User Manual

retinaWISE

General Information	
Filename:	*02-1_UserManual.docx*
Number of Pages:	*38*
Version number:	*2.0*
Issue Date:	*Tuesday, March 05, 2024*

CE

Table of Content

1 GENERAL INFORMATION

1.1 Retina Wise overview

The retinaWISE Medical Device evaluates the sensitivity of retina tissue to specific light stimuli. The evaluation allows the operators to gather objective information that will let them conclude on sensitivity and health of retina tissues. retinaWISE is a medical device for professional use only.

Warning: *Any use of this Device deviating from the prescriptions included in this Manual is strictly forbidden and would be out of the liability of the Manufacturer*

The functioning of the *retinaWISE* Device is based on the monitoring of patients' pupillary reflex by measuring the pupil's diameter dynamic as a function of scotopic light stimuli with defined spectroscopic characteristics.

1.2 Manufacturer

The *retinaWise* medical Device is manufactured following the REGULATION (EU) 2017/745.

	Model	**retinaWISE**
	Category of the Device	Medical Device with relative measuring function
	Classification	Class I (According to REGULATION (EU) 2017/745)
	*Manufactured by*	**Oculox Technologies SA** Via Industria 3 CH-6933 Muzzano Switzerland Tel: +41 91 210 89 61
	EC REP	Qarad EC-REP BV Pas 257 2440 Geel Belgium SRN: BE-AR-000000040

2 SAFETY

2.1 General Safety Information

0. To safely use the Device, knowing all the safety rules according to International Standards is necessary.
1. All the people operating this equipment must understand the operation and safety instructions specified in this Manual.
2. Only authorised individuals with appropriate medical training and knowledge should operate the system.
3. Only authorised Service personnel should access the internal/electrical components of the system.
4. The User Manual must be available in the working area of the Device.
5. Warning labels must be all kept in good condition.

CAUTION: *Using controls, adjustments, or procedures other than those specified herein may result in hazardous radiation exposure.*

CAUTION: US *Federal law restricts this Device to sale by, or on the order of, a physician/surgeon.*

2.2 Training of the Staff

retinaWISE shall be operated only by medical staff with experience in Ophthalmology. According to their expertise, such professionals can decide the correct use of the Device depending on the type of application (Optometrist, Ophthalmologist).

2.3 Working Area

The Device shall be placed on a flat and stable surface.

The Device shall be placed in a darkened room to allow scotopic measurements.

2.4 Interference with Other Devices

This Device is intended to be used in connection with a computer.

Minimum Computer Configuration/Requirements	
Processor (CPU)	Intel Core i3 or equivalent
Operating System	Microsoft Windows 10 x64
RAM Memory [GB]	8 GB RAM
Storage [GB]	100 GB internal storage drive
USB adapter	3.0 type A (or newer)
Monitor/Display	1920x1080 resolution
Antivirus – Software	Update

This Device can be disturbed by the interference of external electromagnetic fields generated by other electrical devices in the closest proximity of the Device.

The Device can work only with the approved software installed on a PC duly protected against malware through state-of-the-art protections such as antivirus, firewall etc.

CAUTION: *Mobile phones and similar electrical devices must be switched off when the Device is working.*

CAUTION: USB port is accessible only by trained and authorized service personnel. Restriction of use are present

This Device must be installed and used according to EMC (Electromagnetic Compatibility) information described in the tables reported in Appendix A: EMC Tables.

2.5 Instructions for the Device Disposal

At the end of its lifetime, the Device must be handled according to the National or Local regulations for electrical and electronic equipment disposal.

The Device is subject to national standards regulating waste disposal, such as electrical equipment.

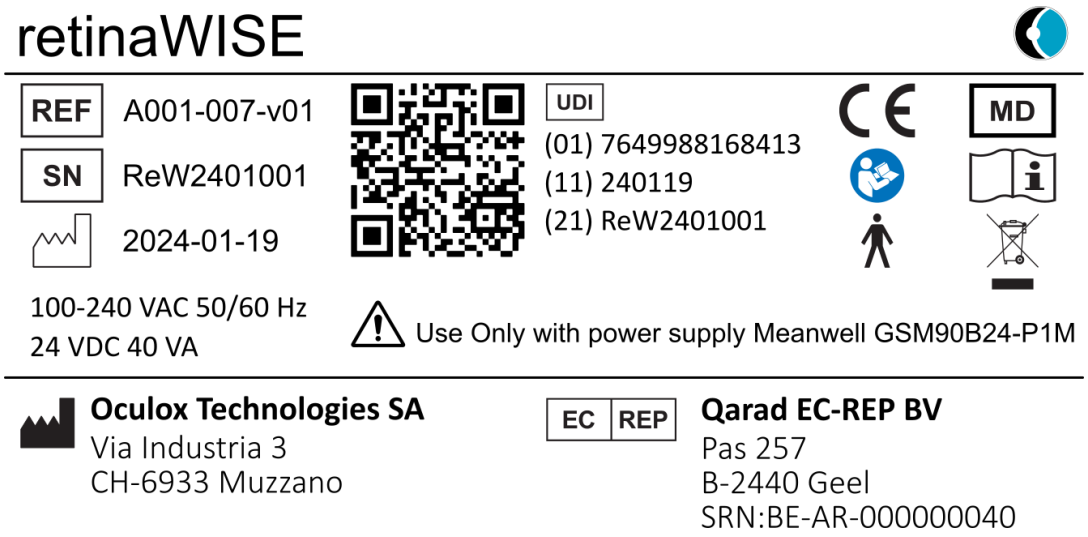
It is forbidden to dispose of the Device as municipal waste. Instead, it must be collected separately according to the WEEE Directive (Waste Electrical and Electronic Equipment).

The penalties for violating law requirements are severe.

2.6 Labels

Please find a representative image of the official label applied to the Device. The labelling plan and the final solution are discussed exhaustively in the corresponding documents (02-2_LabelingPlan).

2.6.1 Main Device's label



2.6.2 Label positioning

3 ENVIRONMENTAL CONDITIONS AND FIRST START-UP

3.1 Responsibility of the Customer

The user is responsible for placing the Device on a stable table in a clean environment (protected from water and dust).

3.2 Requirements for the Electrical Connection

The Device shall be connected to a power socket in compliance with the local electrical safety regulations. Following the Standard IEC/EN 60884-1, the shape and type of the cable's connector shall be adapted to the local power socket of the country where the Device will be installed.

Warning: *The Device shall be installed and used in compliance with your country's national or local requirements.*

3.3 Temperature, Pressure and Humidity

The Device requires a dry, low-dust area with adequate ventilation. Air conditioning is preferable but not essential. Refer to Section 10 of this manual for temperature, pressure and humidity ranges.

3.4 Packaging

The Device is shipped in a dedicated carton box. Packaging includes conformal protective foam. The Client is responsible for reviewing delivered goods, prepare and position the Device in the designed working area ready for installation.

3.5 Physical Installation

The device is constructed to be well balanced, and it is designed to be positioned on a standard ophthalmic table. retinaWISE is provided with the possibility to be rigidly fixed on the ophthalmic table.

CAUTION: retinaWise need to be stably positioned on an ophthalmic table. Consider to use the provided screws to fix the device on the ophthalmic table

3.6 Labelling Check

The user's responsibility is to verify the integrity and readability of the security labels placed on the Device. Damaged labels shall be replaced immediately in compliance with the Labelling shown in §2.6.

3.7 First start-up

The first start-up of the Device must be performed after having red and understood the User Manual. Please do not hesitate to contact our service personnel see §9.3 in case of questions or doubts.

Warning: *Do not start using the Device without reading this Manual. The warranty does not cover damage that occurred before installation.*

The received material shall be inspected immediately upon arrival on the following terms:

- Administrative check:
  Number of packages
  Sizes and weights
- Technical check:
  Packaging condition

These checks must be made visually, with the most outstanding possible care and in the presence of the delivery employee.

The installation procedure shall be performed each time the Device is installed for the first time or after being transported through cars, elevators, trucks, air cargo, etc.

During installation, the Device shall be checked for proper operation, and eventual malfunctions due to transportation must be corrected.

The installation procedure also includes a training course from the Distributor to the user concerning the use of the medical Device.

The first turn-on procedure may take several hours. During this time, access to the installation site is forbidden.

