

# 2WIN

## OPERATOR MANUAL



# Revision notes

|                                |                          |
|--------------------------------|--------------------------|
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| Hardware configuration version | Version 17.0 and earlier |
| Software configuration version | 4.1                      |

# 1 Summary

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## 1. Manufacturer identification

|              |  |  |
|--------------|--|--|
| Manufacturer | Adaptica S.r.l.                                  |  |
| Address      | Via San Marco, 9/H<br>35129 Padova (PD)<br>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   |

### 3. Glossary

|                         |   |
|-------------------------|---|
| <b>Accommodation:</b>   | 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.                                   |
| <b>Anisometropia</b>    | A condition in which the refractive power of the eyes is unequal.   |
| <b>Astigmatism</b>      | 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. |
| <b>Auto Shutdown</b>    | A procedure whereby 2WIN stops to work and switches off automatically.  |
| <b>Auxiliary window</b> | Graphical window that displays additional data.   |
| <b>Binocular vision</b> | The use of both eyes simultaneously in such a manner that each retinal image contributes to the final percept of a single image.  |
| <b>Diopter</b>          | The refractive power of a lens. It is used as a unit of measurement in refraction.  |
| <b>Esophoria</b>        | A tendency for the eyes to turn inward, when fusion is suspended.   |
| <b>Esotropia</b>        | Marked turning inward of the eye; crossed eyes.   |
| <b>Exophoria</b>        | A tendency for the eyes to turn outward, when fusion is suspended.  |
| <b>Exotropia</b>        | Divergent strabismus; abnormal turning outward of one or both eyes.   |
| <b>Fixation</b>         | Movement of the eyes so that the visual axes meet and the image of an object falls on the corresponding points of each retina.  |
| <b>Focal point</b>      | The point to which rays are converged after passing through a lens.   |
| <b>Heterophoria</b>     | A tendency for deviation of the eyes, when fusion is suspended.   |
| <b>Heterotropia</b>     | 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.

**Packages**

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, via dynamic photoskiaskopy.

## **5. Classification and Applied Standards**

### **Classification according MDD 93/42/EEC, Annex IX**

Class IIa

### **Classification and type of applied parts**

There are no applied parts.

### **IP classification**

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

### **Electromagnetic compatibility**

This device has been classified as class B according to the normative IEC60601-1-2.

### **Applied standards**

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

## 6. Quick user guide

Register your 2WIN: registration takes less than 1 minute!



It's highly recommended to register your 2WIN at:

<http://www.adaptica.com/user-registration/>

or sending an e-mail to [register2win@adaptica.com](mailto:register2win@adaptica.com) containing your **Name**, **Surname** (or the **name of your Organization**), **your Nationality** and **2WIN serial number**. Product Registration allows us to send:

- **software updates**
- **additional software packages**
- **service information**
- **helpful hints related to your product.**

### Important

- The 2WIN is a binocular refractometer and vision analyzer. It measures refraction of both eyes at the same time, at a 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.
- Please familiarize yourself with the measurement conditions and techniques of the 2WIN in order to exploit its full potential.

### 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.

- 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.

## Main applications

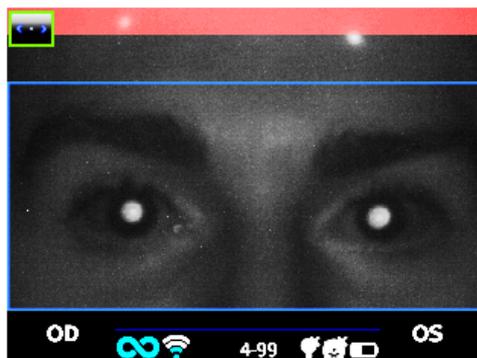
- Refraction of infants and children from 2 months of age, seniors, impaired and non-cooperative patients.
- Early detection and documentation of multiple amblyogenic factors.
- Un-aided binocular refraction of all other patients
- Over-refraction of glasses or contact lenses.

## Exam conditions

- The patient shall sit comfortably in a suitable exam room; infants should sit in an adult's lap. A uniform dim light environment is necessary.
- The 2WIN accuracy is affected by external sources of 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.

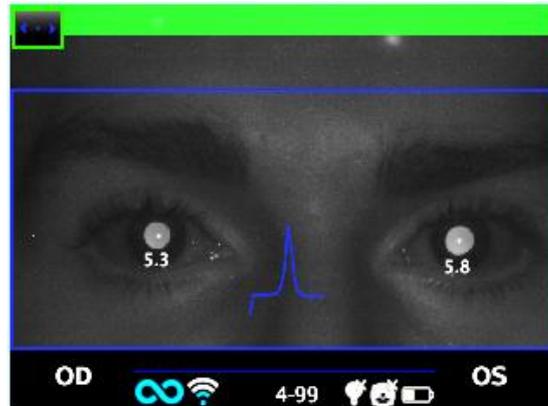
## Exam procedure

- Turn the 2WIN ON by pressing the ON/OFF button for 1 sec. and wait until the stand-by screen appears.
- Instruct the patient to keep his/her eyes wide open, clear of eyelids or eyelashes, and to fixate the centre of the camera (possibility to activate a small central LED in the 2WIN Menu). 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 reaches the highest peak (as shown in the following photo) release the BUTTON S1/S2.



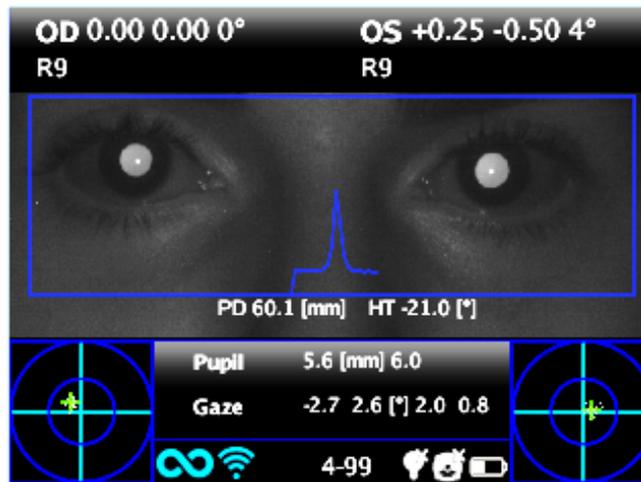
Examination screen – focus OK

- 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

## Measurement tips

- For both Sph and Cyl, measurement accuracy is  $\pm 0.25$  D in the range of  $\pm 5$  D. The cylinder axis is calculated between  $1^\circ$  and  $180^\circ$  (step  $1^\circ$ ) 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 Live Display (see 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.
- Make sure the Reliability Index of the refraction measurement is higher than 5 (max. is 9). In case of Reliability Index of 5 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.

## 7. Description of the device

The measuring principle of the device is based on eccentric photo-retinoscopy. 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.

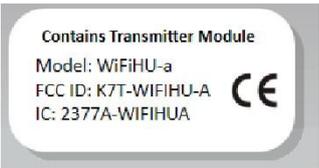
The device accepts a pupil diameter between 4 and 7 millimeters (it is possible to measure down to 3.5 and up to 11 mm but this depends on good environmental conditions. Outside the 4-7 range the overall precision could decrease) and is compatible with the measure in mydriasis and in miosis.



It incorporates sight and sound stimula for use with children and uncooperative patients. 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. It can be connected to a mini-printer, via IrDA (Infrared Data Association) interface, to print the measurement results onto a strip of paper.

2WIN can be accessorized with a Wifi transmitter module. A label inside the USB & SD connection door identifies the presence of the Wifi module.

## Labels

| Label   | Detail   | Explanation   |
|---|--|---|
|  <p>Adaptica S.r.l.<br/>Via San Marco, 9H<br/>35129 Padova - Italy<br/>model: 2WIN<br/>s/n: 2WIN-EA00101<br/>3.6V 2013</p> |  Adaptica S.r.l.<br>Via San Marco, 9H<br>35129 Padova - Italy | Manufacturer identification data: name and address  |
|   | model: 2WIN  | Model name  |
|   | s/n: 2WIN-EA00101  | Serial number, including manufacturing date:<br>2WIN = model code<br>D = year (A=2009 B=2010 ..)<br>F = lot<br>00001 = unique serial number |
|   | 3.6V   | Battery operating voltage   |
|   | CE<br>0123   | CE mark and Notified Body identification code   |
|   |   | Electrical / electronic device subject to the WEEE Directive on waste disposal  |
|  <p>Contains Transmitter Module<br/>Model: WiFiHU-a<br/>FCC ID: K7T-WIFIHU-A<br/>IC: 2377A-WIFIHUA</p>                   | Model<br>Fcc ID<br>IC  | Identifies the Wifi transmitter module  |



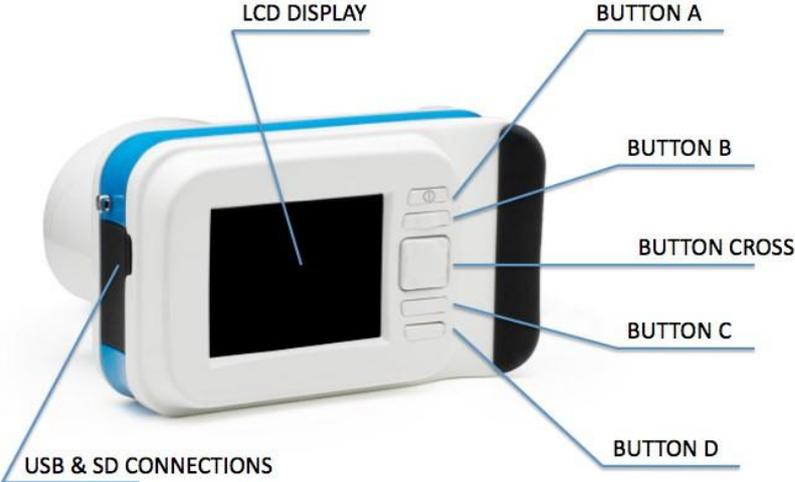
## Package labeling

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

# 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

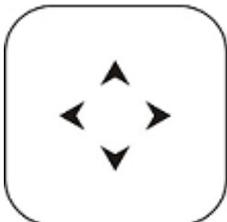
*Operator side:*



BUTTON A



BUTTON B



CROSS BUTTON



BUTTON C



BUTTON D



**IMPORTANT NOTE:** the buttons have different behaviors 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 package (screening) and additional packages;
- long LEFT push: activates keyboard to insert patient name and date of birth;
- 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:**

