:

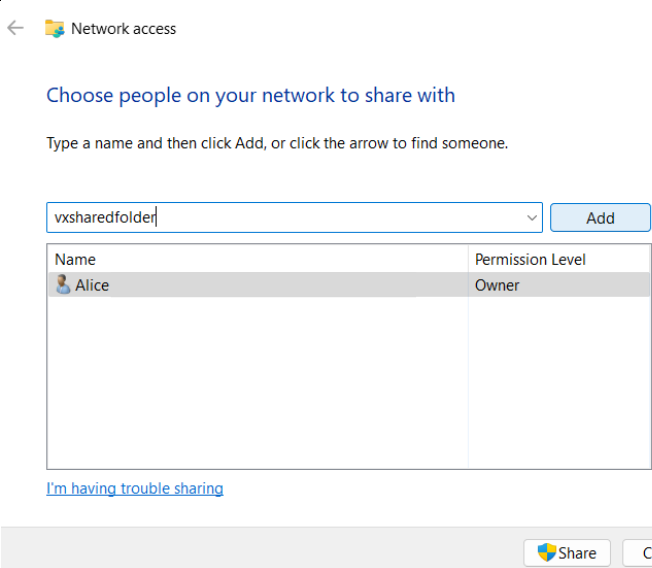
On Windows 10 and 11:

On the computer, open the « computer management ».

Local Users and Groups	
Select Users More Actions => new user	

Create your user name by using what you want, same for the password. Then, click on “Create” and “Close”	
You can now see the new user.	
On your local disc “C” create a file with the same name as the one the user created before.	
Click right on the file => properties And then on “Sharing”	

Write the same name that you've just created and click on "add"



Network access

Choose people on your network to share with

Type a name and then click Add, or click the arrow to find someone.

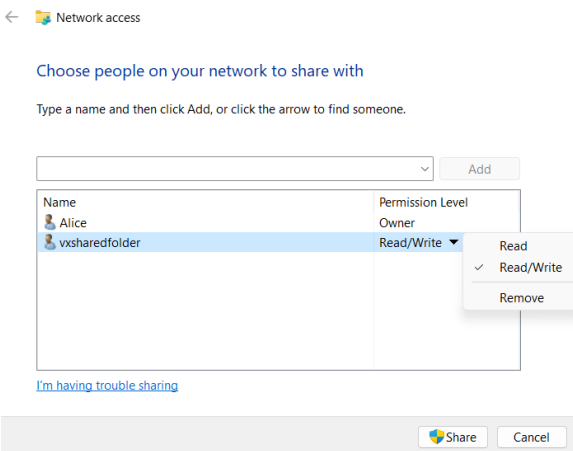
vxsharedfolder Add

Name	Permission Level
Alice	Owner

[I'm having trouble sharing](#)

Share Cancel

**Read / write
And validate by clicking on share.
And then done
And close.**



Network access

Choose people on your network to share with

Type a name and then click Add, or click the arrow to find someone.

vxsharedfolder Add

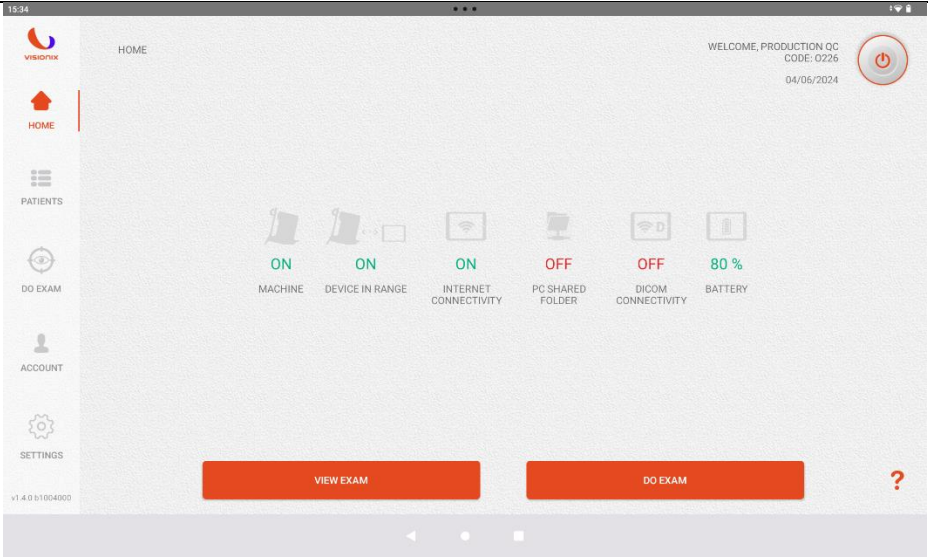
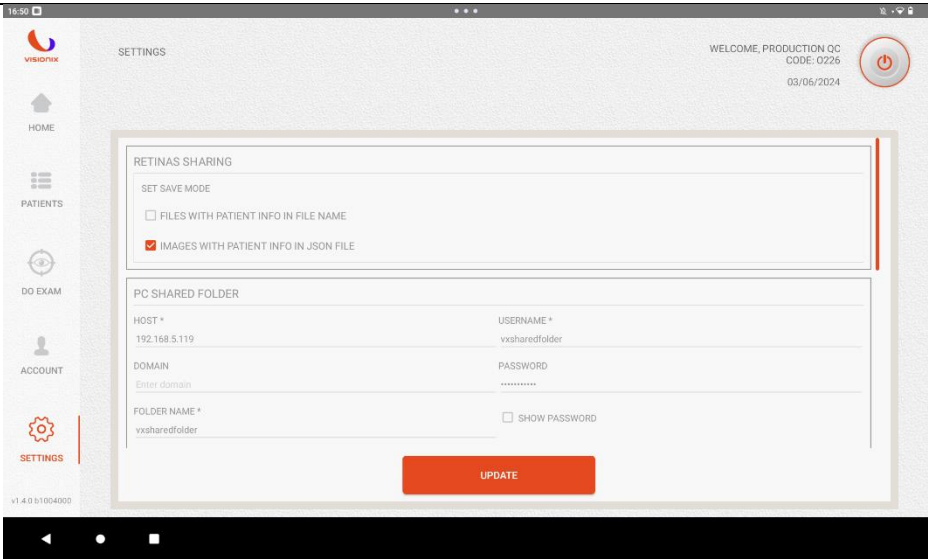
Name	Permission Level
Alice	Owner
vxsharedfolder	Read/Write

[I'm having trouble sharing](#)

Share Cancel

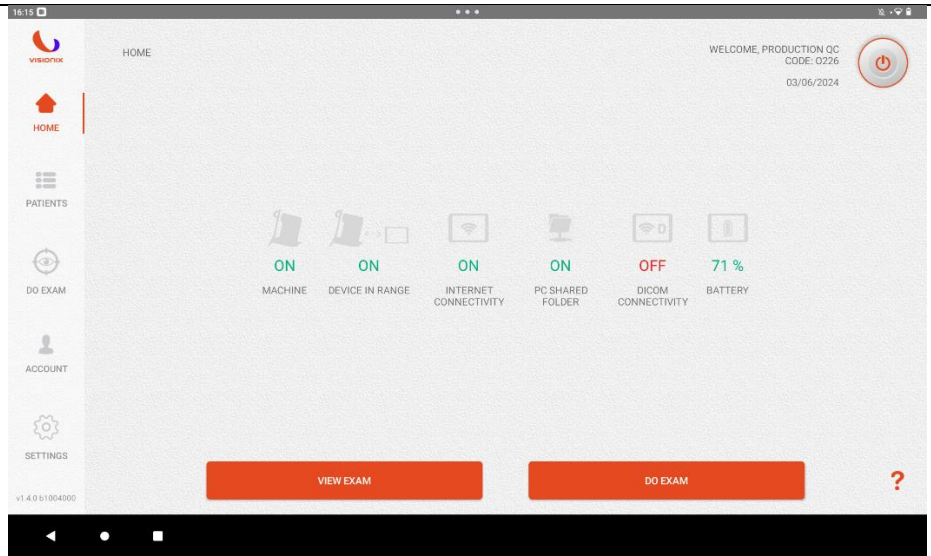
2) Take note of the name of the shared folder file, the username and the password. And the IP address (IPv4).

