

2WIN / 2WIN-S

OPERATOR MANUAL



Revision notes

| | |
|--------------------------------|--------------------------|
| Software configuration version | 2WIN/2WIN-S 5.5.4 |
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| Hardware configuration version | Version 33.1 and earlier |
| Rev Num. | 9.7_ENG |

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1 Manufacturer identification

| | | |
|--------------|--|--|
| Manufacturer | Adaptica S.r.l. |  |
| Address | Via San Marco, 9/H 35129 Padova (PD) Italy | |
| Telephone | +39 049 773 968 | |
| Mail: | contact@adaptica.com | |
| Web: | www.adaptica.com | |

2 Legend of symbols

| | |
|---|---|
|  | Manufacturer identification data |
|  | Date of manufacturing |
|  | Electrical / electronic device subject to the WEEE Directive on waste disposal |
|  | CE mark: this device complies the base requirements of the Medical Device Directive 93/42/CEE |
|  | Direct current (DC) |
|  | Warning: necessary information for safety |
|  | Important information |
|  | Read user manual before use |
|  | Indoor use only |
|  | Polarity of the power supply plug |
|  | Applied part – comes into contact with the patient |

3 Glossary

| | |
|-------------------------|---|
| Accommodation: | The power (or ability) of the eye to alter the shape of its lens so that it can adjust the focus of the eye for distance and closeness. |
| Anisometropia | A condition in which the refractive power of the eyes is unequal. |
| Astigmatism | A condition in which the optical (or outer) surfaces of the eye are distorted so that light rays are not sharply focused on the retina for either near or distant vision. |
| Auto Shutdown | A procedure whereby 2WIN stops to work and switches off automatically. |
| Auxiliary window | Graphical window that displays additional data. |
| Binocular vision | The use of both eyes simultaneously in such a manner that each retinal image contributes to the final percept of a single image. |
| Diopter | The refractive power of a lens. It is used as a unit of measurement in refraction. |
| Esophoria | A tendency for the eyes to turn inward, when fusion is suspended. |
| Esotropia | Marked turning inward of the eye; crossed eyes. |
| Exophoria | A tendency for the eyes to turn outward, when fusion is suspended. |
| Exotropia | Divergent strabismus; abnormal turning outward of one or both eyes. |
| Fixation | Movement of the eyes so that the visual axes meet and the image of an object falls on the corresponding points of each retina. |
| Focal point | The point to which rays are converged after passing through a lens. |
| Heterophoria | A tendency for deviation of the eyes, when fusion is suspended. |
| Heterotropia | A manifest deviation of the eyes resulting from the absence of binocular equilibrium. |
| Hypermetropia | Hyperopia. |

| | |
|--------------------------|--|
| Hyperopia | Farsightedness is a refractive error in which the image does not come to focus before striking the retina in the relaxed eye. Accommodation may be used to overcome small amounts of hyperopia. |
| Monocular | Involving the use of a single eye. |
| Myopia | Nearsightedness is a refractive error in which the point of focus for light rays is in front of the retina, resulting in blurred distant vision. |
| Occlusion | Obscuring the vision of one eye to test the vision or force the use of the other eye. |
| Orthophoria | Parallelism of visual axes, the normal eye muscle balance. |
| 2WIN Applications | Additional software features that can be installed directly on 2WIN. |
| Refraction | When referred to human eye, this term, or the term Refractometry, are used to indicate the measurement of the Refractive Error, that is the error in the focusing of light by the eye. |
| Refractive Error | Equivalent to ametropia, it is usually decomposed into a spherical error and a cylindrical error. Types of ametropia include myopia, hyperopia and astigmatism. |
| Spherical error | Occurs when the optical power of the eye is either too large or too small to focus light on the retina. |
| Strabismus | Failure of the two eyes to direct their gaze at the same object because of inappropriate neuromuscular control or because of fibrosis or paralysis of one or more extraocular muscles, as in crossed eyes or walleyes. |

4 Intended use of the device

Instrument for the measurement of binocular and monocular refraction based on infrared photorefractometry.

5 Classification and Applied Standards

5.1 Classification according MDD 93/42/EEC, Annex IX

Class IIa

5.2 Classification and type of applied parts

When used without the KALEIDOS accessory, there are no applied parts.

When used in the 2WIN-S configuration, with the KALEIDOS accessory, the applied part is Class I, Type B.

5.3 IP classification

IPX0 (degree of protection provided by the external plastic shells with reference to the penetration of any special material or water).

5.4 Electromagnetic compatibility

This device has been classified as class B according to the standard IEC 60601-1-2.

5.5 Applied standards

EN 60601-1; EN 60601-1-2; EN ISO 15004

6 Precautions

Electromagnetic compatibility

 This device has been tested and found to comply to the limits for medical devices contained in IEC60601-1-2 and in Medical Device Directive 93/42/EEC. These limits are intended to provide reasonable protection against harmful interference in a typical medical installation. This instrument generates, uses and can radiate radio frequency energies and, if not installed and used in accordance with these instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If the system does cause harmful interference to other devices, which can be determined by turning the system off and on, try to eliminate the interference by adopting one or more of the following measures:

- reorient and/or relocate the receiving device;
- increase the distance between the devices;
- In case of charging of the device, connect the system to an outlet on a different circuit than that to which the other devices are connected;
- consult the manufacturer or field service technician for help.

 This equipment has been verified to comply with the limits for a class B computing device, pursuant to FCC Rules. In order to maintain compliance with FCC regulations, shielded cables must be used with this equipment. Operation with non-approved equipment or unshielded cables is likely to result in interference to radio and TV reception. The user is cautioned that changes and modifications made to the equipment without the approval of manufacturer could void the user's authority to operate this equipment.

 Portable and mobile RF communications equipment, such as cell phones, can affect medical electrical equipment: any RF communications equipment shall be used no closer than 30 cm (12 inches) to any part of the 2WIN, including its cables.

 The area where the device is to be installed has to comply to the IEC/ISO standards related to the medical use of an area.

 The device must NOT be used in oxygen rich environments or in presence of flammable products.

 The device must not be installed in a room exposed to chemical-physical aggressive agents (such as sulfides, salt, dust, etc.), nor exposed to direct sunlight or lack of ventilation, high humidity, sudden surges or drops in temperature. The safety and efficiency of the instrument are not guaranteed under these conditions.

 This device is designed to be used indoor. Do not expose the device to water: this could lead to fire or electric shock.

Light radiation

 CAUTION – The light emitted from this instrument is potentially hazardous. The longer the duration of exposure, the greater the risk of ocular damage. Exposure to light from this instrument when operated at maximum intensity will exceed the safety guideline after 30 minutes.

 Do not stare at the light sources of the device from a distance lower than 1 m.

 When the device is used in the 2WIN-S configuration, with the KALEIDOS accessory applied, the patient applied part, i.e. the face cushion, **shall be disinfected** before each patient change, to avoid patient contamination by infectious agents. Please follow instructions provided on *Chapter 18 – Disinfection* of present manual.

Precautions and general warnings

 The clinical interpretation of the data provided by the device is restricted to licensed eye care practitioners.

The process of making a diagnosis using the device results is the responsibility of the eye care practitioner.

A device specific training is required for any operator to become able to use the system.

For the correct use of the device it is mandatory to read carefully the instructions in *Chapter 9 - Operative information*.

 Do not open the device: this could lead to electric shocks or damage to the system. No modification of this equipment is allowed. Do not use the instrument if the cover or other parts of the device have been removed.

Only technicians authorized by the Manufacturer may service the device. The Manufacturer cannot be held responsible for system safety should the device be opened, repairs carried out, third party's software be installed, or parts be replaced by unauthorized persons.

Inside the 2WIN SD memory card is stored the patient data. This information can contain personal information such as name/surname/age. This information management is responsibility of the operator.

 Do not use the device while it is attached to the wall adapter for charging the battery.

 Any USB wall adapter and any battery charger used to charge the battery, when not provided by the manufacturer, shall comply EN 60950-1.

In the 2WIN-S configuration, only the power adapter provided by Adaptica with the system can be used to charge the KALEIDOS battery pack, for safety reason.

In the 2WIN-S configuration, do not use the tablet while it is connected to the power supply.

 The battery of the 2WIN and the cells of the KALEIDOS cannot be replaced with equivalent item not provided by Adaptica, for safety reason (risk of explosion).

 The battery cells contained in the KALEIDOS accessory cannot be replaced by the user, but only by authorized service personnel.

 The device needs to be operated in a semi dark room, in order to help pupil dilation. This rule does not apply to the 2WIN-S configuration, when the KALEIDOS is applied.

 Do not use different configuration of 2WIN and KALEIDOS to compose the 2WIN-S. Serial number of 2WIN and KALEIDOS are matched to create the 2WIN-S configuration, for manufacturing and warranty reasons.

 The operator is not allowed to perform a DOWNGRADE of the 2WIN software. Adaptica is not responsible for the improper use of the device with a downgraded software version.

 Do not place objects on top of the device and do not try to sit onto the device. Be sure that the device is steady on the floor and not over other objects that can affect its stability.

7 Quick user guide

Important

- Read carefully the Chapter 6 – Precautions of the present manual before operating the device.
- The 2WIN is a binocular refractometer and vision analyser. It measures refraction of both eyes at the same time, at the distance of 1 meter.
- The 2WIN should not be confused with a table-top auto-refractometer (AR). ARs are designed to measure refractive errors of one eye at time, in an artificial condition of far fixation. Please do not consider the 2WIN a small portable auto-refractometer or two small ARs glued together!
- Working in natural binocular conditions the 2WIN allows to evaluate simultaneously not only refractive errors, but also gaze direction, ocular alignment, pupil diameter, pupil distance and the accommodative balance/unbalance between the 2 eyes. Many other features can be measured by the 2WIN using optional Applications (2WIN APPs).
- Please familiarize yourself with the measurement conditions and techniques of the 2WIN in order to exploit its full potential.

7.1 The 2WIN

- The 2WIN detects a patient's real-time refraction in the most natural environmental conditions.
- It is a binocular instrument that measures refraction on the basis of eccentric InfraRed photo-refraction (also photo-retinoscopy). Both eyes are measured at the same time in free space, while fixating at 1 meter.
- It must be operated in a dim light environment to ensure sufficient pupil size and reduce accommodation, except if used with KALEIDOS accessory.
- It is hand-held, battery operated, very light, non-invasive, fast and easy to use.
- It automatically measures binocular refraction, pupil distance, pupil size, direction of gaze, and fixation abnormalities.

7.2 Main Applications

- Refraction of infants and children from 2 months of age, seniors, impaired and non-cooperative patients.
- Early detection and documentation of multiple amblyogenic factors.
- Un-aided binocular refraction of all other patients
- Over-refraction of glasses or contact lenses.
- OPTIONAL (APPs)
 - Phoria/tropia measurements
 - Dynamic pupil response time and size caused by artificial light created by 2WIN
 - Centering of the visual axis on the glasses frame
 - Addition power measurement at the 66 cm distance from the patient

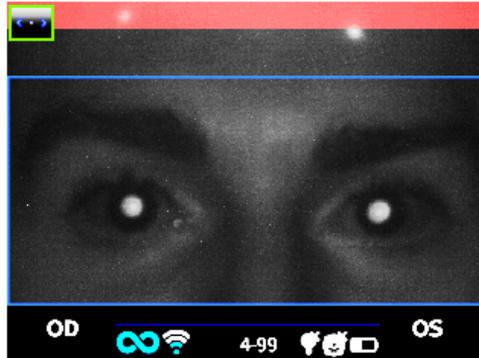
7.3 Exam conditions

- With reference to electromagnetic compatibility, the device is designed for use in a Professional healthcare facility environment.
- The patient shall sit comfortably in a suitable exam room; infants should sit in adult's lap. A uniform dim light environment is necessary, except in presence of the KALEIDOS accessory.
- The 2WIN accuracy is affected by external sources of light in particular HOT lights halogen or incandescent lamps because of the presence of high infrared content of the light; please make sure no direct light hits the patient's face and ensure uniform light on both eyes.
- A stable measurement distance of 1 meter is also important.

7.4 Exam procedure

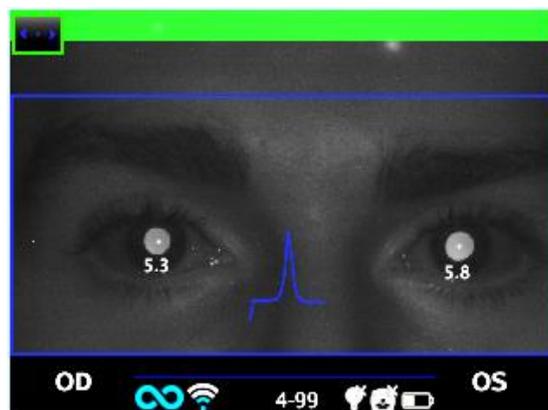
- Turn the 2WIN ON by pressing the ON/OFF button for 1 sec. and wait until the stand-by screen appears. A beep sound stands for 2WIN turning ON.
- Please take care to modify the patient age before saving the 2WIN measurement. The 2WIN results in young patient with hyperopia error can be dependant to the patient's age. To change the patient age "long-press" to the RIGHT button of the joystick and follow the instructions in the 2WIN display.

- Instruct the patient to keep his/her eyes wide open, clear of eyelids or eyelashes, and to fixate the centre of the camera. Hold the 2WIN horizontally with both hands, approximately at the same height of the patient's eyes, and at a distance of 1 meter.
- Press and hold the START button to enter the focusing phase.
- Center the eye / eyes of the patient in the active display within the blue rectangle (measurement area)



Screen examination – blurred, not in focus. Adjust the distance from the patient

- Adjust the distance to focus the image until the top bar is green and the focusing indicator based on corneal reflex shape appears in the centre of the screen.
- When the top bar is PERMANENTLY green and the focusing indicator (in the center of the image) reaches the highest peak (as shown in the following photo) release the BUTTON S1/S2.



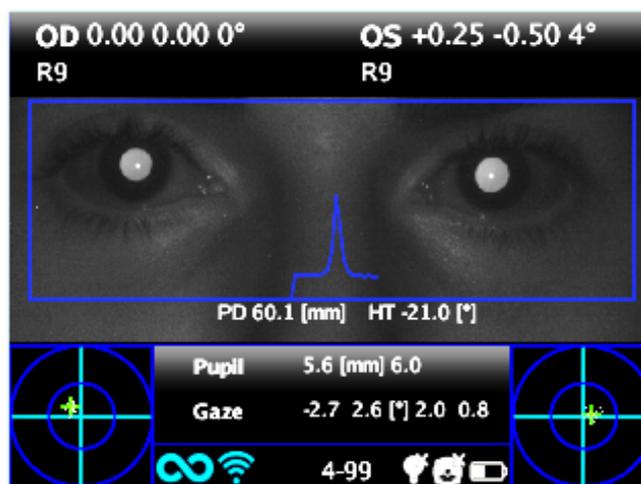
Examination screen – focus OK

- Stay firmly in the condition in which the upper bar is green and the focusing indicator is sharp until the message DATA PROCESSING appears on the display.



Data Processing message

After Data Processing measurement results will be displayed.



Measurement screen

7.5 Measurement tips

- For both Sph and Cyl, measurement accuracy is ± 0.25 D in the range of ± 5 D. The cylinder axis is calculated between 1° and 180° (step 1°) with precision of $\pm 5^\circ$. For higher refractive errors, the 2WIN displays “high M” (myopia) or “high H” (hyperopia). In the case the 2WIN displays “high M” or “high H” without displaying a numerical result, 2WIN will write in the upper part of the display “n.a.” (not accessed measurement). For big refractive errors, in the case 2WIN succeeds to estimate the spherical power only, this estimation will appear in the upper part of the display. This maximum spherical estimation is 15D.
- Make sure the cylinder notation (minus or plus) is set to your preference.
- During the measurement mode, please make sure that both eyes appear within the Graphical User Interface paragraph; if necessary, slightly tilt the 2WIN.

- If you wish to refract infants, young children and any non-cooperative patients, you can turn the audible and/or the visible fixation targets ON. Audio fixation (attraction system) is preferable to the visible small lights fixation.
- Make sure the Reliability Index of the refraction measurement is higher than 6 (max. is 9). In case of Reliability Index of 6 or less a message with a hint will be displayed. Please repeat the measurement, if possible.
- Over-refraction with contact lenses is as easy and accurate as without correction.
- For accurate over-refraction with glasses, please make sure that no stray light reflexes disturb the pupil detection; should such reflexes be present, please slightly tilt the glasses down.
- Please remember that free space, non-cycloplegic refraction can vary depending on several conditions and parameters pertaining to the binocular visual function; in some specific patients, including accommodating children, the 2WIN measurements may vary.

8 Description of the device

8.1 2WIN

The measuring principle of the device is based on infrared photorefraction. In this technique, infrared light is projected through the pupils of the patient onto the retina. Depending on the refractive error, the reflected light forms a specific crescent-shaped brightness pattern within the pupil. The spherical refraction is calculated based on this crescent pattern. Cylinder and axis measurements are based on the same kind of calculation, repeated on four meridians.

This device performs the measurement 1 meter (3 feet 3 inches) away from the patient (contact-less), with continuous tracking of the corneal reflex, for the analysis of the binocular alignment, and with sensor for checking the measurement distance.

The device accepts a pupil diameter between 4 and 7 mm and it is compatible with the measure in mydriasis and in miosis. It is possible to measure down to 3.5 and up to 11 mm, but this depends on good environmental conditions. Outside the 4-7 mm range the overall precision could decrease.



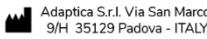
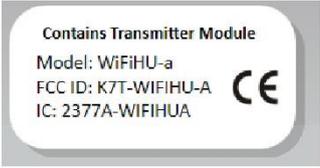
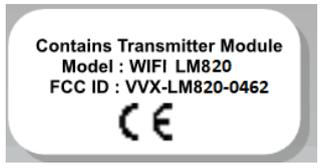
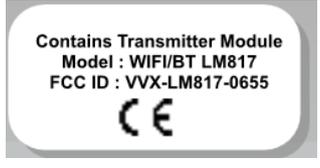
It incorporates sight and sound stimula for the use with children and uncooperative patients (sound is preferable to sight stimula). The device is portable, battery powered, equipped with a computing integrated unit and with a display for verification of the conditions of measurement and for displaying the results. This is controlled via push buttons. 2WIN data can be saved inside the 2WIN and downloaded outside the instrument through USB connection or WiFi LAN. Moreover, data can be sent through email service to the operator email address once it is saved in the 2WIN or finally can be sent to an email printing enabled WiFi printer.

ATTENTION: during any data access to the 2WIN data and in particular when connecting 2WIN to a computer via USB or WiFi the SD card of 2WIN must be inside inside the 2WIN SD card connector (SD card filesystem must be FAT32).

8.2 2WIN-S

2WIN-S comprises 2WIN and KALEIDOS, an accessory. Please refer to Chapter 12 – KALEIDOS.

8.3 Labels

| Label | Detail | Explanation |
|---|---|--|
|  |  | Manufacturer identification data: name and address |
| | Model: 2WIN | Model name |
| | SN :serial number | Serial number |
| | CE 0123 | CE mark and Notified Body identification code |
| |  | Electrical / electronic device subject to the WEEE Directive on waste disposal |
|  | Model: WiFiHU-a FCC ID IC | Identifies the Wifi transmitter module |
|  | Model: LM820 FCC ID | Identifies the Wifi transmitter module |
|  | Model: LM817 FCC ID | Identifies the Wifi/Bluetooth transmitter module |



8.4 Package labeling

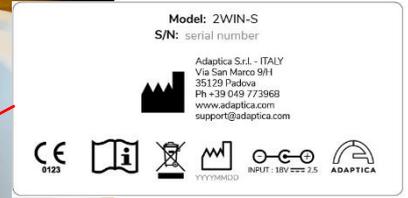
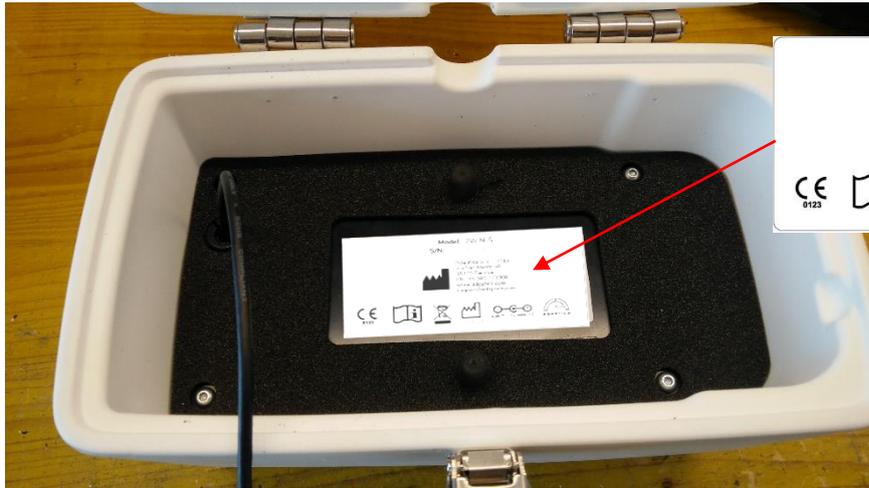


| Label | Detail | Explanation |
|-------|--|---|
| | Adaptica S.r.l. Via San Marco, 9H 35129 Padova - Italy | Manufacturer identification Data: name and address |
| | | Fragile – handle with care |
| | | This side up – do not reverse |
| | | Keep dry |
| | | Storage minimum and maximum temperature |

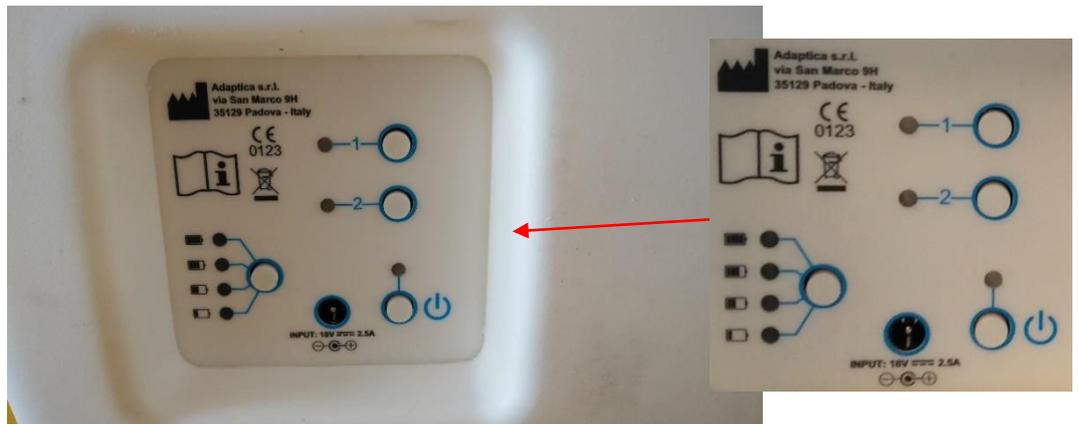
8.5 KALEIDOS labeling (2WIN-S only)

| Label | Detail | Explanation |
|-------|--|--|
| | Adaptica S.r.l. Via San Marco, 9H 35129 Padova - Italy | Manufacturer identification data: name and address |
| | model: 2WIN-S | Model name |
| | | Connector polarity |
| | 18V 2.5A | Input C.C. voltage and current |
| | | CE mark and Notified Body identification code |
| | | Electrical / electronic device subject to the WEEE Directive on waste disposal |
| | | Read manual strictly before operation |
| | | Turn on device |
| | 1 | Button 1 (see operation instructions) |
| | 2 | Button 2 (see operation instructions) |
| | | Battery fully charged |
| | | Battery discharged |
| | :serial number | Serial number |
| | IP00 | Not protected against ingress of objects and water |
| | | Indoor use only |
| | | Year of production |
| | | Applied part type B |

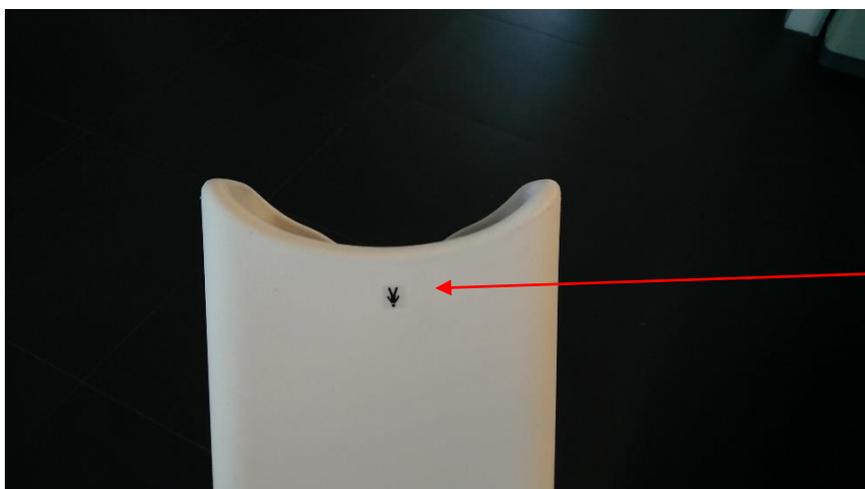
- **BACK INDOOR**



- **CONTROL PANEL**



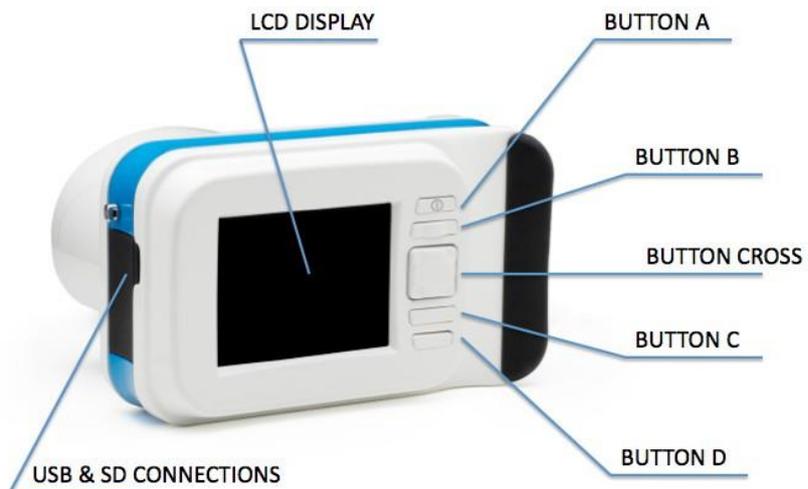
- **UPPER SIDE**



8.6 Interfaces



Front View



Rear View

Inside the USB & SD connection door there are a Micro USB port and a Micro SD card holder.



Open connection door

On the bottom of the device there is also a 1/4"-20 threaded hole for a tripod.
A summary of the functions of the buttons is reported below.

Patient side: BUTTON S1 & S2

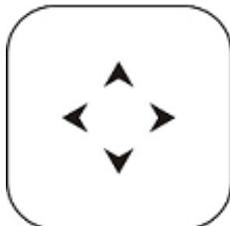
Operator side:



BUTTON A



BUTTON B



CROSS BUTTON



BUTTON C



BUTTON D



IMPORTANT NOTE: the buttons have different behaviours within the different submenus, these will be described in the manual in the corresponding paragraphs.

Long CENTRE push to display Contextual help that explain buttons functionality.

The **CROSS BUTTON** features contextual functions:

At starting the CROSS BUTTON is used to activate the menu and navigation:

- push CENTRE to enter menu or to say OK;
 - push RIGHT to go down into the submenu;
 - push LEFT to go up from the submenu;
 - push UP to scroll up the menu;
 - push DOWN to scroll down the menu;
- fast RIGHT push: activates auxiliary window. This window displays the results of main Application (screening) and additional Application;
- long RIGHT push: Screening Mode: Selection of age interval for standard screening: push RIGHT to switch between 'Ok' button, 'Cancel' button and the list of age intervals. To move inside the list of age intervals, press CENTRE button. (NOTE: if the date of birth has been already inserted via the long LEFT push, then the age interval is automatically set);
- long UP push: changes positive and negative cylinder representation for the running measurement;

Menu tree is described in the Menu paragraph.

During the examination some keys change their function:

- push LEFT to toggle ON/OFF the sound;
- push RIGHT to toggle ON/OFF the light;

After the measurement:

- push CENTRE to enter menu;
- push RIGHT to display the auxiliary window;

Active keyboard mode buttons:

- Cross button CENTRE: select the field (or letter) highlighted;
- Start button: Enter;
- Cross button, UP/DOWN/RIGHT/LEFT buttons: move between characters;
- Button A: exit;
- Button B: moves the cursor in different fields;
- Button C: backspace;
- Button D: resume;

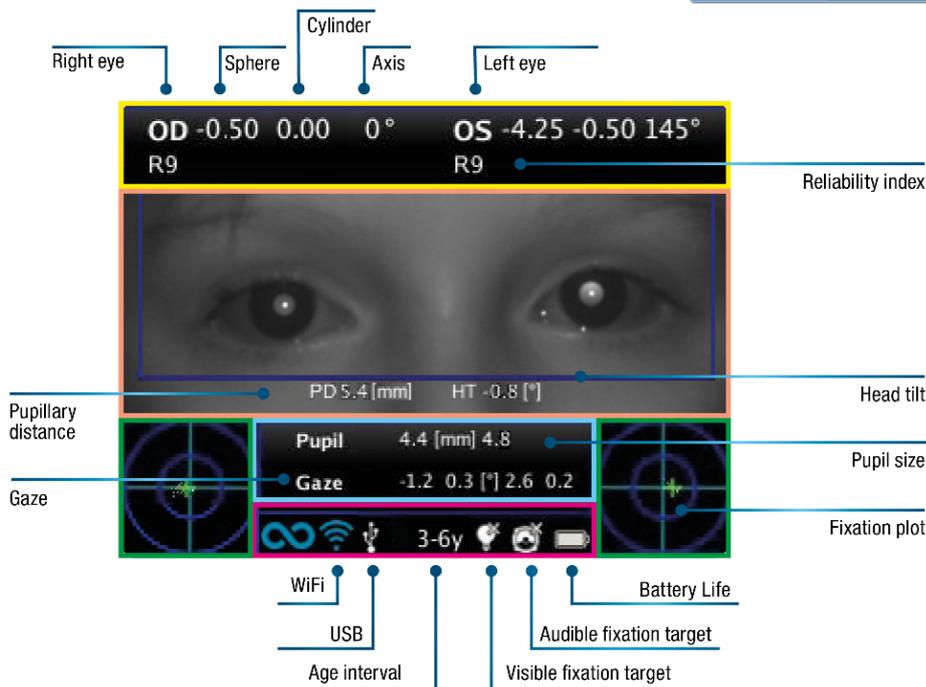
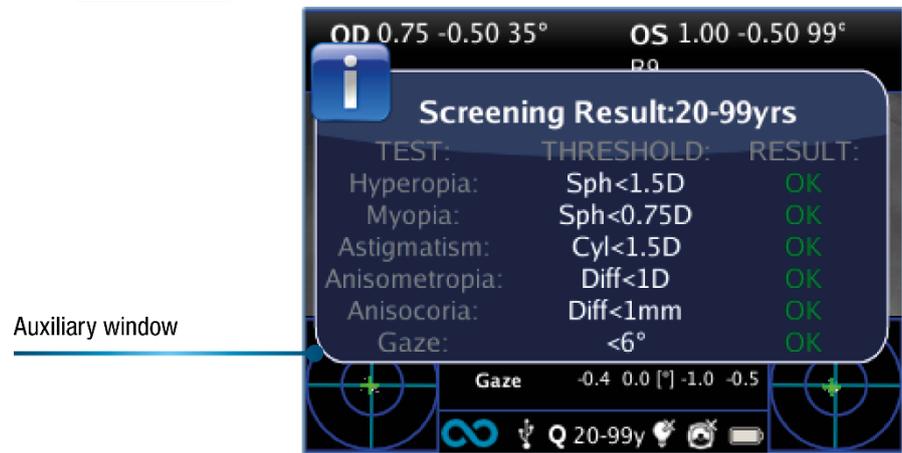
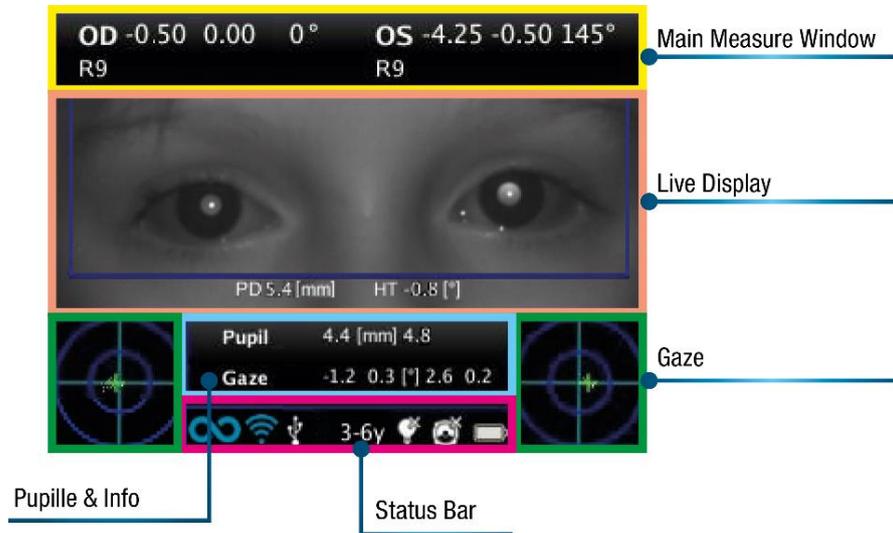
All the button functions are summarized in the following figure:

(* In KALEIDOS mode)

| BUTTON | HOME | BROWSE | KEY-BOARD | DATE TIME | SCREEN AGE | MENU | IN MEASURE |
|-------------------|---|-----------------------------------|------------------|------------------|-------------------|-------------------|--------------------------|
| <i>Hold A</i> | on/off | on/off | | | | | |
| <i>A</i> | 2WIN Applications | Exit | Exit | cancel | cancel | exit | -- |
| <i>Hold B</i> | print | Print | | | | | |
| <i>B</i> | Zoom | Zoom | Change field | Change field | Change field | Change field | -- |
| <i>Up</i> | -- | Patient UP | move | Increase | change field | Move Up | Increase light intensity |
| <i>Up-hold</i> | toggle refraction | toggle refraction | -- | -- | -- | -- | -- |
| <i>Down</i> | Transfer data to VFIT or 2WIN App | Patient DOWN | move | Decrease | change field | Move Down | Decrease light intensity |
| <i>Down-hold</i> | BROWSING on | Transfer data to VFIT or 2WIN App | -- | -- | -- | -- | -- |
| <i>Menu</i> | Enter menu | Enter menu | Ok | Click | Click(Select) | Select | -- |
| <i>Menu-hold</i> | help | Help | Help | help | help | help | -- |
| <i>Left</i> | restore last valid measure | show patient data | move | change field | change field | Go to Parent/Exit | Toggle Sound |
| <i>Left-hold</i> | Keyboard | Keyboard | -- | -- | -- | -- | -- |
| <i>Right</i> | screenResult | screenResult | move | change field | change field | Go to child | Toggle Light |
| <i>Right-hold</i> | screenAge | screeninAge | -- | -- | -- | -- | -- |
| <i>C</i> | change eye | -- | canc | -- | -- | -- | -- |
| <i>Hold C</i> | Notification Center | Notification Center | -- | -- | -- | -- | -- |
| <i>D</i> | Attention (*Start Live mode measure / start acquisition / stop measure) | BROWSE FILTER | resume | -- | -- | -- | -- |
| <i>Hold D</i> | quick menu | -- | -- | -- | -- | -- | -- |
| <i>S1/S2</i> | Start Measure | browseOFF | done | -- | -- | -- | Stop Measure |
| <i>Hold S1/S2</i> | Focusing | -- | -- | -- | -- | -- | -- |

8.7 Graphical user interface

The graphical user interface is displayed in these figures:



9 Operative information

9.1 Operating conditions

The device needs to be operated under the following environmental conditions:

| | |
|-----------------|--------------------------|
| Temperature: | 10 – 40 C° (50 – 104 F°) |
| Humidity (max): | 90% not condensing |

9.2 Unpacking

The box contains (default configuration):

- the electronic version of the operating manual (inside the microSD)
- the 2WIN device
- two rechargeable batteries
- a microSD memory card
- a USB cable (microUSB to USB-A)
- an external battery charger to charge the battery outside 2WIN
- an occluder (infrared patient's eye occlusion system)

Open the battery lock and insert the battery. Close the battery door and lock it (follow the following instructions to insert the battery in the proper way).



Before inserting the battery, charge it totally.

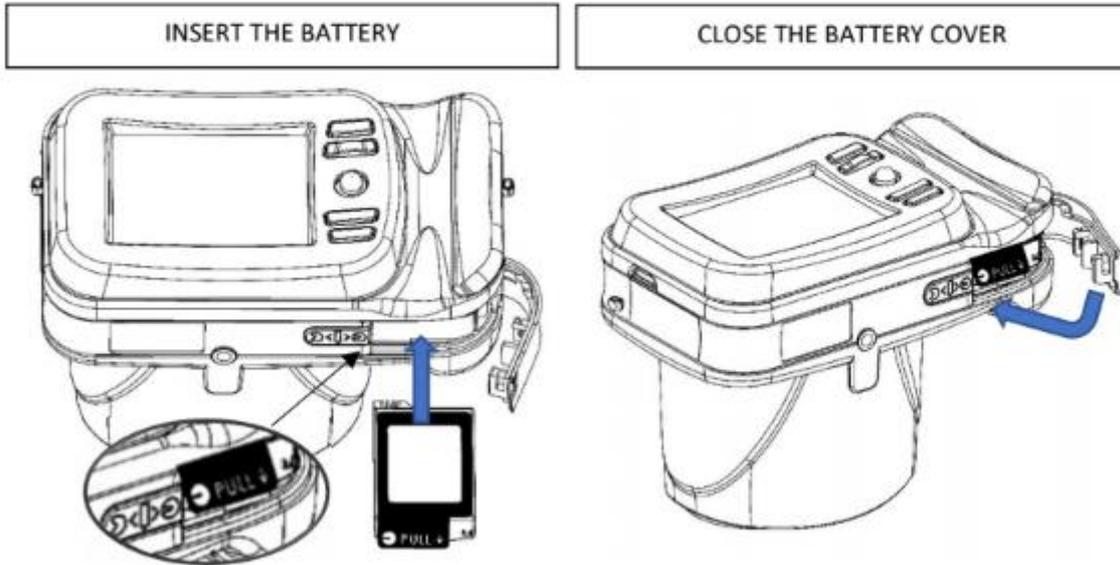
9.3 Insert battery

To insert the battery: slide the battery lock, hold it and gently open the battery door located in the lower side of the device. Insert the battery. Pay attention in inserting the battery with its connector facing down towards the instrument's inside so that the connector of the battery matches the connector inside the device.

Close the battery door and lock it.

ATTENTION! INSERT THE BATTERY AS SHOWN IN THE FIGURES BELOW

BATTERY INSERTION



9.4 Extract battery

To extract the battery: slide completely the battery lock, hold it firmly and gently open the battery door located in the lower side of the device.



WARNING: Don't try to force the opening of the battery door if the battery lock is not completely opened.

BATTERY EXTRACTION

OPEN THE BATTERY COVER

TO EXTRACT THE BATTERY, PULL THE TONGUE



9.5 Battery-charging

- i** Please load the batteries with the external battery charger provided.
- i** On first usage the battery needs to be charged for at least 4 hours.
- i** Batteries must be charged at least once every 30 days.



Slide completely the battery lock and extract the battery, insert the battery into the external battery charger. Please align battery contacts with charger. When the battery is fully charged, the light of the charger will become completely green.

The recharge option via USB port connected to the computer is not allowed. In fact, to extract the battery and use an external battery charger is the correct procedure allowing a good life cycle of both battery and 2WIN device.

- i** **WARNING:** to guarantee the correct battery charging keep the battery charger horizontal with respect to the ground during the whole charging process.



Please notice that the device will not be able to perform any exam while connected via micro-USB port.



When the device is connected to a computer via USB port the turning off is prevented. When you try to switch off the 2WIN a warning will advise you to remove USB cable.

9.6 Before operation

After charging the battery, be sure to set up date and time. Current date and time will be used into measurement printout. As soon as the battery is assembled and charged, and time has been set, the device is ready for operation.

The device has an automatic hardware self-test procedure that can be activated as an option on the instrument MENU under FUNCTIONS/AUX/AUTO TEST. This procedure may be executed any time to verify hardware integrity.

9.7 Data management disclaimer

When turned on the first time, 2WIN present a disclaimer document related to the management of data telemetry of the instrument. The operator is asked to read the document and accept the terms, if not 2WIN will work but some functionalities will be disabled (Telemetry and Remote access). You can read the document at the end of this manual (Appendix A) for all the details.

9.8 Software language

2WIN Software is available in the following languages:

- English
- French
- German
- Italian
- Spanish
- Turkish

The default language for 2WIN Software is English.

Follow these instructions to load a different language pack in your 2WIN:

1. Download the translation file of interest on your pc from the following link: <https://www.adaptica.com/products/2win/> from the section SOFTWARE TRANSLATIONS
2. Connect 2WIN to your pc through the microUSB cable
3. Create new folder named TR in the root directory of the MicroSD card
4. Copy the translation file in the TR directory
5. Safely remove the MicroSD device from your pc and disconnect your 2WIN from the pc
6. Reboot your 2WIN
7. At the next start 2WIN Software will be loaded with the selected language pack.

Follow these instructions to return to the default English translation:

1. Connect 2WIN to your pc through the microUSB cable
2. Create a new text file named resetTranslation.xxx.txt in the TR folder
3. Safely remove the MicroSD device from your pc and disconnect your 2WIN from the pc
4. Reboot your 2WIN
5. At the next start 2WIN Software will be loaded with the default English translation.

9.9 Important notes on Battery

Before inserting 2WIN battery, charge it totally (at least 4 hours). Batteries must be charged at least once every 30 days.



If used properly, 2WIN batteries have a lifecycle of 400 cycles of complete charge/discharge.



WARNING! Do not charge 2WIN battery through USB cable. The external wall adapter (provided with 2WIN) must be used to charge the batteries.



WARNING! Do not use 2WIN batteries more than 3 years old. Do not use swollen or damaged batteries.



WARNING! When 2WIN is used in 2WIN-S configuration, connected to the battery pack through the USB cable, 2WIN's internal battery must be removed.

The software will advise when this operation needs to be done, according to the configuration.

2WIN-S cannot charge the 2WIN battery via USB cable. Charging 2WIN battery via USB cable is deprecated.

10 Operative instructions

(Please refer to Paragraph 8.5 and 8.6 for fast reference)

Power ON / Power OFF

To power on the 2WIN device, push the BUTTON A.

To power on the 2WIN-S device, push the on/off button on the Control Panel of the KALEIDOS.

(To turn OFF the device long press the BUTTON A then, when the question “Are you sure you want to quit?” appears, push the CROSS BUTTON, centre, to answer OK)

While the instrument is on, the monitor reduces the brightness after 30 seconds of inactivity. Then the monitor switches off after 30 seconds more. After 600 seconds, the device turns on, emits a sound alert, and shows a warning telling that after 30 seconds it will automatically shut down.



NOTE: 2WIN-S has not auto-shutdown timer.



Default Autosutdown Time is 10 min.

Autosutdown time (changeable from a minimum of 10 to a maximum of 180 minutes, in steps of 5 min), can be customized by selecting from **Menu > Settings > Aux > Autosutdown Time**. In order to operate the instrument it is important to execute the following four steps:

- a) Environment setup
- b) Instrument setup
- c) Preparation of the patient
- d) Measurement

10.1 Environment setup

For a proper use of the device it is important to prepare the environment for the examination.

✓ Verify adequate light conditions

Except when the device is used in the 2WIN-S configuration, with the KALEIDOS accessory applied, **the ambient light should be dim, there should be no direct light pointed towards the instrument and every direct source of light should not be seen by the device or reflected by eyes of the patient.** In case of bad light conditions during the measurement a message may appear indicating the specific condition.

The device can be optionally used to perform an evaluation of the ambient light: in Menu > Functions > Light Meter the following screen will be displayed.



Then press CENTRAL BUTTON to answer OK to confirm light measurement mode and press S1 or S2 button to start the evaluation:

- Wait that the “age circle highlight” disappears and read the VIS and IR values
- VIS and IR represent respectively visible light evaluation, in a 0 to 65535 range, and infrared light evaluation, in a 0 to 255 range.

Press S1 or S2 button to stop the evaluation.



Good light conditions are equivalent to a value of VIS between 30 and 80, and of IR less than 30.

10.2 Device setup

As soon as powered ON, the device will perform a fast auto-test, then it will turn directly to exam mode, and the display will show the screen depicted below.



As the device features different kinds of measurements, and different exam modalities, an instrument setup must be performed before starting an examination or a sequence of examinations.

Main settings are related to measured eye and interactivity.

Other settings are described in the Menu paragraph.

10.3 Eye selection

There are three options related to which eye of the patient is being measured. By pushing the Eye Selection Button (BUTTON C) on the device the user can toggle between three type of measurements:

- LEFT EYE: only left eye is measured (the blue rectangle covers only the right side of the live area on the display).
- RIGHT EYE: only right eye is measured (the blue rectangle covers only the left side of the live area on display).
- BOTH EYES: both eyes are measured (the blue rectangle covers the whole live area on the display).

The choice is shown on the display by the presence of the signs OS or OD or both on the appropriate side of the display.

Please notice that there is an inversion of left and right due to the fact that the patient and the machine are one in front to the other. Therefore, the sign OS will appear on the right half of the screen, and vice versa.

Performing a monocular examination, the contralateral eye can be covered or kept open at (choice of the Operator).



Power-ON screen with OS

10.4 Interactivity/attraction of the patient

Interactivity represents the set of features built to attract the attention of the patient and they are changed by means of BUTTON D. Interactivity can be of three types:

- SOUND: at the beginning of each measurement the system starts a Jingle to catch the patient's attention. The Jingle and the volume can be chosen by the operator through the menu.
- COLOR LED: at the beginning of each measurement the system starts a flash sequence of red green and blue led in order to catch patient's attention. The LED sequence, the color and the intensity can be set through the menu.
- SOUND + COLOR LED: both the previous.

The type of operative interactivity is indicated on the bottom bar by means of these symbols on the top bar:



light on



light off



sound on



sound off

10.5 Patient data

From version 5.0_170911 and above 2WIN uses the age of the patient information as a corrective parameter for determining the patient refraction. This information is used in particular to compensate accommodation in young patients with hyperopia-based refraction error. Please take care of selecting the age of the patient (long press the "RIGHT" joystick button) before making the measurement.

The age can be modified also after the measurement is acquired by the 2WIN, but it is mandatory to select it before saving the patient data. As already described before, when the operator saves the measurement (long press the "PRINT" button) he is certifying that the patient information (age and optionally name and surname) are correct. Please take into consideration that by default the patient age range is set to 15-50 years.

10.6 Browsing Mode

The browsing mode allows to recover patient's data previously saved in the 2WIN SD memory. Holding the down button in the Home window, the Browsing mode is entered. The UP and DOWN buttons permit to move between different patients: the data (Patient number, name, date of birth, Age Selection, exam date) is shown for some seconds and then disappears. However, patient data can be recalled by pushing the left button. When the list of patients is at the end of the browsing, the display restarts from the first patient and a circular-shaped arrow icon appears.

If a stored patient data has been saved with a 2WIN software version previous to 2.0 (but not lower than 1.4), then the browsing mode shows an exclamation point icon indicating that some fields are incomplete.

It is possible to add a filter in the patient name and / or number for the search of a specific patient by pressing the Button D; if filter is inserted, an icon shows that the filter is active.

If an error occurs during the measurement and the message appears, this last message can be recalled by holding the button C.



Browsing mode: recall of a possible patient.

When pressing the left arrow button the patient's data is shown overlaying the image for a couple of seconds. The following data are displayed: patient number, patient name, date of birth, age selection, folder name, exam date and software version used to acquire and save the exam.

10.7 Preparation of the patient

During the exam the patient must look at the device, staring to the central front hole of the device.

The operator shall instruct the patient to look at the device and to try to open wide his eyes so to avoid eyelashes covering the pupils.

In case the patient is not collaborative, the operator should use interactivity features to attract the attention of the patient itself, by activating either visible flickering lights, or sound, or both. We recommend activating first the sounds and the light only in extreme case when the sounds are not enough.

In case of infants, the patient may be held on the parent's legs during the examinations.

Also, it is a good practice to ask the patient to try to keep the head horizontal, although the device will evaluate and automatically compensate for inclination, when measuring the axis of the refraction.

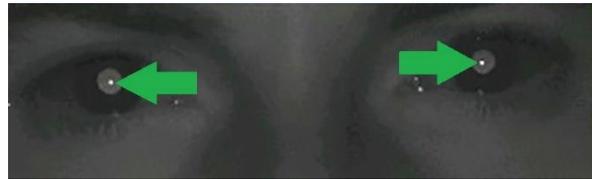
In case of monocular measurement, ask the patient to cover his other eye with a hand.