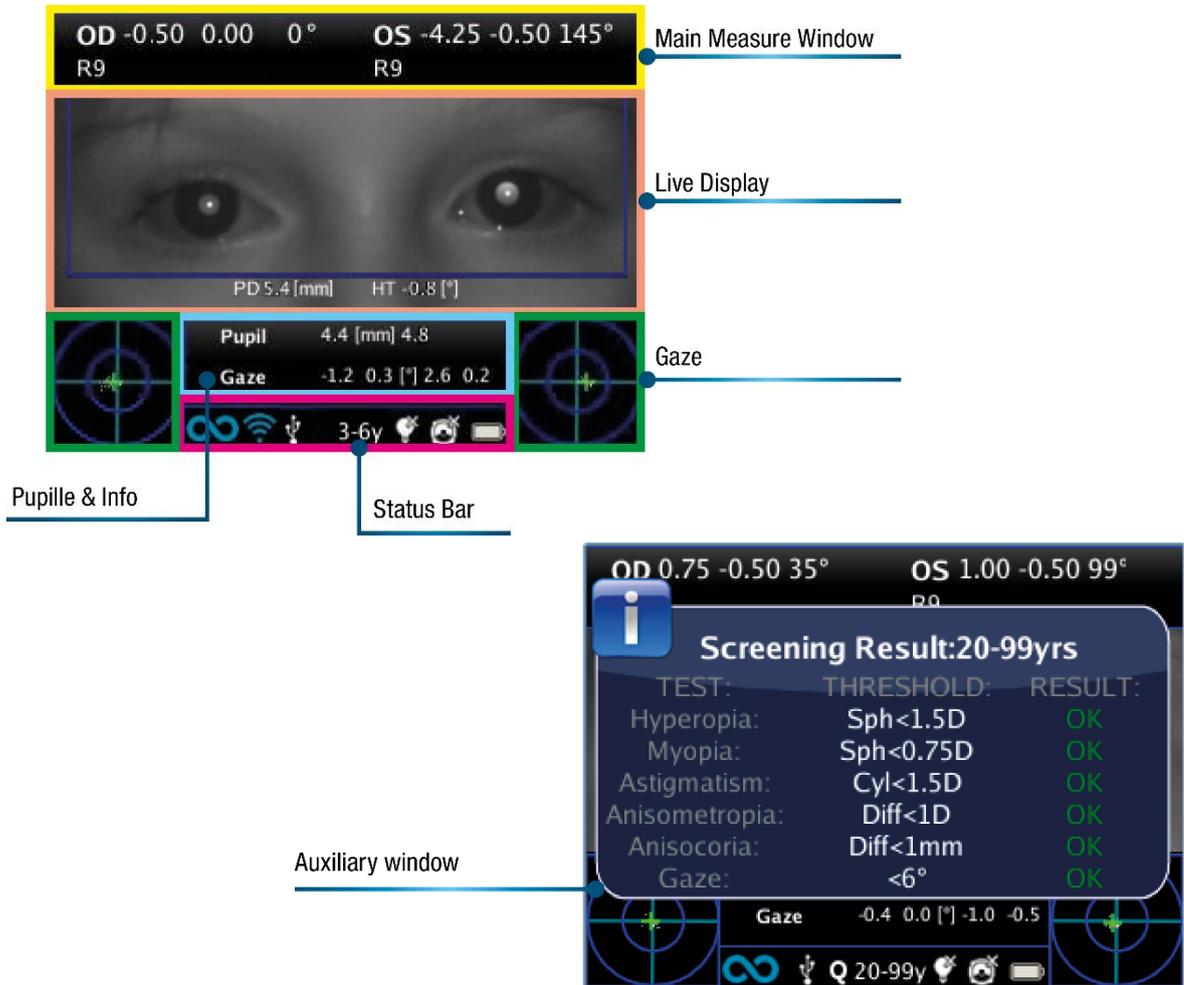
- Cross button CENTRE: select the field (or letter) highlighted;
- Start button: Enter;
- Cross button, UP/DOWN/RIGHT/LEFT buttons: move between characters;
- Button A: exit;
- Button B: moves the cursor in different fields;
- Button C: backspace;
- Button D: resume;

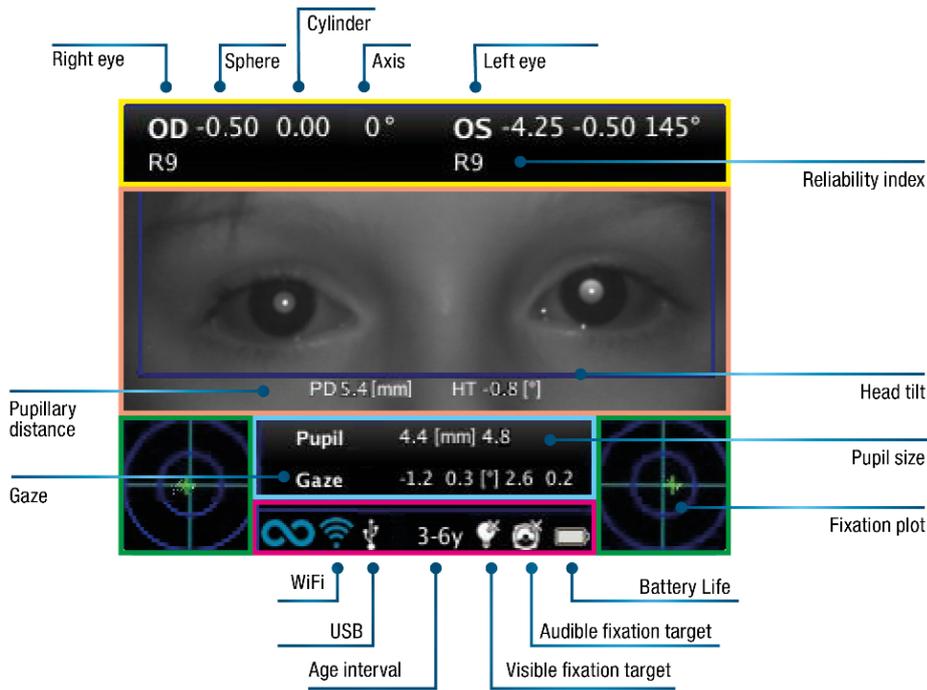
All the button functions are summarized in the following figure:

| <b>BUTTON</b>     | <b>HOME</b>                | <b>BROWSE</b>       | <b>KEY-BOARD</b> | <b>DATE TIME</b> | <b>SCREEN AGE</b> | <b>MENU</b>       | <b>IN MEASURE</b> |
|-------------------|----------------------------|---------------------|------------------|------------------|-------------------|-------------------|-------------------|
| <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>          | --                         | packages            | Change field     | Change field     | Change field      | Change field      | --                |
| <i>Up</i>         | --                         | Patient UP          | move             | Increase         | change field      | Move Up           | --                |
| <i>Up-hold</i>    | toggle refraction          | toggle refraction   | --               | --               | --                | --                | --                |
| <i>Down</i>       | --                         | Patient DOWN        | move             | Decrease         | change field      | Move Down         | --                |
| <i>Down-hold</i>  | BROWSING on                | BROWSING off        | --               | --               | --                | --                | --                |
| <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                  | BROWSE FILTER       | resume           | --               | --                | --                | Toggle Sound      |
| <i>Hold D</i>     | quick menu                 | --                  | --               | --               | --                | --                | --                |
| <i>S1/S2</i>      | Start Measure              | browseOFF           | done             | --               | --                | --                | Stop Measure      |
| <i>Hold S1/S2</i> | Focusing                   | --                  | --               | --               | --                | --                | --                |

## Graphical user interface

The graphical user interface is displayed in these figures:





## 8. 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 is connected;
- consult the manufacturer or field service technician for help.



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.

 **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.

**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 § 8 - 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 in the event that 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 parties software be installed, or parts be replaced by unauthorized persons.

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

 Do not expose the device to water: this could lead to fire or electric shock.

 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.



The device needs to be operated in a semi dark room, in order to help pupil dilation.

## 9. Operative information

### Register your 2WIN

Registration takes less than 1 minute!



It's highly recommended to register your 2WIN at:

<http://www.adaptica.com/user-registration/>

### 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

### Unpacking

The box contains (default configuration):

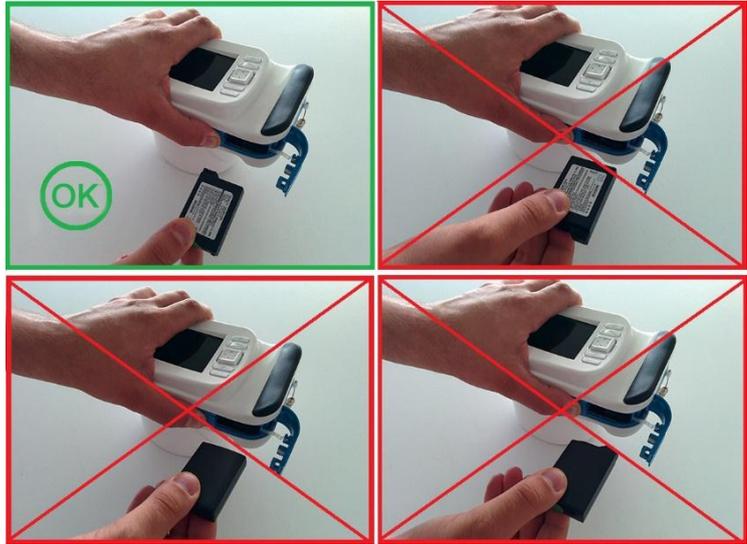
- the electronic version of the operating manual (inside the microSD)
- the 2WIN device
- two rechargeable batteries
- a microSD memory card
- a USB cable (microUSB to USB-A)
- an external battery charger to charge the battery outside 2WIN
- an occluder

Open the battery lock and insert the battery. Close the battery door and lock it.

## 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.



## Extract battery

To extract the battery: (1) slide completely the battery lock, (2) hold it firmly and (3) 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-charging

-  Please load the batteries with the external battery charger provided.
-  On first usage the battery needs to be charged for at least 4 hours.
-  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 for emergencies. In fact, to extract the battery and use an external wall battery charger is the usual procedure allowing life cycle of both battery and 2WIN device.

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.

### 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.

## Operative instructions

(Please refer to Chapter 7, Par. **Interfaces** for fast reference)

### Power ON / Power OFF

To power on the device, push the BUTTON A.

(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, center, 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. The 2WIN goes in standby after 1 min if normal or 10 min if WiFi is activated). After 600 seconds of standby mode, the device turns on, emits a sound alert, and shows a warning telling that after 30 seconds it will automatically shutdown.



Default Autoshutdown Time is 10 min.

Autoshutdown time (modifiable 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 > Autoshutdown 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**

## a Environment setup

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

### ✓ Verify adequate light conditions

The ambient light should be low, there should be no lamps directly 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.

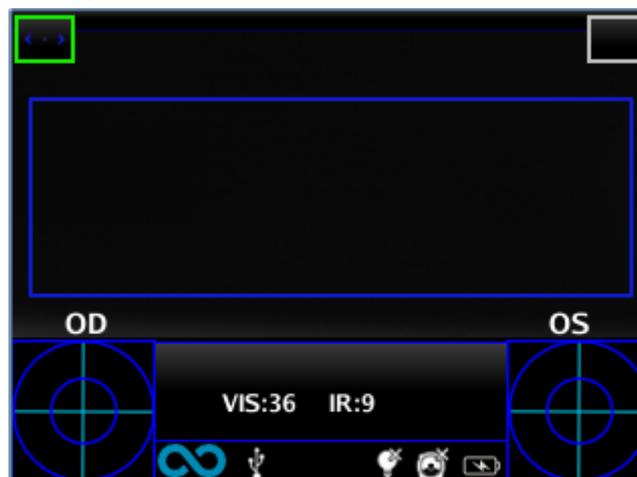
The device can be used to perform an evaluation of the ambient light: in Menu > Functions > Light Meter the following screen will be displayed.



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

- VIS and IR will represent 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.

An **UP arrow** inside the rectangle means that the distance is too high, and the operator needs to get closer to the patient, while a **DOWN arrow** means that the distance is too small, and the operator needs to get away from the patient.

## **b Instrument 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 performing an examination or a sequence of examinations.

Main settings are related to measured eye and interactivity.

Other settings are described in the Menu paragraph.

### **Eye selection**

There are three options related to which eye of the patient is being measured. By pushing in sequence 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 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 of the other. Therefore the sign OS will appear on the right half of the screen, and viceversa.