On the tablet:

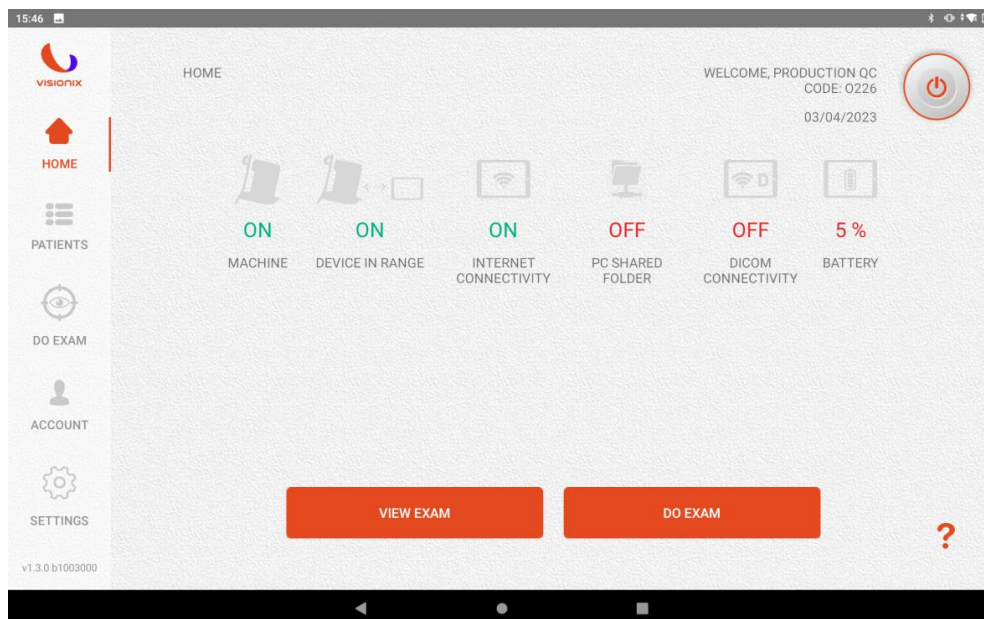
Go to “Home” PC shared folder is still OFF.	
Go to Settings	
Fill in the different fields	Host : IP address of the computer Username : Name of the user that you’ve created on the computer Password : Same password used for the username created Foldername : name of the file created on your local disc C.

Validate by clicking on “update”, and go to “Home”.

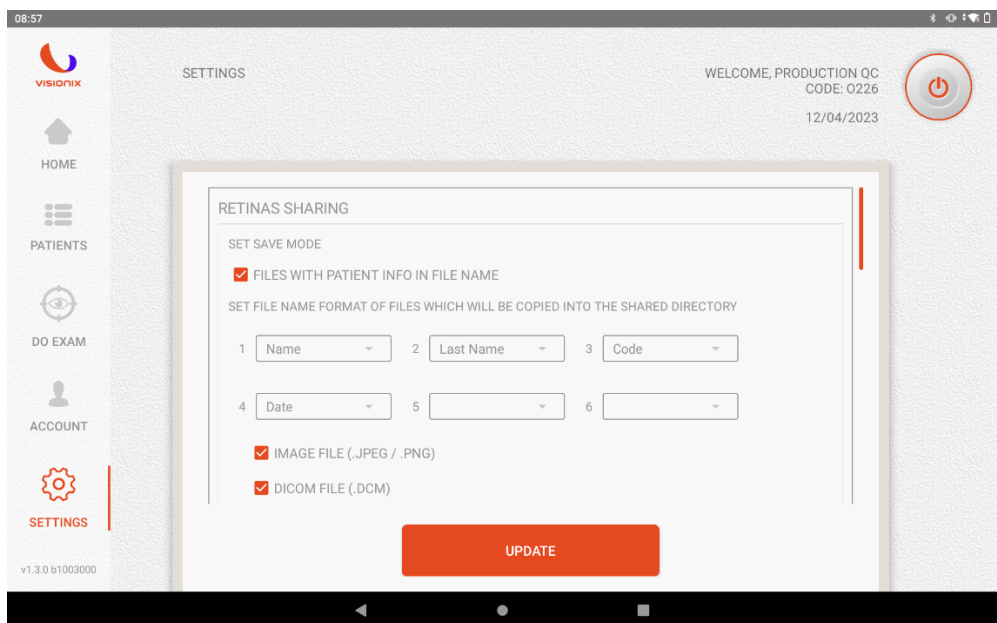
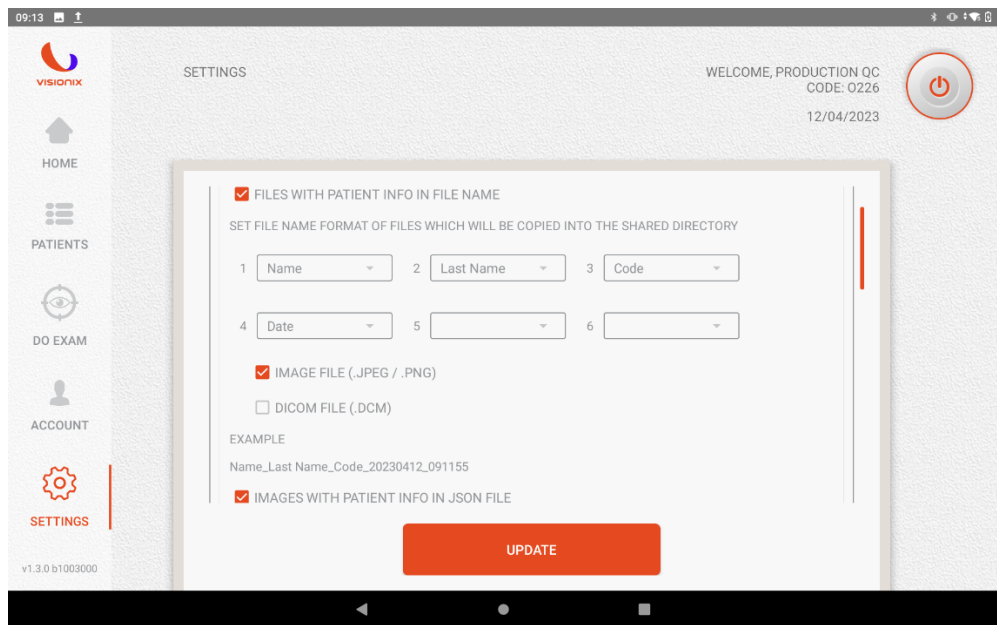
Now you can see the status is “ON”.



- 3) You should see an icon PC SHARED FOLDER on dashboard. At first the icon will be red (OFF). If there is no icon, try log out and then back in.

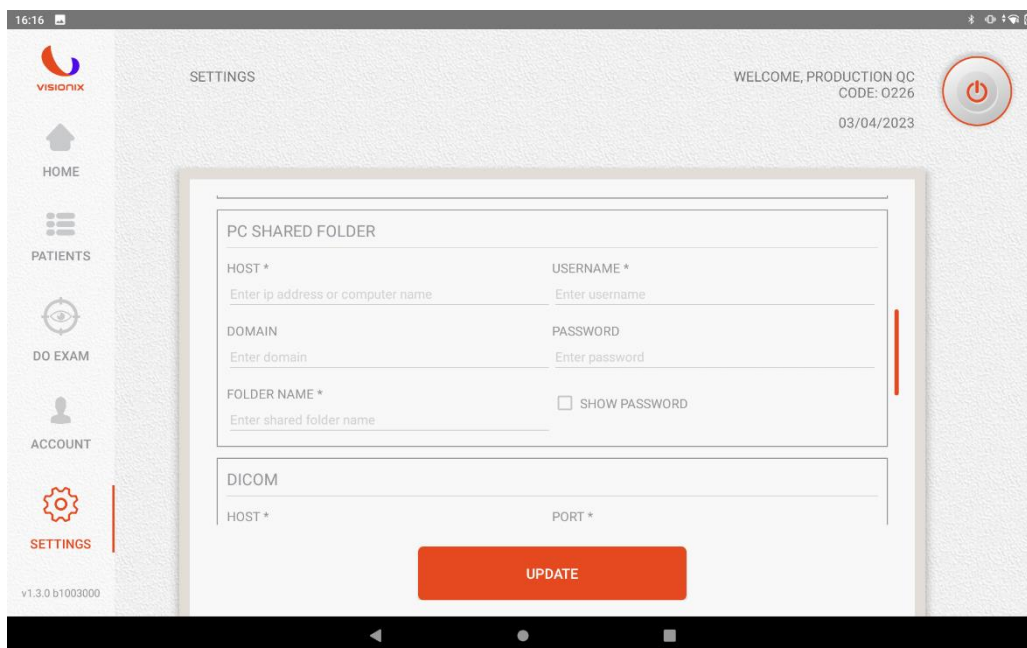


- 4) Tap on the Settings icon on the lower left corner (see the figure below) and choose what kind of sharing you need: either .jpg images with the patient's info in the file name, or a combination of .jpg and .json files, the latter holding the patient's info.
- 5) By selecting the "IMAGES WITH PATIENT INFO IN IMAGE FILE NAME", you also get to choose what kind of information to display, and in what order (see figure below), by using the combo boxes elements. Below the combo boxes you also get an example of the resulting filename. The option "IMAGES WITH PATIENT INFO IN THE JSON FILE" don't have this kind of option, because all the patient's info is contained in the json: it's up to the program that reads it to pick the information that it needs.
- A combination of the above save mode solution is allowed.



