



Instructions for Use Part 1 **VisionOne**



VisionOne V.1.0.1
November 2024

SWISS MADE 

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1. General Information

1.1 Device Description

PeriVision has developed a portable visual field-testing device that can run visual field tests on a Virtual Reality (VR) headset in much less time allowing more efficient clinical workflow while increasing patient comfort and compliance.

VisionOne is a mobile and light-weight perimeter, an alternative to the standard stationary perimeters. The software runs visual field testing on a virtual reality (VR) goggle which is connected to a server (Cloud or On-Premises).

VisionOne also includes a web application where the healthcare professionals can control the settings of the test as well as view and process the results.

The operation of VisionOne is similar to standard stationary perimeters

- Instead of projecting light stimuli inside a bowl-shaped device as in the standard perimeters, VisionOne shows light stimuli on the VR screen.-
- The patient's non-tested eye does not need to be occluded in VisionOne.
- The VR device enables the required dark environment for a visual field test, so VisionOne does not require a dark room.

1.2. Version of Medical Software: v1.0.1

1.3. Description and Requirements for System Hardware Components:








Virtual-Reality (VR) Hardware:

- Pico Neo 3 Pro Eye VR Headset and
- Controllers Puck's clickers


















Requirements for Frontend Application Software for Dashboards:
Computers with min. 8GB Ram and 80GB memory space

VisionOne software is only to be used with the Pico Neo 3 Pro Eye VR Headset. And Controllers as well as with the Puck's clicker

1.4. Important Information and Symbols

 UDI 764025502TD016S22	 EC REP Emergo Europe Westervoortsedijk 60 NL - 6827 AT Arnhem	 MD Medical Device
 Effectum Medical AG Kirchgasse 11 CH-4600 Olten www.effectummedical.com info@effectummedical.com	 0297	
 22.11.2024	 As long as VR operating system is supported	

Description of symbols

 Caution	 Read Instructions For use	 Conformité Européenne (European Conformity)
 Medical Device	 Keep Dry	 Do not discard as unsorted waste ; send to separate collection facilities for recovery and recycling
 Lot Number	 European Authorised Representative	 Reference Number
 Serial Number	 Use by date	 Do not use if damaged
 Date of Manufacture	 Humidity limitation	 Temperature limit
 Manufacturer	 Unique Device Identifier	

2. Intended Purpose and Use

2.1. Intended Purpose

The VisionOne software is intended to measure a patient's visual field, configure perimetry tests and display test results which are used to aid in the detection, diagnosis and monitoring of ocular and neurological diseases.

2.2. Intended Users

The intended users are Healthcare professionals trained in Ophthalmology / medical Technicians / Assistants /Nurses as operators and Patients / Laypersons only the as Test Participants

2.3. Intended Patient Population

VisionOne is intended for use on patients aged above 18 that have the physical and mental ability to perform the visual field test.

2.4. Medical Conditions to be diagnosed

VisionOne can be used for the diagnosis and monitoring of visual field loss which is one of the indicators for (but not restricted to) the following medical conditions:

- Glaucoma
- Stroke
- Neuro-ophthalmic conditions
- Multiple sclerosis (optic neuritis)
- Hyperthyroidism
- Pituitary gland disorders
- Intracranial and central nervous system disorders/tumours

2.5. Indications

Indications are: Visual field loss

2.6. Contraindications

VisionOne and its accessory are not intended to be used by people with:

- Claustrophobia
- Epilepsy
- Cognitive impairment
- Balance and orientation disorders
- Patients under the age of 18

2.7. Use environment

- VisionOne is intended to be used in facilities of ophthalmologists or optometrists' office rooms and/or similar available spaces in hospitals, clinics, physicians' offices, emergency centers, and nursing homes.



- The Intended Use Environment of VisionOne does not currently cover Home use under the sole control of Laymen.

- Our Intended Use, however, includes Visual Field Eye-tests, which are performed in a professional healthcare environment and under supervision of a physician or at least one healthcare professional. In such cases a detailed analysis of the requirements of Cybersecurity safety and HIPAA rules for protection of ePHI must be undertaken and according measures guaranteed. Please coordinate such uses in every case upfront with Perivision.

2.8. Product Claims and Medical Benefit

2.8.1. Performance Claims

The VisionOne system complies with the ISO standard EN ISO 12866:2000: Ophthalmic instruments: Perimeters. It meets the requirements defined in Section 4 of the EN ISO 12866:2000.

2.8.2. Benefits

The VisionOne System provides comfortable testing to the patients.

2.8.3. Non Medical Claims

The VisionOne System is easy-to-use and allows flexible clinical workflows.

2.9. General Warning

Execution of HEALTH SOFTWARE on an IT-NETWORK could result in previously unidentified RISKS to patients, USERS, or third parties

2.10. Electronic IFU and availability of print versions

- The electronically available (in the web application) English User Manual is for VisionOne v1.0.1. the source language, source of truth and shall prevail.
- It consists of of Part 1: e-IFU and part 2 (Detailed User Manual for execution of VisionOne)
- A printed version of this IFU can be ordered at Perivision SA, Route de la Corniche 3, 1066 Epalinges, Lausanne, Switzerland: please contact support@perivision.com

3. Warnings & Safety



3.1 General Safety Information on using the VR Headset

- This product is designed and intended to be used in an open and safe indoor area, free of any tripping or slipping hazards.
- To avoid accidents, remain conscious to the potential confines of your physical area and respect the boundary of your virtual area whenever you see it.
- Be sure to wear the lanyard when using the Controllers. Make sure that there is enough space around your head and body (at least 2 meters by 2 meters) to stretch your arms to avoid damage or injury to yourself, others, and your surroundings.
- This product is designed to accommodate most prescription glasses. Take care to wear the VR Headset in a manner, in which the VR Headset lenses do not rub or impact your prescription lenses.
- You may be able to relieve eye strain by watching distant objects. If you feel any discomfort, please stop using the product immediately.
- Do not expose the optical lenses to direct sunlight or other strong light sources. Exposure to direct sunlight may cause permanent yellow spot damage on the screen. Screen damage caused by sunlight exposure or other strong sources of light is not covered by the warranty.

3.2 Specific Safety Warnings

Please read the following warnings and information carefully before using the VR Headset and follow all guidelines on safety and operation. Failure to follow these guidelines may result in physical injuries

- Ensure that this product is used in a safe environment. By using this product to view an immersive virtual reality environment, users will not be able to see the physical environment.
- Move only within the safe area that you set and keep your surroundings in mind. Do not use near stairs, windows, heat sources or other hazardous areas.
- Confirm that you are in good health before using. Consult a doctor before using if you are pregnant, elderly, or have serious physical, mental, visual, or heart problems.
- A small number of people may experience epilepsy, fainting, severe dizziness, and other symptoms caused by flashes and images, even if they have no such medical history. Consult a doctor before using it if you have a similar medical history or have ever experienced the symptoms listed above.

Specific Safety Warnings continued

- Some people may experience severe dizziness, vomiting, palpitations and even fainting when using VR Headsets. Consult a doctor if you have experienced any of the symptoms listed above.

- Some people may be allergic to plastic, PU, fabric, and other materials used in this product. Long-term contact with skin may result in symptoms such as redness, swelling and inflammation. Stop using the product and consult a doctor if you experience any of the symptoms listed above.
- This product is not meant for extended use over 30 minutes at a time with rest periods of at least 10 minutes between uses. Adjust resting and usage periods if you experience any discomfort.
- If you have a big difference in binocular vision, or a high degree of myopia, astigmatism or far-sightedness, it is suggested that you wear glasses to correct your eyesight when using VR headset.
- Stop using the product immediately if you experience visual abnormalities (diplopia and sight distortion, eye discomfort or pain, etc.), excessive sweating, nausea, vertigo, palpitations, disorientation, loss of balance, etc.
- This product provides access to immersive virtual reality experiences and some types of content may cause discomfort. Stop use immediately and seek medical treatment if the following symptoms occur.
- Epilepsy seizures, loss of consciousness, convulsions, involuntary movements, dizziness, disorientation, nausea, somnolence, or fatigue.
- Eye pain or discomfort, eye fatigue, eye twitching, or visual abnormalities (such as illusion, blurred vision, or diplopia).
- Itchy skin, eczema, swelling, irritation or other discomforts.
- Excessive sweating, loss of balance, impaired hand-eye coordination, or other similar motion sickness symptoms.
- Do not operate a motor vehicle, operate machinery, or engage in activities that may have potentially serious consequences until you have fully recovered from these symptoms.
- Radio waves generated by this product and its accessories may affect the normal operation of implantable medical devices or personal medical devices, such as pacemakers, cochlear implants, hearing aids, etc.
- Please consult the medical device manufacturer about the restrictions on the use of this product if you use these medical devices.
- Keep a distance of at least 15cm from the implanted medical devices (such as pacemakers, cochlear implants, etc.) When this product and any accessories are connected. Stop using the headset and/or its accessories if you observe a persistent interference with your medical device.

3.3. Important Safety Information before and during Test Execution

3.3.1. Patients and Test Execution



- Patients should sit or lie comfortably and not stand or walk around while wearing the headset to avoid falls, bumping, or disorientation
- If patients report dizziness, claustrophobic feeling, or other discomfort before or

during a Visual Field Test (VFT), please ask them to stop the test immediately

- Please observe and ask whether headset sits tight but not too tight, and generally appears to sit comfortably and correct on Patient's head
- Generally, Patients with glasses can keep them on; Please advise people with glasses to place the headset carefully over the glasses from the front to avoid physical hurt or damaging of the glasses
- Please provide patients several minutes recovery time to address the risk of temporarily limited vision after the test.

3.3.2. Specific further risks and mitigations to enhance test validity and avoid erroneous results

- Please confirm before a VFT that all electrical components are charged and connected (recharge latest when less than 20% level on dashboard or VR headset)
- Please confirm by checking in the VR or asking the Patient, that the Patient has been assigned the correct test
- Please make sure that the test room is neither too bright nor too dark
- Ideally put test results in context with former VFTs and other eye tests and check consistency with these other results.
- Do not base diagnosis on one single test result.
- Please note that In Cases of very advanced Glaucoma lower luminance levels of VR-based perimetry can lead to unreliable stimuli responses in test regarding degree of visual field loss and to difficulties to recognize further progression. In such cases it is recommended to retest with a stationary perimeter or to increase stimuli sizes.
- If the patient should experience VR sickness symptoms such as dizziness or nausea,
 - they should remove the headset immediately. This product is designed to accommodate most prescription glasses up to a width of 160mm. Make sure to wear the headset in a manner to not scratch the lenses with the glasses. However, the eye tracking functionality might be compromised.
- Do not expose the optical lenses to direct sunlight or strong light sources. The exposure can cause serious and immediate damage to the headsets optical system.
- Make sure the test environment is neither too dark nor too bright. Ideally, the room is homogeneously illuminated. If the room is too dark, the four tracking cameras on the outside of the headset will fail. If the room is too bright, or the patient sits with a window or bright light source in their back, reflections on the lenses may compromise measurements heavily.
- The normative database may be racially biased for SORS test strategies
- Ophthalmology best practice would not suggest basing a diagnostic decision on one eye-measuring methodology, like VFT alone. Best Practice would also include

the use of IOP (intraocular pressure), OCT (optical coherence tests) as well as regular checks of former VFT-results of this patient.

3.4. Disinfection

- The applied parts of the device should be always disinfected prior to any re-use of a device with a new patient. We recommend as an example "Clinell Universal Sanitizing Wipes", which should be widely available
- Do not use strong chemicals, cleaning agents or detergents to clean the product or its accessories, which may cause material changes that affect eye and skin health. Please follow the instructions in "product care" to take care of the equipment. Allow children or pets to bite or swallow the product or its accessories.

3.5. Transportation safety

- Do not use the product when walking, cycling, driving, or other situations that require full visibility.
- Do not use the device outside of its medical use environment

3.6. Charger safety

- Only charging devices provided in the product package or specified as an approved device by the manufacturer should be used.
- When charging is completed, disconnect the charger from the equipment and unplug the charger from the power outlet.
- If the charging adapter or cable is damaged, discontinue using to prevent the risk of electric shock or fire.
- Do not operate the equipment or charger with wet hands to avoid short circuits, failure or electric shock.
- Do not use the charger if wet.

3.7. Battery safety

- VR Headsets are equipped with non-removable internal batteries. Do not attempt to re-place the battery, as doing so may cause battery damage, fire or human injury. The battery can only be replaced by Pico or Pico authorized service providers.
- Do not disassemble or modify the battery, insert foreign objects, or immerse in water or other liquid. Handling the battery as such can cause chemical leakage, overheating, fire, or explosion. If the battery appears to be leaking material, avoid any contact with skin or eyes.
- In case of material contact with skin or eyes, immediately rinse with clear water and contact your local poison authority.
- Do not drop, squeeze or puncture the battery. Avoid subjecting the battery to high temperatures or external pressure, which may result in corruption and overheating of the battery.

3.8. Incidents

- Any serious incident that has occurred in relation to the device must be reported to the manufacturer and the competent authority of the state in which the user and/or patient is established.

4. Operating environment

- Do not use the equipment in dusty, humid, dirty or near strong magnetic fields, so as not to cause internal circuit failure of this product.
- Do not use this equipment during thunderstorms. Thunderstorms may cause product failure and increase the risk of electric shock.
- Protect your lenses from light. Keep the product away from direct sunlight or ultraviolet rays, such as windowsills and automobile dashboards or other strong light sources.
- Keep the product and its general purpose equipment away from rain or moisture.
- Do not place the product near heat sources or exposed flames, such as electric heaters, microwave ovens, water heaters, stoves, candles or other places that may generate high temperatures.
- Do not apply excessive pressure to the product during storage or when in use to avoid damage to the equipment and lenses.

5. Requirements for general purpose equipment

- Only general purpose equipment approved by the product manufacturer, such as power supplies and data cables, can be used with the product.
- The use of unapproved third-party general purpose equipment may cause fire, explosion or other damages.
- The use of unapproved third-party general purpose equipment may violate the warranty terms of the product and the relevant regulations of the country where the product is located. For approved general purpose equipment, please contact Perivision.

6. Environmental protection

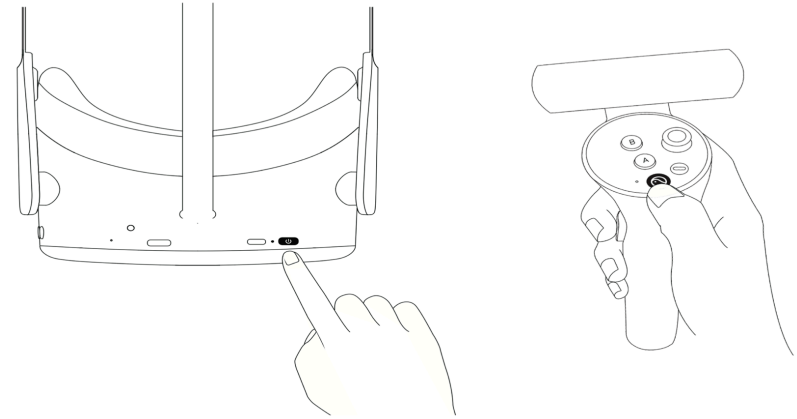
- Dispose of your headset and/or the Clicker properly. Do not dispose of the headset or Clicker in a fire or incinerator, as the battery may explode when overheated. Dispose of separately from household waste.
- Please comply with the local laws and regulations on the disposal of electrical and electronic equipment to dispose of this product and its general purpose equipment.

7. Device Components Overview

A VisionOne Box contains:

- 1 x Pico Neo 3 Pro Eye VR Headset
- 1 x Headset (contains internal battery)
- 2 x VR Motion Controller (uses 2 x AA battery each)
- 1 x Power Adapter and Cable
- Pico Neo 3 Pro Eye commercial user brochure
- 1 x One-button Patient Clicker (uses CR2023 Lithium Cell)

Switching on the Pico VR Headset and the Controllers



Use the power button **(1)** to turn on the VR Headset and press the controller's pico button **(3)** to turn on the controller(s).

VR Headset components

You are given a pair of the Pico Neo 3 Pro Eye Virtual Reality (VR) goggles with PeriVision's VisionOne VR Application installed (see **Figure 1**). Including a left and a right controller (see **Figure 2**). The labeled controls (1 - 4) are all the functions you are going to need to operate the VR headset. The Controller's layout is mirrored and can be used by right and left handed users and patients.