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



Power-ON screen with OS

## 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

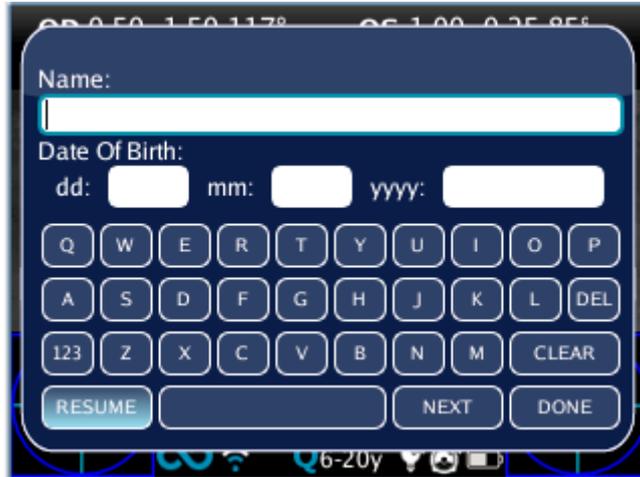


sound off

## Patient data

After a measurement patient data can be inserted.

In the CROSS button press and hold the left button until the patient data keyboard appears. Insert name of the patient and date of birth (optional), as shown in the following figure:



During active keyboard, use the following buttons:

- Cross button center: select the field (or letter) highlighted
- Start button: Enter
- Cross button up/down/right/left buttons: move between characters
- Cross button, central button and/or Start button: Enter
- Button A: exit
- Button B: move cursor in different fields
- Button C: backspace
- Button D: resume



**IMPORTANT NOTE.** A new measurement cancels the patient data.

To resume the last patient data, enter in keyboard active mode (long press left) and press Button D / resume.



**IMPORTANT NOTE:** If 2WIN has Wi-fi capabilities, it's possible to insert patient data in a different way. Look at paragraph 9 "Wi-fi connection" pag.61.

## 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, screening age, 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 refreshing icon (circular shape arrow) appears.

If a stored patient data has been saved with a 2WIN sw 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 button the patient's data is shown overlaying the image for a couple of seconds. Data shown are: patient number, patient name, date of birth, screening age, folder name, exam date and software version used to acquire and save the exam.

## **c 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.

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.

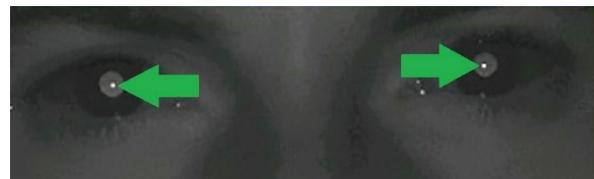
In case of monocular measurement, ask the patient to cover his other eye with a hand.

## d Measurement

The instrument, since the beginning of the examination, uses a 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.**

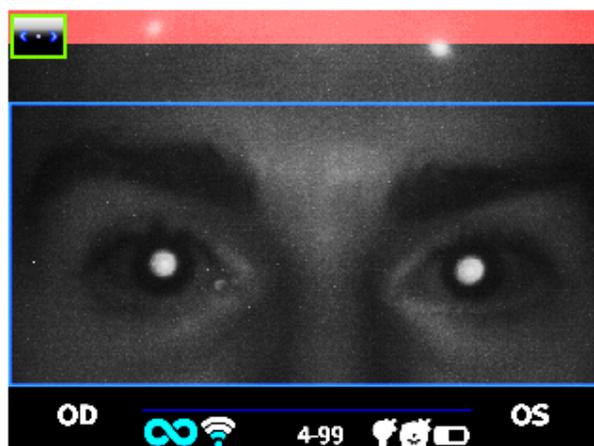
**Try every time to focus as best as you can, looking at the corneal reflex. The corneal reflex focusing indicator must be as sharp as possible and as high as possible.**



Sharp corneal reflexes

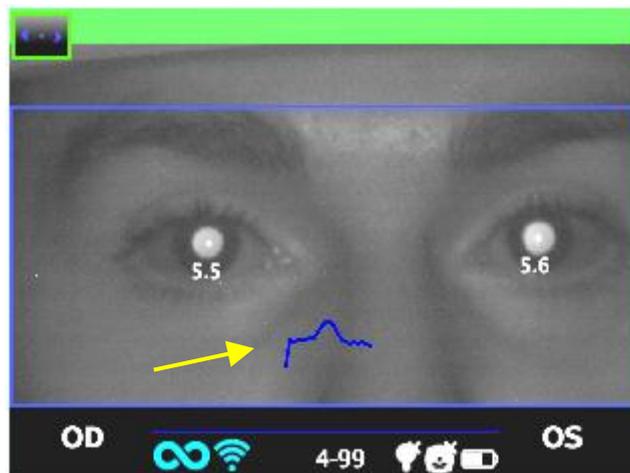
The steps to perform a measurement are summarized in the following list:

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. Center the eye/s of the patient in the display live area, inside the blue rectangle (measurement area) – the message **“FOCUSING”** will appear.

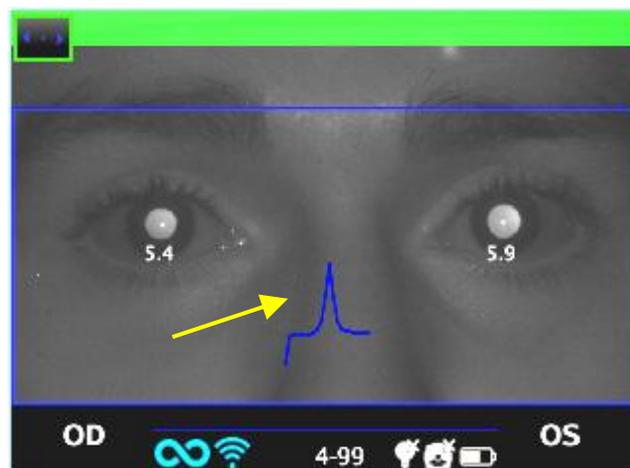


Examination screen – bad focus

- 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 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.



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

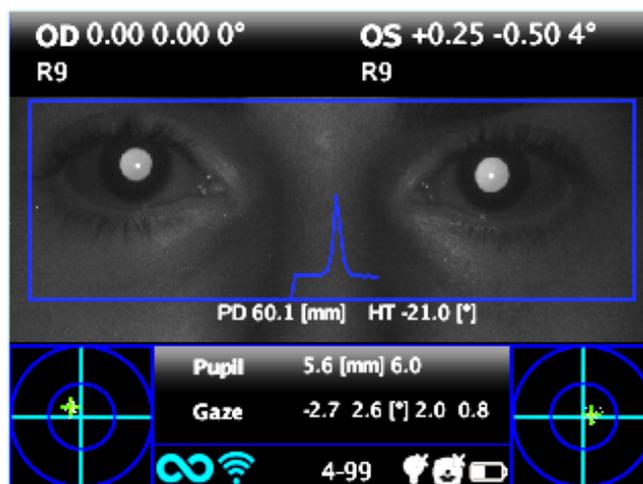
- *If in binocular refraction the two eyes have very different pupil diameters (that means anisocoria) a popup will appear on the display. It is suggested to measure eyes singularly in two different measurements.*



Possible anisocoria

For any problem during operation, please refer to the chapter “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 centers 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 center 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 print button to save data to SD memory card and/or sent data to IrDA printer (see Print paragraph);
- 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.
- long left push: activates keyboard to insert patient name and date of birth: ACTIVE KEYBOARD MODE.
- long right push: 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 center button to select the item highlighted (N.B. If the date of birth has been already inserted via the long left press, then the age interval is automatically set). Push “Ok” to save the choice.

## Menu

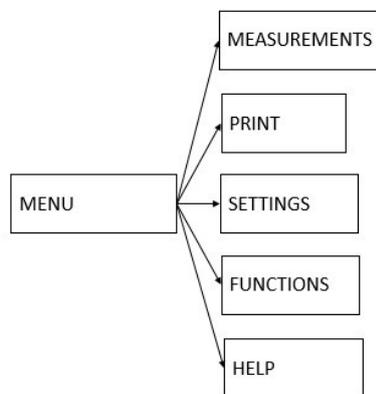
Through the menu it is possible to configure all the features and the working modes of the device.

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:

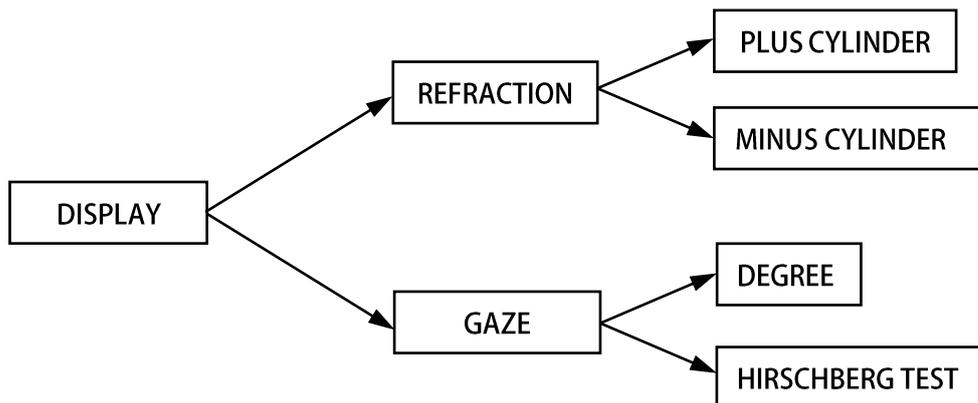


The first level menu entries are described in the following paragraphs.

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



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

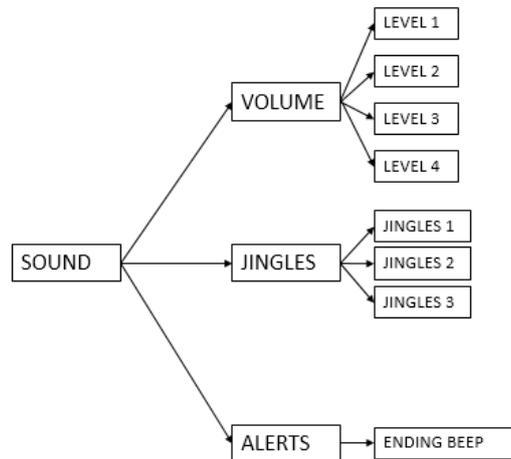


**Refraction:** allows choice between plus and minus cylinder visualization. Once the measure is displayed, it is still possible to toggle between the two visualization modes by pressing the UP arrow on the cross button.



**NOTE:** If Wide live is activated it is not possible to measure the ambient light

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

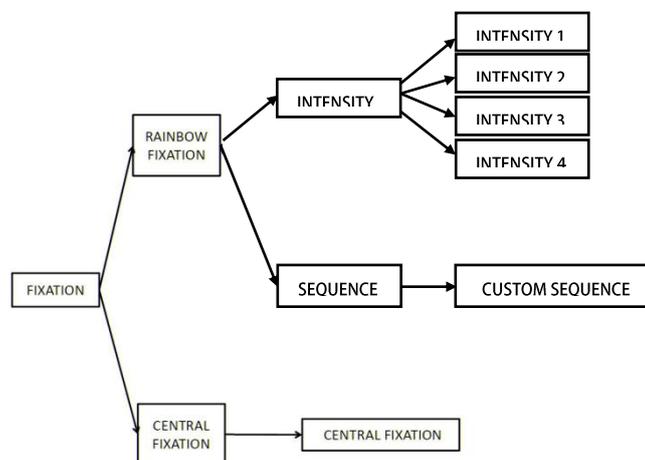


**Volume:** sets audio power output for the interactivity sound, within a range of four levels.

**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.

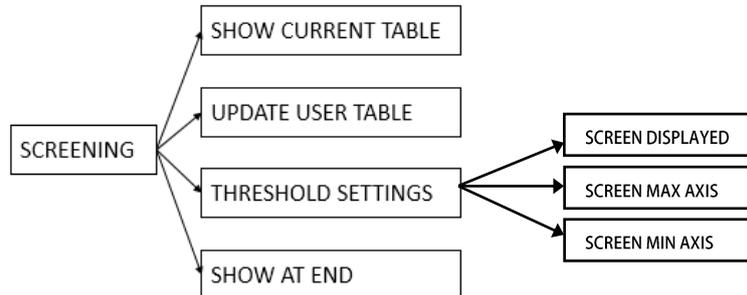
- The submenu **Fixation** configures the interactivity light.