10.8 Measurement

The instrument, since the beginning of the examination, uses a top bar in the display that gives feedback on the conditions for measurement: in particular, this bar becomes red or green. When the bar is red, there are no conditions to acquire the images correctly, on the contrary, when the bar is green, correct conditions for measuring are satisfied and images can be acquired and processed correctly.

Measurement tips: usually the RED condition depends on a bad distance between the 2WIN and the patient. When the top bar is RED adjust the distance between the 2WIN and the patient in order to focus the image and to obtain a GREEN top bar.

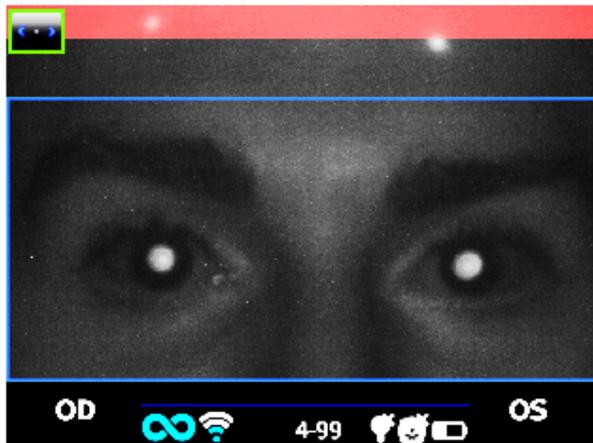
Try every time to focus as best as you can, looking at the corneal reflex. The corneal reflex focusing indicator must be as sharp as possible and as high as possible.



Sharp corneal reflexes

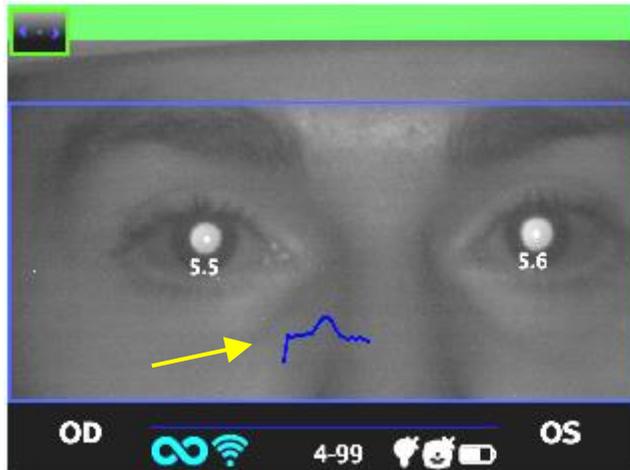
The steps to perform a measurement are summarized in the following list:

1. Once the conditions for the measurement are met, hold the device in your hands and point it towards the patient.
2. Press **and hold** **BUTTON S1 or S2**, in order to start the measurement.
3. Centre the eye/s of the patient in the display live area, inside the blue rectangle (measurement area) – the message “**FOCUSING**” will appear.

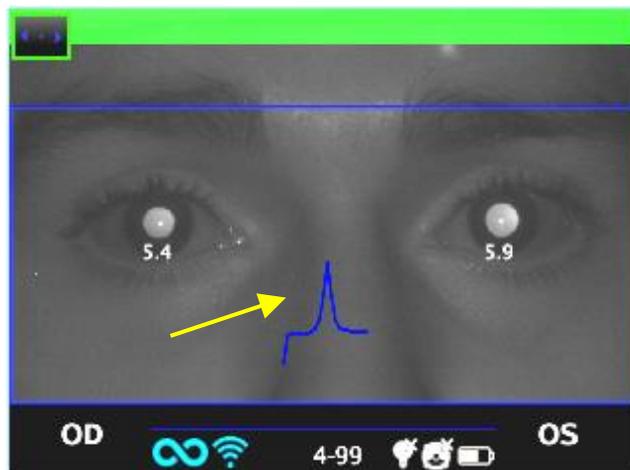


Examination screen – bad focus

4. Adjust the distance to focus the image until the top bar is green and the focusing indicator based on corneal reflex shape appears in the centre of the screen.



- When the top bar is PERMANENTLY green and the focusing indicator reaches the highest peak (as shown in the following photo) release the BUTTON S1/S2.



Examination screen – focus OK

- Stay firmly in the condition in which the upper bar is green until the message DATA PROCESSING appears on the display.



Data Processing

Wait until the measurement process is finished and the results of the measurement are displayed on the screen.

A two-beep sound indicates that the measurement has been correctly taken (this is an option selectable from **Measurement>Sound>Alerts>Ending Beep**).

- *If the ambient light is too high a message will appear warning about the unsuitable condition.*
- *If something goes wrong during measurement, the measurement ends showing a message indicating the cause of failure. These can be:*
 - *Pupil/s too small or large;*
 - *High IR noise;*
 - *Unstable conditions of the data due to other eye problems;*
 - *Other unexpected facts;*

If this would happen try again. If the problem persists, suggest the patient to have a specialist ocular examination.

- *If an error occurs during the measurement and the message appears, this last message can be viewed by Notification Center.*
- *If pupils diameter change during measurement, a message will be shown to display after the measurement, please try to repeat the exam in stable light conditions.*



Pupil diameter unstable

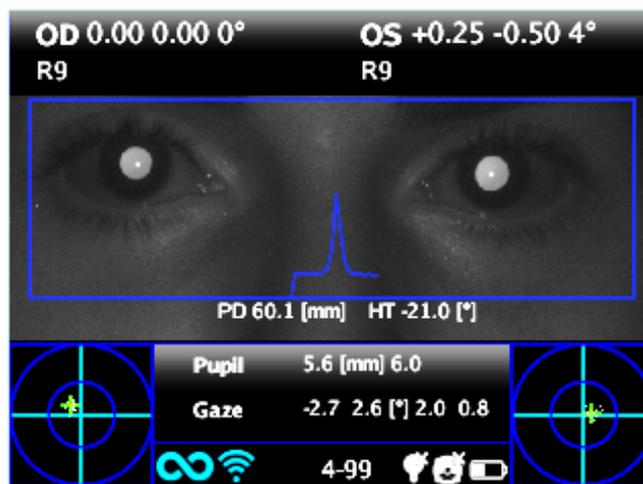
- *If in binocular refraction the two eyes have very different pupil diameters (that means anisocoria) a popup will appear on the display. It is suggested to measure eyes singularly in two different measurements.*



Possible anisocoria

For any problem during operation, please refer to Chapter 21 - Troubleshooting.

7. At the end of the measurement the results are displayed:



Measurement screen

The results of the measurement are here described.

The top box contains, for OD and OS respectively, the values for sphere and cylinder, the axis and the “reliability index”, a number between R1 to R9 (the higher the index, the more reliable the measure). A measure with a low reliability index should be repeated. Please notice that high ambient light will affect reliability index.

The message High M (Myopia) or High H (Hypermetropia) can appear below the OD/OS symbol. This label indicates if the eye presents a diopters value higher than 5 D of spherical equivalent.

If n.a. is displayed when High M/H appears, this indicates that the refraction is outside the range of the 2WIN measurements range.

In case of binocular measurement, two values are shown overlapped to the image, inside the blue rectangle; they are

PD = pupillary distance

HT = inclination of the line connecting the centres of the two pupils, referred to the ground

Axis angles are expressed according to TABO system.

Numbers for “Pupil” and for “Gaze” represent, for OD and OS respectively, pupil diameters and horizontal and vertical (in this order) offset angles of the average position of the corneal reflex on respect of the centre of the detected pupil.

The Gaze is also graphically depicted for each eye in the two bottom corners of the display in the form of a cloud of dots and an averaging cross inside two concentric blue circles.

When the cross is inside the smaller circle, the attention of the patient was high enough during the examination.

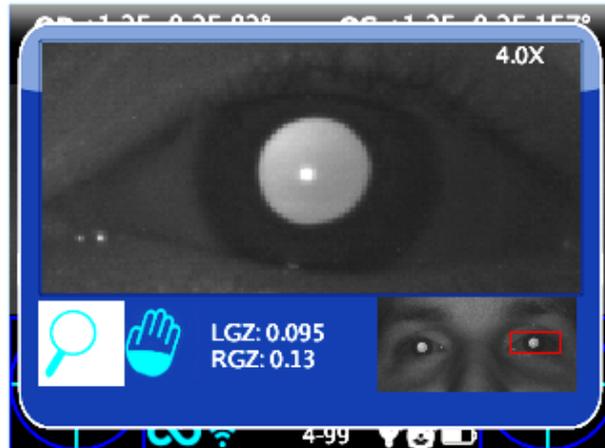
In case of high Gaze values (cross outside inner circle) and collaborative patient, it is recommended to repeat the exam after instructing again the patient about the need to stare at the device, or, further, performing a monocular exam for each eye.

From the measurement screen the options are:

- Press and hold print button to save data to SD memory card;
- Press print button to make a ZOOM on the patient eye, move from the left to the right simply switching with the right and left arrows of the joystick.
- Press S1 or S2 button (START BUTTON) to start a new measurement;
- Press C or D BUTTONS to change device setup for the next measurement;
- Press CENTRAL BUTTON to enter MENU (see Menu paragraph)
- Press LEFT BUTTON to recall last valid measurement performed (in case of invalid, uncompleted measurement).
- Press RIGHT BUTTON for auxiliary window results, in normal 2WIN activities this will bring to the amblyopia screening table.
- Long press RIGHT BUTTON: Screening Mode. Selection of age interval: push right/left/up/down to switch between 'Ok' button, 'Cancel' button and the list of age intervals. Press the centre button to select the item highlighted (N.B. If the date of birth has been already inserted, then the age interval is automatically set). Push “Ok” to save the choice.

10.9 Zoom function

When the measurement is performed, the operator can make a zoom on the acquired pupils of the patient. In order to do that SHORT PRESS the PRINT button. In order to come back to the main visualization just short press the power button.



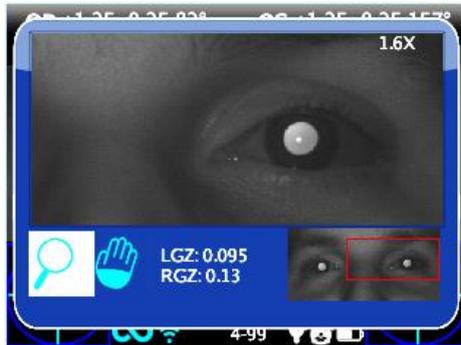
The Zoom App has two main functions on the bottom left of the screen: the Zoom function (lens) and the Pan function (hand). The function in use is indicated with a lighter square. You can change function by pressing the central button of the joystick or by the sound/attention lights button (Button D) .

In normal condition the Zoom frame will automatically get in position (clicking on print button from the main result window) on the left pupil zoomed to the maximum (4x). If it couldn't identify the pupils (failure measurement or measurement done without Zoom function) maybe the pupils haven't been identified and in this case the Zoom will get in position on the center of the image

The zoom function indicated by the magnifying glass is the function that allows you to increase or decrease the zoom power on the image by the up or down buttons from a maximum of 4x to a minimum of 1x. The steps are 0.2x each.



If you hold the down button the zoom will become 1x, if you hold the up button the zoom will become 4x centered on the selected pupil.



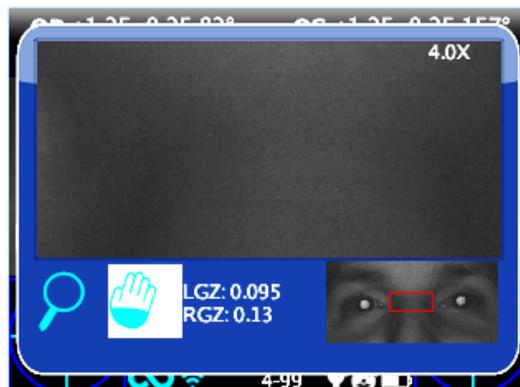
If you want to change pupil you have to press the right and the left buttons that allows you to choose on which of the two pupils the zoom will take place.

You can center and zoom another image detail by selecting it with the Pan function and then adjusting the zoom power by the up and down buttons.

The zoom function centers automatically the selected pupil but in case of changing to the Pan function the zoom will leave the the pupil center and the system will point to the new position selected by the PAN function. To return to the automatic zooming on the pupil you have to press one of the right and left buttons.

Pan Function

The pan function allows you to locate any detail of the image. After selecting it, you have to use the arrow buttons to browse in the image. For a rapid movement you have to hold the arrow (joystick) button to the direction you want. After positioning on the detail you can change the function to choose the zoom power you want by the up and down buttons without losing the center of the image.

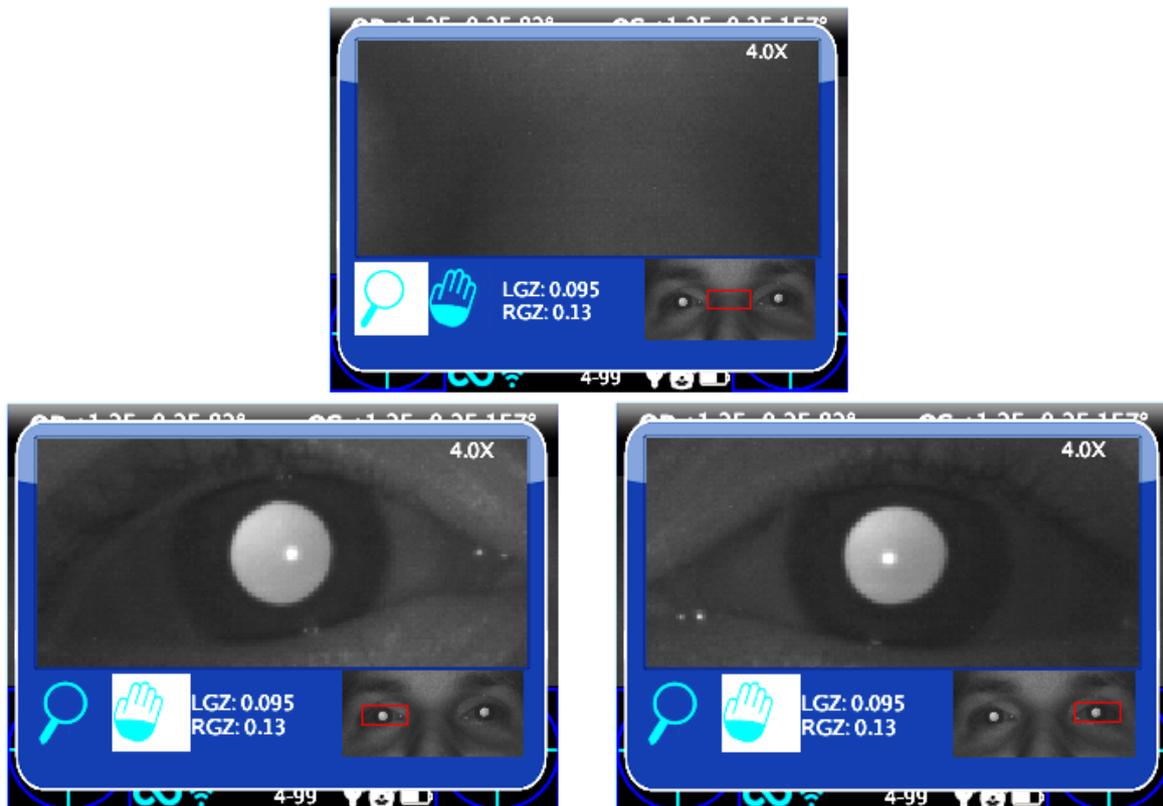


Auto-research of pupils

In case of automatically identifying of the pupils, the situation will be the same as the normal situation shown earlier. You can try to change pupil to confirm that both pupils have been identified. If it doesn't work, the zoom window will automatically get in position on the right pupil and that means it has identified only one of them. If the zoom will get in position on the center of the image it means that no pupil has been identified in the image and you have to go forward with the manual positioning.

Manual research of pupils

If the zoom opens on the center of the image it means the pupils haven't been recognized (or you used a 2WIN without Zoom App). In this case you can search for the pupils using pan function and then save their positions by pressing the pupil button.



After saving the two pupils positions you have to return to the main screen by pressing the power button and then you can save the exam and the pupils position by holding the print button.

Once the new position has been saved you just need to reload the new exam from the SD memory to use the Zoom App again

10.10 Menu

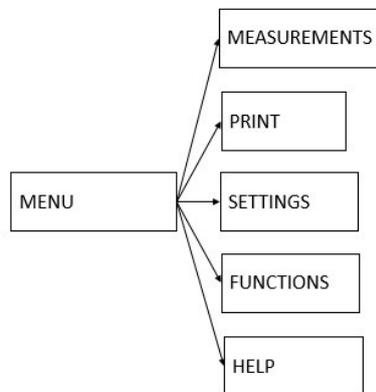
Through the menu it is possible to configure all the features and the working modes of the device.

The menu is activated by pressing the centre of the cross button. To exit the menu press left on the main menu page.

To navigate on the menu, use the arrows on the cross button:

UP and DOWN buttons will move up and down the highlighted choice, RIGHT button will select the highlighted choice navigating deeper by one level in the menu, LEFT button will step back to previous menu level towards main menu page.

Main menu page is schematized in the following picture,

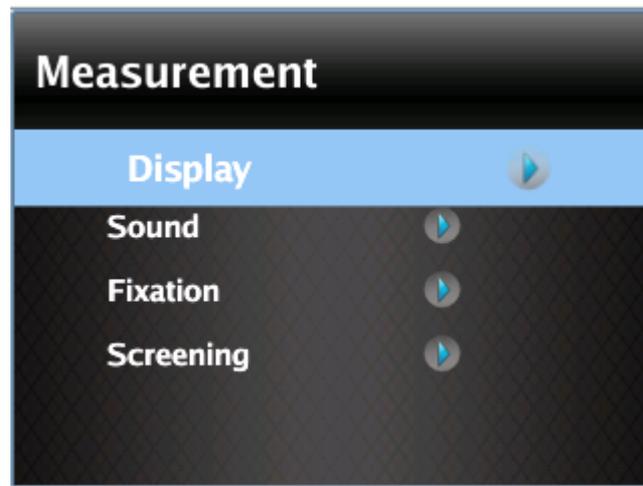


while this is how the display will appear entering the menu:

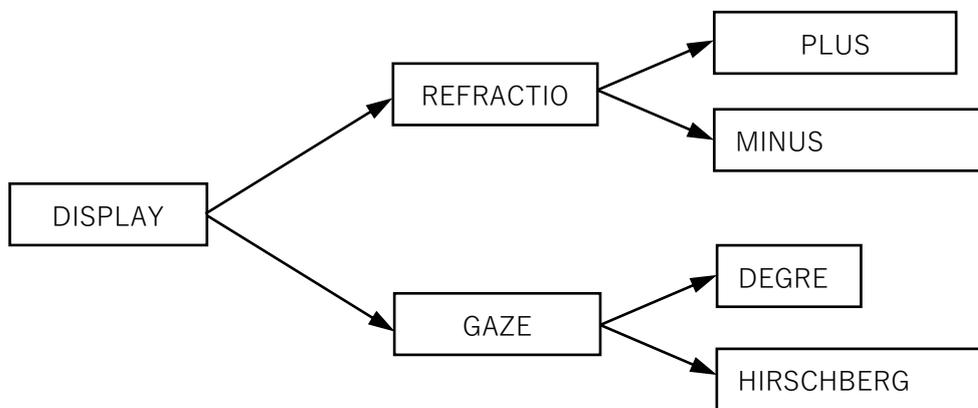


The first level menu entries are described in the following paragraphs.

- The submenu **Measurement** collects the settings related to the examination:

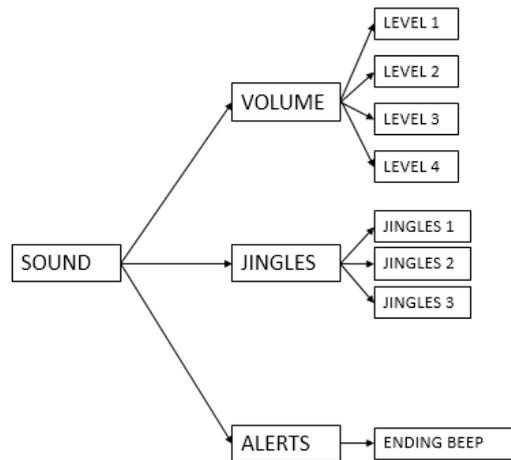


- The submenu **Display** allows to change the way results are presented on the display.



Refraction: allows choice between plus and minus cylinder visualization. Once the measure is displayed, it is still possible to toggle between the two visualization modes by pressing the UP arrow on the cross button.

- The submenu **Sound** configures the interactivity sound. It consists of three items: **Volume**, **Jingle** and **Alerts**.

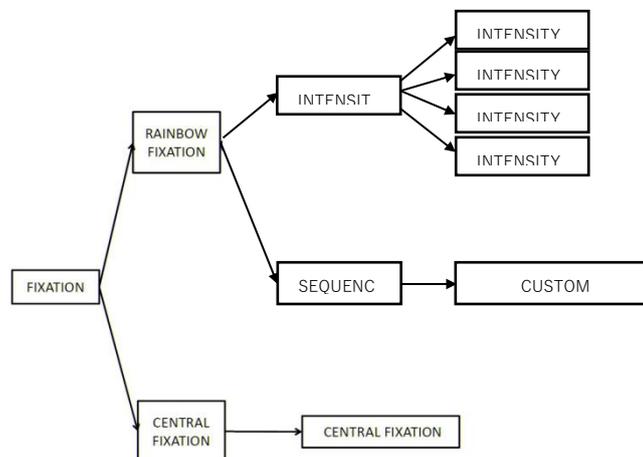


Volume: sets audio power output for the interactivity sound, within a range of four levels.

Jingle: allows to choose the Jingle for the interactivity sound, out of three available melodies.

Alerts: allows to activate the ending beep at the end of the measurement.

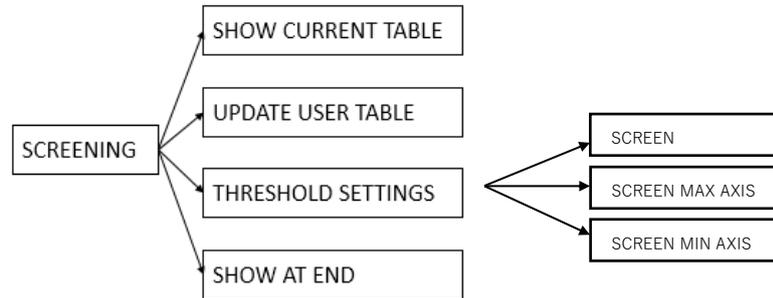
- The submenu **Fixation** configures the interactivity light.



Most of the items in the submenu **Rainbow Fixation** are self-explanatory. They are different ways of turning on the visible led in front of the 2WIN. Custom sequence is to be configured by placing a proper custom file in the SD card. See the Customization paragraph for details

Selecting **Central Fixation**, and then toggling ON the item **Central Fixation**, will enable a visible central fixation light, as help to patient's attention.

- In the submenu **Screening**, '**ShowCurrentTable**' displays the current Screening table, either the default table or the one compiled by the user.

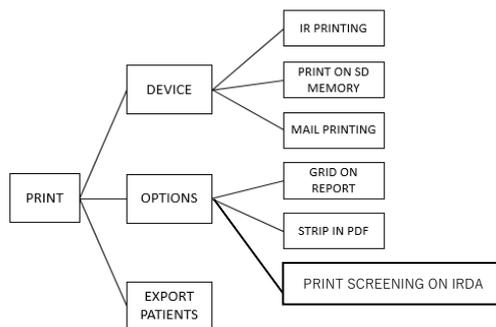


'**Update User Table**' is selected when uploading a user table, and for uploading a newly compiled user table.

'**Threshold Settings**': (a) **Screen Min Axis**: you are measuring with a notation that minimize the sphere –this mode is independent by how the data is displayed; (b) **Screen Max Axis**: you are measuring using a notation that maximize the sphere - sphere –this mode is independent by how the data is displayed; (c) **Screen Displayed**: you are measuring what you see on screen - this mode is dependent by how the data is displayed;

'**Show at end**' displays the auxiliary window of relative Application at the end of measurement automatically.

- The submenu **Print** (see section “**PRINT**” in the following) allows to select the Device, configuring the exam printout to printer and/or to file. Please check the Printing paragraph for details.



IR Printing: enables/disables printing through IrDA to portable printer.

Print on SD memory: enables/disables saving the exam onto SD card.

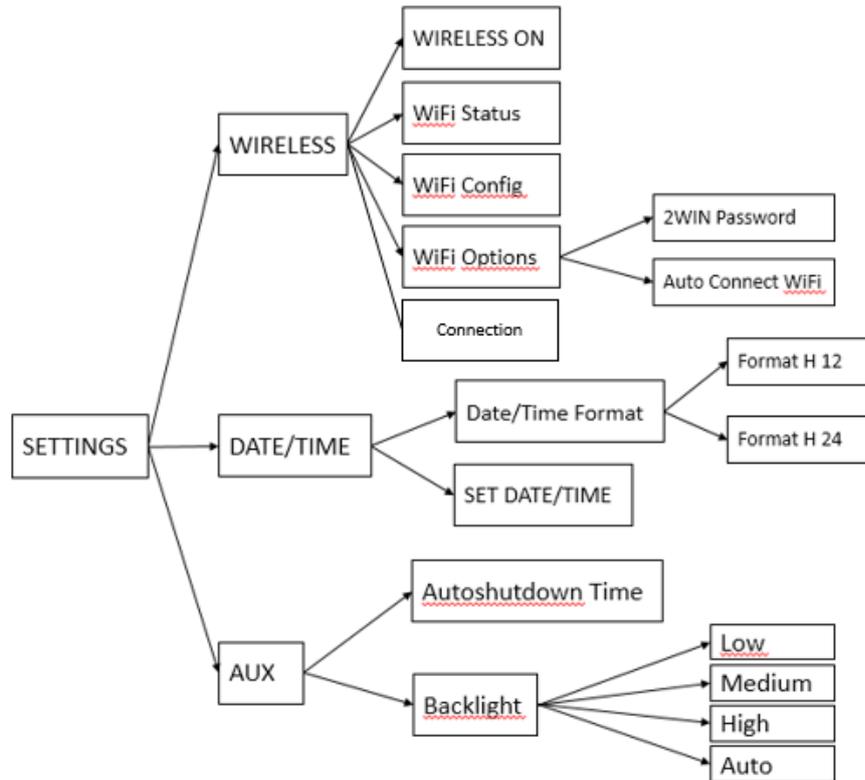
Mail Printing: enables/disables Mail Printing service.

Grid on Report: enables/disables overlay of a grid on the exam report saved onto the SD card.

Strip in Pdf: enables/disables the saving of a pdf file similar to the IrDa strip.

Print screening on IRDA: enables/disables printing the full exam through IrDA to portable printer

- The menu **Settings** configures three more features:



Wireless (optional, this item is visible only in devices with the WiFi module installed) is described in Chapter 11.

Date/Time:

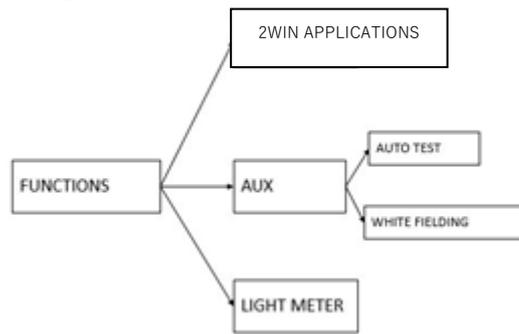
Date/Time Format allows to choose between H12 or H24 format.

Set Date/Time allows to set current date and time.



AUX: Autoshutdown sets the autoshutdown timing. **Backlight** sets the LCD display backlight intensity, either between low, medium and high levels, or enabling automatic light dimming, driven by an ambient light sensor. Please notice that the brighter the display, the faster the battery gets discharged.

- The menu **Functions** configures three features:



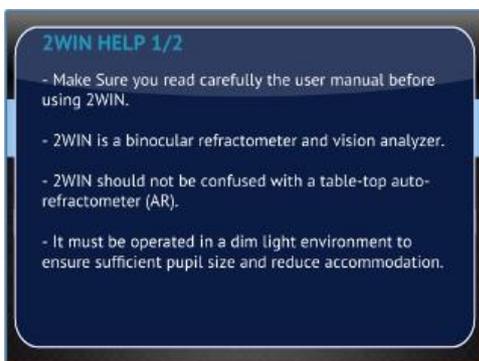
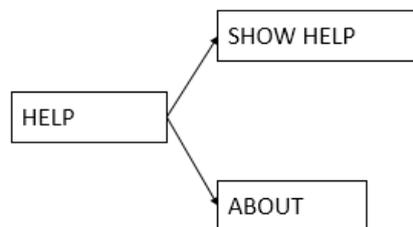
2WIN Applications: from this menu it is possible to set some Options for the available Applications. For more information refer to Chapter 20 – 2WIN Applications specific manuals.

AUX: Auto test allows to make a self hardware test of the device.

White Fielding will enable, on next measurement, a device verification test called white fielding. See the related paragraph.

Light Meter enables an evaluation of the ambient light.

- From the **Help** submenu, it is possible to view the Help page and the About window, which shows information about the device, such as the software version and the hardware version.



First page of help



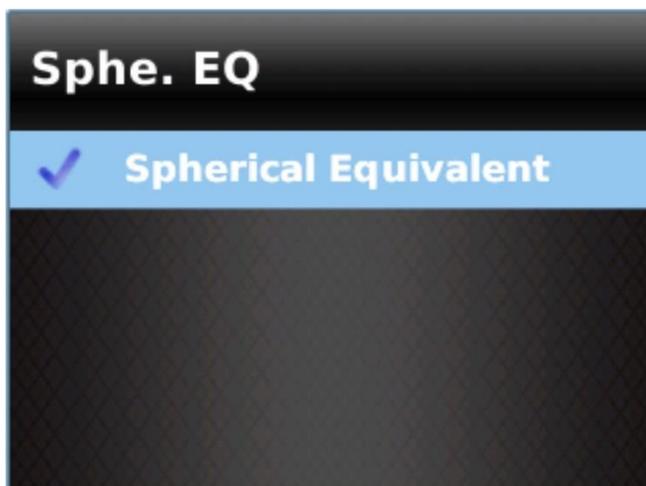
About' message

This information should be used for the reporting abnormalities to your distributor.

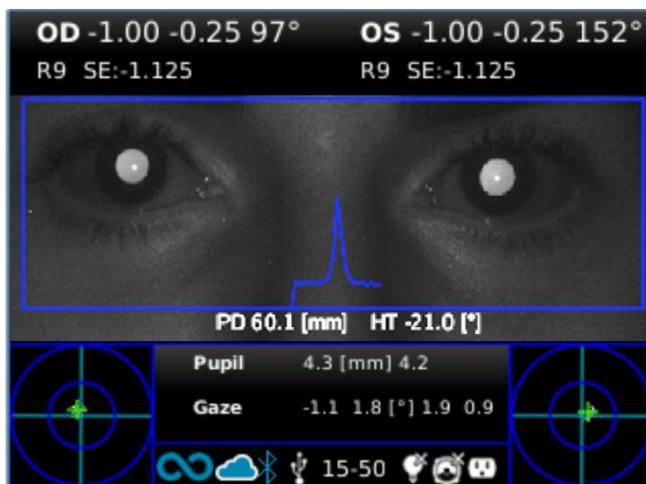
10.11 Spherical Equivalent

Starting from 2WIN software version 5.5.0 it is possible, thanks to an option in 2WIN menu, to display the Spherical Equivalent together with 2WIN refraction results.

To display Spherical Equivalent, browse 2WIN menu > Measurement > Display > Sphe. EQ and enable Spherical Equivalent option.



Spherical Equivalent value will be displayed both in measurement mode and in browsing mode.

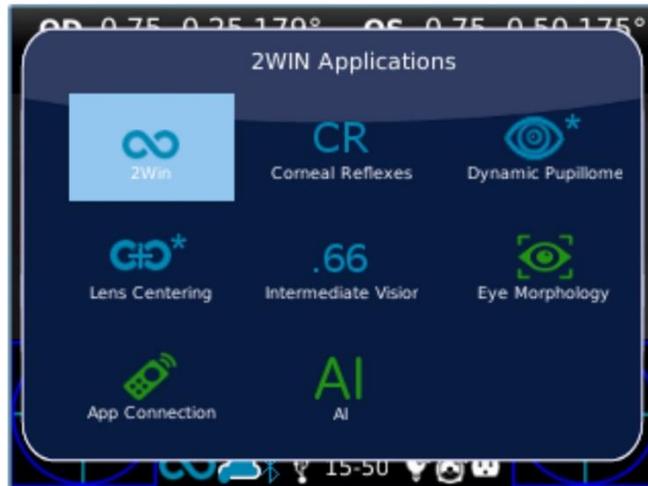


10.12 2WIN Anterior Segment Hint

Anterior Segment Hint is an innovative A.I. based algorithm running on Adaptica Cloud, developed to give additional information to the user if 2WIN is not able to refract the patient.

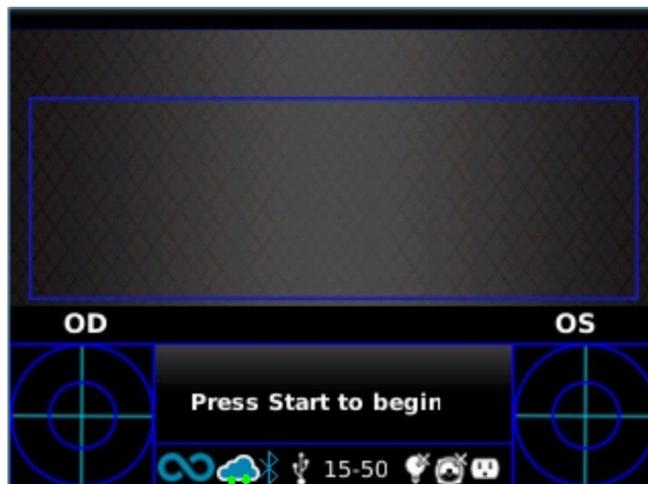
-  2WIN Anterior Segment Hint requires an activation code. Please contact your local distributor to get the activation code.
-  To work properly, Anterior Segment Hint needs the 2WIN to be connected to a WiFi network having internet access.

You can check if Anterior Segment Hint is active by entering 2WIN Applications selection window:



If the AI plugin logo is not followed by an asterisk, as in the picture above, it means that Anterior Segment Hint is active.

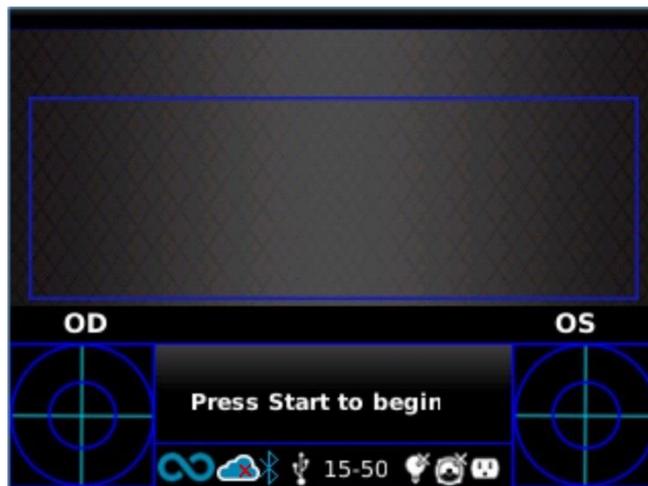
When 2WIN is connecting to Adapptica Cloud the WiFi icon on 2WIN display turns into a cloud icon with two green arrows, as shown in the figure below:



When 2WIN is correctly connected to Adapptica Cloud the cloud icon becomes steady blue, and a notification is displayed in Notification Center (see Paragraph 10.20):

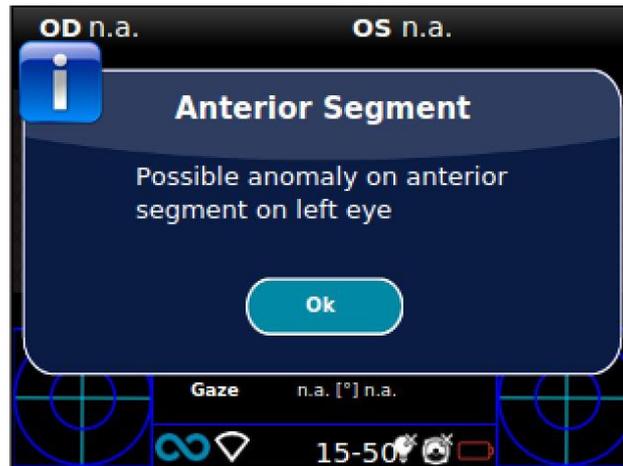


If any error occurs during the connection to Adaptica Cloud or during the upload of the pupils images, the cloud icon changes to cloud error icon:



When 2WIN is connected to the cloud, data collected during 2WIN exams are instantly processed by Anterior Segment Hint A.I. algorithm.

If 2WIN is not able to refract the patient and any suspect anomaly of the anterior segment is detected, the warning “Possible anomaly of the Anterior Segment” is given to the operator with the indication of the eye (left, right or both).



⚠ WARNING: the message “Possible anomaly of the Anterior Segment” shall not be misunderstood as a diagnosis or a hint for diagnosis. For instance, a foreign object put in front of the eye during the exam could result in an anomaly of the eye profile not related to any pathology. The measurement shall in any case be used to refer the patient to an eye care professional for further evaluation.

10.13 Quick menu

In order to get access to the preferred and most used functions of the 2WIN, it is possible to activate the Quick Menu. With this Menu is possible to recall rapidly any 2WIN function/item that is commonly used by the operator. It is enabled by keeping pressed button D. The Quick Menu items appears top right, the '+' button allows to add new items (all items from the main menu can be added by pressing the central button) to the quick menu. Items can be erased and moved pressing long the left arrow.



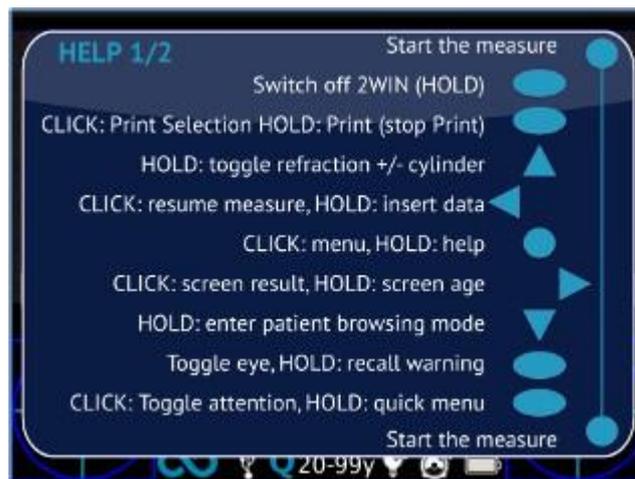
How to add an item in the quick-menu.



Possible configuration of the quick-menu.

10.14 Contextual Help

At any time, holding the menu button, a help page is shown if the page provides one. Pages with the help option are: Main/Home, Menu, Keyboard, Age Selection, Browsing Mode, Data and Time Modification.



Example of contextual help. Note that the two light blue circle at the top and at the bottom of the window represent the two frontal START buttons, while the other symbols all the 2WIN backside button

10.15 Summary of menu entries

| | | | |
|------------------------|---------------|--------------------------|------------------------------|
| 1.0 Measurement | 1.1 Display | 1.1.1 Cylinder | 1.1.1.1 Plus Cylinder |
| | | | 1.1.1.2 Minus Cylinder |
| | | 1.1.2 Sphe. EQ | 1.1.2.1 Spherical Equivalent |
| | | 1.1.3 Gaze | 1.1.3.1 Degrees |
| | | | 1.1.3.2 Hirschberg Test |
| | 1.2 Sound | 1.2.1 Volume | 1.2.1.1 Level 1 |
| | | | 1.2.1.2 Level 2 |
| | | | 1.2.1.3 Level 3 |
| | | | 1.2.1.4 Level 4 |
| | | 1.2.2 Jingles | 1.2.2.1 Jingle 1 |
| | | | 1.2.2.2 Jingle 2 |
| | | | 1.2.2.3 Jingle 3 |
| | | 1.2.3 Alerts | 1.2.3.1 Ending Beep |
| | 1.3 Fixation | 1.3.1 Rainbow Fixation | 1.3.1.1 Intensity |
| | | | 1.3.1.2 Sequence |
| | | 1.3.2 Central Fixation | 1.3.2.1 Central Fixation |
| | 1.4 Screening | 1.4.1 Show Current Table | |
| | | 1.4.2 Update User Table | |
| | | 1.4.3 Threshold Settings | 1.4.3.1 Screen Displayed |
| | | | 1.4.3.2 Screen Max Axis |
| | | | 1.4.3.3 Screen Min Axis |
| | | 1.4.4 Show At End | |

| | | |
|------------------|---------------------|-------------------------------|
| 2.0 Print | 2.1 Device | 2.1.1 IR Printing |
| | | 2.1.2 Print on SD memory |
| | 2.2 Options | 2.2.1 Grid on Report |
| | | 2.2.2 Strip in PDF |
| | | 2.2.3 Print Screening on IRDA |
| | 2.3 Export Patients | |

| | | | |
|---------------------|---------------|--------------------------|------------------------------|
| 3.0 Settings | 3.1 Wireless | 3.1.1 Wireless ON | |
| | | 3.1.2 WiFi Status | |
| | | 3.1.3 WiFi Config | |
| | | 3.1.4 WiFi Options | 3.1.4.1 2WIN Password |
| | | | 3.1.4.2 Auto Connect WiFi |
| | | 3.1.5 Connections | 3.1.5.1 VisionFit Connection |
| | | | 3.1.5.2 APP Connection |
| | 3.2 Bluetooth | 3.2.1 Bluetooth ON | |
| | | 3.2.2 Bluetooth Status | |
| | | 3.2.3 Bluetooth Options | 3.2.3.1 Set Bluetooth pin |
| | 3.3 Kaleidos | 3.3.1 Kaleidos | |
| | 3.4 Date/Time | 3.4.1 Date/Time Format | 3.4.1.1 Format H12 |
| | | | 3.4.1.2 Format H24 |
| | | 3.4.2 Set Date/Time | |
| | 3.5 Aux | 3.5.1 Autoshtutdown Time | |
| | | 3.5.2 BackLight | 3.5.2.1 Low |
| | | | 3.5.2.2 Medium |
| | | | 3.5.2.3 High |
| | | | 3.5.2.4 Auto |

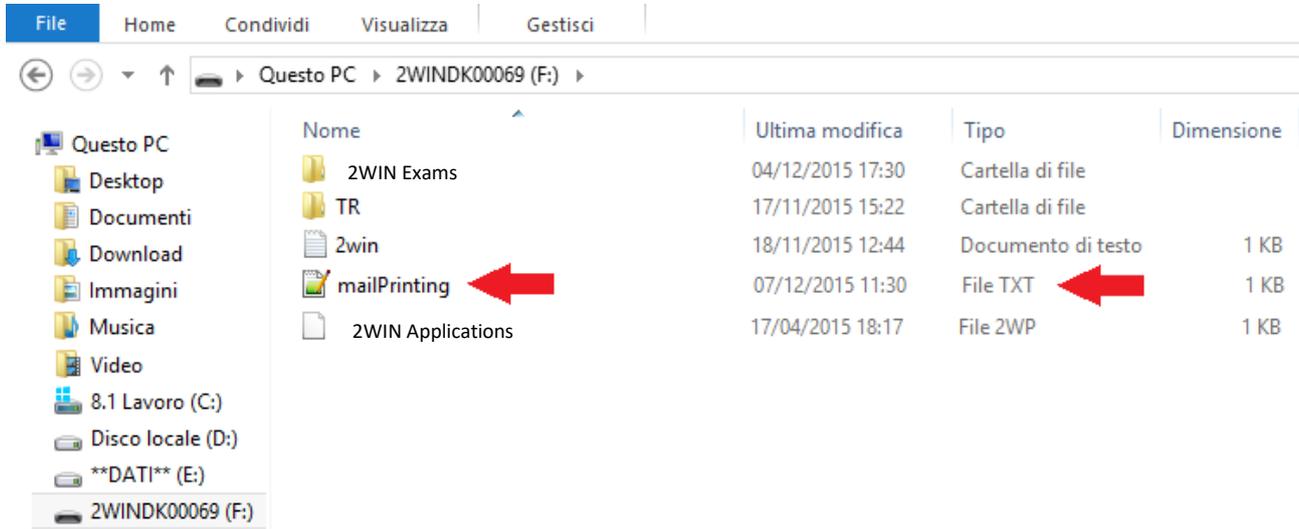
| | | | |
|----------------------|-----------------------|----------------------------|------------------------------|
| 4.0 Functions | 4.1 2WIN Applications | 4.1.1 Corneal Reflexes | 4.1.1.1 Corneal Reflexes |
| | | | 4.1.1.2 Reset |
| | | | 4.1.1.3 Options |
| | | 4.1.2 Intermediate Vision | 4.1.2.1 Intermediate Vision |
| | | 4.1.3 Lens Centering | 4.1.3.1 Lens Centering |
| | | 4.1.4 Dynamic Pupillometry | 4.1.4.1 Dynamic Pupillometry |
| | | 4.1.5 Zoom | 4.1.5.1 Zoom |
| | 4.2 Aux | 4.2.1 Auto Test | |
| | | 4.2.2 White Fielding | |

| | | | |
|--|-----------------|--|--|
| | 4.3 Light Meter | | |
|--|-----------------|--|--|

| | |
|-----------------|---------------|
| 5.0 Help | 5.1 Show Help |
| | 5.2 About |

10.16 Mail Printing

It is possible to send a mail with 2WIN pdf attachment in order to allow mail printing from 2WIN or to receive via email the measurement. In order to activate this service, place a file (*.txt file) named **mailPrinting** in the SD root **containing the email you want the files to be sent to** (ex. *abc@de.com*).



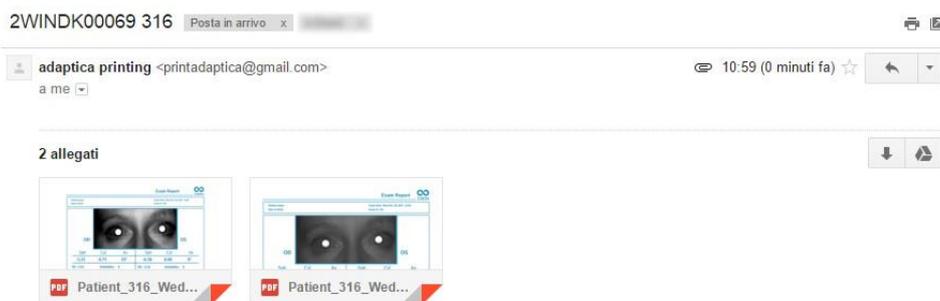
Reboot the machine and a new menu item will appear under **Menu>Print>Device>Mail Printing**. If checked, after the presson of Button B, an email will be sent automatically to the specified address with attachments. The email can be a personal email or a printer email. The email service used for email sending is Gmail.



NOTE: Remember to activate WiFi and to be connected to a WiFi network to use Mail Printing service. If not activated, mail will not be delivered.



NOTE: If you modify the email address remember to reboot the device to apply the modification.



10.17 Save exam

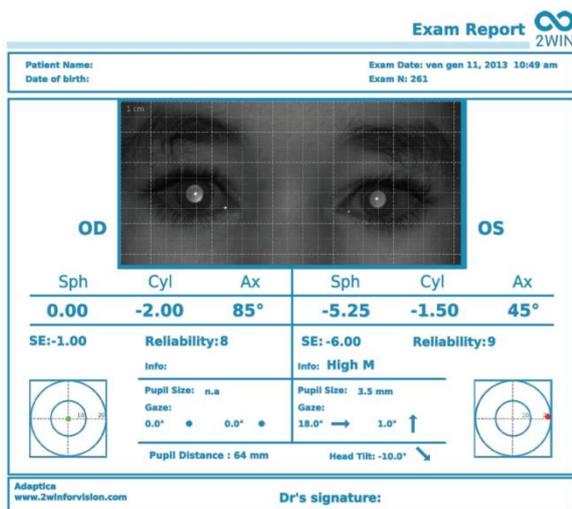
If the SD card printing is inserted, a set of 4 files for each examination will be saved into the SD card, into the folder Patients ("2WIN Exams" if the software version is the 4.0 or more), there creating a subfolder named 2WINExam _date_ number, where date is current date and number is a sequential number. The same number will be mentioned in the "Printing: done" message, so enabling the user to connect the examination to the specific patient.

