Instructions for Use
Part 1
VisionOne

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VisionOne V.1.0.0
March 2024

SWISS MADE

Table of Content

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: v1.0.0

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

1.5. 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	CE	0297
	2024-02-21		As long as VR operating system is supported

Description of symbols

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

Table of Content

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 v1.0.0. 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

Table of Content

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 your 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 con- tact 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 , orastigmatism 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 im- plants, 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

Table of Content

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 to 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 theoutside 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 anew 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.

Table of Content

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 in- creases 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 ex- posed 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 head-set 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 equip-ment.

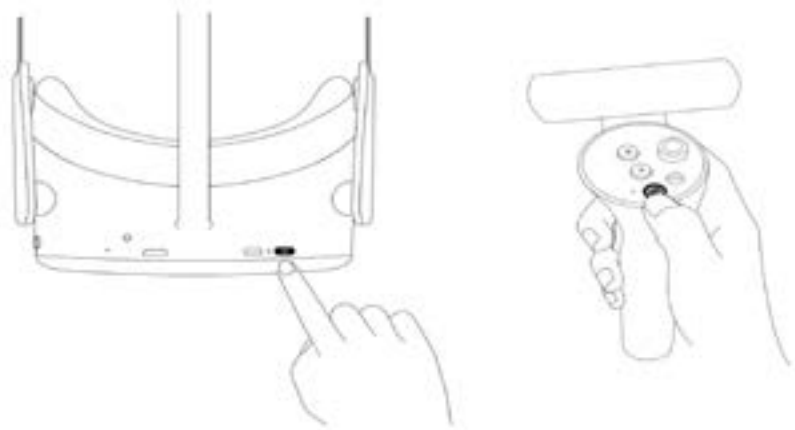
Table of Content

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

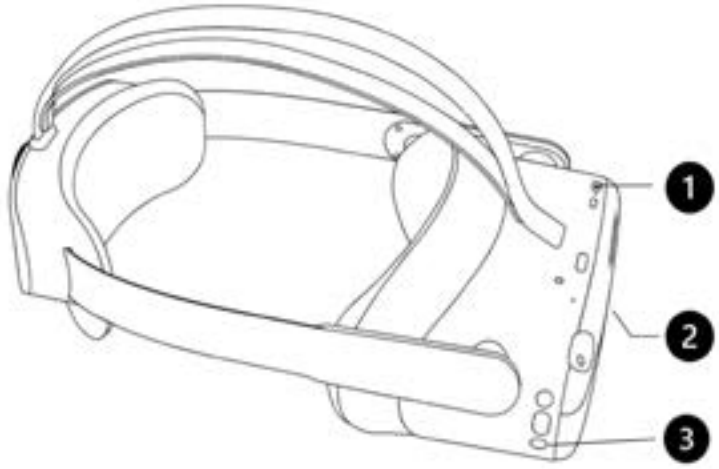


Figure 1 VR headset

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

The left and right hand controllers

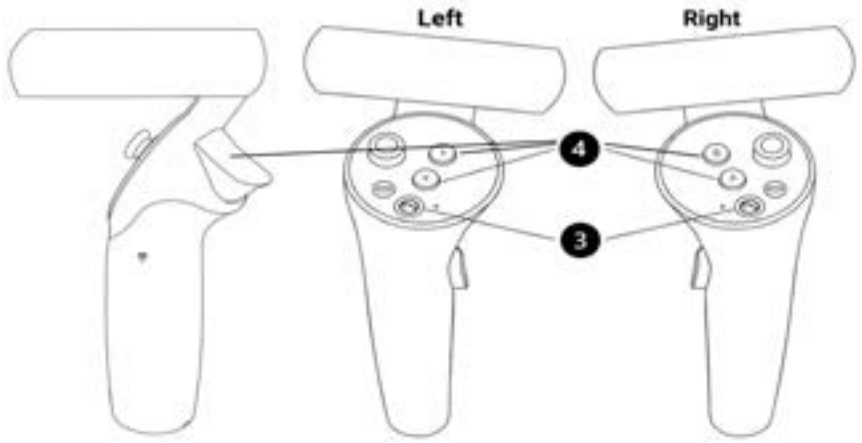


Figure 2
Left and right controllers with **(4)** X/Y/Trigger (left) and A/B/Trigger (right) buttons for patient's response and controlling the VR headset, **(3)** Pico button for general settings of the Pico VR headset.

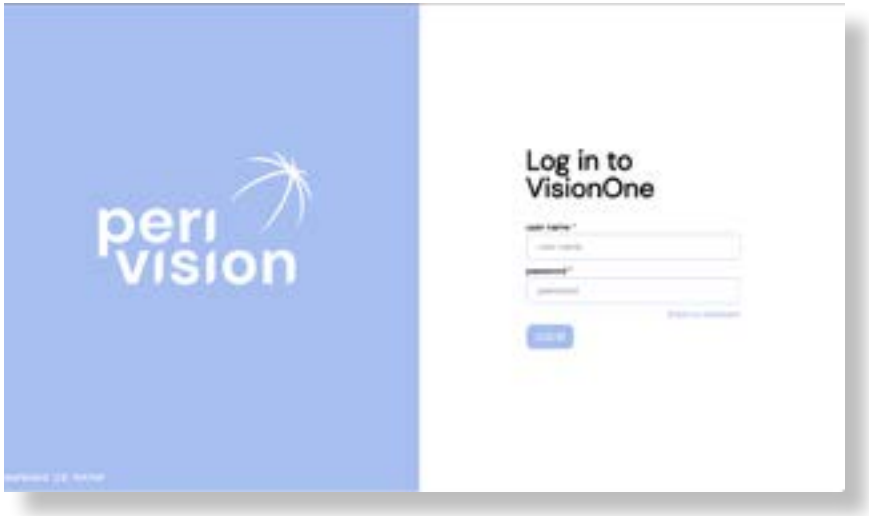
Table of Content

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.