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 an 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.

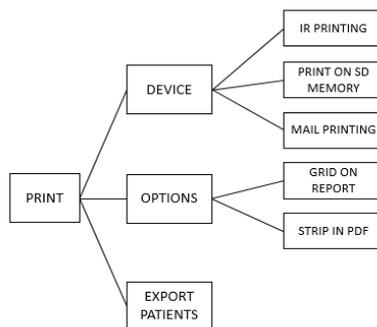


'**Update User Table**' is selected when uploading a user table, and for uploading a newly compiled user table.

'**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 package 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.

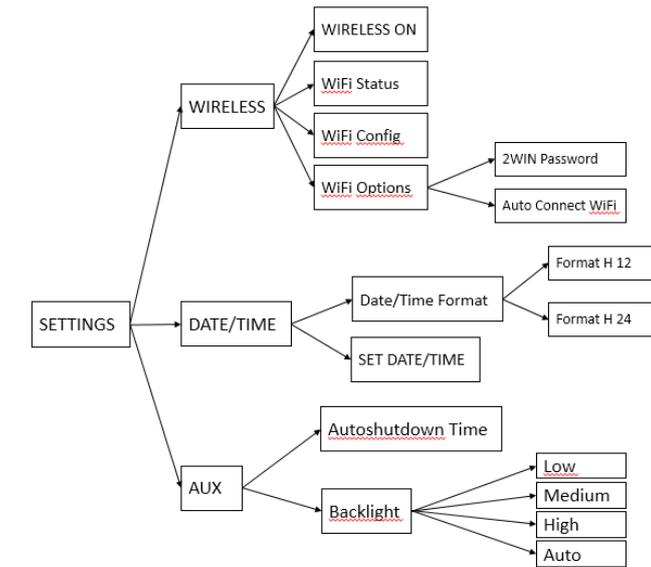
**Print on SD memory**: enables/disables saving the exam onto SD card.

**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.

- 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 9.

#### Date/Time:

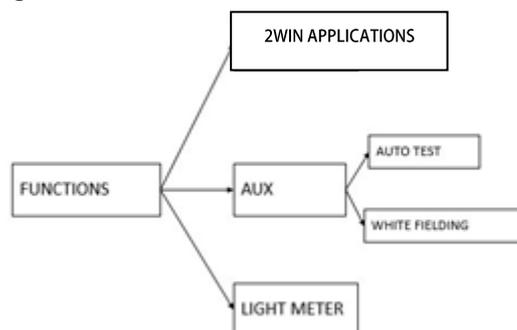
**Date/Time Format** allows to choose between H12 or H24 format.

**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 feature:





From this menu it is possible to activate **2WIN Applications**. This functions is described in chapter 9.

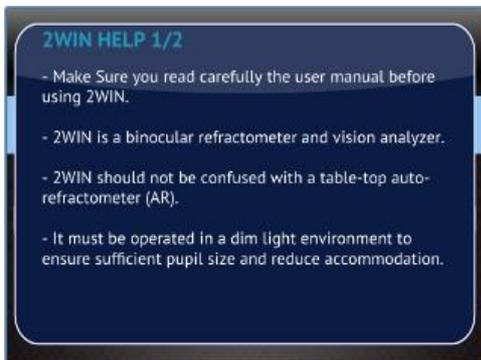
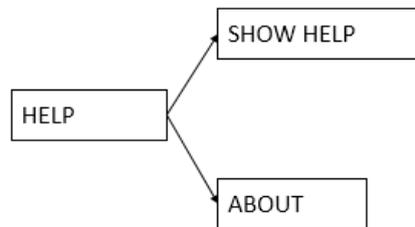
**AUX: Auto test** allows to make a self hardware test of the device.

**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 (Do not use the “Wide Live” option when evaluating the ambient light or you will not be able to see the light meter values).

In the **Help** submenu, it is possible to select the Help page and the menu item About shows information about the device, such as the software version and the hardware version.

- In the Help submenu, it is possible to select the page of Help / Help, while the item About / Info displays information about the device, such as the software version and the firmware version.



First page of help

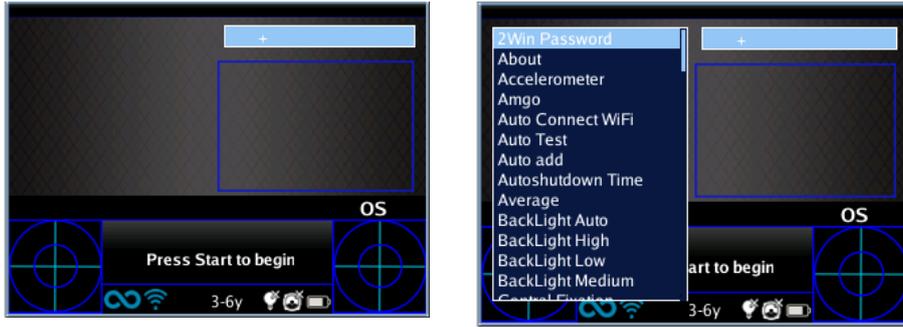


About' message

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

## 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.



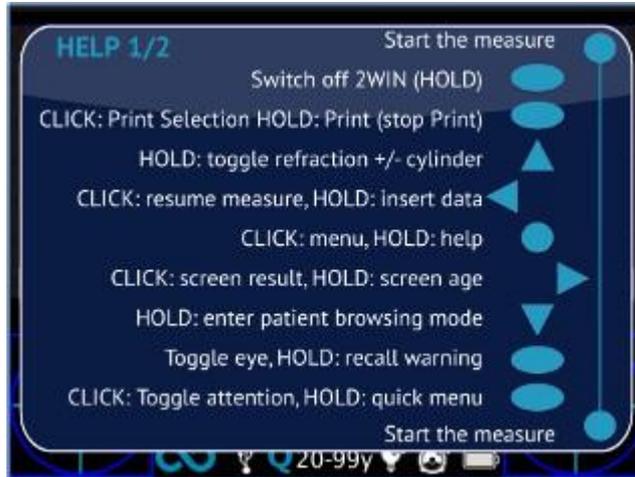
How to add an item in the quick-menu.



Possible configuration of the quick-menu.

## Contextual Help

At any time, holding the menu button, an help page is shown if the page provides one. Pages with the help option are: Main/Home, Menu, Keyboard, Screening 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 buttons.

## Summary of menu entries

|                        |               |                          |                          |
|------------------------|---------------|--------------------------|--------------------------|
| <b>1.0 Measurement</b> | 1.1 Display   | 1.1.1 Refraction         | 1.1.1.1 Plus Cylinder    |
|                        |               |                          | 1.1.1.2 Minus Cylinder   |
|                        |               | 1.1.2 Gaze               | 1.1.2.1 Degrees          |
|                        |               |                          | 1.1.2.2 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        |                          |

|                  |                     |                               |
|------------------|---------------------|-------------------------------|
| <b>2.0 Print</b> | 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 |                               |

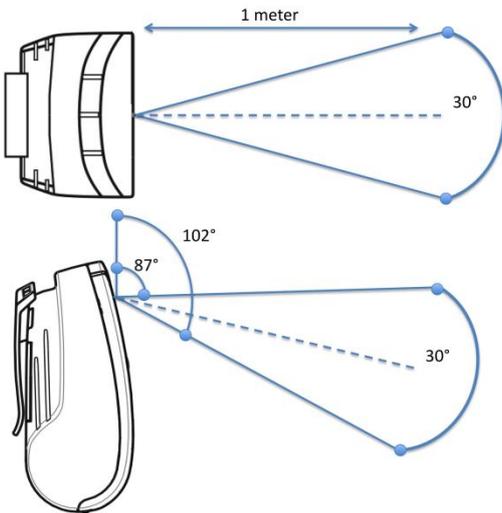
|                     |               |                         |                              |
|---------------------|---------------|-------------------------|------------------------------|
| <b>3.0 Settings</b> | 3.1 Wireless  | 3.1.1 Wireless ON       |                              |
|                     |               | 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 |
|                     | 3.2 Date/Time | 3.2.1 Date/Time Format  | 3.2.1.1 Format H12           |
|                     |               |                         | 3.2.1.2 Format H24           |
|                     |               | 3.2.2 Set Date/Time     |                              |
|                     | 3.3 Aux       | 3.3.1 Autoshutdown Time |                              |
|                     |               | 3.3.2 BackLight         | 3.3.2.1 Low                  |
|                     |               |                         | 3.3.2.2 Medium               |
|                     |               |                         | 3.3.2.3 High                 |
|                     |               |                         | 3.3.2.4 Auto                 |

|                      |                       |                            |                              |
|----------------------|-----------------------|----------------------------|------------------------------|
| <b>4.0 Functions</b> | 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       |                            |                              |

|                 |               |
|-----------------|---------------|
| <b>5.0 Help</b> | 5.1 Show Help |
|                 | 5.2 About     |

## Print

In order to print or to save the data press **BUTTON B**, once the measurement is done. If you want to print via the external optional portable IrDA (Infrared Data Association) printer, remember to point the machine towards the printer according to the following diagram before pressing the button.



IrDA Printing positioning



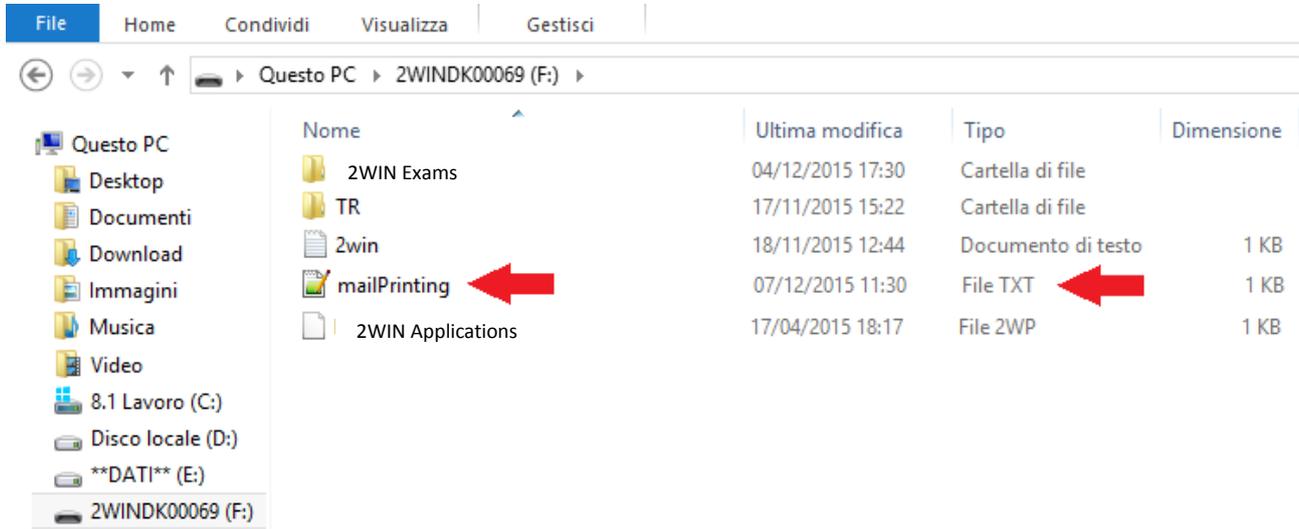
IrDA portable printers

You can print the same exam as many times as needed.