The headset

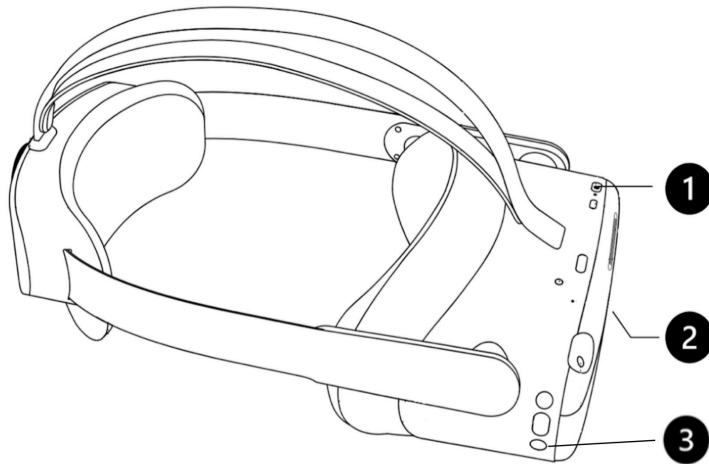


Figure 1 VR headset

1. Power button
2. Volume control (bottom side)
3. Pico button

The left and right hand controllers

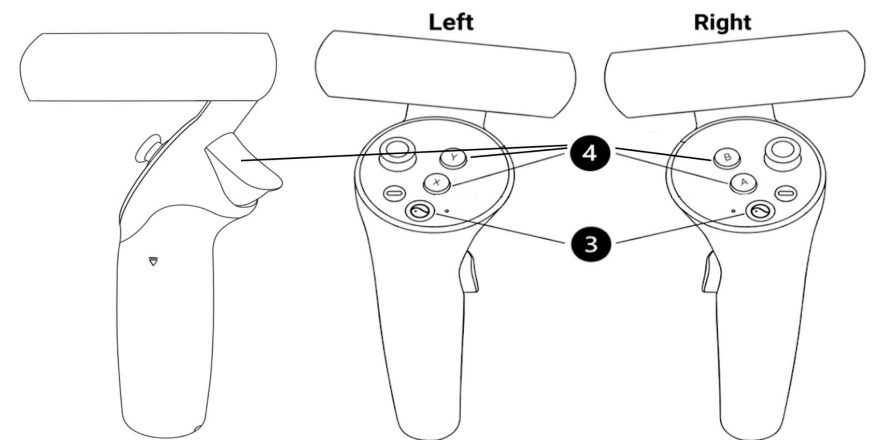


Figure 2

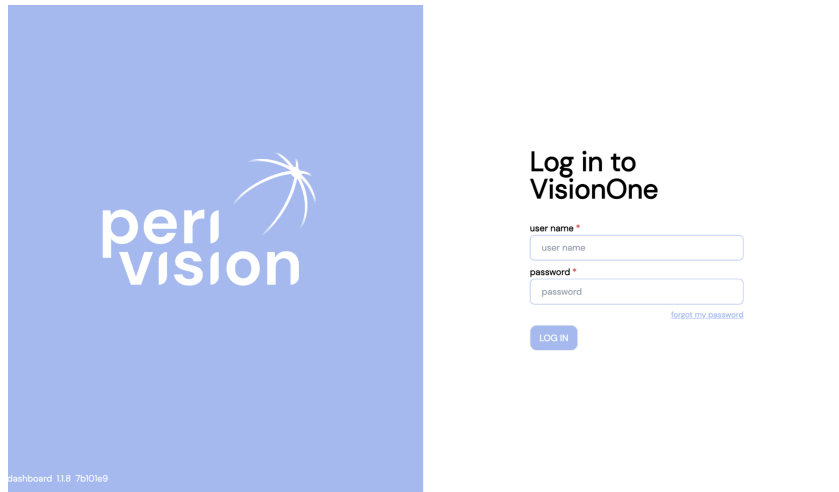
Left and right controllers with **(4)** X/Y/Trigger (left) and A/B/Trigger (right) buttons for patient's response and controlling the VR headset, **(3)** Pico button for general settings of the Pico VR headset.

8. Device Set-up

8.1. Web Application VisionOne

In order to view VR visual field test results, PeriVision provides a web application VisionOne.

8.1.2. Logging in



To access VisionOne, connect to the web page: <https://visionone.peri.vision>. Note that https is required, and that you may have to bypass any security warnings created by your firewall. Once connected, you are welcomed by a login dialogue. Please log in using your usual login data.

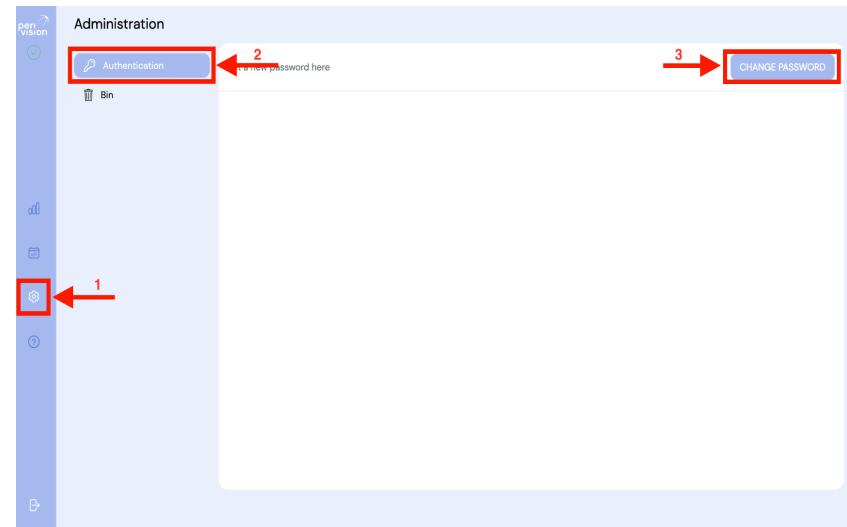
We recommend using Google Chrome as a browser. Fill up the user-name and password fields with your credentials and click the log in button to log in the clinician dashboard.

8.1.2 Password Reset

Follow the forgot my password link on the login page and follow the link that has been sent to the email inbox associated with the VisionOne user's account to set the new password for this user.

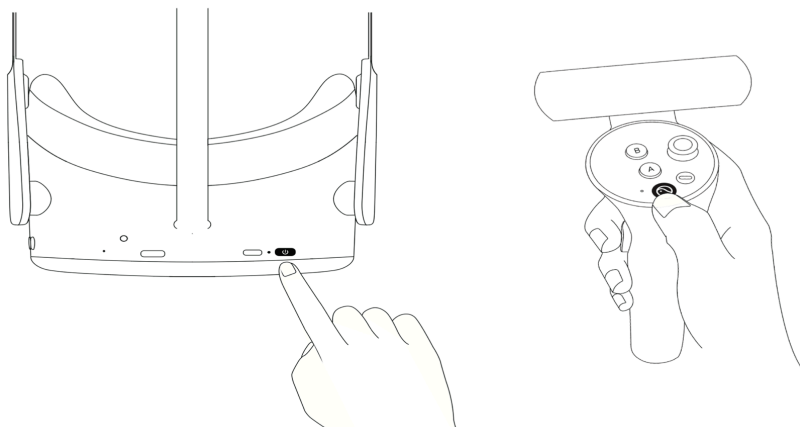
8.1.3. Password change

Once logged in, to change the existing password, go to settings, then to the authentication section and click on the CHANGE PASSWORD button:



The new window will open with the form to fill. Fill it in following the password requirements instructions and submit the change to set as the new password for this logged in User:

8.2. Switching on the Pico VR Headset and the Controllers



Use the power button (1) to turn on the VR Headset and press the controller's pico button (3) to turn on the controller(s).

The LED next to the power button indicates the VR headset status.

Blue: Powered on with battery over 20%

Red flashing: battery is less than 20%

Green: Charging complete

Off: Sleeping or powered off

Blue flashing: shutting down

Yellow: Charging battery is less than 98%

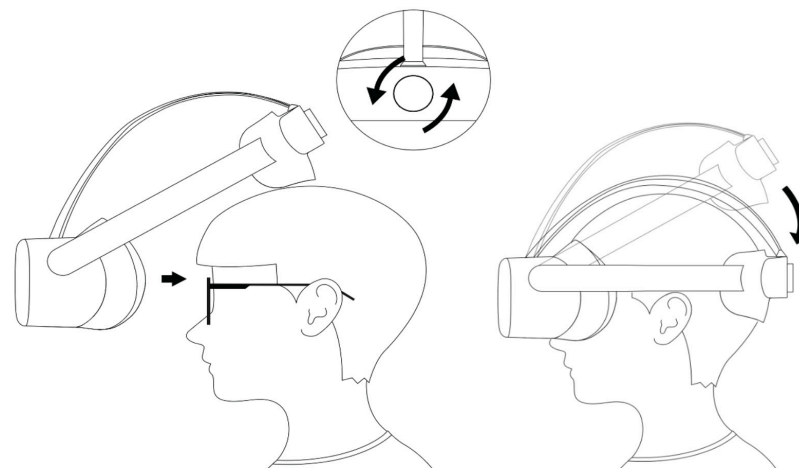
Red: Charging battery is less than 20%

8.3. Positioning VR headset (critical !)

Once the device is turned on, the healthcare specialist shall help the patient put on the VR headset. Turn the strap dial counter clockwise to loosen the strap. Place the headset starting from the front. Make sure to pull down the strap at the back of the head and tighten it, turning the dial clockwise. Check in with the patient, if they feel comfortable or if they experience any reflections on the lens or feel pressure points. This step is very important. A good fit will ensure that there is no pressure on the nose and that the patient views the VR display at the correct angle.

Setting up the VR headset for a new patient measurement

Please review detailed instructions incl. Screenshots on User Manual pages.



8.4. One-button clicker

The device is shipped with the manufacturer's original controllers as well as the one-button clicker.

VisionOne Patient Clicker

Please consider detailed instructions and screenshots in User Manual, pages for:

- How to use the one-button clicker
- Useful infos for Patients
- Useful infos for Clinicians
- Connecting the clicker to headsets
- Using the clicker versus the VR controller
- Battery level and charging batteries
- Resetting the clicker
- Clicker Trouble-shooting



9. Managing Patients and Measurements

9.1. Clinician dashboard

Please consider detailed instructions and screenshots in the Operations User Manual for:

- Adding new patients,
- changing or deleting existing patient data
- viewing measuring results,
- viewing visual field charts,
- saving PDF or printing visual chart
- Looking at progression chart

9.2. Technician dashboard

Please consider detailed instructions and screenshots in the Operations User Manual for:

- Adding new measurements
- Reordering measurements between devices
- Editing/Cloning/Deleting of non-taken Measurement
- other functions

9.3. Putting the Device into Stand-alone mode

Warning: Dear Client, please be aware that, while VisionOne can be set on stand-alone mode, VisionOne's intended use does not yet cover home use at a patient's home and the application through a lay person alone. If you provide VisionOne to the private environment of patients, the usage would be considered off-label and at your risk.

Stand-alone mode can run either when Device is offline or online, so there is no need for Patient to set the WiFi at home. The taken Measurements are stored securely (encrypted) on the device and are going to be uploaded to the server automatically when the network connection is again established.

Please consider detailed instructions and screenshots in the Operations User Manual for this function

10. Glossary

- VisionOne: VisionOne web app and VR app as a system
- VisionOne Web App: the web app for managing Patients and their Measurements
- VisionOne: VR Application: the VR app for taking visual field tests
- Organization: an entity that represents a clinic, hospital or a single MD clinic
- User: a healthcare specialist, technician or nurse that has access to the system and belongs to an organization
- Patient: an entity of a patient in VisionOne
- Measurement: an entity of a visual field test
- Device: an entity of the VR devices
- SORS: Sequentially Optimized Reconstruction Strategy:
Standard automated perimetry (SAP) testing is an inherently time-intensive and noisy process. Over time, the patient's response reliability declines due to fatigue. Therefore, the goal of SAP testing strategies is to optimize the trade-off between accuracy and speed. VisionOne offers the application a novel artificial intelligence-based testing strategy "Sequentially Optimized Reconstruction Strategy" (SORS) for SAP testing.
SORS allows reconstructing visual fields from a limited number of measurements i.e., testing a sparser grid of locations by assuming the existence of correlation between visual field locations.
In an initial training phase, we sequentially determined locations that most effectively reduce visual field estimation errors. We then exploit these locations at examination time in combination with the 40 commonly known staircasing scheme used in Dynamic Strategy (DS) where the intensity of presented stimuli changes in fixed step sizes.
SORS's only additional parameter to be defined is the number of tested locations (also referred to as stage). The stage determines the sparsity of the grid and therefore the degree of approximation. Assuming the G-pattern is used, the SORS stage can be chosen anywhere in the range of 4 to 59 [1].

11. References

- [1] S. Kucur and R. Sznitman, "Sequentially optimized reconstruction strategy: A meta strategy for perimetry testing," PLOS ONE, vol. 12, p. e0185049, 10 2017.



Instructions for Use Part 2

VisionOne

(Operations User's Manual)

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1 Introduction

1.1 About This User Manual

This User Manual is part of Perivision's Instructions for Use and focuses on the details of the set-up and operations of the device.

It should always represent the most updated functionalities and versions of VisionOne.

For Regulatory Information as well as Safety Information and Warnings please refer to Instructions for Use, Part 1, VisionOne

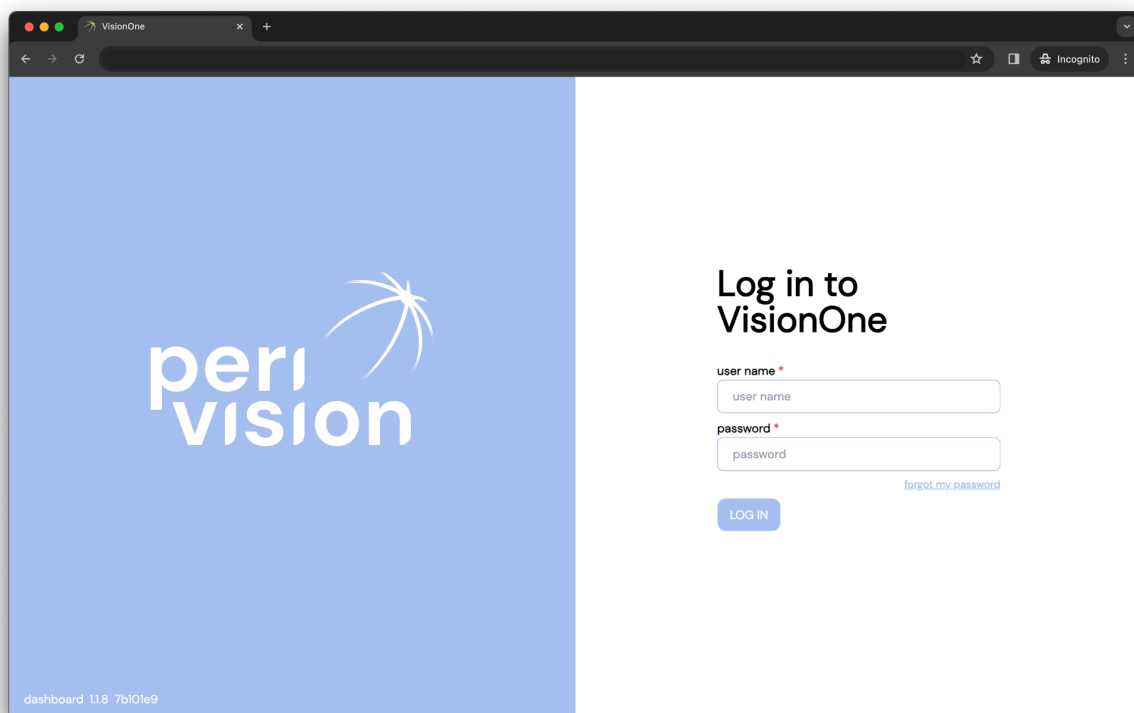
For further questions and information, please contact support@perivision.com

2 Web Application VisionOne

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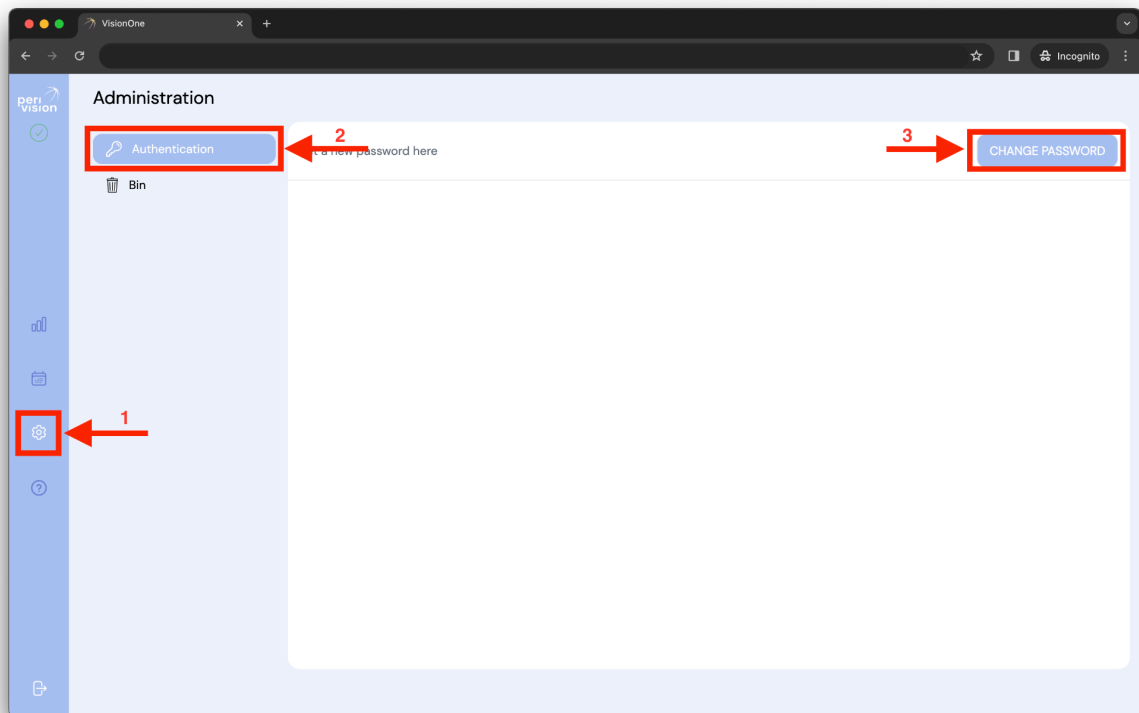
Fill up the user name and password fields with your credentials and click the log in button to log in the clinician dashboard.