- 6) By scrolling up a bit (see figure below), you will see a page titled “PC SHARED FOLDER” asking you the HOST, the FOLDER NAME, the USERNAME, and the PASSWORD (optionally the DOMAIN). Fill the fields using the data from step 1). Please

note that the fields are case sensitive.

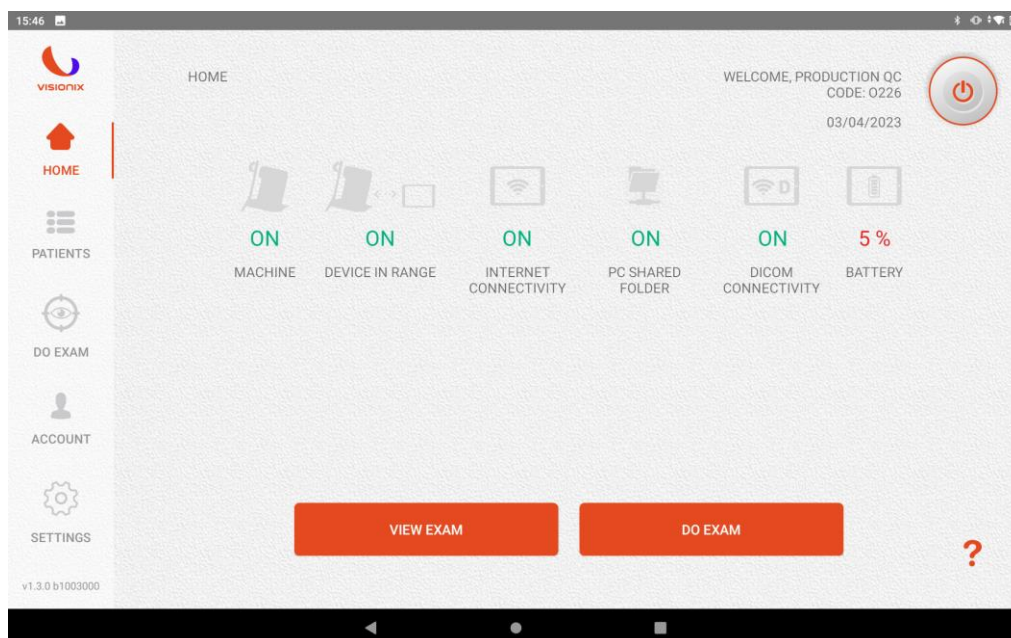


9.1) The HOST is the name or the IP address of the PC that contains the shared folder (i.e. laptopo-7gu05p3u or 192.168.1.100).

9.2) The FOLDER NAME refers to the name of the shared folder (i.e. “Shared” in the image above).

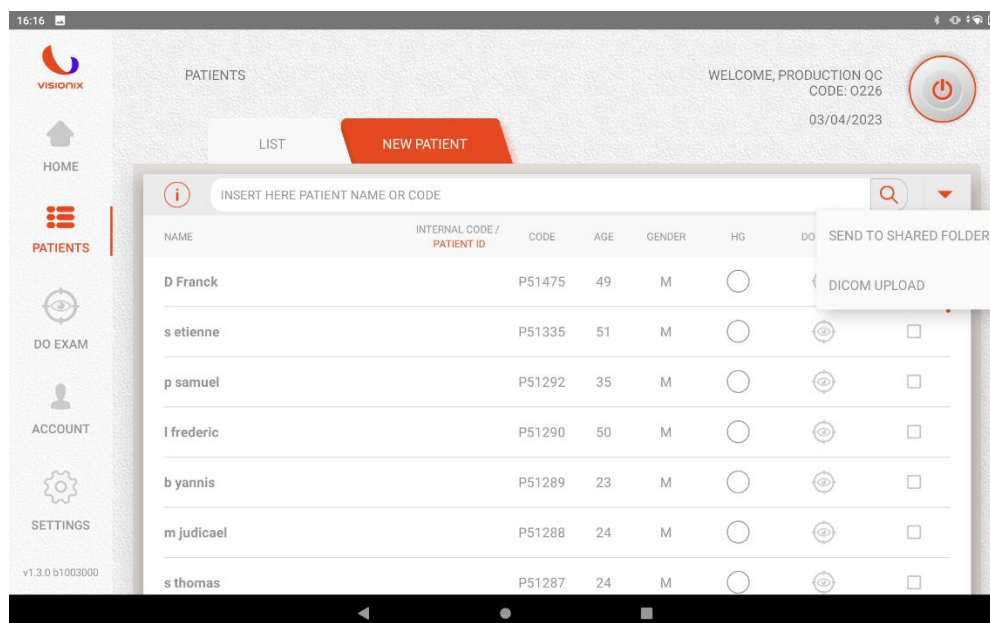
7) Tap on UPDATE and then log out and then log in using your credentials.

8) On the HOME icon (upper left on the tablet); if all goes well the icon SHARED FOLDER should turn green (ON).

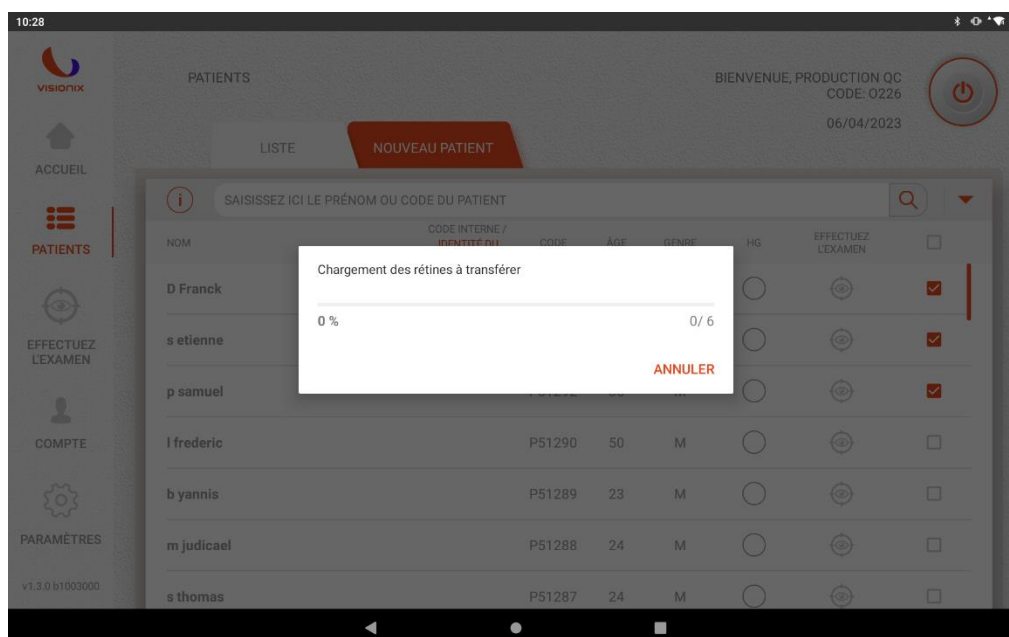


9) From now on, every exam performed using this tablet should create a .jpg file and/or a .json in the shared folder on the PC.

10) If you need to re-send one or more exams, tap the **PATIENTS** icon on the left; you should see a column of checkboxes on the right - one for every patient (see figure below). Check the patients that you want to re-send, then tap the orange downward-pointing triangle at the top of the column and choose “**SEND TO SHARED FOLDER**”. The selected patients should appear as a set of .jpg and/or .json files on the shared folder.