When printing to IrDA printer, the data transmission can be interrupted and aborted by keeping the **BUTTON B** pressed for 1 second.

## 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.



Ex. Mail printing

## Save exam

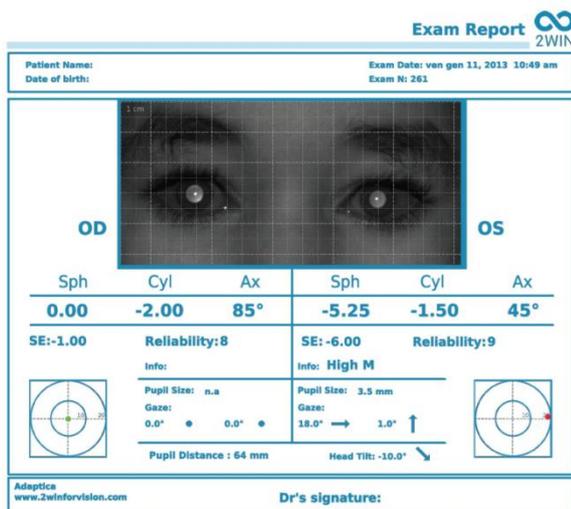
If the SD card printing is inserted, a set of 4 files for each examination will be saved into the SD card, into the folder Patients (“2WIN Exams” if the software version is the 4.0 or more), there creating a subfolder named 2WINExam \_date\_number, where date is current date and number is a sequential 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 will contain at least 4 file, with the same name as the folder, but different extensions:

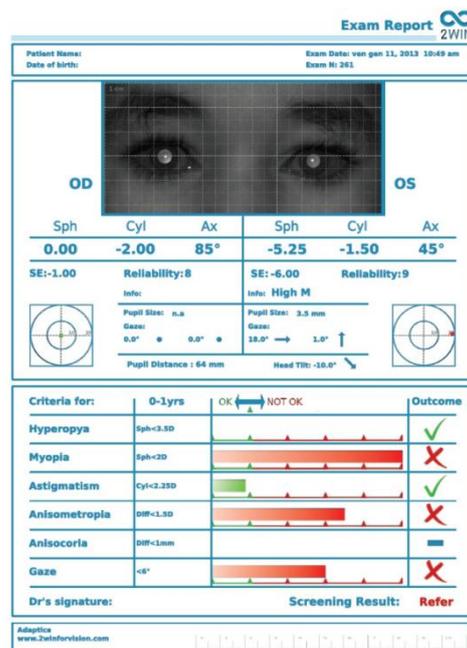
- \*.pdf = examination results form for a A4 size paper (printable from a personal computer), other pdf can be written by specific functions.
- \*.jpg = original picture of the eyes of the patient
- \*.xml = xml file version of the measurement results
- \*.2win = binary file (for service purposes only)

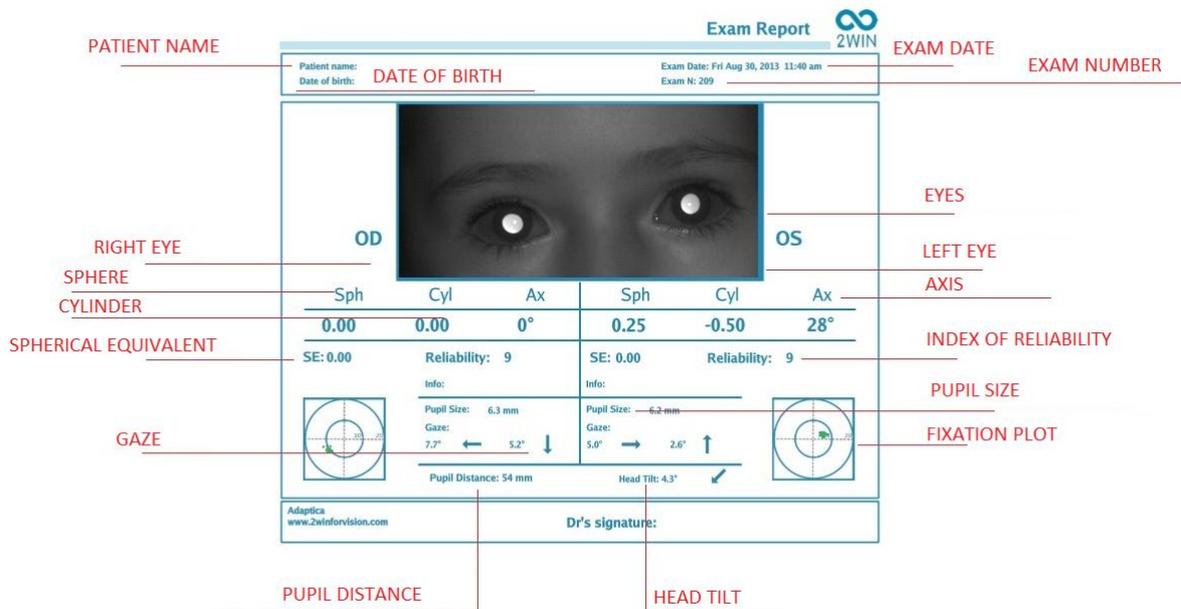
For data saved in pdf format., a grid on exam report can be added selecting the option 'Grid on Report' from Menu Print/Options/Grid on Menu.

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

## 2WIN

Wed Jun 01, 2016 12:36 am  
No: 744

OD:  
SPH CYL AX  
-2.25 -0.75 137 9  
Ø Pupil:5.5 Gaze:-1.7 -0.4

OS:  
SPH CYL AX  
-3.25 0.00 0 9  
Ø Pupil:6.1 Gaze:3.5 1.0

PD: 64 mm

Adaptica  
www.adaptica.com

Printout sample from portable IrDA printer

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 options 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 patient data 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.



## Meters

The device features two meters: an accelerometer/inclination meter and a distance meter.

When measuring, and in case the meters are enabled (see Menu section) on the top corners of the display two boxes will monitor the status of the two meters: on the left corner for inclination and on the right corner for distance.

The status of the meters is highlighted by means of box border color coding, according to the following rule:



GREEN: the measurement is in progress and the distance/inclination is OK



YELLOW: the measurement is in progress but the distance/inclination can be improved



RED: the measurement is in progress and the monitor indicates a bad indication of the meter



GRAY: the meter cannot perform the measurement.

The meters can be disabled in the Menu.

### Accelerometer/Inclination Meter:

The inclination meter is used to give a feedback to the user about the 2WIN inclination. The indicator is a double arrow that moves indicating the inclination. A gray box means that the meter is inactive, so the double arrow is to be disregarded. A red box indicates an excessive inclination.

During the measurement a line connecting the two eyes on the display gives the measure of the angle of inclination of the patient's head with respect to the ground.

### Distance Meter:

The distance monitor gives an indication of the position to be kept from the patient during the measurement. The indicator will be an arrow indicating in which direction the machine shall be moved to reach a better distance. The arrow can be yellow or red according to the monitor state.

It is important to notice that the distance meter can give a rough indication of the position to be taken during the measurement, but the focus monitor output should be the preferred criteria.

Moreover, it is not guaranteed that distance measure is always performed, due to long patient hairs or other interferences. When the monitor box border is gray, and no indicator

is displayed, the refraction measurement can be performed anyway without prejudice for the results.

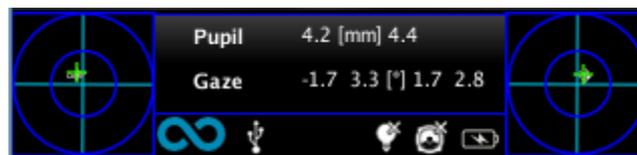
## Gaze

“Gaze” values measure horizontal and vertical (in this order) offset angles, in degrees, of the average position related to the main corneal reflex on respect of the center of the patient's pupil.

The corneal reflex is on the virtual line connecting the 2WIN camera with the patient cornea and the fovea, that is the virtual patient's fixation direction.

The gaze measurement of the 2WIN is calculated representing the average of the positions of the corneal reflex (1st Purkinje image) collected 10 times per second during the measurement time .

The Gaze direction is measured as the distance between the corneal reflex and the geometric center 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 center, 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:



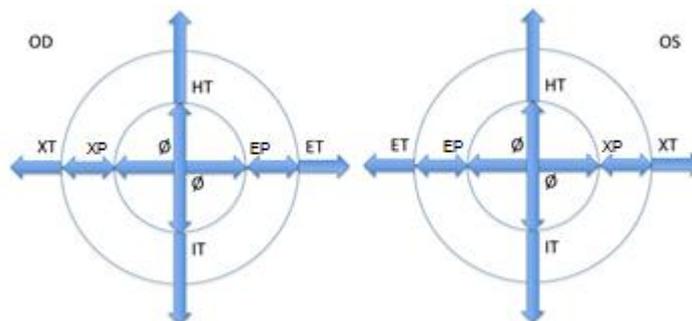
Low fidelity message

## 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.



## 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

## Notification Center

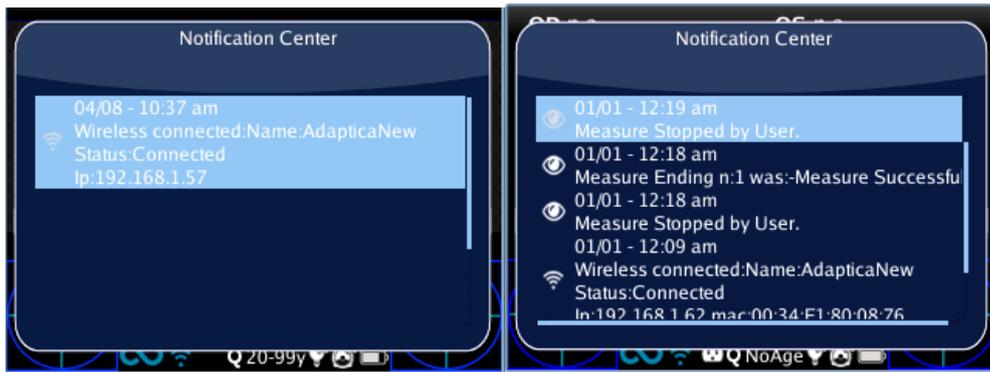
This feature allows the real time monitoring of 2WIN messaging and logs. There are reported 3 different types of information: notifications on the measurements, notifications on the WiFi networking status and logins and notifications on the additional software packages installed.

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.



## Screening Mode

If date of birth is not inserted, an age interval can be selected: from the home display, in the Cross button keep pressed the right button to display the 'Screening Mode'.



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 screening age 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.

## 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.

### Customization



|           | HYP: | MYO: | AST: | ANM: | ANC: | GAZ: |
|-----------|------|------|------|------|------|------|
| 1-2.5yrs: | 4.5  | 3.5  | 2    | 2.5  | 9    | 4.6  |
| 2.5-4yrs: | 4    | 3    | 2    | 2    | 9    | 4.6  |
| 4-99yrs:  | 3.5  | 1.5  | 1.5  | 1.5  | 9    | 4.6  |
| 4-99yrs:  | 3.5  | 1.5  | 1.5  | 1.5  | 9    | 4.6  |
| 4-99yrs:  | 3.5  | 1.5  | 1.5  | 1.5  | 9    | 4.6  |

To insert a custom table, a file 'screeningTable.txt' has to be written and inserted in the SD memory card.