2.2 Password reset

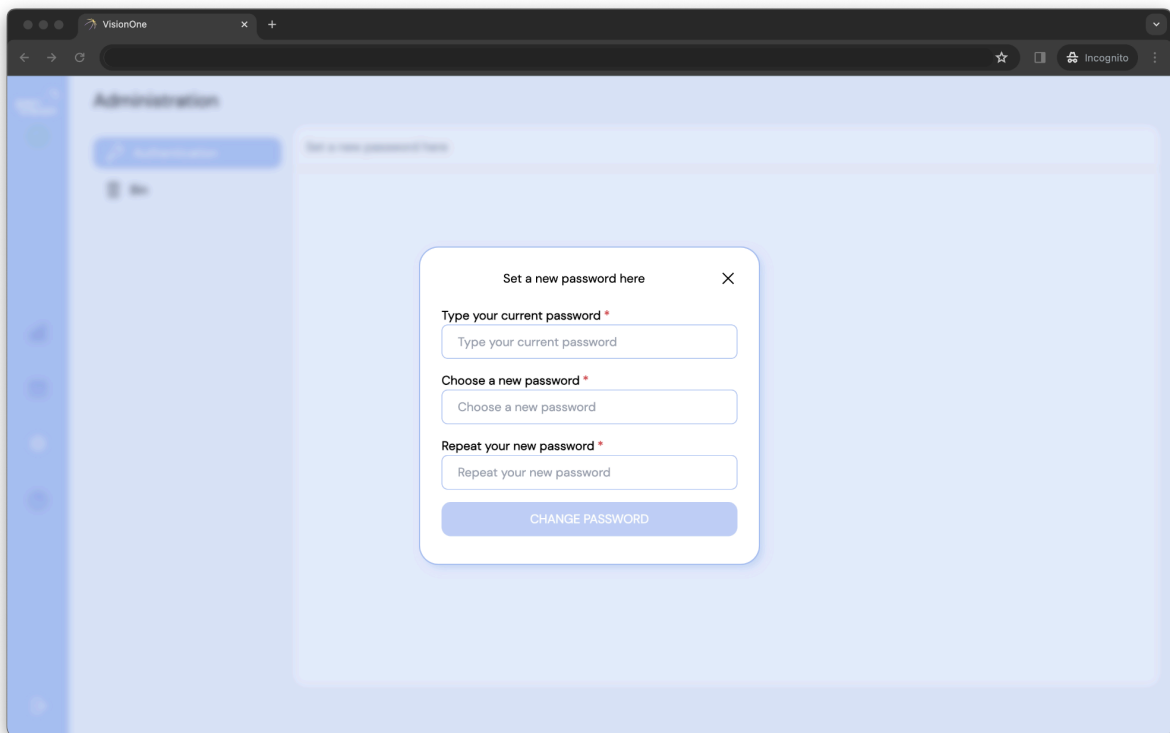
Follow the *forgot my password* link on the login page and follow the link that has been sent to the email inbox associated with the VisionOne user's account to set the new password for this user.

2.3 Password change

Once logged in, to change the existing password, go to settings, then to the authentication section and click on the *CHANGE PASSWORD* button:



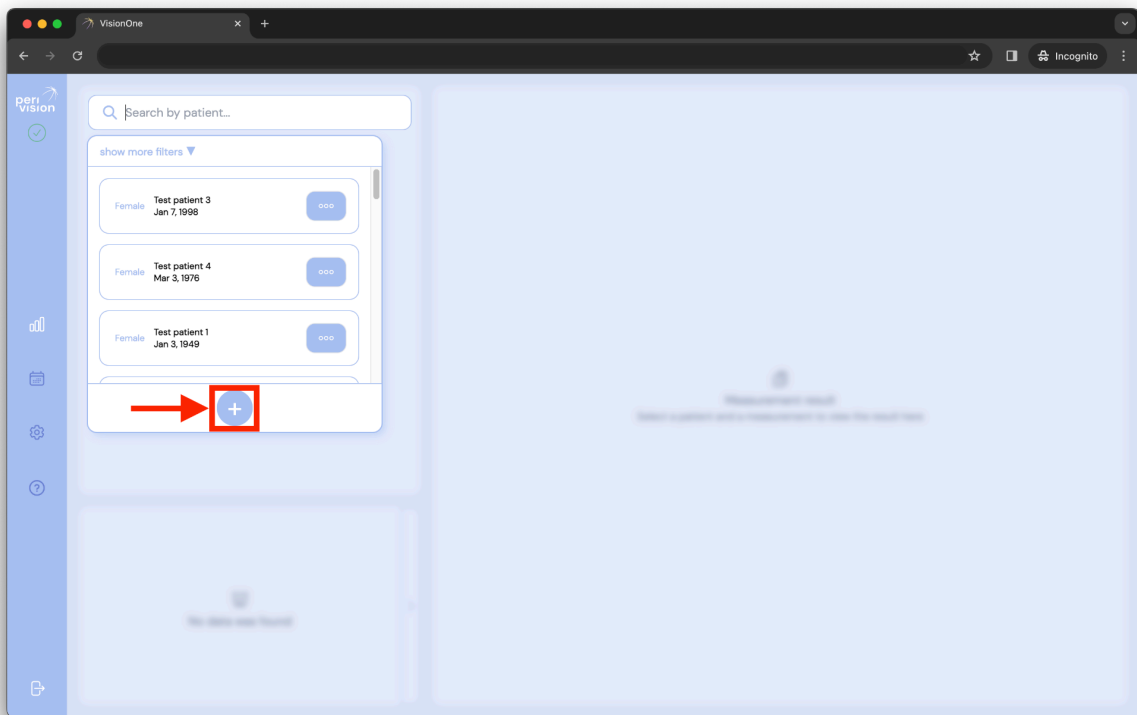
The new window will open with the form to fill. Fill it in following the password requirements instructions and submit the change to set as the new password for this logged in User:



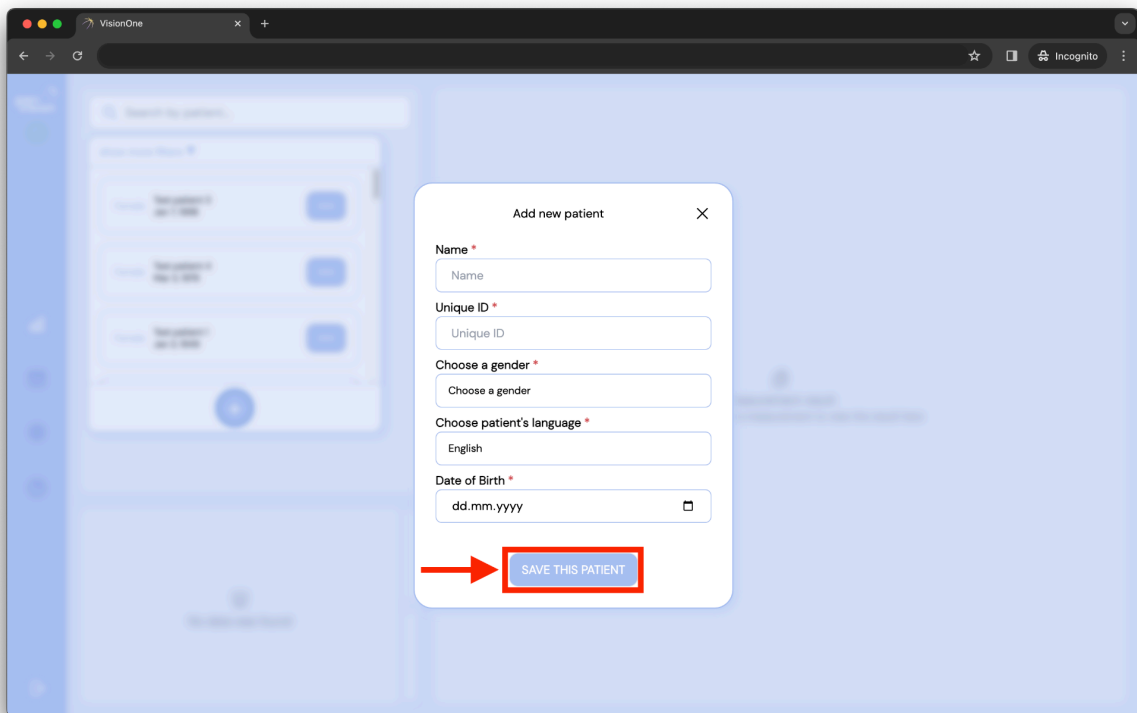
3 Clinician dashboard

3.1 Adding a new Patient

In order to add a new patient, click on the search bar and then click on the highlighted plus button.

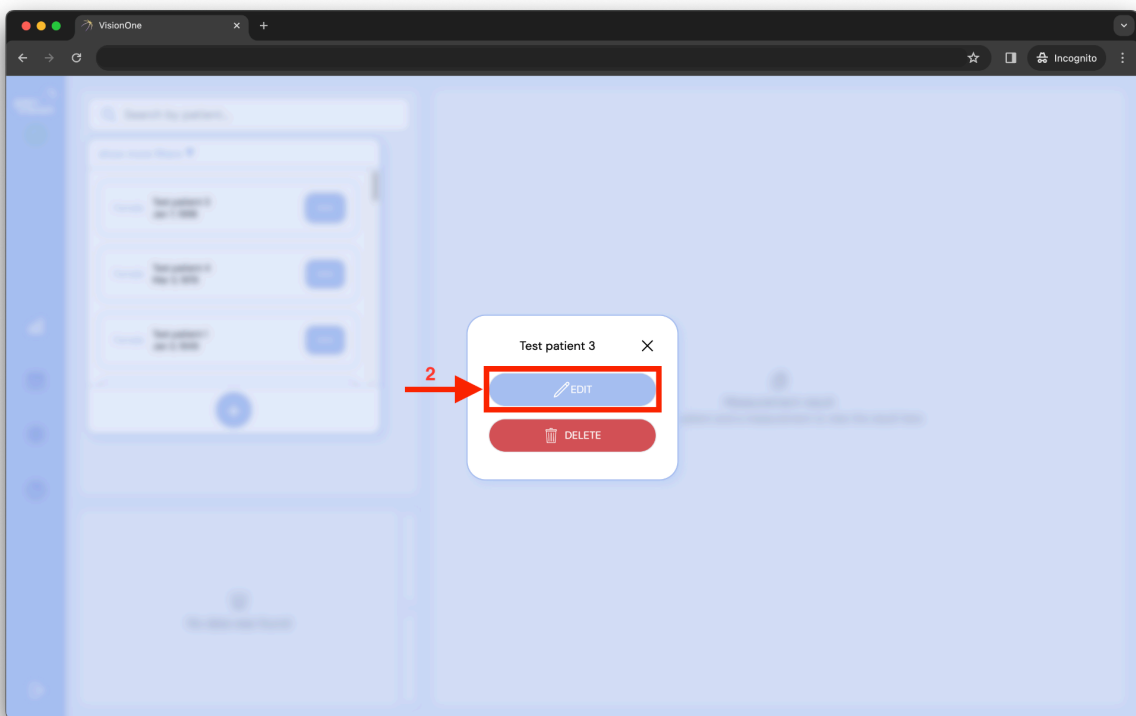
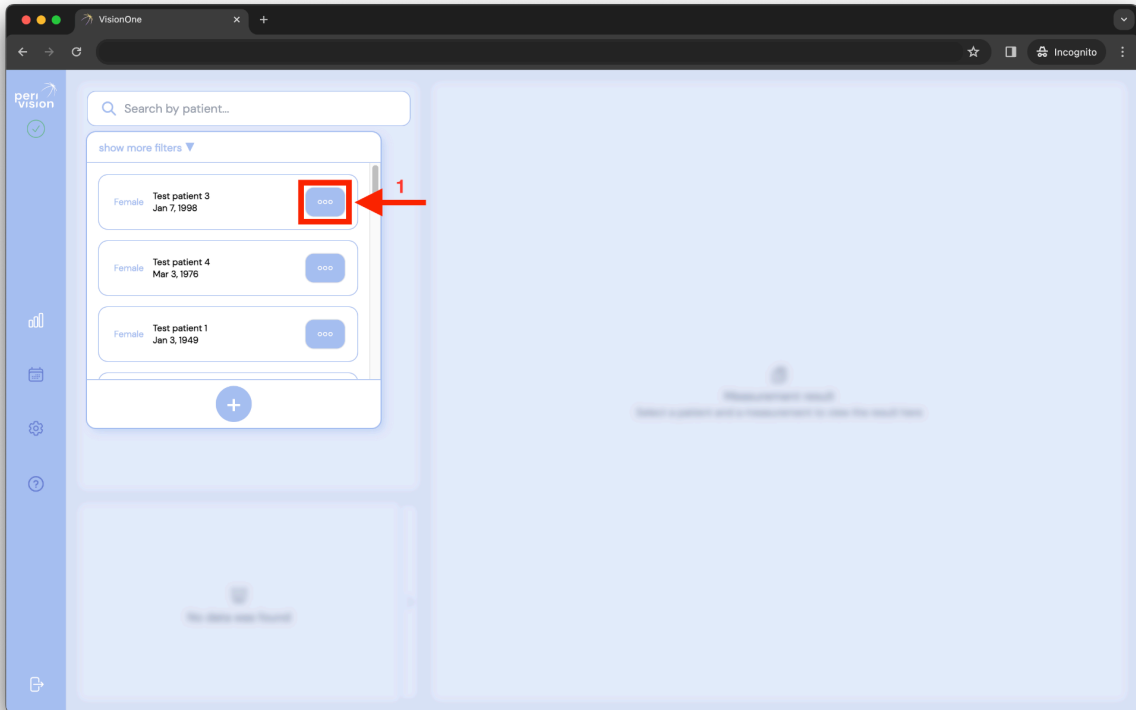


The pop-up with the new patient form will appear. Please fill in the patient information in the respective fields and click Save the patient to save the new Patient. This new Patient will then appear in the patient dropdown search list (see above).

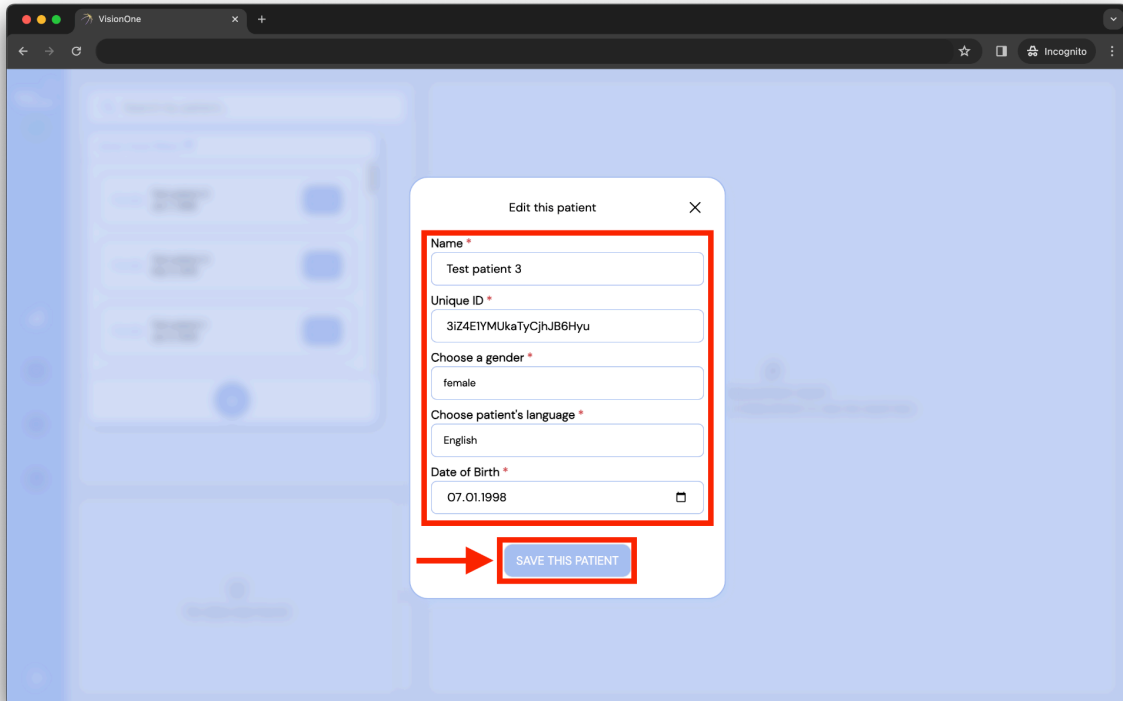


3.2 Editing/Deleting of existing Patient's data

In order to edit the Patient's data click on the three dots symbol on the Patient's card. The context menu for that patient will appear. Choose the edit option by clicking on it (analogically for delete functionality):