The packed materials shall be checked immediately upon their arrival, if possible, in the presence of the shipper's delivery employee, as follows:

- Open the packaging and put the Device in a proper site for a general check
- Perform the following operations for the general check:
  - No obvious damage occurred during the shipping
- Perform further controls or additional tests
- Perform training for the End User on the operation of the Device

3.8 Device Connections

The Device is delivered with its specific power supply; no other power supplies are allowed.

The Device's connection with the pc is made with the delivered USB cable or another USB cable with at least a 3.0 communication standard.

3.9 Software installation

The installation of the software and the setting of the parameter for the usage of the Device has to be done by a technical specialist from Oculox Technologies.

4 DESCRIPTION OF THE DEVICE

retinaWise general description and details of the main components and accessories.

4.1 System Overview

The retinaWise presents as a standard ophthalmic appliance mounted on a joystick and interfaces the patients through a chin rest. The joystick allows the Operator to align the Device's projection optics to the patient's eyes. The Operator drives the measurements from the computer adequately connected to the Device.

4.2 Hardware

The Device is composed of an ophthalmic joystick that moves the optical system to allow the operators to align it with the patient eyes.

The Device is connected to a PC through a USB cable.

A power switch ON and OFF is mounted on the Device.

The software needs to be installed on the PC to allow the connection to the Device.

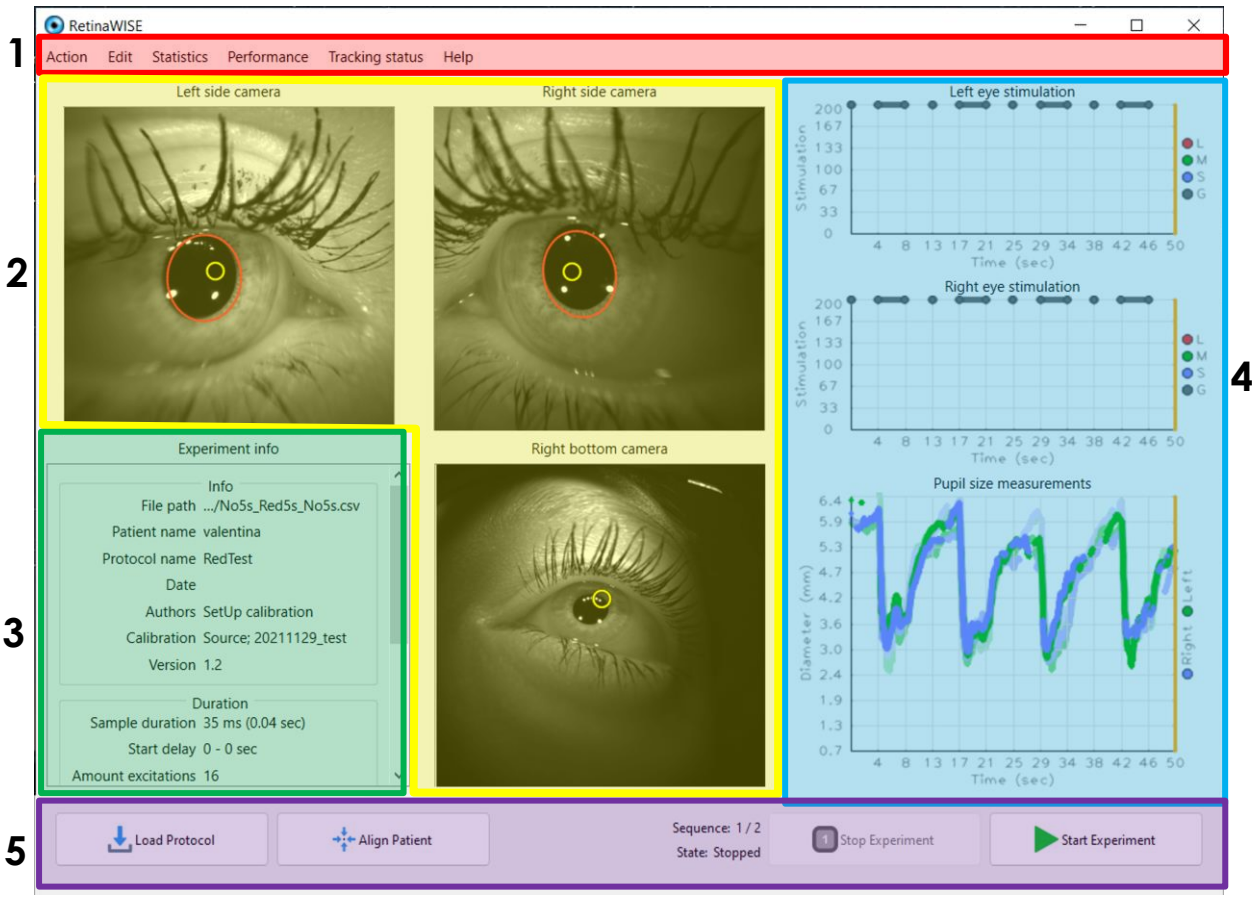
4.3 User Interface

The software that drives the Device is property of Oculox Technologies

CAUTION: Only the supplied software can be used to control the Device.

The user interface is composed of the following main zones:

1. *Menu Bar*
2. Patient's eye image stream
3. Summary of the measurement session
4. Graphic representation of excitation & data plots
5. *Functional Button Zone*



4.3.1 Menu Bar

In the menu bar, there are six extendable menus:

- Action
  - Users can start all the steps needed to perform the analysis; these commands are also accessible from the *Function Button Zone* in the main window.
- Edit
  - Users to edit the Device's settings; the section is reserved only for qualified technical personnel; in case of troubleshooting, contact Oculox Technologies
- Statistics
  - Device usage and pupil diameter statistics.
- Performance
  - Acquisition and data storage performances and details
- Tracking Status
  - Details and objective evaluations on the pupil detection algorithm
- Help
  - Software's version
  - Technical support - Automatic ticketing system in direct connection with technical support.

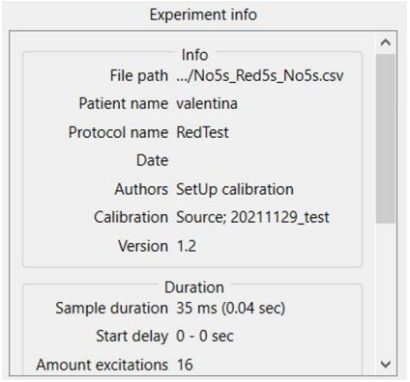
4.3.2 Patient's eye image stream

Realtime images are acquired from the monitoring cameras embedded into the Device; the user visually checks the alignment status to apply corrections by acting on the joystick to allow proper data collection.

To support the alignment procedure, an augmented reality algorithm projects the detected pupil circumference on top of the patient's eye streams.

4.3.3 Summary of a measurement session

Simple and synthetic portion providing a summary of patient data and the protocol's details.



4.3.4 Graphic representation of excitation & data plots

Excitation settings and data plots are presented in two distinct zones:

1. The two graphs on the higher portion plot the time information about the light stimuli
    a. Left eye, and
    b. Right eye

2. In the lower portion, the graph plots the real-time measure pupil's diameter for both eyes.

    NOTE: the user can perform the same protocol several times; in this case, the previous results will be displayed in transparency on the lower graph.

4.3.5 Functional Button Zone

Control zone to successfully perform the analysis.