Data must be written in the first five lines of the file. Each line corresponds to an age interval (maximum five intervals).

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 pupils 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 above condition has to be verified together with the condition that the distance between the Purkinje reflection, normalized to the center, must lower than the threshold.

The following as an example:

|    |    |     |      |      |     |   |   |
|----|----|-----|------|------|-----|---|---|
| 0  | 1  | 3.5 | 2    | 2.25 | 1.5 | 1 | 6 |
| 1  | 3  | 3   | 2    | 2    | 1   | 1 | 6 |
| 3  | 6  | 2.5 | 1.25 | 1.75 | 1   | 1 | 6 |
| 6  | 20 | 2.5 | 0.75 | 1.5  | 1   | 1 | 6 |
| 20 | 99 | 1.5 | 0.75 | 1.5  | 1   | 1 | 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.

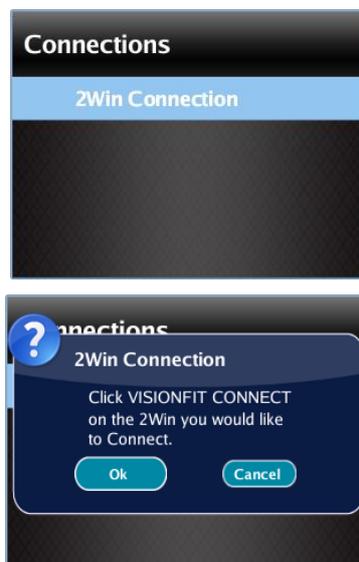
## Pairing and transferring a 2WIN test to VisionFit

### a) Pairing VisionFit and 2WIN

1. Activate WI-FI on VisionFit
2. Activate WI-FI on 2WIN and choose the same WI-FI Network as the VisionFit
3. Select the **2WIN Connection** from *Menu > Settings > Wireless > Connections > 2WIN Connection*



Do not close the window.



4. Select **VisionFit Connection** from *Menu > Settings > Wireless > Connections > VisionFit Connections*



A new window notifying the correct pairing will be displayed



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



**NOTE:** remove the pairing (from VisionFit) by selecting: *Menu > Settings > Wireless > Connections > 2WIN Connection*.



#### b) Transferring a 2WIN test to VisionFit

To transfer a 2WIN measurement to VisionFit, follow the steps below:

5. **Perform a test using the 2WIN.** Press the joystick down in 2WIN. 2WIN data will appear instantly on the right side in VisionFit (Reference data area). If the 2WIN test has already been performed, browse the 2WIN “Browsing Mode” and hold the joystick down. Data will appear in the Reference area in VisionFit data.
6. **Press VisionFit joystick** (menu button) **to the left** if you want to add data to the Subjective Area.



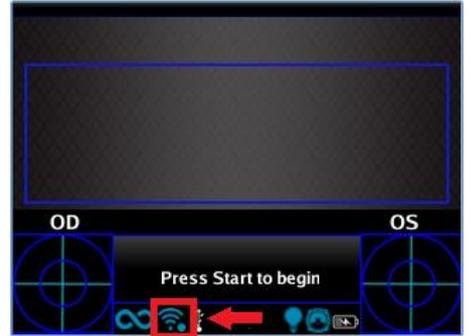
Since two devices (2WIN and VisionFit) are paired, transfer will be performed following steps 5 and 6. Pairing must be performed again only if you change devices (2WIN or VisionFit) .



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



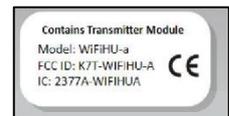
Blue sphere near WiFi symbol indicates the connection with the VisionFit.



# 10. Wireless connections

## 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.

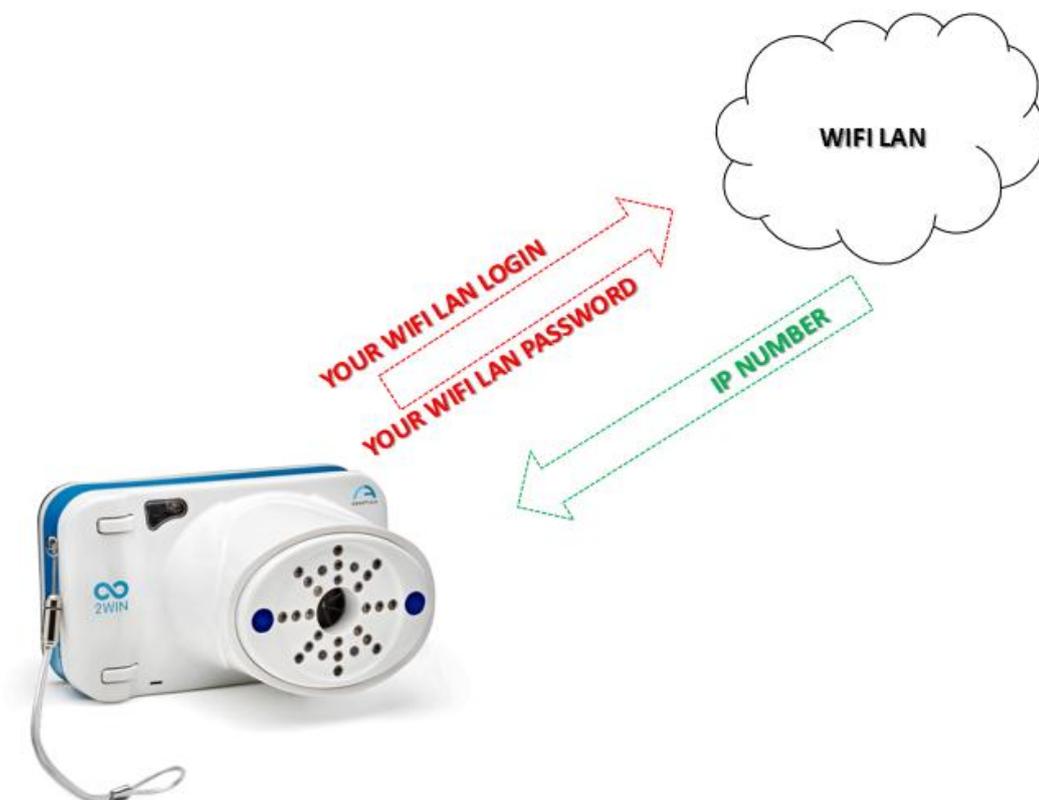


- a) It is possible to **download** and **visualize patient data from the 2WIN** to an external device (e.g. Tablet, smartphone).

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

- b) 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 a iOS and Android smartphone/tablet device or in a personal computer with Windows or MAC OS.



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 a IP number to the 2WIN

In order to enable the wireless (WiFi connectivity) in the 2WIN-W is necessary to follow the following steps:

In order to enable the wireless (WiFi connectivity) in the 2WIN-W is necessary to follow the following steps:

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

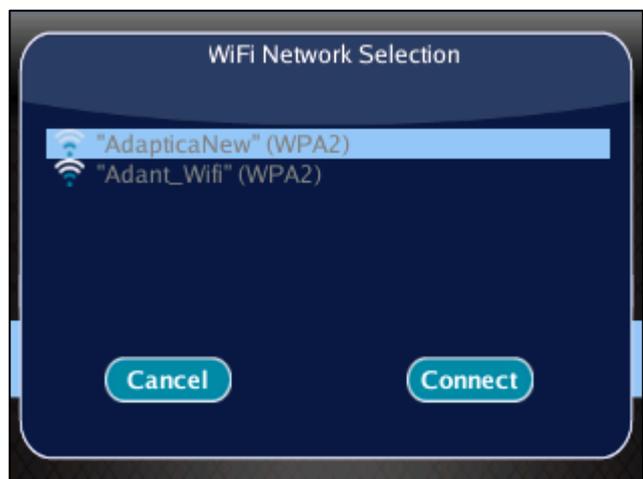
You will see the item Wifi Activation and a tick will be displayed next to the label Wireless ON.



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

3. Select your favourite Wifi network, then push the cross button to make appear the network password insertion window.

- Insert the **Password** of the network;
- select and push the button “**Done**”;
- select and push the button “**Connect**”.



If you want, select **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 will be **activated** automatically after power-on.



4. Click on the item **WiFi Status** (or directly from Notification Center) to (1) **check if the 2WIN is connected to your network** and to (2) **determine the IP 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.

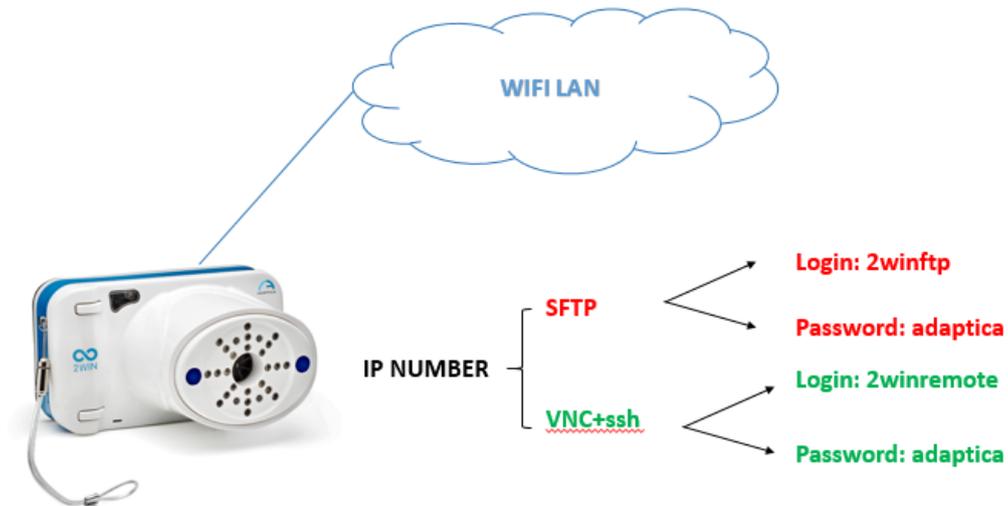
To change the password, go to “**WiFi Option**” and set the new security key.

 **NOTE:** For security reasons, It's



recommended to change the password as the default one is common to all 2WIN.

## Sftp e vnc + ssh access credentials



The sftp access to 2WIN is carried out with the following setting:

**User:** 2winftp      **Password:** adaptica\*

There must be a Micro SD card to view the content.

**Port:** 22

\*adaptica is the default password if not changed by user

-----

The VNC+SSH access to 2WIN is carried out with the following setting:

**User:** 2winremote      **Password:** adaptica\*

**Port:** 5900

\*adaptica is the default password if not changed by user

## SFTP and VNC+SSH suggested softwares

|                  | MAC OS X<br><i>(computer)</i> | ANDROID<br><i>(tablet)</i> | iOS<br><i>(iPhone - Ipad)</i> | PC WINDOWS<br><i>(computer)</i> |
|------------------|-------------------------------|----------------------------|-------------------------------|---------------------------------|
| <b>SFTP</b>      | Filezilla                     | Turbo ftp                  | FTP Manager Free              | Filezilla                       |
| <b>VNC + SSH</b> | TightVNC<br>Java Viewer       | BVnc                       | REMOTER Pro*                  | TightVNC<br>Viewer<br>Java      |

\*At the date of this manual review this application is not free

**NOTE: Adaptica suggests the use of the above applications/software for working with the SFTP and VNC + SSH services of the 2WIN.**



**The specific (1) installation procedure, (2) use and (3) support of these apps can be acquired reading the specific apps user manuals. The 2WIN user MUST read those manuals.**

### Keyboard command for the use of vnc+ssh

Once the VNC + SSH app is connected to the 2WIN, the procedure to input patient data (after the measurement) is:

- 1.** Type with your virtual keyboard the Enter button.