The same pop-up like for Patient first creation will appear, but with the currently edited Patient's data. Modify the form and click save the patient's data:

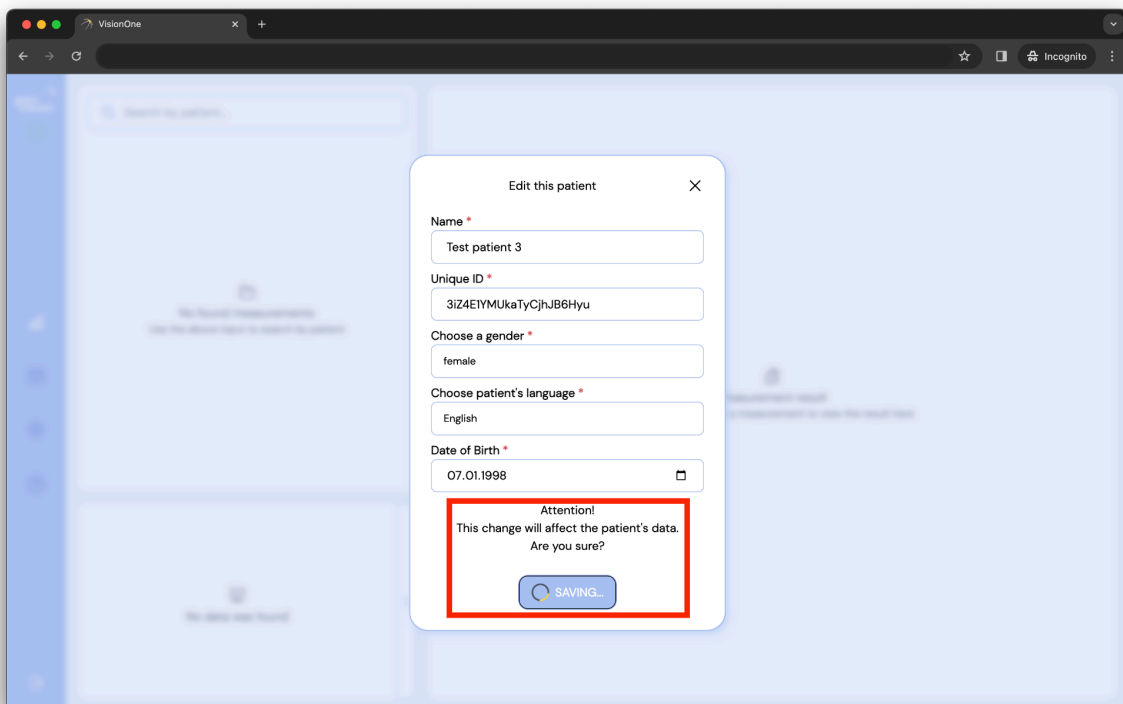


The screenshot shows a web browser window with the VisionOne application. A modal titled "Edit this patient" is displayed. The form contains the following fields:

- Name *: Test patient 3
- Unique ID *: 3iZ4EiYMuKaTyCjhJB6Hyu
- Choose a gender *: female
- Choose patient's language *: English
- Date of Birth *: 07.01.1998

A red rectangle highlights the entire form. A red arrow points to the "SAVE THIS PATIENT" button at the bottom of the form.

When editing, you will be asked if you are sure to save that data. Confirm or cancel your action by clicking the button:



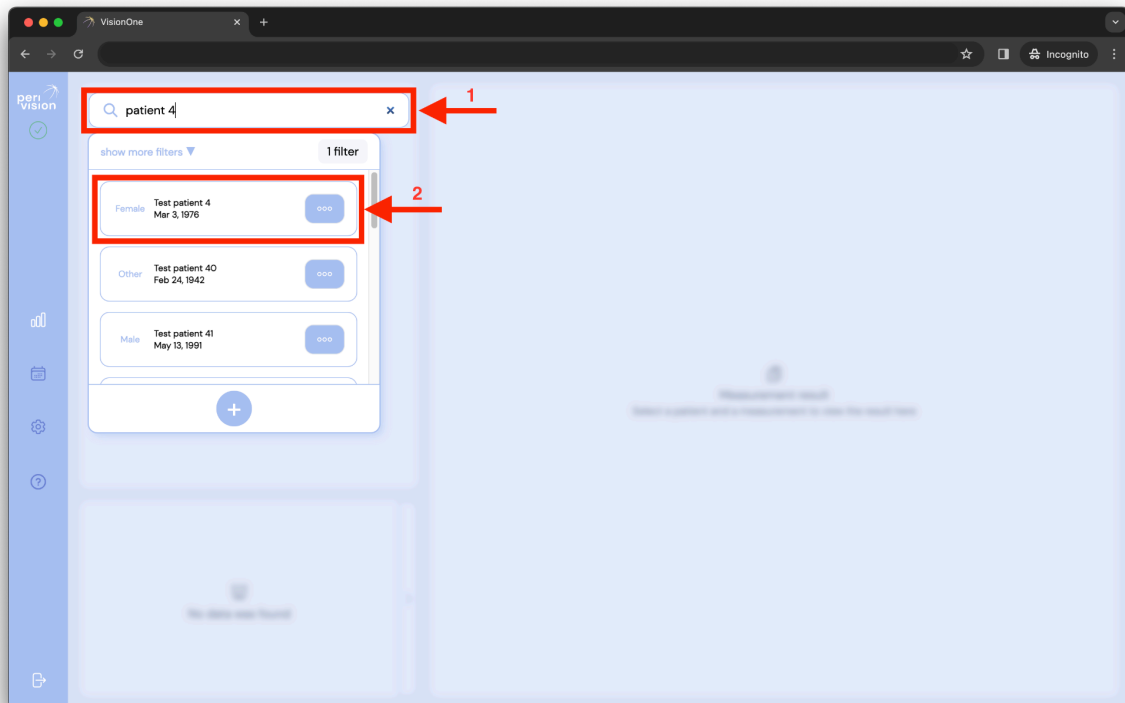
The screenshot shows the same "Edit this patient" form as in the previous image. Below the form, a confirmation dialog is displayed with the following text:

Attention!
This change will affect the patient's data.
Are you sure?

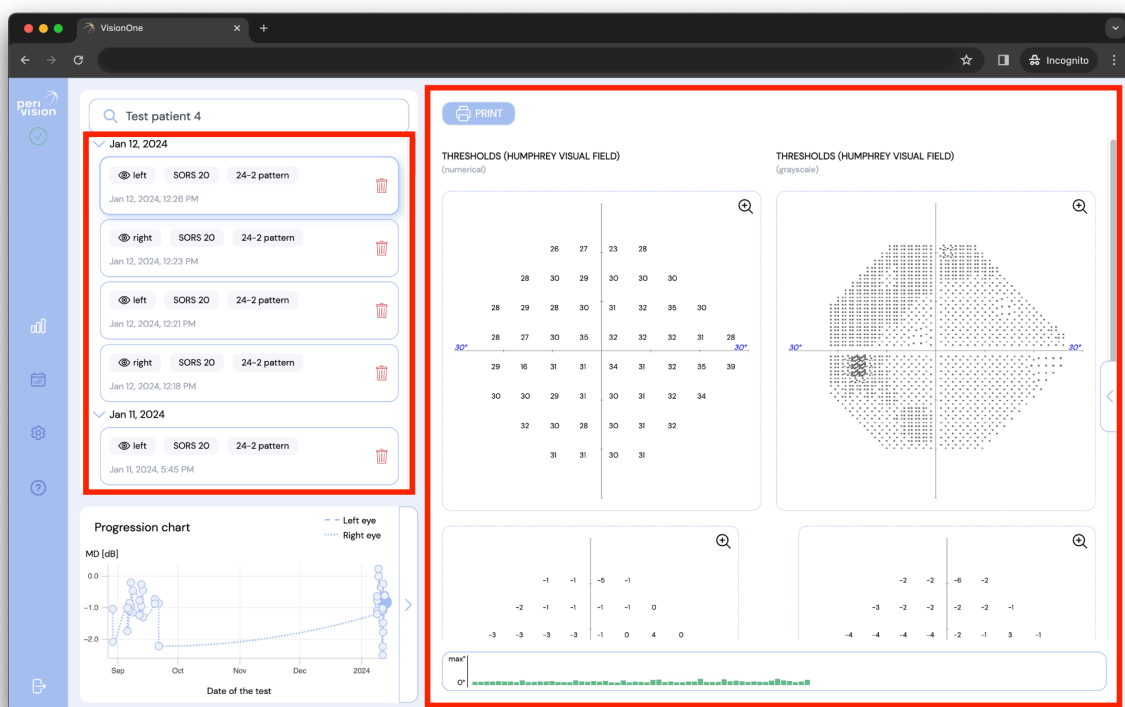
A red rectangle highlights the confirmation dialog. Below the text is a button labeled "SAVING..." with a loading spinner.

3.3 Viewing the Measurement's result

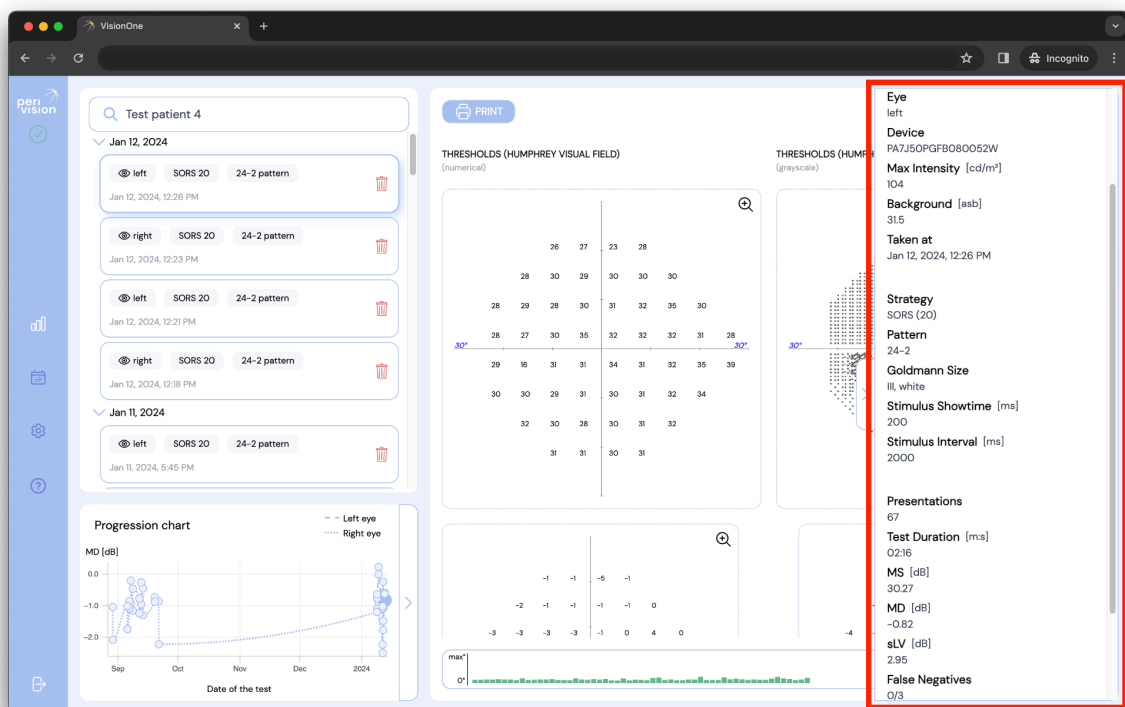
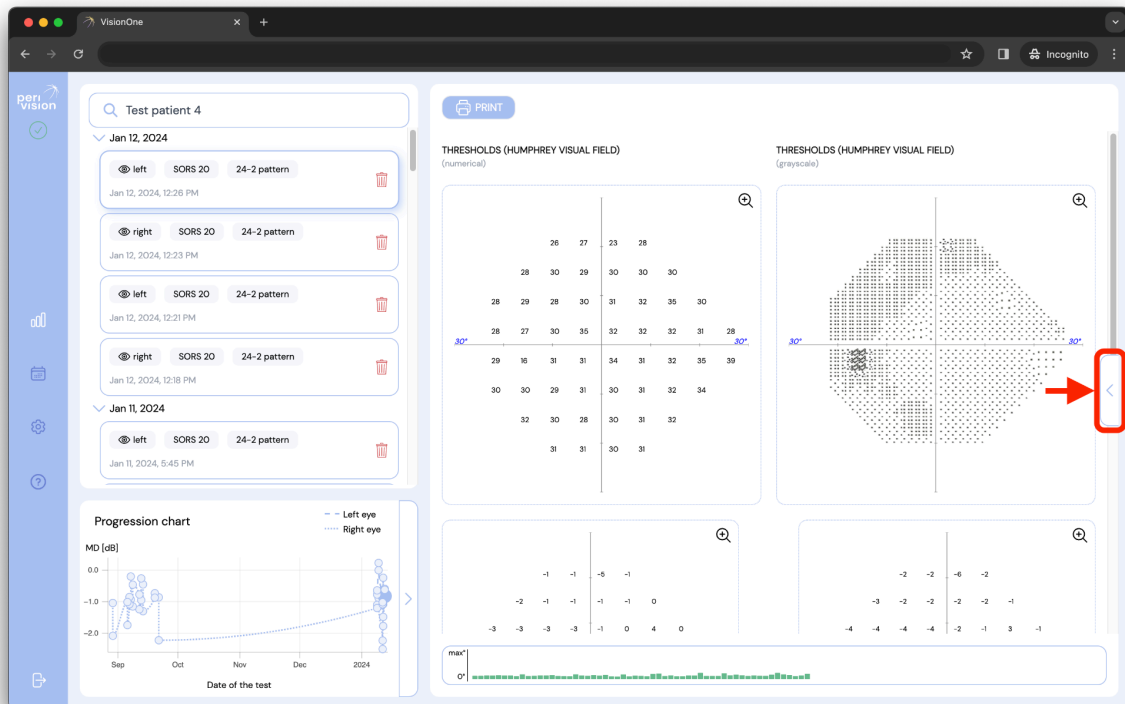
Select a Patient by either typing patient name in the search box or by clicking on the search box and choosing from the dropdown and clicking on the chosen Patient:



Selecting a patient will show Patient's previous Measurements (list on the left) and selected Measurement's result (visual field test result, on the right):



Clicking on the arrow icon is going to expand details of the measurement.



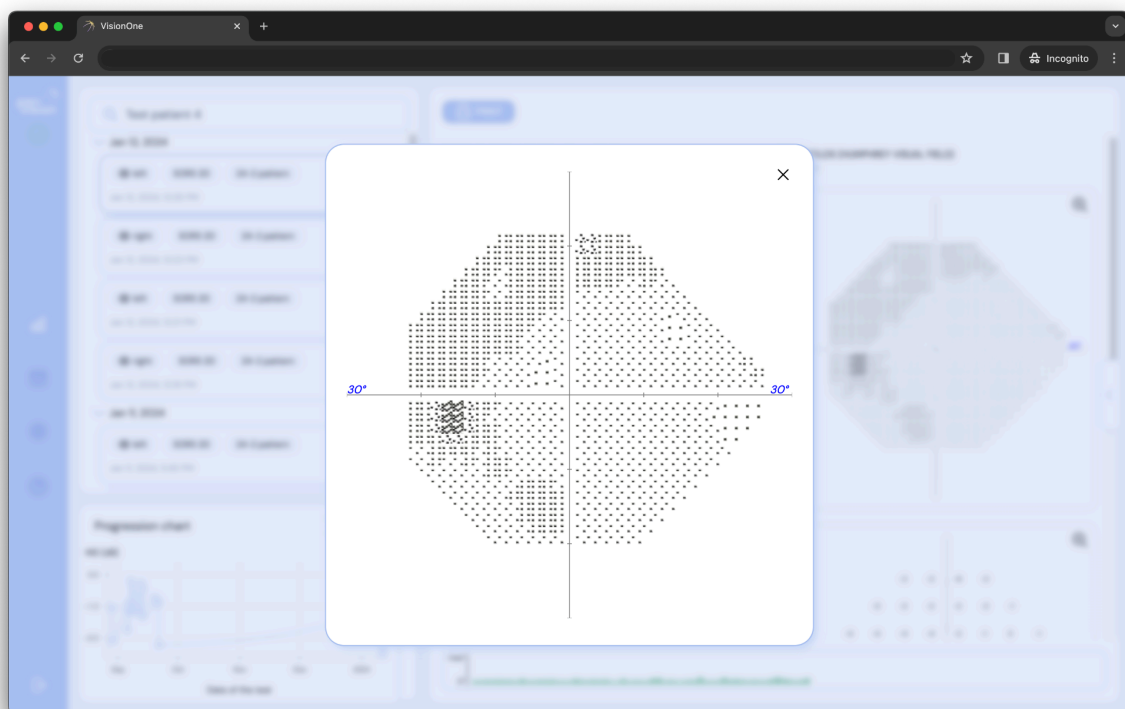
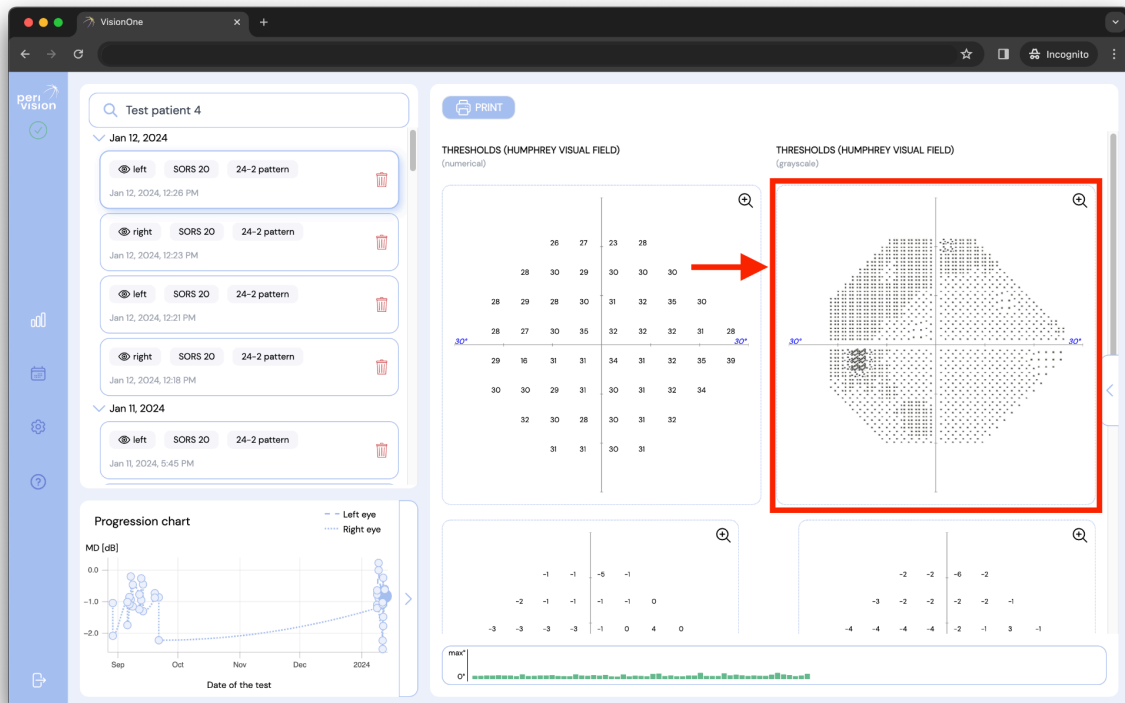
The details of the measurement contain:

- Patient: The name of the Patient that took the test
- Eye: The eye that was measured (left or right)
- Device: The identifier of the VR headset used for the test
- Max intensity: The device's maximum light intensity
- Background: The background luminance that is set for the visual field test

- Taken at: The date and time when the test was taken
- Strategy: Testing strategy used for the test (Normal strategy, Dynamic strategy and SORS Screening, SORS or Supra-threshold)
- Pattern: Pattern used for the test (G, 24-2, 10-2 or 30-2)
- Goldman size: the stimulus size (sizes I to V are available)
- Stimulus showtime: The duration of the shown stimuli
- Stimulus interval: The duration between two subsequent stimuli
- Presentations: Number of stimuli shown over the course of the test
- Test duration: The total time that the test took
- MS: Mean sensitivity
- MD: Mean defect
- sLV: square root loss variance
- False negatives: The ratio between the number of false negative responses to the false negative catch trials
- False positives: The ratio between the number of false positive responses to the false positive catch trials
- Fixation losses: The number of positive responses to the stimuli shown at the blind spot (Heijl-Krakau method)
- Gaze tracker fixation: The percentage of the times when the patient was in focus as measured by the built-in eye tracker (is 0% if tracker was turned off). The higher value means better fixation.

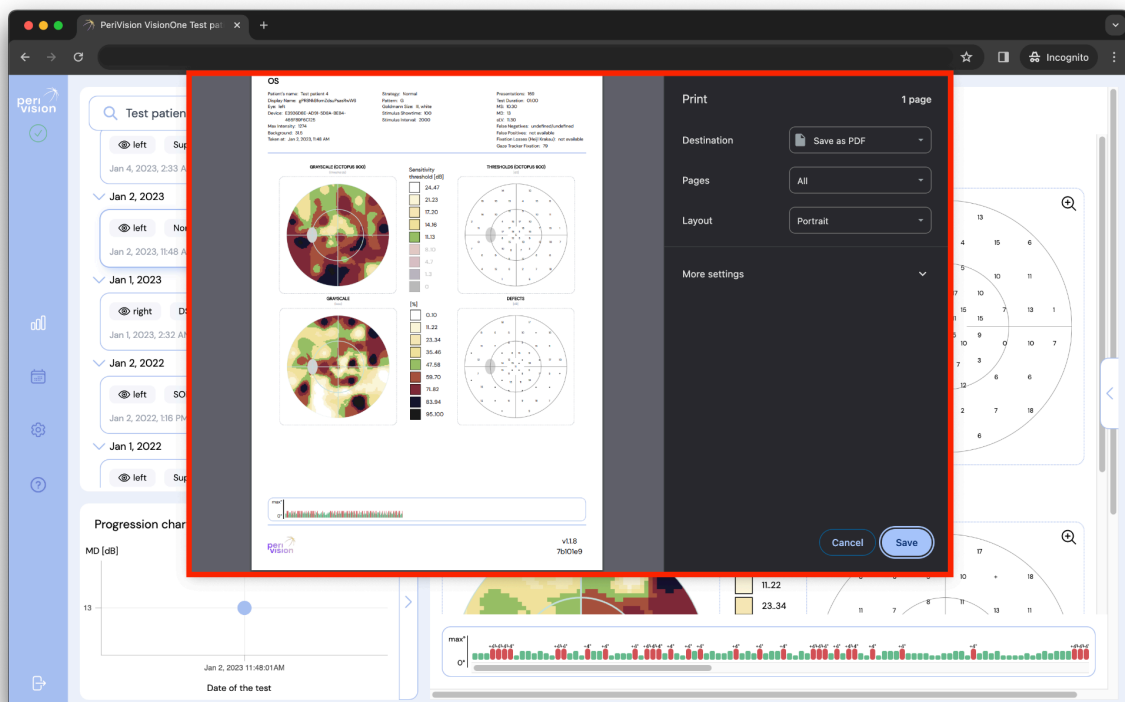
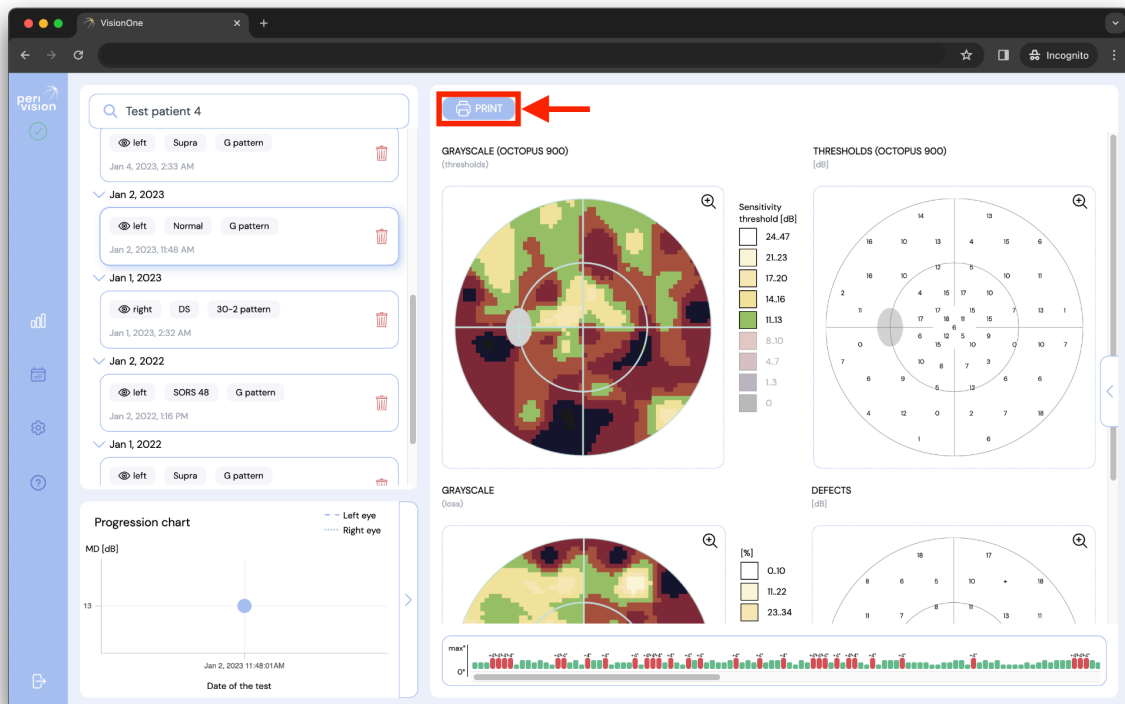
3.4 Maximizing the Visual Field Chart

In order to maximize the Visual Field Chart (Octopus-like or Humphrey-like), simply click on the chart, that is wished to be examined and it will expand into a separate window:



3.5 Saving PDF/Printing of taken measurements

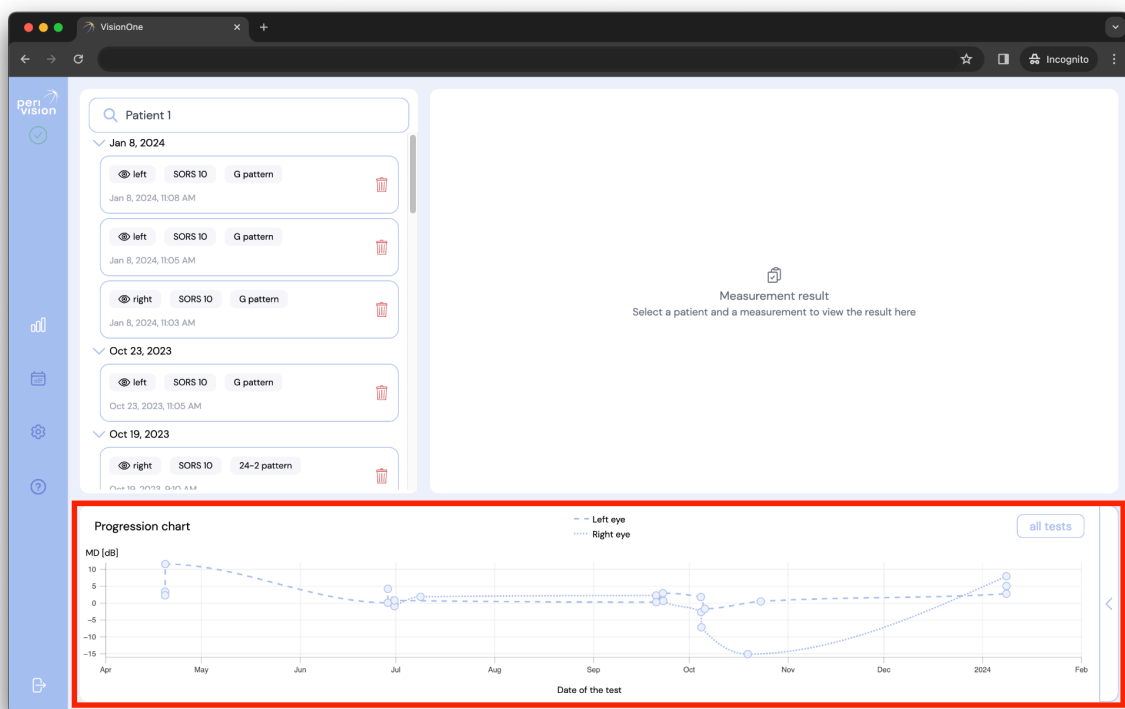
When selecting the test, the test result is presented on the right side of the screen. It also can be printed by clicking the PRINT button in the top left corner of the result:



As shown above, it is possible to use the system window to print or save the measurement in a common visual field test format (Octopus-like or Humphrey-like outputs).

3.6 Perimetry Progression Chart

When a selected Patient has completed at least two tests per eye, the chart will show the progression of the mean defect (MD) values of a visual field test on the progression chart. The X-axis represents time and Y-axis represents the mean defect. The dotted line represents the right eye and the dashed line represents the left eye progression.



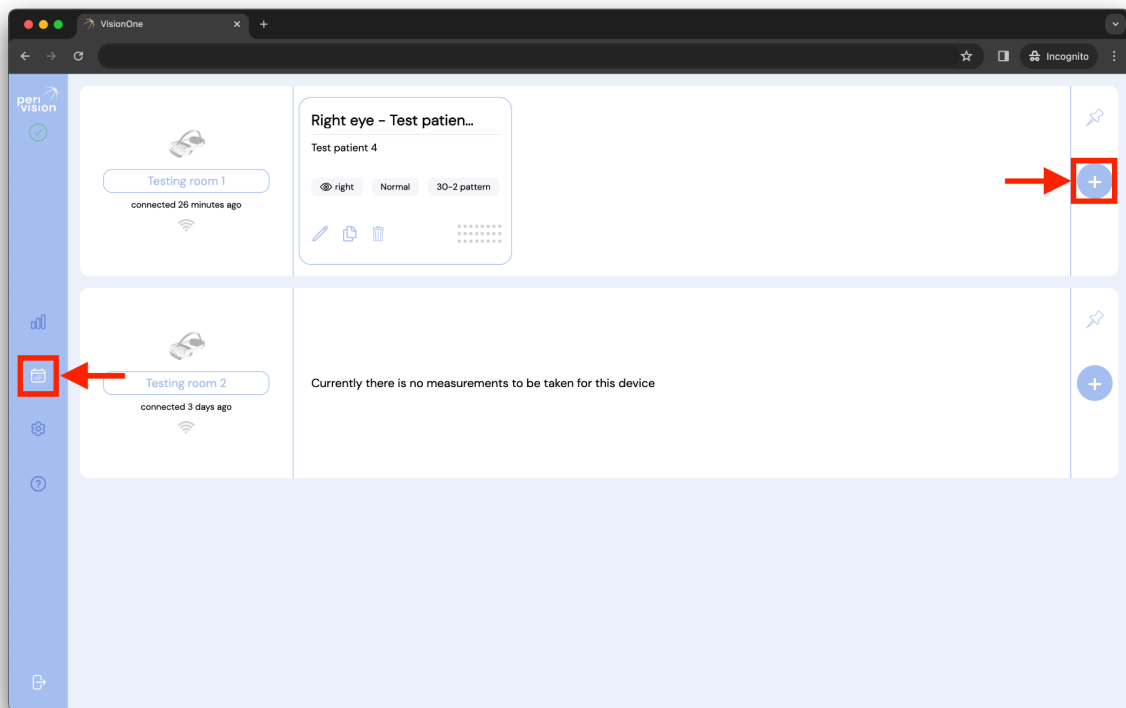
Each dot represents the taken Measurement over time. Clicking on a dot will select the corresponding Measurement in the list in the top left corner.

4 Technician dashboard

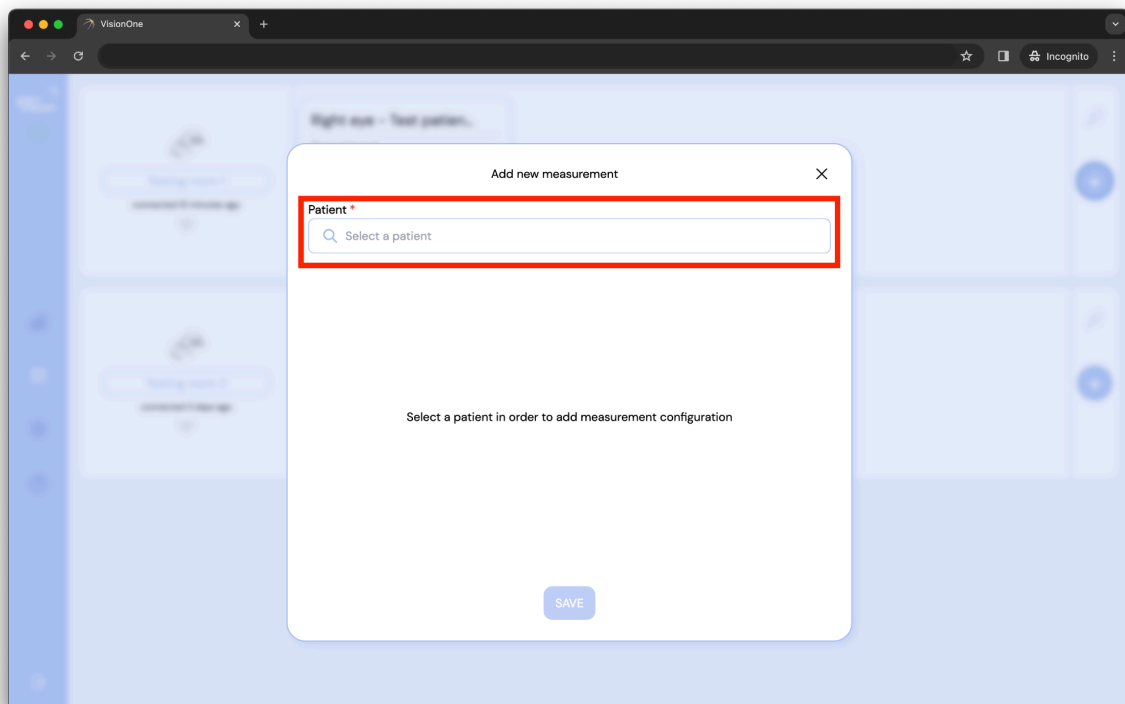
The Technician dashboard is the place in the VisionOne web app to manage your devices and yet to take measurements.