The subfolder contains at least 4 files, with the same name as the folder, but different extensions:

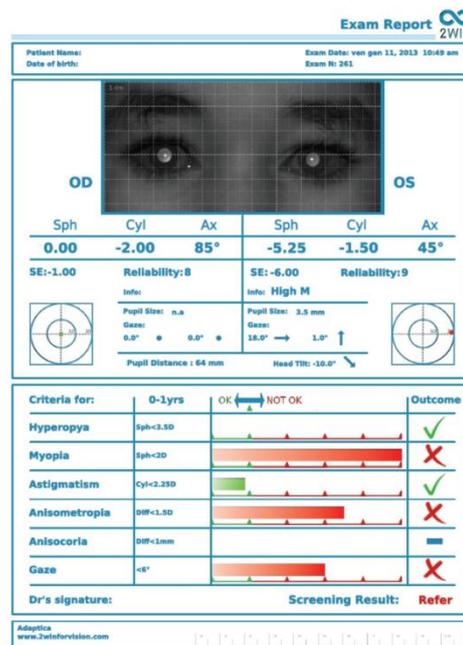
- *.pdf = examination results form for a A4 size paper (printable from a personal computer), other pdf can be written by specific functions.
- *.jpg = original picture of the eyes of the patient
- *.xml = xml file version of the measurement results
- *.2win = binary file (for service purposes only)

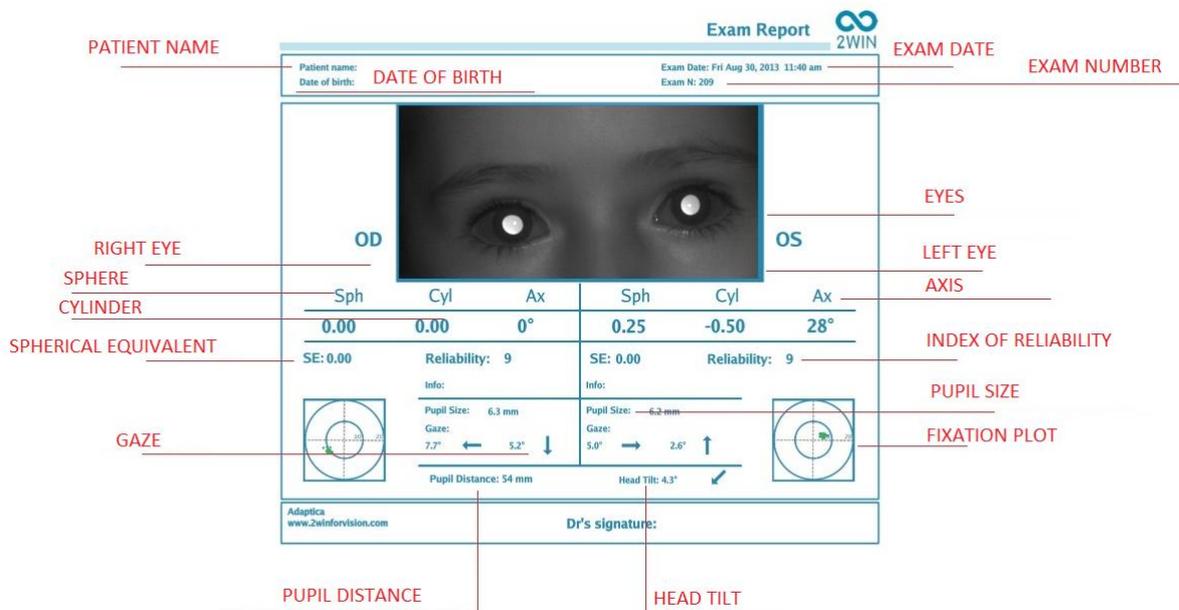
For data saved in pdf format., a grid on exam report can be added selecting the option 'Grid on Report' from Menu Print/Options/Grid on Menu.

An example of the exam report in .pdf (with Grid on Report option) is shown in the following Figure



An example of the extended exam report for screening in .pdf (with Grid on Report option) is shown in the following Figure





Exam report in .pdf

There are a limited number of prints before the machine starts rewriting oldest files. When printing, "Printing: done" message will also show the internal memory total exam capacity (1000 patients).



"Printing: done" message

Data saved in the file Patient_date_number, with the different extensions listed above, can be extracted from the SD card by connecting the 2WIN to a PC by means of the USB cable supplied. The 2WIN is seen as an external memory storage, when the USB symbol appears on the 2WIN display it is possible to copy data from the 2WIN SD card to the PC.

It is important to safely remove (unmount, check the PC Operative System for this) the external memory storage of the 2WIN from the PC after data have been saved on PC and before disconnecting the USB cable.

Strip in Pdf

| 2WIN | | | | |
|---------------------------|------|----------------|---|--|
| Tue Mar 25, 2014 12:04 pm | | | | |
| No: 215 | | | | |
| OD: | | | | |
| SPH | CYL | AX | | |
| -1.00 | 0.00 | 0° | 6 | |
| Ø Pupil: 5.0 mm | | Gaze:-4.6 -2.9 | | |
| OS: | | | | |
| SPH | CYL | AX | | |
| -1.00 | 0.25 | 115° | 6 | |
| Ø Pupil: 5.1 mm | | Gaze:3.7 -3.0 | | |
| PD: 61 mm | | | | |
| Adaptica | | | | |
| www.2winforvision.com | | | | |

This option allows the creation of a strip similar to the IrDa strip in pdf format. It can be enabled from Menu>Print>Options>Strip in Pdf.

CVS Exporter Tool

The 2WIN permits to export all the exams stored in the SD card in a CVS (Comma Separated Value) file. This text-based file can be used to share data from 2WIN and spreadsheet documents.

Select "Export Patient" from Menu>Print



Once activated the export patient, the 2WIN will create in the root of the SD memory card the CVS file with the following name-format: Resume_Date_Hour.



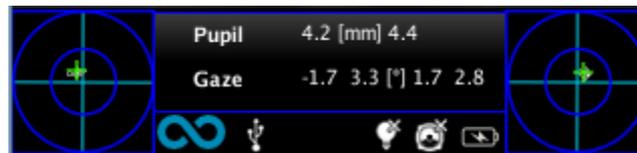
10.18 Gaze

The maps indicate the gaze (that is the eye position), not the corneal reflex. The eye position is calculated on the base of corneal reflex position compensated because the light is not centred, and the direction of eye movement is opposite compared to movement of reflex.

The Gaze information on the refraction module shows the displacement of visual axis on respect to the pupil centre. This displacement can be a strabismus factor, but it normally corresponds to the K angle.

This indication on refraction module for a correct diagnosis must be confirmed with the CR Application, which allows to identify Gaze independently from K angle (refer to Chapter 20.3 of this Operator Manual).

The Gaze direction is measured as the distance between the corneal reflex and the geometric centre of the pupil.



Please consider that the corneal reflex is represented on the graph in an inverted position: if the corneal reflex is nasal to the centre, it is represented as temporal in the diagram time.

The direction of gaze as measured by this tool is not directly related to the measurement in cover test.

It is a graphical representation that suggests the presence of orthotropia, exo/eso tropia, hyper/hypo tropia and stability or instability of fixation.

Range: +/-20°;

Out of range: +/- 10° refraction is not displayed (fixation error)

Resolution: 0.1°

The precision is (0.2°) on a standard eye with a corneal radius of 7.75 mm (The value is calculated on the standard corneal radius, which is assumed to be 7.75 mm).

If a patient doesn't focus on the central front led a warning will appear on the display:



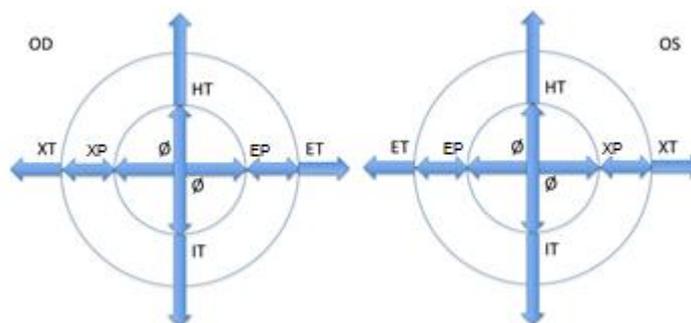
Low fidelity message

Hirschberg Test

If “Hirschberg test” is selected for the representation of the gaze, either in the MENU or by toggling the visualization type via cross button (DOWN arrow), the results for patient's fixation will be expressed by the Hirschberg test coding:

- ET = esotropia
- EP = esophoria
- HT = ipertropia
- IT = ipotropia
- XP = exophoria
- XT = exotropia
- O = ortotropia

The following picture gives a graphical representation of the codes.



10.19 Customization

Some features of the device can be customized by the user. To do this the user shall take the SD card out of the device, write it by means of a personal computer, then reinsert it in the device.

Please notice that in order to extract and insert the SD card, the device shall be OFF.

Custom printouts

By creating in the root folder of the SD card a file named

printoutPersonalData.txt

printouts (both to portable printer and to file) will be customized by adding the first three lines contained in such file.

Sample:

Winning Eye Clinic

5, Trafalgar Sq. London

www.winningeye.com



NOTE: The text file must be saved in UTF-8 codification from your text editor.

Custom RGB sequence

By creating in the root folder of the SD card a file named

rgbCustomSequence.txt

and enabling custom sequences in the menu, the interactivity light can be personalized.

The file shall contain 30 or less rows (exceeding rows will be ignored) coded as follows:
each row contains 4 numbers

- first number must be in the range 0-5 and codes the mode:
 - 0=off
 - 1=rotating rgb
 - 2=fixed white
 - 3=rotating black on blue
 - 4=fixed green
 - 5=flashing red
- second number is a parameter in the range 50-1000: for modes 1 and 3 it represents the delay, that is the reciprocal of rotational speed
- third number is the intensity, in the range 0-255
- fourth number is the duration (of the mode described by the line), in the range 1-30

For example:

1 100 10 2

0 0 0 1

4 0 15 1

3 500 20 2

3 200 10 2

will perform:

2 seconds rotating with a 100ms delay and intensity 10

1 second OFF

1 second fixed green with intensity 15

2 seconds black rotating on blue with a 500ms delay and intensity 20

2 seconds black rotating on blue with a 200ms delay and intensity 10

10.20 Notification Center

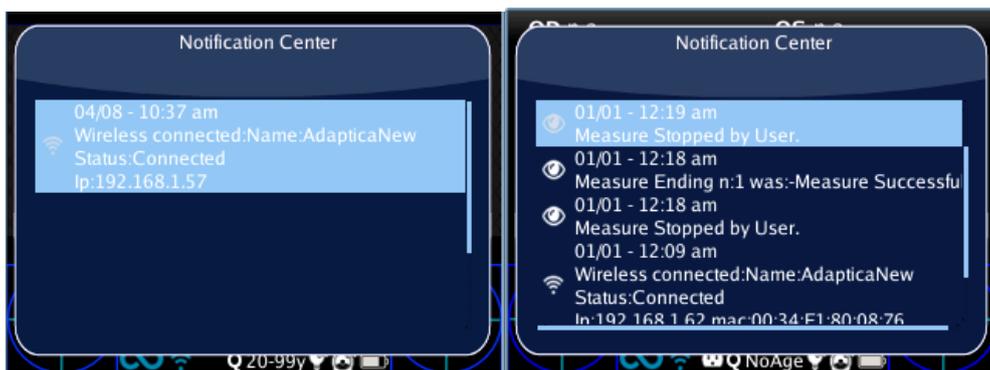
This feature allows the real time monitoring of 2WIN messaging and logs. There are reported 3 different types of information: notifications on the measurements, notifications on the WiFi networking status and logins and notifications on the additional software Applications installed.

When a new notification is added to Notification Center, 2WIN logo will be shown with a red background.



The notifications are stored in the Notification Center in a recursively way, the last 20 information are always showed.

In order to see the Notification Center press and hold the “eye” button, you can then consult the list of notifications. In order to exit from the center just press the “esc/Power” button.



10.21 Age Selection and Screening Mode

In order to perform the measurement correctly, it is needed to select the correct age range for each patient. From the home display, in the Cross button keep pressed the right button to display the “Age Selection”, which is called Screening Age from software version 4.1 and above.

Please take care to modify the patient age before saving the 2WIN measurement. The 2WIN results in young patient with hyperopia error can be dependant to the patient's age. To change the patient age “long-press” to the RIGHT button of the joystick and follow the instructions in the 2WIN display.

To select the different Screening modes, use the following buttons:

Cross button, push RIGHT or LEFT, UP or DOWN to switch between the list of age intervals, the 'Ok' button, and the 'Cancel' button.

Cross button, push CENTRE button to save the selected interval, then choose 'Ok' or 'Cancel'. (NOTE: if the date of birth has been already inserted via the long left press, then the age interval is automatically set).

The current value selected is saved and the is visualized in the status bar at the bottom of the display.

When the patient date of birth is inserted via the active keyboard mode, the age selection range is automatically set.

IMPORTANT NOTE: you can always check the current age interval just looking at the centre bottom of the instrument's display, and note that during the first seconds of the measurement the selected age selection is enlighten by means of a red circle in the bottom centre of the display.

10.22 Screening Table

Visualization

To display the Screening Table, select 'Show Current Table' from the menu Measurement>Screening, the current table, either default (based on AAPOS guidelines) or custom (defined by the user), is displayed. The screening table is the set of thresholds that are used by the 2WIN to determine if a patient is inside or outside the guideline for amblyopia detection screenings.

| | HYP: | MYO: | AST: | ANM: | ANC: | GAZ: |
|-----------|------|------|------|------|------|------|
| 0-2.5yrs: | 4.5 | 3.5 | 2 | 2.5 | 1 | 4.6 |
| 2.5-4yrs: | 4 | 3 | 2 | 2 | 1 | 4.6 |
| 4-15yrs: | 4 | 3 | 2 | 2 | 1 | 4.6 |
| 15-50yrs: | 3.5 | 1.5 | 1.5 | 1.5 | 1 | 4.6 |
| 50-60yrs: | 3.5 | 1.5 | 1.5 | 1.5 | 1 | 4.6 |
| 60-99yrs: | 3.5 | 1.5 | 1.5 | 1.5 | 1 | 4.6 |

Customization

To insert a custom table (in order to follow regional or different rules compared to the AAPOS ones), a file 'screeningTable.txt' has to be written and inserted in the SD memory card.

Data must be written in the first six lines of the file. Each line corresponds to an age interval (maximum six intervals). The age intervals are fixed, while it is possible to modify the thresholds values.

The columns correspond to the following entries:

Minimum age, Maximum age: age interval

Hyperopia, Myopia, Astigmatism, Anisometropia, Anisocoria, Gaze: numerical thresholds

A measurement is considered positive (the screening is passed) if the value is compliant to the following thresholds:

Hyperopia: the measured spherical value on all meridians must be lower than this threshold [in Measurement>Screening>Threshold Settings there are three possibilities: (a) Screen Min Axis, (b) Screen Max Axis, (c) Screen Displayed]

- (a) Screen Min Axis: you are measuring with a notation that minimize the sphere – this mode is independent by how the data is displayed;
- (b) Screen Max Axis: you are measuring using a notation that maximize the sphere - sphere –this mode is independent by how the data is displayed;
- (c) Screen Displayed: you are measuring what you see on screen - this mode is dependent by how the data is displayed;

Myopia: the measured spherical value on all meridians must be lower than this threshold [in Measurement>Settings>Threshold there are three possibilities: (a) Screen Min Axis, (b) Screen Max Axis, (c) Screen Displayed]

Astigmatism: the measure of the absolute value of the cylinder must be lower than this threshold

Anisometropia: the difference between absolute value of myopia or astigmatism between the two eyes must be lower than this threshold

Anisocoria: the difference between the two pupil diameters must be lower than the threshold

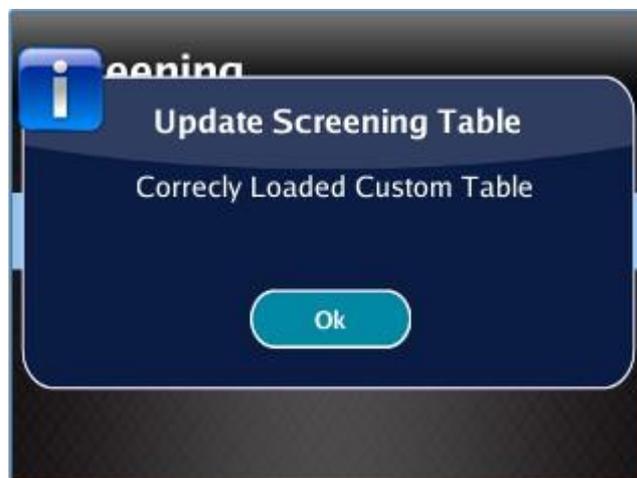
Gaze: if a single eye is measured, the mean gaze position, measured in x and y degrees, must be lower than this threshold. If both eyes are measured, the evaluation for warning conditions is performed only on the difference of these values. In other words, the distance between the two horizontal and vertical Purkinje reflections, normalized to the center, must be lower than the threshold.

The following as an example:

| | | | | | | | |
|-----|-----|-----|-----|-----|-----|---|-----|
| 0 | 2.5 | 4.5 | 3.5 | 2 | 2.5 | 1 | 4.6 |
| 2.5 | 4 | 4 | 3 | 2 | 2 | 1 | 4.6 |
| 4 | 15 | 4 | 3 | 2 | 2 | 1 | 4.6 |
| 15 | 50 | 3.5 | 1.5 | 1.5 | 1.5 | 1 | 4.6 |
| 50 | 60 | 3.5 | 1.5 | 1.5 | 1.5 | 1 | 4.6 |
| 60 | 99 | 3.5 | 1.5 | 1.5 | 1.5 | 1 | 4.6 |

Upload

Uploading a table: from the menu Screening, select 'Update User Table', a message indicates which table is uploaded (default or user) and if the table has been correctly loaded.



Screening Measurement Result

To display the Screening Measurement result, from the home screen, press the right button of the Cross button.

The following window is visualized:



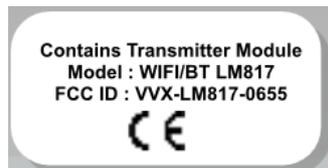
NOTE: Screening Measurement Result is an **Auxiliary window**. Read the relative paragraph for more information.

11 Wireless Connections



11.1 Bluetooth connectivity

2WIN equipped with Bluetooth module (a label under the USB connection door identifies the presence of module) can be connected to a Bluetooth connection, provided that 2WIN has software version 5.4 or higher.



- It is possible to control remotely the 2WIN by means of an external APP made by Adaptica running on Android tablets;
- If the 2WIN is equipped with the KALEIDOS accessory, so forming the 2WIN-S, it is possible to control the 2WIN by means an external APP made by Adaptica running on Android tablets;
- It is possible to transmit some of the 2WIN results to the Adaptica VisionFit SC (you need a VisionFit SC paired to the 2WIN (refer to Paragraph 11.3 for the pairing instructions)).

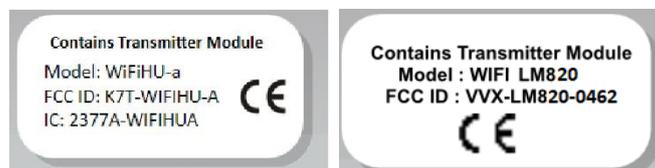
To enable the Bluetooth connectivity in the 2WIN enable Bluetooth option from Menu > Settings > Bluetooth. When Bluetooth connectivity is active Bluetooth icon is shown on the 2WIN's display:



 NOTE: Bluetooth connectivity is enabled by default on the 2WIN.

11.2 WiFi connectivity

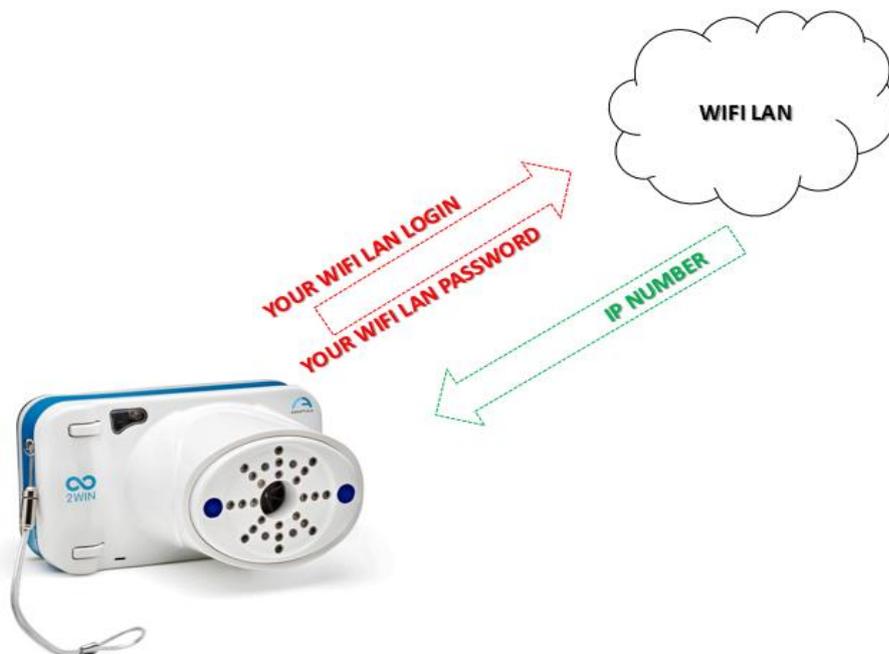
2WIN equipped with WiFi module (a label under the USB connection door identifies the presence of module) can be connected to a WiFi connection.



d) It is possible to **download** and **visualize patient data from the 2WIN** to an external device (e.g. Tablet).

This can be done with the use of any SFTP client - Secure File Transfer protocol.

- e) You can also **insert patient data** details such as **name, surname, date of birth from an external keyboard**. This can be done with an application (VNC +SSH software) to be installed in an iOS and Android tablet device or in a personal computer with Windows or MAC OS.
- f) It is possible to transmit some of the 2WIN results to the Adaptica VisionFit SC (you need a VisionFit SC connected to the same WiFi network of the 2WIN)
- g) It is possible to control remotely the 2WIN by means of an external 2WIN APP made by Adaptica running on Android and tablet.
- h) If the 2WIN is equipped with the KALEIDOS accessory, so forming the 2WIN-S, it is possible to control the 2WIN by means of the WiFi connectivity and a remote APP.



This picture shows that before starting any networking operations the 2WIN must be connected to a wifi Local Area Network. The user must insert the appropriate credentials in order to log the 2WIN to the Wifi access point present in the office/room. The access point will assign an IP address to the 2WIN

In order to enable the WiFi connectivity in the 2WIN it is necessary to follow the following steps:

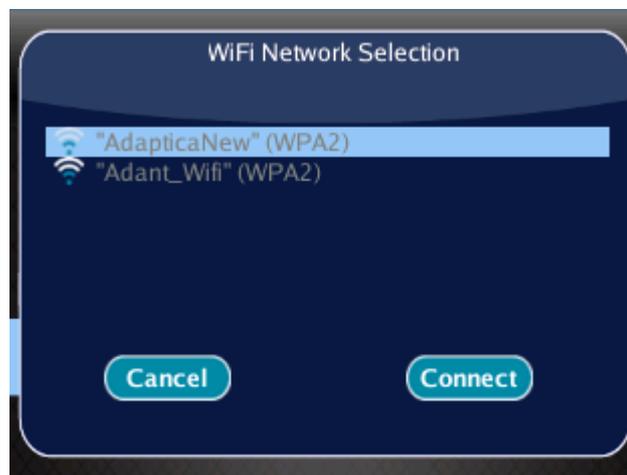
1. Click on **“Wireless ON”** from **Menu > Settings > Wireless > Wireless ON**

You will see the item Wifi Activation and a tick will be displayed next to the label Wireless ON.



2. Select the option “**WiFi Config**” and push the cross button to find the available networks.

Select your favourite Wifi network, then push the cross button to make appear the network password insertion window. Insert the network **Password**, then select and push the button “**Done**”. Select and push the button “**Connect**” to connect to the selected network.



You can also enable **Autoconnect** in “**WiFi Options**” (**Menu > Settings > Wireless > WiFi Options**). In this way, if you lose connection, 2WIN will reconnect to the network automatically.



 **NOTE:** if selected, wireless connectivity will be automatically activated after 2WIN power-on.

3. Click on **WiFi Status** feature to (1) **check if the 2WIN is connected to your network** and to (2) **determine the IP address of 2WIN.**

 **WARNING!** The default password of 2WIN for networking services (SFTP and VNC + SSH) is adaptica.

The 2WIN password is a security key for the system. To change the password, go to “WiFi Option” and set the new security key.





NOTE: For security reasons, it is recommended to change the password as the default one is common to all 2WIN.

11.3 Pairing and transferring a 2WIN exam to VisionFit SC

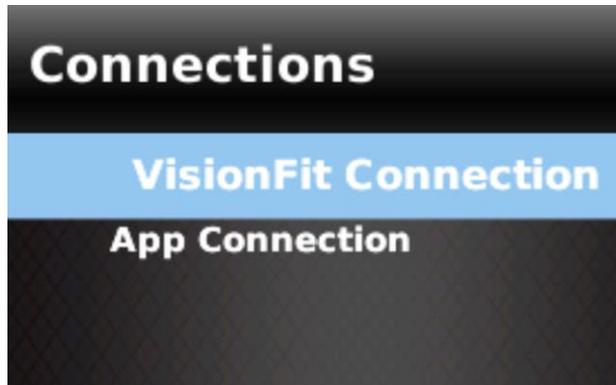
Adaptica's VisionFit SC is a mobile and wearable subjective refractor (phoropter) which can be used in combination with 2WIN or 2WIN-S.

Once 2WIN (or 2WIN-S) are paired it is possible to transmit 2WIN (or 2WIN-S) objective refraction results to VisionFit SC in order to speed up the subjective refraction measurement.

Transferring an exam from 2WIN (or 2WIN-S) to VisionFit SC using WiFi connection

The first time you want to transfer an exam to VisionFit SC you have to pair the devices. Follow these steps:

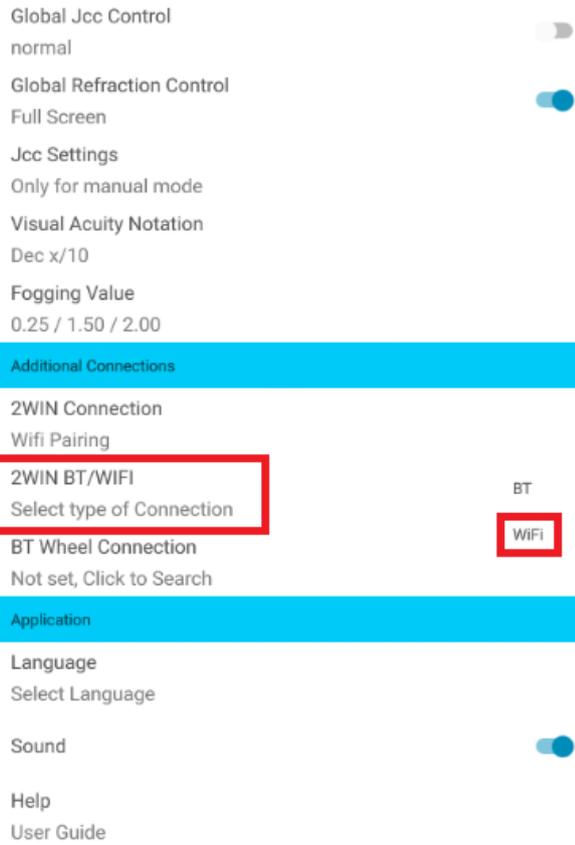
1. From 2WIN Menu > Settings > Wireless > Connections enable VisionFit Connection



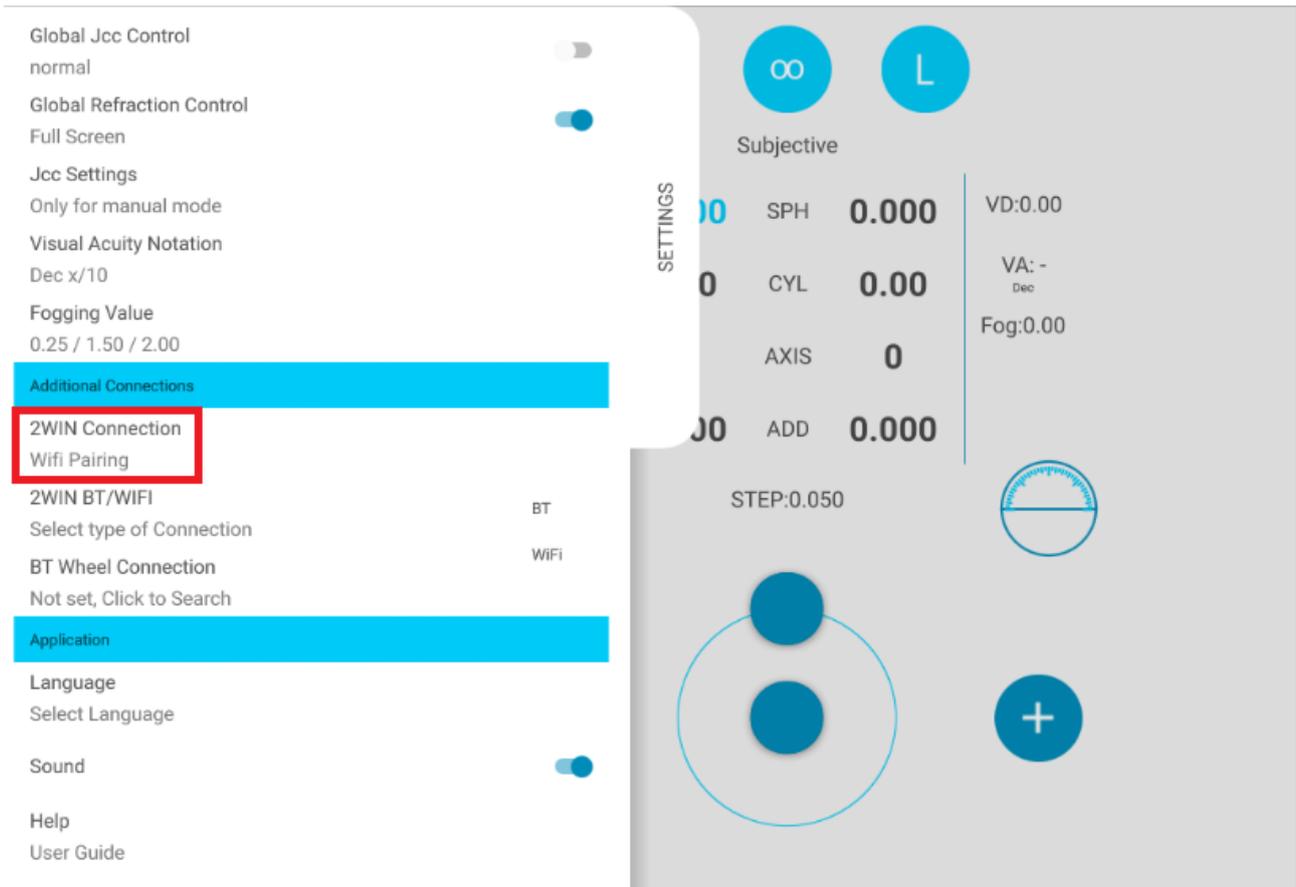
2. The following message appears:



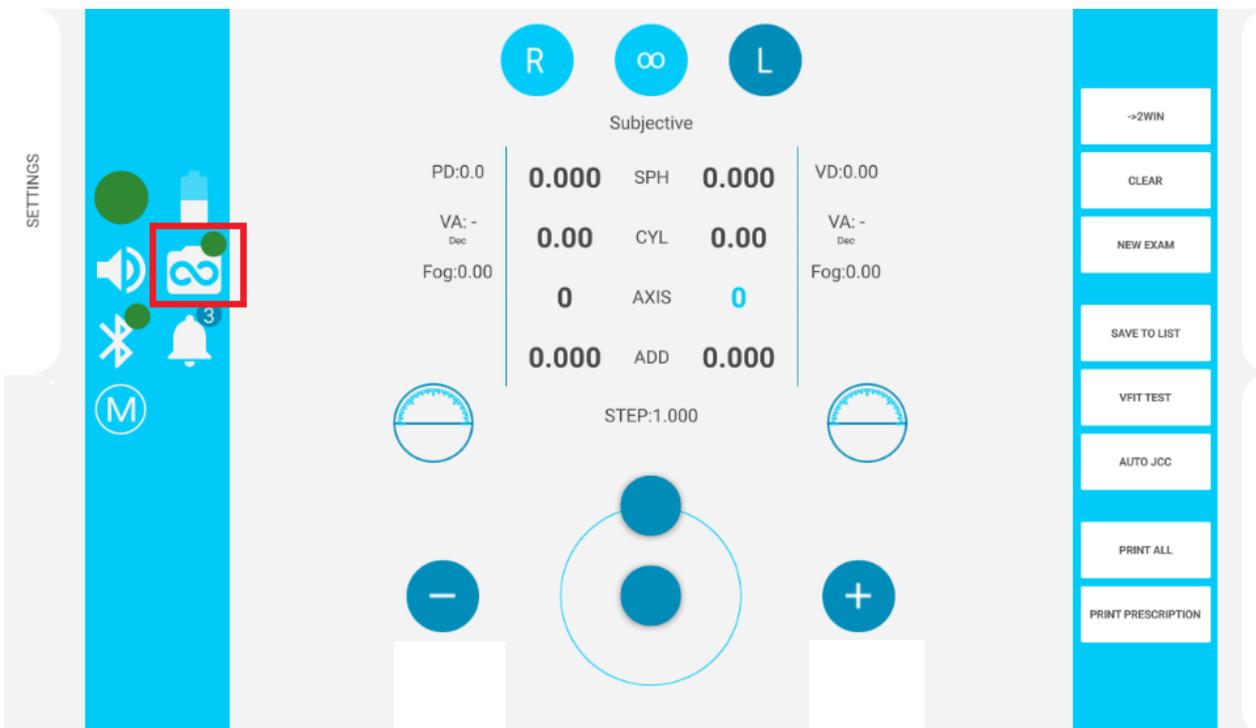
3. From VisionFit SC tablet application enter Settings and set 2WIN Connection type: WIFI



4. From VisionFit SC tablet application enter Settings and select 2WIN Connection. The pairing between the two devices automatically starts.



5. When the pairing is complete a green circle appears on 2WIN icon on VisionFit SC application.



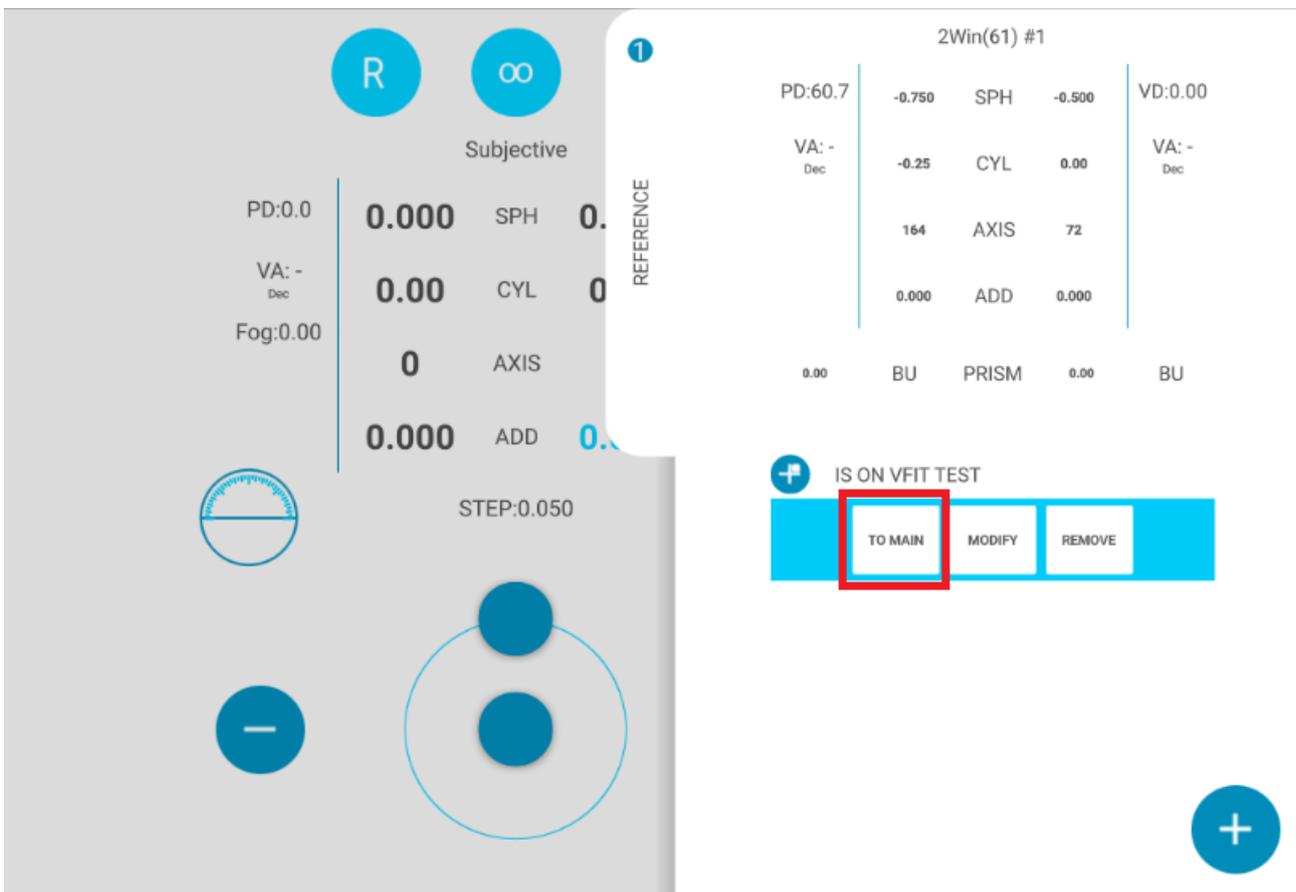
i NOTE: pairing does not have a preferred sequence order (VisionFit SC - 2WIN). Pairing can also be performed in reverse order (2WIN-VisionFit SC).



Pairing is needed only the first time. Pairing must be performed again only if you change devices (2WIN or VisionFit SC).

To transfer a 2WIN/2WIN-S measurement to VisionFit SC follow the steps below:

1. Perform a test using 2WIN/2WIN-S and save it. Short press the down arrow button in 2WIN (or in 2WIN tablet application). 2WIN/2WIN-S data will appear instantly on the right side in VisionFit SC application (Reference data area). If the 2WIN/2WIN-S test has already been performed, browse the 2WIN/2WIN-S “Browsing Mode” and long press the down arrow button. Data will appear in the Reference area in VisionFit SC Application.
2. Press TO MAIN button on VisionFit SC application to add data to the Subjective Area.



Not available measurement from 2WIN can't be transferred on VisionFit SC.



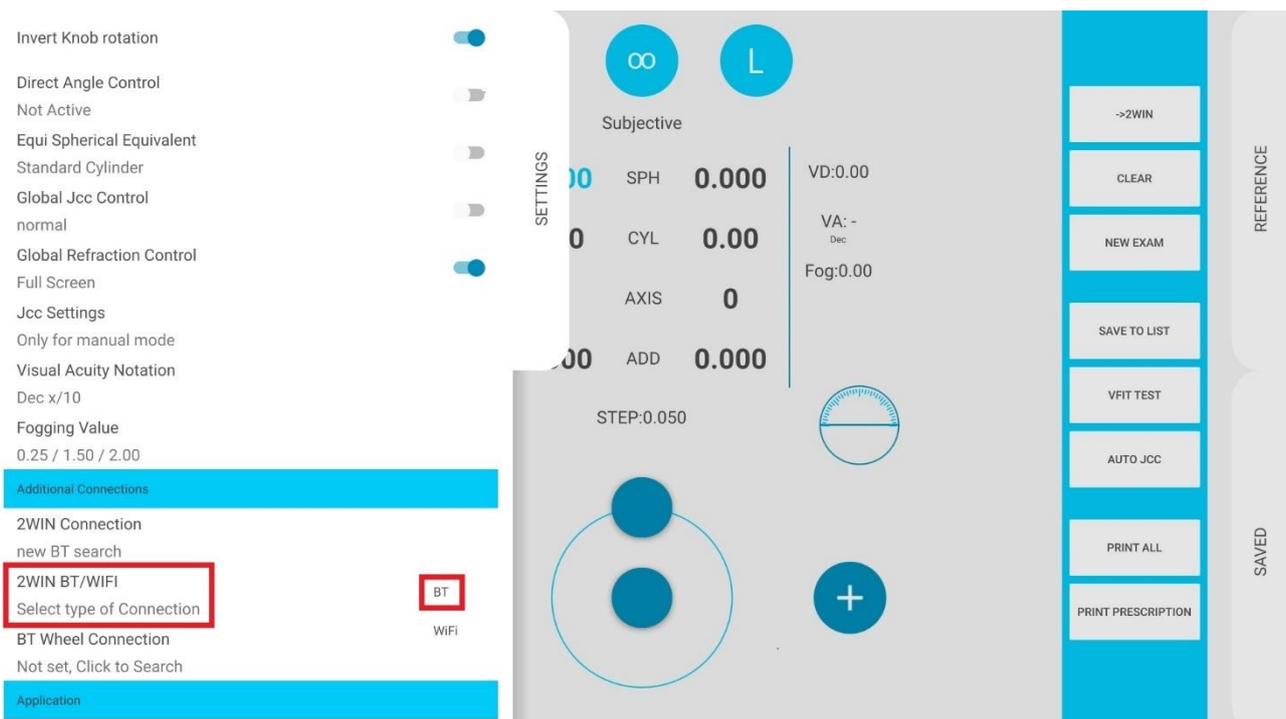
Blue sphere on the right side of WiFi symbol indicates the connection with the VisionFit SC.



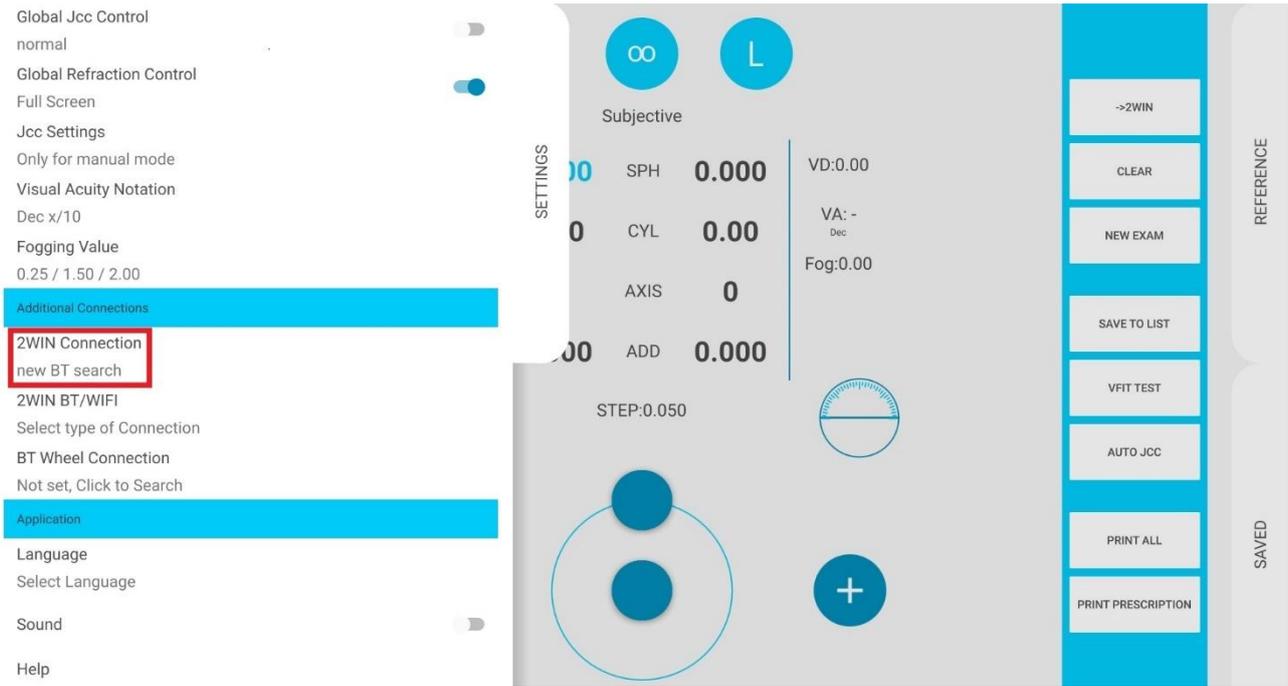
Transferring an exam from 2WIN (or 2WIN-S) to VisionFit SC using Bluetooth connection

The first time you want to transfer an exam to VisionFit SC you have to pair the devices. Follow these steps:

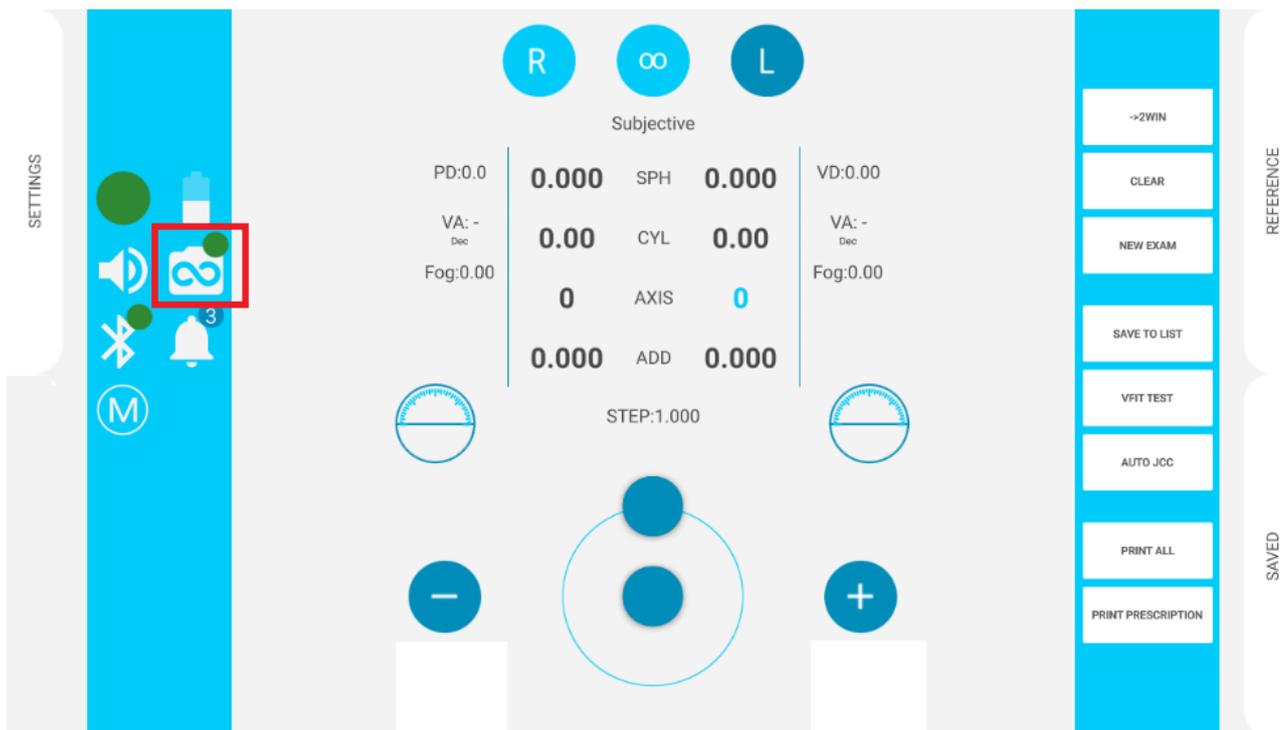
1. Enable Bluetooth on 2WIN from Menu > Settings > Bluetooth
2. From VisionFit SC tablet application enter Settings and set 2WIN Connection type: BT



3. From VisionFit SC tablet application enter Settings and select 2WIN Connection. The pairing between the two devices automatically starts.



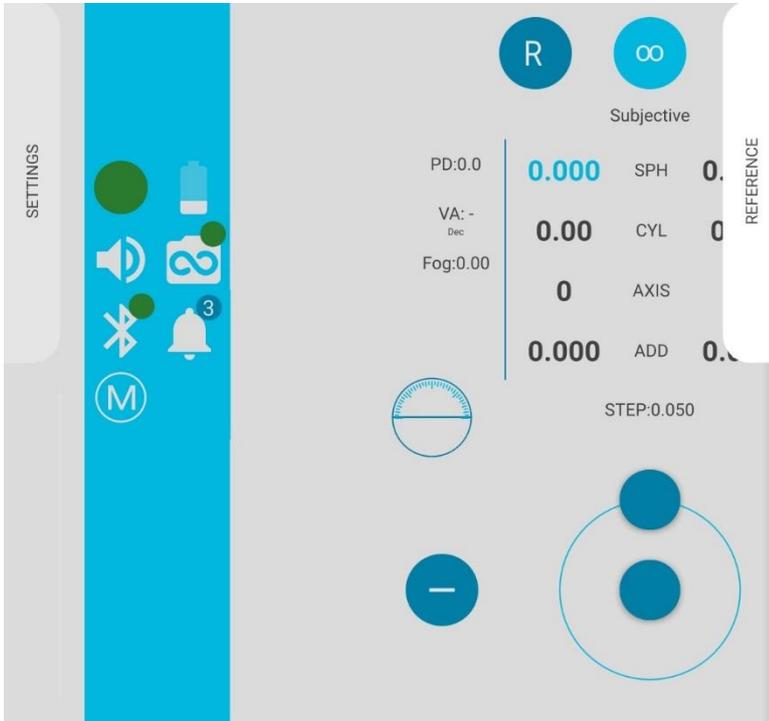
- When the pairing is complete a green circle appears on 2WIN icon on VisionFit SC application.



