



**Instructions for Use
Part 2**

VisionOne

(Operations User's Manual)

Contents

1	Introduction	3
1.1	About This User Manual	3
2	Web Application VisionOne	3
2.1	Logging in	3
2.2	Password reset	4
2.3	Password change	4
3	Clinician dashboard	5
3.1	Adding a new Patient	5
3.2	Editing/Deleting of existing Patient's data	7
3.3	Viewing the Measurement's result	9
3.4	Maximizing the Visual Field Chart	13
3.5	Saving PDF/Printing of taken measurements	14
3.6	Perimetry Progression Chart	15
4	Technician dashboard	16
4.1	Adding a new Measurement	16
4.2	Reordering of Measurements between devices	18
4.3	Editing/Cloning/Deleting of non-taken Measurement	19
5	VR stand-alone mode	19
5.1	How to activate the stand-alone mode	19
6	VisionOne VR Headset	21
6.1	Component overview	21
6.2	VR Headset components	21
6.3	Setting up the Pico VR Headset	22
6.4	Positioning VR headset (critical !)	23
6.5	Setting up the VR headset	24
6.6	Quitting VisionOne VR Application	24
6.7	Controlling the 3D view	25
6.8	Conducting a Perimetry Examination	25
6.9	VR Headset cleaning instructions	27
6.10	Changing the batteries on the VR Controllers	27
7	One-button clicker	28

7.1	How to use the one-button clicker	28
7.2	For patients	28
7.3	For healthcare specialists	29
7.4	Connecting the clicker to the VR headset	29
7.5	Using the clicker vs the VR controller	29
7.6	Battery level and changing the batteries	29
7.7	Resetting the clicker	30
7.8	Clicker Troubleshooting	30
8	Glossary	32
8.1	VisionOne	32
8.2	VisionOne Web App	32
8.3	VisionOne VR Application	32
8.4	Organization	32
8.5	User	32
8.6	Patient	32
8.7	Measurement	32
8.8	Device	32
8.9	SORS	32
9	References	33

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

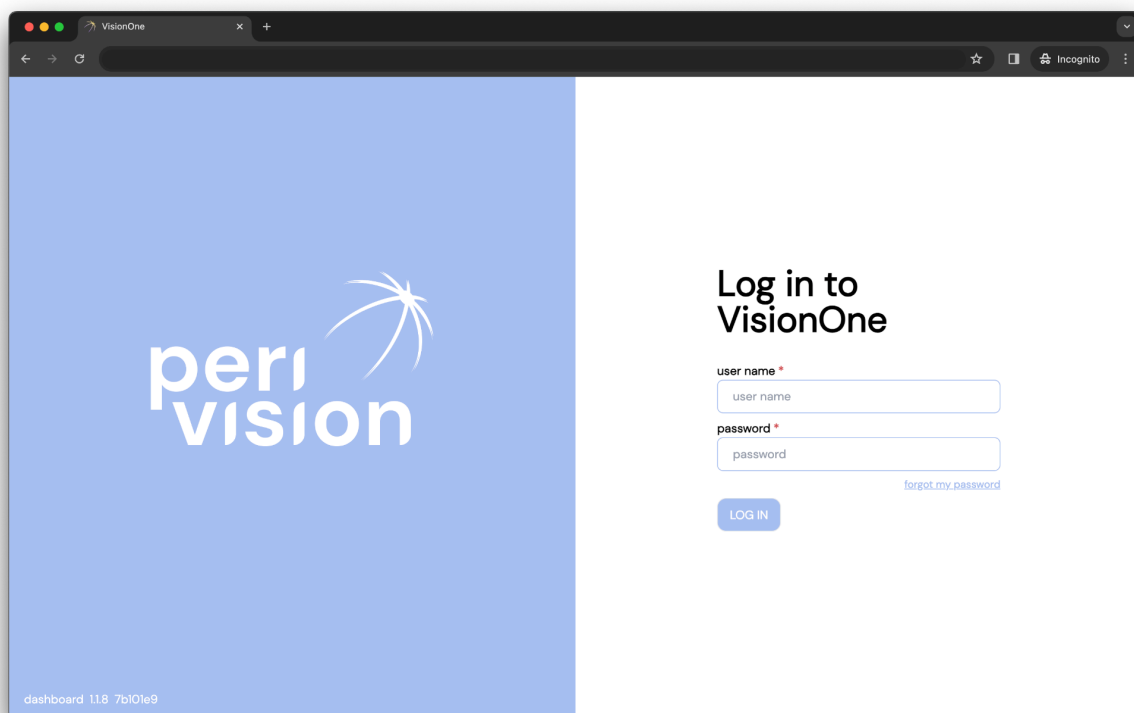
For further questions and information, please contact support@perivision.com

2 Web Application VisionOne

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

2.1 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.



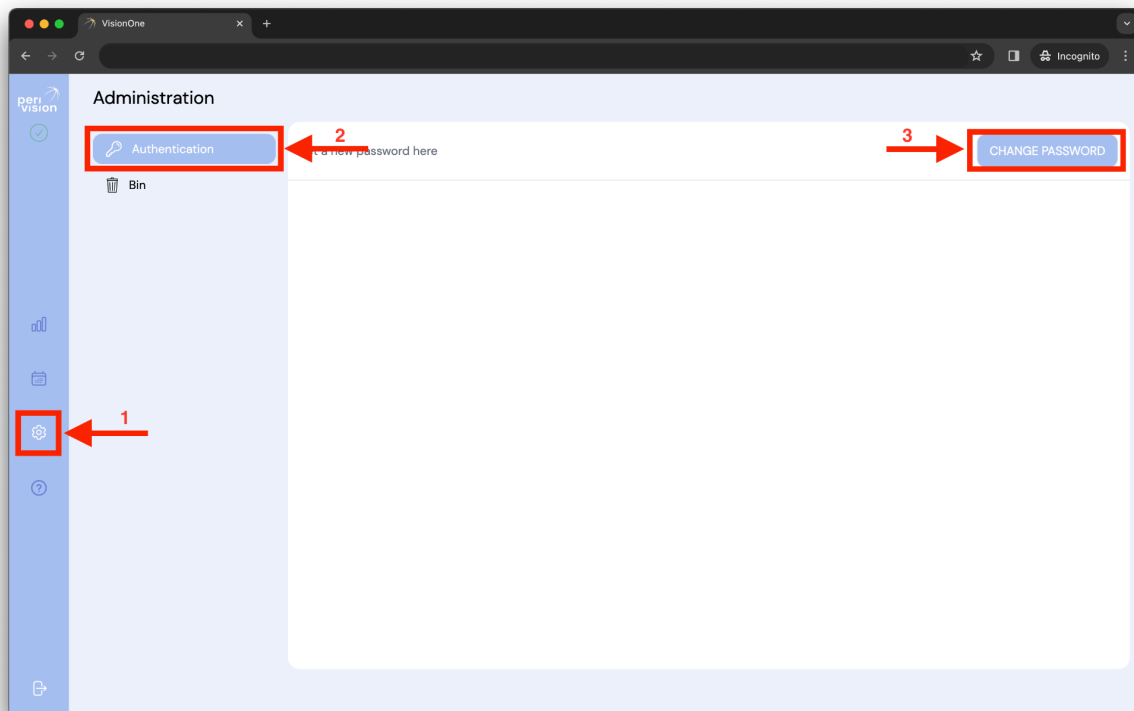
Fill up the user name and password fields with your credentials and click the log in button to log in the clinician dashboard.

2.2 Password reset

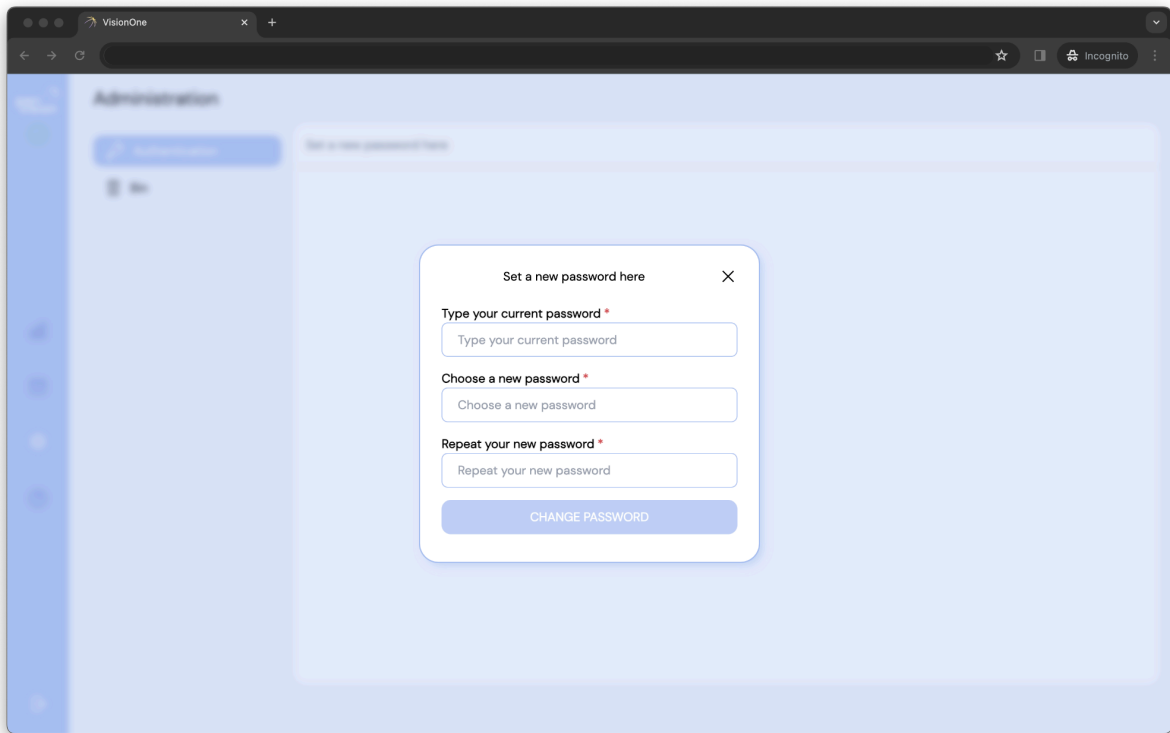
Follow the *forgot my password* link on the login page and follow the link that has been sent to the email inbox associated with the VisionOne user's account to set the new password for this user.

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:



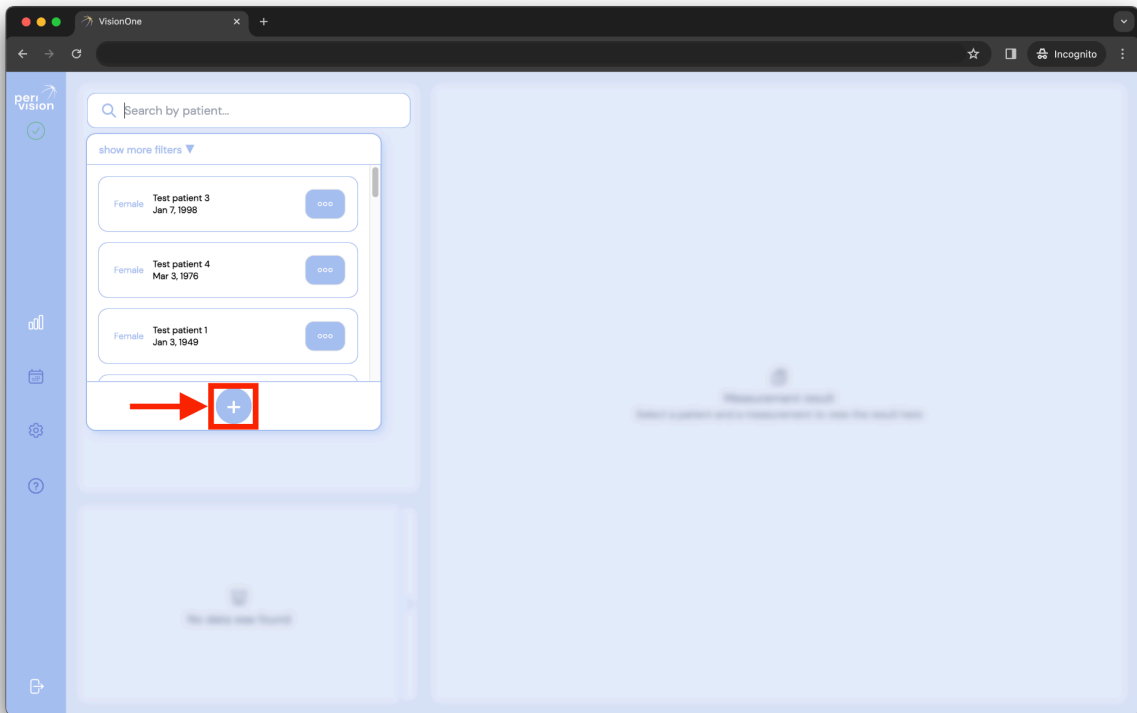
The new window will open with the form to fill. Fill it in following the password requirements instructions and submit the change to set as the new password for this logged in User:



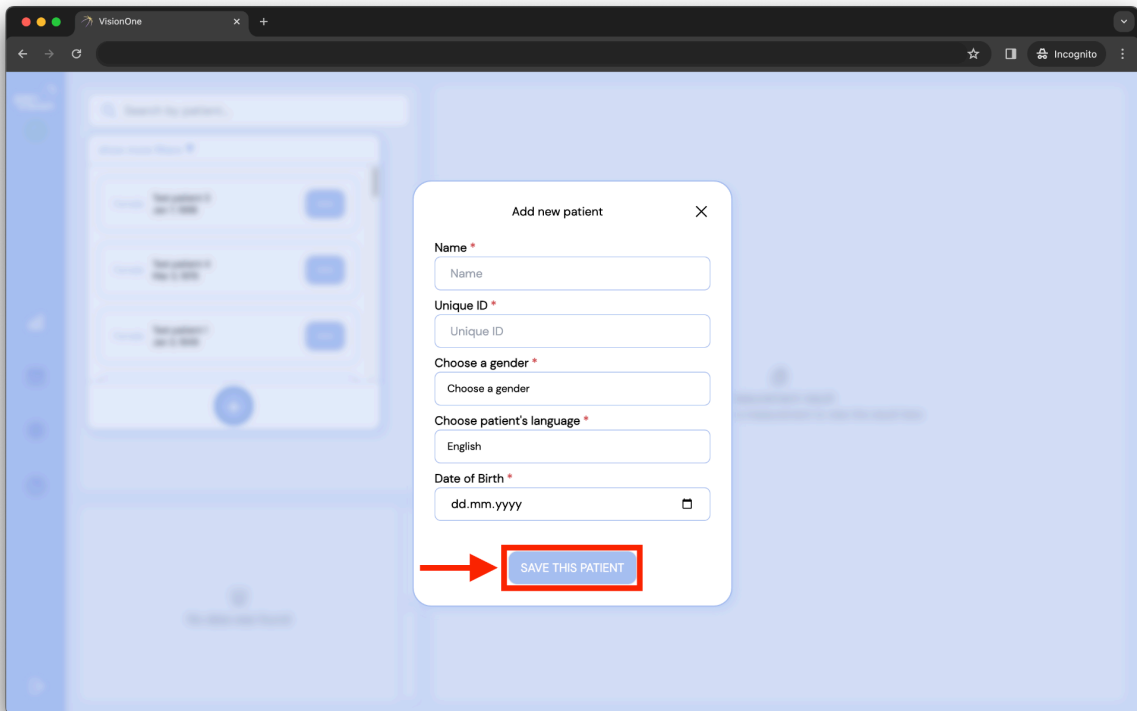
3 Clinician dashboard

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.

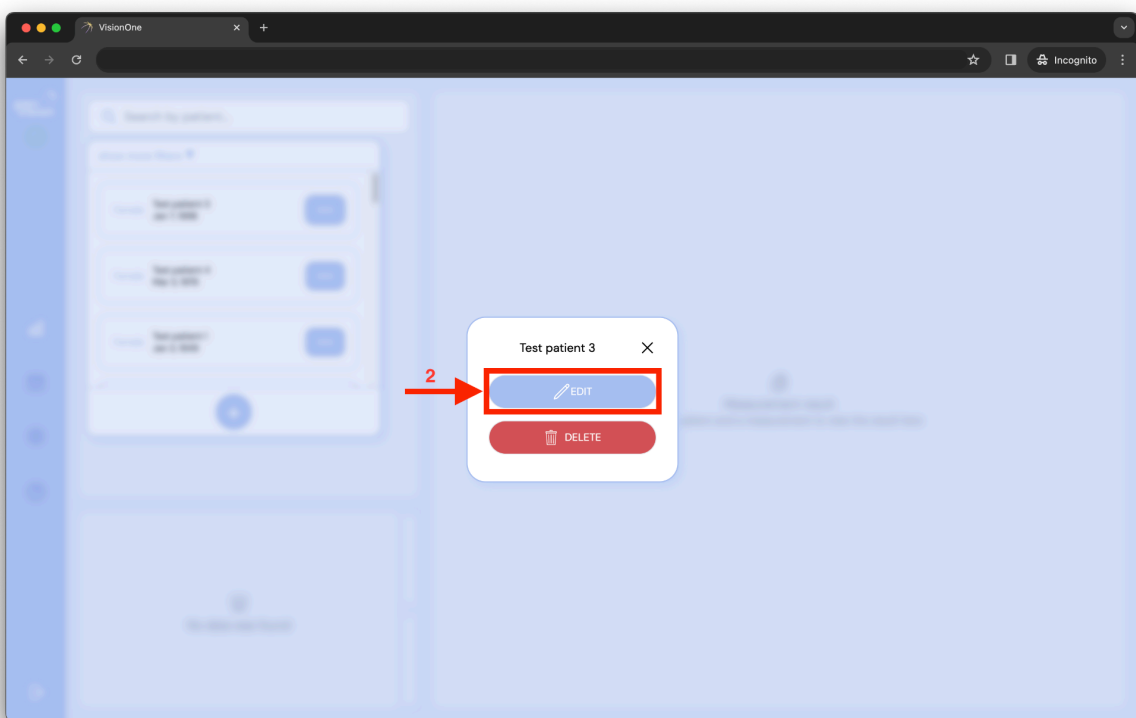
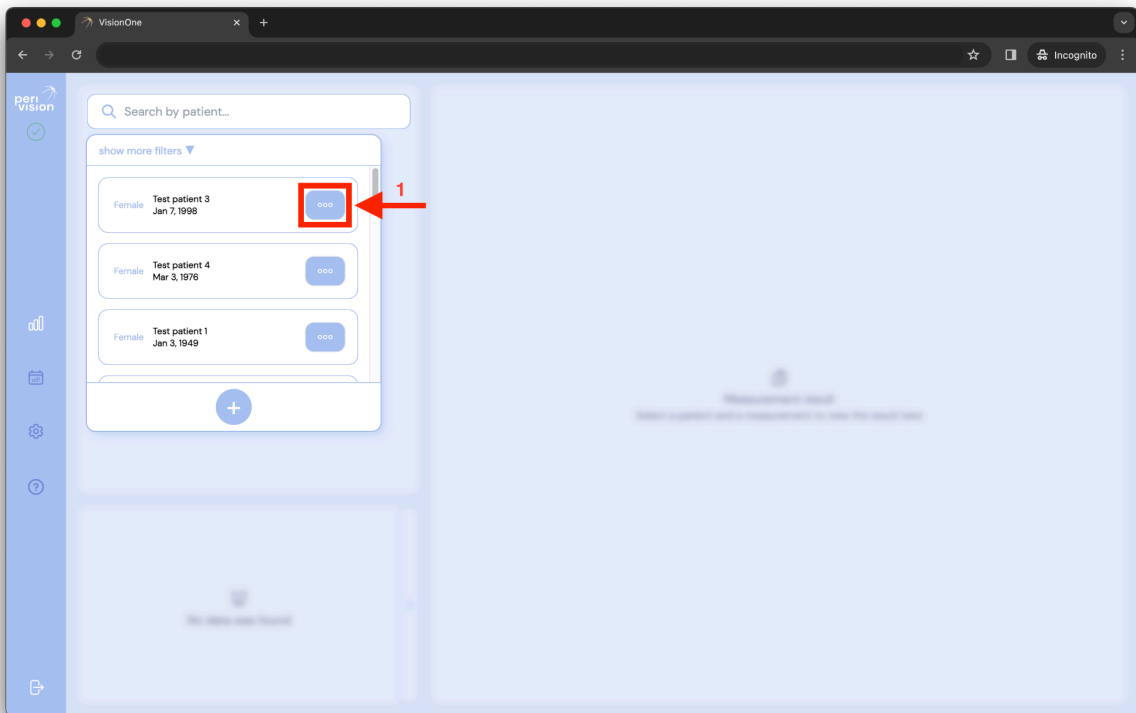


The pop-up with the new patient form will appear. Please fill in the patient information in the respective fields and click Save the patient to save the new Patient. This new Patient will then appear in the patient dropdown search list (see above).