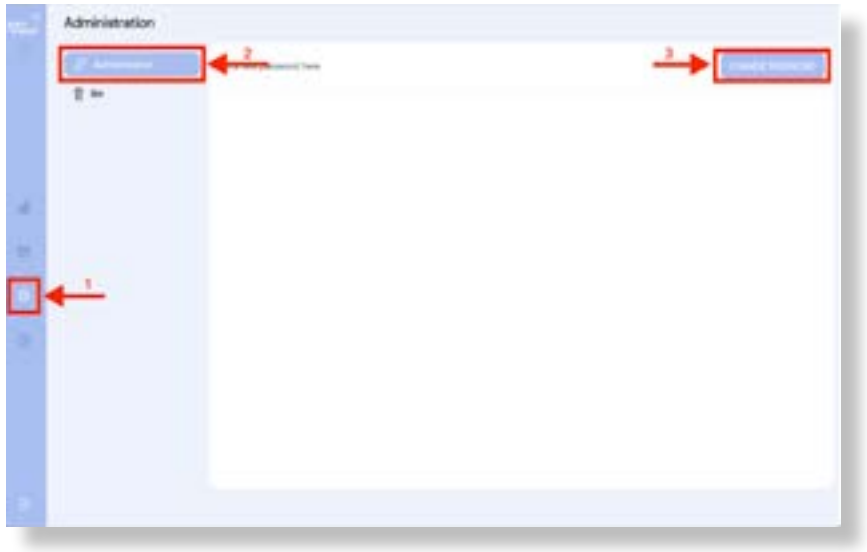
We recommend using Google Chrome as a browser.
Fill up the user-name and password fields with your credentials and click the log in button to log in the clinician dashboard.

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

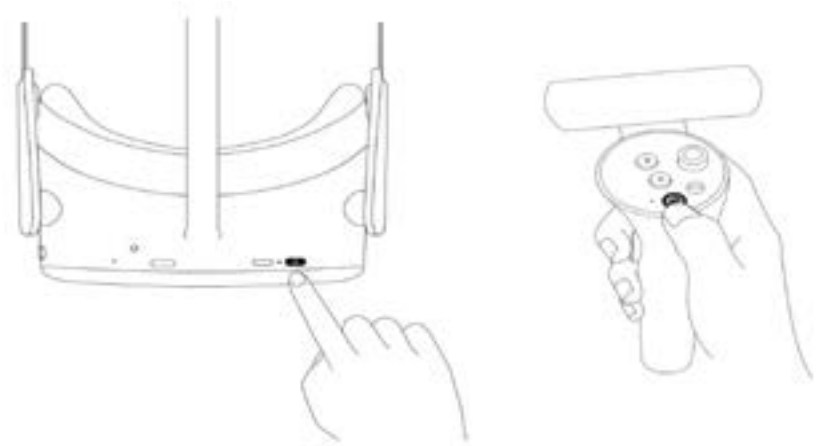
Once logged in, to change the existing password, go to settings, then to the authentication section and click on the CHANGE PASSWORD button:



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:

Table of Content

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

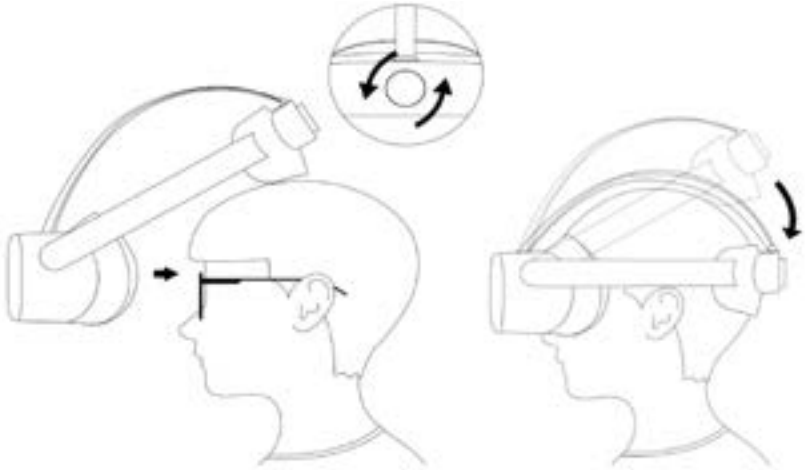
Off: Sleeping or powered off
Blue flashing: shutting down
Yellow: Charging battery is less than 98%
Red: Charging battery is less than 20%

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 chnaging batteries
- Resetting the clicker
- Clicker Trouble-shooting

Table of Content

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.

Table of Content