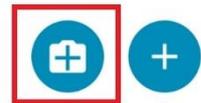
NOTE: Pairing is needed only the first time. Pairing must be performed again only if you change devices (2WIN or VisionFit SC).

To transfer a 2WIN/2WIN-S measurement to VisionFit SC follow the steps below:

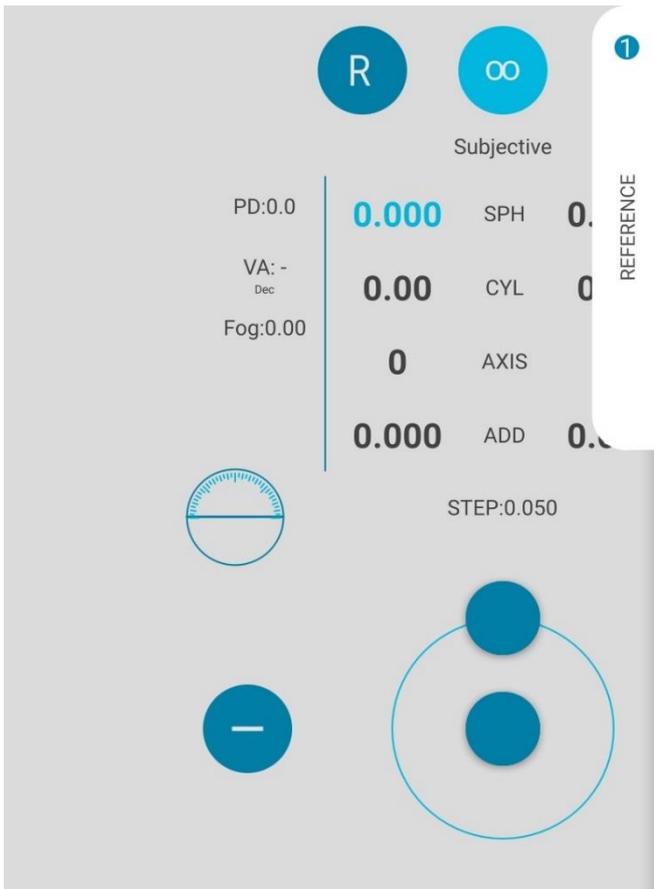
1. Perform a test using 2WIN/2WIN-S and save it.
2. Enter Reference area in VisionFit SC tablet application and tap on the 2WIN+ button.



No measure Inserted
Add measures by pressing the button.

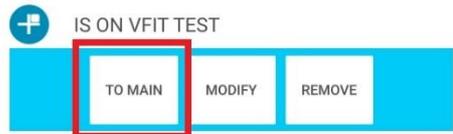


3. 2WIN/2WIN-S data will appear instantly on Reference area in VisionFit SC application.
4. Press TO MAIN button on VisionFit SC application to add data to the Subjective Area.



2Win(63) #1

| | | | | |
|--------------|--------|-------|--------|--------------|
| PD:59.7 | -1.000 | SPH | -1.000 | VD:0.00 |
| VA: - Dec | -0.25 | CYL | -0.25 | VA: - Dec |
| | 102 | AXIS | 170 | |
| | 0.000 | ADD | 0.000 | |
| 0.00 | BU | PRISM | 0.00 | BU |



i Not available measurement from 2WIN can't be transferred on VisionFit SC.

i Blue sphere on the right side of WiFi symbol indicates the connection with the VisionFit SC.



12 KALEIDOS

2WIN instrument is sold also in the 2WIN-S configuration, with the KALEIDOS accessory. This optional configuration is a set of a 2WIN and an electromechanical system to improve some specific characteristics of the 2WIN. With KALEIDOS, the measurement can be done without handling the 2WIN (by the operator), controlling the measurement process by means of a remote control APP and having the possibility to take a measurement in particularly intense light environment.



Note 1: In order to use the KALEIDOS, the 2WIN inside KALEIDOS and the control tablet running the remote APP must be connected on the same WiFi network.



Note 2: For the KALEIDOS configuration and how to assembly the KALEIDOS instrument, please refer to the **KALEIDOS Installation Guide** provided with the system.



Note 3: Please remove the battery from 2WIN when used in 2WIN-S configuration.



Note 4: Taking off the USB cable, the 2WIN will switch off in 3 sec.

12.1 KALEIDOS accessory models

There are two models of KALEIDOS accessory: KALEIDOS and KALEIDOS 3D.

KALEIDOS is the latest version and it is powered by an embedded battery pack. KALEIDOS 3D, instead, is the older version and it is powered by a power bank.

You can recognise if your 2WIN-S system is made of a KALEIDOS or a KALEIDOS 3D by checking KALEIDOS bottom. The following pictures show you how to distinguish between the two different models:



KALEIDOS bottom and control panel



KALEIDOS 3D bottom

The following paragraphs describe the setup instructions for KALEIDOS and KALEIDOS 3D.

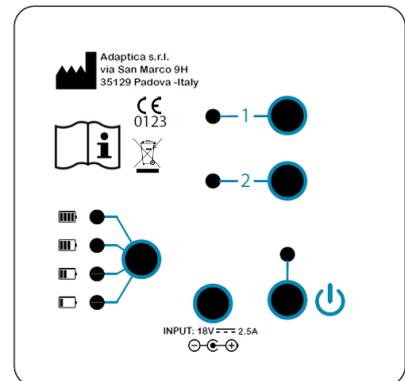
12.2 KALEIDOS: How to start

 **WARNING!** When 2WIN is used in 2WIN-S configuration, connected to the battery pack through the USB cable, 2WIN's internal battery must be removed.

To switch ON/OFF the system

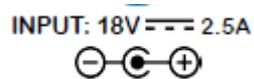
1. Short press the switch-on/off button to switch the system on. A beep sound stands for turning on the system.
2. Hold for 2s the switch-on/off button to switch the system OFF.
 - 2.1 A longer press will force power – OFF

Note: Do NOT switch the 2WIN on in 2WIN-S configuration using the BUTTON A (See Paragraph 8.6 - Interfaces).

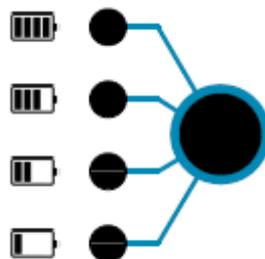


To charge the system

1. Connect the provided power supply cable to the INPUT 18V – 25A



2. Connect the other end of the power supply to the line.
3. In order to monitor the battery charge level, press the battery charge button.



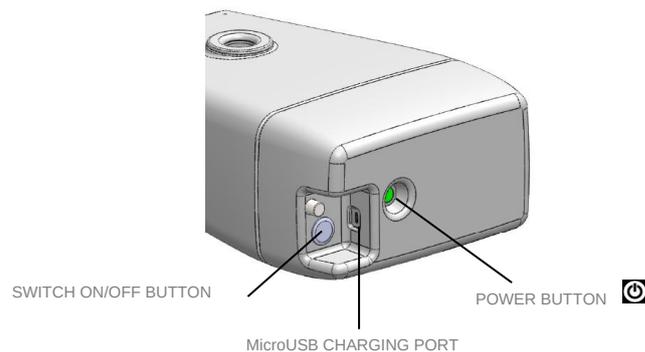
Configuration steps

Please refer to Chapter 13 of this Operator Manual for KALEIDOS configuration using the Wi-Fi tablet application and refer to Chapter 14 of this Operator Manual for KALEIDOS configuration using the Bluetooth tablet application.

12.3 KALEIDOS 3D: How to start

To switch ON/OFF the system

1. To switch the system on press the Switch-on/off button, then press the power button (power button stays white after startup). A beep sound stands for turning on the system.
2. To switch the system off press the Switch-on/off button, then execute a long tap on Power button in the remote APP user interface.



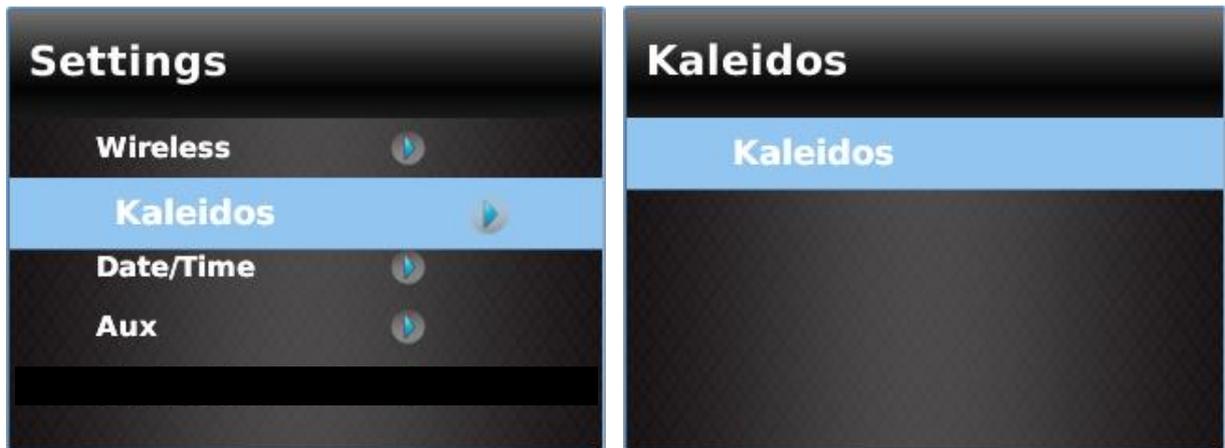
To charge the system

1. Connect the provided power supply cable to the INPUT 18V – 25A
2. Connect the provided USB cable to the MicroUSB input of KALEIDOS 3D.
3. Connect the other end of the USB charging cable to any active USB port of charging adapter
4. A green battery indicator means the unit is charging, and it becomes white when fully charged.
5. Battery level is indicated by the LED indicator light.

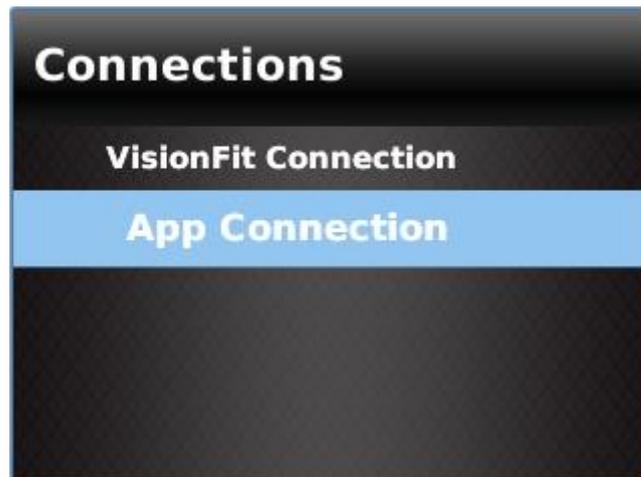
| Red light | Green light | White light |
|-----------|-------------|-------------|
| 0-30% | 30-70% | 70-100% |

Configurations steps

1. To configure the 2WIN to be used inside KALEIDOS 3D enter the 2WIN Menu -> Settings -> KALEIDOS and select KALEIDOS option.



2. When this option is turned on, the 2WIN must be used inside the KALEIDOS 3D system only.
3. The next configuration is to pair the 2WIN with its remote control APP (running on Android tablet): enter the 2WIN Menu -> Settings -> Wireless -> Connections and enable the App Connection by clicking on it, like in the following picture.



12.4 KALEIDOS packing list

The box contains (default configuration):

- the electronic version of the operating manual (inside the microSD)
- the 2WIN device inside KALEIDOS
- two rechargeable batteries (one already inside the 2WIN)
- a microSD memory card with SD Adapter
- a USB cable (microUSB to USB-A)
- an external battery charger to charge the battery outside 2WIN
- an occluder (infrared patient's eye occlusion system)
- KALEIDOS Power Supply/Charging Adapter
- EU/US AC wall adapter
- Top, middle, bottom of the KALEIDOS pieces (part A, part B, part C respectively)
- base-support (part D)

12.5 KALEIDOS 3D packing list

The box contains (default configuration):

- the electronic version of the operating manual (inside the microSD)
- the 2WIN device inside KALEIDOS
- two rechargeable batteries (one already inside the 2WIN)
- a microSD memory card with SD Adapter
- a USB cable (microUSB to USB-A)
- an external battery charger to charge the battery outside 2WIN
- an occluder (infrared patient's eye occlusion system)
- KALEIDOS Power Supply/Charging Adapter
- EU/US AC wall adapter

12.6 CONTROL PANEL FUNCTIONALITIES

| | | Button | | |
|-------|-----------------|--|---|--|
| | | Power | 1 - Measure | 2 - Network |
| State | Flashing Green | The system is booting up | Measure ongoing | - |
| | Fixed Green | The system has successfully started, there is a blinking when the activity is normal | Measure well done | 2WIN correctly connected to the application |
| | Fixed Red | Error, please shut down the system and power it on again. | Measure error. please repeat the measurement. | WiFi NOT Connected, check 2WIN WiFi settings |
| | Flashing Orange | System Shutting Down | - | WiFi connection ongoing |
| | Fixed Orange | - | - | WiFi ON but NOT connected to the application |
| | Flashing Blue | - | - | Pairing ongoing |
| | Fixed Yellow | Firmware Updating | - | - |

| | | Button | | |
|----------|-------------|---|--|---|
| | | Power | 1 - Measure | 2 - Network |
| Function | Short press | System Power-UP | 2 sec to start a measurement. Please notice that the measure will be automatically saved on the SD card of the 2win. | 2sec (until flashing orange): WiFi reset. This operation may require up to ten seconds. |
| | Long press | 2sec: System Power-Down More: Forced Power-OFF | - | 4sec (until flashing white): Pairing Reset |

13 Remote control 2WIN App

When using the KALEIDOS system or simply when the operator wants to remote control a 2WIN, it is possible to use the remote control 2WIN App running on an Android tablet. 2WIN App provides Wi-Fi connectivity; please refer to Chapter 14 if you want to use Bluetooth connectivity between KALEIDOS and tablet.

The tablet shall satisfy the following requirements:

- Android version 8.0, 8.1, 9, 10
- Display size 10 inches or more
- Processor type: ARMv7

Recommended tablet models are:

- Huawei MediaPad T5
- Lenovo TB-X605L
- Lenovo TB-X306X

You can download 2WIN Wi-Fi tablet Application on your device from Adaptica's [website](#) in the section Products > Kaleidos > Downloads > KALEIDOS App Wi-Fi.



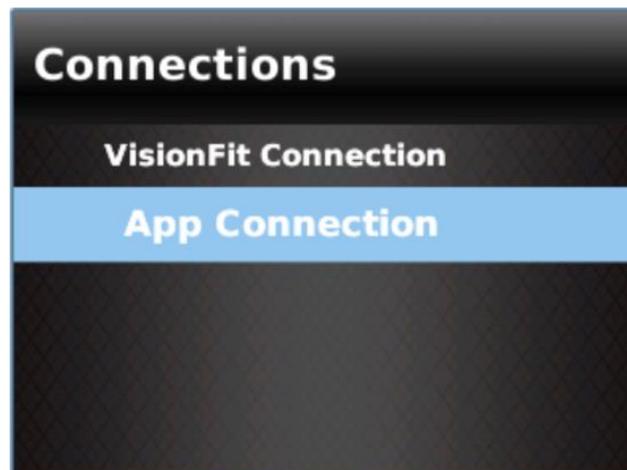
WARNING! Tablet's operating system updates are not recommended, since they could compromise 2WIN App functioning.

13.1 2WIN App installation and configuration

In order to use the 2WIN App, either for 2WIN-S or 2WIN remote control, the device and the Application must be paired for the first time.

Please follow these configuration instructions to pair 2WIN-S and the tablet Application:

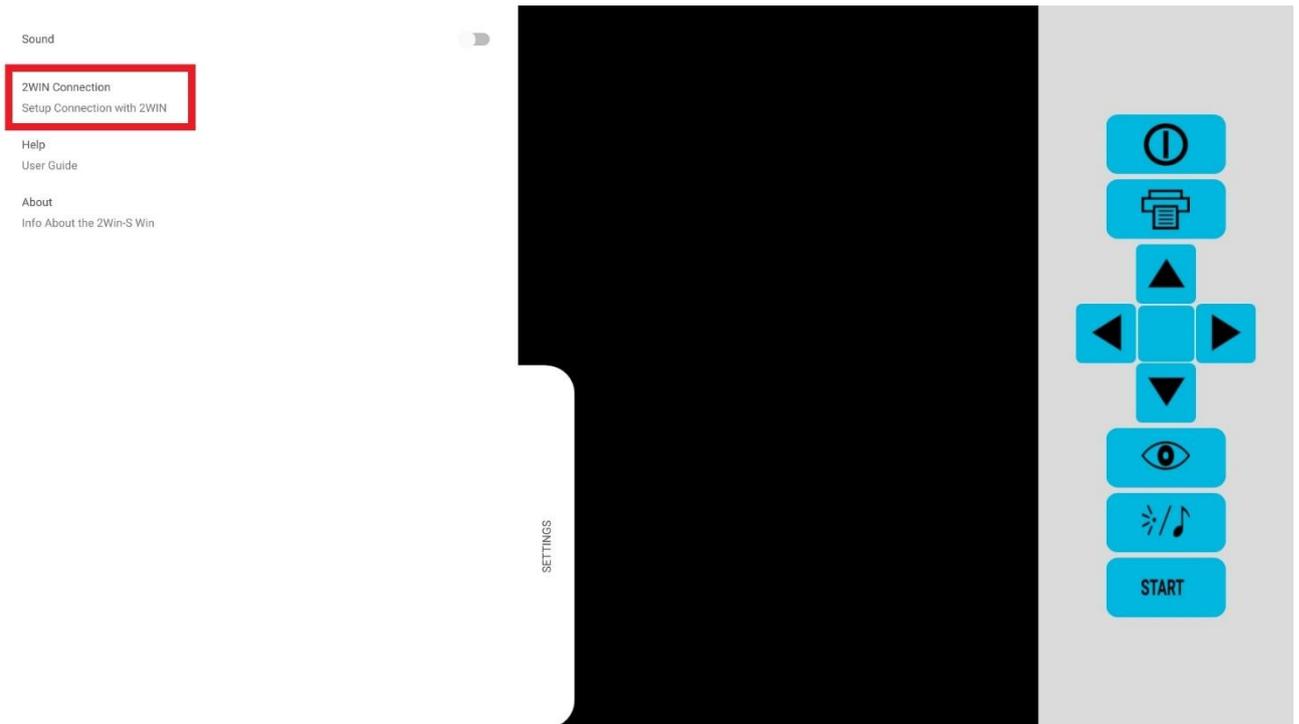
1. Install the 2WIN App on your device and run the Application.
2. Switch the 2WIN-S on
3. Check that 2WIN and tablet are connected to the same WiFi network. If necessary, set 2WIN's WiFi connection following the instructions on Paragraph 11.2 – WiFi Connectivity.
4. Enter 2WIN's menu > Settings > Wireless > Connections and enable App Connection option.



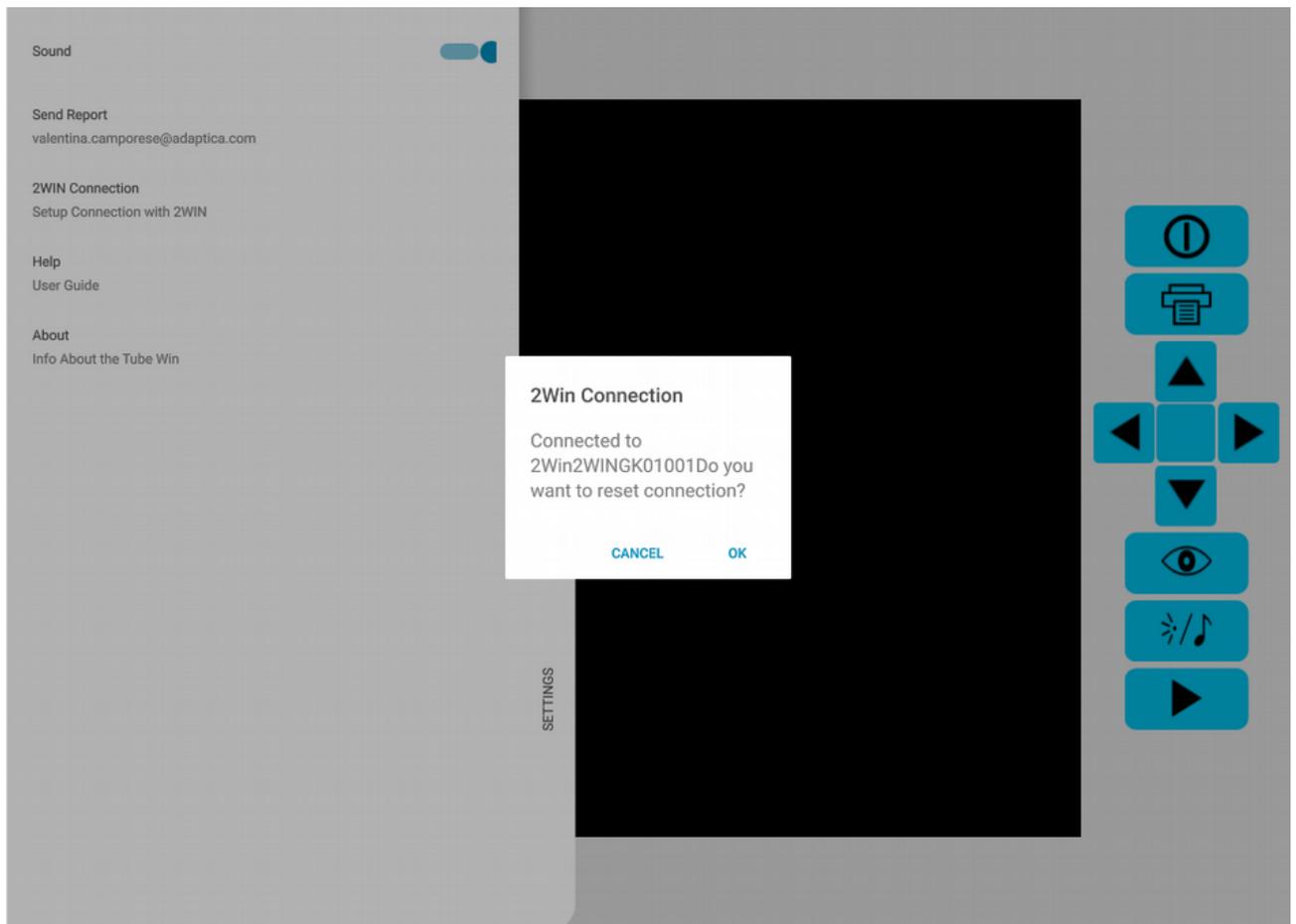
5. The following window Appears on 2WIN's display:



6. From the tablet Application open the Settings panel and select 2WIN Connection



7. The following window appears on the tablet Application:



8. Press button number 2 on KALEIDOS control panel until the LED becomes blue. Then release the button.
9. If the pairing succeeds LED number 2 on KALEIDOS control panel becomes green and 2WIN icon on the tablet Application becomes green as well.

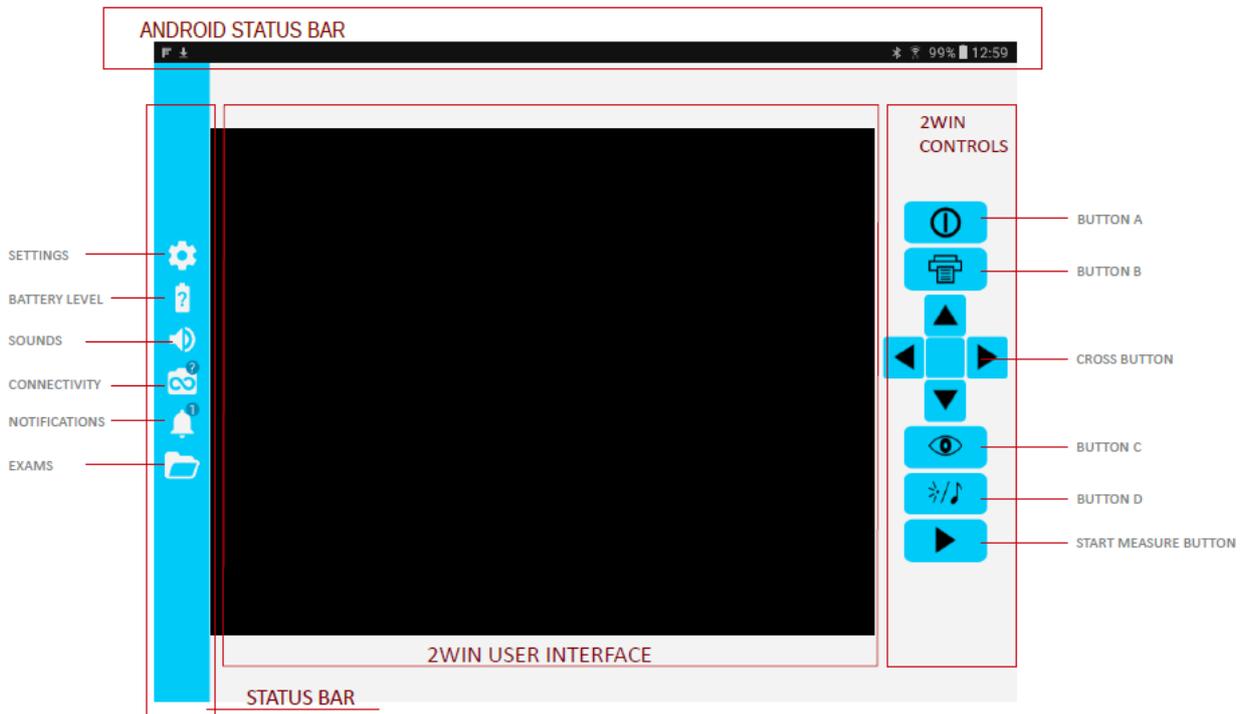


NOTE: to use the remote Application to control 2WIN follow the pairing instructions from step 1 to step 6.

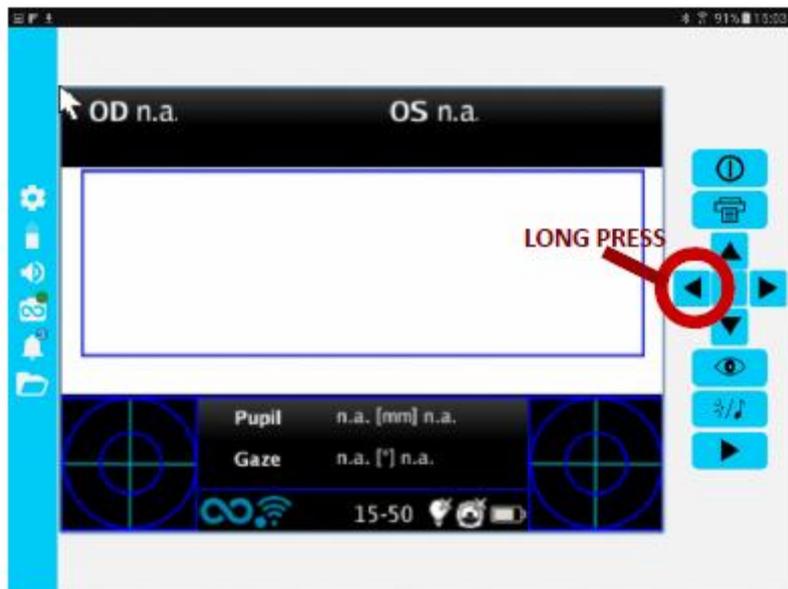
When paired for the first time, the application will show the S/N of the 2WIN. From this moment it is possible to use the KALEIDOS controlling it with the remote 2WIN App. During next measurement sessions it is not necessary to pair again the 2WIN and the remote application.

If you want to remove the pairing, in order to connect another 2WIN or another KALEIDOS to the remote application, simply tap again on the 2WIN App settings > 2WIN Connection and follow the instructions in the application.

13.2 How to use the 2WIN App



The right-side buttons of the 2WIN App are the replica of the 2WIN buttons, so all the functions of 2WIN's physical buttons are controlled by the App.



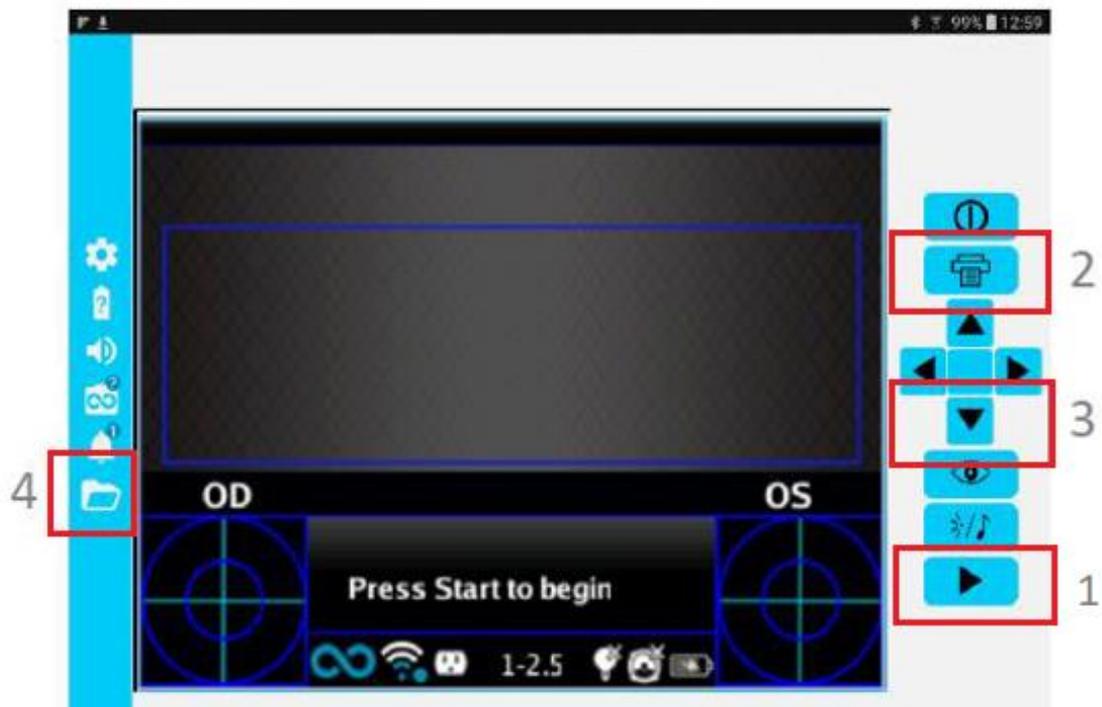
On the left side of the 2WIN App there are all the status icons and settings of the App. Note that the icon representing the 2WIN must contain a GREEN dot. If this is not present even if the 2WIN and tablet are connected and paired correctly, please tap on the 2WIN icon. This will make a refresh of the connection.

How to transfer 2WIN measurement to the 2WIN App

Follow these instructions:

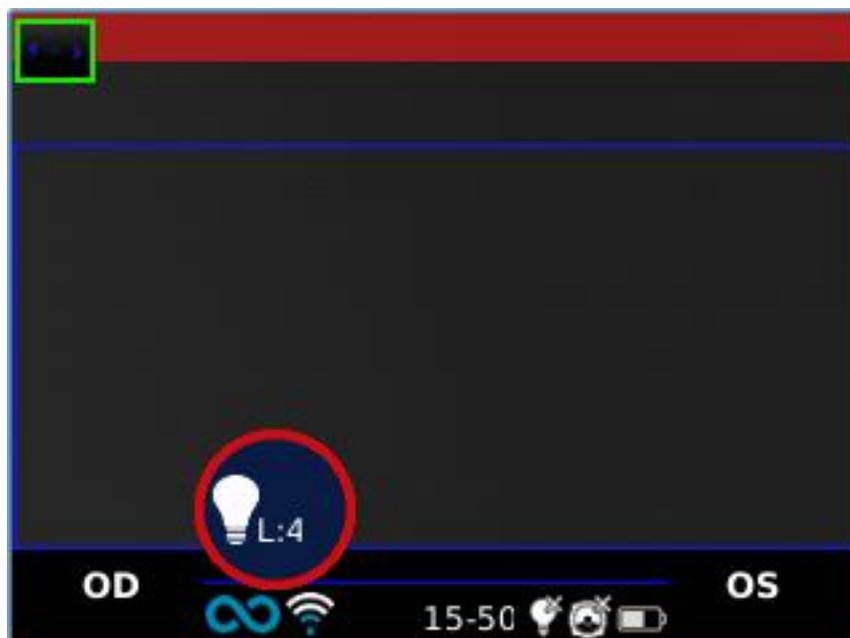
1. Start the measurement using the START button
2. Long press PRINT button to save your data. A PDF report is created.
3. Short press DOWN button to import the report into your tablet.

4. The report is saved in the EXAM folder. Open the folder tapping on the folder icon.



Live Mode Function

When used in KALEIDOS mode, the BUTTON D (see Paragraph 8.6 - Interfaces) has a different function: short pressing BUTTON D a live mode visualization starts and it is possible to see the live of the video, looking at the pupils. You can adjust the pupils size dimension with CROSS BUTTON up/down arrows, modifying the 2WIN's white LED intensity. A bubble with an intensity level appears on the display.



14 Remote control KALEIDOS App

When using 2WIN-S in KALEIDOS Bluetooth or KALEIDOS Plus configuration, it is needed to use the remote control KALEIDOS App running on an Android tablet.

KALEIDOS App provides Bluetooth connectivity between KALEIDOS and tablet.

The tablet shall satisfy the following requirements:

- Android version 8.0, 8.1, 9, 10
- Bluetooth version 4.0 Low Energy or later
- Display size 10 inches or more
- Processor type: ARMv7

Recommended tablet models are:

- Huawei MediaPad T5
- Lenovo TB-X605L
- Lenovo TB-X306X

You can download 2WIN WiFi tablet Application on your device from Adaptica's [website](#) in the section Products > Kaleidos > Downloads > KALEIDOS App BT.



WARNING! Tablet's operating system updates are not recommended, since they could compromise KALEIDOS App functioning.

14.1 KALEIDOS App installation and configuration

In order to use the KALEIDOS App for 2WIN-S remote control, the device and the Application must be paired for the first time.



WARNING: KALEIDOS App is compatible with 2WIN-S having software version 5.4.2 or higher and hardware version 29.1 or higher.

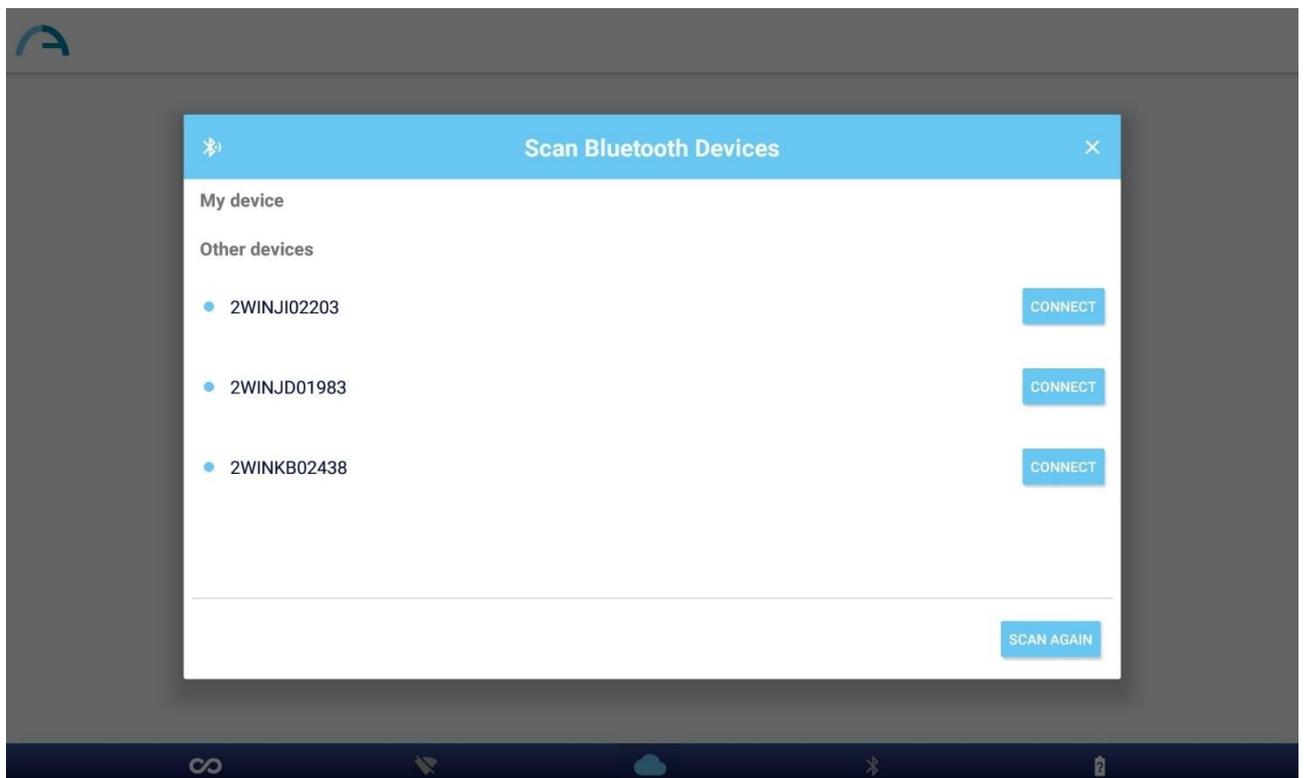
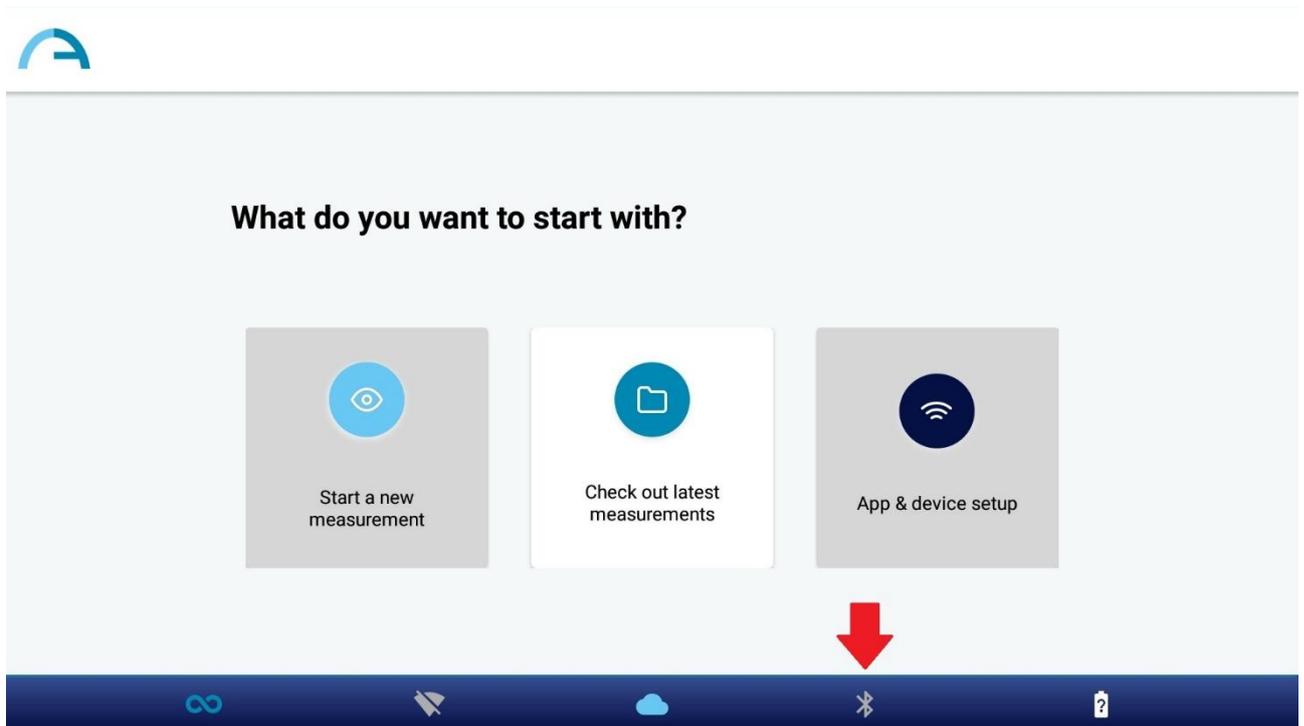


WARNING: In order to use KALEIDOS App a screen lock mechanism must be enabled on the tablet. If such mechanism is not active the App won't start.

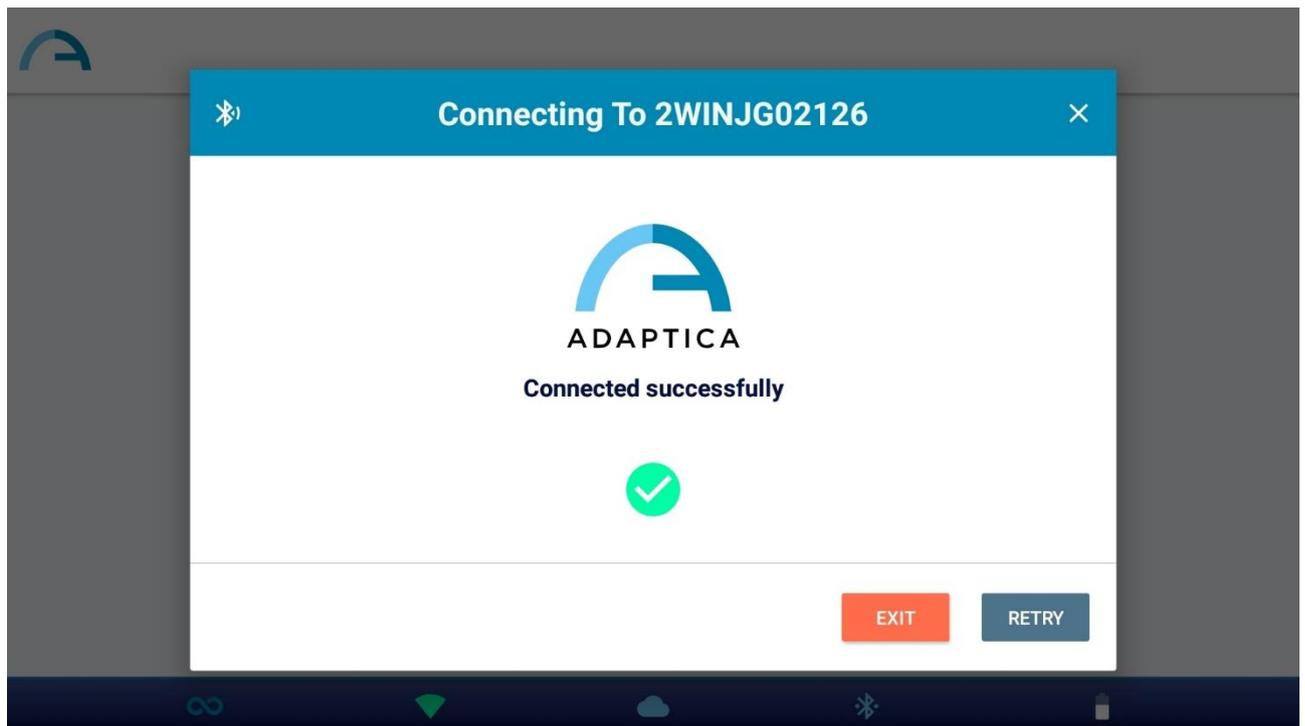
Please follow these configuration instructions to pair 2WIN-S and the tablet Application:

1. Install the KALEIDOS App on your device
2. Check that Bluetooth is enabled on the tablet
3. Switch the 2WIN-S on
4. Run KALEIDOS App

5. Tap on the Bluetooth icon on the KALEIDOS App to start available Bluetooth devices search. A window showing all the available 2WIN-S will open.



6. Connect to the desired 2WIN-S. When the pairing is complete a confirmation message will appear.

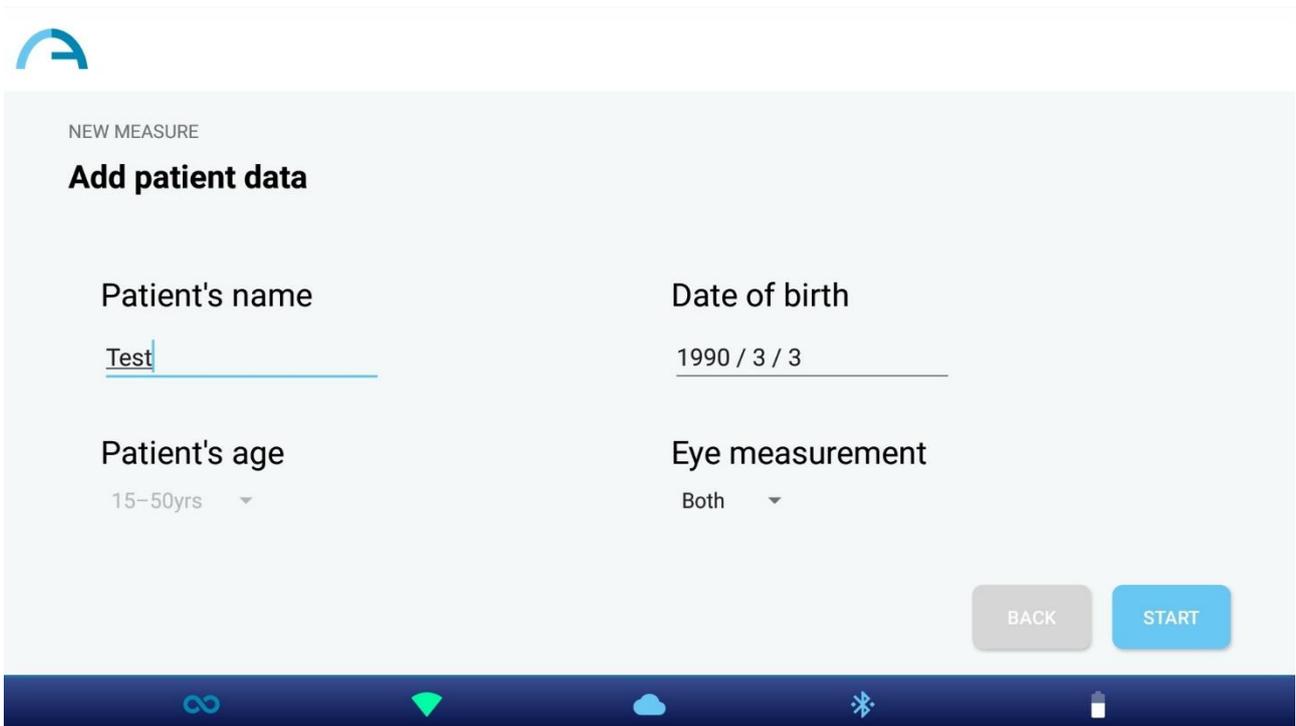
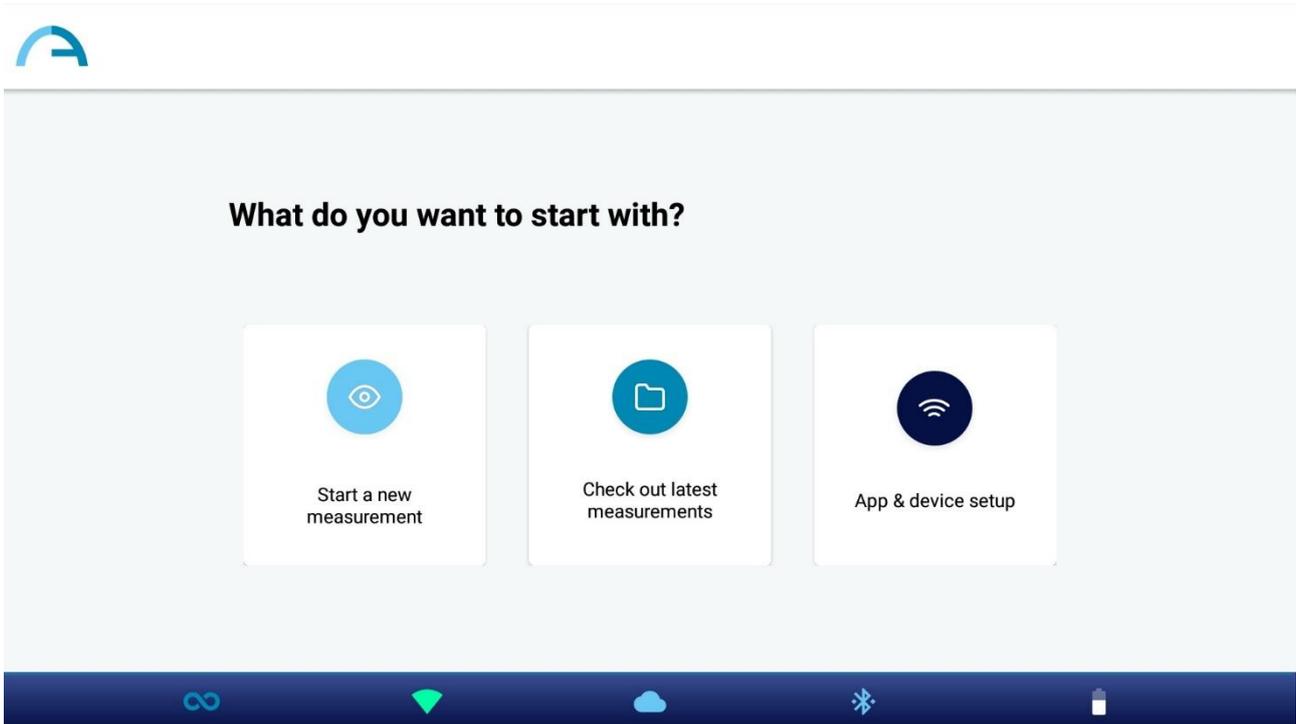


-  At the next launch KALEIDOS App will automatically reconnect to the paired 2WIN-S, unless the user disconnects it.
-  KALEIDOS App is intended to be used to control 2WIN-S and it does not allow 2WIN remote control.