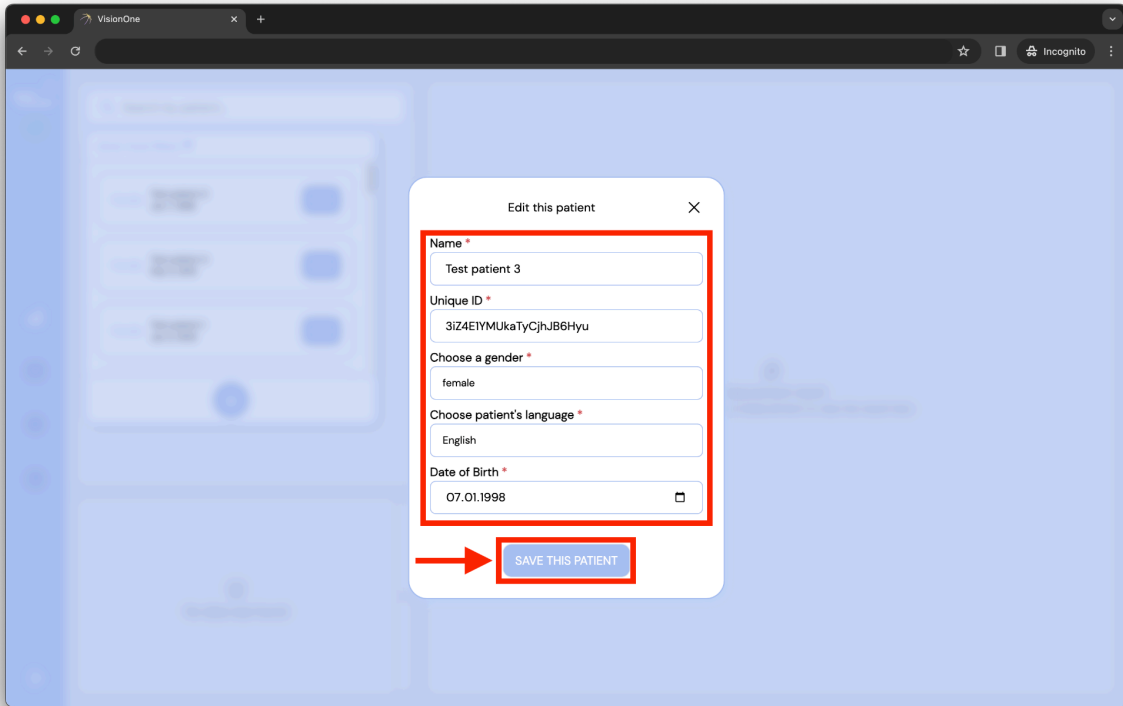


3.2 Editing/Deleting of existing Patient's data

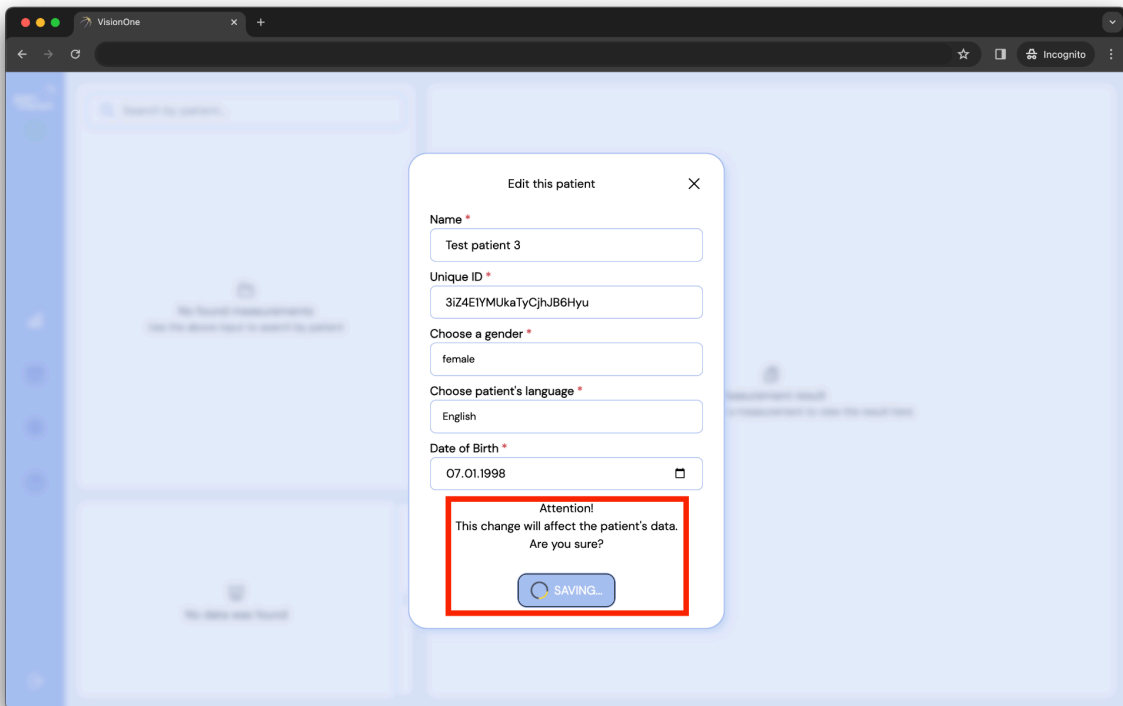
In order to edit the Patient's data click on the three dots symbol on the Patient's card. The context menu for that patient will appear. Choose the edit option by clicking on it (analogically for delete functionality):



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:

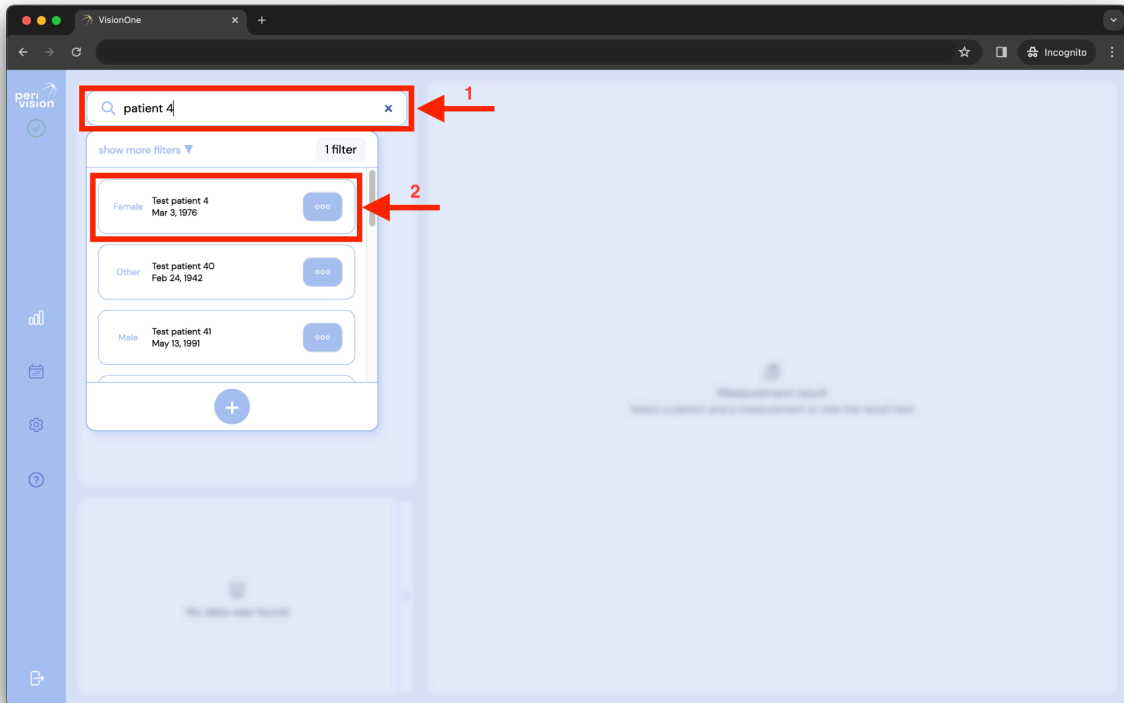


When editing, you will be asked if you are sure to save that data. Confirm or cancel your action by clicking the button:

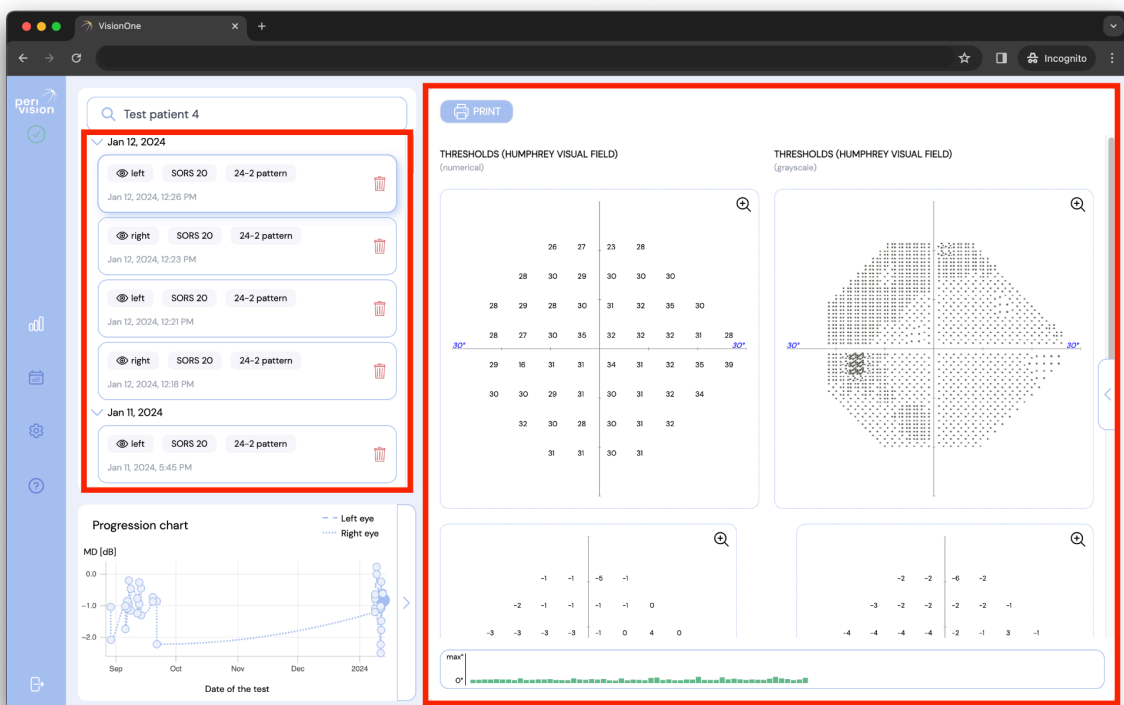


3.3 Viewing the Measurement's result

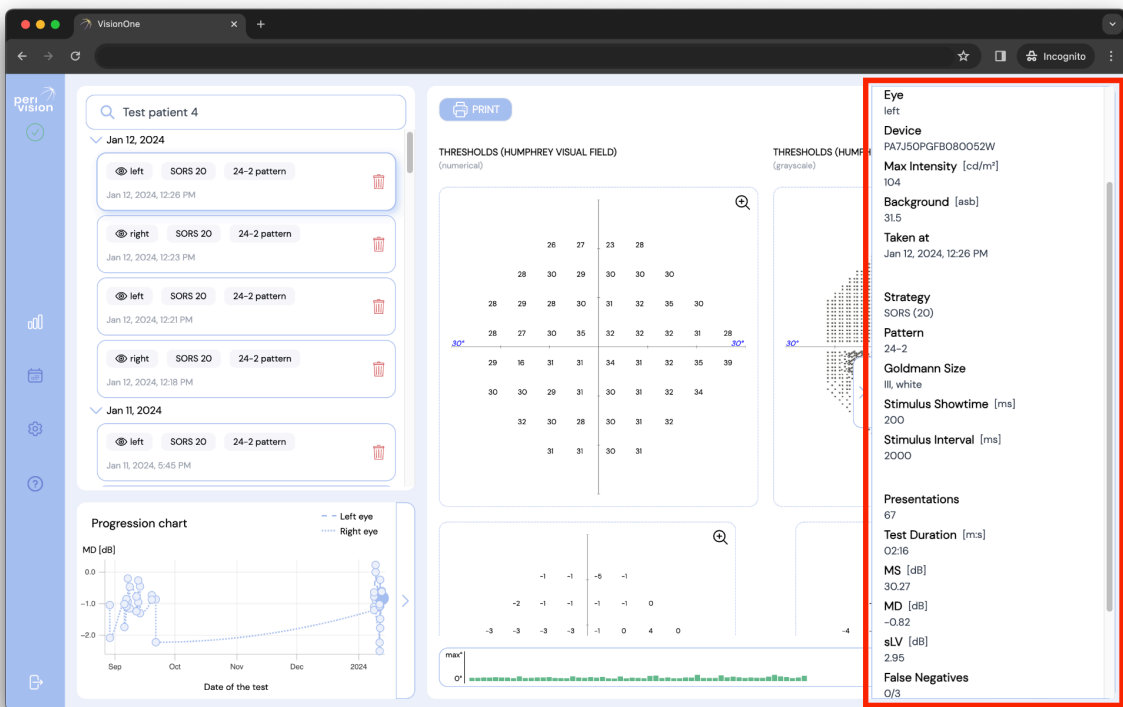
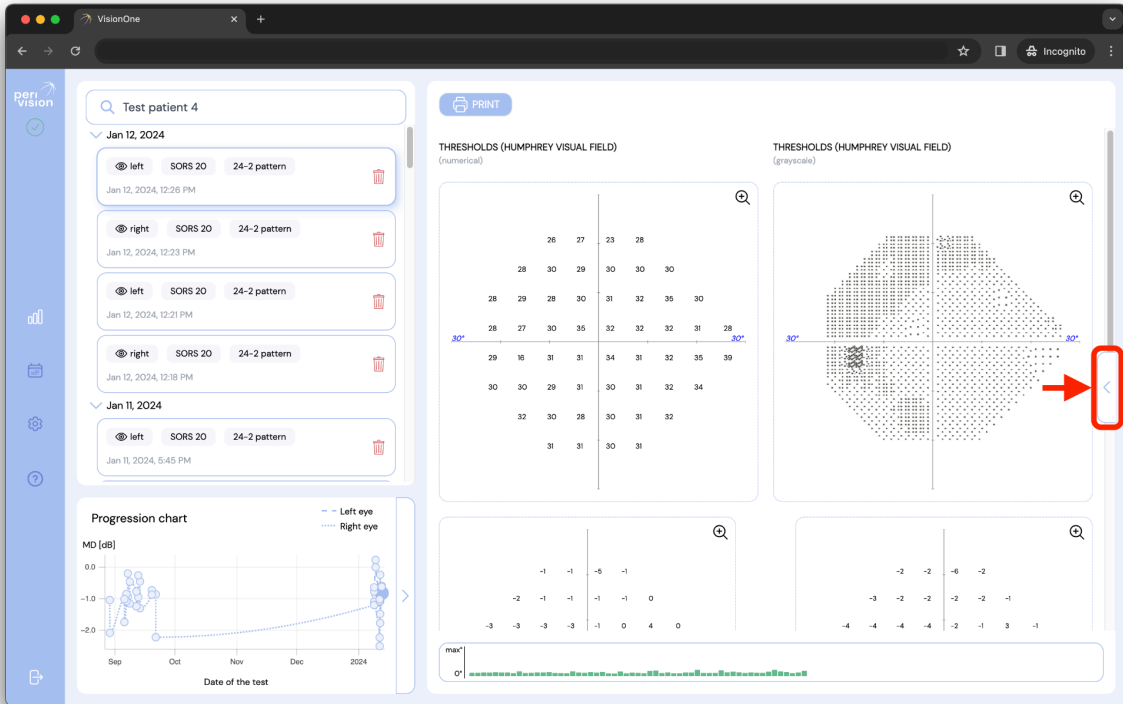
Select a Patient by either typing patient name in the search box or by clicking on the search box and choosing from the dropdown and clicking on the chosen Patient:



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.