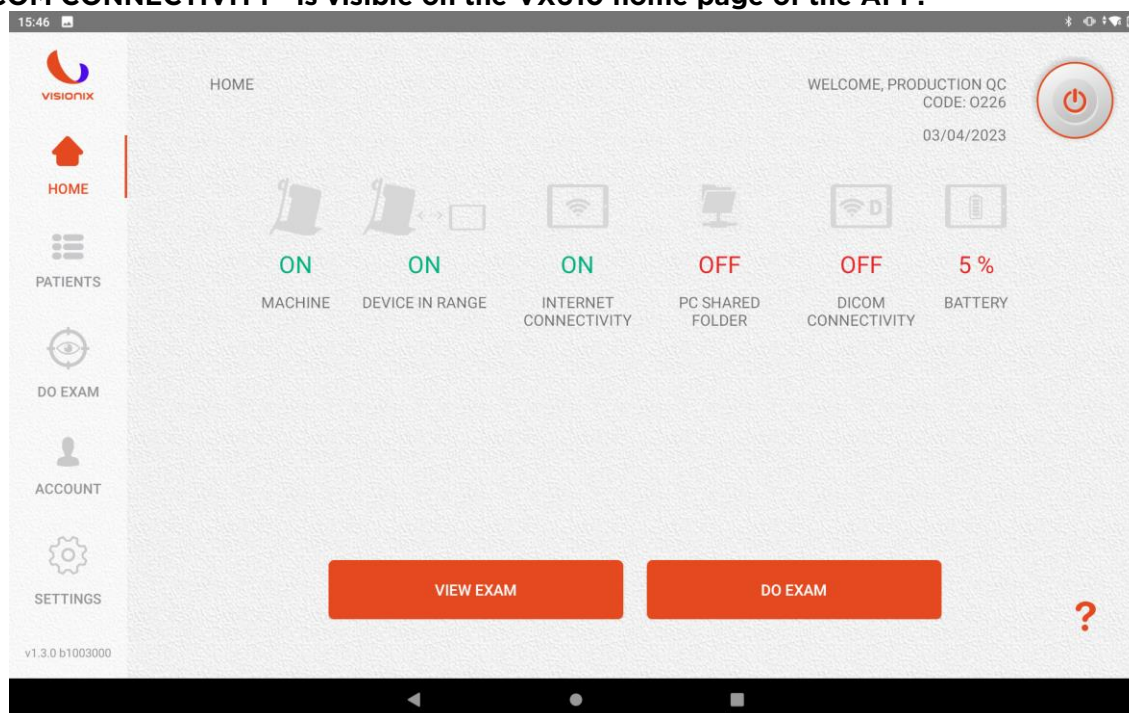


Then wait for the transfer to take place.

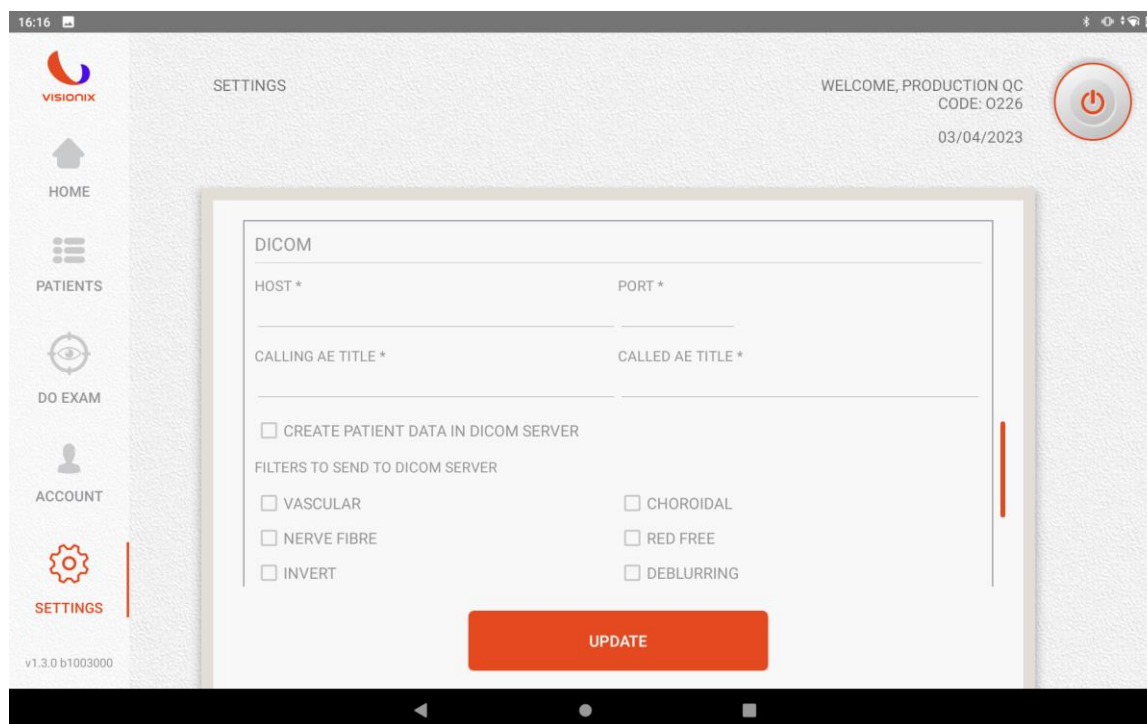


6.g) DICOM Setting

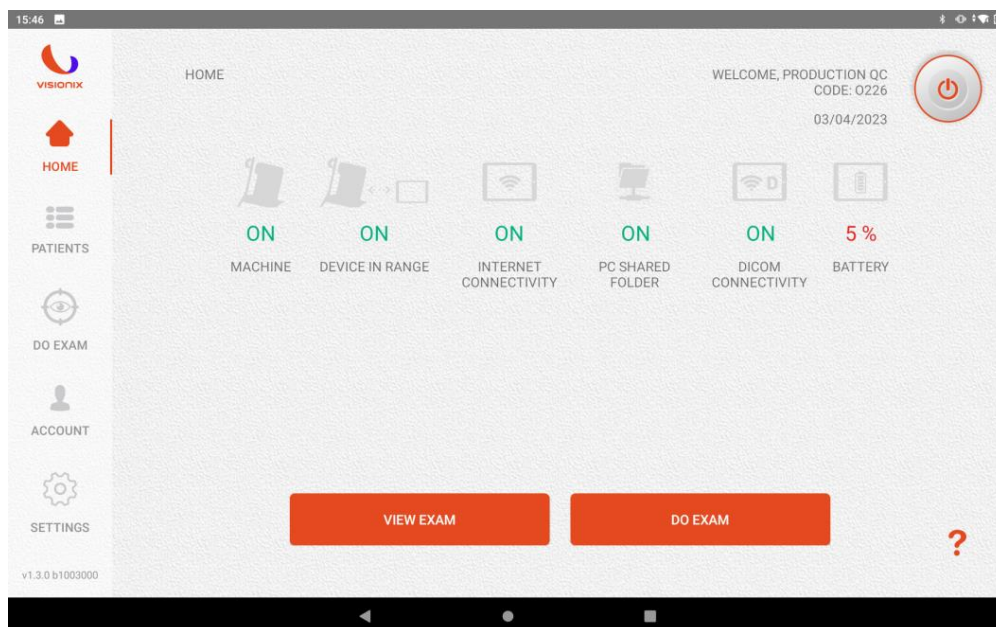
If DICOM connectivity is available (but not yet configured) on your account, the dedicated icon “DICOM CONNECTIVITY” is visible on the VX610 home page of the APP.



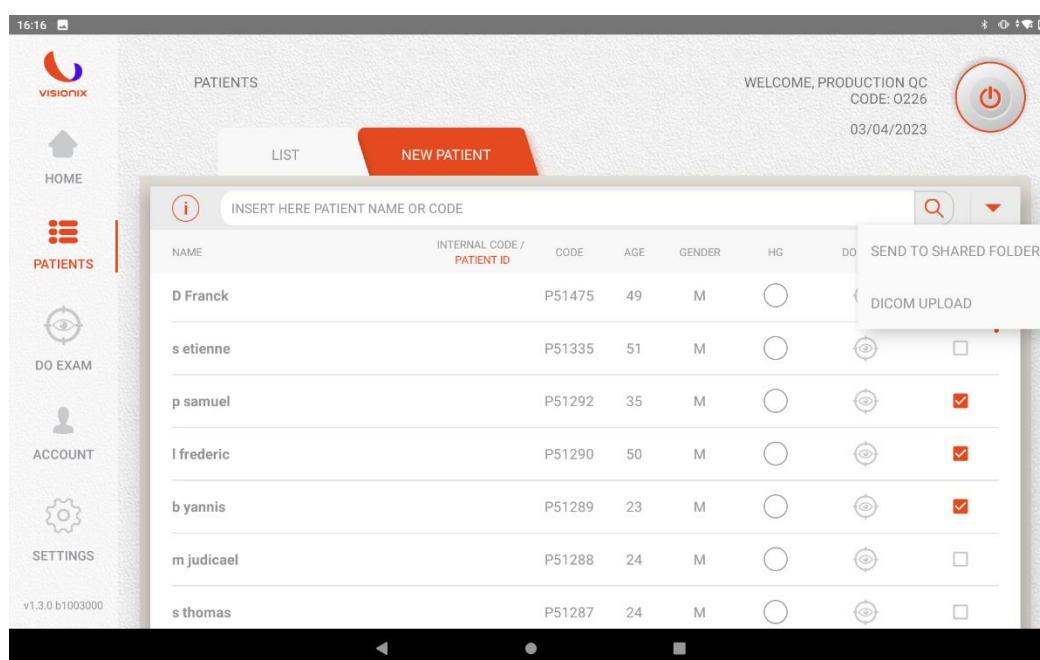
To configure the DICOM server, click on the settings icon and enter the references to fill in the fields shown in the figure:



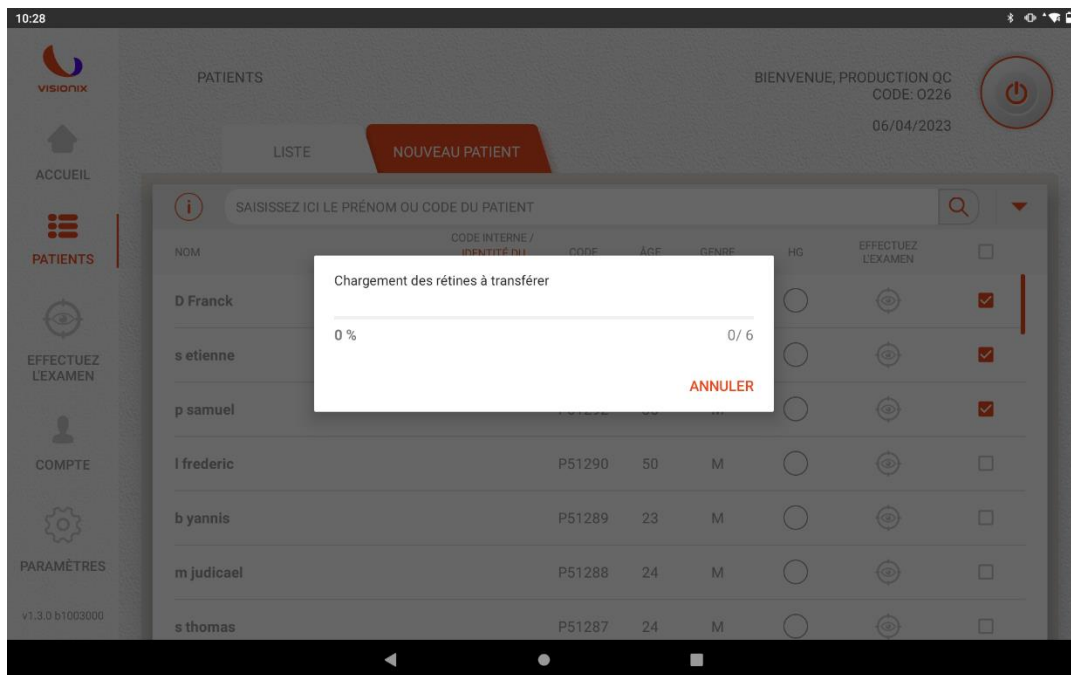
The active connections are shown on the Home as shown in the figure below.



If the status of the DICOM indicator is ON (as in the figure) the captured images are automatically sent to the DICOM server while still keeping the copy on tablets and servers. The user can still send images to the DICOM server at any time by clicking on the drop-down menu at the top right, select "DICOM UPLOAD."



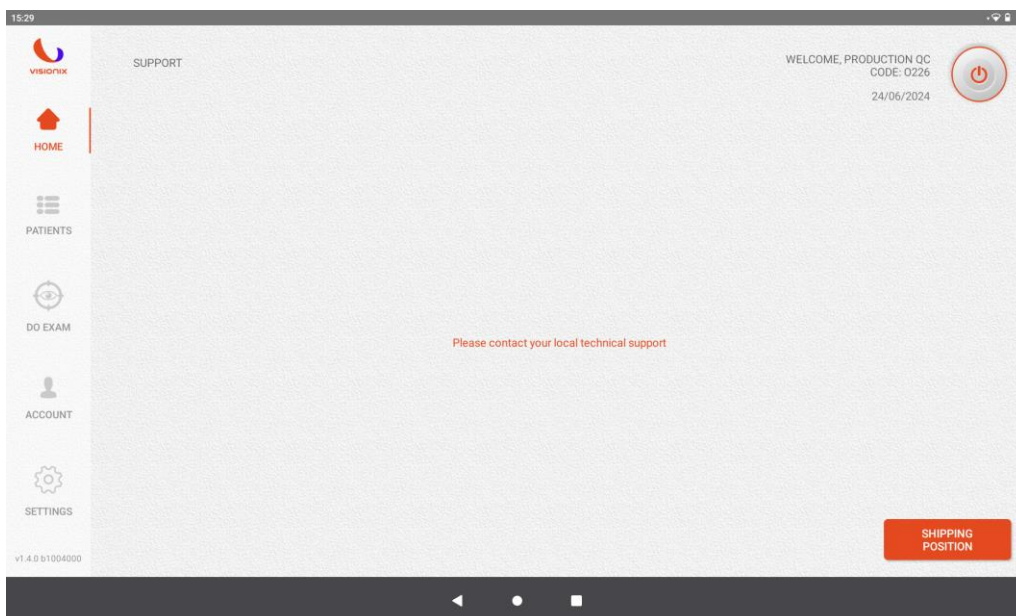
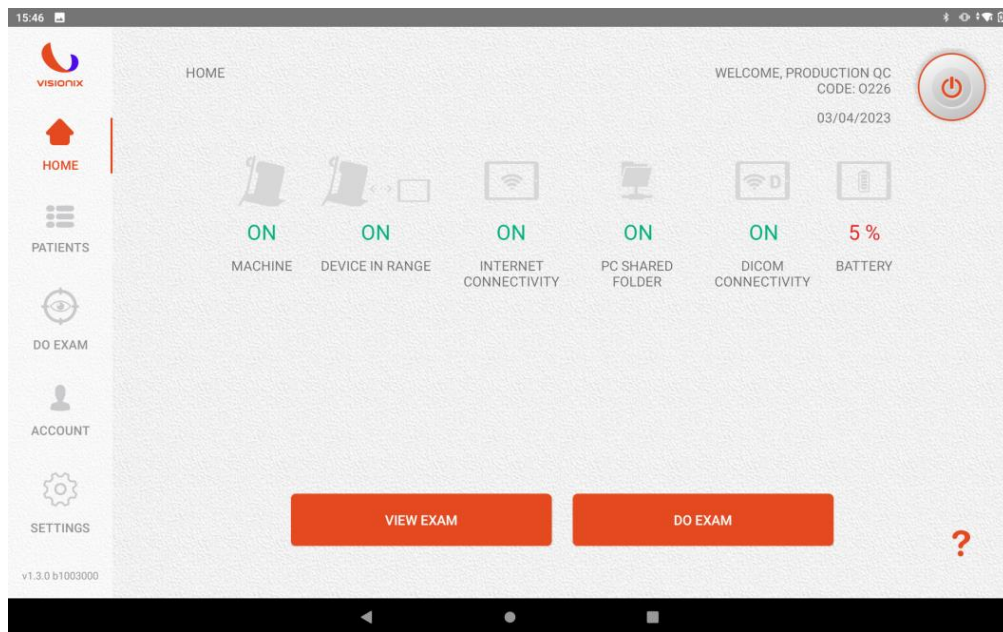
Then wait for the transfer to take place.



6.h) Optional Functionality Of TeamViewer For Remote Support

This feature is used by both Visionix service personnel and the distributor in case it has been authorized by Visionix to perform remote support from a tablet. In the event that the distributor takes care of the remote support, he must have purchased the license of TeamViewer necessary to provide this type of support to its customers.

To make the service staff turn on the tablet to identify the problems encountered by the user, the user must click on the icon 



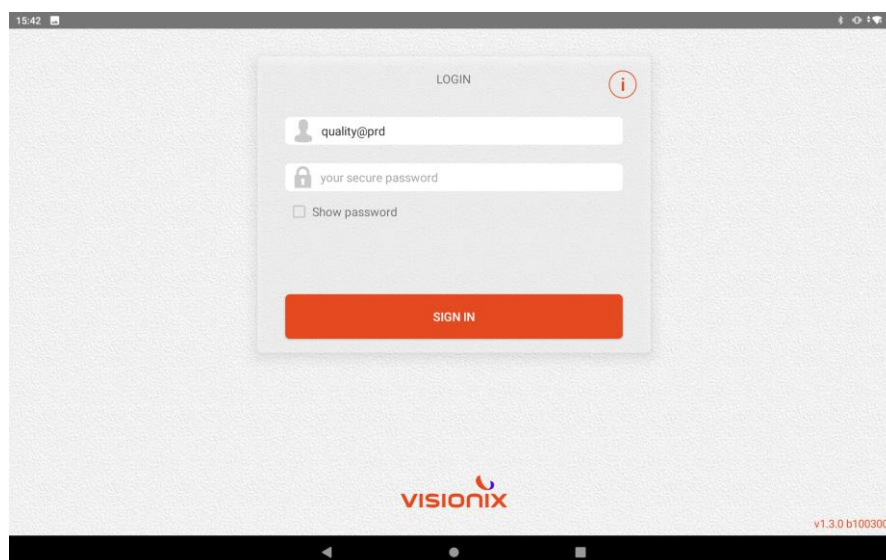
Before sending the device back you need click on the bottom “Shipping Position” first.