From left to right, the user will need to pass through every button which corresponds to different action:

- Aligning the patient
- Load the protocol
- Start the sequence of analysis
- Stop the sequence of analysis
    - Only if necessary

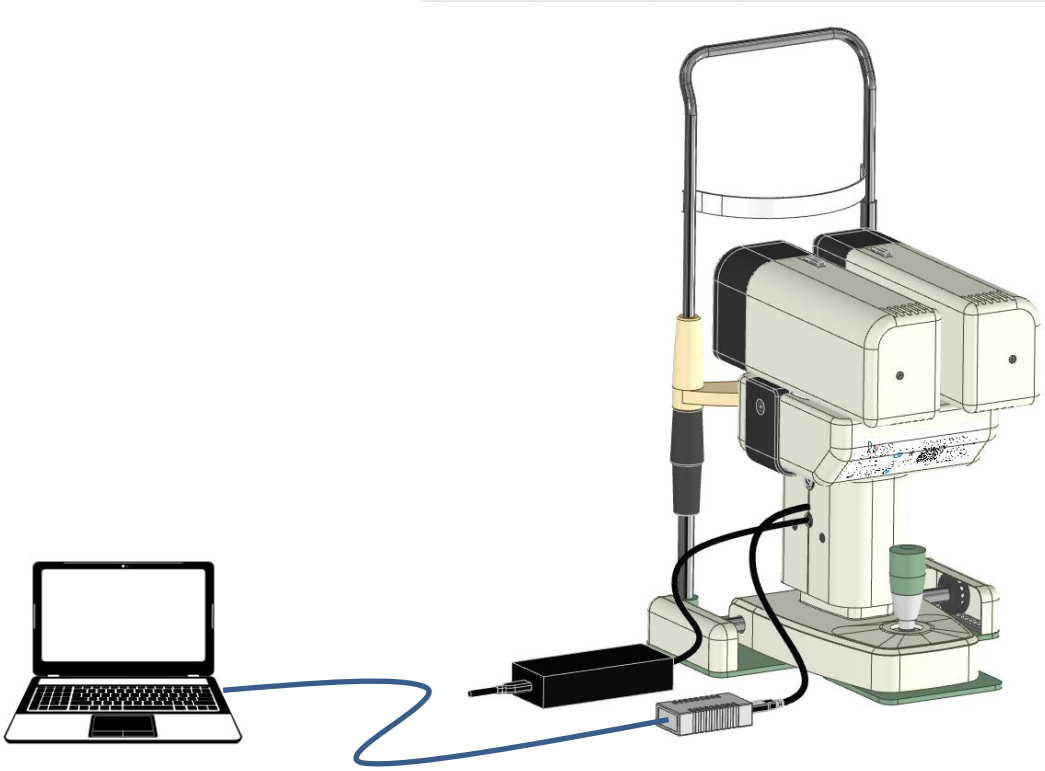
5 OPERATING INSTRUCTIONS

5.1 First configuration

Before starting to use the Device, please ensure that the Device is adequately placed on a flat, stable surface.
Oculox Technicians will do the initial configuration; the user does not need to take care of setting up the Device.

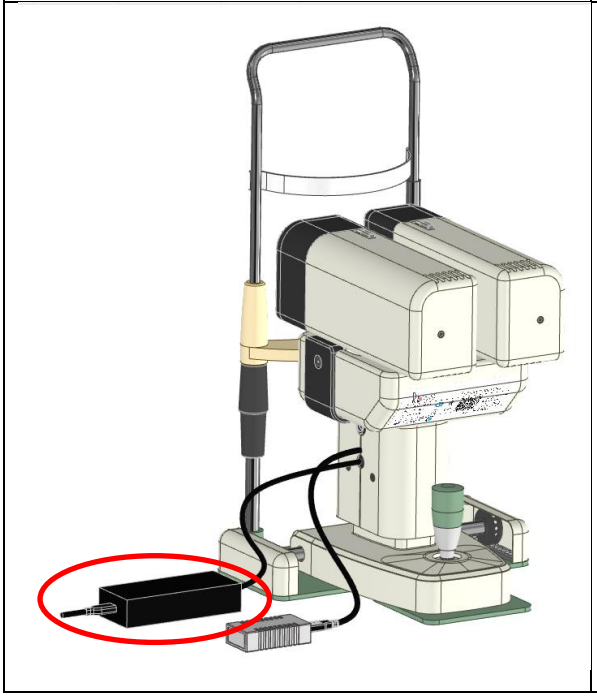
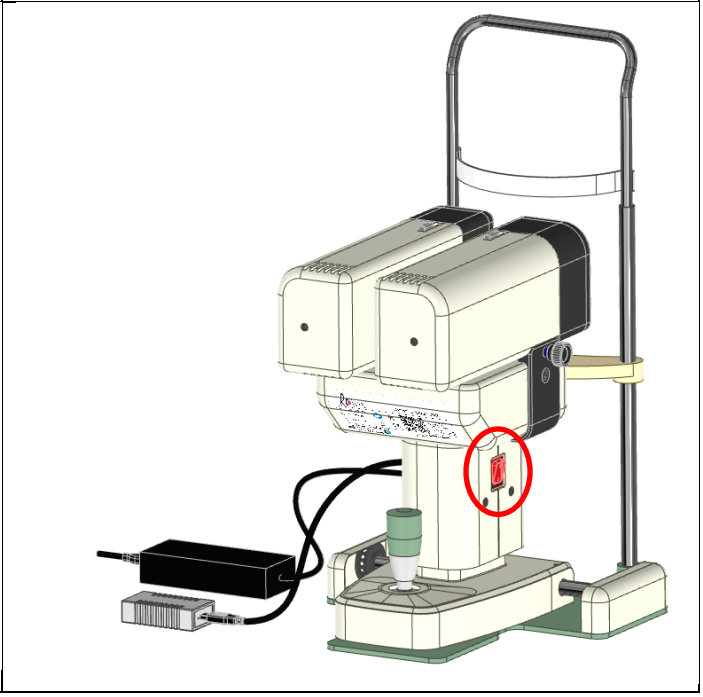
5.2 Connect the communication port

Connect the supplied USB cable via the supplied optoisolator, to the Device on one side and the computer on the other.



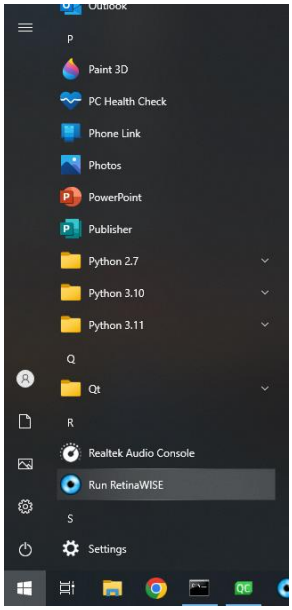
5.3 Connect the power supply and power on the Device

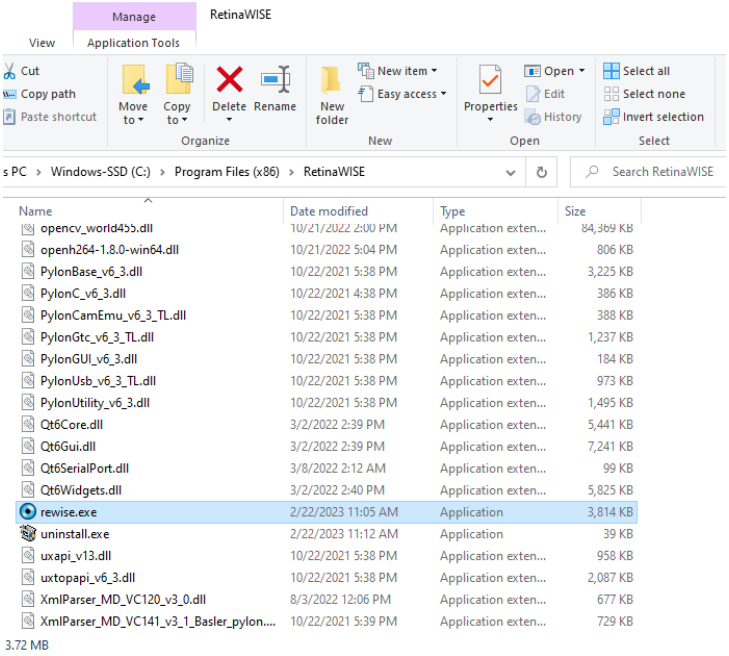
Connect the supplied power supply to the Device and position the main ON-OFF switch.

Connect the power supply	Switch on the device
	

5.4 Start the software

Start the installed software retinaWISE "Run RetinaWISE or the executable file rewise.exe.