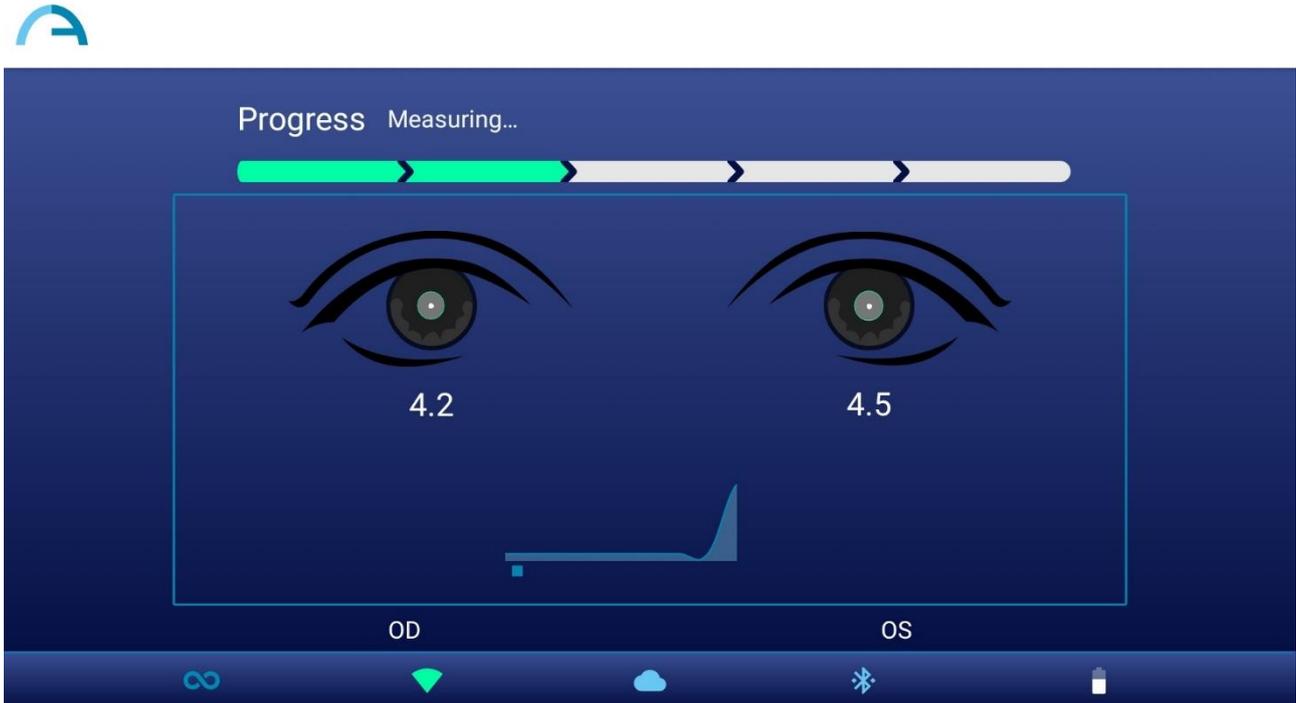
14.2 Refraction exams using KALEIDOS App

To take an exam using KALEIDOS App follow these steps:

1. Select "Start a new measurement" from KALEIDOS App main window
2. Insert patient name and date of birth. When the patient's date of birth is set, the correct age range is automatically selected. Then set the type of the measurement: right eye, left eye or both eyes.
As alternative, you can just select the patient age range, without inserting patient's personal data.



3. Once the data are set press the START button. The measurement starts and a progress bar is displayed:

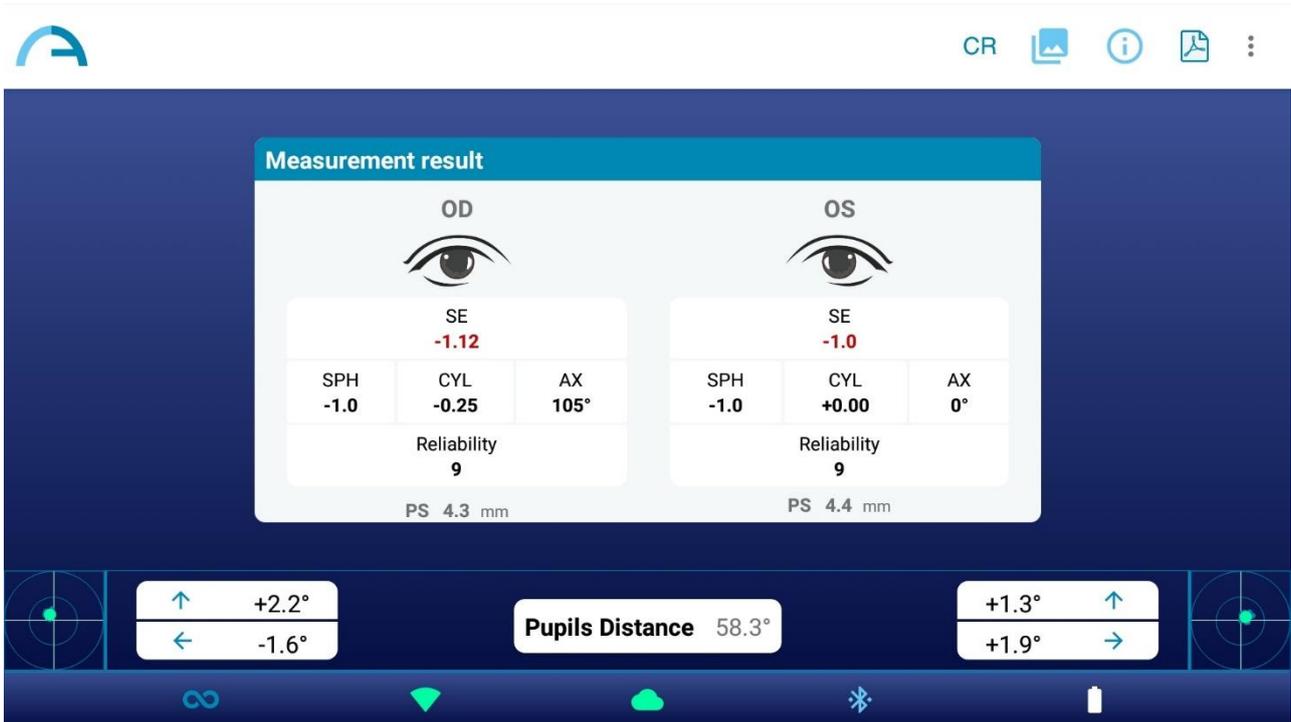


4. During the measurement the patient's pupils are circled in green. If the patient's pupils are circled in red the measurement is not correct and shall be repeated. Pupil diameters are displayed below the eyes image during the measurement phase. The graph on the bottom of the window is the focusing meter, maximizing the value of the graph will lead to a better measurement.

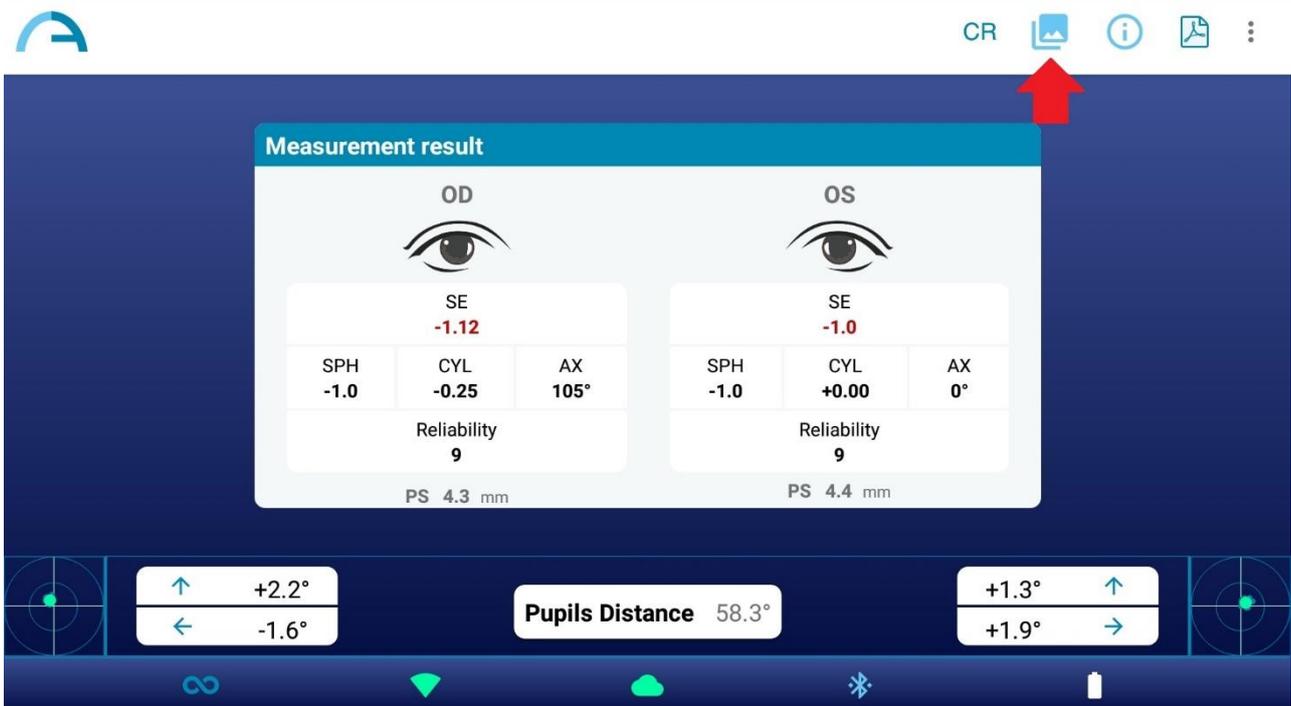
NOTE: If the patient is not positioned correctly during the measurement the rectangle which frames the eyes image up becomes red. In this case the operator must ask to the patient to get closer to KALEIDOS and look inside the tube trying not to move.

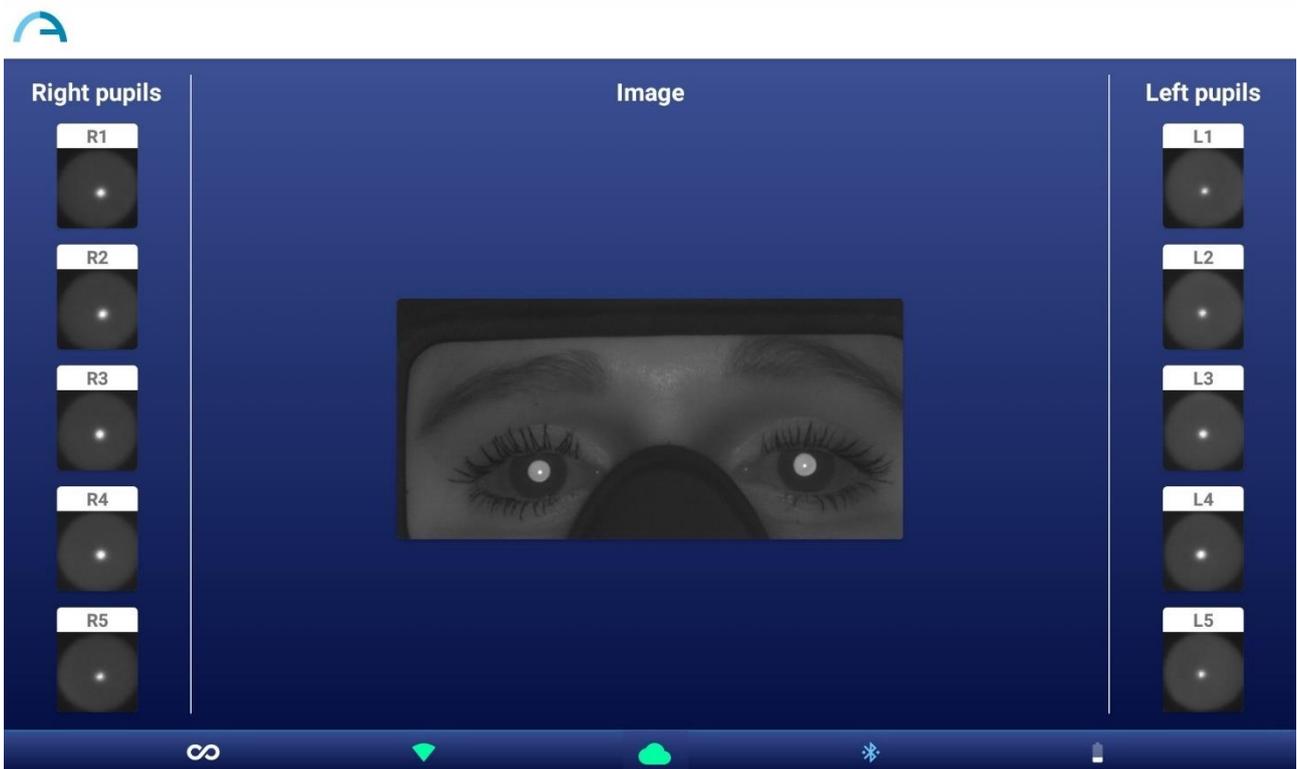
5. Exam results are displayed. From top to bottom:
 - Spherical Equivalent (SE)
 - Refraction results (Sphere, Cylinder and Axis)
 - Reliability index, calculated independently for right eye and for left eye
 - Pupil size (PS)

In the bottom part of the results window fixation plots, gaze information and pupils distance are displayed.

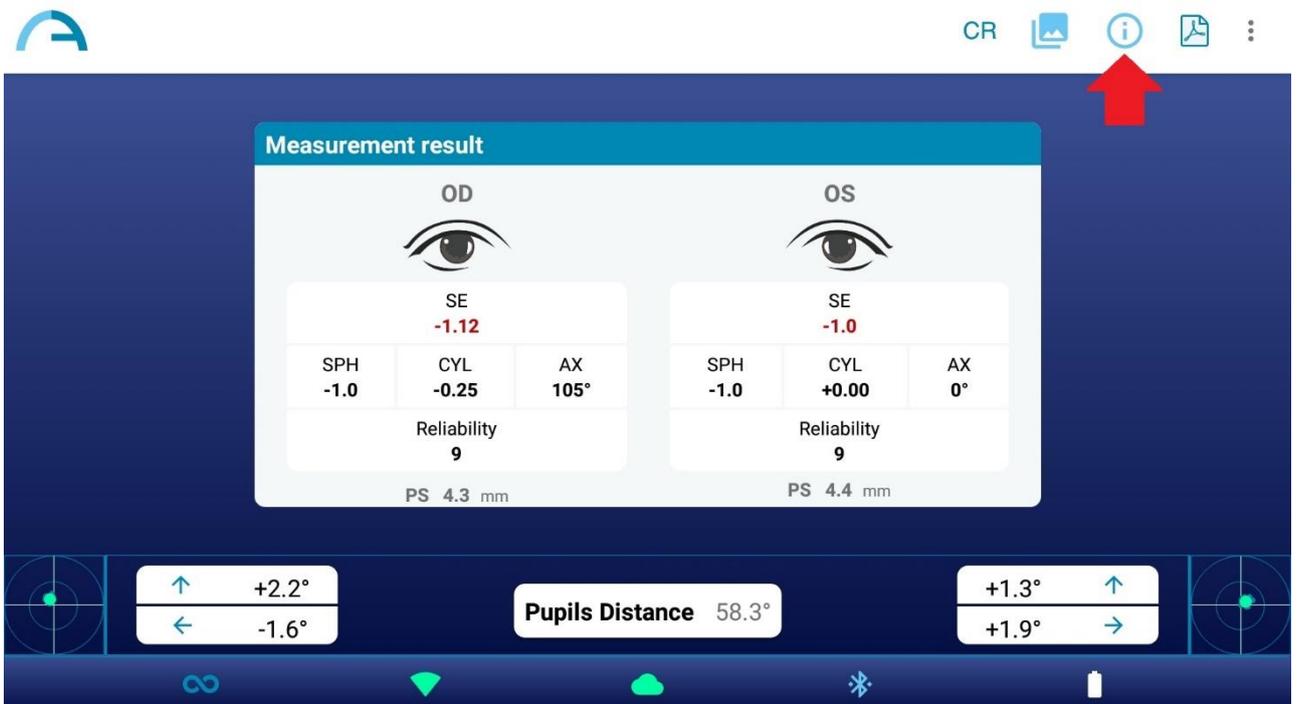


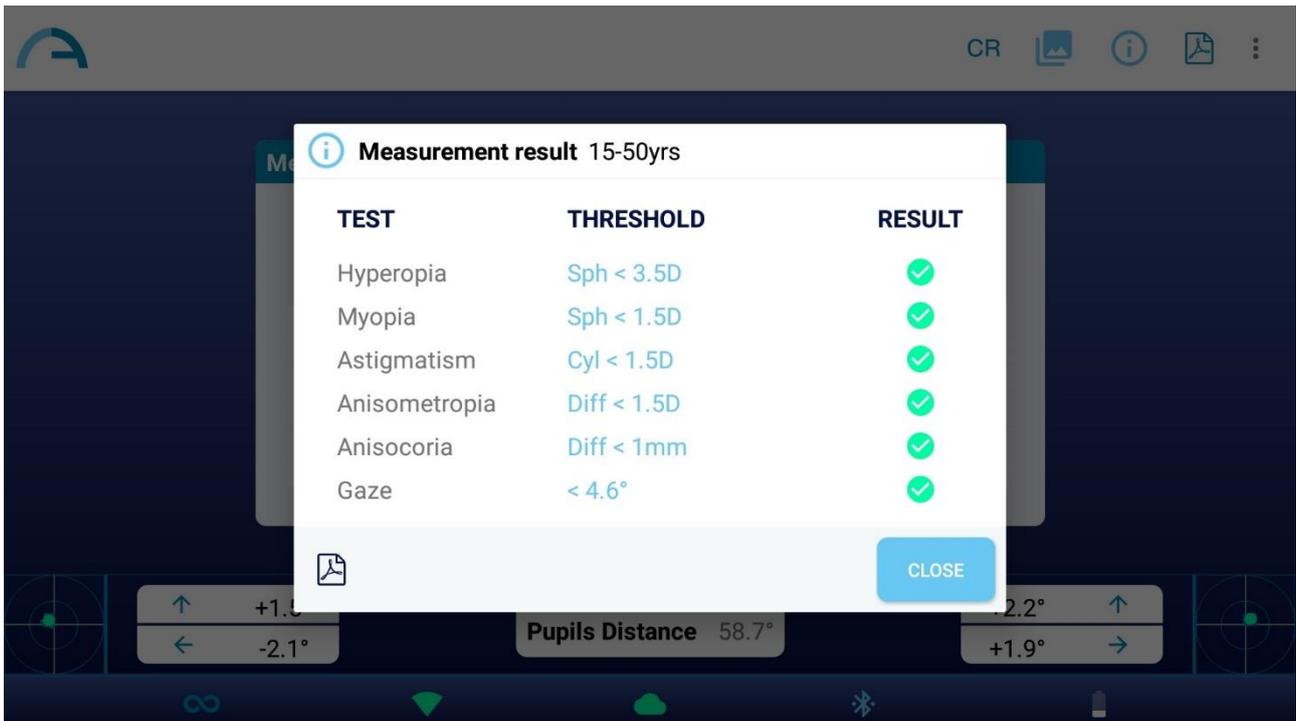
6. Press on the Image button on the top right of the results window to visualize the patient's eyes and pupils images:





7. To see the screening results press on Info button of the top right of the results window:

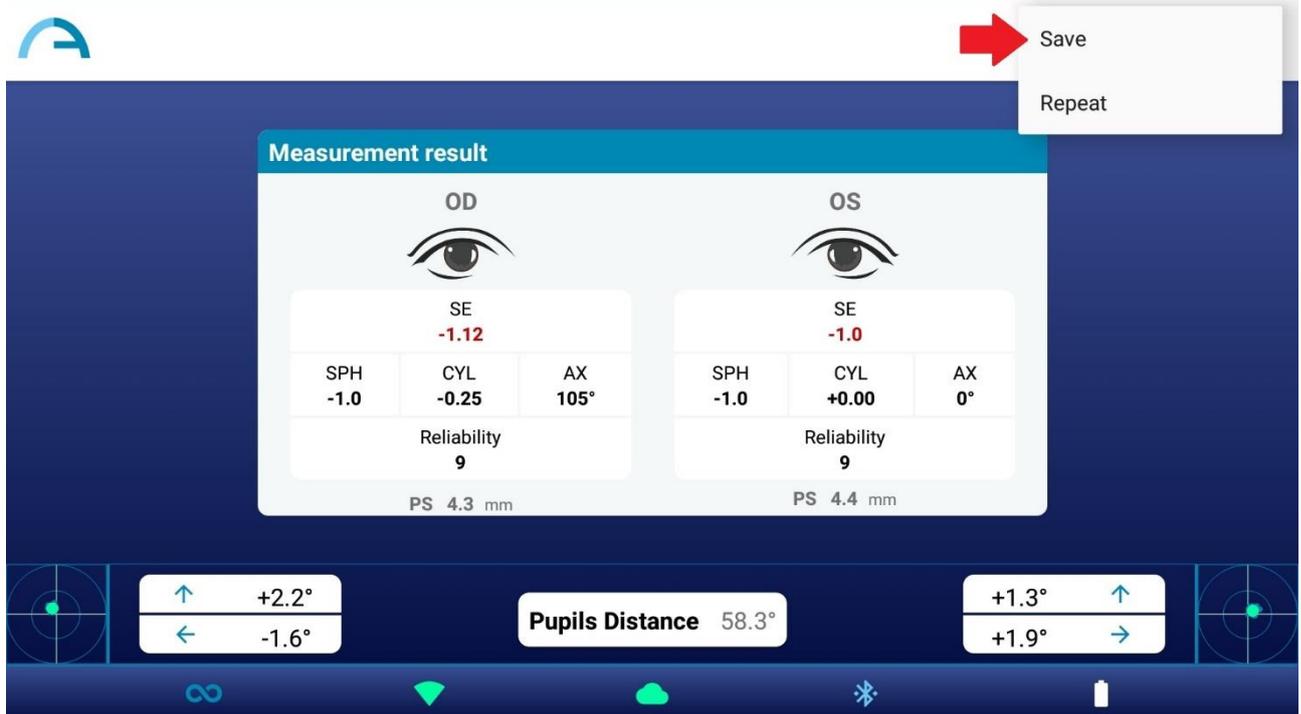
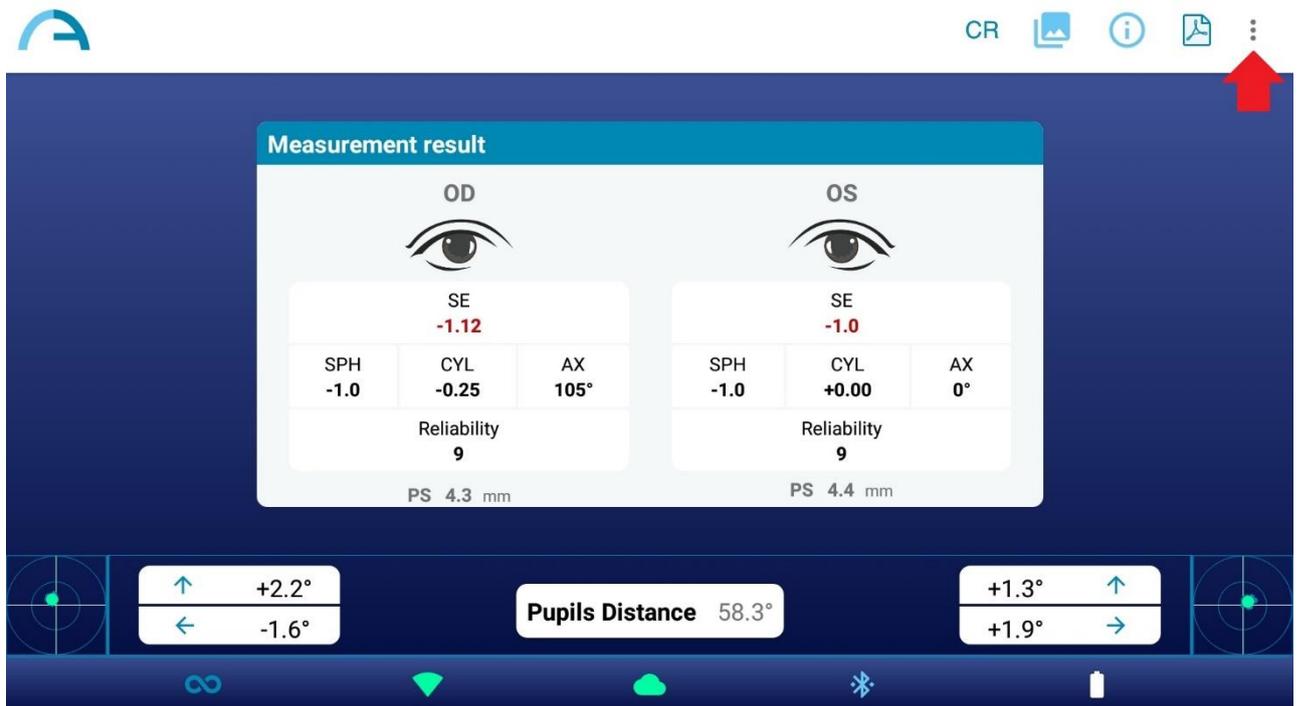




- Tap on the PDF icon below the screening results table to generate the PDF report of the exam. As alternative, you can create the PDF report tapping on the PDF icon on measurement results window.



- To save the measurement press Save button on the dropdown menu that appears clicking on the three dots on the top right of the results window. After saving, a confirmation message appears.

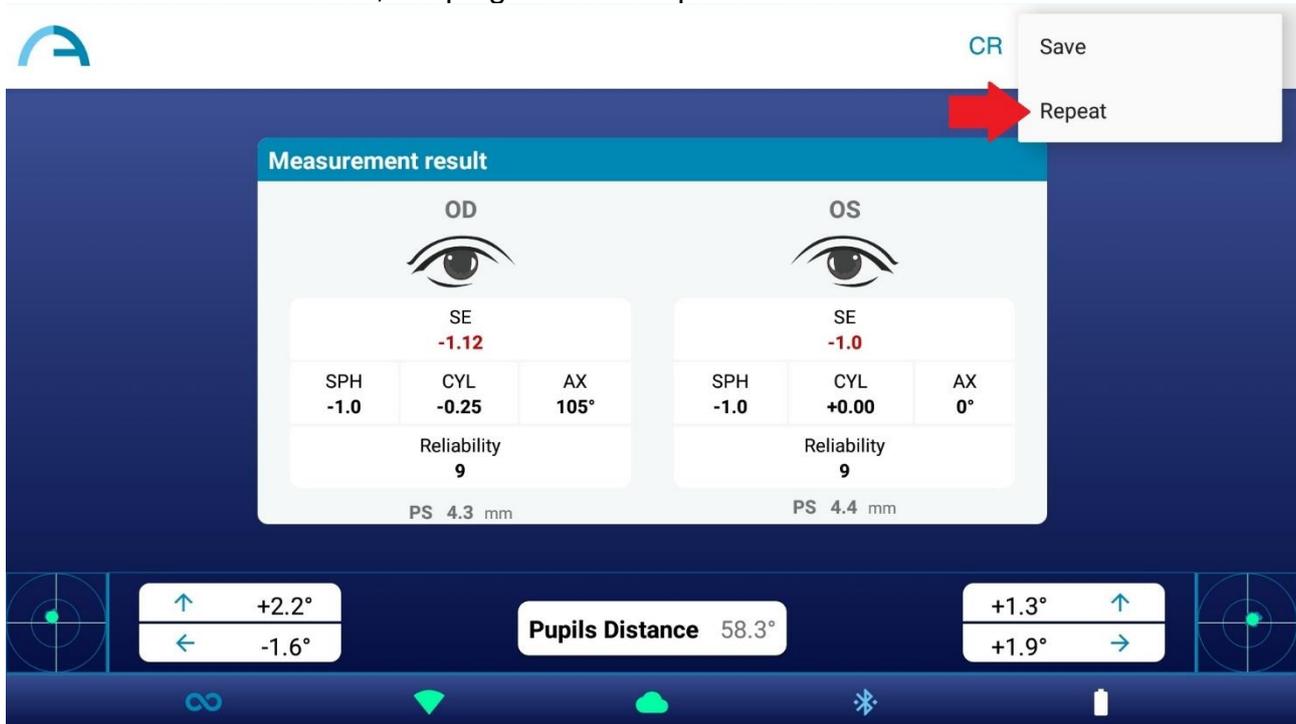


NOTE: Pressing the Save button the exam is automatically saved both in the tablet and in the 2WIN's microSD card. The PDF report is saved only in the tablet.

NOTE: The path in which the PDF reports are saved is:
Internal Storage\Documents\Adaptica.

If you don't want to save the measurement just exit the Application or go back to the Home window to start a new measurement.

If you want to repeat the measurement press Repeat button on the dropdown menu that appears clicking on the three dots on the top right of the results window. A new measurement will start, keeping the current patient data.

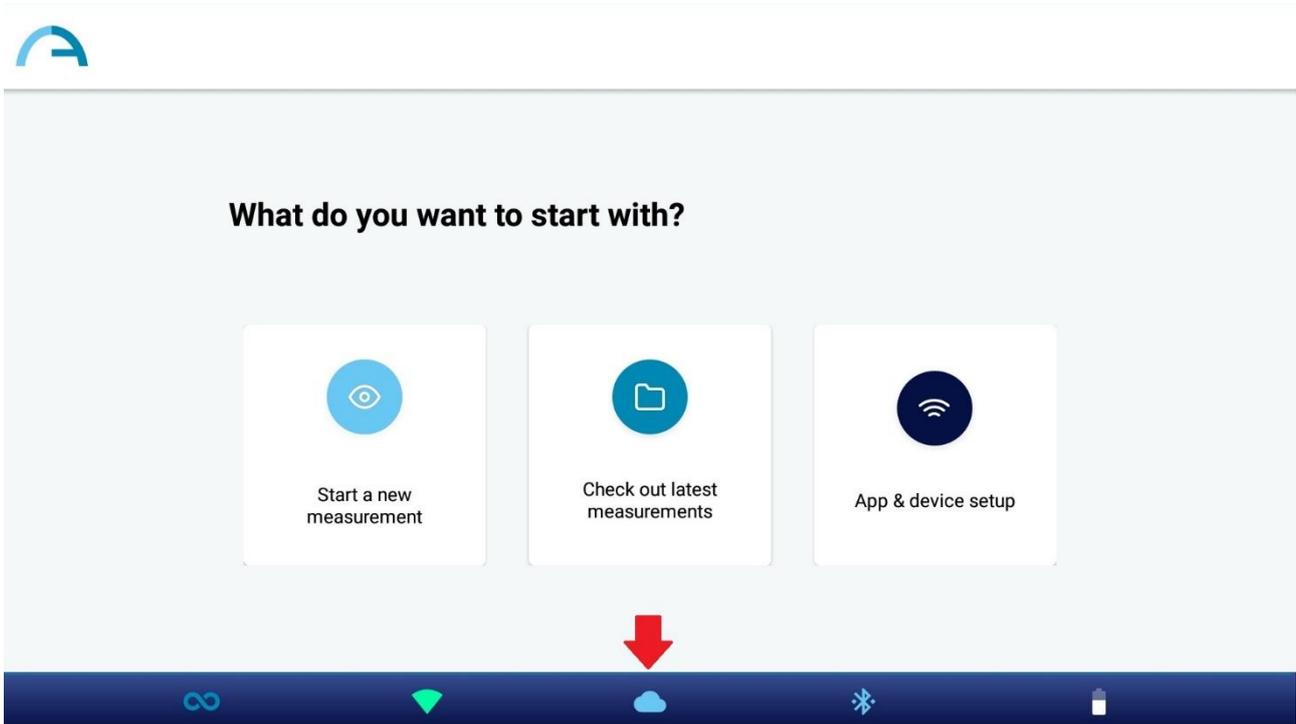


14.3 KALEIDOS App Anterior Segment Hint

Anterior Segment Hint is an innovative A.I. based algorithm running on Adaptica Cloud, developed to give additional information to the user if 2WIN-S is not able to refract the patient.

-  Anterior Segment Hint is already active if you are using a KALEIDOS Plus. Otherwise, it requires an activation code. Please contact your local distributor to get the activation code.
-  To work properly, Anterior Segment Hint needs the tablet to be connected to a WiFi network having internet access.

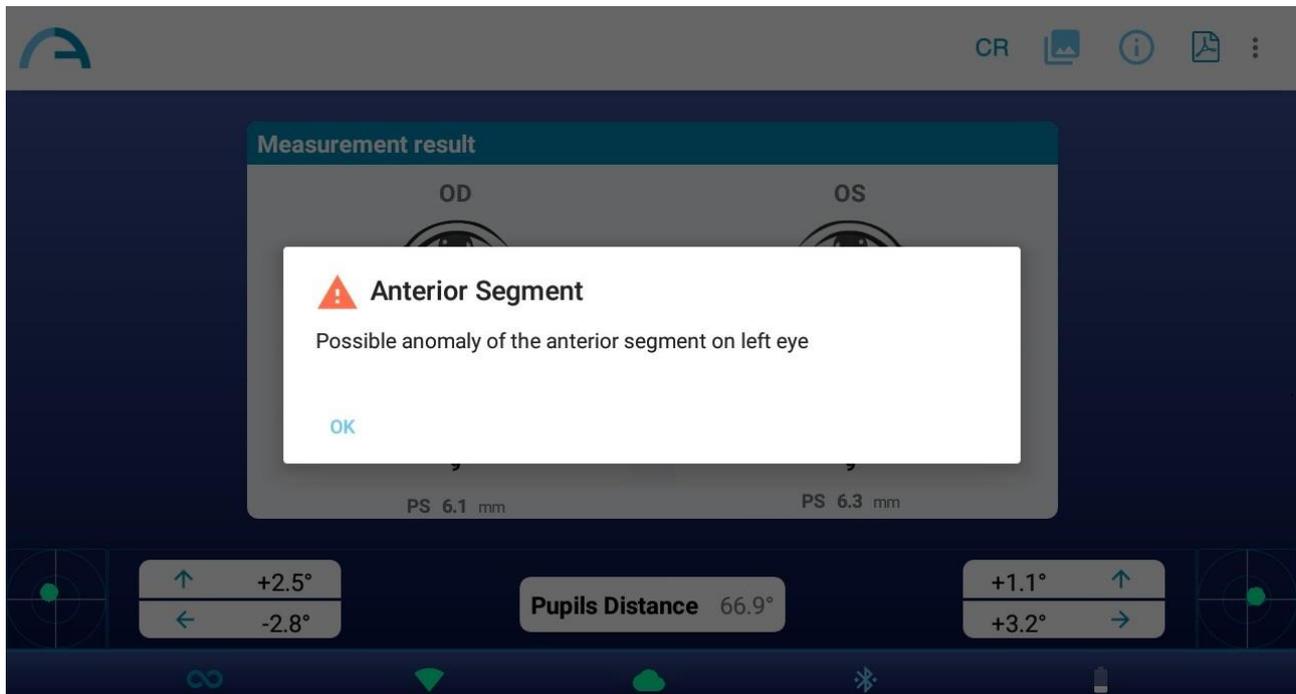
If Anterior Segment Hint is enabled on your 2WIN-S and if the tablet is connected to a WiFi network having internet access, the cloud icon on KALEIDOS App is blue, as shown in the figure below. Otherwise, the cloud icon is grey.



Data collected during the 2WIN (Refraction) exam are instantly processed by Anterior Segment Hint A.I. algorithm. When the exam is processed, the cloud icon on Measurement result window turns from blue to green.

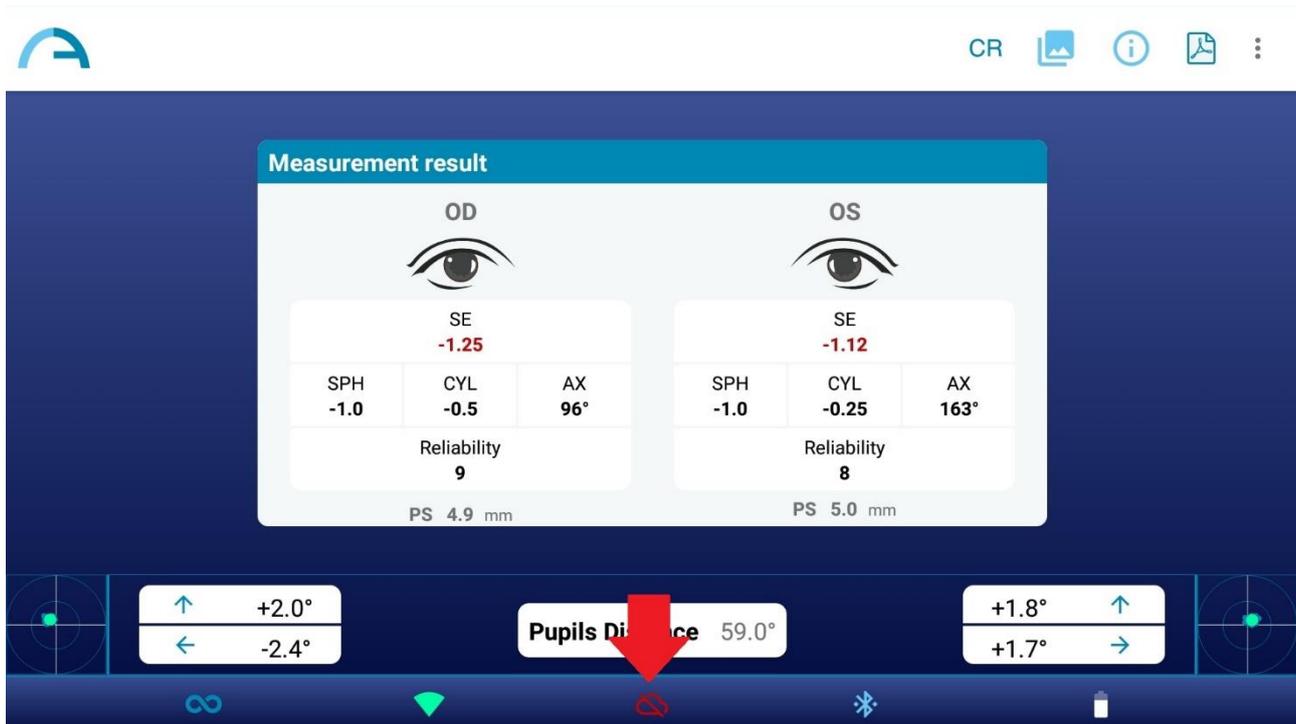


If 2WIN-S is not able to refract the patient and any suspect anomaly of the anterior segment is detected, the warning “Possible anomaly of the Anterior Segment” is given to the operator with the indication of the eye (left, right or both).



 **WARNING:** the message “Possible anomaly of the Anterior Segment” shall not be misunderstood as a diagnosis or a hint for diagnosis. For instance, a foreign object put in front of the eye during the exam could result in an anomaly of the eye profile not related to any pathology. The measurement shall in any case be used to refer the patient to an eye care professional for further evaluation.

If any error occurs during the connection to Adaptica Cloud or during the upload of the pupils images, the cloud icon changes to cloud error icon:



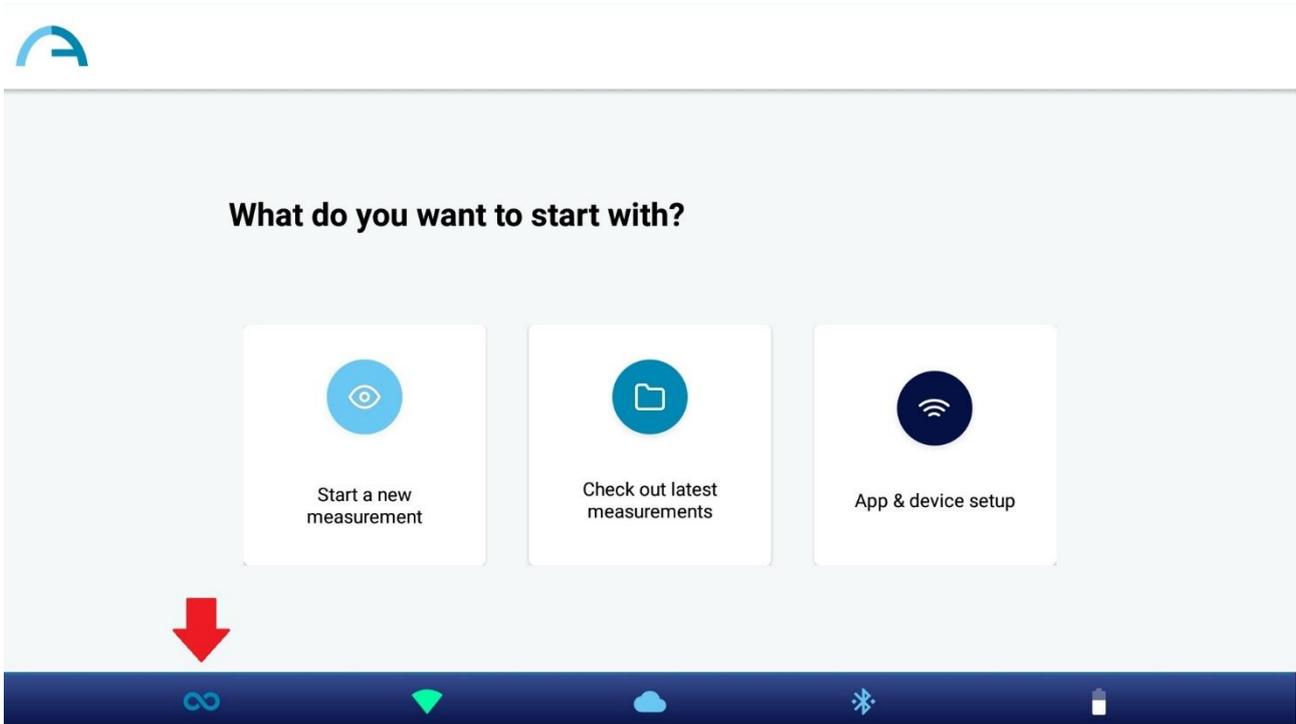
14.4 CR exams using KALEIDOS App

From KALEIDOS App it is possible to select Corneal Reflexes (CR) measurement mode.

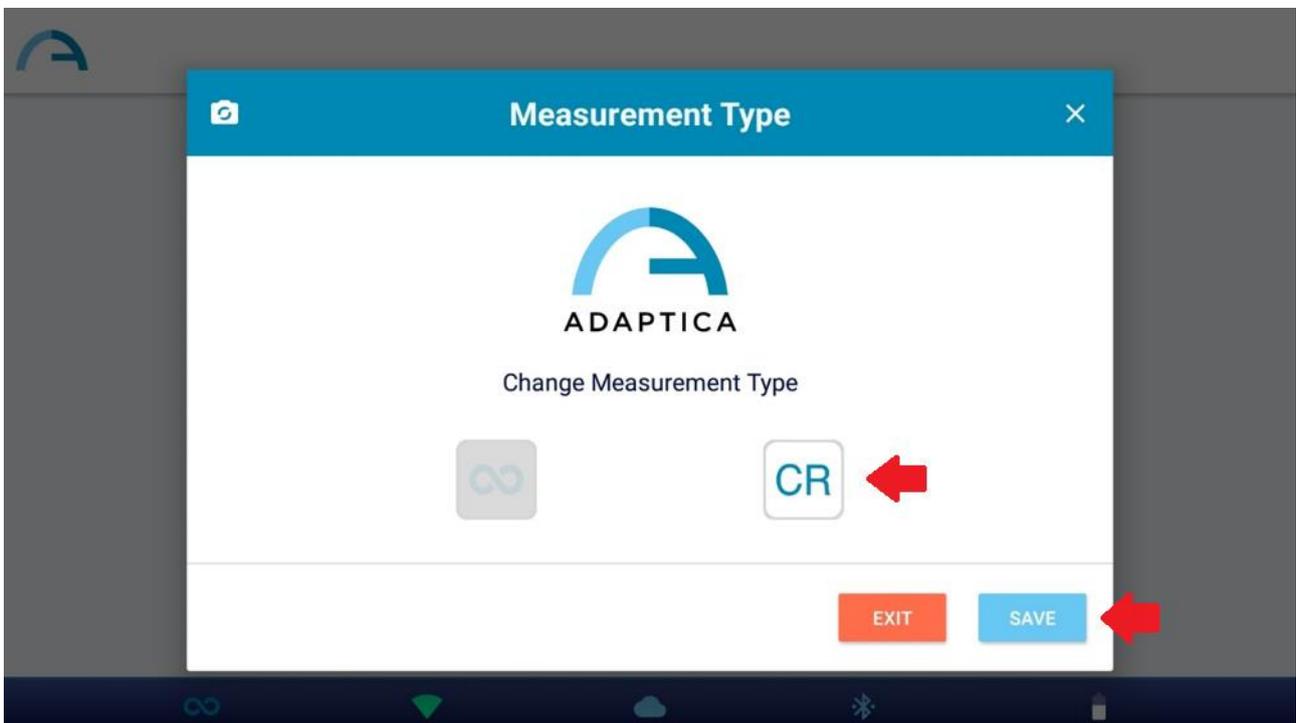
CR measurement mode provides information regarding the corneal reflexes position, giving hints about possible phorias and tropias.

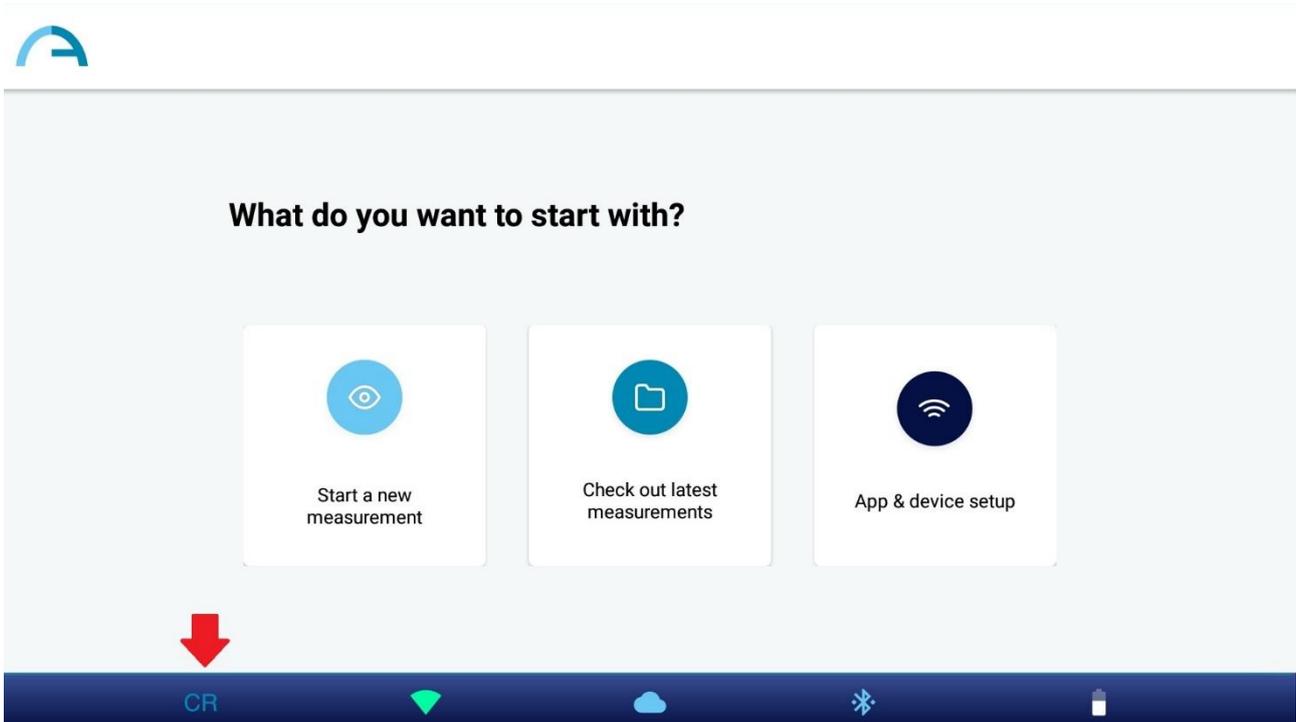
 CR measurement mode is already active if you are using a KALEIDOS Plus. Otherwise, it requires an activation code. Please contact your local distributor to get the activation code.