This will show in the smartphone/tablet and in the 2WIN the KEYBOARD MODE.

- 2.** In the virtual keyboard you can input data, switching between the data fields using the “full stop” (.) button.
- 3.** When the input of the data is finished press again the Enter button in your virtual keyboard.
- 4.** You can continue working on the 2WIN for saving or printing data.

# 11. 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 package will be described in a specific package manual. You will be notified via email about the availability of a new 2WIN software package. In this document it is described the installation/management of additional packages.

## Installation

Send an e-mail for a package request with the serial number of your 2WIN. The complete list of 2WIN software package at [www.adaptica.com](http://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.

## Activation

After the installation, a package is not enabled by default. To activate the package earlier installed, navigate the menu to Menu>Functions>Packages and see all installed packages. Push right the CROSS button to go into the submenu and select the item that you want to activate.

Push center the CROSS button to activate the package.

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



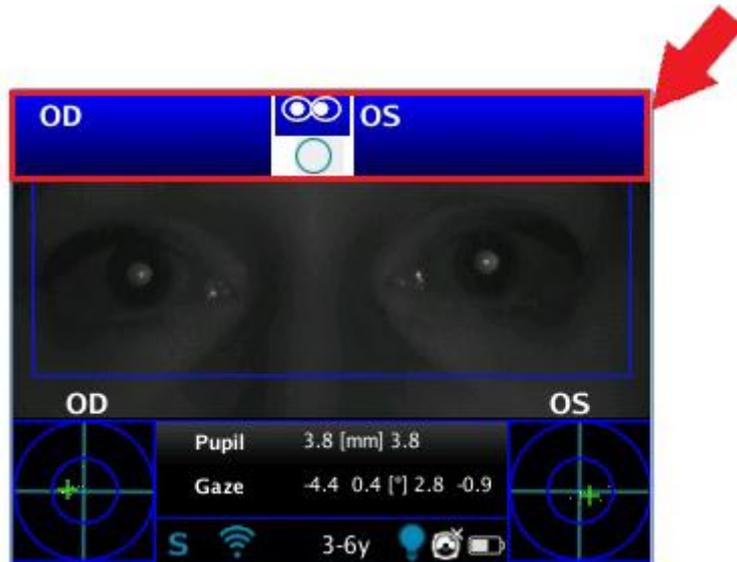
Icon of the main package active

## Visualization

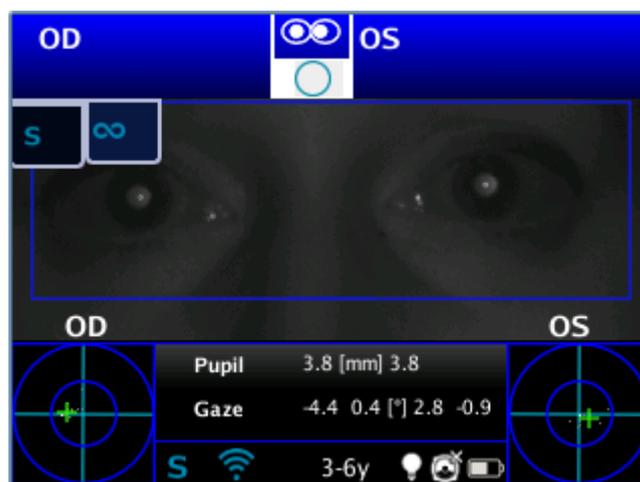
The package display can impact on three types of display, (1) Live Display (during measurement), (2) Main visualization (measurement results), (3) Auxiliary (to display something more than the result itself (eg screening in normal function).).

The main package is the displayed one that appears in the main visualization at the end of the measurement.

**i** When you don't use the default package for refraction measurement, the main measure window is blue coloured.

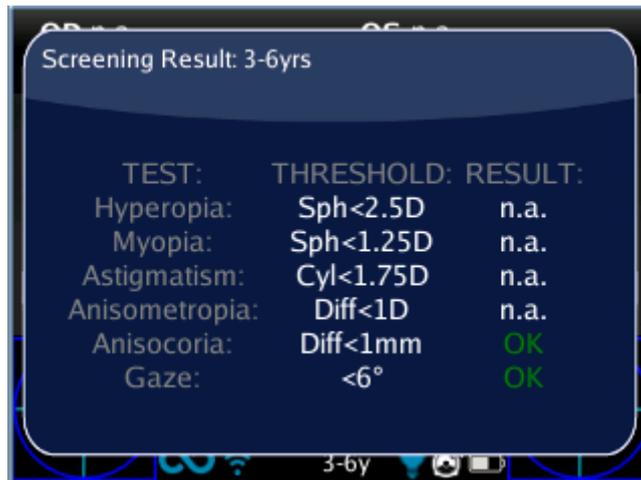


To modify the main visualization windows Press BUTTON B (print button) to display the Main Visualization Window choosing tab. With LEFT and RIGHT button you can choose your preferred window. (Note: you can select the default Main Visualization Windows to be showed by pressing up the CROSS button. The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



### Auxiliary Windows

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

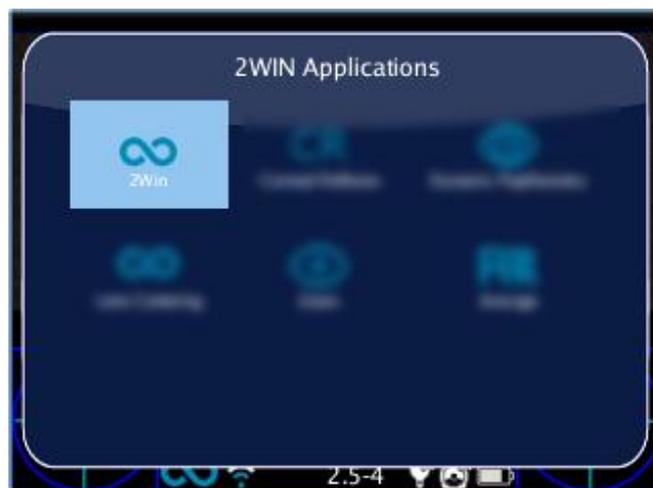


es. Screening Results

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

### Modes (2WIN Applications)

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)



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

## Interaction

To change package settings navigate the menu to Menu>Functions>Packages and select the item that you want to set into the submenu related to your package.

## Packages notification

When a package generate a notification, the notification center shows a P like icon to show that the notification comes from packages.

## Print

Each package gives you the ability to print data in a combination of 3 modes: irda print, pdf Strip, pdf.

# 12. 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.

# 13. Maintenance and cleaning instructions

No maintenance operations are required by the system.

If the measurement never ends correctly and the hardware test does not reveal any hardware problem, the system may be periodically verified, by means of a procedure called "white fielding". For such verification follow these instruction:

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;

If necessary, it is possible to clean the device with a lightly moist microfiber cloth in the external chassis. In order to clean the frontal camera lens use any cotton-tipped swab and, if necessary, use also some dust-aid cleaner liquid with no-alcohol.

Do not use sprays or alcohol to clean the system.

## **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        |

## **Instructions for correct disposal of the device**

The device is made of different materials, such as plastics, aluminum, 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.

## **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).

# 2WIN Applications specific manuals

## Legends of symbol

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

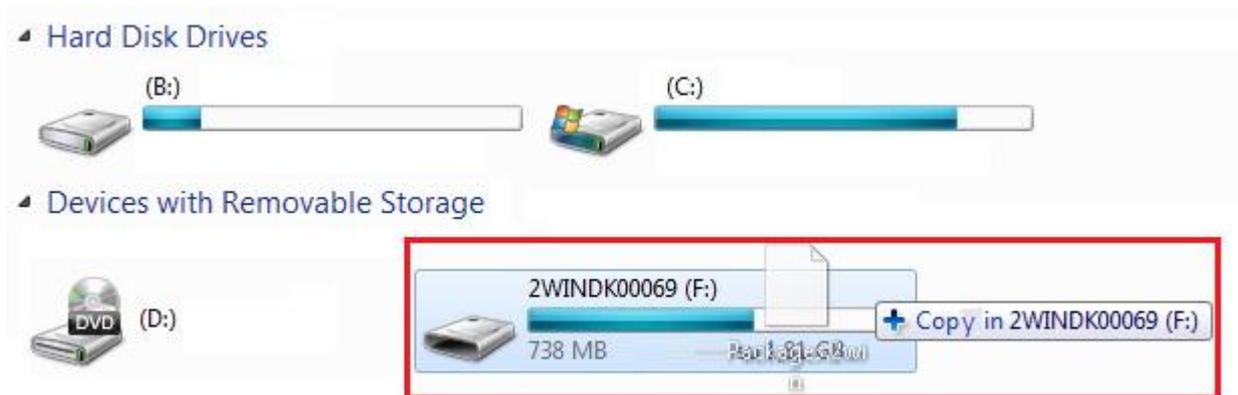
## Package installation (the same steps for every app)

- 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 “Packages.2wp” on the new device icon or with the file Explorer of your computer copy the file “Packages.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 package is now available for activation;

## **Analysis of Corneal Reflexes Position**

**This function can provide information regarding the corneal reflexes position.** The App will add the feature to collect data from 3 measurements and analyze the corneal reflex.

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.

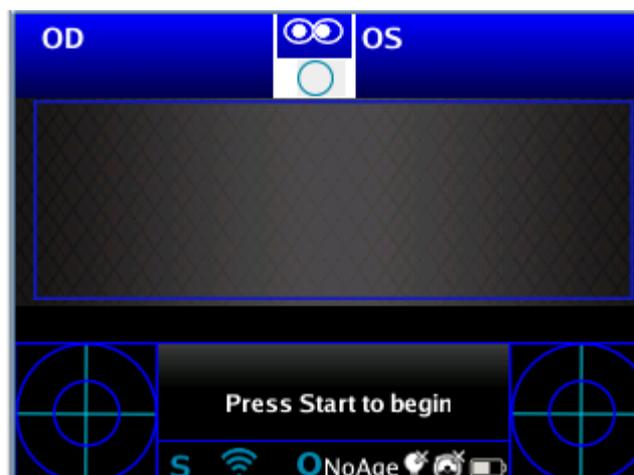
Activation: click the BUTTON A (  ) 2WIN Applications screen will be shown to display.

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

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



*Modes screen*



*Main Visualization - Corneal Reflexes*

# Corneal Reflexes exam

## Tips for patient

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



*White led*

## Exam

The procedure is the same as refraction measurements. You can do 'Corneal Reflexes exam' both in Quick mode (Menu > Measurement Mode> Quick mode) and in Normal Mode Menu > Measurement Mode > Normal mode).

### For Quick Mode:

By default measurement mode is the Quick Mode (Menu> Measurement Mode> Quick mode). Note that in this mode the instrument, since the beginning of the examination, uses a 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.