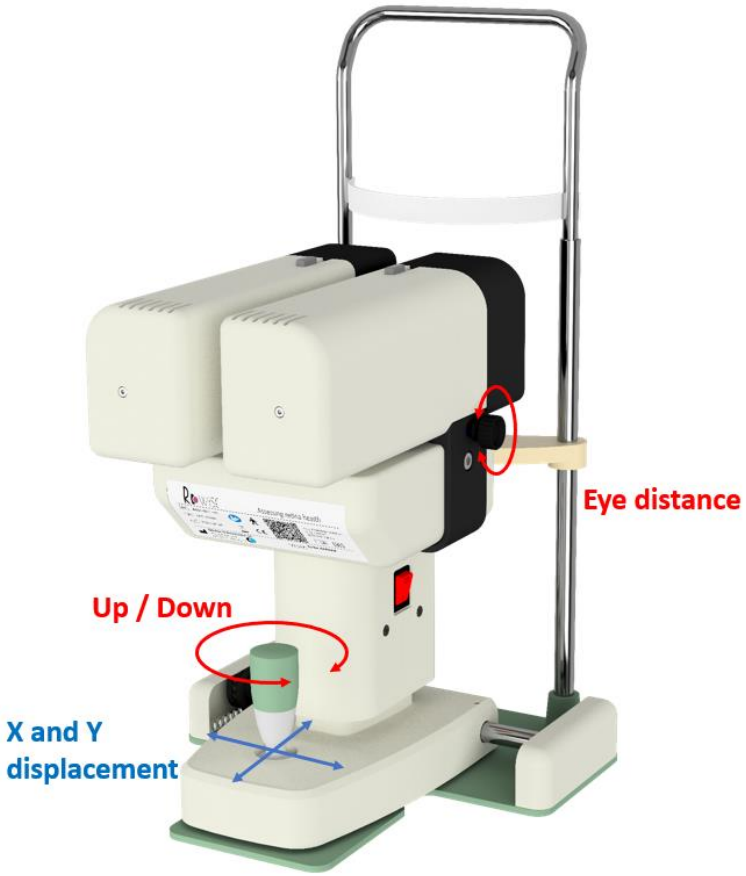


The programs start, and the Device is ready to operate.

5.5 Alignment procedure

The Device is built to be adjusted along multiple mechanical degrees of freedom. The strategy allows the alignment of a fixed patient on the moving Device's optics.

The joystick allows the horizontal movement to align with the right eye; by rotating the handle, the vertical position of the Device will be adapted to the patient's height.



In addition to the degrees of freedom provided by the joystick, it reveals to be vital the possibility to adapt the height of the headrest to adjust to the different head anatomies

Before starting the procedure, place the vertical position of the joystick in the middle position by rotating the handle.

5.5.1 Pre-alignment of the patient

Before inviting the patient to accommodate on Device's chin rest and avoid uncomfortable neck and back positions for the patient, adapt sequentially:

i) The ophthalmic table height, and
ii) The patient's chair height.

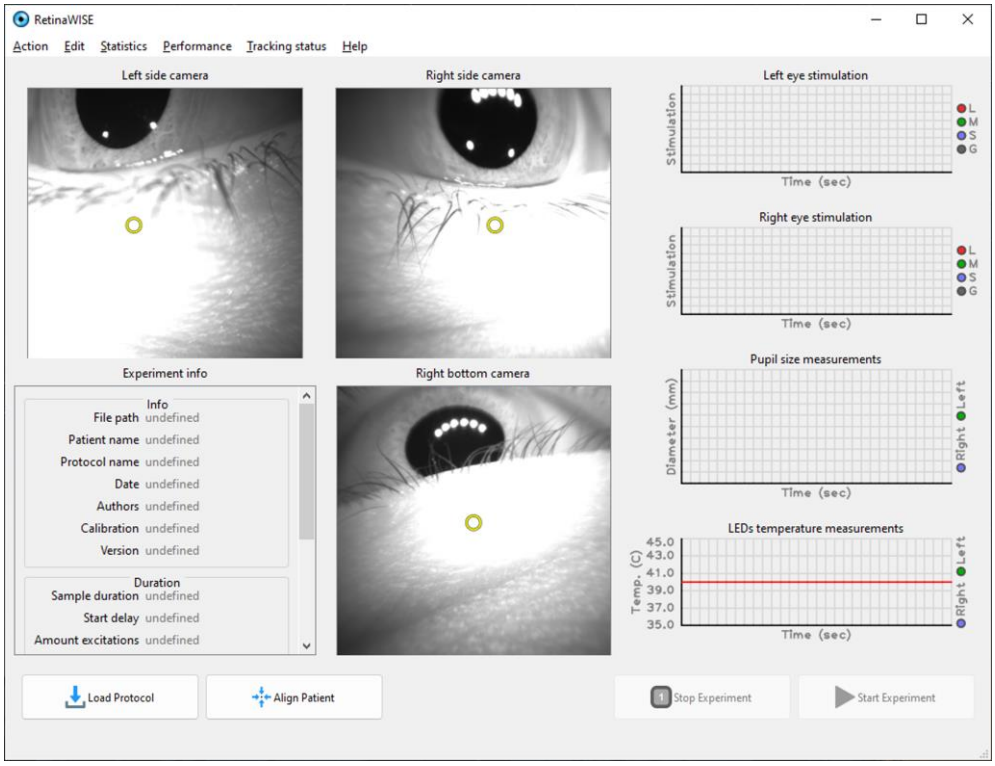
Once the patient is comfortably placed, invite him to put his chin on the chin guard and rest the forehead against the support.

Verify if the eyes are at the same level comparing with the camera of the Device, if not turn the handle on the headrest to adjust the vertical position of the chin guard.

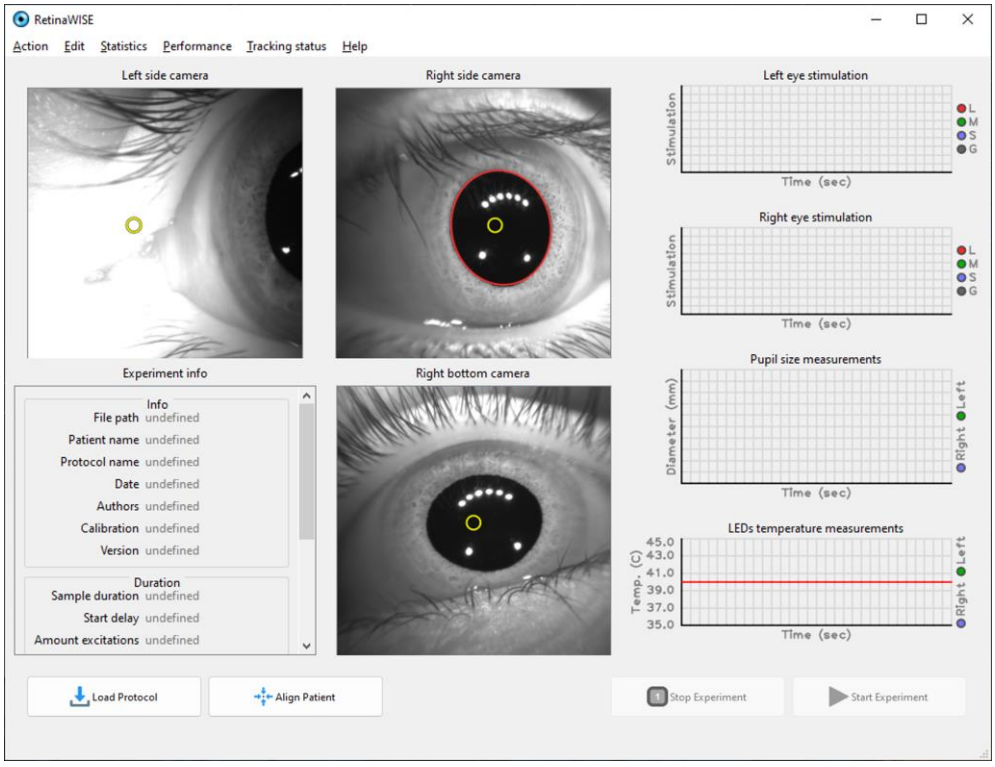
5.5.2 Patient right eye

On the UI press the "Align Patient" button to start the alignment procedure.

Move the joystick horizontally and vertically (moving and rotating the handle) aligning the right eye of the patient in front of the Device by looking at the streamed image on the User Interface Window.



Move the Device to reach the situation where the small yellow circle is centred with the right pupil.