To enable Corneal Reflexes measurement mode, tap on the measurement mode icon on the home page of the Application:



“Measurement Mode” dialogue window appears. Select the desired mode and press SAVE button. When Corneal Reflexes mode is selected the Application icon in the home page of KALEIDOS App changes and displays CR icon.





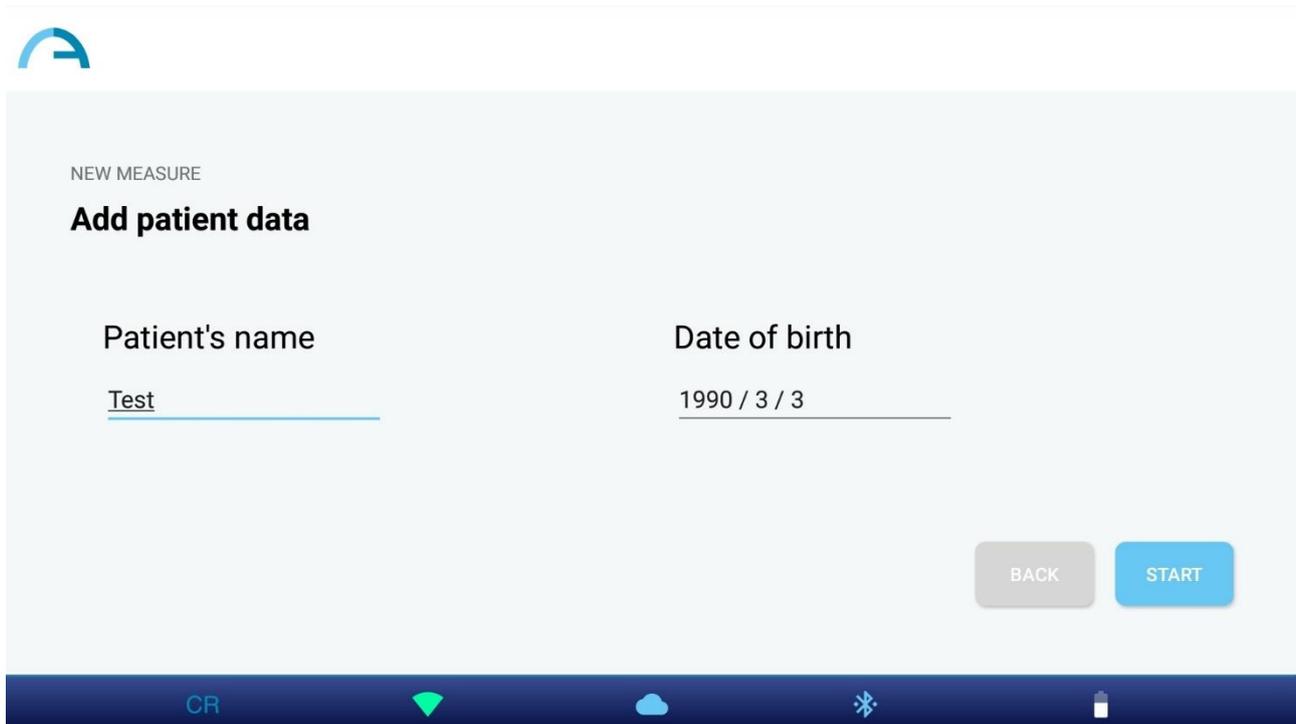
NOTE: Default mode is 2WIN (Refraction) mode. When KALEIDOS App is restarted 2WIN (Refraction) mode is loaded.

CR Exam Procedure

CR exam consists of a sequence of three acquisitions: one binocular and two cover tests under an infrared occluder. The patient must gaze at the white LED that turns on during the measurement.

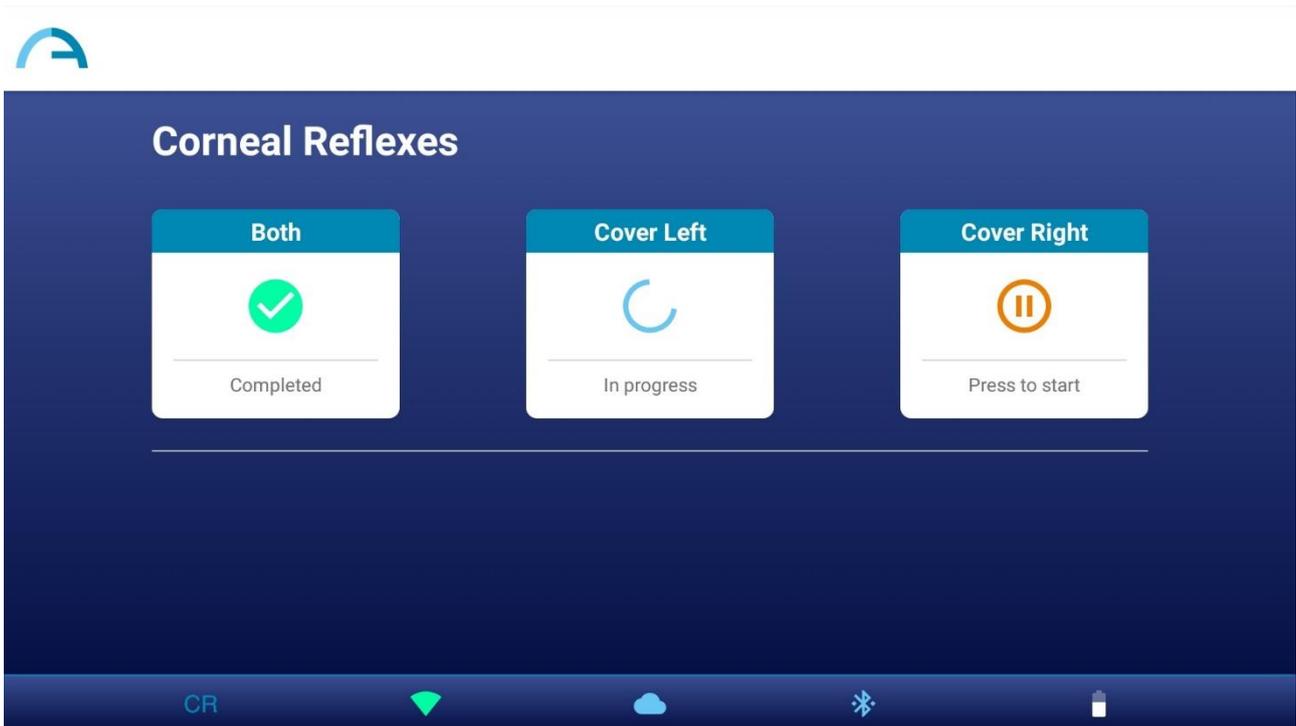
To perform a Corneal Reflexes measurement, follow these steps:

1. Select CR mode, as described above
2. Tap on “Start a new measurement” button
3. Enter patient’s name and date of birth. If needed, patient data insertion can be skipped.

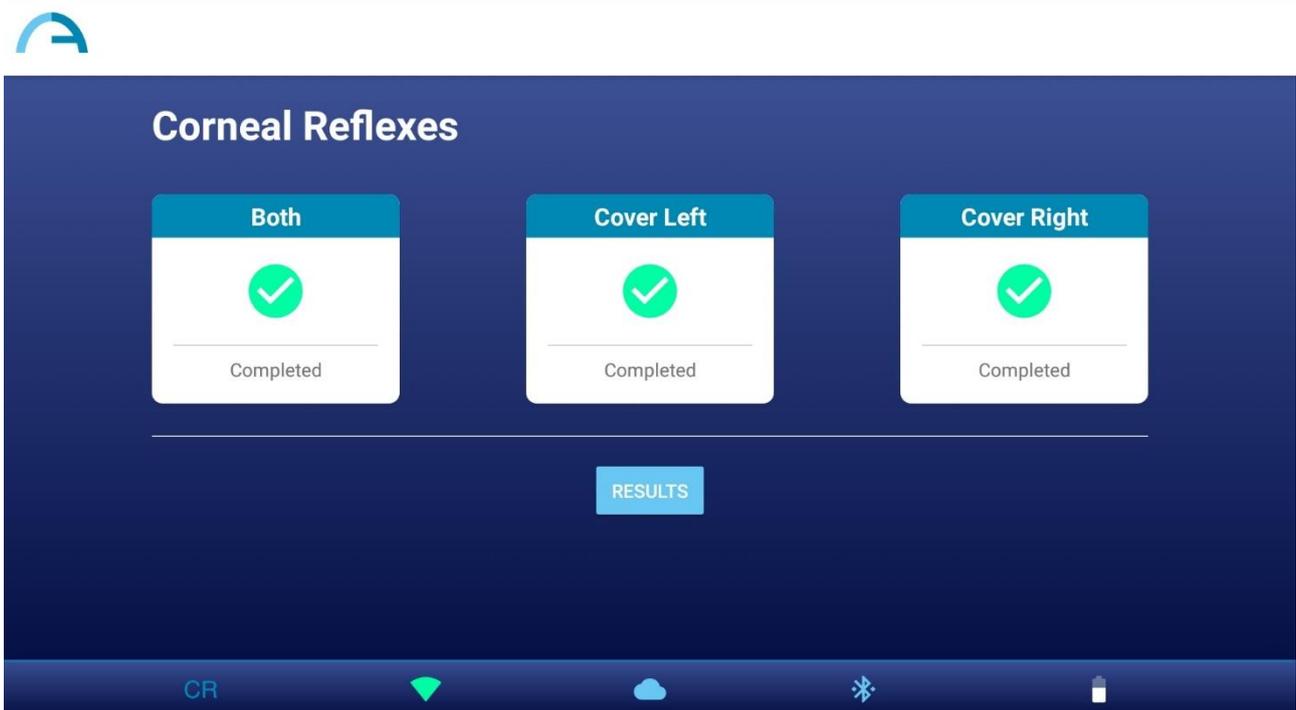


4. Corneal Reflexes measurement window opens.
5. Ask the patient to look inside the 2WIN-S and gaze at the white light. Press on one of the pause buttons to start the corresponding measurement. You can perform the three measurements in any order.

When you perform any of the cover tests use the IR occluder provided by Adaptica (NOT OTHER OCCLUDERS) to cover the contralateral eye.



6. When all the needed measurements are completed the button RESULTS appears. Tap on the button to see the patient's pupils shots and the exam results.



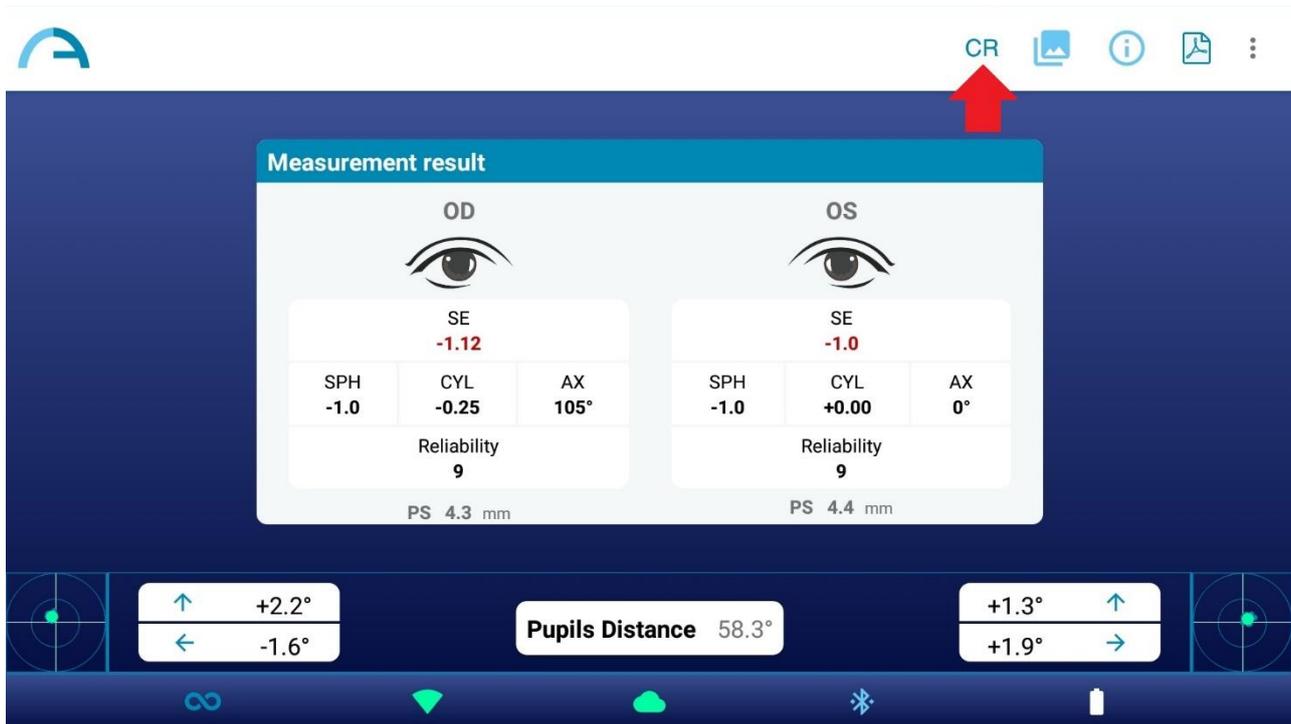
NOTE: You can repeat each measurement as many times as you want, just tapping on the corresponding button. After you press the button RESULTS you can't modify the measurements anymore.

7. In CR Measurement Result window the patient's pupils, acquired in the three measurements, are displayed. Next to the pupils the result of the cover test is reported. Please refer to the following paragraph for the interpretation of CR Measurement results.



8. Create the exam report by pressing on the PDF Report button on CR Measurement Result window.
9. To save the measurement press SAVE button on CR Measurement Result window. When the saving is complete a confirmation message appears.

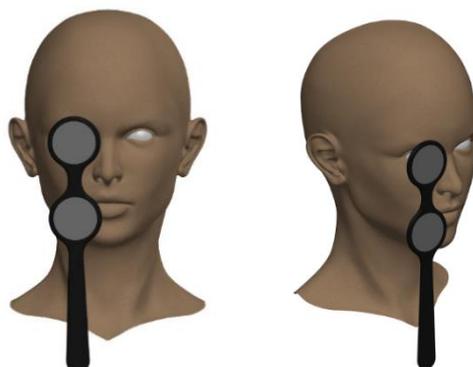
NOTE: You can also start a CR exam just after a 2WIN (Refraction) exam, by tapping on the CR button in 2WIN exam Measurement Result window. In this way, the CR exam will start with the same patient data used for the 2WIN (Refraction) exam.



NOTE: When you perform any of the cover tests use the IR occluder provided by Adaptica (NOT OTHER OCCLUDERS) to cover the contralateral eye.

Follow these instructions for the correct IR occluder positioning:

- Hold the occluder in a vertical position and with the handle downwards
- Hold the occluder using the ipsilateral hand to the covered eye (for example: hold the occluder with the right hand if you need to cover the right eye, and vice versa)
- Place the occluder in front of the eye, keeping the edge of the occluder in contact with the side of the nose
- Do not press the occluder against the eye: eyelid movements shall be possible and comfortable
- Look into KALEIDOS keeping the occluder in the correct position. Pay attention to fit KALEIDOS aperture: ambient light must not enter the device during the exam.



CR Exam Results

In the CR Measurement Result window three pairs of pupil images are displayed.

The images represent from top to bottom:

- Both eyes free (not covered)
- Right eye free, Left eye covered
- Right eye covered, Left eye free

NOTE: The covered eye is highlighted by a grey square.

From the pupil images it is possible to identify the position of the corneal reflexes with respect to the pupillary geometrical center.

When the position of the corneal reflexes, comparing the binocular test with the monocular infrared cover test of each eye, is not significantly changing (that is when the barycenter changes its position less than the 4DP threshold value) the output is **ORTHO**.

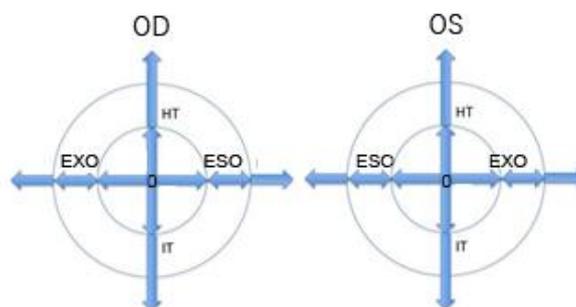
When a manifest asymmetry of the corneal reflexes is detected without cover test the output is: **ET** (esotropia) or **XT** (exotropia).

When an asymmetry of the corneal reflexes appears only under infrared cover test the output is: **EP** (esophoria) or **XP** (exophoria).

If a vertical deviation is present the output follows the same rules above exposed: **HT** (hypertropia), **IT** (ipotropia), **HP** (hyperphoria), **IP** (ipophoria).

The angle of deviation is expressed in Prism Diopters.

The following picture gives a graphical representation of the possible exam outputs:



WARNING: the messages ET, XT, EP, XP, HT, IT, HP and IP shall not be misunderstood as a diagnosis or a hint for diagnosis. For instance, a loss of fixation by the patient during the exam could cause an asymmetry not related to any pathology. The measurement shall in any case be used to refer the patient to an eye care professional for further evaluation.

The default output shows also a value for the k angle:

- **Horizontal k angle** (labelled as '**kx**'): the output is '+' when the corneal reflex lays nasal to the center of the pupil, '0' when the corneal reflex coincides with the geometrical center of the pupil, '-' when the corneal reflex is on the temporal side.
- **Vertical k angle** (labelled as '**ky**'): the output is 'S/D' when the corneal reflex of the left eye lays superior to the corneal reflex of the right eye, 'D/S' in the opposite case. When there is a vertical disparity inferior or equal to the established threshold, no vertical disparity message is given.

NOTE: Please note that cover test can be done both with an infrared occluder or with a conventional occluder. However, phorias can be detected and measured only with the infrared occluder.

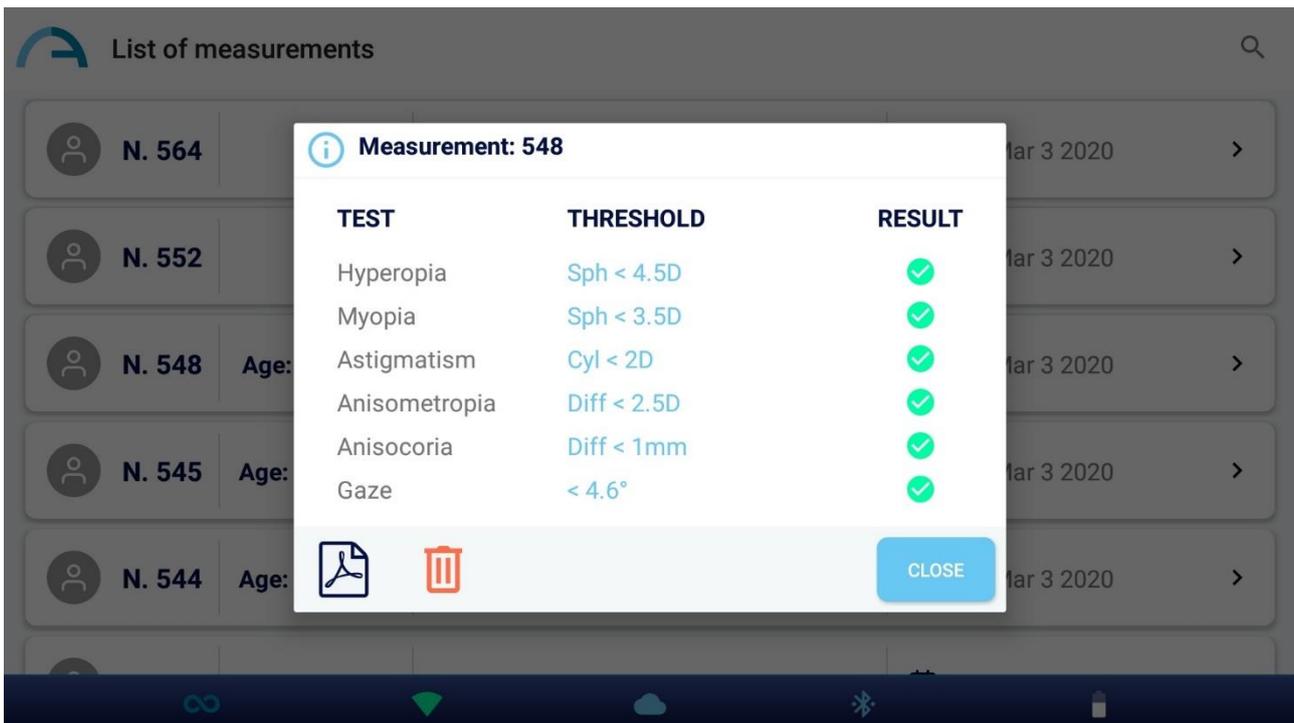
14.5 Review exams using KALEIDOS App

To browse previously acquired exams select “Check out latest measurements” from KALEIDOS App main window. The list of acquired exams is displayed.

| Icon | Measurement ID | Age | Measurement | Date | Action |
|------|----------------|---------------|-----------------------|----------------|--------|
| | N. 564 | - | CR Mode | Tue Mar 3 2020 | > |
| | N. 552 | - | CR Mode | Tue Mar 3 2020 | > |
| | N. 548 | Age: 0-2.5yrs | Measurement: BOTH | Tue Mar 3 2020 | > |
| | N. 545 | Age: 15-50yrs | Measurement: BOTH | Tue Mar 3 2020 | > |
| | N. 544 | Age: 15-50yrs | Measurement: LEFT_EYE | Tue Mar 3 2020 | > |

Exams acquired in 2WIN (Refraction) mode report the indication of the examined eye: both eyes, left eye or right eye. CR exams, instead, are marked with a “CR Mode” label.

Clicking on 2WIN (Refraction) exams it is possible to review the exam Screening Table and to open, share and print the PDF report.



Clicking on CR exams it is possible to open the PDF report, that can be also shared or printed.

Clicking on the bin icon it also possible to delete the selected exam.

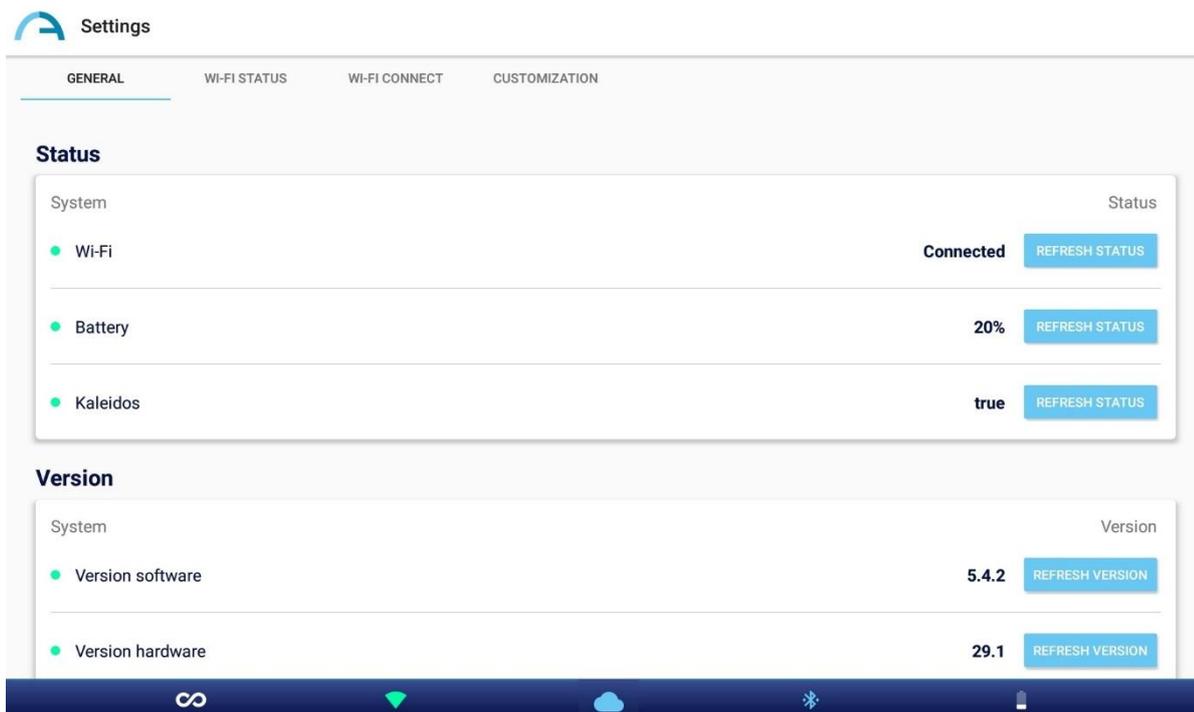
14.6 KALEIDOS App Settings

KALEIDOS App allows to read several parameters of the 2WIN and also to configure the WiFi connection. To enter Settings menu, select “App & device setup” from the Application’s main window.

GENERAL

In GENERAL tab the following information are displayed:

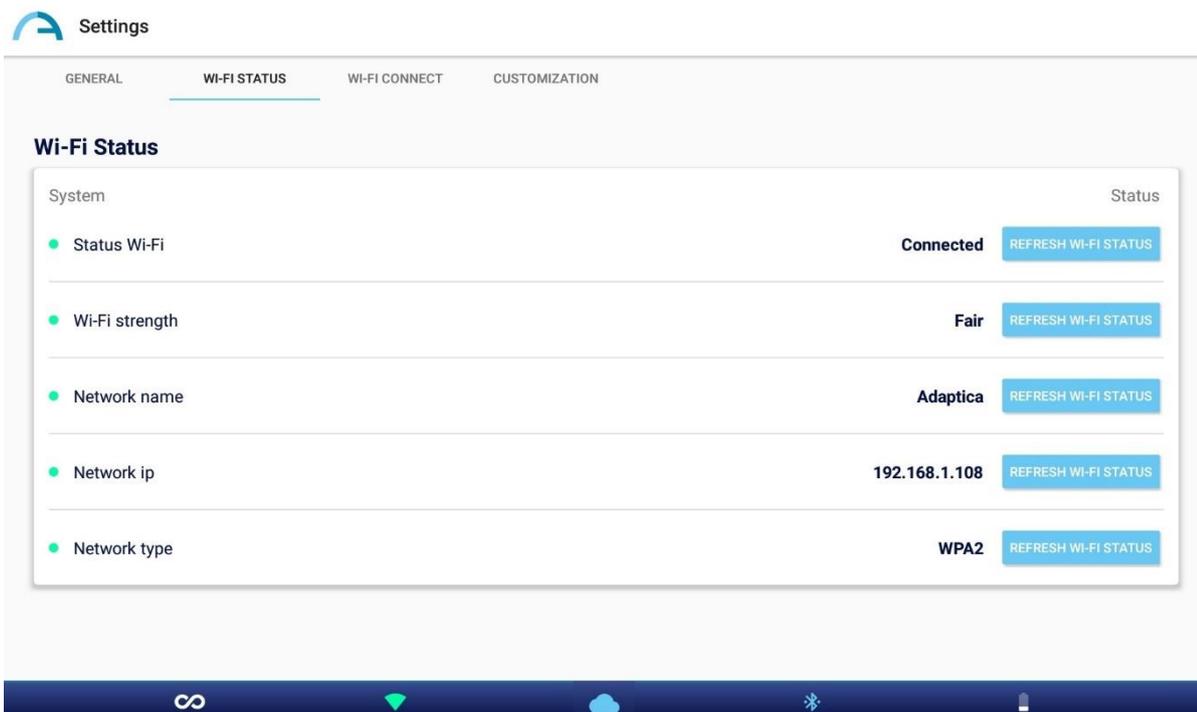
- **Status:** WiFi status, Battery status, Kaleidos mode
- **Version:** 2WIN’s software version, 2WIN’s hardware version, 2WIN BT protocol version, 2WIN’s serial number
- **System:** the button SHUT DOWN allows you to switch the 2WIN-S off



WI-FI STATUS

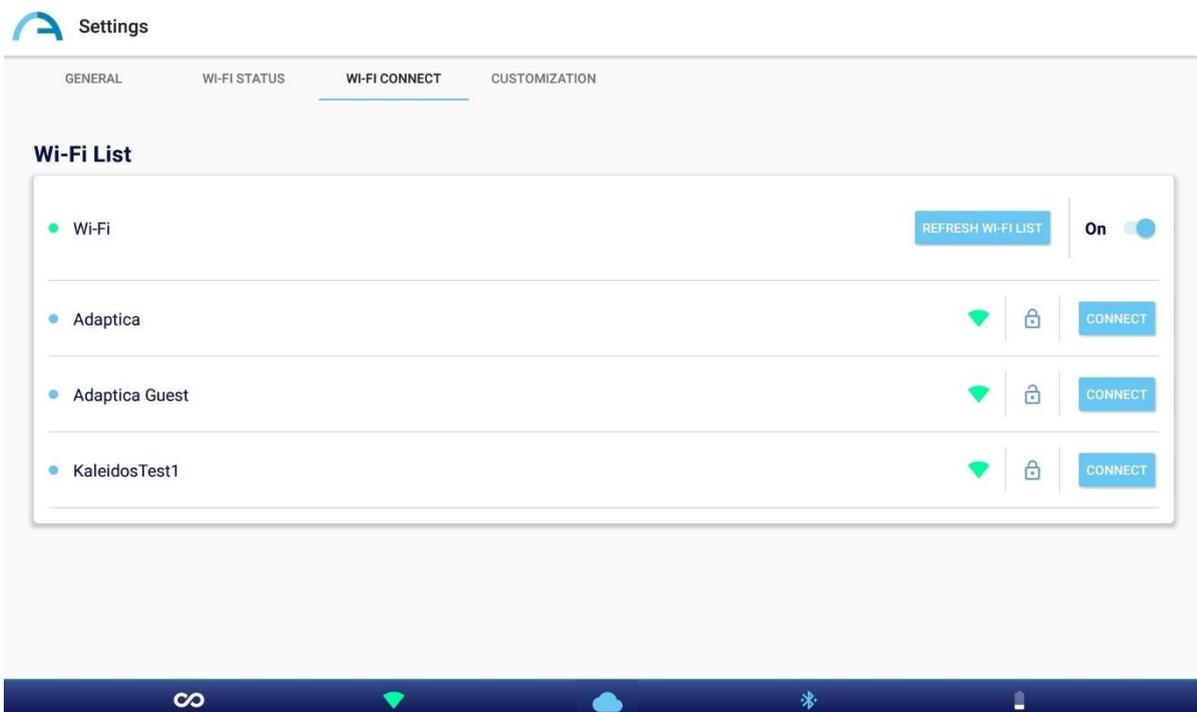
From WI-FI STATUS tab it is possible to get information about 2WIN's **WiFi connection**:

- WiFi status
- WiFi strength
- Network name
- Network IP
- Network type



WI-FI CONNECT

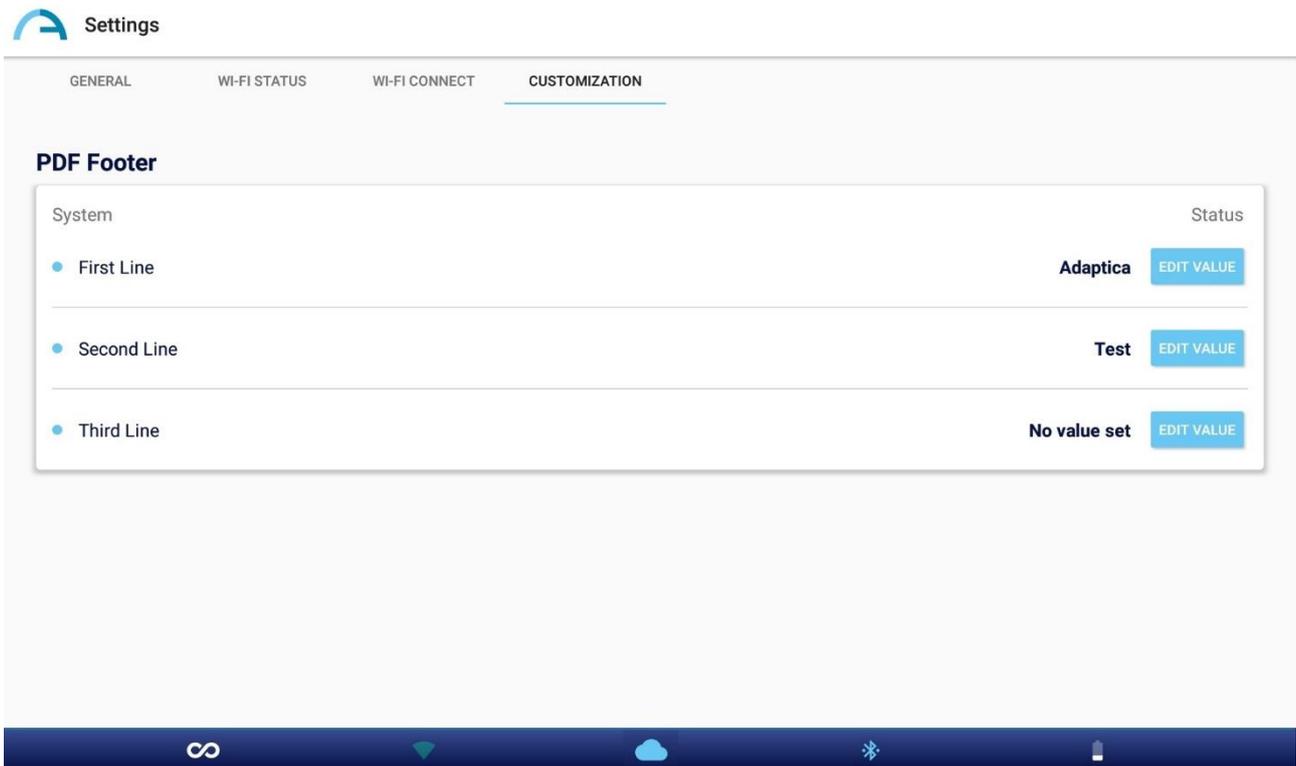
From WI-FI CONNECT tab it is possible to scan for the **available WiFi networks** and to connect to a WiFi network:



CUSTOMIZATION

From CUSTOMIZATION tab it is possible to customize the PDF report footer and to set up the EMR connection.

In order to customize the PDF report, you can edit up to three custom lines. These lines will be added to the report's footer.



In order to set up the EMR connection, please refer to Paragraph 14.7.

14.7 EMR connection setup

EMR connection feature allows to import patient data from an EMR system to the KALEIDOS App and to send automatically the exam results from the KALEIDOS App back to the EMR system.



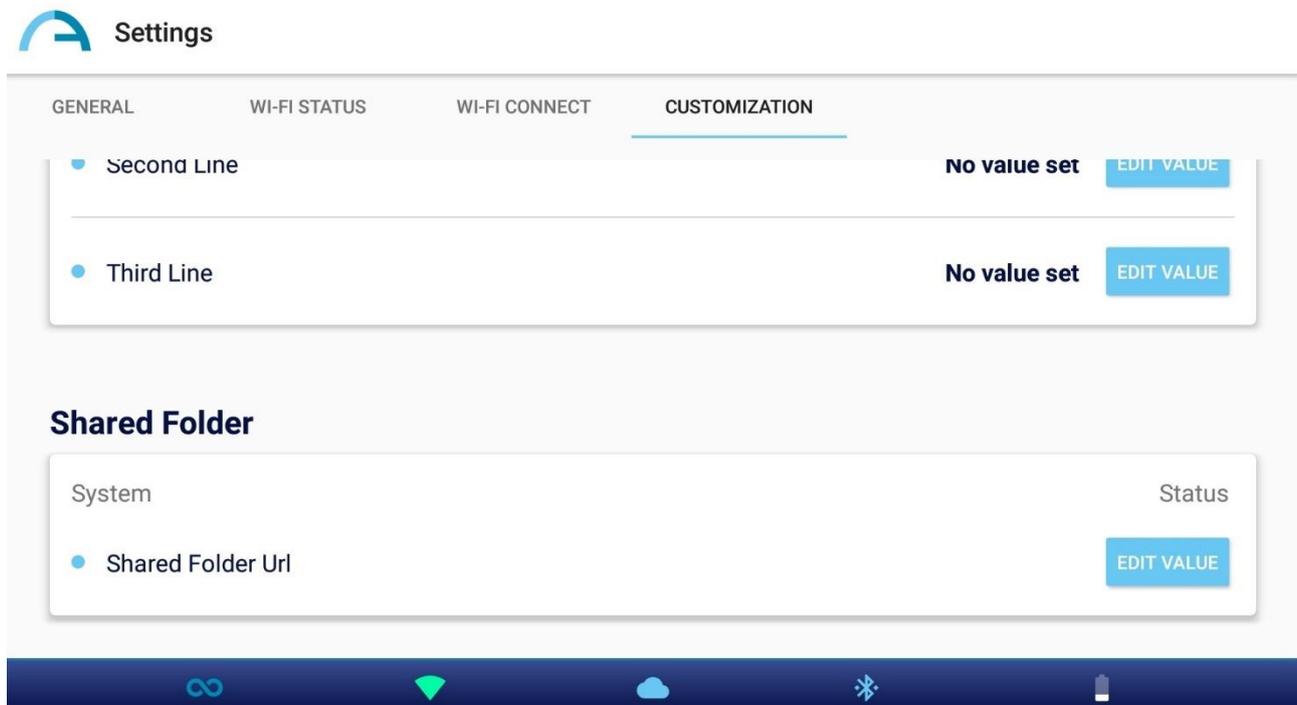
EMR connection feature is already active if you are using a KALEIDOS Plus. Otherwise, it requires an activation code. Please contact your local distributor to get the activation code.

To setup EMR connection follow these steps:

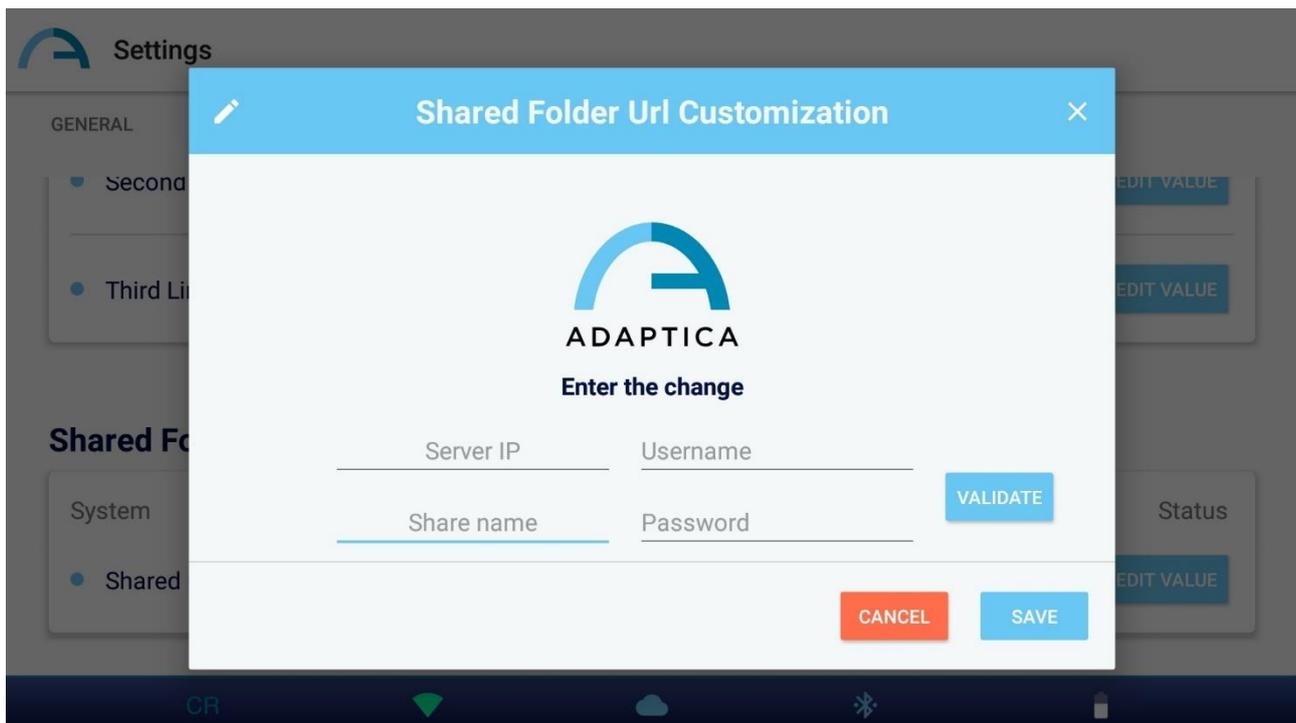
1. Be sure that the tablet running KALEIDOS App and the EMR system PC are connected to the same WiFi network.
2. Create a folder on the EMR system PC and share it on the network. This folder will be the Shared Folder.

NOTE: if you create the Shared Folder as a subfolder, you must share the subfolder only.

3. Run KALEIDOS App and tap on “App & device setup” icon, then select CUSTOMIZATION tab.



4. In the Shared Folder section, set the following values:
 - Server IP: the EMR system PC's IP address
 - Share name: the name of the Shared Folder to be paired to the current 2WIN-S
 - Username: a network user having read/write permissions on the Shared Folder
 - Password: the password for the selected user.



Pressing VALIDATE button you can check if the inserted data are correct.
Pressing SAVE button you will confirm the Shared Folder configuration.

5. Setup your EMR system so that it generates a CSV input file in the Shared Folder, containing the selected patient's data. Please refer to Appendix B of this Operator Manual for the CSV input file specifications.
6. Setup your EMR system so that it accepts data from the CSV output file created by KALEIDOS App after the measurement. Please refer to Appendix B of this Operator Manual for the CSV output file specifications.

Once the EMR connection setup is completed, follow these steps to start a measurement:

1. Select a patient in your EMR system. The CSV input file is automatically created in the Shared Folder.

2. Start a new 2WIN (Refraction) measurement from KALEIDOS App. KALEIDOS App imports the patient data from the CSV input file and displays the data. After the import is completed, KALEIDOS App will delete the CSV input file from the Shared Folder.

NOTE: KALEIDOS App is automatically checking the Shared Folder approximately every 2 seconds for a new input file.

3. If the patient data displayed in KALEIDOS App are correct, start the measurement.
4. Save the exam. The CSV output file containing the exam results is automatically created in the shared folder and it is retrieved by the EMR system. Then the EMR system deletes the CSV output file.
5. Review the patient's exam results on the EMR system.

 A CSV input file triggers an output file. If your EMR system does not provide an input file in the Shared Folder to begin with, your device will not write output files, and the Shared Folder will remain empty.

 Once a CSV input file is provided, the manual entry of patient data in the KALEIDOS App user interface is disabled.

 Once a CSV input file is provided, the exam will start when the home page of KALEIDOS App is displayed.

 You can manage multiple 2WIN-S on the same EMR system. Different 2WIN-S devices work on different Shared Folders, so you must create a dedicated Shared Folder for each 2WIN-S.

15 Applications (Packages)

It is possible to increase the 2WIN capabilities/functions with the installation of additional software packages (from version 4.0 the new name of these packages is “APPLICATIONS”); Each Application will be described at the end of this manual. You will be notified via email about the availability of a new 2WIN software Application. In this document it is described the installation/management of additional Applications.

15.1 Installation

Send an e-mail for an Application request with the serial number of your 2WIN. The complete list of 2WIN software Applications at www.adaptica.com.

A file will be sent to you by mail; copy this file in the root of your SD card. After copying, restart the 2WIN.

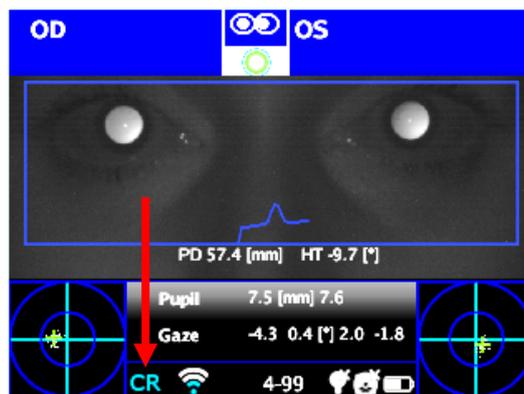
15.2 Activation

After the installation, the Application will be not enabled by default. To activate the Application earlier installed, navigate the menu to Menu>Functions>2WIN Applications and see all installed Applications.

Push right the CROSS button to go into the submenu and select the item that you want to activate.

Push the CROSS button in the centre to activate the Application.

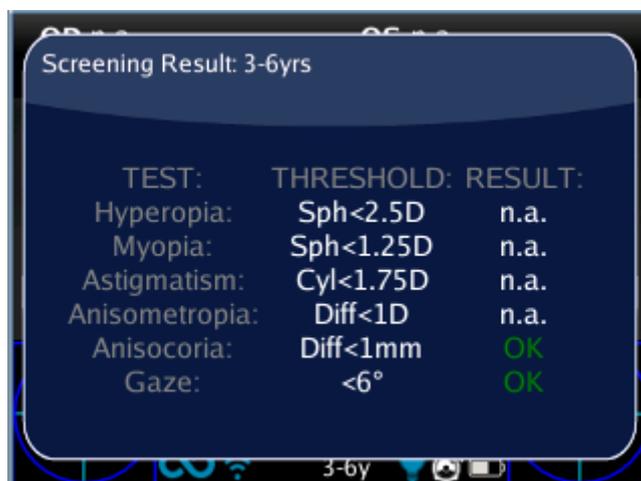
The icon of the main Application active for the main visualization window is well visible in the status bar.



Icon of the main Application active

15.3 Auxiliary Windows

From Main Screen of 2WIN, push right the CROSS button to display the Auxiliary window (default is screening result).



| TEST: | THRESHOLD: | RESULT: |
|----------------|------------|---------|
| Hyperopia: | Sph<2.5D | n.a. |
| Myopia: | Sph<1.25D | n.a. |
| Astigmatism: | Cyl<1.75D | n.a. |
| Anisometropia: | Diff<1D | n.a. |
| Anisocoria: | Diff<1mm | OK |
| Gaze: | <6° | OK |

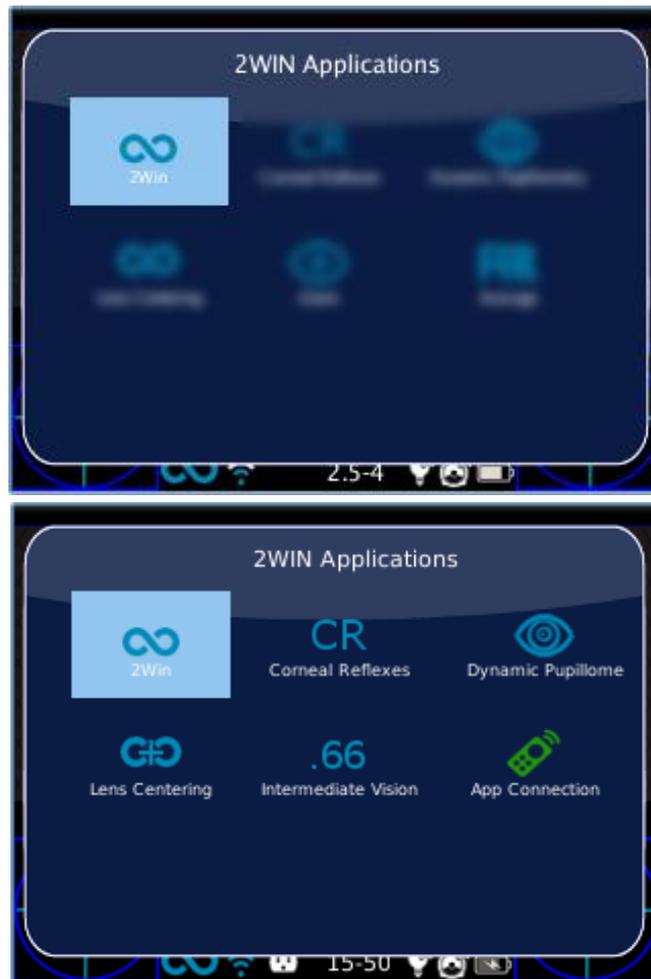
es. Screening Results

Press BUTTON B (print button) to display the Auxiliary Window choosing tab. With LEFT and RIGHT buttons you can choose your preferred window. (Note: you can select the default Auxiliary Windows to be showed by pressing up the CROSS button. The Application will be highlighted, so that by pushing LEFT or RIGHT you can move it in the preferred position. The Application on the left is the default Auxiliary window showed. Press up again to exit the moving option).

15.4 Modes (2WIN Applications)

Modes selection in 2WIN

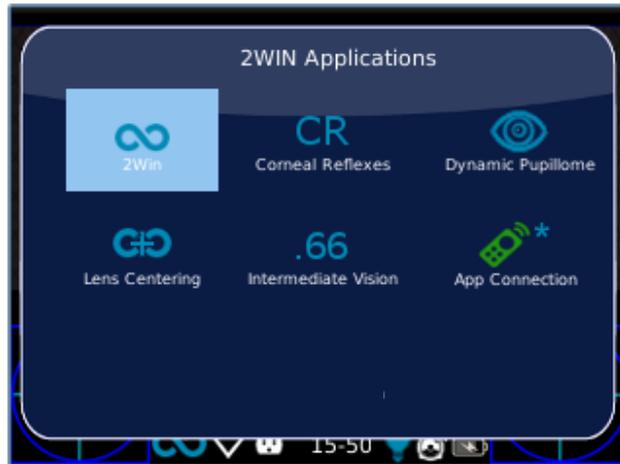
If you click the BUTTON A (On/Off) Modes screen will be shown to display (from version 4.0 this window is called 2WIN Applications)



There are two sets of icons: regular ones and green ones. The latter are options of the 2WIN that, if enable, permit to the instrument to add some special functionality. E.g. the App Connection icon (green icon) means that in that particular 2WIN is enabled the communication with a controlling APP in an external Android Tablet.