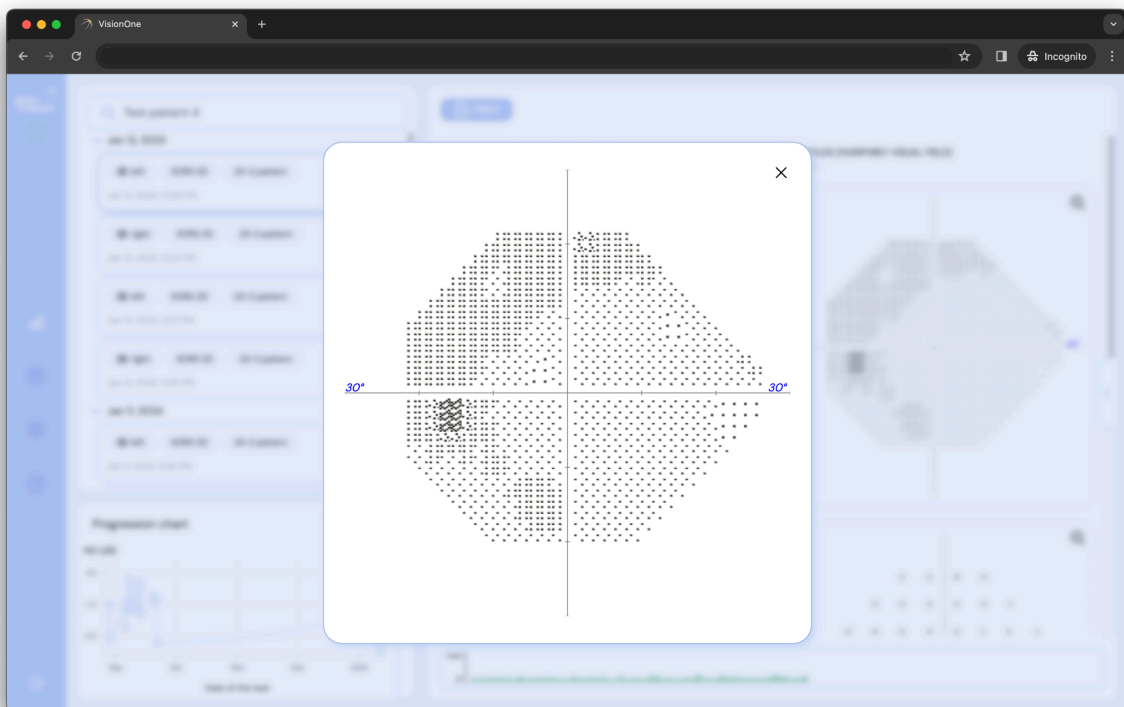
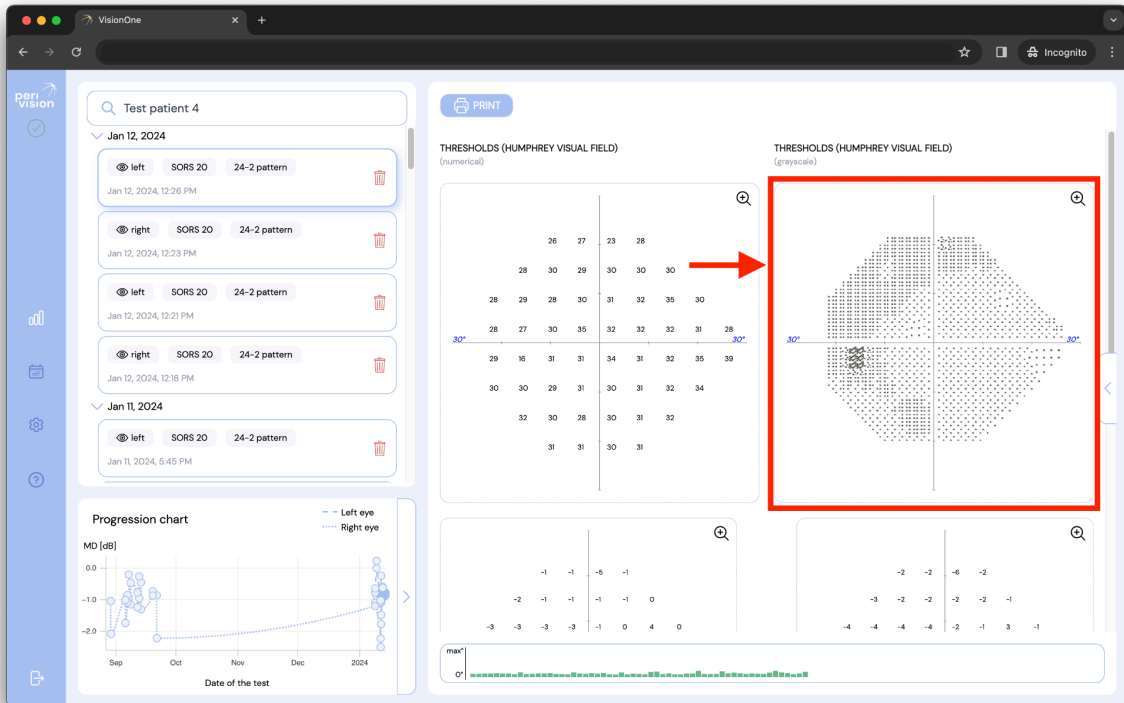
The details of the measurement contain:

- 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.

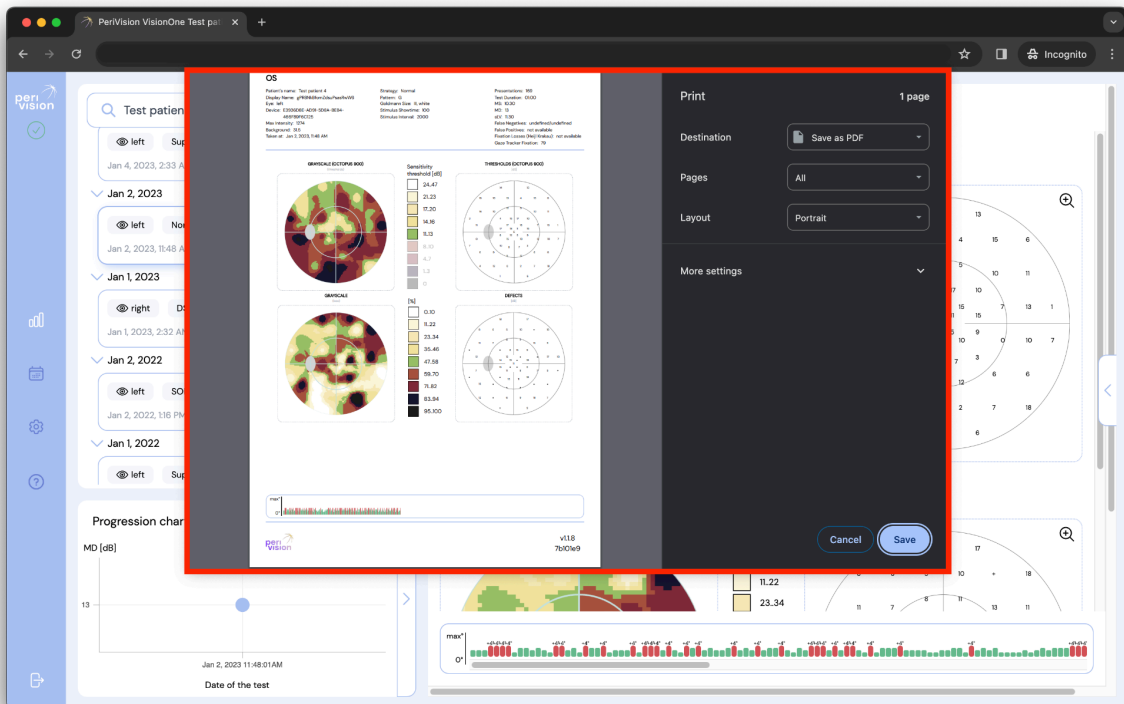
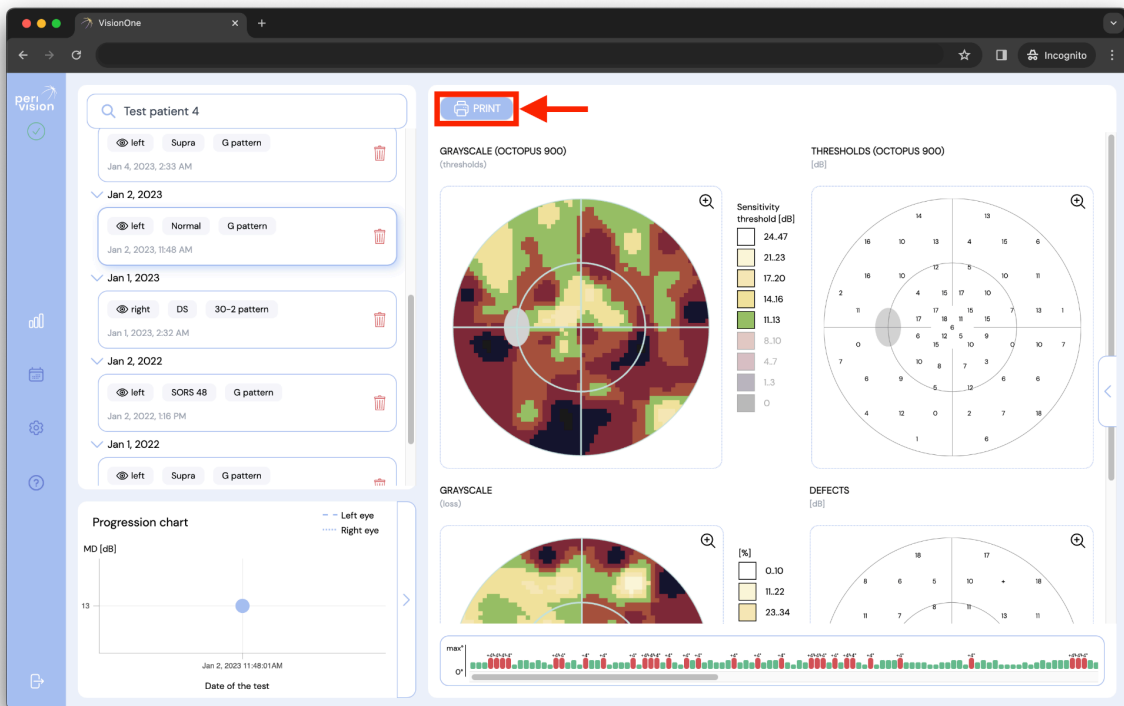
3.4 Maximizing the Visual Field Chart