Then you will need to lock the device by using the flat screwdriver, and screw the locking screw.

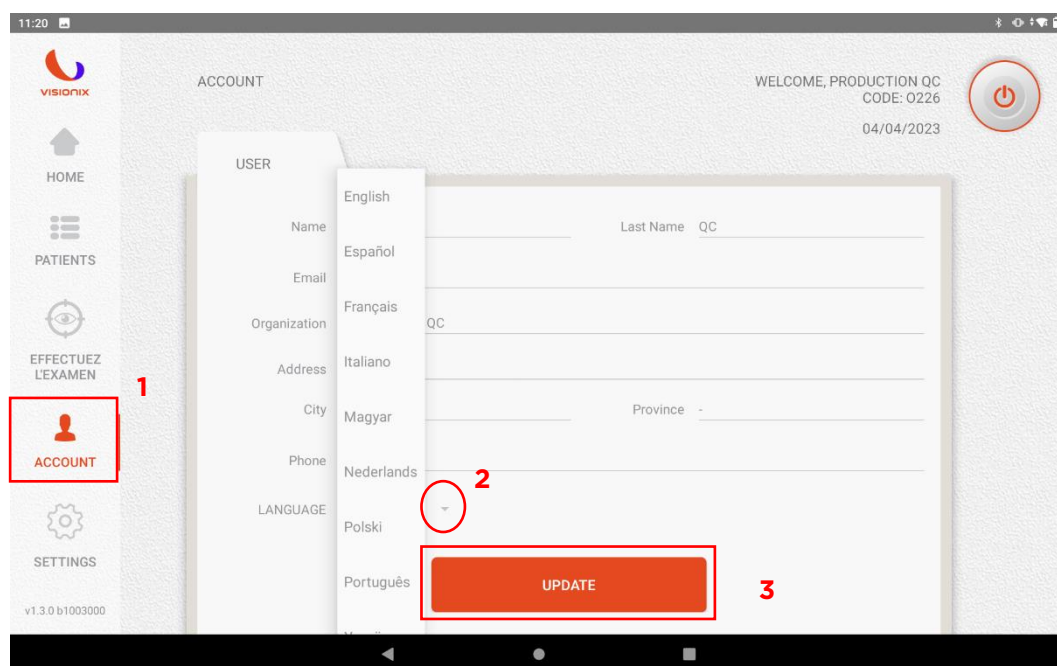


VIII - Change APP language

1. Take the tablet and (using your own credentials) login on the VX610 APP

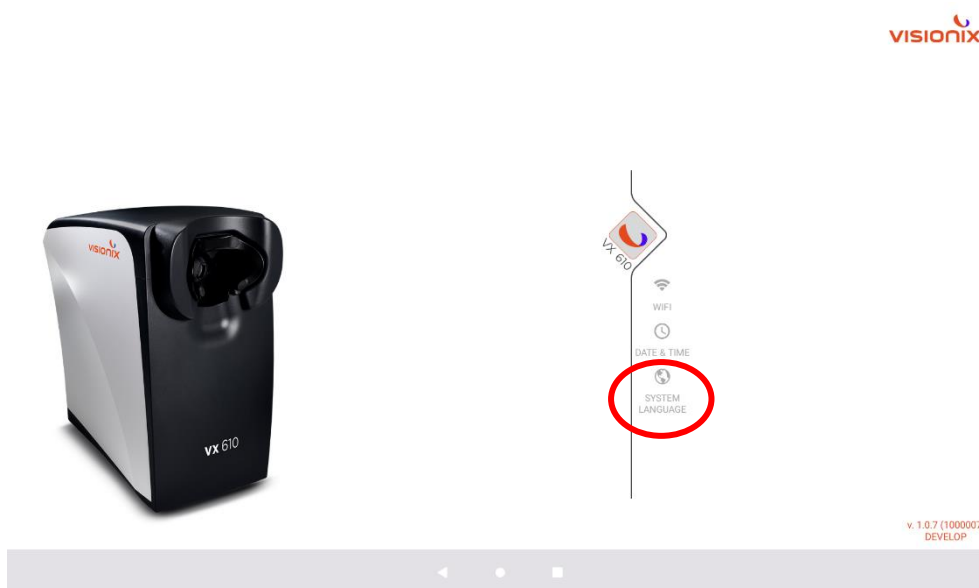


2. Go on the section "Account" (1), click on the triangle red circled on the figure below (2) and choose the language desired; then click on "UPDATE" (3).

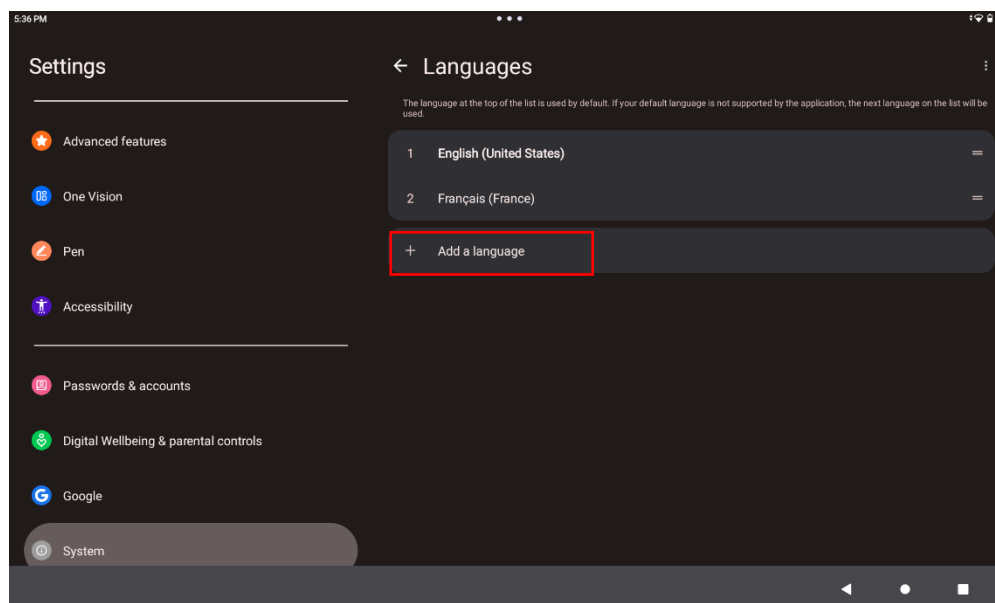


IX - Change system language

1. On the first page, select “System Language” red circled on the image below:



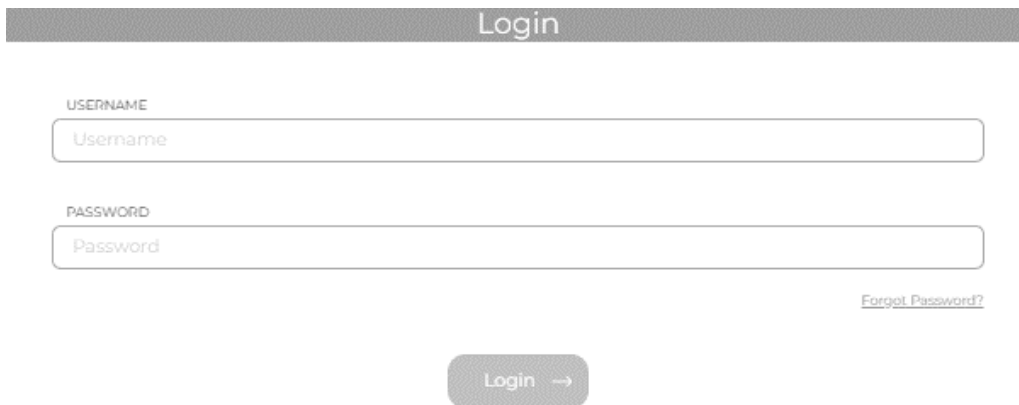
2. The page shown below will open; the user can select the desired system language from the list by clicking on “Add a language”.