It is possible to navigate and to see all installed Applications into the device. By clicking with the cross BUTTON on the Application icon, this Application will be the principal one in Main Display and it will be set first in Auxiliary Windows automatically.

If close to a specific icon in the 2WIN Application window a *-symbol is present, this condition means that in the instrument is not installed that particular Application or enable that specific (green) feature. In the next figure an example of this situation.



If the user tries to activate a specific 2WIN App that have the *-symbol, the 2WIN shows a warning message like the next figure.



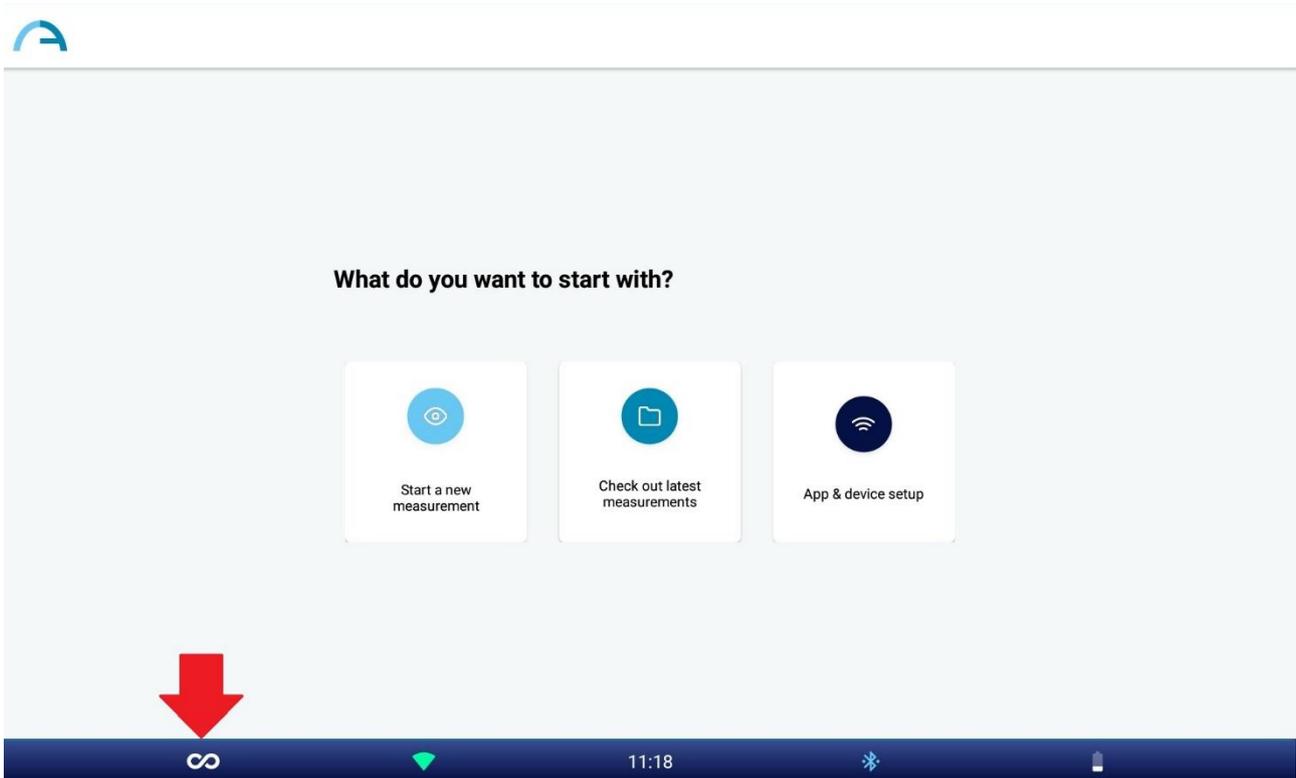
The message suggests the user to send an email to the contact address of Adaptica: contact@adaptica.com in order to purchase the specific Application.

NOTE: To change Application settings navigate the menu to Menu>Functions>2WIN Applications and select the item that you want to set into the submenu related to your Application.

NOTE: When an Application generates a notification, the notification centre shows a P like icon to show that the notification comes from Applications.

Modes selection in KALEIDOS App

To switch between different acquisition modes in KALEIDOS App tap on the Application icon on the home page of the Application:



“Measurement Type” dialogue window appears. Select the desire mode and press SAVE button. When a particular mode is selected the Application icon in the home page of KALEIDOS App changes and displays the icon on the selected mode.

NOTE: Default mode is 2WIN mode. When KALEIDOS App is restarted 2WIN mode is loaded.

16 Manual Software upgrade instructions

In case of future software releases to upgrade the 2WIN, the user will be contacted by means of an information note (email/fax/phone call) containing the description step by step of the instructions to upgrade the device.

ATTENTION: the operator is not allowed to perform a DOWNGRADE of the 2WIN software. Adaptica is not responsible for the improper use of the device with a downgraded software version.

ATTENTION: when the software update procedure will be performed, the 2WIN battery must be fully charged.

17 Automatic Software upgrade procedure



In order to exploit automatic update 2WIN must be connected to a Wi-Fi network with internet access.

An automatic software upgrade procedure is available for 2WIN. If a new software version is released and the 2WIN is connected to the Wi-Fi network with internet access the upgrade procedure will prompt the user.

At 2WIN start-up, when a network connection with internet access is available, the system checks if a new system update is available. If a new software is released for your machine, a message will appear. The new software version and release date are reported and it is possible to decide to download it or not.



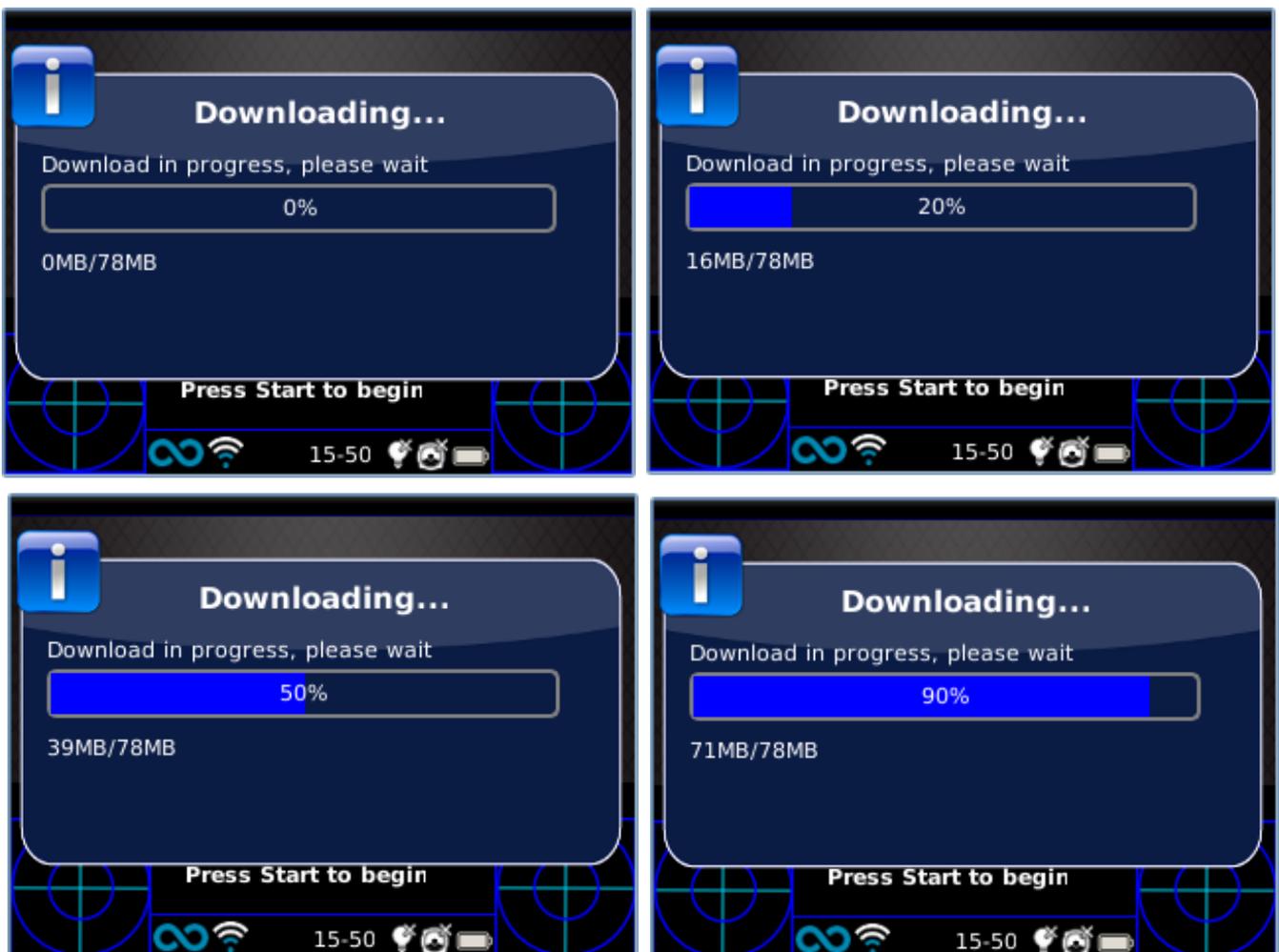
 NOTE: make sure that the microSD card is inside the 2WIN, and that the 2WIN is not connected to any PC with USB cable before proceeding.

 NOTE: make sure that 2WIN or 2WIN-S battery is fully charged before starting the software update procedure.

If you decline the update pressing CANCEL the message will disappear until next update check, if you want to update your 2WIN press OK button, and the software download will start.

Software update size is about 80MB, with a standard ADSL/VDSL/FIBER connection the download should take just few seconds or minutes, depending from the internet access speed.

 NOTE: please do not remove the battery or the microSD card during this procedure.



After the download, 2WIN will extract the update inside the microSD card, this procedure takes less than a minute and the 2WIN will show you a waiting message until extraction has finished.



NOTE: please do not remove the battery or the microSD card during this procedure.



After the extraction file, 2WIN will prompts the request of immediate or delayed installation. If OK button is pressed, 2WIN will restart and run the system update. Press the CANCEL button to delay the update (the update will take place at next 2WIN reboot). System update will start at next startup.

If the 2WIN is in 2WIN-S configuration, inside a KALEIDOS accessory, after the system update, the 2WIN will restart again for the KALEIDOS firmware update.



NOTE: 2WIN after firmware upgrade may reboot one or two times, depending from the firmware version. Wait for the end of the procedure without removing the SD card of the device and without switching the device off.

18 Disinfection

When using the KALEIDOS accessory, in the 2WIN-S configuration, it is necessary to disinfect the area where the face of the patient will contact the device, before any change of patient.

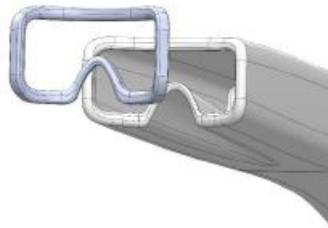
Disinfection should be achieved by means of single-use disinfecting pads, such as individually wrapped sterile Alcohol Wipes, with 70% ethyl alcohol, or other single-use antiseptic sanitizer swab, rubbing it onto all the contact surface of the KALEIDOS mask, according instructions provided by swab labeling, and in any case for at least 1 minute.

Reusable pads are to be avoided.

The disinfection procedure here described is conceived to avoid transmission of pathogens from and to intact skin. Special precautions must be applied to avoid the contact of wounded skin with the device.

For further indication please check:

<https://www.cdc.gov/infectioncontrol/guidelines/disinfection/>



19 Maintenance and cleaning instructions

No maintenance operations are required by the system.

The system may be periodically verified, by means of a procedure called “white fielding”. For such verification follow these instructions:

1. Take a commonly used A4/letter/legal printer/copy machine white sheet of paper and place it at 1 m distance from the instrument;
2. Turn on the system, enter the menu and then the Functions/Aux sub-menu;
3. Select White Fielding option;
4. Start an acquisition while pointing the system to the white sheet of paper;
5. A message will appear showing the test result;

19.1 How to clean the system

If necessary, it is possible to clean 2WIN with a lightly moist microfiber cloth in the external chassis.

It is recommended to clean 2WIN lenses at least once a year – more frequently if 2WIN is exposed to dust. Use compressed air to clean 2WIN’s frontal objective (compressed air cans for cleaning computers are fine).

Do not use solvents, sprays or alcohol to clean the system.

2WIN-S face cushion shall be disinfected before each patient change, to avoid patient contamination by infectious agents. For 2WIN-S disinfection, please follow instructions provided on Chapter 18 of present manual.

19.2 Storage instructions

The device needs to be stored under the following environmental conditions:

Temperature: -10 – 60 C° (14 – 140 F°)

Humidity (max): 90% not condensing

19.3 Instructions for correct disposal of the device

The device is made of different materials, such as plastics, aluminium, electronic parts: in case of instrument disposal, please separate the various materials and follow the laws and regulations regarding disposal or recycling for each material effective in your own country.

19.4 Separate collection for electrical and electronic equipment

The European Directive 2002/96/EC establishes the separate collection for Waste of Electrical and Electronic Equipment (WEEE). The users of Electric and Electronic Equipment (EEE) have not to dispose of WEEE as unsorted municipal waste, they have to collect such WEEE separately. The available return and collection system is defined by the local public administration, or in alternative an authorized company can recycle the WEEE. Please refer to public administration about the separate collection, if this information is not available, contact the manufacturer of the equipment.

Users have a fundamental role in contributing to reuse, recycling and recovery of WEEE. The potentially dangerous substances contained in the WEEE can pollute the environment and produce harmful effects to the human health.

Below, there are a few indications of specific dangers of some substances, which may leach in the environment and in the water system.

- Lead: damages the nervous system of humans, it affects the endocrine system, the cardiovascular system and kidneys. It accumulates and is very toxic for animals, plants and micro-organisms.
- Cadmium: accumulates with a half-life of 30 years and can damage the kidneys and cause cancer.
- Mercury: it is easily accumulated in organisms and concentrates through the food chain. It has chronic effects and can cause brain damage.
- Chromium (Hexavalent): easily absorbed into cells with toxic effects. The results can be allergic reactions, asthma and it is considered to be genotoxic (damages the DNA). Especially dangerous when incinerated.
- Brominated Flame Retardants: widely used to reduce flammability (e.g. cables, connectors and plastic cases).

19.5 Instructions for correct disposal of 2WIN and 2WIN-S packaging

2WIN and 2WIN-S packaging is made of expanded polyethylene foam, which is present inside the device suitcase and between the suitcase and the shipment box.

Such foam is eco-friendly and 100% recyclable.

20 2WIN Applications specific manuals

20.1 Legend of symbols

| | |
|---|---|
|  | Warning: necessary information for safety |
|  | Important information |

20.2 2WIN Applications installation

To install 2WIN Applications follow these steps (which are the same for every Application):

1) Connect the 2WIN, with MicroSD plugged in, to your computer with the USB cable;



NOTE: if 2WIN is turned off, wait till it turns ON automatically once connected to USB cable.

2) A new device will appear on the computer where you attached the 2WIN.

- Drag and drop the file “2WIN Applications.2wp” on the new device icon or with the file Explorer of your computer copy the file “2WIN Applications.2wp” and past it in the Root directory of the new device.



- safely remove the device from your pc;
- unplug the USB cable from the 2WIN and from the PC;
- turn the 2WIN off;

3) turn the 2WIN on;

4) the 2WIN Application is now available for activation;

20.3 Corneal Reflexes Application (CR-App)

This function provides information regarding the corneal reflexes position, giving hints about possible phorias and tropias up to 30 prism diopters. CR-App feature allows to collect data from 3 measurements (one binocular and two cover tests under an IR occluder) and to analyze the corneal reflexes.

Results are expressed either in prism diopters or in degrees.

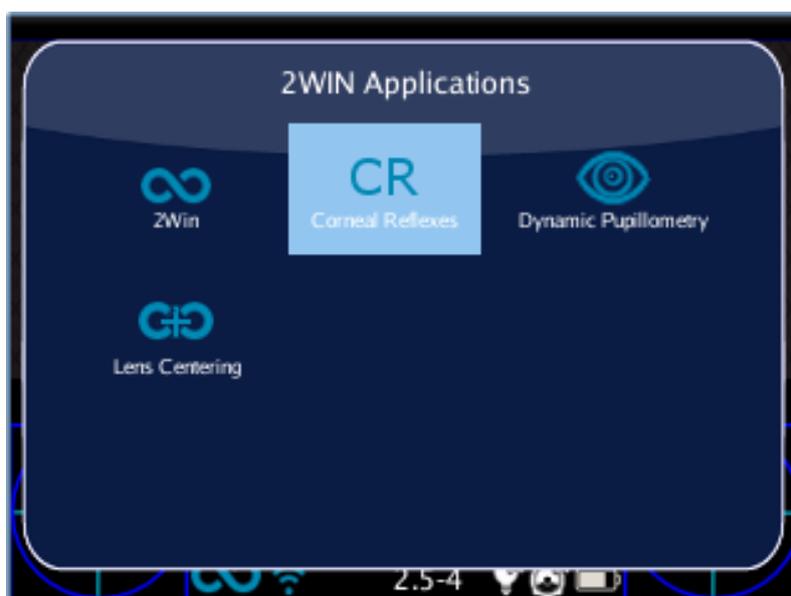
Corneal Reflexes App activation

After the installation this App must be activated to be utilized.

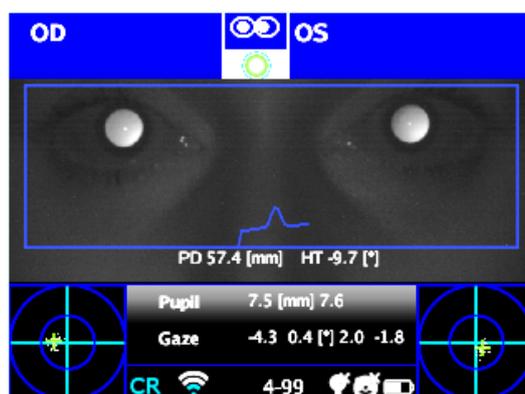
Activation: click the BUTTON A () 2WIN Applications screen will be shown to display.

Doing this, it is possible to navigate and to see all installed Applications into the device.

By clicking with the cross BUTTON on the corneal reflexes Application icon, this Application will be the principal one in Main Display and it will be set first in Auxiliary Windows automatically.



Modes screen



Corneal Reflexes exam

Tips for the patient

Patient must gaze the White led that turns on during measurement with 'Corneal Reflexes'.



Exam procedure

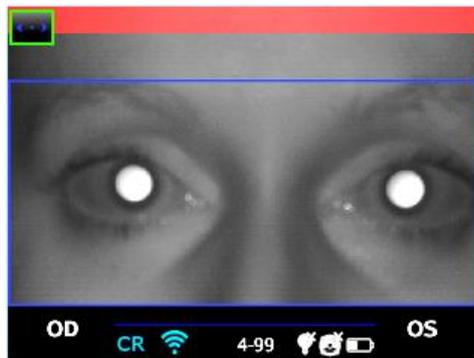
The procedure is the same as refraction measurements (however, the single acquisitions are much faster as the Application is dedicated to eye alignment and not to refraction measurement)

Use the top bar that gives feedback on the conditions for measurement: in particular, this bar becomes red or green. When the bar is red, there are no conditions to acquire the images correctly, on the contrary, when the bar is green, correct conditions for measuring are satisfied and images can be acquired and processed correctly.

Measurement tips: usually the RED condition depends on a bad distance between the 2WIN and the patient. When the top bar is RED adjust the distance between the 2WIN and the patient in order to focus the image and to obtain a GREEN top bar.

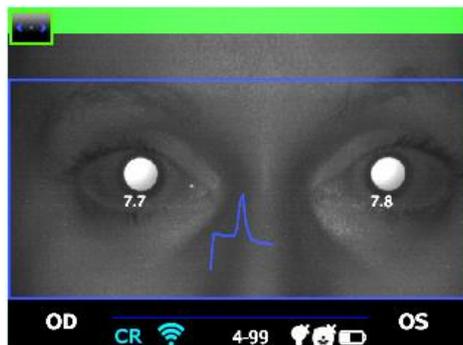
The steps to perform a measurement are summarized in the following list:

1. Once the conditions for the measurement are met, hold the device in your hands and point it towards the patient.
2. Press and hold BUTTON S1 or S2, in order to start the measurement.
3. Center the eye/s of the patient in the display live area, inside the blue rectangle (measurement area) – the message “FOCUSING” will appear.



Examination screen – bad focus

4. Adjust the distance to focus the image until the top bar is green (for details on screen tips also see: Verify the position of the subject in 2WIN Operator Manual).
5. When the top bar is STEADILY green release the BUTTON S1/S2 – the message "MEASURING" " " will appear. PLEASE hold the 2WIN position until the message DATA PROCESSING appears on the display.

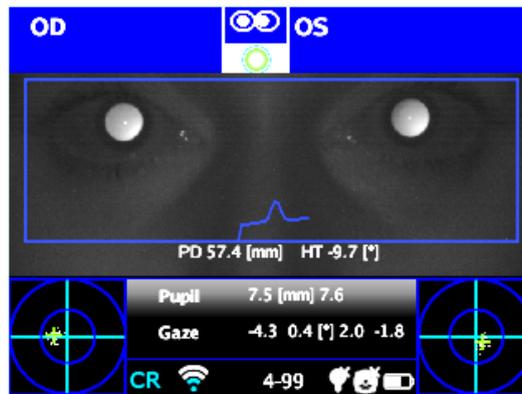


Examination screen, top bar green - focus OK



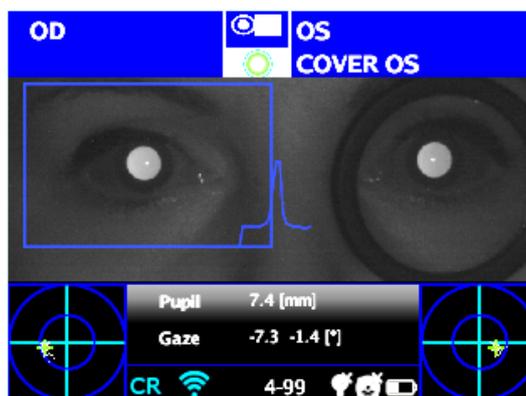
Data Processing

6. After the measurement a green indicator on the top bar of the display, at the center, will give you the feedback of correct measurement:



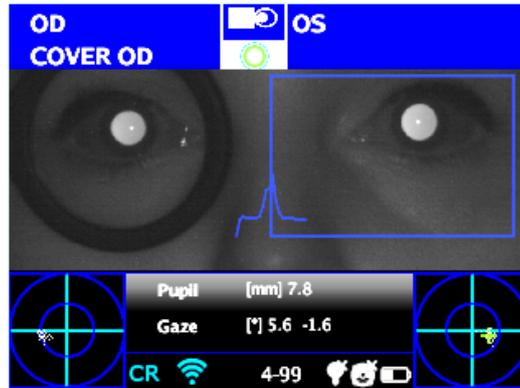
Green Indicator

7. Click the BUTTON C () and select the eye where you want to perform the cover test, using the Binocular Occluder provided by Adaptica (NOT OTHER OCCLUDERS) to cover the contralateral eye.



Cover OD

- Repeat the steps 1 to 6 to get the measurement.
- Click the BUTTON C () and repeat the procedure on the other eye, moving the eye occluder onto the contralateral eye.



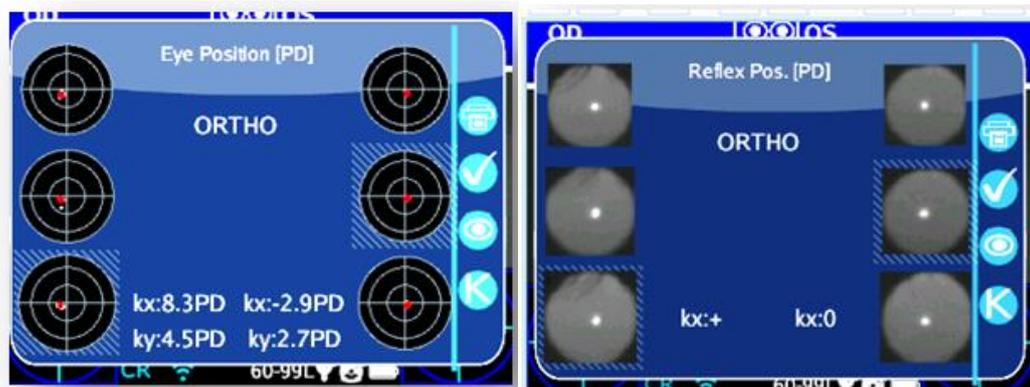
Cover OS

- Repeat the steps 1 to 6 to get the measurement.

Exam Results from 'Corneal Reflexes' App

Once completed the test, auxiliary window for the corneal reflexes analysis is opened automatically (Menu > Functions > 2WIN Applications > Corneal Reflexes > Options > Show at End).

This is an example of exam results of Reflex Symmetry Application:



There are 2 columns with 3 circles, on the left and right side, related to the left and the right eye information. The size of the circle is proportional to the pupil size.

The images represent from top to bottom:

- both eyes free (not covered)**

- right eye free, left eye covered
- right eye covered, left eye free



The covered eye is highlighted by a light blue square.

The cloud of points in each image graphically reports each individual corneal reflex collected during the exam.

The red marker point in the mean of each distribution is the average position of the corneal reflexes.

Note that the operator can switch between this description (barycentral fixation) to the simple pictures of the pupils just pressing the EYE button on the 2WIN.

When the position of the corneal reflexes comparing the binocular test with the monocular infrared cover test of each eye is not significantly changing, that is when the barycenter changes its position less than the threshold value (mm) selected in the settings (*Menu > Functions > 2WIN Applications > Corneal Reflexes > Options > Threshold*), the output is "ORTHO".

When a manifest asymmetry of the corneal reflexes is detected without cover test the output is **ET**: esotropia; **XT**: exotropia.

When an asymmetry of the corneal reflexes appears only under infrared cover test the output is **EP**: esophoria; **XP**: exophoria.

If a vertical deviation is present the output follows the same rules above exposed (**HT**: hypertropia; **IT**: ipotropia; **HP**: hyperphoria; **IP**: ipophoria).



WARNING: the messages ET, XT, EP, XP, HT, IT, HP and IP SHALL NOT be misunderstood as a diagnosis or a hint for diagnosis. For instance, a loss of fixation by the patient during the exam could cause an asymmetry not related to any pathology. The measurement shall in any case be used to refer the patient to an eye care professional for an evaluation.

The angle of deviation can be expressed either in prism diopter (**PD**) or in **degrees** (°): to change Notation **Menu > Functions > 2WIN Applications > Corneal Reflexes > Options > Notation**). K angles values are displayed on the bottom of the auxiliary window.



Please note that cover test can be done both with an infrared occluder or with a conventional occluder. However, phorias can be detected and measured only with the infrared occluder.

The default output shows the following:

- **Horizontal k angle** (labelled as 'kx'): the output is '+' when the corneal reflex lays nasal to the centre of the pupil, '0' when the corneal reflex coincides with the geometrical centre of the pupil, '-' when the corneal reflex is on the temporal side.

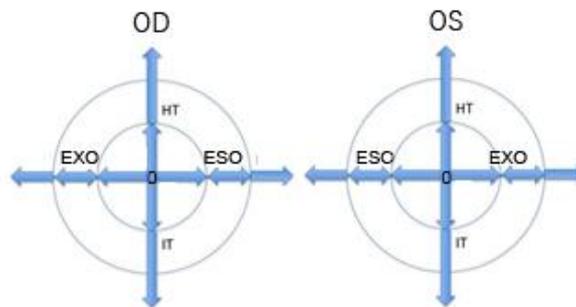
- **Vertical k angle** (labelled as 'ky'): the output is 'S/D' when the corneal reflex of the left eye lays superior to the corneal reflex of the right eye, 'D/S' in the opposite case. When there is a vertical disparity inferior or equal to the established threshold, no vertical disparity message is given.

By clicking on the C button (), it is also possible to toggle between this and a second layout, where k-angle is expressed in terms of its horizontal e vertical coordinates.



Default threshold levels are factory set to 5DP for the kx output and to 4DP for the ky output. Threshold values can be changed from Menu > Functions > 2WIN Applications > Corneal Reflexes > Options > Threshold.

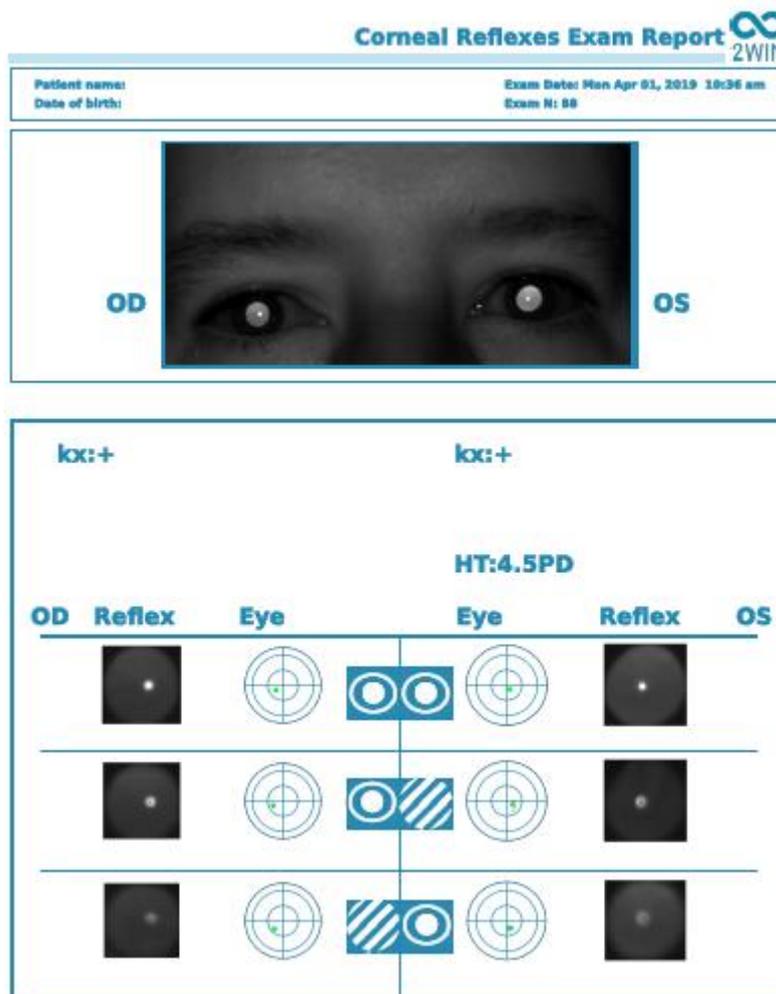
The following picture gives a graphical representation of the codes:



Exam print

Results can be saved on SD memory by clicking the B button () directly from the Auxiliary window displayed.





An example of Corneal Exam Report (PDF)

In the printout the results are displayed in degrees or prism diopters, the concentric circles representing 10 units steps of that unit (10, 20, 30 Prism diopters or degrees). The pupil is sized accordingly and cropped if bigger than 7 mm. In the report is also possible to see all the pupil pictures.

Measurement reset

If you want to perform a new examination or to avoid results just made, measurement may be reset in three ways:

- By choosing a new Application
- By clicking Reset from Menu > Functions > 2WIN Applications > Corneal Reflexes > Reset



Reset in Corneal Reflexes

New measurement overwrites old data with new data automatically.

20.4 Dynamic Pupillometry Application (DP-App)

This function provides information regarding the pupils response (diameter during time) when the eyes of the patient are stimulated with a known visible and programmable white light created by the 2WIN.

The visible stimulus light can be programmed by the operator in intensity and duration.

Results are expressed in a graphical image showing the pupil response to the visible stimulus and through some parameters showing the estimation of pupil response time, reaction time and slopes of the changes of diameter versus time.

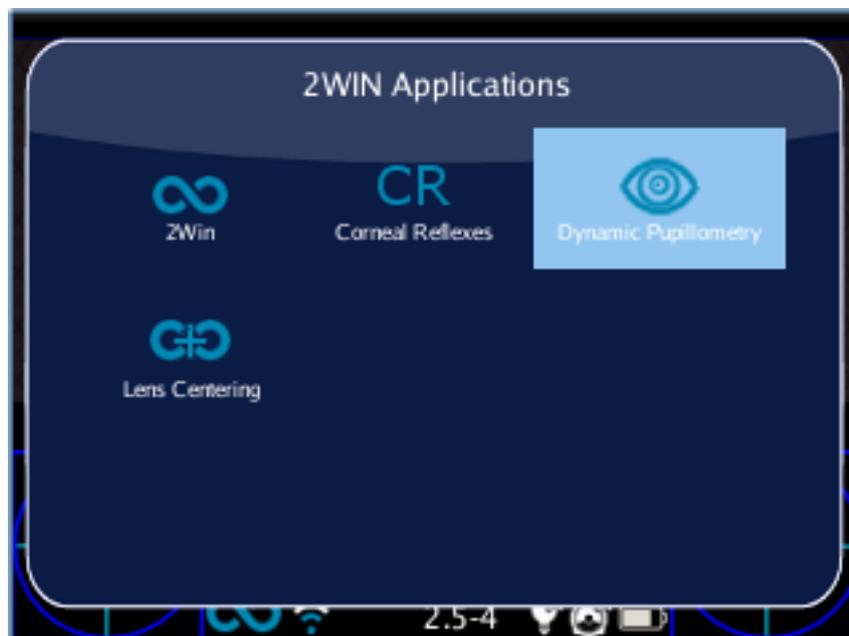
Dynamic pupillometry Application activation

After the installation this Application must be activated to be utilized.

Activation: click the 2WIN BUTTON A () 2WIN Applications screen will be shown to display.

Doing this, it is possible to navigate and to see all the installed Applications into the device.

By clicking with the cross BUTTON on the Dynamic Pupillometry Application icon, this Application will be the principal one in Main Display and it will be set first in Auxiliary Windows automatically.



Dynamic Pupillometry exam and modes

There are three operative modes for this Application:

- 1) **Default mode:** This mode makes a first calibration of the eye response values taking into account also the ambient illumination
- 2) **Manual mode:** the operator can configure manually the set of visible light stimuli. The duration of each stimulus lasts minimum 2 seconds. For configuring this mode, the operator has to write a TEXT file in a normal text editor in a computer and save that file in the SD memory of the 2WIN.
- 3) **Calibration mode:** like the Manual mode, this exam mode needs a configuration file written in the SD card of 2WIN. At the beginning of the exam this mode illuminates the patient with 4 calibration impulses in order to understand automatically the good final exam impulse. This final light signal will be used in the last part of the measurement. 2WIN takes into account also the ambient light, on this base 2WIN decided to use the 50% of the intensity or not in the first calibration pulses and in the final one.

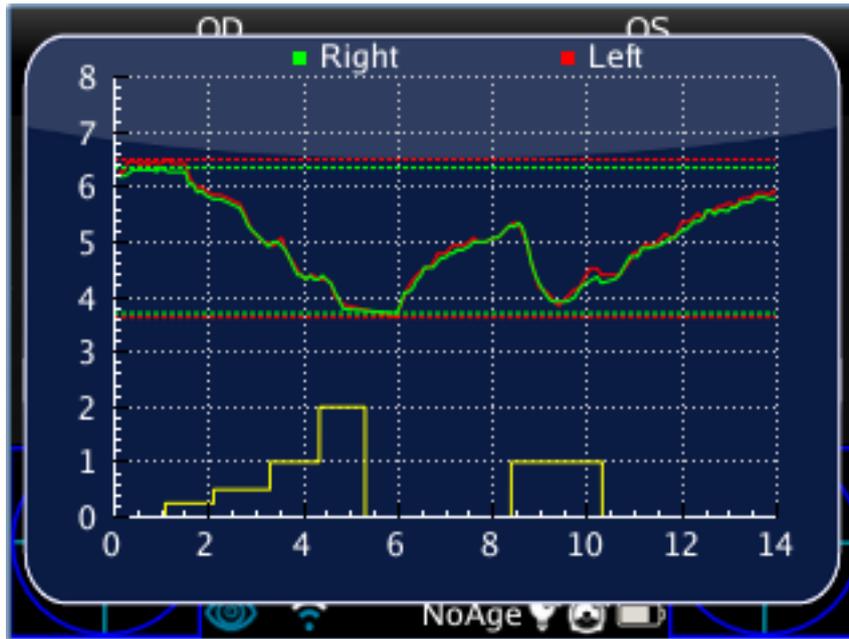
The overall measurement lasts 14 seconds in all the operative modes.

Exam procedure

The procedure to take the exam is the same as the normal 2WIN refraction measurements. There's a slight difference related only on the 2WIN graphical interface.

FOCUSING PHASE: start the focusing aiming at the two eyes of the patient keeping pressed the S1/S2 button of the 2WIN. Move the 2WIN toward or backward and try to maximize the length of the color moving bar on the bottom of the user interface. When you reach the maximum, please release the S1/S2 button in order to start the measurement phase;

MEASUREMENT PHASE: the patient shall stay in the position.



When you released the S1/S2 button till the exam automatically finish (after 14 seconds).

Standard mode

The standard mode is activated in the Dynamic Pupillometry Applications only if the right configuration file is not present in the 2WIN SD card or if this file is corrupted. The standard mode creates (after a dark second) a sequence of 4 bright light impulses. During these pulses 2WIN detect the pupillary reaction. If the pupil diameter, during any of the 4 pulses, decreases below the 10% of the initial state (when the measurement begins) or it reaches a dimension less than 3.5mm then the initial calibration of this mode stops and then a final bright pulse will be turned on (in this case this pulse will have double intensity compared to the last that caused the stop of the calibration). Moreover, if the ambient light is too low all the pulses (calibration and final one) will be reduce by half (in this case in the display of 2WIN the maximum value will be 1 instead of 2).

Manual mode

In order to activate this operating mode the operator has to write with a text editor a file (named pupilresponse.txt) and copy it in the SD memory of the 2WIN.

The file must contain 7 rows, each row represents a 2 seconds phase of the measurement. The numerical value to be written in the raw represents the intensity of light in a scale spanning from 0 to 100.

Example configuration file

```
0
8
0
16
0
32
0
```

This file creates the following sequences of exam phases:

- Phase1 = dark condition (no visible illumination), 2 seconds
- Phase2 = 8% of the maximum visible light is turned on, 2 seconds
- Phase3 = dark condition, 2 seconds
- Phase4 = 16% of the maximum visible light is turned on, 2 seconds
- Phase5 = dark condition, 2 seconds
- Phase6 = 32% of the maximum visible light is turned on, 2 seconds
- Phase7 = dark condition, 2 seconds

NOTE that any value greater than 100 value will be considered 100%, while 0 stands for dark condition. The configuration file will not be considered if there will be a different number of rows or different kind of characters, 2WIN will use the standard measurement mode in this case.

Calibration mode

In this operating mode it is necessary to edit a file “pupilresponse.txt” and copy it in the SD card of the 2WIN.

The operator must decide 2 parameters and then 4 intensities of light for the calibration of the system in this specific mode.

The two parameters are:

- T = is the minimum pupil diameter limit threshold. If during the 4 calibrating intensities of light the pupil diameter of any patient pupil goes under this value, then during the last and final measurement phase the 2WIN will use the corresponding light intensity that caused that specific threshold crossing.
- M = multiplication factor of the calibration impulse
- P = is the desired percentage of pupil diameter variation

The four calibration intensities are written in the configuration file with A,B,C,D letters. A,B,C,D values must be placed in ascending order.

The 2WIN during this calibration mode will start the exam with a starting 1 second of dark condition, then it will switch between the 4 A,B,C,D calibration intensities, each of them turned on for 1 second).

If the pupil diameter percentage variation is greater than the P parameter or if the minimum pupil diameter is lower than T parameter then 2WIN will store the intensity value (one of the A,B,C,D) that caused one of the above conditional pupil reactions (T or P parameter). This value will be used to illuminate the patient in the final phase of the measurement.

Example (pupilresponse.txt) file in the SD 2WIN card:

T4.2

P15

M1.5

A8

B16

C32

D64

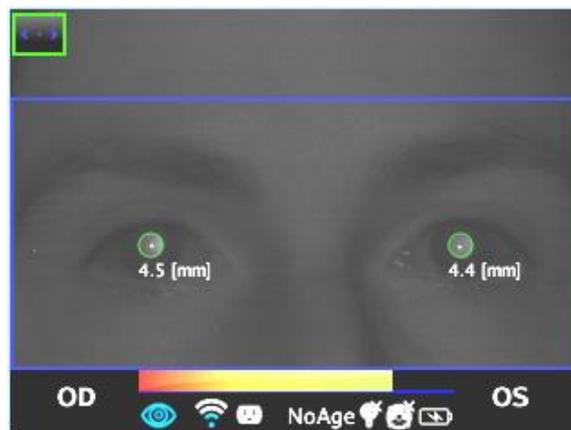
In this example the 4 light intensities at the beginning of the measurement will be 8%, 16%, 32% and finally 64% of the maximum light intensity. At the end of the measurement it will be used a final light impulse that will cause a pupil diameter lower than 4.2 mm or will create a percentage pupil variation that will overcome the 15% value, multiplied finally by a factor of 1.5.

NOTE: in the case T value is missing in the configuration file, then the standard mode will be used by the 2WIN. On the other hand if any of the other numerical values (P,A,B,C,D) are missed in the configuration file (or written in the wrong format), then 2WIN will use the calibration mode with a default sequence of: T=4, P=10, A=8, B=16, C=32, D=64.

Exam display

While the examination is running 2WIN will show the pupil diameter value closed to the pupils of the patient, this will happen after a small time after the release the S1/S2 button. The exam will finish after 14 seconds.

After that, the main window of the 2WIN will display in the upper part the maximum and minimum pupil diameter for each OD and OS. By pressing the RIGHT button in the 2WIN Joystick it's possible to analyze the complete result of the exam.

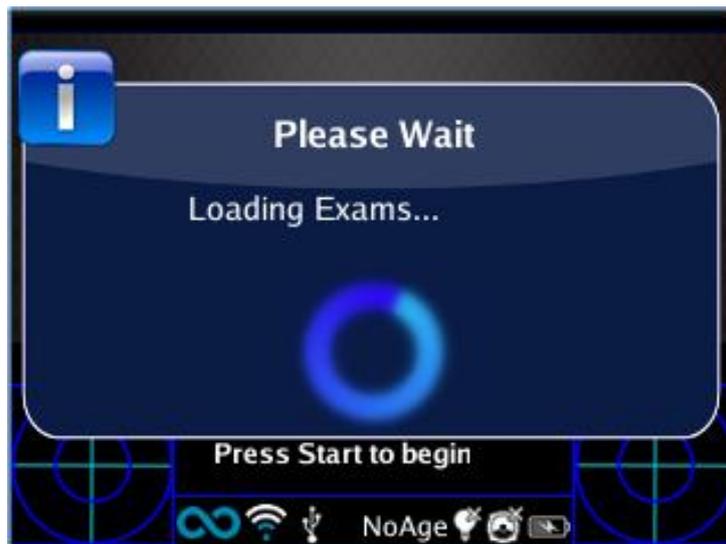


In the following image an example of the auxiliary window showing the full analysis of the examination.



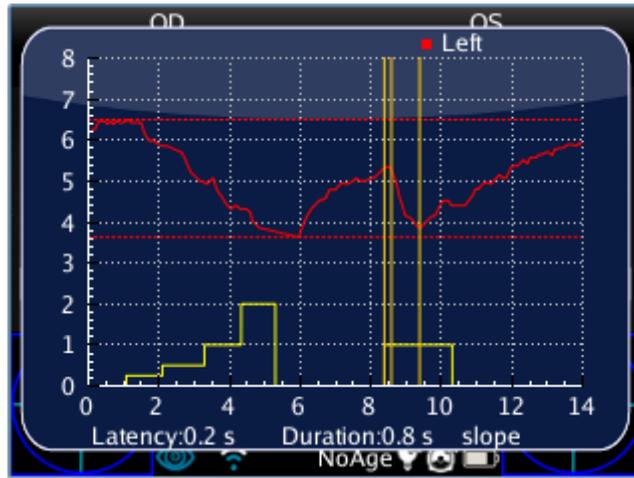
Browsing mode

It's possible to load a previously saved Dynamic Pupillometry exam: long push on the DOWN button of the 2WIN joystick. Then the operator can read/browse the previous exams by pushing the UP or DOWN button. Then, the main window of the 2WIN will display in the upper part the maximum and minimum pupil diameter for each OD and OS. By pressing the RIGHT button in the 2WIN Joystick it's possible to analyze the complete result of the exam.



Post exam measurements

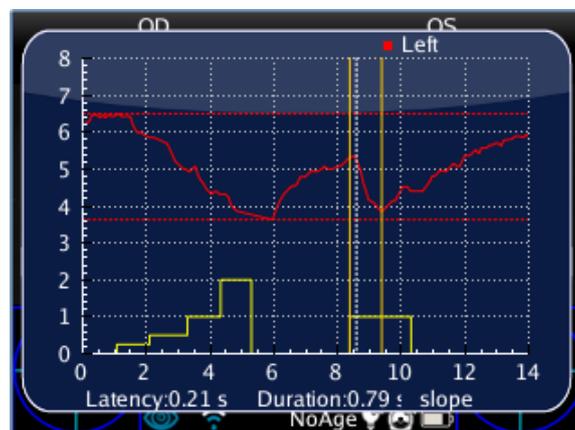
It's possible to measure some details of the final result of the Dynamic Pupillometry Application. In order to start this post exam analysis, the operator must press the EYE button () in the 2WIN when in the auxiliary window (after pressing the RIGHT button). The system will automatically discover a transition event and will place several lines in the graph starting with the SX pupil.



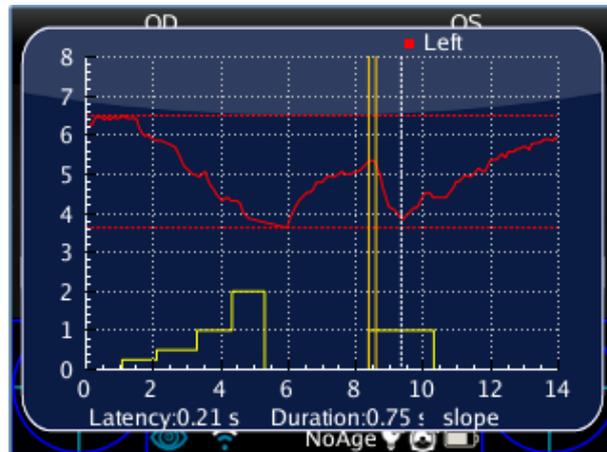
NOTE: if the Application is in the DEFAULT or CALIBRATION mode, 2WIN will recognize automatically the calibration pulses. In this case it will be possible to measure only the last pulse (not calibration one).

NOTE: if the Application is in MANUAL mode, 2WIN permits to measure all the single pulses but in the final PDF report data will be saved only referring to the first valid impulse.

The first line is automatically placed on the first front of variation of the emitted light (this line position is not adjustable). The second line can be adjusted manually by long pressing the MENU button (CENTRAL button of the 2WIN joystick). When the line is selected it becomes dashed and white colored, in this form the operator can move it toward the left or the right of the display by pressing LEFT or RIGHT button in the joystick. This line should represent the starting time when the pupil diameter starts to react to light stimulus. In the following figure an example of the second line positioning.

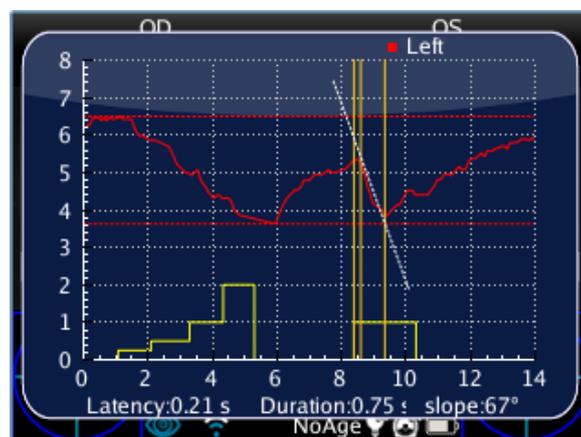


When the second axis (line) is positioned, automatically the response time of the pupil (in seconds) will appear in the lower part of the display of the auxiliary window of the 2WIN. On the next pressing of the MENU button the selected (and editable) line will be the third, showing the exact time the pupil response finishes to react to the light illumination impulse.



When the third axis (line) is positioned, automatically after next pressing of MENU Button the overall time reaction time of the pupil (in seconds) will appear in the lower part of the display of the auxiliary window of the 2WIN.

On the next pressing of the MENU button a further line will be introduced in the display. This line represents the “slope” in the change of the pupil diameter. It is possible to move the slope line with all the arrow of the joystick (UP, DOWN to move up and down; while RIGHT and LEFT to rotate it).