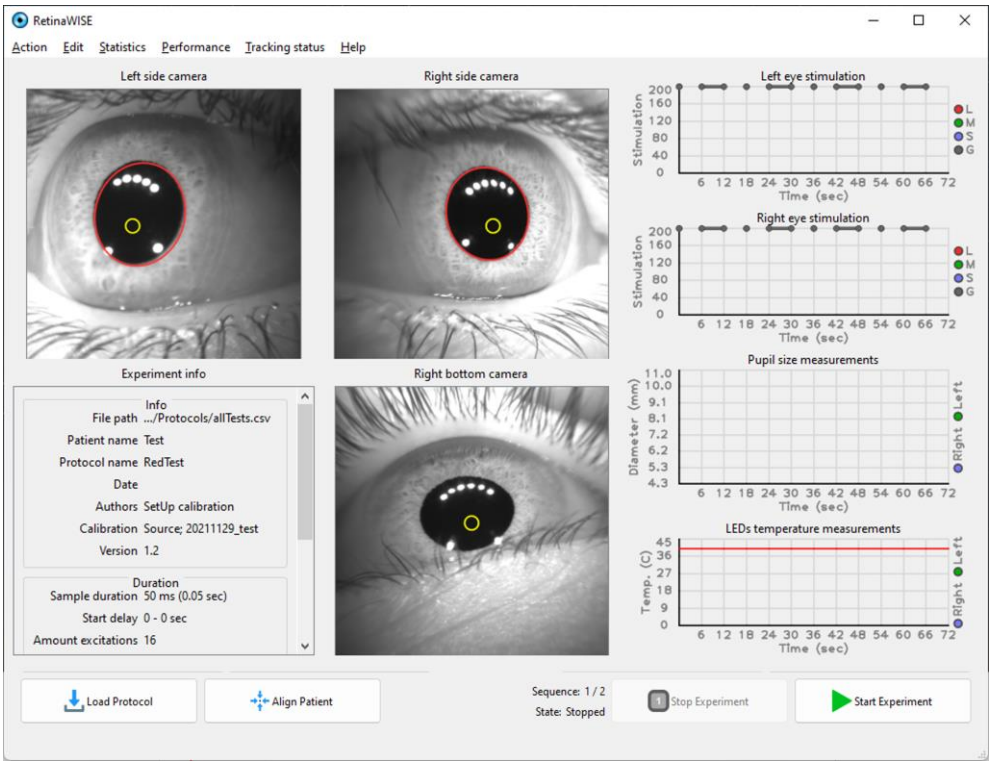


5.5.3 Patient left eye

Rotate the nut placed on the right side of the Device to adjust the ocular distance until the left eyes is detected by the software.

NOTE: It will be possible that the medics need to ask the patient to tilt a bit the head to align the right eye and the left eye horizontally.

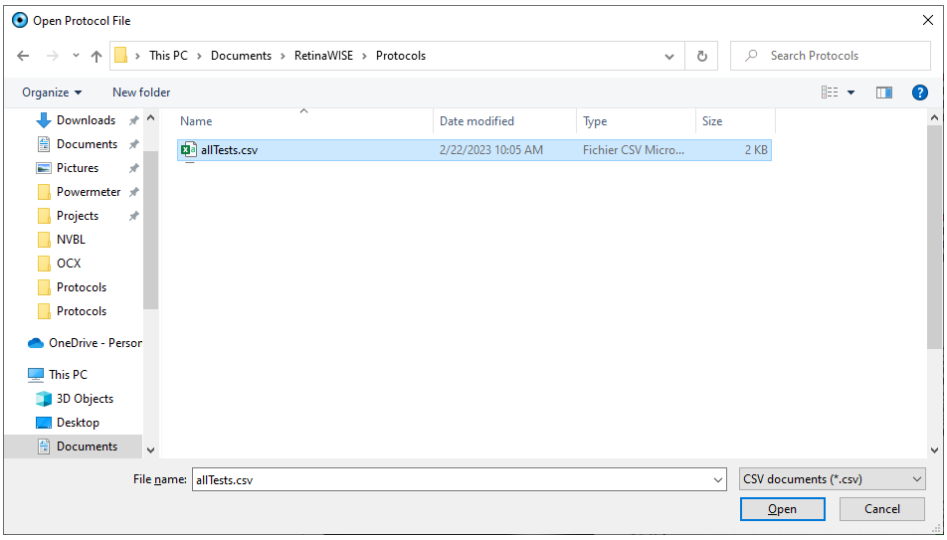
The final alignment situation will be:



5.6 Loading a protocol

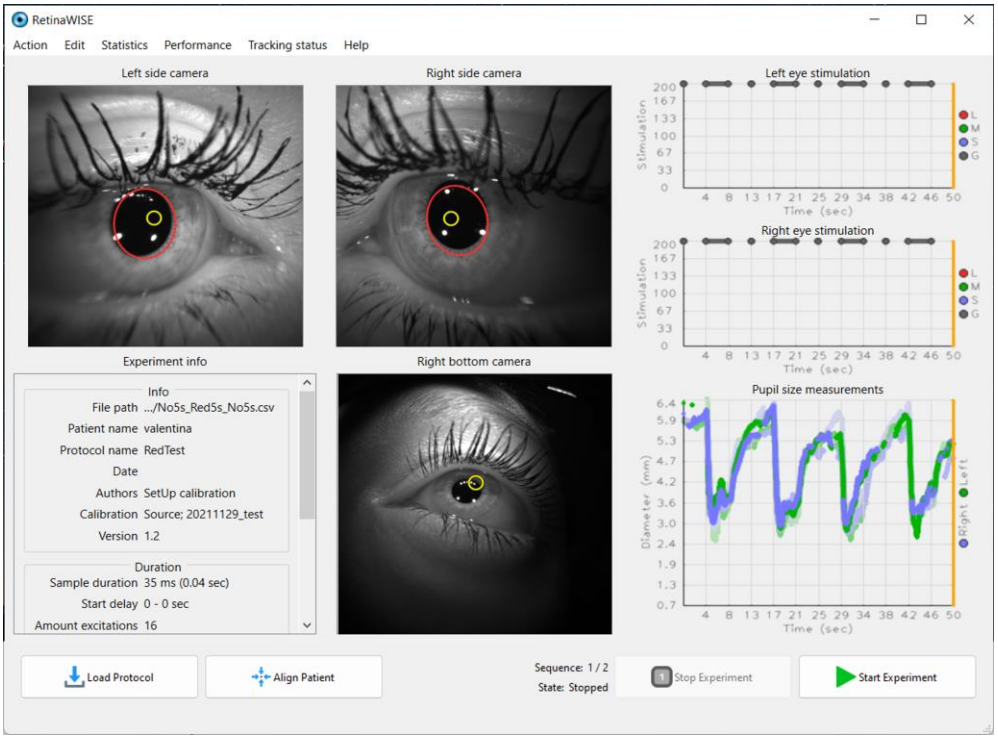
We assume that a protocol already exists. It can be loaded either with the button on the bottom or white the menu action.

Select file of the desired protocols from the opened window



5.7 Launch the experiment

After selected the protocol to use, press "Start Sequence" button. The Experiment is now performing, the window will be filled with the results of the experiment in real time.

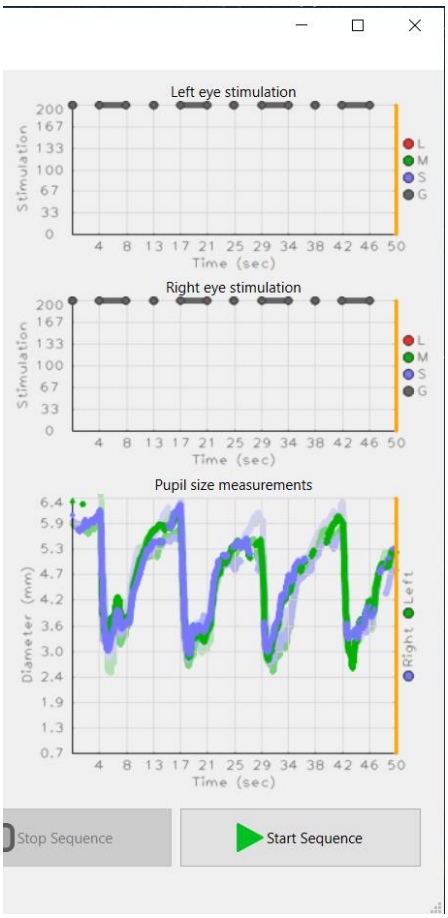


5.8 Analyse the results

5.8.1 Application information

The results of the experiments are reported directly on the window, the two upper graphs show the light protocol directed on the eyes as function of the time for the left and right eye.

The lower graph shows the pupil diameter reaction to these light stimuli as a function of time.



5.8.2 Further analysis – saved data layout

The software saves automatically some files related to the experiment done under a predefined folders that can be chosen in according with the specialist that install the Device.