4.1 Adding a new Measurement

In order to add a new measurement, head towards the technician dashboard and click the round plus button in the swimlane that represents the device you are wishing for to create a measurement:



Fill in the form by first choosing a patient:



Right eye - Test patient.

Add new measurement

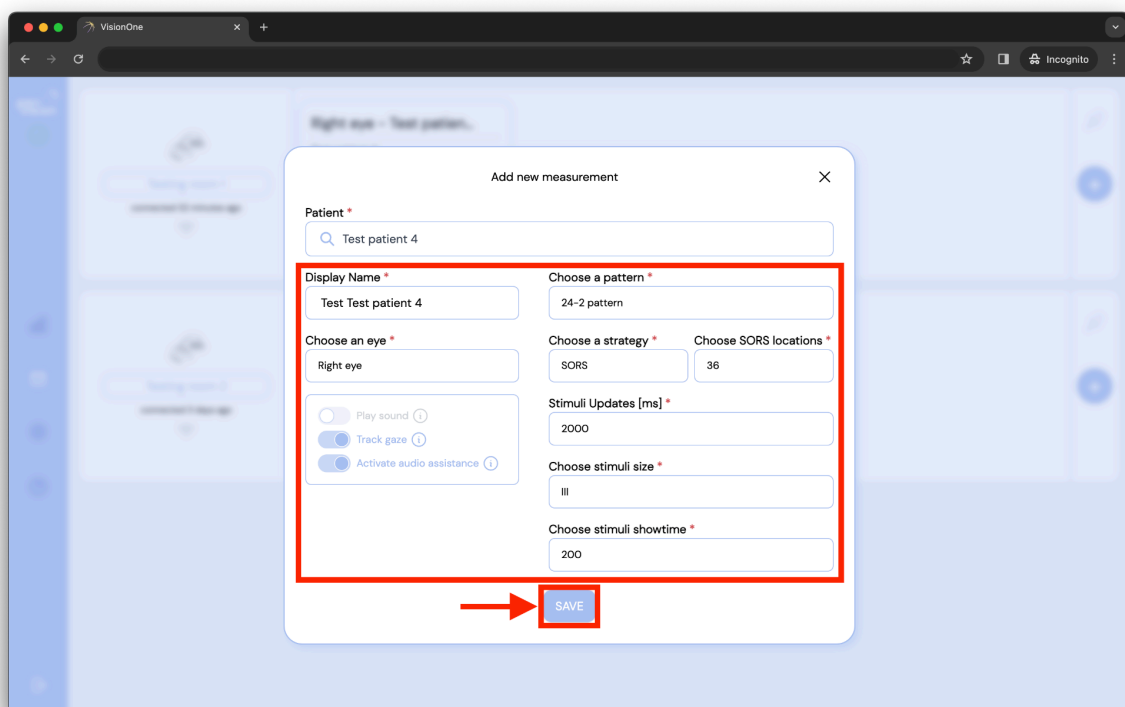
Patient *

Select a patient

Select a patient in order to add measurement configuration

SAVE

And correct configuration and save in order to add this new measurement:



Add new measurement

Patient *

Test patient 4

Display Name *

Test Test patient 4

Choose a pattern *

24-2 pattern

Choose an eye *

Right eye

Choose a strategy *

SORS

Choose SORS locations *

36

Stimuli Updates [ms] *

2000

Choose stimuli size *

III

Choose stimuli showtime *

200

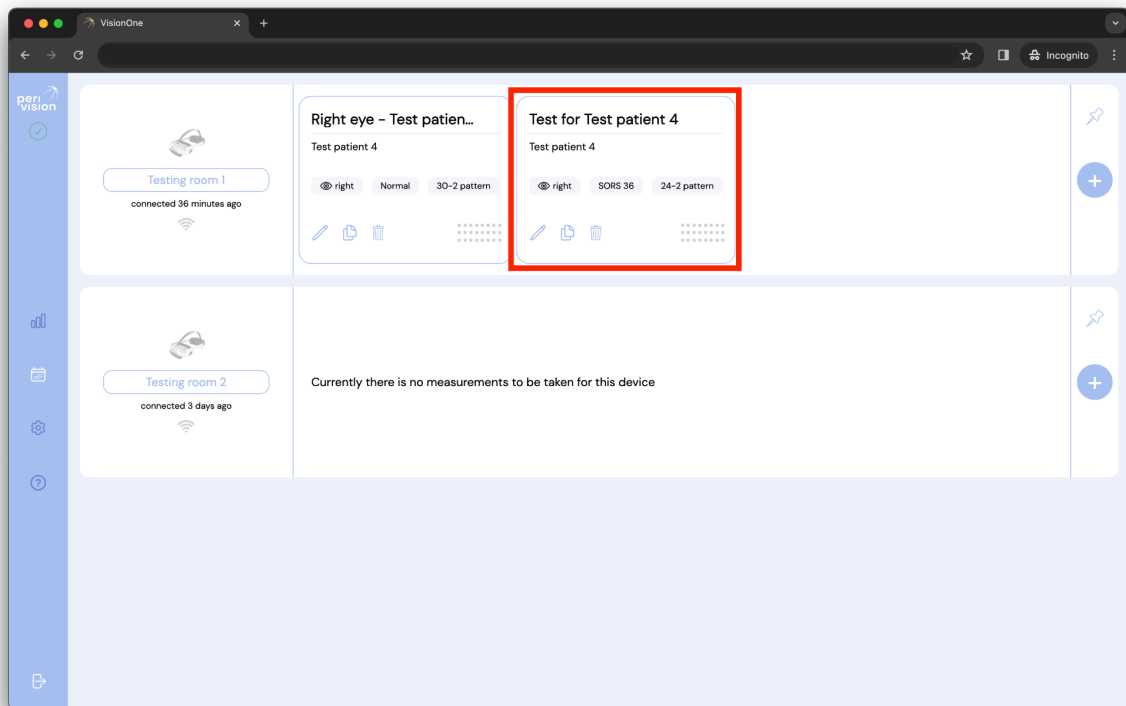
Play sound

Track gaze

Activate audio assistance

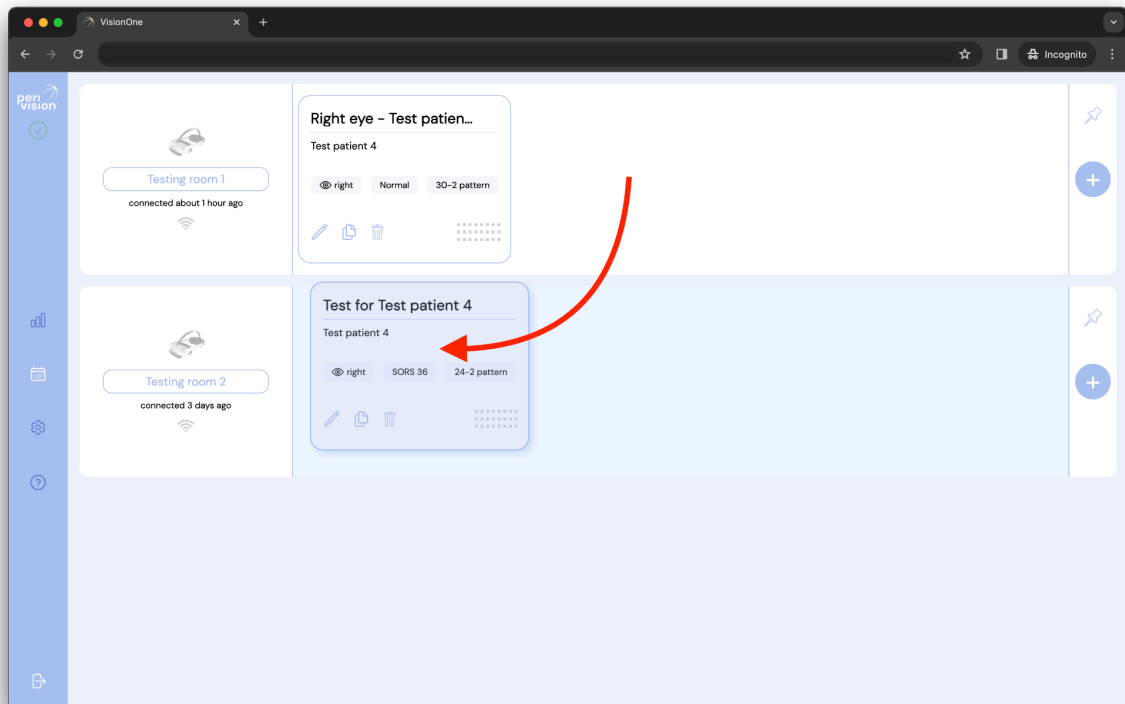
SAVE

Saving the form with the “SAVE” button will create a new measurement, placing it into the device’s swimlane. The Measurements are waiting for their turn to be taken, with the most left Measurement to be taken as next. Your new measurement will appear right after it:



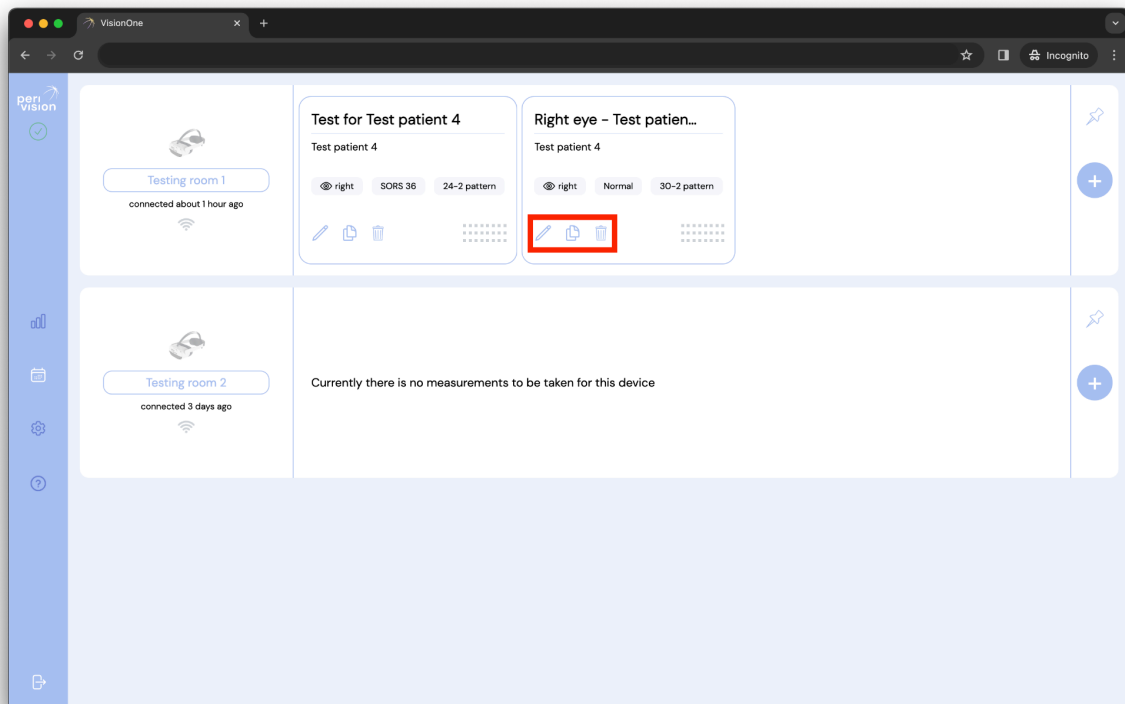
4.2 Reordering of Measurements between devices

In order to move a Measurement into another device, simply drag and drop it into another device:



4.3 Editing/Cloning/Deleting of non-taken Measurement

Every Measurement that is in the device's swimlane can be either edited, cloned or deleted as long as it hasn't been taken yet. In order to edit/clone/delete a non-taken Measurement, click on one of the corresponding icons on the card:



5 VR stand-alone mode

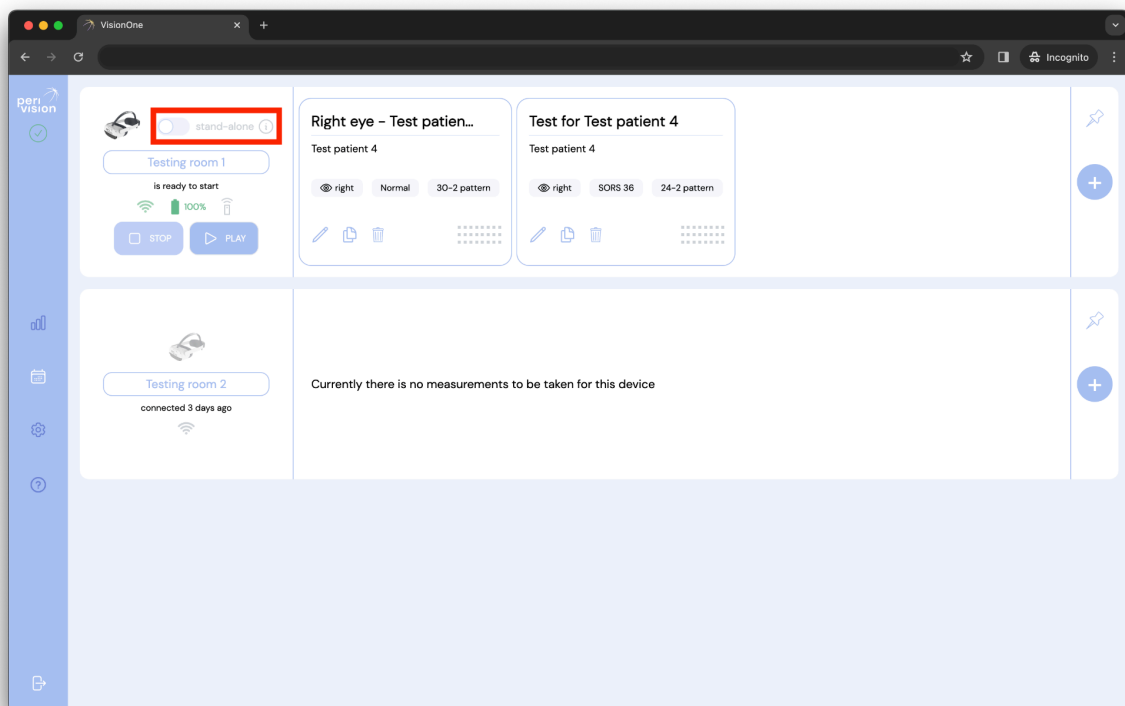
Warning: Dear Client, please be aware that, while VisionOne can be set on stand-alone mode, VisionOne's intended use does not yet cover home use at a patient's home and the application through a lay person alone. If you provide VisionOne to the private environment of patients, the usage would be considered off-label and at your risk.

Please consider the possibilities discussed under C) Intended Use Environment

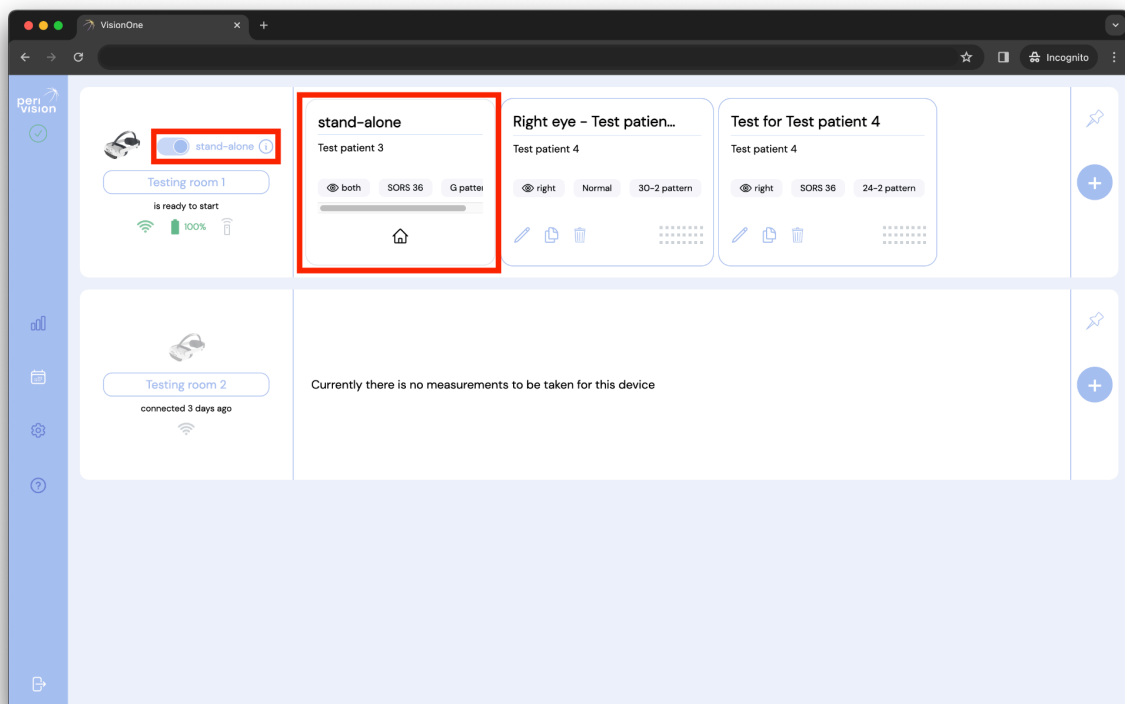
Stand-alone mode can run either when Device is offline or online, so there is no need for Patient to set the WiFi at home. The taken Measurements are stored securely (encrypted) on the device and are going to be uploaded to the server automatically when the network connection is again established.