X - Change password

1. Go on the “Reserved area” at the web site <https://nexus.visionix.com/login> and insert the credentials:

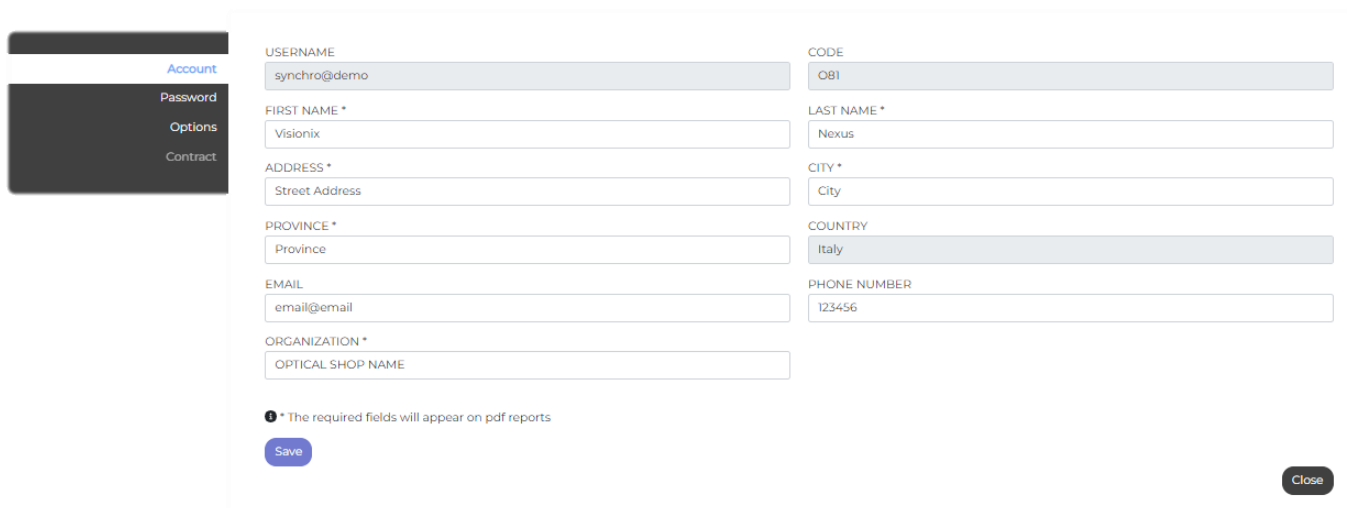
- **USERNAME:** insert the username of your account
- **PASSWORD:** insert the password of your account



The screenshot shows a login page with a dark header containing the word "Login". Below the header, there are two input fields: "USERNAME" with the placeholder text "Username" and "PASSWORD" with the placeholder text "Password". To the right of the password field is a link that says "Forgot Password?". At the bottom center, there is a button labeled "Login" with a right-pointing arrow.

Then Click on “Login”.

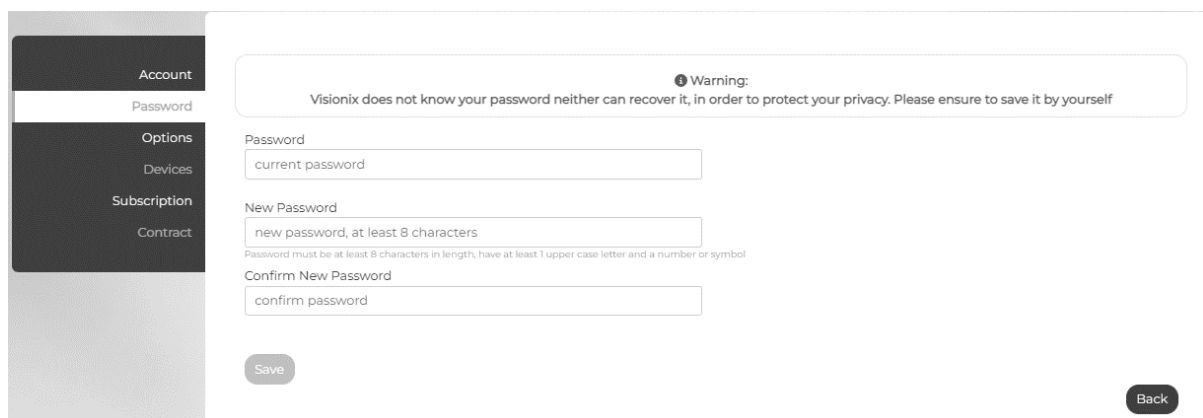
2. Go on “Profile” section



The screenshot shows a profile editing page. On the left is a dark sidebar with a menu containing "Account", "Password", "Options", and "Contract". The "Account" option is highlighted. The main content area contains a form with the following fields: USERNAME (filled with "synchro@demo"), CODE (filled with "081"), FIRST NAME * (filled with "Visionix"), LAST NAME * (filled with "Nexus"), ADDRESS * (filled with "Street Address"), CITY * (filled with "City"), PROVINCE * (filled with "Province"), COUNTRY (filled with "Italy"), EMAIL (filled with "email@email"), and PHONE NUMBER (filled with "123456"). There is also an ORGANIZATION * field with the placeholder "OPTICAL SHOP NAME". A note at the bottom left states: "The required fields will appear on pdf reports". At the bottom left of the form is a "Save" button, and at the bottom right is a "Close" button.

And click on “Password”.

3. Then insert current password, new password and insert again the new password chosen on the field “Confirm the new password”.



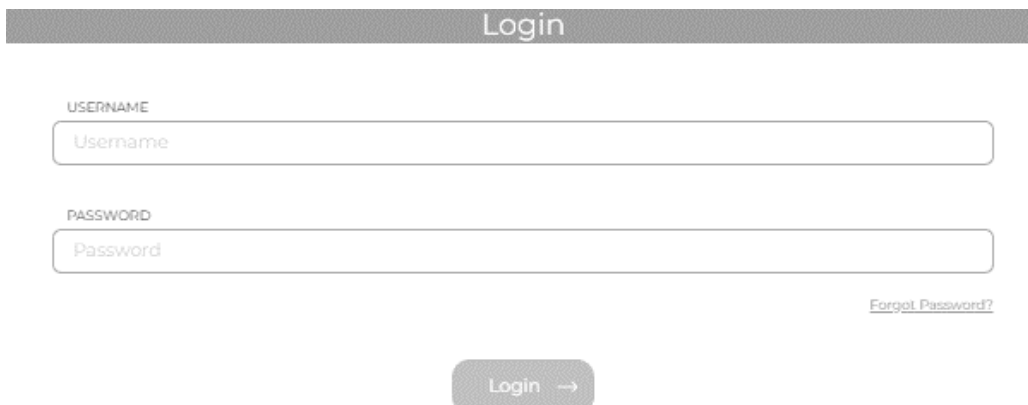
The screenshot shows a password change page. On the left is a dark sidebar with a menu containing "Account", "Password", "Options", "Devices", "Subscription", and "Contract". The "Password" option is highlighted. The main content area features a warning message at the top: "Warning: Visionix does not know your password neither can recover it, in order to protect your privacy. Please ensure to save it by yourself". Below the warning are three input fields: "Password" (filled with "current password"), "New Password" (filled with "new password, at least 8 characters"), and "Confirm New Password" (filled with "confirm password"). A note below the "New Password" field states: "Password must be at least 8 characters in length, have at least 1 upper case letter and a number or symbol". At the bottom left of the form is a "Save" button, and at the bottom right is a "Back" button.

Then click on “Save. This new password, will be the new password for the device too.

XI - Recover your lost password through the PUK code

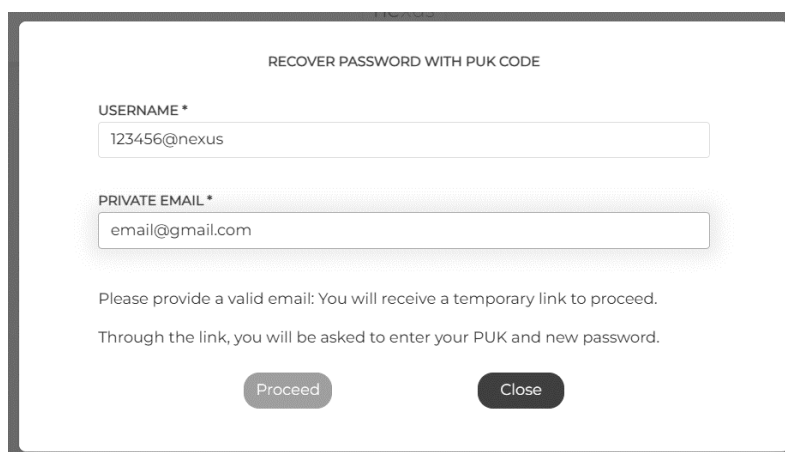
Password can be recovered with PUK code following the instructions below:

1. Go on the reserved area at <https://nexus.visionix.com/>
2. On the login page click on “Forgot password?” option to enter the recovery section



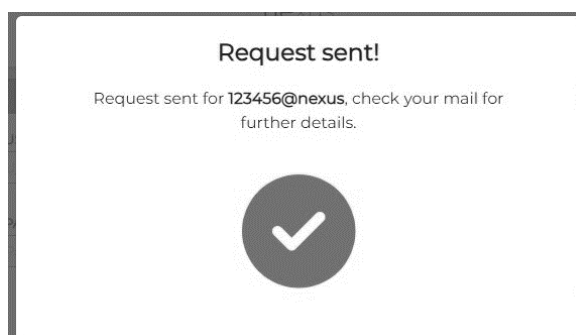
The login form is titled "Login" in a grey header bar. It contains two input fields: "USERNAME" with a placeholder "Username" and "PASSWORD" with a placeholder "Password". Below the password field is a link labeled "Forgot Password?". At the bottom center is a grey button labeled "Login" with a right-pointing arrow.