The data are exported to a .csv file with the following definition:

Timi	Excitation Inde	Left - Is foun	Left - Size M	Left - Area M	Left - RadiusA	Left - RadiusB	Left - PosX (	Left - PosY (	Left - Distance from focu	Left - Leds terr	Right - Is foun	Right - Size M	Right - Area M	Right - RadiusA	Right - RadiusB	Right - PosX	Right - PosY	Right - Distance from focu	Right - Leds terr
2.002	2	VRAI	6.49392	33.12103	123.03398	168.25145	521.84265	553.56403	22.66434	24.73152	VRAI	6.41042	32.27479	128.55362	156.90578	475.47913	551.8985	64.81723	-0.50195
4.012	3	VRAI	6.51685	33.3553	123.79502	168.39383	521.51727	553.65455	23.03831	24.70817	VRAI	6.41312	32.30198	128.8278	156.71103	475.17285	552.08944	65.15529	-0.50195
6.002	4	VRAI	6.52851	33.47476	124.66026	167.82396	520.72113	553.55164	23.58526	24.71595	VRAI	6.43355	32.50911	129.57974	156.73587	475.8086	552.23779	64.56211	-0.50195
8.002	5	VRAI	6.50394	33.28464	123.61031	168.2942	522.03174	553.55511	22.50777	24.70428	VRAI	6.40971	32.26764	129.07737	156.2462	474.85245	551.64813	65.3826	-0.50195
10	5	VRAI	6.50851	33.26999	123.6431	168.17552	521.72925	553.83325	22.91679	24.70817	VRAI	6.41845	32.35563	129.05264	156.69783	475.31909	552.18774	65.0321	-0.50195
12	5	VRAI	6.49622	33.14453	123.42216	167.84126	521.50323	553.76111	23.05425	24.71206	VRAI	6.4166	32.33701	128.89637	157.04121	475.78934	552.08258	64.5503	-0.50195
14.02	6	VRAI	6.50246	33.2082	123.46027	168.11177	521.91705	554.26074	23.02958	24.71595	VRAI	6.40096	32.17959	128.45462	156.57082	475.41956	551.79547	64.8552	-0.50195
16	7	VRAI	6.49013	33.08241	123.87768	166.91068	521.41003	553.04399	22.71319	24.71206	VRAI	6.43753	32.54896	129.66849	156.88545	475.48688	551.9906	64.82802	-0.50195
18	7	VRAI	6.5052	33.23615	123.56039	168.11696	521.52155	554.02502	23.19816	24.71984	VRAI	6.41165	32.28711	128.58418	156.93564	475.3602	552.0517	64.96438	-0.50195
20.01	8	VRAI	6.50342	33.21796	123.55473	168.03261	521.66431	553.92719	23.02529	24.71595	VRAI	6.41254	32.2961	128.86551	156.63666	475.61755	552.16827	64.73591	-0.50195
22	9	VRAI	6.50516	33.23578	123.75162	167.8553	521.31238	553.69445	23.16228	24.71984	VRAI	6.41522	32.32314	128.59274	157.10034	475.62319	552.08704	64.71322	-0.50195
24	9	VRAI	6.51853	33.37253	124.14056	168.01785	521.35288	553.78845	23.15315	24.72763	VRAI	6.43723	32.54533	129.87665	156.61342	476.13431	552.48694	64.29613	-0.50195
26	10	VRAI	6.48936	33.07451	122.99367	168.06198	522.29419	553.80127	22.44929	24.70817	VRAI	6.41119	32.28251	128.59091	156.90509	475.32422	551.68542	64.33874	-0.50195
28.01	11	VRAI	6.5094	33.19734	123.16906	168.45415	521.683	554.14331	22.98369	24.71984	VRAI	6.4181	32.33152	128.66652	157.0529	475.59778	551.93756	64.70875	-0.50195
30	11	VRAI	6.52191	33.40717	124.00928	168.37033	521.1347	554.06362	23.53422	24.70817	VRAI	6.44343	32.60801	129.55846	157.30356	476.254	552.04102	64.08689	-0.50195
32.01	11	VRAI	6.50789	33.26366	123.44292	168.41621	521.88678	554.3538	23.11477	24.73152	VRAI	6.41402	32.31105	128.79684	156.73269	475.59305	552.03375	64.73268	-0.50195
34.01	11	VRAI	6.53507	33.54207	124.40602	168.51106	521.16382	554.20619	23.59395	24.71206	VRAI	6.42457	32.41734	129.35156	156.6339	476.37076	551.8819	63.94033	-0.50195
36	12	VRAI	6.51464	33.33273	123.51116	168.67284	521.56122	554.21521	23.2822	24.70428	VRAI	6.418	32.35114	129.41086	156.24532	475.73068	552.03601	64.59833	-0.50195
38	13	VRAI	6.50539	33.23616	124.07192	167.43391	521.55646	553.52405	22.8706	24.72374	VRAI	6.42474	32.41915	129.13806	156.90158	475.71814	552.16144	64.63604	-0.50195
40	14	VRAI	6.50353	33.21913	123.71417	167.82198	521.71021	553.99072	23.02731	24.72763	VRAI	6.41553	32.32623	129.11497	156.47384	475.93201	551.49335	64.29351	-0.50195
42	15	VRAI	6.50564	33.24067	123.71594	167.92839	521.57825	554.0083	23.14289	24.73152	VRAI	6.41806	32.35171	129.14931	156.56155	475.78322	552.16028	64.56622	-0.50195
44.01	16	VRAI	6.50302	33.21398	123.57536	167.98421	521.63617	554.20429	23.2762	24.71595	VRAI	6.4242	32.41362	129.3386	156.63013	475.85359	552.0965	64.48434	-0.50195
46.01	17	VRAI	6.51561	33.34262	123.79377	168.32939	521.07953	554.43903	23.80062	24.73152	VRAI	6.4051	32.22123	129.1292	155.95444	475.38959	551.64697	64.85546	-0.50195
48	17	VRAI	6.51691	33.356	123.73325	168.48746	521.47028	554.00708	23.22819	24.72374	VRAI	6.4215	32.38642	128.78401	157.1741	475.85559	552.0672	64.48231	-0.50195
50.02	17	VRAI	6.51741	33.23962	123.45086	168.58743	521.33081	553.97705	23.32159	24.71984	VRAI	6.42766	32.44854	129.44255	156.67442	476.03503	551.87329	64.26748	-0.50195
52	18	VRAI	6.51267	33.31254	123.79258	168.18727	521.4853	554.28862	23.38545	24.73152	VRAI	6.42173	32.38871	128.71362	157.27115	475.57883	552.61804	64.86676	-0.50195
54	19	VRAI	6.50228	33.20632	123.19833	168.45969	521.85706	553.86737	22.83573	24.71595	VRAI	6.43383	32.51086	129.53125	156.79523	476.23779	551.81506	64.05717	-0.50195
56.02	19	VRAI	6.50947	33.27963	123.37836	168.58539	521.5343	554.07568	23.17099	24.70817	VRAI	6.42186	32.39008	129.54494	156.26854	475.7236	551.74451	64.54708	-0.50195
58	20	VRAI	6.52286	33.4169	124.32182	167.99594	521.52557	554.24951	23.33137	24.72763	VRAI	6.42585	32.43027	129.27266	156.79186	475.97232	552.11255	64.37723	-0.50195
60	21	VRAI	6.505	33.23414	123.17651	168.63068	521.35774	553.82357	22.68766	24.73541	VRAI	6.41312	32.30194	128.51334	157.09428	475.42384	552.23236	64.94439	-0.50195
62.02	22	VRAI	6.51346	33.32069	123.77775	168.2489	521.51935	554.13013	23.2636	24.7383	VRAI	6.43091	32.4814	129.29482	157.01216	475.77475	551.94855	64.53756	-0.50195
64.02	23	VRAI	6.51703	33.35717	124.01572	168.10959	521.34198	554.492	23.62498	24.73541	VRAI	6.42267	32.39822	129.23006	156.68969	475.92734	552.30536	64.46079	-0.50195
66	23	VRAI	6.50237	33.2073	123.69456	167.8974	521.54169	554.10193	23.22873	24.70817	VRAI	6.43183	32.49071	129.61906	156.66441	476.1683	551.83606	64.12945	-0.50195
68	23	VRAI	6.53168	33.50737	124.70919	167.92751	520.86407	553.6814	23.5237	24.73152	VRAI	6.40664	32.23667	128.62828	156.63676	475.5488	551.76575	64.72263	-0.50195
70.01	23	VRAI	6.50176	33.20102	123.46574	168.06798	521.53931	554.10736	23.23392	24.71984	VRAI	6.42721	32.44408	129.06261	157.11403	476.01263	552.43286	64.4038	-0.50195
72	24	VRAI	6.53076	33.4379	124.17245	168.60573	521.2326	554.29218	23.58986	24.73541	VRAI	6.40961	32.26657	128.55684	156.86919	475.81323	551.65614	64.48138	-0.50195
74.01	25	VRAI	6.50359	33.21971	123.63142	167.93721	521.92065	553.96309	22.85584	24.72374	VRAI	6.40579	32.2281	128.51048	156.73869	475.62399	552.05981	64.70763	-0.50195
76	27	VRAI	6.53066	33.43685	124.3794	168.3193	520.89978	553.7724	23.54777	24.72374	VRAI	6.41324	32.30311	128.91995	156.60449	475.96783	551.68671	64.29624	-0.50195

6 CLINICAL APPLICATION

6.1 Training requirements

The users should be familiar with Ophthalmology. It is important to provide the patients with the clinical judgment from the side of a Physician, to verify the suggested protocols according to the specific patient under consideration for treatment.