5.1 How to activate the stand-alone mode

In order to activate the stand-alone mode, turn on the device and connect it to the WiFi network. The device will pair with the Technician dashboard showing the right connectivity icons and presenting the status of the device (below status is awaiting measurement):



Click on the stand-alone toggle to turn the mode on. Choose the Patient and Measurement that must run on the VR device when in stand-alone (same form as creating a new Measurement) and click ACTIVATE STAND-ALONE MODE button. The Device's swimlane will now present a “template” of Measurement, that is set for this stand-alone mode use:



The Device will now run this Measurement repeatedly until the stand-alone mode toggle is unchecked for this Device.

6 VisionOne VR Headset

6.1 Component overview

A VisionOne Box contains:

- 1 x Pico Neo 3 Pro Eye VR Headset
 - 1 x Headset (contains internal battery)
 - 2 x VR Motion Controller (uses 2 x AA battery each)
 - 1 x Power Adapter and Cable
 - Pico Neo 3 Pro Eye commercial user brochure
- 1 x One-button Patient Clicker (uses CR2023 Lithium Cell)

6.2 VR Headset components

You are given a pair of the Pico Neo 3 Pro Eye Virtual Reality (VR) goggles with PeriVision's VisionOne VR Application installed (see Figure 1). Including a left and a right controller (see Figure 2). The labeled controls (1 - 4) are all the functions you are going to need to operate the VR headset. The Controller's layout is mirrored and can be used by right and left handed users and patients.

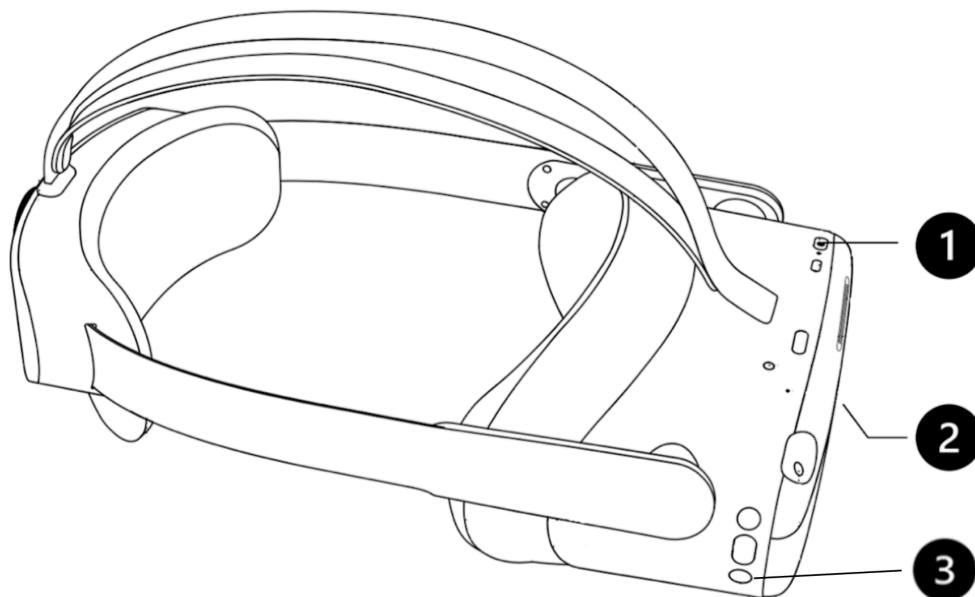


Figure 1 VR headset with (1) power button, (2) volume control (bottom side) and (3) Pico button

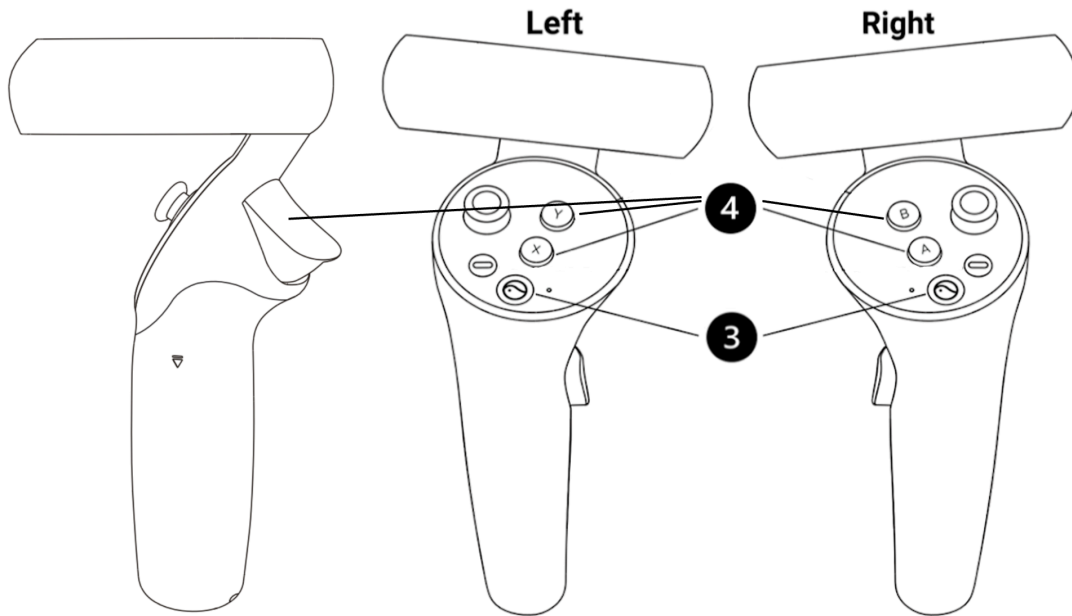
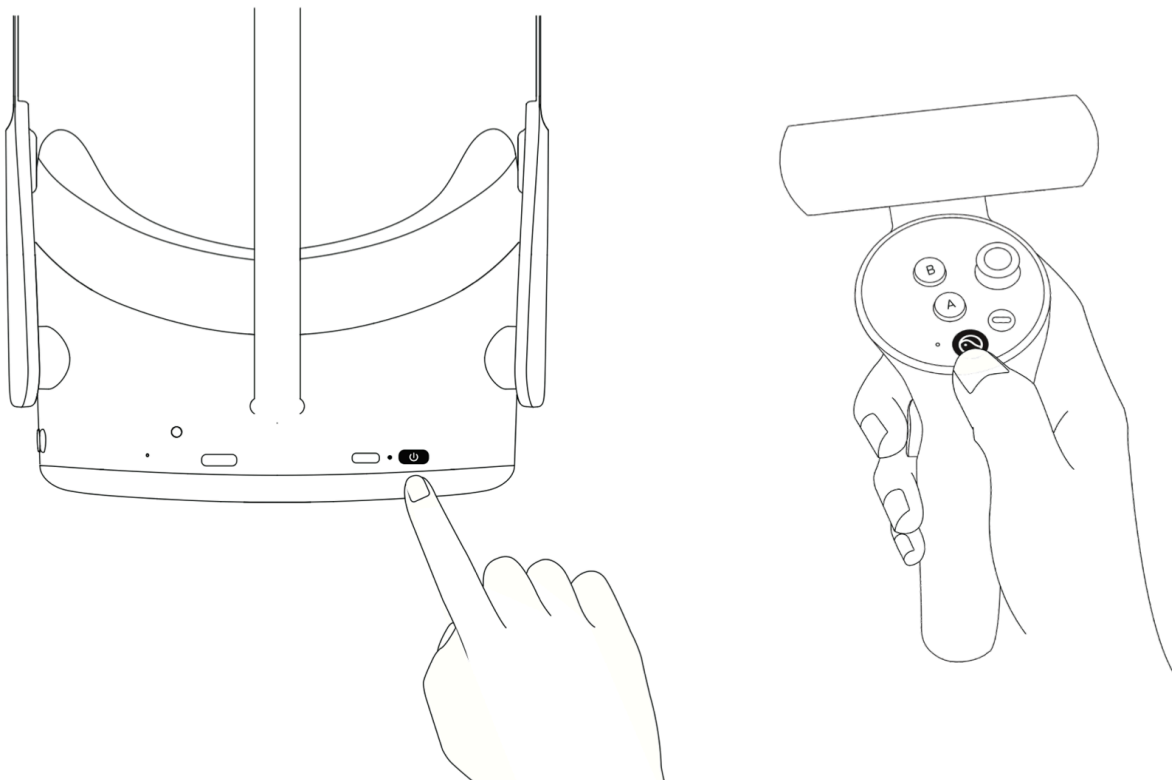


Figure 2 Left and right controllers with (4) X/Y/Trigger (left) and A/B/Trigger (right) buttons for patient's response and controlling the VR headset, (3) Pico button for general settings of the Pico VR headset.

6.3 Setting up the Pico VR Headset

Use the power button (1) to turn on the VR Headset and press the controller's pico button (3) to turn on the controller(s).



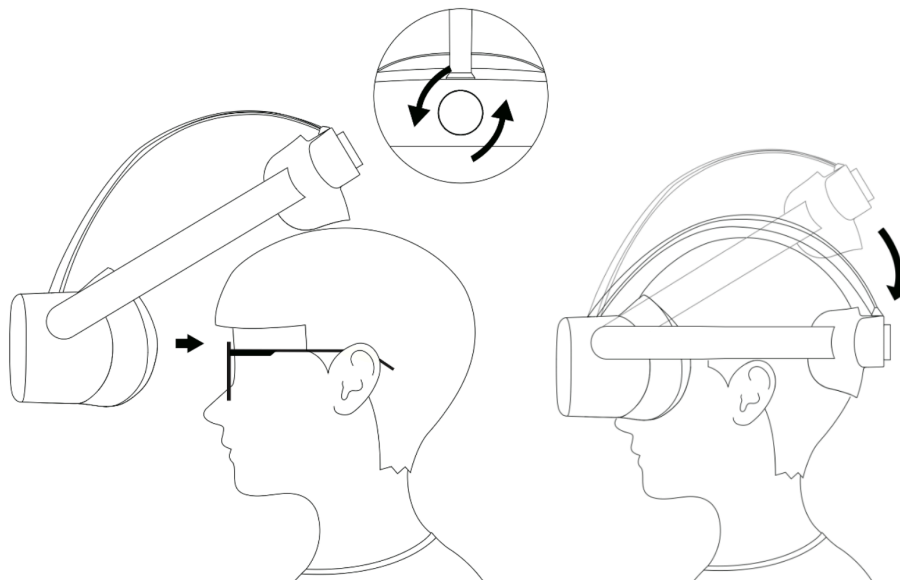
The LED next to the power button indicates the VR headset status.

- Blue: Powered on with battery over 20%
- Red flashing: battery is less than 20%

- Green: Charging complete
- Off: Sleeping or powered off
- Blue flashing: shutting down
- Yellow: Charging battery is less than 98%
- Red: Charging battery is less than 20%

6.4 Positioning VR headset (critical !)

Once the device is turned on, the healthcare specialist shall help the patient put on the VR headset. Turn the strap dial counter clockwise to loosen the strap. Place the headset starting from the front. Make sure to pull down the strap at the back of the head and tighten it, turning the dial clockwise. Check in with the patient, if they feel comfortable or if they experience any reflections on the lens or feel pressure points. This step is very important. A good fit will ensure that there is no pressure on the nose and that the patient views the VR display at the correct angle.



6.5 Setting up the VR headset

The first screen visible when the VR Headset is turned on. The only thing left to do before the device is ready to conduct a Perimetry examination is to connect the VR Headset to your local network using the WiFi icon (1). Once connected, the VisionOne VR Application (3) can be started. Note that, if you wish, you can cast the VisionOne VR Application to your computer's browser using the cast button (2)

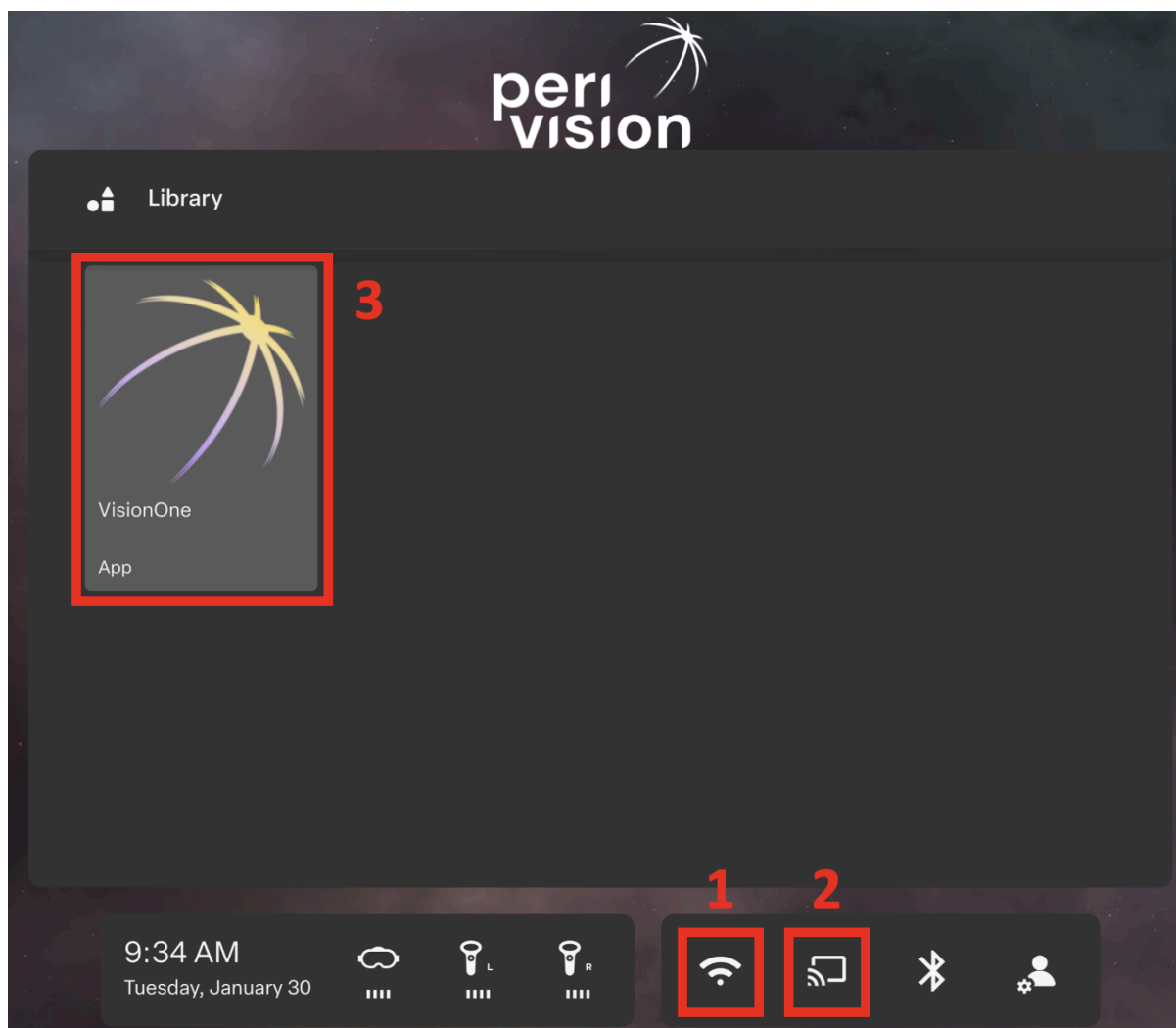


Figure 3 VR Home Screen with (1) WiFi connection, (2) Screen casting option and (3) VisionOne VR Application

6.6 Quitting VisionOne VR Application

We put a serious emphasis on the quality and stability of VisionOne. Nevertheless it can happen that the VR application becomes unresponsive. In that case, and in any other situation where the VR application needs to be closed or restarted (receiving updates, connecting to a Network, etc.), please **short-press the Pico Button** (3) on either of the controllers controller, or the right side of the VR headset. This will open a dialog presenting you with the option to resume, restart or exit the VisionOne VR Application.