3. Insert the username and a private accessible email address to proceed with the recovery: the user will receive an email with a 24-hours token in the mailbox



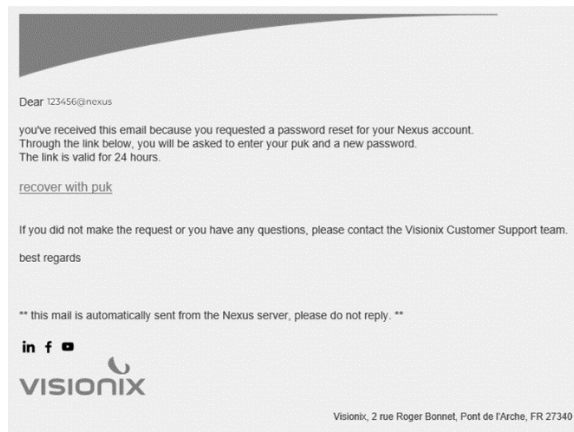
The form is titled "RECOVER PASSWORD WITH PUK CODE". It has two input fields: "USERNAME *" with the value "123456@nexus" and "PRIVATE EMAIL *" with the value "email@gmail.com". Below the fields, it says: "Please provide a valid email: You will receive a temporary link to proceed. Through the link, you will be asked to enter your PUK and new password." At the bottom are two buttons: "Proceed" and "Close".

4. When the request is sent, a message informs the user and ask to check the mail for further instructions (see image below).



The message box is titled "Request sent!". It contains the text: "Request sent for 123456@nexus, check your mail for further details." Below the text is a large circular icon with a white checkmark on a dark grey background.

5. User receives an email from noreply@nexus.visionix.com with the following subject: "**Nexus - Reset password with Puk**" to proceed with the recovery.
- If there is no e-mail in the Inbox, it's recommended to:
- check the Spam/Bulk/Junk folder
 - check the username inserted and/or
 - check if the email address is correct and valid.



Note: Password request recovery link expires within 24 hours. In case of expiry, when the link is clicked, a message informs the user (see image below) and a new recovery request must be sent.

Error, Token expired: The access token was revoked

OK

Note: Please note that a maximum of 10 attempts per day (24 hours) is allowed.

6. By clicking on the link "Recover with Puk" the user is automatically redirected to the page for the password recovery (see image below) to complete the fields shown in the image below.
- All fields are mandatory: username, PUK code, New Password, Confirm New Password**

RECOVER PASSWORD WITH PUK CODE

USERNAME *

PUK *

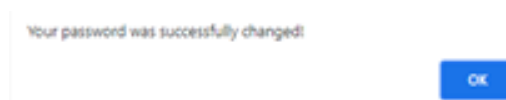
NEW PASSWORD *

Password must be at least 8 characters in length, have at least 1 upper case letter and a number or symbol

CONFIRM NEW PASSWORD *

Proceed Close

7. When "Proceed" button is clicked, in case of success of the procedure, a message informs the user.



XII - Problems - causes - solutions - alarms

PROBLEM	PROBABLE CAUSE	POTENTIAL SOLUTION
The device does not turn on	AC/DC adaptor is not plugged in	Connect the AC/DC plug adaptor to a power outlet with suitable power supply
	VX610 not connected to the AC/DC adaptor	Connect the jack of the AC/DC adaptor into the socket on VX610 device
The tablet does not turn on	Tablet batteries are not charged	Connect the tablet's charger and its microUSB cable to a power outlet with suitable power supply
Unable to log in on the initial screen of the tablet	No internet connection	If the tablet is connected to a Wi-Fi network, ensure that the network name and password are correct. If the tablet is equipped with a SIM card, verify the remaining credit.
	Incorrect username and/or password	Ensure that the username and password are correct. If they have been forgotten, go to the Visionix web site and follow the password recovery procedures.
The device does not respond to commands sent via tablet	Wi-Fi connection between tablet and VX610 failed	Connect VX610 to the Wi-Fi network via tablet
	The tablet is too far away from the device	Move the tablet closer to the device
The device's optical head continues to rotate without getting close to the patient	The device is unable to identify the patient's pupil	Remove the lens cover, if any.
		Ensure the correct positioning of the patient's forehead and cheekbones on the appropriate rests.
		Ask the patient to keep the eye wide open during the exam.
		The environment is too bright; turn off the lights in the room or reduce their brightness.
The optical head slowly approaches the patient, then stops and turns back	The patient is blinking too frequently	Ask the patient to keep the eye wide open during the exam.
The optical head quickly approaches the patient, then stops and turns back	This behaviour is normal if it only occurs once or twice; otherwise it is possible that the patient has moved	Ask the patient to remain still for the duration of the exam.

ALARM	CAUSE	REMEDY
Contact your service representative and report error code no. x	Internal malfunction no. x	Contact technical support
Make sure there are no obstacles in the path of movement of the machine and try again	Possible presence of obstacles that impede the movement of the optical head	Remove the obstacles and re-start the exam
The exam cannot be terminated. Make sure that the patient is correctly positioned in front of the machine and try again.	Incorrect positioning of the patient's forehead and cheekbones on the rests	Properly position the patient and start the exam again



If the device continues to present any anomaly which limits (even in part) the correct operating conditions despite of the verifications and interventions listed above, it is compulsory for the operator and user to immediately contact the authorised Technical Assistance of the dealer or manufacturer.



XIII - Maintenance

This section shows the maintenance operations permitted for the operator to perform. Maintenance must be carried out with the device turned off and the cable disconnected from the wall.

XIII.1 - Cleaning

Cleaning of plastic parts and the casing must be done with a damp soft cloth. Always avoid directly spraying the parts of the machine.

XIII.2 - Cleaning the lens

Particular attention must be paid to the cleaning of the front lens in order to not remove the anti-reflection coating, decreasing its exam performance. "Berkshire Bluesorb® 750" cloth moistened with 96% neutral pure ethyl alcohol or moistened "ZEISS Lens Cleaning Wipes" can be used.

XIII.3 - Cleaning the cheekbone and forehead rests

All parts in contact with the patient must be disinfected after each exam with a cloth moistened with a common disinfectant.



The use of jets or sprays of water or other substances that can damage the surfaces is not permitted.

XIII.4 - Periodic checks

The integrity of the power cord and any cracks on the casing of the device or AC/DC adaptor must be checked on a weekly basis; in the event of breakage, immediately contact your service representative.

XIV - Appendices

XIV.1 - Assistance

Visionix offers technical assistance, which can be reached by directly contact.

XIV.2 - Notifications – Alert

Any accident, malfunction and/or dysfunction, deterioration in the characteristics and performance of the device that has caused or may potentially be liable to cause harmful events for the operator/patient must be promptly reported by contacting the Manufacturer, in order to take all appropriate measures, including recalls.

XIV.3 - Manufacturer's declaration of electromagnetic emissions

The electro-medical device requires special precautions regarding EMC (Electromagnetic Compatibility) and must be installed and commissioned in accordance with the EMC information contained in the accompanying documents.

Portable and mobile radiocommunication devices can affect the operation of the EUT (Equipment under test).

The use of accessories, transducers and cables other than those specified, with the exception of those sold by the manufacturer as spare parts for internal components, may cause an increase in emissions and a decrease in immunity.

The appliance or the system must not be used near other equipment and, if it is necessary to use it near other equipment, the medical electrical equipment must be observed to check normal operation in the configuration in which it is used.

The electro-medical device has been tested and found to comply with the emission and immunity limits of electro-medical devices according to IEC 60601-1-2: 2014. These limits are designed to provide adequate protection against harmful interference in a typical medical installation. However, there is no guarantee that interference will not occur in a particular installation. If the electro-medical device, interacting with another device, causes or receives detectable interferences, the user is invited to limit the interference by adopting one or more of the following measures:

1. redirect or reposition the receiving device;
2. increase the distance between the devices;
3. connect the equipment into an outlet on a circuit different from or to the devices that cause interference.

XV - Contact information

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