CAUTION: *Device shall be operated only by medical staff with experience in Ophthalmology.*

According to their expertise, such professionals can decide the correct use of the Device depending on the type of application

6.2 Intended use

RetinaWise measures the patient's pupil diameter as a function of time and specific scotopic light stimuli of the retina.

Disclaimer:

Eye pupil diameter variation depends on the level of light exposure. Eye pupil dynamics and pupil reflex is a patient's eye health index. The physician is the sole responsible to define any diagnosis or therapy based on the measurement taken with *retinaWISE*.

6.3 Patient Population

No restriction.

6.4 Contraindications

Patient with pathology as Migraine, Uveitis, Albinism, Aniridia Blepharitis, Coloboma, Amblyopia, and other need to be evaluated by medical doctors before being subjected to the analyses.

6.5 Side Effects

No side effect.

6.6 Residual Risk

No residual risks.

6.7 Warnings related to the applications

No warnings related.

Contact your Customer Service Representative for further instructions.

6.8 Precautions

Precaution shall be taken during Device operation since it requires dark or extremely dimmed light examination rooms. In such conditions patients might be disoriented. The room's floor must be free of obstacles to avoid accidents.

The examination could take several minutes up to 10 minutes. It is recommended to configure the exam room to be quiet, with a pleasant controlled ambient temperature so as to allow the patient to relax for optimal data acquisition.

6.9 Adverse events management

In case of adverse events such as.

- fuse failure or repeated fuse failure,
- stimulation spectroscopy does not correspond to specifications,
- field of view is not homogeneous,

manage them according to appropriate clinical practices and inform us (see §9.3 for contacts).

7 MAINTENANCE

This Device is designed for maximum safety and performance.

Ordinary & Extraordinary Maintenance of the Device	
Under carful and normal operating condition	Intensive use, dust, or continuous relocation
Every 6 Months	**More frequent review required: every 3 months**

7.1 Checking the line cable

The Device is provided with an external power supply. The line cable of the power supply can deteriorate over time and therefore it is necessary to periodically check the status of the line cable. In case of damages, contact Oculox Technologies for a replacement power supply.

Warning: *Power supply cord can be replaced by authorized personnel only*

7.2 Checking the labels

It is under the user's responsibility to keep the safety labels in good condition.

It is necessary to replace all the labels that are damaged.

7.3 Cleaning

All the cleaning procedures must be performed after the Device is switched off.

Warning: *Before performing any cleaning action, be certain that the Device is switched OFF*

7.3.1 Cleaning of the "Headrest"

Applied parts such as the forehead band, the chin rest cup and the handles of the headrest are made of easy-to-clean materials.

To comply with general hygiene requirements and to prevent the transmission of infections, the applied parts should be disinfected prior to every examination.

Several disinfection solutions exist, e.g., with 70% isopropyl alcohol, or ready-for-use disposable 70% ethanol disinfectant wipes.

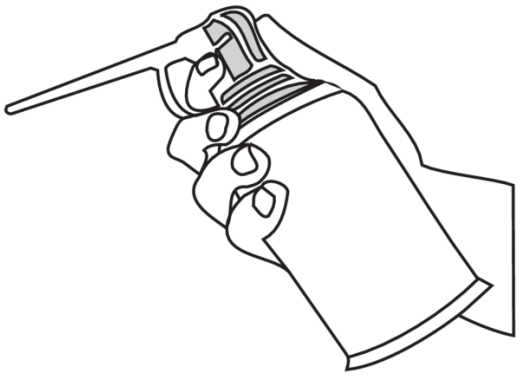
Surface friendly disinfectants (containing aldehyde or aldehyde-free) are also permitted, such as Kohrs Olin FF.

WARNING!

- The efficacy of the disinfectants are determined by the disinfection manufacturers.
- The efficacy of the disinfectants mentioned above was not tested on their correct disinfection effect on the headrest.
- The efficacy of the disinfectants must be guaranteed by the user or the reprocessing responsible person with the validation of their own disinfection process.
- Comply with the stipulated exposure time.
- Observe the manufacturer's safety instructions.
- Too strong or aggressive disinfectants or cleaning liquids e.g. hydrogen peroxide will damage the finish and coating of the device.
- Do not use sprays.
- Do not use any cloths that drip.
- Wring out any soaked cloths before use when necessary.
- Ensure that no liquid penetrates the device.

7.3.2 Cleaning of the Cameras

Before cleaning the lenses, verify that there are not dust on the surface which can damage the lenses surface, remove the dust with a Optic Bulb Blowers or a dust and oil free air flow.



Once removed the dusts, the surface can be cleaned with Isopropanol and a Microfiber or equivalent tissue.

7.3.3 Cleaning of the external covering panels

Clean periodically the external covering panels of the Device using a cloth dampened with a standard cleaning solution. Avoid spraying directly the cleaning solution on the panels.

Warning: *Avoid penetration of the cleaning solution inside the Device.*

7.3.4 Contact for Information Request

If any further information is needed about cleaning, please contact Oculox Technologies

8 TROUBLESHOOTING

Issue	Possible cause	Solution
The device does not swich ON	The power cord is not correctly inserted in the grid wall plug	Control cabling
Device does not connect to PC	Device is not recognised by PC's USB port	Restart PC to reset and allow USB port configuration
Connection with monitoring camera fails	System configuration is corrupted	Setup and configure system
Monitoring camera image stream is not centred	System configuration is corrupted	Setup and configure system
Device joystick is blocked	Joystick brake is tight and block the system	Unblock joystick brake
Patient alignment fails	Alignment procedure is not followed correctly	Refer to User Manual to properly align device

9 CUSTOMER SERVICE

9.1 Warranty and Manufacturer's responsibilities

The Limited Warranty provided by Oculox Technologies applies to physical goods, and only for physical goods (the "*Physical Goods*").

This Limited Warranty covers any defects in material or workmanship under normal use during the Warranty Period.

During the Warranty Period, Oculox Technologies will repair or replace, at no charge, products or parts of a product that proves defective because of improper material or workmanship, under normal use and maintenance. Oculox Technologies will either repair the Product at no charge, using new or refurbished replacement parts.

The Warranty Period for Physical Goods purchased from Oculox Technologies **is 1 year (366 days) from the date of purchase**.

A replacement Physical Good or part assumes the remaining warranty of the original Physical Good or 366 days from the date of replacement or repair, whichever is longer.

This Limited Warranty does not cover any problem that is caused by:

- malfunctions or damage not resulting from defects in material or workmanship.

To obtain warranty service, you must first contact us to determine the problem and the most appropriate solution for you.

9.2 Repairs and modifications of the Device

- Only authorised service personnel can execute repairs and maintenance,
- It is recommended that you follow the standard maintenance program,
- It is recommended that you replace all damaged components,
- Use only original spare parts,
- Constructive modifications are not permitted.

9.3 Contacts

Oculox provides its customers with email and telephone troubleshooting, apart from the on-site customer trainings, repairs and maintenance.

Please contact Oculox Service Department through the contacts reported here below. Please keep on hand the Serial Number of your Device.