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

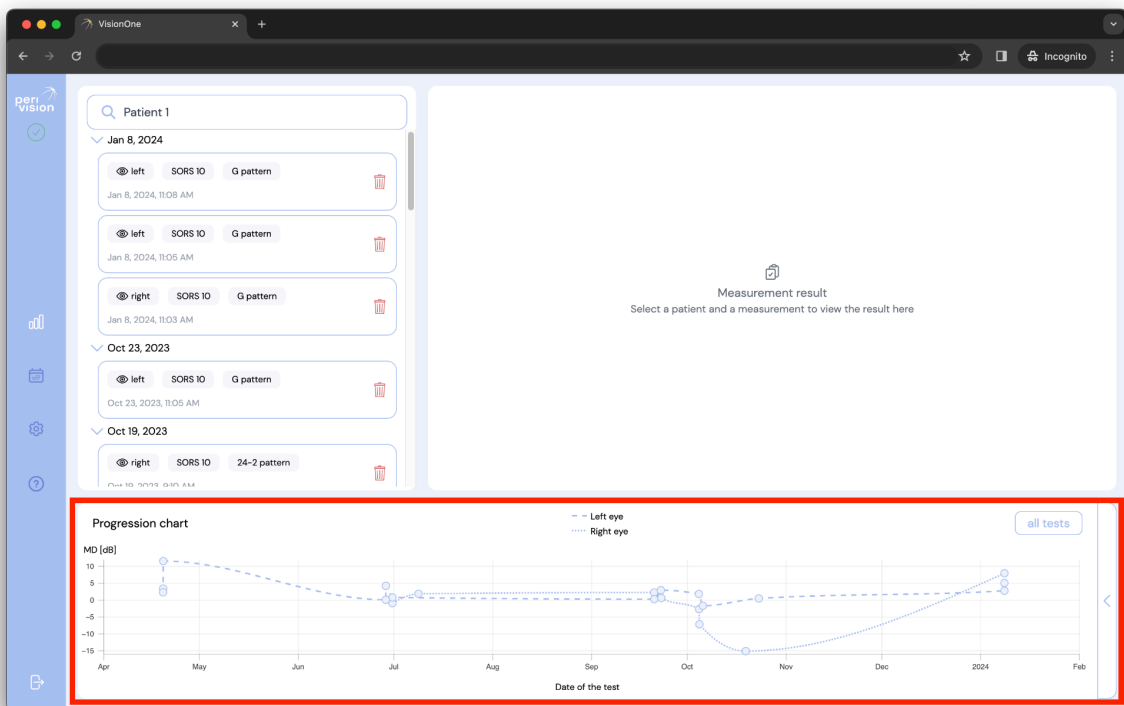
When selecting the test, the test result is presented on the right side of the screen. It also can be printed by clicking the PRINT button in the top left corner of the result:



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.



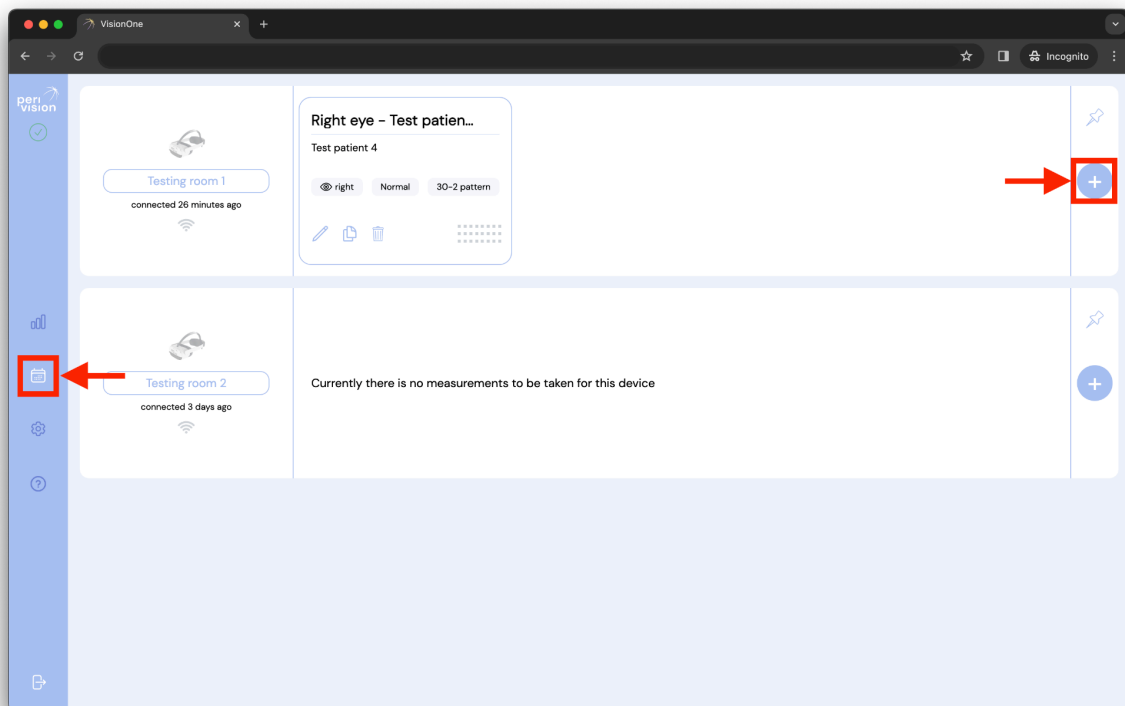
Each dot represents the taken Measurement over time. Clicking on a dot will select the corresponding Measurement in the list in the top left corner.

4 Technician dashboard

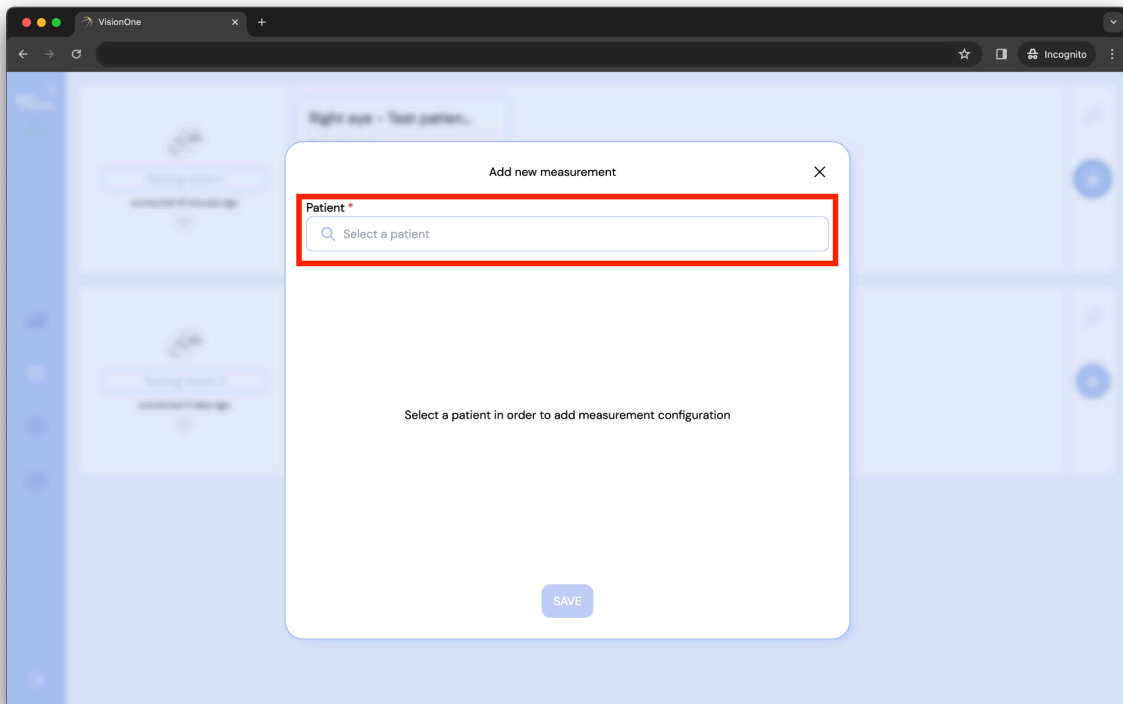
The Technician dashboard is the place in the VisionOne web app to manage your devices and yet to take measurements.

4.1 Adding a new Measurement

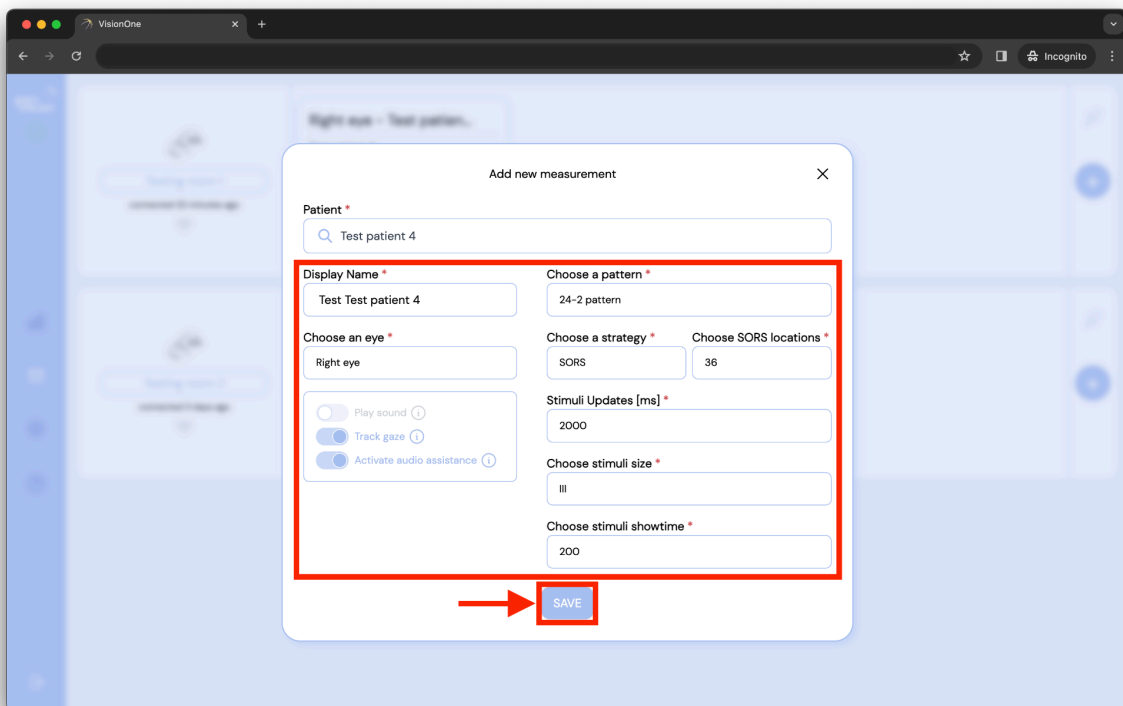
In order to add a new measurement, head towards the technician dashboard and click the round plus button in the swimlane that represents the device you are wishing for to create a measurement:



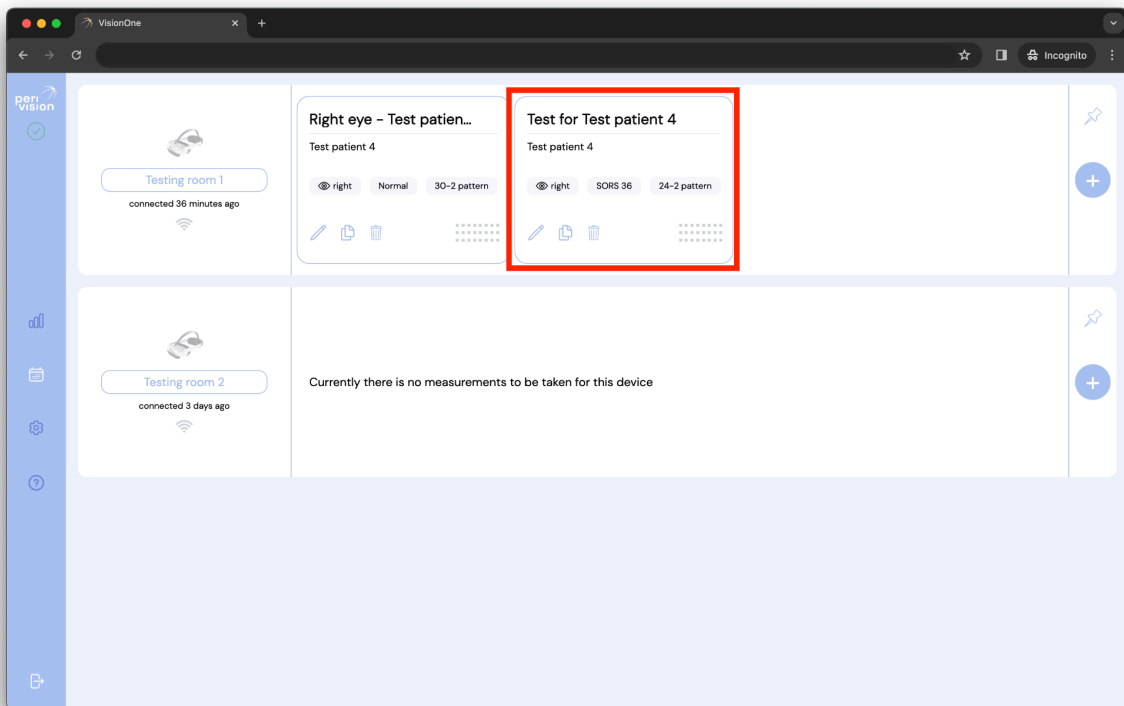
Fill in the form by first choosing a patient:



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

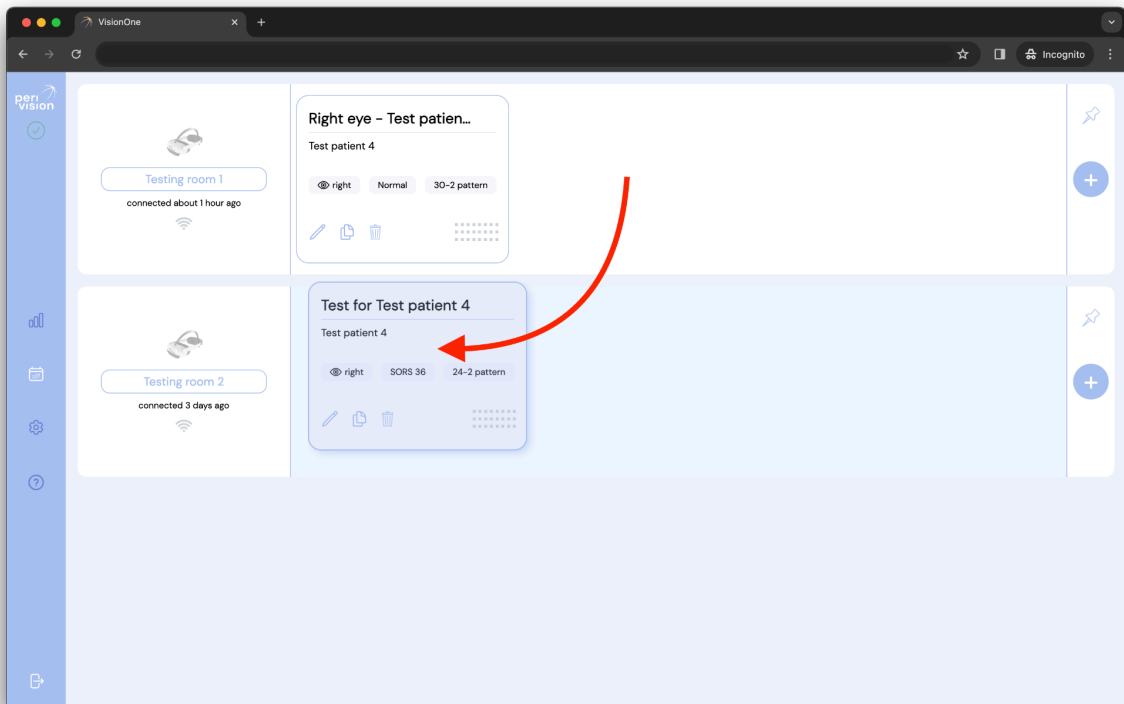


Saving the form with the “SAVE” button will create a new measurement, placing it into the device’s swimlane. The Measurements are waiting for their turn to be taken, with the most left Measurement to be taken as next. Your new measurement will appear right after it:



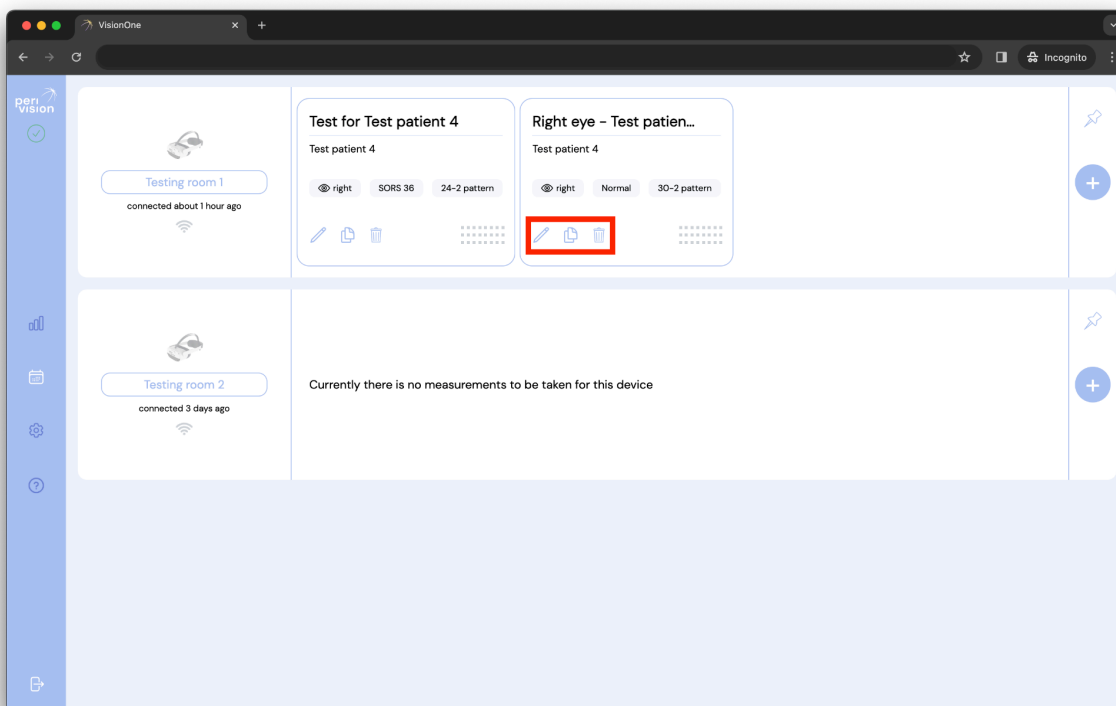
4.2 Reordering of Measurements between devices

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

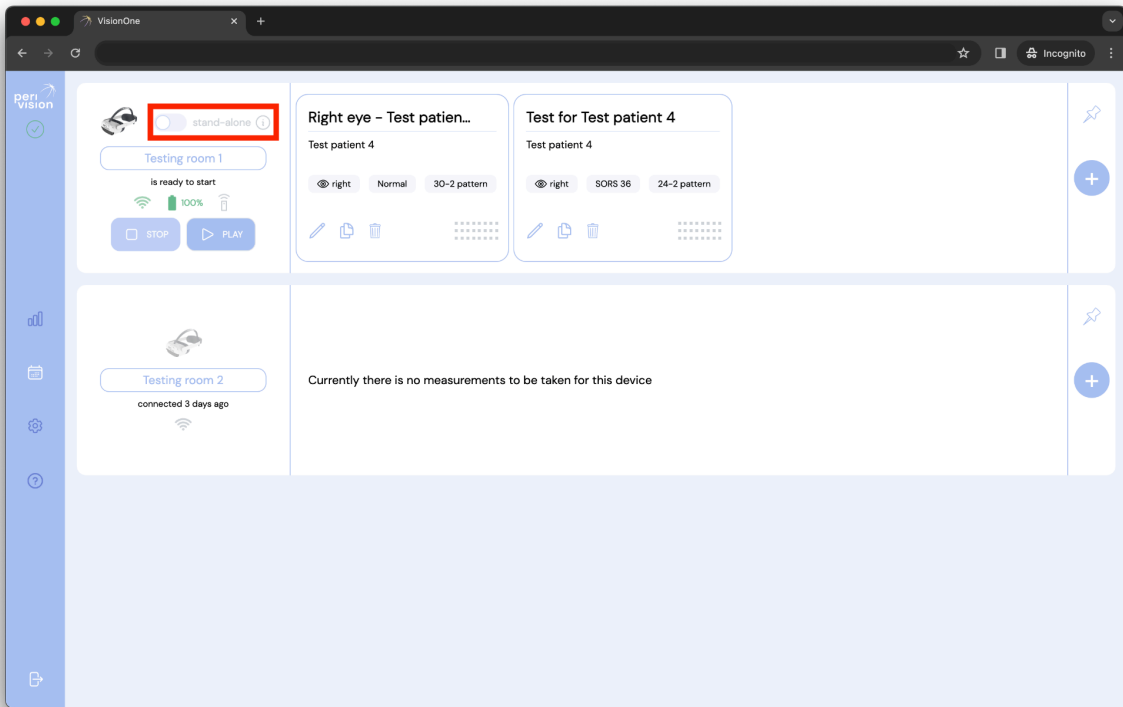
Warning: Dear Client, please be aware that, while VisionOne can be set on stand-alone mode, VisionOne's intended use does not yet cover home use at a patient's home and the application through a lay person alone. If you provide VisionOne to the private environment of patients, the usage would be considered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

Please consider the possibilities discussed under [C\) Intended Use Environment](#)

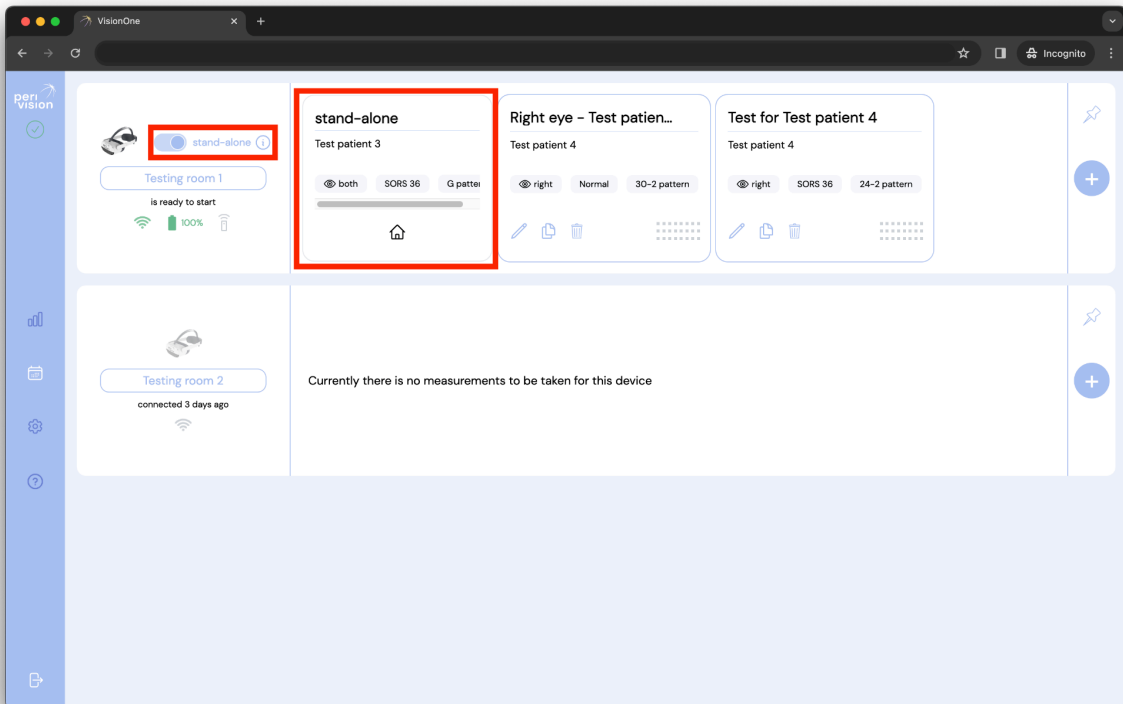
Stand-alone mode can run either when Device is offline or online, so there is no need for Patient to set the WiFi at home. The taken Measurements are stored securely (encrypted) on the device and are going to be uploaded to the server automatically when the network connection is again established.

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.