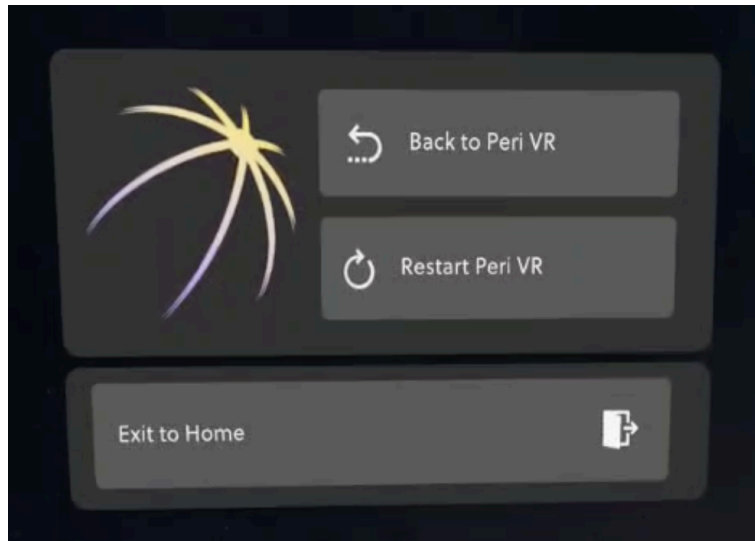


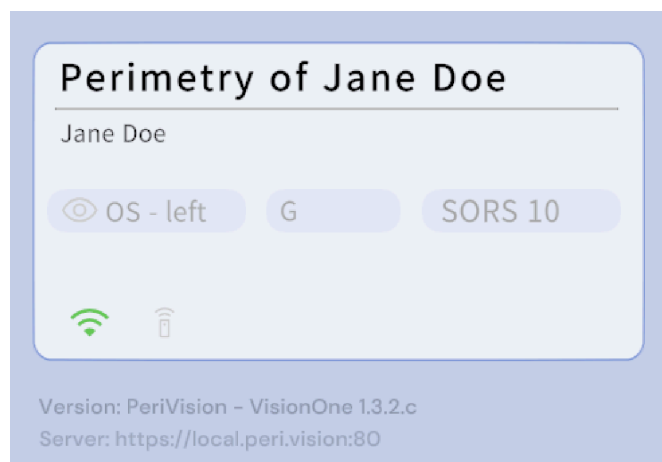
Figure 4 Short-press the pico button to exit VisionOne VR App

6.7 Controlling the 3D view

The VR Home Screen is not fixed to the user's head orientation. This means that the user may not see the content in front, but rather in any other direction around them. Instead of turning the head, the user may **long-press the pico button** (3) whilst viewing in the desired direction. The content will recenter in front of the user.

6.8 Conducting a Perimetry Examination

Assuming a perimetry test has been configured in the Web Application VisionOne and the VisionOne VR Application has been started, the test will be shown in the VR Headset:



The device is now ready to be put on by the patient (This is a critical step. See chapter 6.4). For ease of use, the patient may use any of the response buttons on the VR controllers (depending on their preference of right or left, response buttons include A, B, X, Y, Triggers) or the PeriVision Patient's Clicker. When the patient clicks once, and the audio guide is enabled, the test will start by guiding the patient through the eye tracking fixation calibration (if activated) and the Perimetry test itself. Without audio guide enabled, the eye tracking calibration and, subsequently, the Perimetry examination, will start immediately.

Although the gaze tracking sensors of the Pico VR Headset are calibrated to pick up gaze information independent of facial geometry or other factors, our Gaze Tracking Calibration helps compensate for any individual offset that might occur. The calibration will also determine if it is possible to track the patient's gaze at all. In case that the sensors cannot pick up the gaze properly (i.e. some glasses, eyelid, ..) or the patient is not able to follow the green cross with sufficient fixation, gaze tracking will be automatically disabled as the fixation information reported would not be reliable in that case. The patient gets three attempts at calibration.

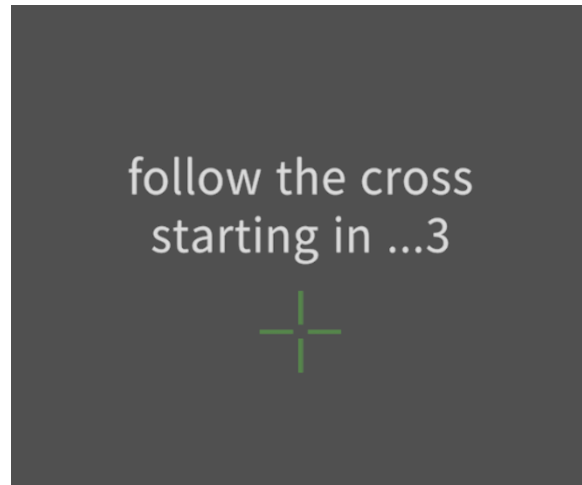


Figure 5 Gaze Tracking Calibration starting view. The patient is asked to follow a green cross on its trajectory



Figure 6 Perimetry examination with a bright stimulus (left) and a dimmer stimulus (right)

When the test is finished, the Patient will see this message:

You have finished your test
for the left eye. You can
now remove the headset.

After 10 seconds, the VR will automatically go back to the initial message, either waiting for a new test, or displaying the next one if already set up.

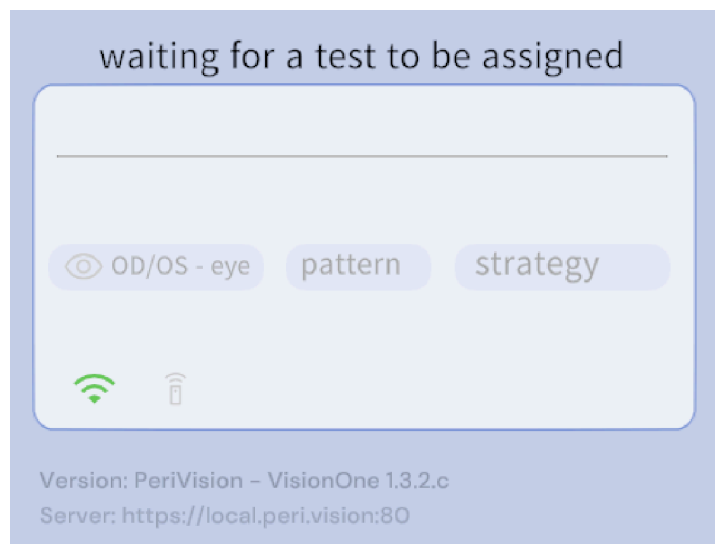


Figure 7 VisionOne VR App waiting for a new test to be assigned

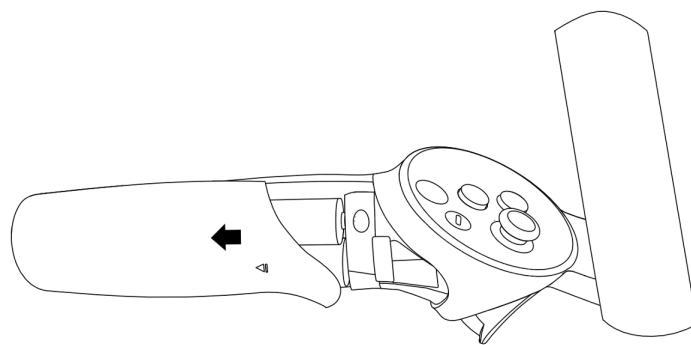
6.9 VR Headset cleaning instructions

Clean the black rim around the lenses to ensure there is no dirt obstructing the eye-tracking system.

Disinfect the Headset between the Patients with the standard hospital's disinfection solution. Wipe the parts that are in contact with the Patient's face and head as well as the used clicker (one button clicker or VR controller) with a cleaning product and/or replace the hygiene cover.

6.10 Changing the batteries on the VR Controllers

The VR home screen displays the battery level of the two VR controllers. To exchange the batteries, press and slide down the cover as shown in the picture. Each controller takes two 1.5V AA type batteries.



7 One-button clicker

The device is shipped with the manufacturer's original controllers as well as the one-button clicker.

7.1 How to use the one-button clicker

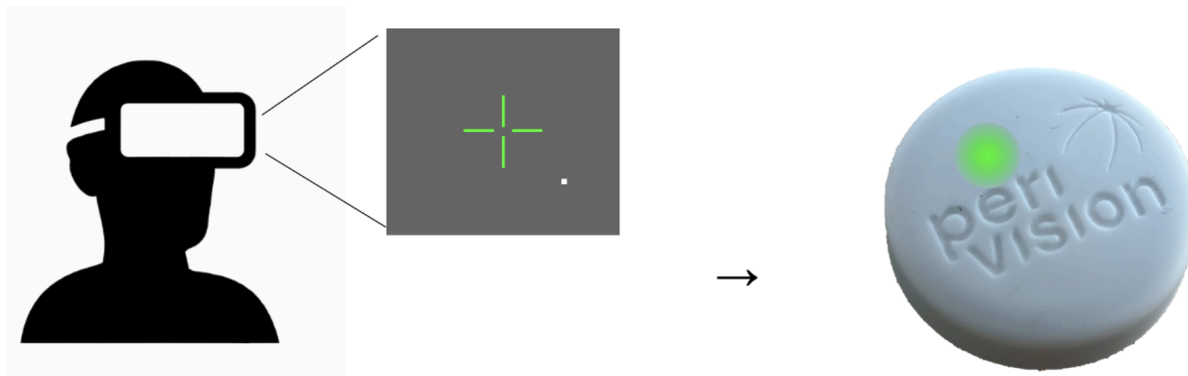
Whilst taking the perimetry exam, the patient can use the clicker to send information to the VR Headset. The Clicker provides a more user-friendly alternative to the VR Controllers. It can only be used within the VisionOne VR Application as controlling the VR headset outside the VisionOne VR App required pointing (which is not possible with the Clicker). Pressing and releasing the Clicker within the VisionOne App is equivalent to pressing any of the response buttons (A, B, X, Y, Triggers).



VisionOne Patient Clicker

7.2 For patients

Once the patient has the VR headset on, they can control VisionOne VR Application the same way they would using the X/A buttons on the original VR controllers.

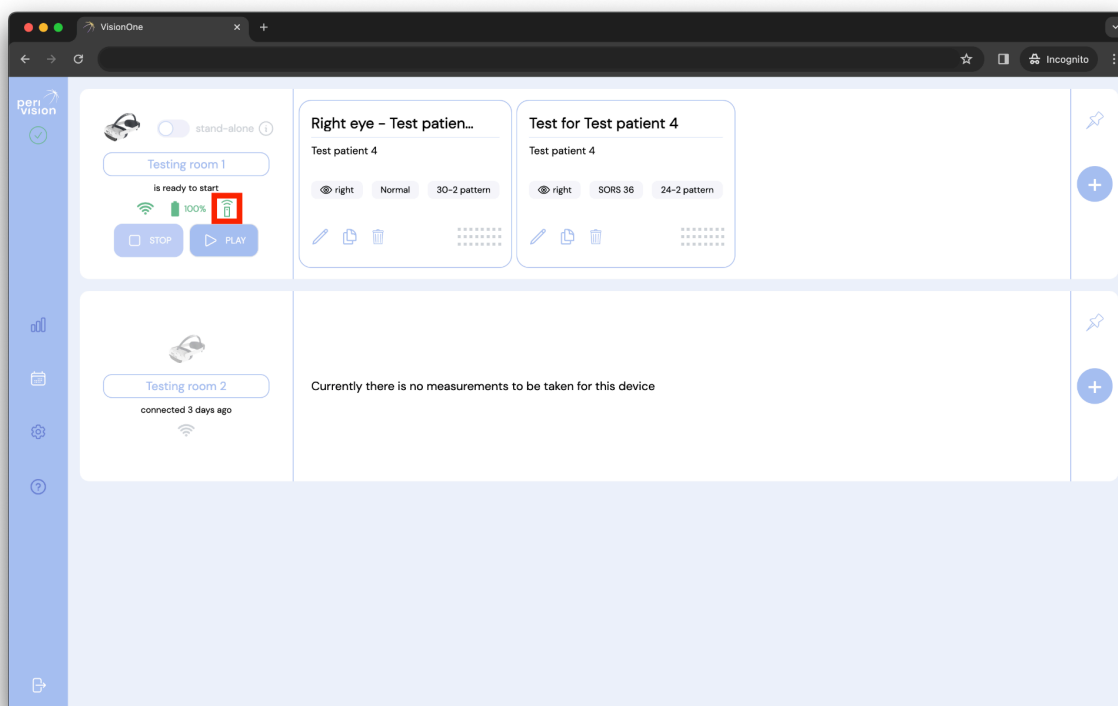


When the button is pressed, a green light will show on the button, this indicates that the button press has been registered. You should also be able to hear a “click” from the button that has been pressed, this gives an audible feedback to the patient.

7.3 For healthcare specialists

7.4 Connecting the clicker to the VR headset

When you get the headset and the clicker, they will already be connected and paired so there is no need to do anything else. You can check the connectivity on the dashboard, there will be a green icon when they are paired:



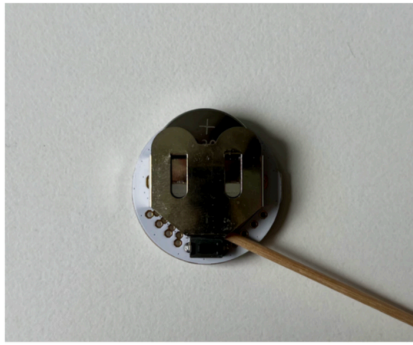
7.5 Using the clicker vs the VR controller

Even though the clicker is being used for the perimetry test, the healthcare specialist will still need to use the VR controller for certain setup steps (such as connecting the VR headset to WiFi and opening the VisionOne VR Application). The clicker is only to be used during the Perimetry examination.

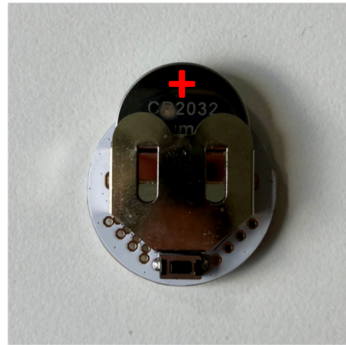
7.6 Battery level and changing the batteries

The battery level of the clicker will be indicated in the clinician dashboard. When the battery level is under 25%, the button will flash a red light instead of a green light when pressing the button, this indicates that the battery level is low. If the battery level is at 0%, in this case, the red (or green) light won't appear when pressing the button, you will need to replace the standard 3V CR2023 Lithium Cell.

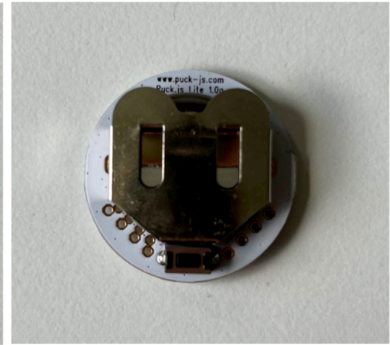
To do this, peel off the white plastic cover of the Clicker and remove the PCB from its black housing. Using any non-conductive tool (i.e. a toothpick, plastic tweezers, ..) press out the battery. Insert the new battery facing the plus pole away from the PCB.



use non-conductive tool to remove



facing the + pole



slide in the battery

Figure 8 How to remove and add 3V CR2032 Lithium Cell of the Patient Clicker

7.7 Resetting the clicker

If for any reason, the clicker stops responding, you can try to reset it. To do that, simply remove the battery and put it back. A red light should flash once when you put back the battery inside.

7.8 Clicker Troubleshooting

If you observe that the clicker is not working reliably, we recommend that you inform us and meanwhile use the VR Controllers to have the patient perform the visual field test. In such a case, please instruct the patient carefully which buttons they can choose from (most patients prefer pressing the Trigger button with their index finger).

8 Glossary

8.1 VisionOne

VisionOne web app and VR app as a system

8.2 VisionOne Web App

the web app for managing Patients and their Measurements

8.3 VisionOne VR Application

the VR app for taking visual field tests

8.4 Organization

an entity that represents a clinic, hospital or a single MD clinic

8.5 User

a healthcare specialist, technician or nurse that has access to the system and belongs to an organization

8.6 Patient

an entity of a patient in PeriStation

8.7 Measurement

an entity of a visual field test

8.8 Device

an entity of the VR devices

8.9 SORS

Sequentially Optimized Reconstruction Strategy:

Standard automated perimetry (SAP) testing is an inherently time-intensive and noisy process. Over time, the patient's response reliability declines due to fatigue. Therefore, the goal of SAP testing strategies is to optimize the trade-off between accuracy and speed.

VisionOne offers the application a novel artificial intelligence-based testing strategy Sequentially Optimized Reconstruction Strategy (SORS) for SAP testing. SORS allows reconstructing visual fields from a limited number of measurements i.e., testing a sparser grid of locations by assuming the existence of correlation between visual field locations. In an initial training phase, we sequentially determined locations that most effectively reduce visual field estimation errors. We then exploit these locations at examination time in combination

with the commonly known staircasing scheme used in Dynamic Strategy (DS) where the intensity of presented stimuli changes in fixed step sizes. SORS's only additional parameter to be defined is the number of tested locations (also referred to as stage). The stage determines the sparsity of the grid and therefore the degree of approximation. Assuming the G-pattern is used, the SORS stage can be chosen anywhere in the range of 4 to 59 [1].

9 References

[1] S. Kucur and R. Sznitman, "Sequentially optimized reconstruction strategy: A meta strategy for perimetry testing," PLOS ONE, vol. 12, p. e0185049, 10 2017.