Technical Support
• Direct connection to technical support portal: From the menu bar *Help* of RetinaWISE programm, selection of *Technical support*, and this will open a direct web link • From the link: *https://oculox.atlassian.net/servicedesk/customer/portal/3*

9.4 Reporting of serious incidents

Any serious incident that has occurred in relation to the Device should be reported to the Manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Service Department
Oculox Technologies SA Via Industria 3 CH-6933 Muzzano Switzerland @-mail: service@oculox.com Phone: +4191 210 89 61

10 TECHNICAL SPECIFICATIONS

10.1 General Specifications

Classification according to Medical Device Regulation	Class 1	
LED Classification according to IEC 62471	Exempt	
Mains	Only supplied power supply can be used – Mean Well GSM90B24-P1M	
	Rating:	100-240 VAC – 50/60 Hz 24V DC
Max power absorption	40VA	
Type of protection against electric shock	Class II	
Applied part	Type B	
Degree of protection against electric shock (EDS)	Level 4	
Degree of protection against the ingress of liquid	IP X0	
Mode of operation	Continuous	
Fuse	5x20mm – 4AF	
Dimension	350 (D) x 330 (W) x 400 (H) mm	
Weight	10 kg	
Operating temperature	10°- 30° C	
Storage/Transport Temperature	Min +5° C / max +40° C	
Operating humidity	30% - 85% (non-condensing)	
Operating pressure	From 800 hPa to 1060 hPa	
Max noise (dBA)	<70 dB	
Shelf life	5 years	

10.2 LED specifications

LED type	General purpose LED
Wavelength	420, 450, 470, 520, 590 and 630 nm
Max irradiance	5 (W/m^2)

11 GLOSSARY

A Glossary of symbols and abbreviations used in this Manual is reported below.

Symbols	Description
	Read the enclosed documentation
CE	CE Mark
	Symbol of applied part type B, according to standard 60601-1
	Symbol indicating that the Device cannot be disposed of as municipal waste, but must be separated in accordance with the WEEE (Waste Electrical and Electronic Equipment)
	Manufacturing date
	Manufacturer
SN	Serial Number
MD	Medical Device Symbol
REF	Catalogue number
EC REP	Authorized representative in the EU
	UDI label
	Attention - consult internal documentation
	Power ON/OFF

12 Appendix A: EMC Tables

CAUTION!

To guarantee the safety of the user, the patient and others, use only accessories and spare parts specified by the Manufacturer of this product. Other accessories or spare parts can cause the emission of increased electromagnetic radiation or reduced immunity against interference.

IMPORTANT!

Medical electrical devices are subject to special precautions with regard to electromagnetic compatibility (EMC) according to IEC 60601-1-2. Make sure you observe the notes on EMC for installation and operation. Medical electrical devices can be influenced by mobile HF communication devices (i.e. mobile phone). If it is necessary to stack the devices or place them next to each other, and HF interference is observed, make sure you observe the intended use of the devices.

<table>
<tr><th colspan="3">IEC 60601-1-2 Table 201
Guidance and Manufacturer's declaration – electromagnetic emission</th></tr>
<tr><td colspan="3">RetinaWISE is intended for use in the electromagnetic environment specified below. The customer or the end user of RetinaWISE should assure that it is used in such an environment.</td></tr>
<tr><th>Emission test</th><th>Compliance</th><th>Electromagnetic environment</th></tr>
<tr><td>RF emission – CISPR 11</td><td>Group 1</td><td>RetinaWISE uses RF energy only for its internal function. As a result,its RF emissions are very low and are not likely to cause any interference in nearby electronicdevices.</td></tr>
<tr><td>RF emission – CISPR 11</td><td>Class B</td><td rowspan="3">RetinaWISE is suitable for use in all environments including households and those directly connected public low-voltage grid supplying buildings used for domestic purposes.</td></tr>
<tr><td>Harmonic emission
IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuation/flicker emission
IEC 61000-3-3</td><td>Compliant</td></tr>
</table>

IEC 60601-1-2 Table 202 Guidance and Manufacturer's declaration – electromagnetic immunity			
RetinaWISE is intended for use in the electromagnetic environment specified below. The customer or the end user of RetinaWISE should assure that it is used in such an environment.			
Immunity test	**IEC 60601 Test level**	**Compliance level**	**Electromagnetic environment**
Electrostatic discharge (ESD) IEC 61000-4-2	In contact ± 8 kV	In contact ± 8 kV	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
	In air ± 2; 4; 8; 15 kV	In air ± 2; 4; 8; 15 kV	
Electrical Fast Transient/Burst IEC 61000-4-4	±2 kV for power supply lines	±2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
	±1 kV for I/O lines	±1 kV for I/O lines	
Surges IEC 61000-4-5	±1 kV differential mode	±1 kV differential mode	Mains power quality should be that of a typical commercial or hospital environment.
	±2 kV common mode	±2 kV common mode	
Voltage Dips, Short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% U_T for 0.5 cycle	0% U_T for 0.5 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of RetinaWISE requires continuous operation during power mains interruptions, it is recommended that RetinaWISE be powered from an Uninterruptible Power Supply or Battery.
	0% U_T for 1 cycle	0% U_T for 1 cycle	
	70% U_T for 25 cycles	70% U_T for 25 cycles	
	0% U_T for 250 cycles	0% U_T for 250 cycles	
Magnetic field at mains frequency (50/60Hz) IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Proximity Magnetic Field IEC 61000-4-39	30 KHz, CW, 8 A/m	30 KHz, CW, 8 A/m	Magnetic fields generated by RFID devices should have levels characteristic of a typical location in a commercial or hospital environment.
	134.2 KHz, PM, 65 A/m	134.2 KHz, PM, 65 A/m	
	13560 KHz, PM, 7.5 A/m	13560 KHz, PM, 7.5 A/m	
Note: U_T is the AC mains voltage prior to application of the test level.			

IEC 60601-1-2 Table 204 Guidance and Manufacturer's declaration – electromagnetic immunity				
RetinaWISE is intended for use in the electromagnetic environment specified below. The customer or the end user of RetinaWISE should ensure that it is used in such an environment. Portable and mobile RF communication equipment should not be used within 30 cm of any part of the device including cables.				
Immunity test	**IEC 60601Test level**	**Compliance level**		**Electromagnetic environment**
Conducted RF IEC 61000-4-6	3 Veff from 150kHz to 80 MHz 6 Veff in ISM frequency	3 Veff		d = 30 cm
Radiated RF IEC 61000-4-3	3 V/m from 80 MHz to 2,7 GHz	3 V/m		d = 30 cm
Immunity to proximity fields from wireless RF communication devices	TETRA 400 380 – 390 MHz	27 V/m	27 V/m	d = 30 cm
	GMRS 460 FRS 460 430 – 170 MHz	28 V/m	28 V/m	
	LTE Band 13, 17 704 – 787 MHz	9 V/m	9 V/m	
	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5 800 960 MHz	28 V/m	28 V/m	
	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 5 1700 – 1990 MHz	28 V/m	28 V/m	
	Bluetooth, WLAN, 802.11 b/g/n, RIFD 2450, LTE Band 70 2400 – 2570 MHz	28 V/m	28 V/m	
	WLAN 802.11 a/n 5100 – 5800 MHz	9 V/m	9 V/m	
Note 1: at 80 MHz and 800 MHz, the higher frequency range applies Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.				

a) Field strength from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Device is used exceeds the applicable RF compliance level above, the Device should be observed to verify normal operation.

If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Device.

b) Over the frequency range 150 KHz to 80 MHz, field strength should be less than 3 V/m

IEC 60601-1-2 Table 206 Recommended separation distances between portable and mobile RF communication equipment and the Device
The equipment is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications

equipment (transmitters) and the Device as recommended below, according to the maximum power of communications equipment.

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter**		
	150 KHz to 80 MHz d=1,17*sqrt (P) m	80 MHz to 800 MHz d=1,17*sqrt (P) m	800 MHz to 2,5 GHz d=2,33*sqrt (P) m
0,01	0,117	0,117	0,233
0,1	0,370	0,370	0,740
1	1,17	1,17	2,33
10	3,70	3,70	7,40
100	11,7	11,7	23,3

For transmitters rated at maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer

Note 1: at 80 MHz and 800 MHz, the higher frequency range applies

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

 BURST:

Upon the occurrence of a voltage transient (BURST) in the device power supply, the communication with the cameras could be lost with a consequent error message. At the end of the disturbance, the SW might prompt again to load the program, then from the main switch turn off and on again.

 Voltage dips/Voltage interruption:

In case of a voltage gap during normal operation, when power returns, the machine may restart by emitting continuous flashes. When power returns, to resume normal operation, permanently turn off the machine from the main ON/OFF switch and then restart.

 ESD:

Upon the occurrence of a possible electrostatic discharge induced toward the machine, communication with the cameras could be lost, with a consequent error message. To resume normal operation, permanently turn off the machine from the main ON/OFF switch and then restart.