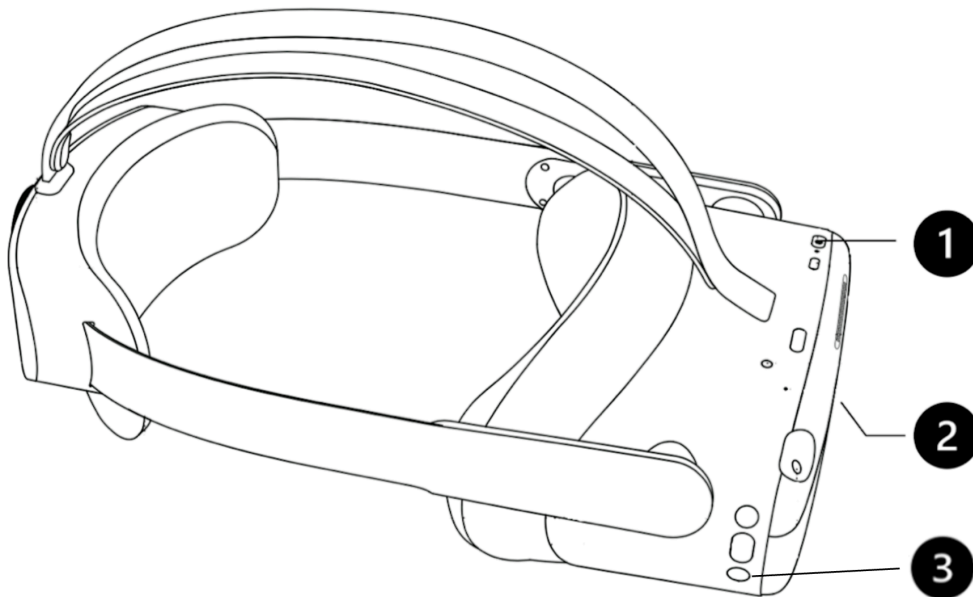


Figure 1 VR headset with (1) power button, (2) volume control (bottom side) and (3) Pico button

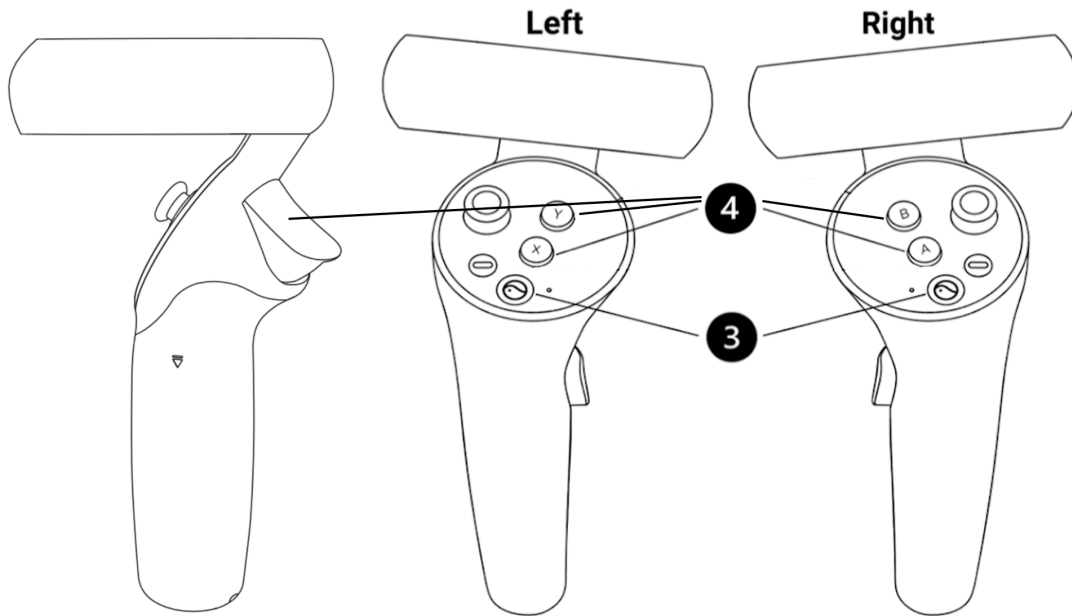
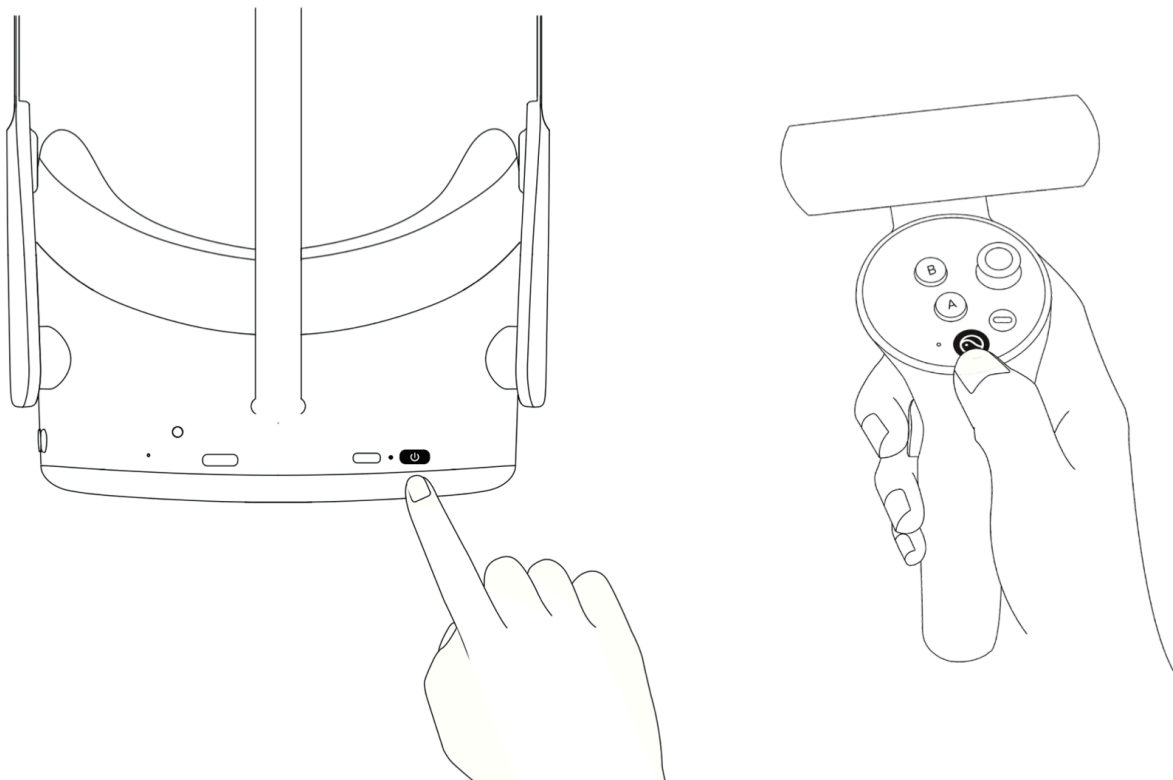


Figure 2 Left and right controllers with (4) X/Y/Trigger (left) and A/B/Trigger (right) buttons for patient's response and controlling the VR headset, (3) Pico button for general settings of the Pico VR headset.

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).



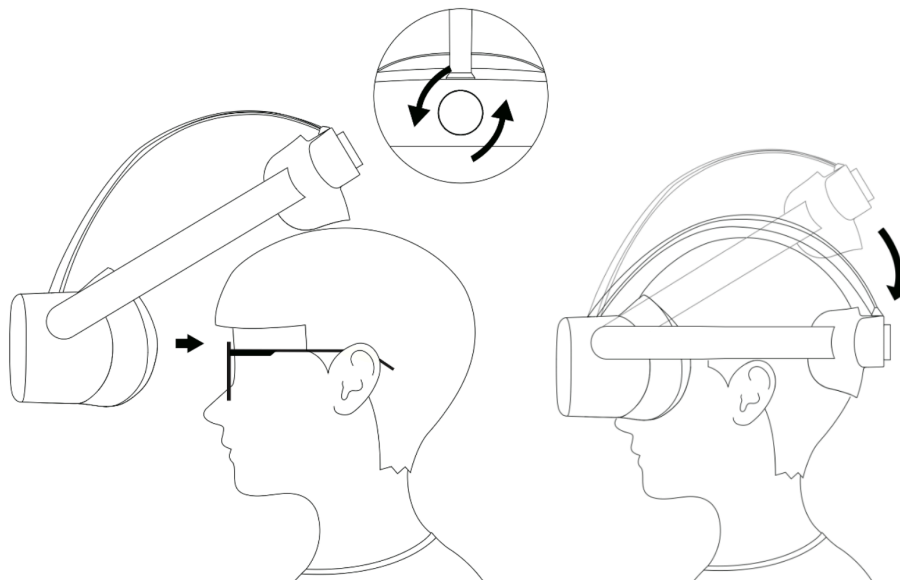
The LED next to the power button indicates the VR headset status.

- 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)

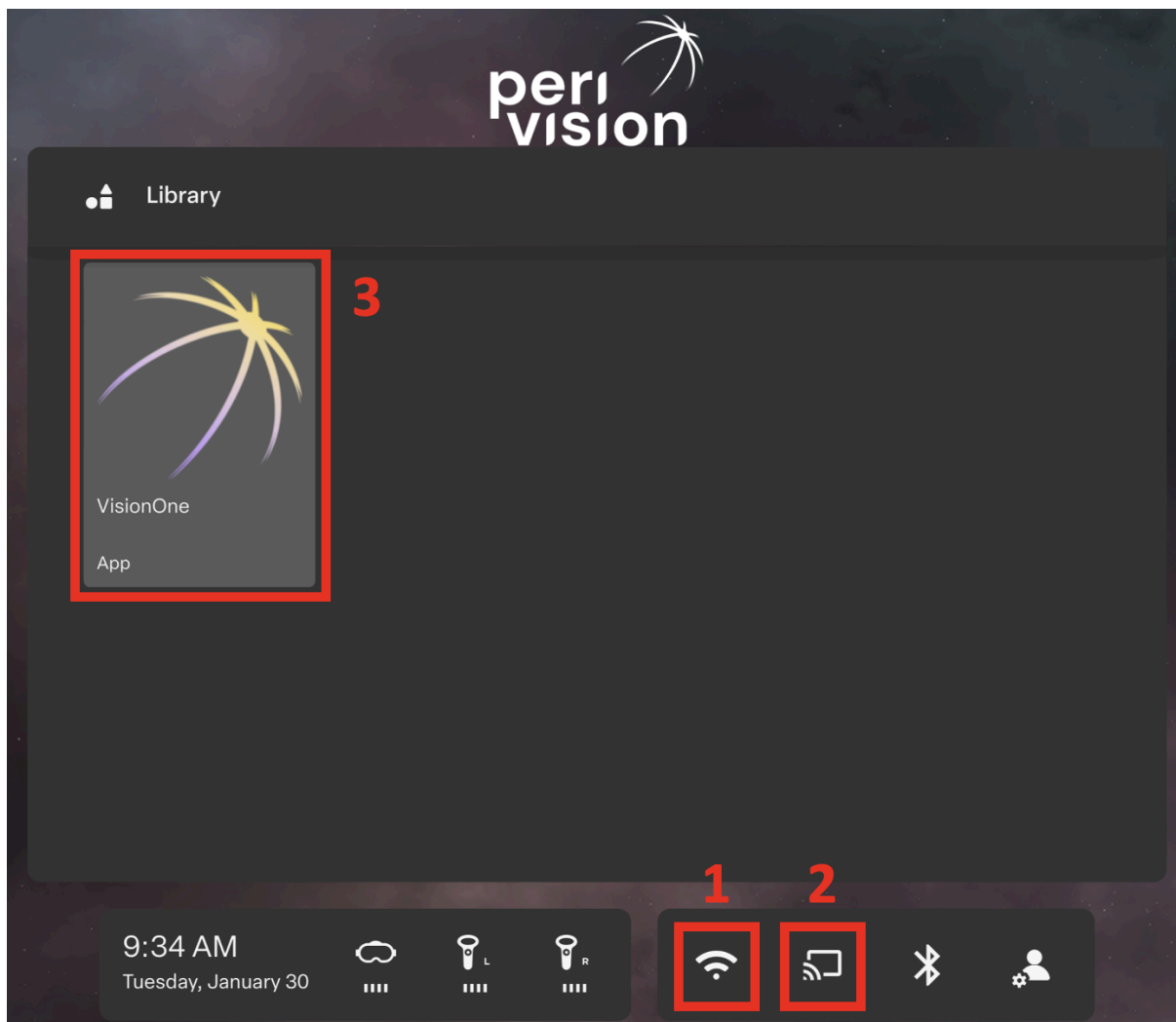


Figure 3 VR Home Screen with (1) WiFi connection, (2) Screen casting option and (3) VisionOne VR Application

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.