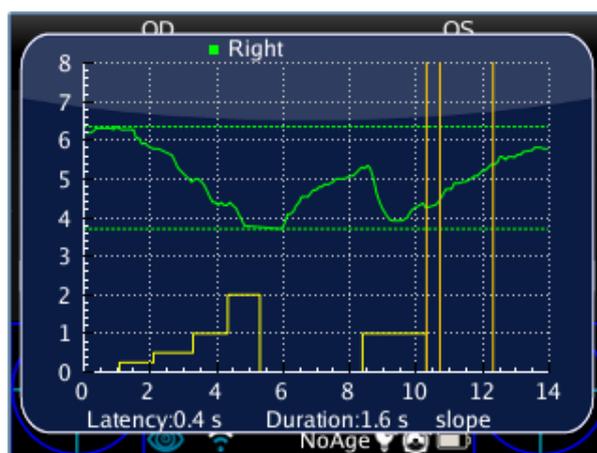
When the slope axis (line) is positioned, automatically the slope angle value will appear in the lower part of the display of the auxiliary window of the 2WIN. This last line will be white

if it is related to a decrease in the pupil diameter, while it will be black if it is related to an increase.

If the operator presses again the MENU button, all the lines will become yellow (it means you have finished positioning them). By pressing the right or left button of the joystick it will be possible to switch side of the light stimulation exam (from the descending to the ascending side) and repeat the axes positioning for that side.



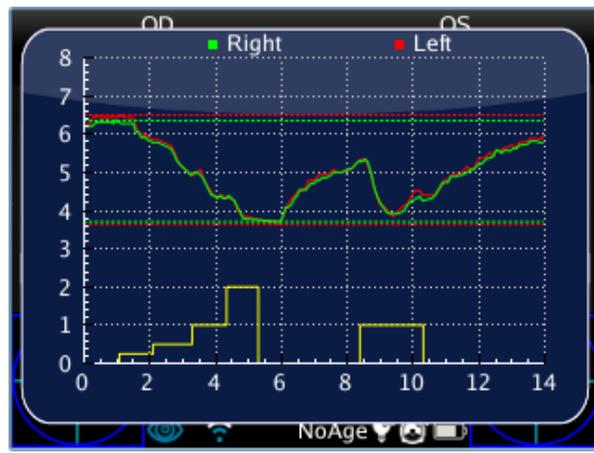
By pressing the EYE (Button D) button in the 2WIN, the system of four lines will be displayed on the following event of transition in the pupil diameter. Then if the EYE button is pressed again the overall measurement procedure will be started in the DX eye.



Saving in SD memory

When finished to measure all the change of the pupil diameters, finally pressing again the EYE button the primary screen of the 2WIN will show a single graph with both SX and DX

pupil responses lines. This action will store temporarily all the examination in the 2WIN memory. If all the change event were discovered, in order to store permanently the exam in the 2WIN SD card, the operator must come to the 2WIN home screen pressing the ESC button, and then press and hold the PRINT button (this will generate the final PDF report of the exam).



PDF Report

The PDF Report is composed of the pupil response graphic and of the corresponding data:

- The graphic includes both the pupil eye responses and a partial reproduction of the axes that have been positioned earlier (axes could be out of the image and consequently you can't see them)
- The data area is divided in three parts which refer to the second pupil stimulation (and not to the calibration):
 1. The "Constriction" phase, the pupil constriction phase.
 2. "Pupil Size", data about the pupils
 3. The "Dilation" phase, the pupil dilation phase

The **Constriction** phase has three variables which are:

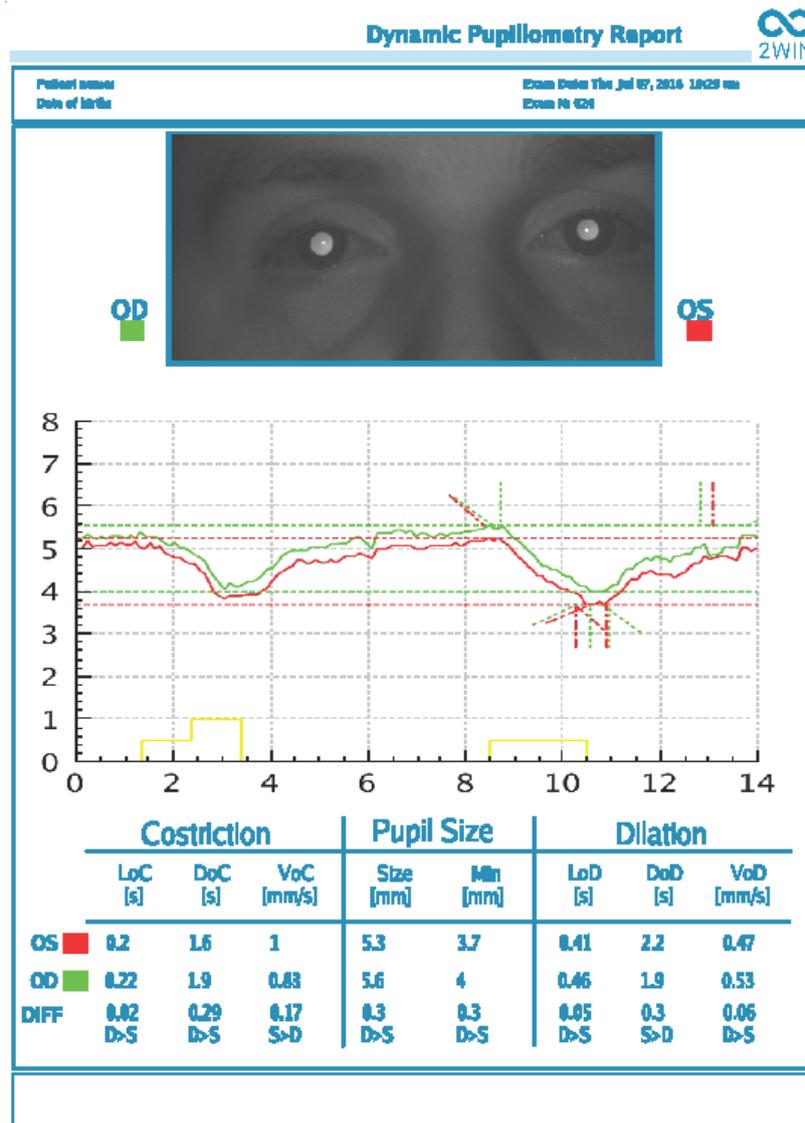
1. LoC = Latency of Constriction, which is the reaction time used by the pupil to start constricting after the light switching on.
2. DoC = Duration of Constricting, which is the time used by the pupil to constrict and stabilize.
3. VoC = Velocity of Constriction, which is the pupil velocity to constrict.

The **Dilation** phase has three variables which are:

1. LoD = Latency of Dilation, which is the time used by the pupil to start dilating after the light switching off.
2. DoD = Duration of Dilation, which is the time used by the pupil to dilate and stabilize.

3. VoD = Velocity of Dilation, which is the pupil velocity to dilate.

DIFF: it's the difference between the right and left eye. It also reports which of the two values is greater.



20.5 Lens Centering Application (LC-App)

Lens Centering Application allows to obtain all the parameters needed for new glasses centering or to check if current glasses centering is correct. During Lens Centering measurement the patient must wear glasses.

Lens Centering Application activating

To activate Lens Centering Application you have to press the Button A, and select the right Application by moving by the arrows of the joystick.

To activate it you have to press the central button of the joystick and the system will return to the main screen.



Exam procedure

When the App is activated, the operator have to make the measurement as in 2WIN standard way following the “green” condition (see previous paragraphs to learn how). The only difference is that the patient have to wear the frame the operator wants to center/measure.



After the measurement is done, the main PD information is displayed at the top of the Application's main display.



Browsing mode

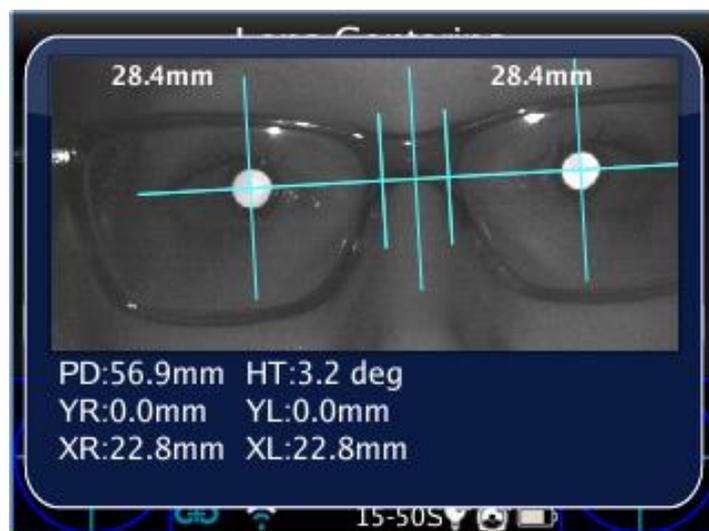
To activate Lens Centering App in a measurement already saved you have to enter in the browsing mode by holding the down button of the joystick till the loading of the exam history.



When the exams have been loaded you can browse them by the down and up button of the joystick and select the exam you want.

Exam results

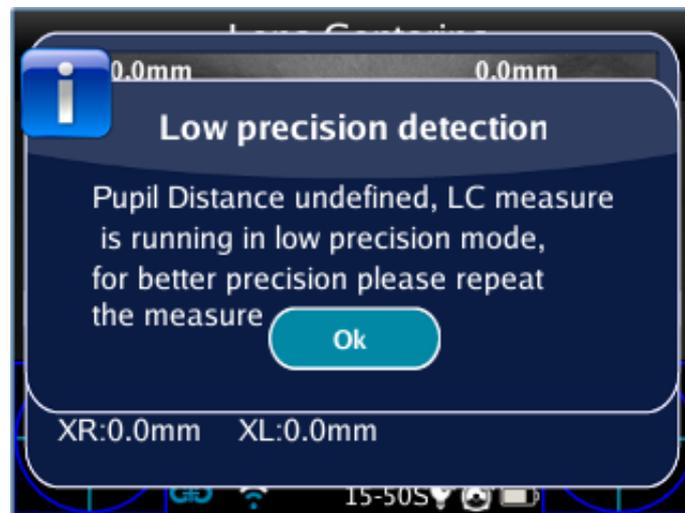
After you have accomplished the measurement you can observe the Lens Centering by clicking the right button, it will take you to the main screen of the Application. The main screen of the Application shows the measure image and it positions the measure axes in a default place, that is: the horizontal axis aligned between the two pupils keeping their base tilt, whereas the two studs are positioned equidistant from the centre.



Lens Centering system allows to position and tilt the axes in order to do the measuring.

If the measuring isn't valid or if it has been loaded another measure of a different App you will see on the display an error message that means the positions of the pupils are not present or an essential data for the measuring.

If the Pupil Distance is not valid, the LC App shows a warning message because has no referring for high precision measure. Using the LC App in this mode, will result low precision measure.

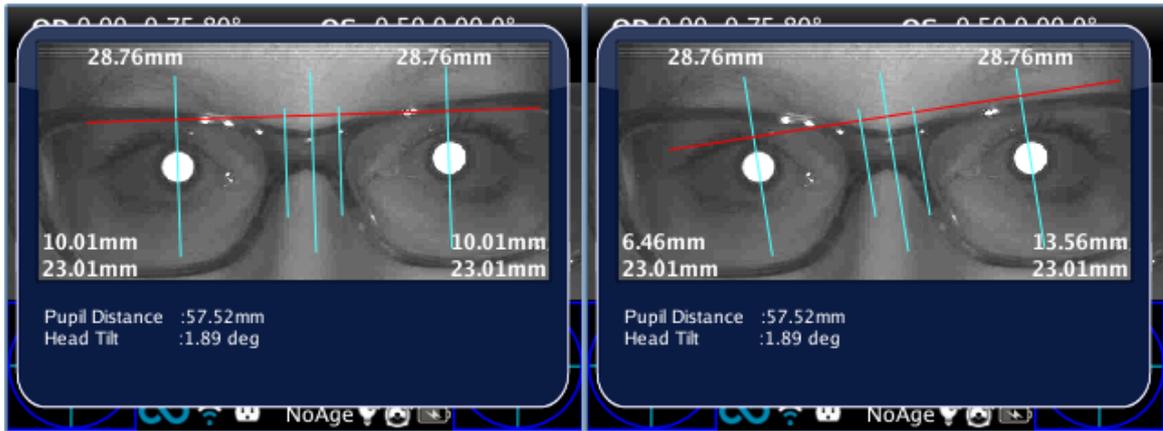


Navigation

You can select the axis you want to move by pressing the central button of the joystick, it will highlight red the axis allowing the changes. At the first pressing you will see the horizontal axis; at the second pressing you will see the vertical axis on the left; at the third pressing you will see the vertical axis on the right; at the fourth pressing you will return at the first step.

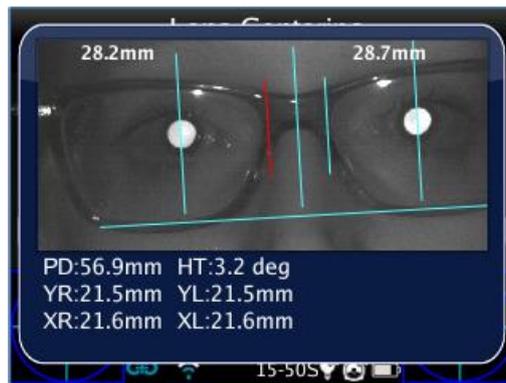
How to position the horizontal axis

After selecting the horizontal axis it will highlight red. This axis can be moved vertically by holding or repeatedly pressing the down or up button of the joystick. You can change the axis tilt by pressing the right or left button. This change implicates an equivalent rotation of all the other axes.



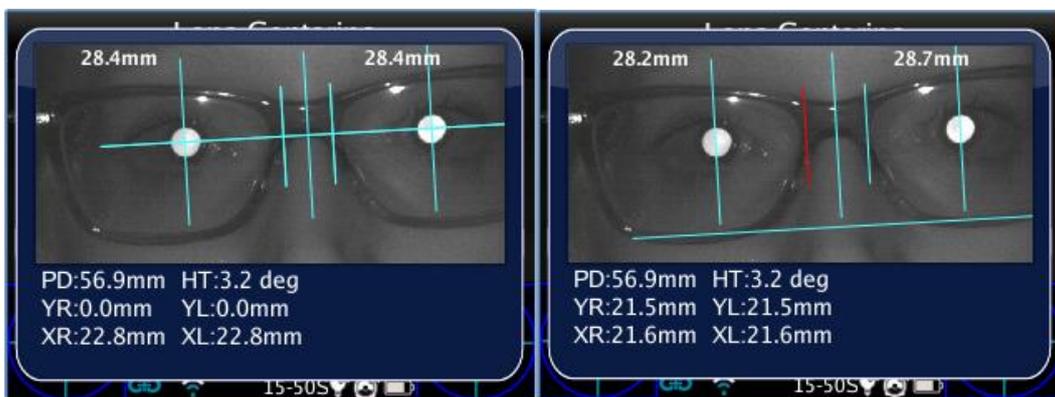
How to position the vertical axes

The positioning of vertical axes can be done by left and right button of the joystick that will move the axes along the horizontal axis between the pupils. The central axis will be automatically located between the two movable axes.



Centering values

You can see the main values written directly on the top of the screen and the auxiliary data written on the bottom of the screen.



Data displayed on the image are:

- Semi inter-pupillary distance measuring, located on the top of the image. They represent the measures between the center of the optic axis and the central vertical axis. Divided to the left and to the right in correspondence to the side they will measure.
- On the bottom on the left and the right of the image you find the following distances (R stand for Right Eye, while L for Left Eye):
 - the greatest value and the distance between the center of the optic axis and the horizontal axis (YR, YL).
 - the lower value and the measure between the center of the optic axis and the corresponding stud (XR, XL).

Under the image there are two other values that represent the head tilt and the distance between the two centers of the optic axes.

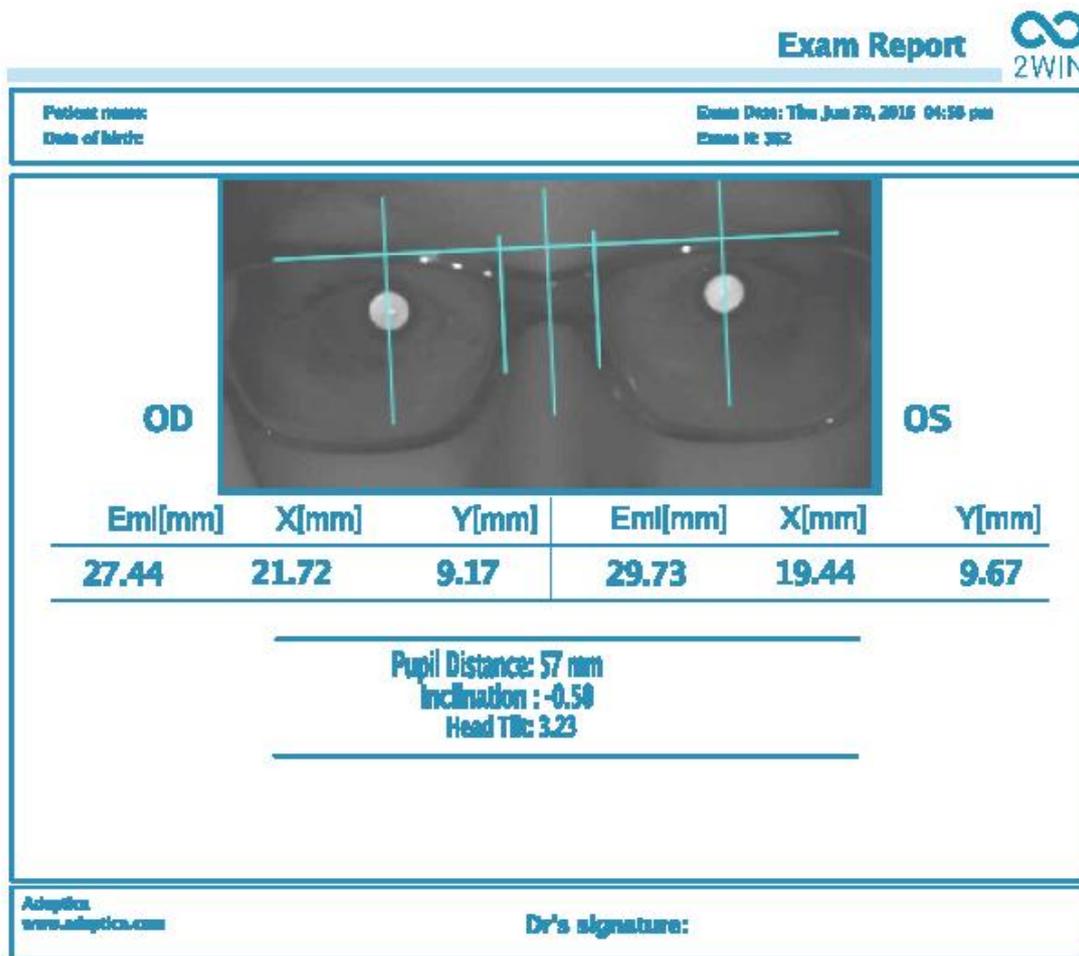


The values written in brackets are the names of the report values.

Printing on SD and creating of the report

After locating the axis you can save their position (for a future review) by holding the Printing button after exiting from the App. In this way it will create a report and the values will be saved on the measuring and next time you will find them in the same position as you set before.

Exam Report



The PDF Report is composed of the lens centering graphic and the corresponding data. The image represents the axes graphic previously positioned.

The report is divided in right and left eye, the values expressed for each eye represent:

- **EMI:** The distance between the pupil and the central vertical axis.
- **X:** The distance between the optic axis center and the external vertical axis of the stud
- **Y:** The distance between the optic axis center and the horizontal axis.

The other values are:

- **Pupil distance:** The distance between the pupil optic axes.
- **Inclination:** The additional inclination added to the head tilt by the operator.
- **Head Tilt:** The optic axis tilt respect to the horizontal axis.

20.6 Intermediate Vision Application (66cm-App)

Thanks to Intermediate Vision Application 2WIN is able to measure the patient's refraction while reading at the distance of 66 cm (24"). In all those cases when reading at such distance proves difficult, the 2WIN calculates the necessary additional power (ADD) to restore best vision.

The reading distance Application requires the use of an additional lens that is inserted in the central aperture of the 2WIN; the additional lens together with a near point reading card completes the kit.

- Detection of refraction at Intermediate Distance;
- Definition of the power of the additional lens to add to the basic prescription;
- Identification of difficulty in visual accommodation at Intermediate Distance;

Components

- Add-on lens (must be placed on the frontal part of the 2WIN);
- Reading Chart with printed types;

Intermediate Vision Application activation

After the installation the Application must be activated to be utilized.

Activation: click the BUTTON A () 2WIN Applications screen will be shown to display.

Doing this, it is possible to navigate and to see all the installed Applications into the device.

By clicking with the cross BUTTON on the Intermediate Vision package icon, this Application will be the principal one in Main Display and it will be set first in Auxiliary Windows automatically.



2WIN Applications screen



Main Visualization – Intermediate Vision

Intermediate Vision Exam Tips

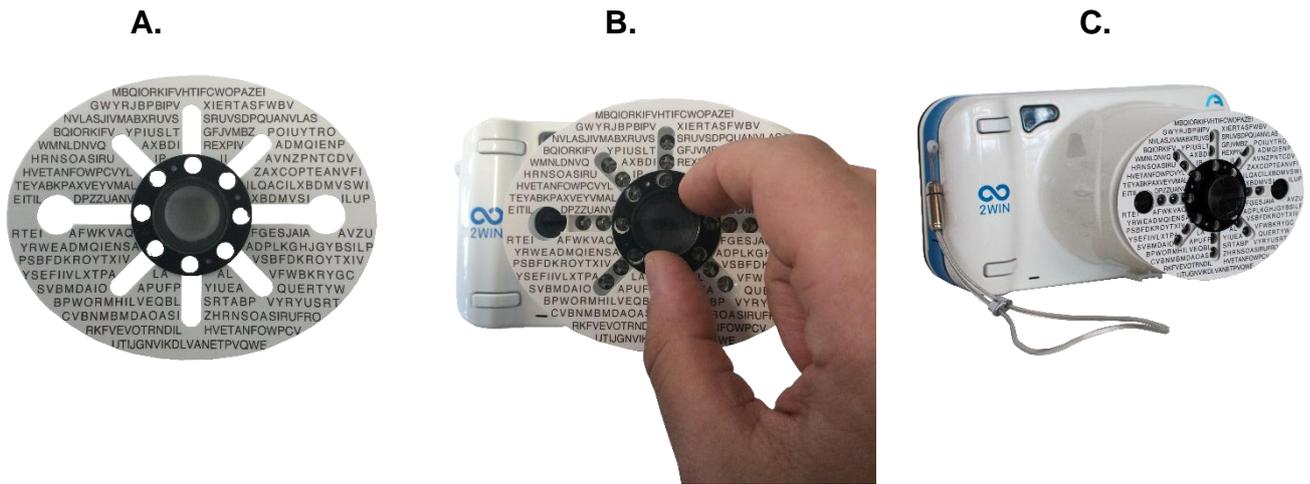
- Intermediate Vision test must be realized asking the patient to wear usual glasses (if typically used) or contact lenses -not reading glasses.
- Before the measurement please make sure “Intermediate Vision Application” is activated (check the icon .66 on the bottom of the display). If you shut the 2WIN down, the Application will be automatically deactivated.



- Unstable (environmental) conditions may provoke accommodation for patient. This reduces reliability index for measurement. In case of unstable measurement the following warning message will appear on the display:



- The operator must apply the chart and the lens on the front side of the 2WIN into the central aperture). Push the add-on (do not force the chart) until a slight resistance is felt.
-  Pay attention not to cover 2WIN frontal LEDs, measurement may not be possible with a wrong chart positioning;
- Remove the add-on taking the black prominence and rotating it while pulling out towards the outside.



Environment setup



It is important to prepare the correct environment for the examination.

Please use an appropriate lamp following these tricks:

- Place the light source behind the patient, out of the FOV (field of view) of the 2WIN. Otherwise, measurement could be unstable and have low index of reliability. With such conditions a warning “**Ambient light too bright**” could be displayed;
- Please make sure that the chart reading is not directly enlightened but visible and readable in semi-darkness;
- Please make sure not to obstruct Operator measurement, in case move the light;

Please make sure that pupil diameter of the Patient is adequate to measurement (ideal pupils dimension are in the range between 3.5 and 5 mm.). Out of range condition may require longer time measurement or not possible examination.

If measurement is difficult, move or change the light to reduce chart brightness, up to pupils become bigger (sufficiently open).

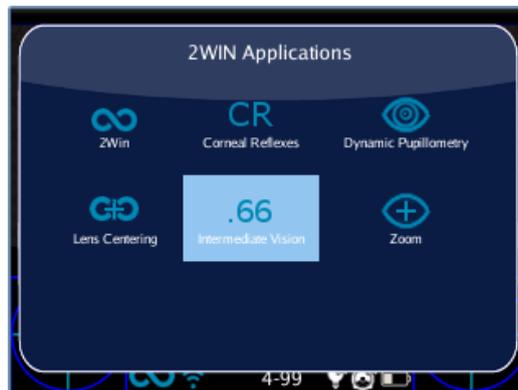
Exam Procedure

1. Apply the add-on lens and the Reading chart on the front side of the 2WIN.



Pay attention not to cover 2WIN frontal LEDs: with a wrong chart positioning measurement may not be possible.

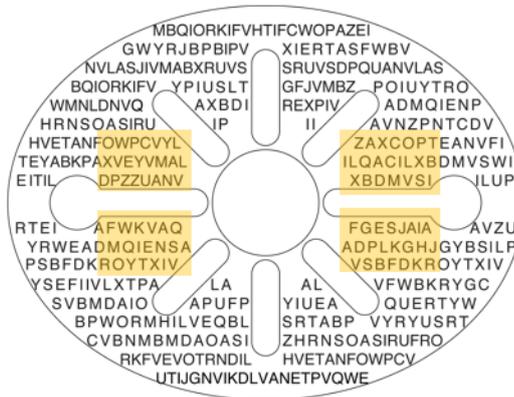
2. Turn the 2WIN on by pressing the **BUTTON A** ;
3. Set the 2WIN to operate at Intermediate Vision Distance:
 - a. Press **BUTTON A**  and view 2WIN Applications Menu.
 - b. Select “Intermediate Vision” Application by pressing the **CROSS BUTTON** .



- c. After selecting “Intermediate Vision” a new symbol (.66) will be displayed. The new Application is activated.



4. Ask the patient to wear glasses if typically worn (distance-vision glasses) or contact lenses, not reading glasses. If patient wears progressive glasses, ask the patient to look the chart through the top-side part of the lenses.
5. Ask the patient to focus central characters of the chart (the letters near to the central lens). See the following picture:



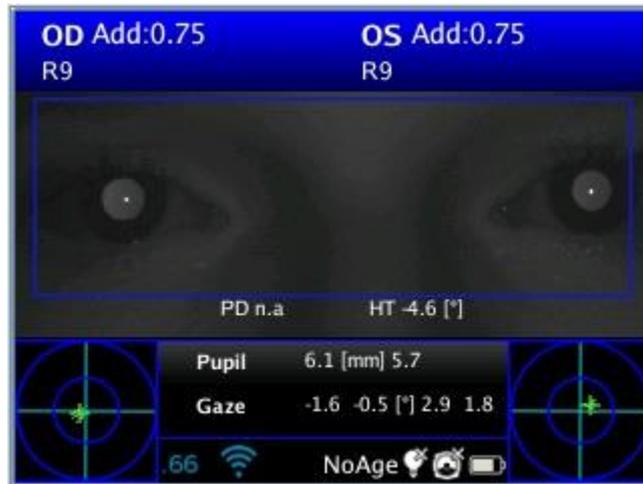
6. Intermediate Vision Exam procedure is the same as refraction measurements (see Chapter 10.8 – Measurement).



Keep pupils within the display during focusing and measuring.

For some patients, because of their pupil distance, the binocular measurement at 66cm might be not possible. In those cases it is highly recommended to take the measurement monocularly.

7. At the end of the measurement the results are displayed:

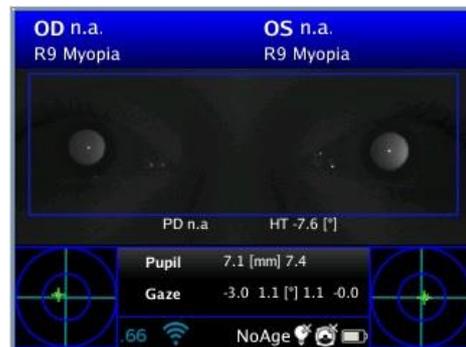
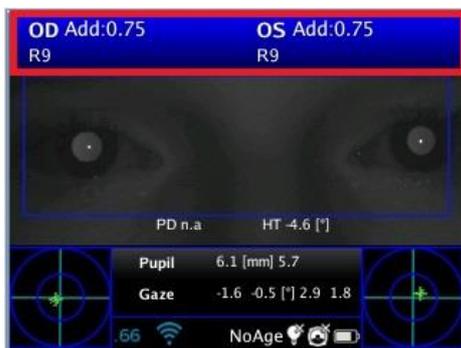


The topside value represents the spherical equivalent.

It is the estimation of the necessary additional power (ADD) to restore best vision (spherical equivalent = sphere + ½ cylinder) at 66cm.

Measurement range of additional power (ADD) is within the value range 0 D – 3.25 D.

Out of this range the output is n.a., with the indication of Myopia or Hyperopia;



Output

The 2WIN assesses reading ability of a patient to 66 cm.

At the end of measurement, the 2WIN provides a power estimation of the positive lens for the best vision to the VDT video display terminal in the conditions in which the examination is taken.

2WIN returns 0 if the patient does not need any additional power to focus at VDU.

On the contrary, if the patient needs an additional power, 2WIN returns a positive value:

- If the measurement is taken wearing distance glasses the ADD power must be added to the patient's glasses power;
- If the measurement is taken without glasses the ADD value is the power of the reading glasses to be prescribed.

20.7 Eye Morphology Application

Eye Morphology Application measures different distances in the eye. This kind of measurements is very useful in determining some key parameters of the so-called Fetal Alcohol Syndrome (FAS). It allows to identify eye width with no care about pupil position.

Eye Morphology Application activation

To install Eye Morphology version 2.0 the operator needs to place an activation code in the 2WIN SD card (follow the same procedure to install any other 2WIN Apps, but Eye Morphology 2.0 will not be visible in 2Win Apps menu). After installation the App will be automatically available in the 2win zoom function.

Exam procedure

To enter zoom mode you just need to press PRINT key after a measure.

Warning: in the next EM-App pictures (2WIN user interface) the EM values are often called FAS.



Press EYE key to enable Eye Morphology functionality when in zoom mode: first pression for vertical mode measurements, second pression to get horizontal mode.



Eye Morphology measure

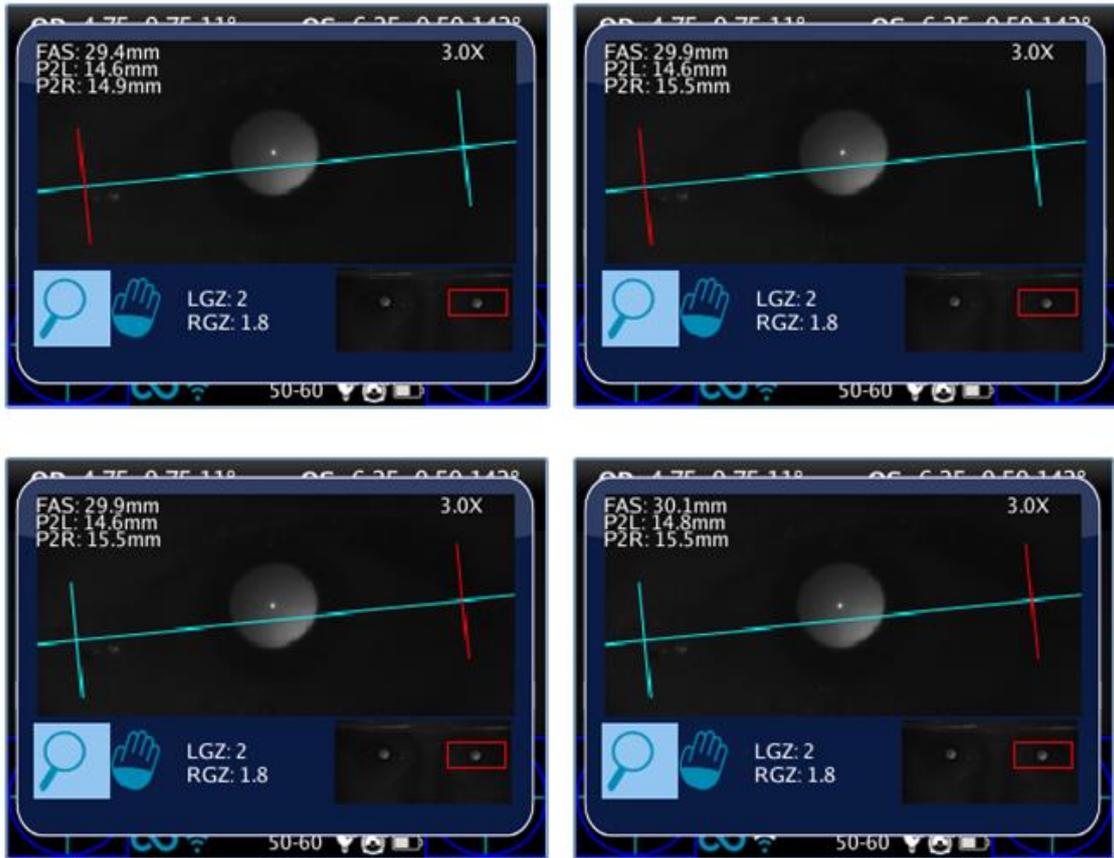
To change eye selection use MENU_LEFT and MENU_RIGHT keys. MENU_UP and MENU_DOWN buttons change zoom value: to get Eye Morphology measure, the minimum zoom factor is 2.8x. It is possible to change eye and zoom when no axes are selected/active (all axes are blue).



With MENU key it is possible to change axis to set its position. First pression to move horizontal axis: when selected the button shifts it up and down with MENU_UP and MENU_DOWN, MENU_LEFT and MENU_RIGHT change inclination to match real eye position.



Press MENU again to select left and right vertical axes and move them with MENU_LEFT and MENU_RIGHT. Pressing MENU again to go out of axes selection and to change eye or modify zoom factor.



Exam Results

Eye Morphology feature extracts three parameters for each eye:

- EM = vertical axes distance in millimetres
- P2L = distance in millimetres from left vertical axis to pupil centre
- P2R = distance in millimetres from right vertical axis to pupil centre

21 Troubleshooting

| #. | Symptom | Possible cause | Solution |
|----|---|---|--|
| 1 | Initial screen does not appear on the display of the device | The battery is completely discharged | Charge the battery |
| 2 | On the display an error message appears. | Electronic malfunctioning | Contact service center, mentioning serial number |
| 3 | On the display an error message appears. | Software malfunctioning | Contact service center, mentioning serial number and message error. |
| 4 | A warning – “Hint check Gaze”- appears on the display | The patient is not looking at the machine | -If collaborative ask he/she to look at the machine -If not collaborative activate the interactivity features. |
| 5 | A warning – “Hint check Gaze”- appears on the display | There may be a strabismus problem. | It is suggested to measure eyes singularly in two different measurements. |
| 6 | A warning – “Possible strong Anisocoria” appears on the display | The two eyes have very different pupil diameters (that means anisocoria) | It is suggested to measure eyes singularly in two different measurements. |
| 7 | The measurement never ended correctly or prematurely quit while the pupils are detected. | There may be an hardware problem. | -Run the Self Test diagnostic through the MENU and contact service. |
| 8 | Printing does not work. | - The printer is powered off/battery low - The printer is not in front of the instrument | -Switch on/recharge the printer - Position the printer in line of sight with the instrument. |
| 10 | For the automatic update, please activate the wifi for the web connection | - Settings update needed. | - Switch on the wifi and connect the 2WIN to the web - In case of no web connection available for the 2WIN, connect to http://www.adaptica.com/2WINCALIBRATION/ with your laptop and follow the instruction. |
| 11 | For the manual update, please visit http://www.adaptica.com/2WINCALIBRATION/ | - Settings update needed. | - Connect to http://www.adaptica.com/2WINCALIBRATION/ with your laptop and follow the instruction. |

22 Additional information

22.1 Technical specifications

Measuring range for spherical defect: $-15,00D +15,00D$
Measurement precision for spherical defect: $\pm 0,25 D$
Measuring range for cylindrical defect: $-5,00D +5,00D$
Measurement precision for cylindrical defect: $\pm 0,25 D$
Measuring range for cylinder axis: 1 – 180 degrees, step 1 degree
Measurement precision for cylinder axis: ± 5 degrees
Measuring range for pupil diameter: 4 – 11 mm, step 0.1 mm
Measurement precision for pupil diameter: ± 0.2 mm
Measuring range for inter-pupillary distance: 30 – 120 mm step 1 mm
Measurement precision for inter-pupillary distance: ± 1 mm

22.2 2WIN Rechargeable battery specifications

Type of Cell: Sealed Lithium-polymer Prismatic
Battery Pack Model: CS-SP112XL
Battery Pack Size: 58 X 36.1 X 12.7 (LxWxH mm)
Rated voltage: 3.7V
Rated capacity: 1800 mAh
Standard charge: CC-CV method with charge current of 360mA
Quick charge current: 1800mA
Replace No.: Sony: PSP-110

Charger model: Lvsun CPSC110 Input: 90-250Vac 50/60Hz 100mA Output: 4.2-8.4Vdc 800mA

22.3 KALEIDOS Rechargeable battery specifications

Type of Cell: Lithium-ion Cylindrical
Cells: 4 x Panasonic NCR18650B
Rated capacity: 4 x 3400 mAh (13600 mAh)
Rated voltage: 4 x 3.7V (14.8V)
Not replaceable by user
Battery Pack Input specification: 18V 2.4A (use provided power adapter only)

Power adapter model: Meanwell GSM40A18-P1J Input: 80-264Vac 47-63Hz 115VA Output: 18Vdc 2.22A

22.4 Wi-Fi modules / Bluetooth adapters

Model: LM Technologies LM817

Compliance: IEEE 802.11b/g/n/d/e/h/i standards, Bluetooth® v2.1 + EDR, v3.0 and v4.0 (Dual Mode) standards

- WiFi 802.11 b/g/n
- Bluetooth® v4.0 (Backwards compatible with Bluetooth® v2.0, v2.1 and v3.0)
- WPA, WPA-PSK, WPA2, WPA2 -PSK and WEP (64bit & 128bit)
- Encryption schemes
- Full speed Bluetooth® Piconet and Scatternet supported
- USB 2.0 (Full Speed) for data and power source
- Operates in 2.4 GHz Frequency bands

Model: LM Technologies LM820

Compliance: IEEE 802.11b/g/n/d/e/h/i standards, Bluetooth® v2.1 + EDR, v3.0 and v4.0 standards

- WiFi 802.11 b/g/n
- Bluetooth® v4.0 (Backwards compatible with Bluetooth® v2.0, v2.1 and v3.0)
- WPA, WPA-PSK, WPA2, WPA2 -PSK and WEP (64bit & 128bit)
- Encryption schemes
- Full speed Bluetooth® Piconet and Scatternet supported
- USB 2.0 (Full Speed) for data and power source
- Operates in 2.4 GHz Frequency bands

22.5 Other specifications

Working distance: 1 m (+/- 5 cm)

Display size: 3.5 inches

Battery charger: AC/DC 110-220 VAC 0.5 A

Weight: 0,84 kg

Dimensions: 165mm x 130mm x 98mm h

22.6 In flight use

Do not use the device during a flight.

22.7 Device warranty

The device has one-year warranty

Information for assistance

For any service requirement, please contact your distributor, or contact directly:

| |
|--|
| Adaptica Srl |
| Via San Marco 9/H - 35129 - Padova (Italy) |
| Tel. +39 049 773968 |
| Fax +39 049 0970901 |
| email: support@adaptica.com |

Note for service personnel only

Adaptica will make available on request circuit diagrams, components part lists, descriptions, calibration instructions or other information that will assist service personnel to repair those parts of the equipment that are designated by Adaptica as repairable by service personnel

Remote control

If the service department of Adaptica suggest this option, the customer/operator of the 2WIN is asked to activate the “Remote Control” option of the 2WIN. This option can be enabled only to the 2WIN with WiFi connection enabled. Through the use of this option a direct connection between the 2WIN and the IT department of Adaptica will be enabled in order to give direct support. The operator will be contacted by the IT department of Adaptica by phone or email and then the operator must follow the direct instructions in order to activate the “Remote Control” option.

NOTE: before activating “Remote Control” the user must remove the SD card from 2WIN (see APPENDIX A).

NOTE: when the “Remote Control” is enabled and used it will not possible to make access to the SD card of 2WIN, the instrument must be rebooted in order to do that.

Telemetry

2WIN telemetry service is used from Adaptica in order to get information on the status of the 2WIN. (See APPENDIX A).

Appendix A – Data management disclaimer

Disclaimer of Adaptica S.r.l. pursuant to Article 13 of Legislative Decree No. 196 of 30 June 2003 (the “Privacy Code”)

We hereby inform that the utilisation of the 2WIN instrument will give rise to the processing of some data relating to its status of operation (the “**Telemetry Data**”), which will be acquired by the IT systems and software procedures for the functioning of this instrument whenever it connects to a wireless network. The information in question is not collected in order to be associated with specifically identified parties, but due to its nature it could – through processing operations and associations with data in the possession of third parties – make it possible to identify the users (hereafter the “**Parties Concerned**”). The Telemetry Data include the software version, the firmware version, the device’s serial number and the number of observations carried out; moreover, the instrument will transmit the list of the Applications operating on the same. The sole purposes of the Telemetry Data processing are to enable Adaptica S.r.l. to constantly monitor the efficiency of the proposed service based on the utilisation of the 2WIN instrument and, in case of malfunctioning of the same, to transmit from the remote server the technical data which are necessary to the reactivation of the relevant parameters. Furthermore, Adaptica S.r.l. may, once a temporary session of remote control has been activated by the user and the instrument has been connected to a wireless network, connect to the 2WIN instrument and obtain parameters of a purely technical nature relating to the handling and the state of health of mechanical, electronic and firmware parts (the “**Remote Control Data**”). In this regard, Adaptica S.r.l. informs that, by way of the remote control connection, also the data saved on the SD card might theoretically be downloaded from the system, should such card be left inserted in the instrument at the moment of the activation of the temporary session; despite this additional information is of no interest for Adaptica S.r.l. and will neither be acquired nor treated by it, it is however advisable to remove the SD card or delete any sensitive data before such activation, in order to avoid the transfer of the same data.

Adaptica S.r.l. also informs that the Telemetry Data and the Remote Control Data do not contain sensitive information relating to users, will be treated only and exclusively in the framework of normal business, in accordance with purposes linked to the achievement of the corporate purpose of the said Adaptica S.r.l., and will be kept by such company. The Telemetry Data will be used only in order to acquire anonymous information on the use of the instrument and to check that it is functioning correctly. The Remote Control Data will be used in order to provide remote assistance to the 2WIN and enable Adaptica S.r.l. to check its functioning and/or carry out particular procedures. The processing of the Telemetry Data and the Remote Control Data will take place mainly through electronic (or in any case automated), IT and telematic instruments, and will be memorised on IT devices, following criteria strictly correlated to the aforementioned purposes, in compliance with the minimum security provisions contemplated by Art. 34 of the Privacy Code and by Schedule B thereof

and, in any event, in such a way as to ensure the security and confidentiality of such Telemetry Data and Remote Control Data. The lack of consent by the Party Concerned to the processing of the Telemetry Data and the Remote Control Data will make the use of the 2WIN instrument impossible to the same. The autonomous owner (“*titolare autonomo*”) of the Telemetry Data and the Remote Control Data is Adaptica S.r.l., a company with its registered office in Padua, Via San Marco 9/H.

The Telemetry Data and the Remote Control Data may be conveyed to the Italian Personal Data Protection Authority as well as any other governmental and regulatory authorities so entitled, in accordance with the Applicable legal and/or regulatory provisions; to advisors and professionals; to service companies; and to any other entities to which such notices have to be conveyed for the purposes of providing the services, and in such a way as to comply precisely and diligently with contractual requirements and obligations imposed by current legislation. In any case, the Telemetry Data and the Remote Control Data will not be disclosed. The complete and updated list of the persons/entities to whom the Telemetry Data and the Remote Control Data may be conveyed and of those who may acquire knowledge thereof as data supervisors (“*responsabili del trattamento*”) (the “**Supervisors**”), together with this disclosure, will be made available at the registered office of Adaptica S.r.l.

Finally, Adaptica S.r.l. informs that the law grants all the Parties Concerned the specific rights that are set out in Article 7 of the Privacy Code; purely by way of example and without limitation, these include the right to ask for, and obtain, confirmation of whether or not Telemetry Data of one’s own exist and to ascertain their origin; the purposes and modalities of the processing; and the updating, rectification and, where required, integration of the said Telemetry Data. The Parties Concerned may also, within the limits imposed by the law, ask for any inexact or incomplete data to be corrected, updated or integrated and, for Telemetry Data processed in breach of the law, to be cancelled or blocked, or oppose their utilisation for justified reasons which must be indicated in the request (pursuant to Art. 7 of the Privacy Code).

I hereby declare that I have read the privacy disclaimer set out above and specifically authorise the processing of the Telemetry Data and the Remote Control Data for the purposes described therein and in order to facilitate compliance with contractual and legal requirements, pursuant to Legislative Decree No. 196 of 30 June 2003, the “Personal Data Protection Code”.

Place and Date _____

Signature of the declarant (legible and written in full) _____

Appendix B – EMR input and output files specifications

This appendix describes how to implement the EMR interface in order to exchange patient data and measurement/screening results between your EMR system and your 2WIN-S device.

The EMR interface needs to be implemented by your EMR System provider. Please note that neither Adaptica nor any Adaptica distributor can perform the needed modifications in your EMR system.

This is a “full” integration, i.e. patient name or ID is sent from the EMR system to 2WIN-S, and measurement/screening results are saved to data fields within the patient’s EMR.

Definitions

- **Shared Folder:** The Shared Folder can be used to exchange input and output files between your EMR system and your KALEIDOS App.

This folder must be created in the EMR system PC and must be shared on the LAN (Local Area Network). The folder must be accessible by your Control Android Tablet, which must be connected to the same network, and by your KALEIDOS App.

Use different Shared Folders for different 2WIN-S.

- **Input file:** A file generated by your EMR system in order to provide patient information prior to a measurement/screening. This file must be named “emr_input.csv”, and it has to be saved in the Shared Folder.
- **Output file:** A file generated by the KALEIDOS App after a measurement/screening that has been performed or has been aborted (i.e. an inconclusive measurement/screening). This file is named “emr_output.csv”, and it can be retrieved in the Shared Folder.

Input file specifications

- Patient information must be put in a CSV File, side by side in one single line and without a space after the separator.
- The sequence for patient information must be the following: last name, first name, date of birth (YYYY-MM-DD), patient ID, location, contact, autostart.

- Autostart field can be 0 or 1. If autostart=0, when the input file is created, KALEIDOS App opens patient data window. The user must press START to start the measurement. If autostart=1, when the input file is created, the measurement automatically starts, without pressing the START button.

Example:

Smith,John,2016-02-24,1234567890,Downtown Clinic,johnsmith@e-mail.com,0
is a valid input file

- Some input file fields could be empty. However, last name, first name and date of birth fields are mandatory.

Example: Smith,John,2016-02-24,,,0 is a valid input file

Output file specifications

The output file presents information in a CSV file. Comma separators are used. There are no headers in the first line. Information of each measurement/screening is presented side by side in a single line in this sequence.



For refraction, always positive cylinder notation is used.

Data in the output file are presented in the following order:

- Date and time stamp, formatted as YYYY-MM-DDThh:mm:ss where T is a separator
- Same last name as provided in input file
- Same first name as provided in input file
- Same date of birth as provided in input file
- Same patient ID as provided in input file
- Same location as provided in input file
- Same contact as provided in input file
- Spherical measurement value of the right eye in diopters [dpt]
- Cylindrical measurement value of the right eye in diopters [dpt]
- Axis measurement value of the right eye in degrees [deg]
- Pupil diameter measurement value of the right eye in millimeters [mm]
- Spherical measurement value of the left eye in diopters [dpt]
- Cylindrical measurement value of the left eye in diopters [dpt]
- Axis measurement value of the left eye in degrees [deg]
- Pupil diameter measurement value of the left eye in millimeters [mm]
- Measurement value of gaze x value for right eye in degrees [deg]
- Measurement value of gaze y value for right eye in degrees [deg]
- Measurement value of gaze x value for left eye in degrees [deg]

- Measurement value of gaze y value for left eye in degrees [deg]
- Distance between left and right pupil in millimeters [mm]
- 2WIN exam number [int]
- 2WIN software version [string]
- Exam ending message in case of inconclusive result [string]
- Exam ending message code [int] (if 0 everything is ok).