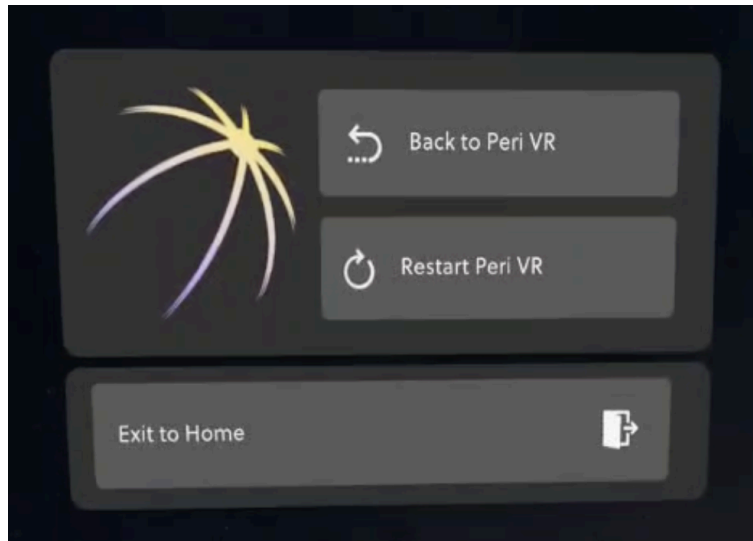


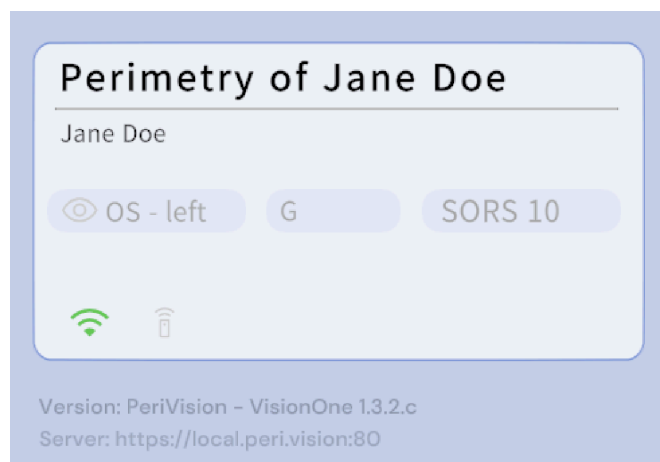
Figure 4 Short-press the pico button to exit VisionOne VR App

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.

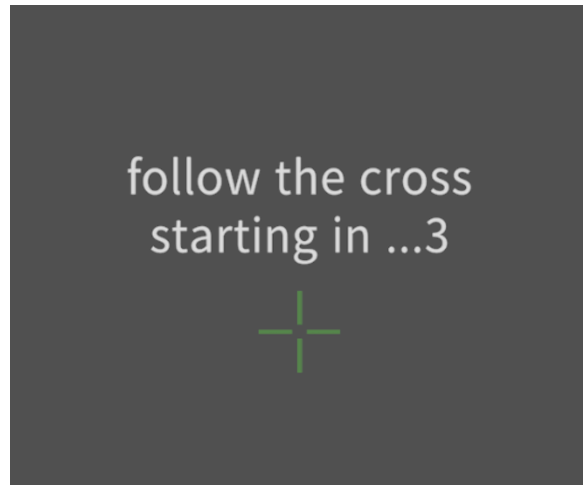


Figure 5 Gaze Tracking Calibration starting view. The patient is asked to follow a green cross on its trajectory



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.

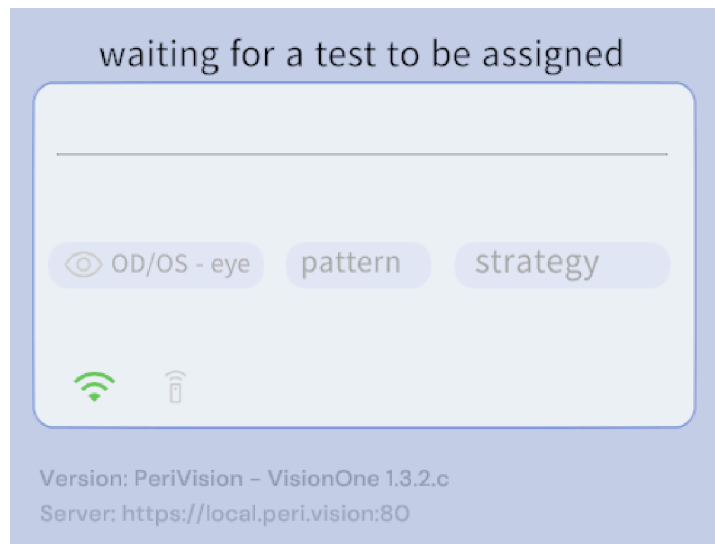


Figure 7 VisionOne VR App waiting for a new test to be assigned

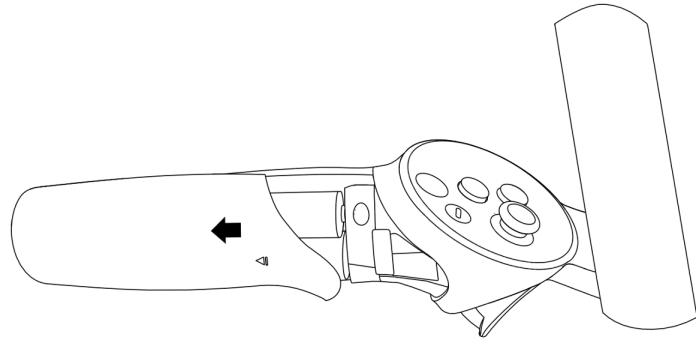
6.9 VR Headset cleaning instructions

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

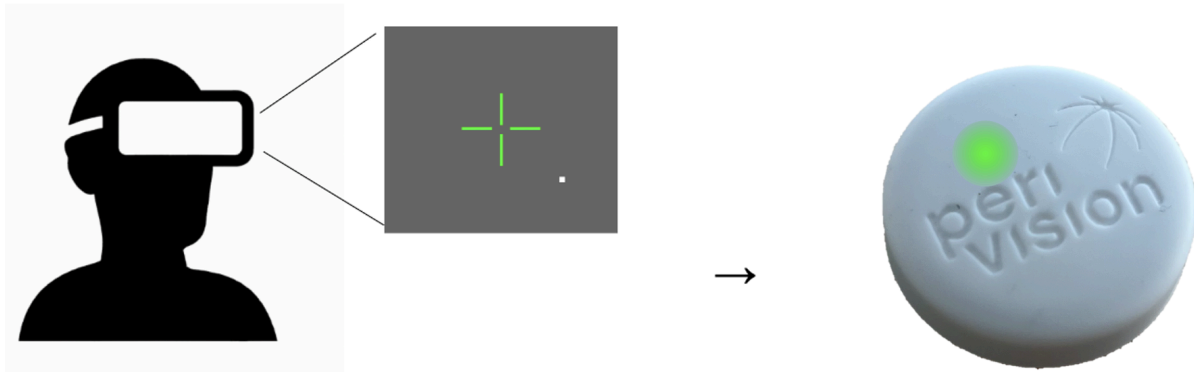
Whilst taking the perimetry exam, the patient can use the clicker to send information to the VR Headset. The Clicker provides a more user-friendly alternative to the VR Controllers. It can only be used within the VisionOne VR Application as controlling the VR headset outside the VisionOne VR App required 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.

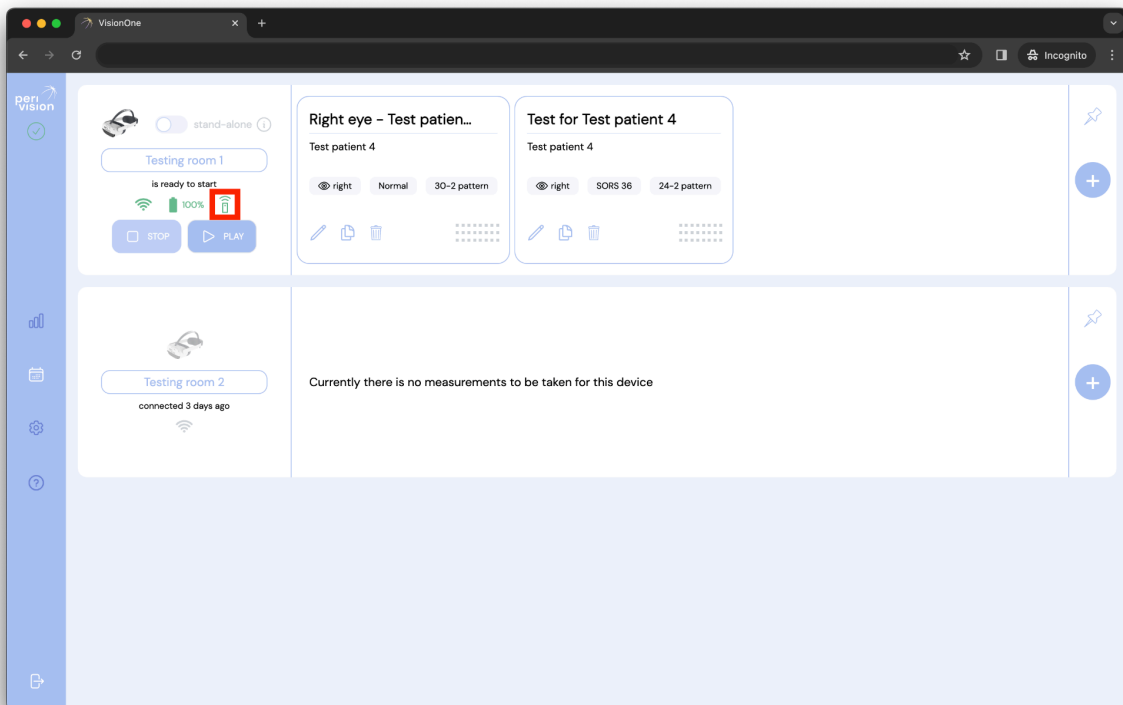


When the button is pressed, a green light will show on the button, this indicates that the button press has been registered. You should also be able to hear a "click" from the button that has been pressed, this gives an audible feedback to the patient.

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.

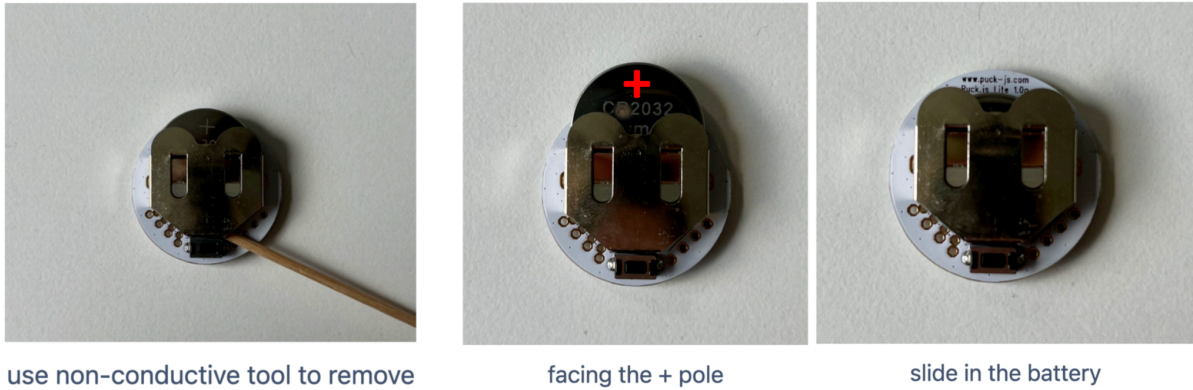


Figure 8 How to remove and add 3V CR2032 Lithium Cell of the Patient Clicker

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.