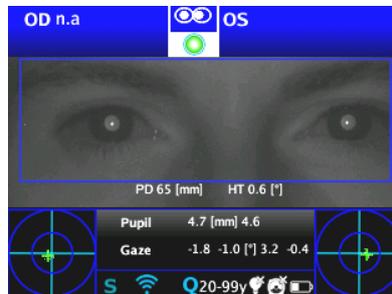


*Examination screen, top bar green - focus OK*



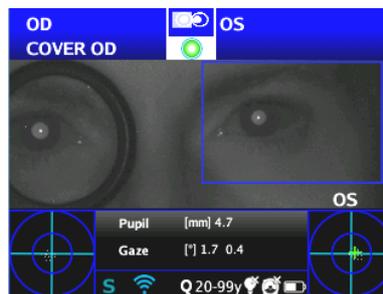
## Data Processing

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



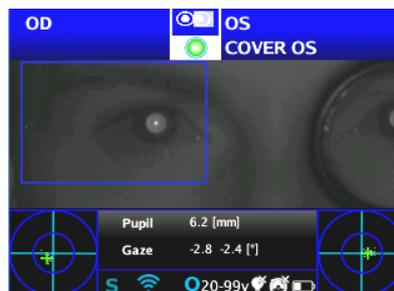
*Green Indicator*

- Click the BUTTON C (  ) and select the eye where you want to perform the cover test, using the Binocular Occluder provided by Adaptica 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.



Adaptica's Binocular Occluder. If no information about phorias is required, a traditional eye occluder can be alternatively used.

*Adaptica's Binocular Occluder*

## Exam Results from 'Corneal Reflexes' App

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

This is an example of exam results of Reflex Symmetry package.



There are 2 columns with 3 circles, on the left and right side, related to the left and the right eye information.

The circles on the columns display the position of the corneal reflex with respect to the pupillary geometrical centre. The size of the circle is proportional to the pupil size.

The images represent from top to bottom:

- **both eyes open**
- **right eye open, left eye cover**
- **right eye cover, left eye open**



**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 baricentral position of the corneal reflexes.

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 baricenter changes its position less than the threshold value (mm) selected in the settings (*Menu > Functions > Packages > 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.

When a vertical deviation appears 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 an 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 practitioner 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**)



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

K angles values are displayed on the bottom of the auxiliary window.

The default output shows the following:

- **Horizontal kangle** (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.

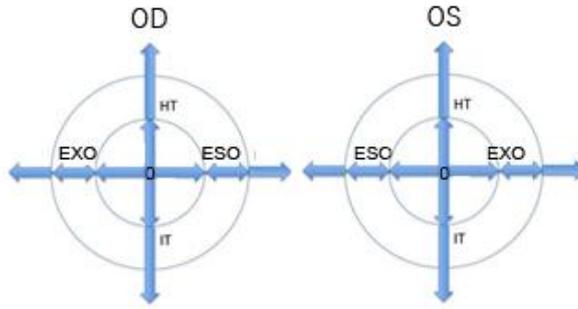


**Threshold levels can be changed, by default they are factory set to 5DP for the kx output and to 4DP for the ky output.**

**Menu > Functions > 2WIN Applications > Corneal Reflexes > Options > Threshold**



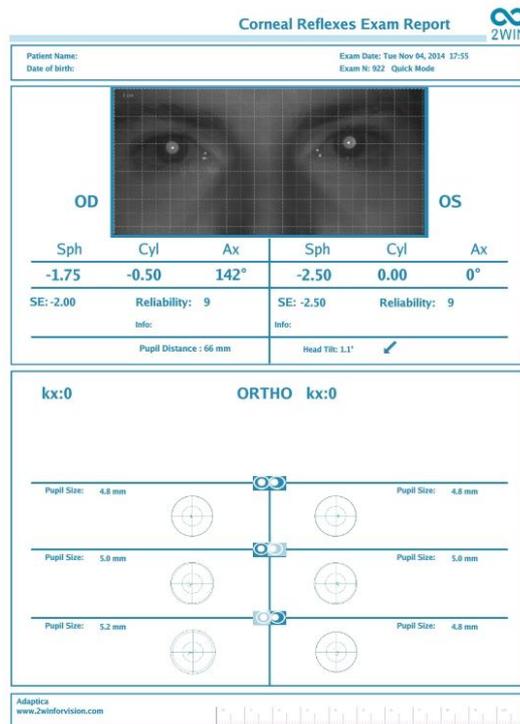
**The following picture gives a graphical representation of the codes.**



## Print

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

## Measurement reset

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

- By saving data on SD memory
- By choosing a new package
- By clicking Reset from Menu > Functions > 2WIN Applications > Corneal Reflexes > Reset



*Reset in Corneal Reflexes*

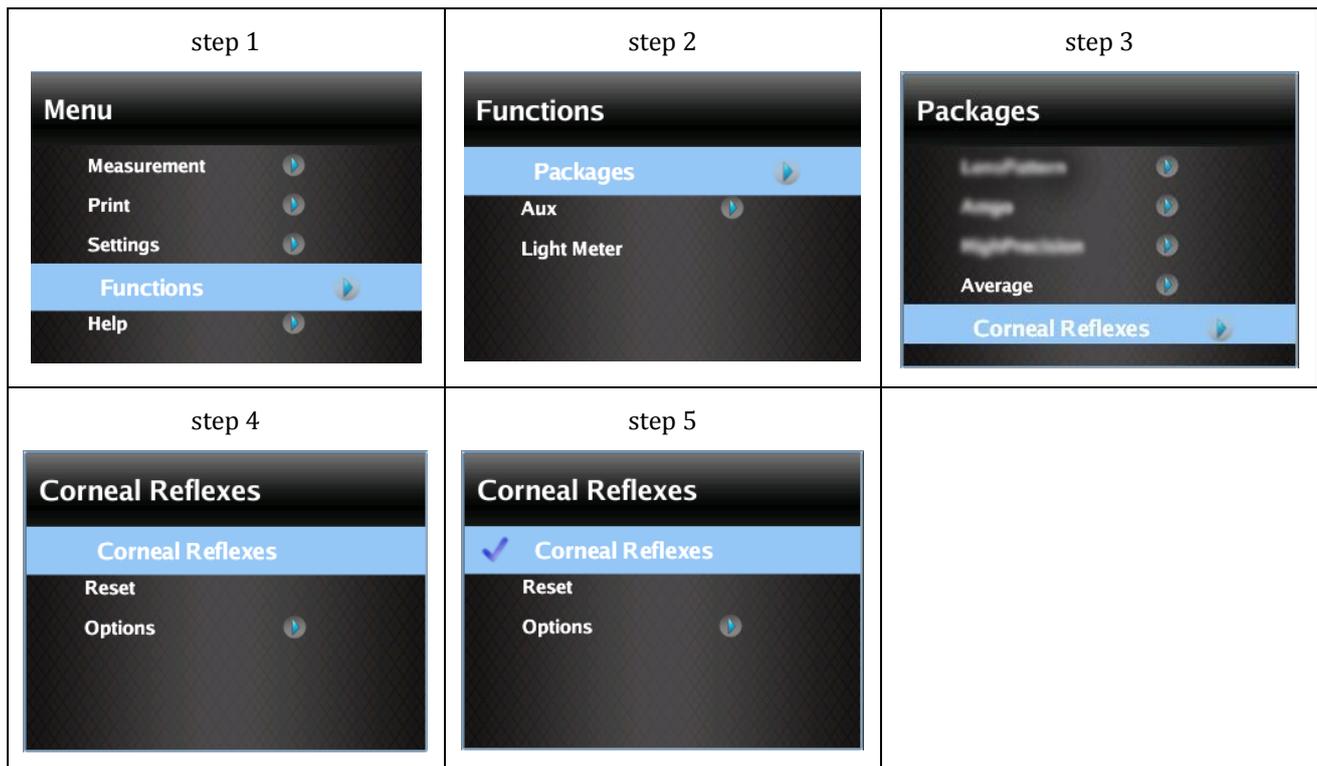
New measurement overwrites old data with new data automatically.

## Advanced use

### Choice of App: Corneal Reflexes

This App can be chosen from the Menu.

Click on Corneal Reflex from **Menu > Functions > 2WIN Applications > Corneal Reflexes > Corneal Reflexes**. A thick (☑) will be displayed next to the label **Corneal Reflexes**.



*Corneal Reflexes package activation*

### Main display setup

To modify the main visualization window (to perform the examination of corneal reflexes) press BUTTON B (  ), the choosing tab.

With LEFT and RIGHT button you can select the  preferred package. Select your favourite “Main Visualization Windows” and press  the CROSS button . (By pushing the CROSS BUTTON it will be moved in the first position. Press Button A  to exit the moving option).

|   |   |  |
|---|---|--|
| <p>Step1: Your main visualization window</p>   | <p>Step2: Press B Button (  ) to display the Main Visualization Window choosing tab</p>  | <p>Step3: Select S (Corneal Reflexes package) and click the cross button. The display top bar will become blue</p>  |
| <p>Step 4: Press Button A (  ) to exit the moving options</p>  |   |  |

*Main Display Setup*



The icon for active 'Corneal Reflexes' package [S symbol] will be visible on the main visualization window, in the status bar.



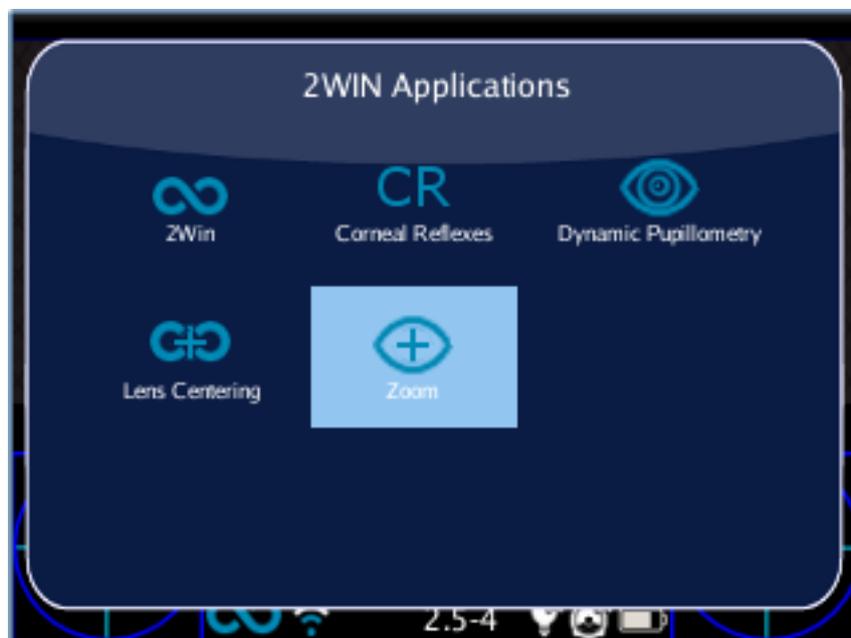
*Icon for active package*

## ZOOM Application

### Zoom App Activating

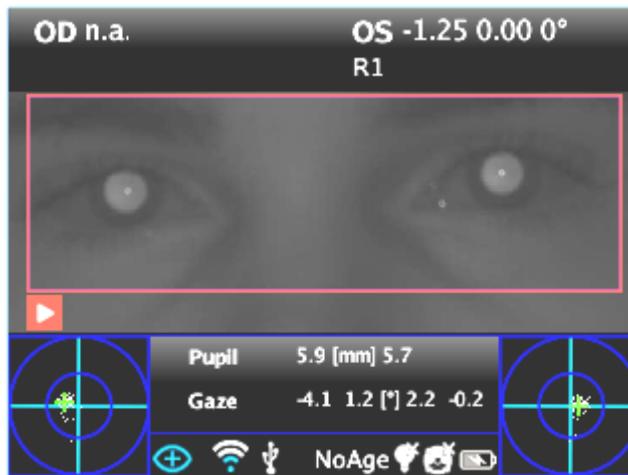
To activate Zoom App you have to press the Button A, and select the right Application by moving by the arrows of the joystick.

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



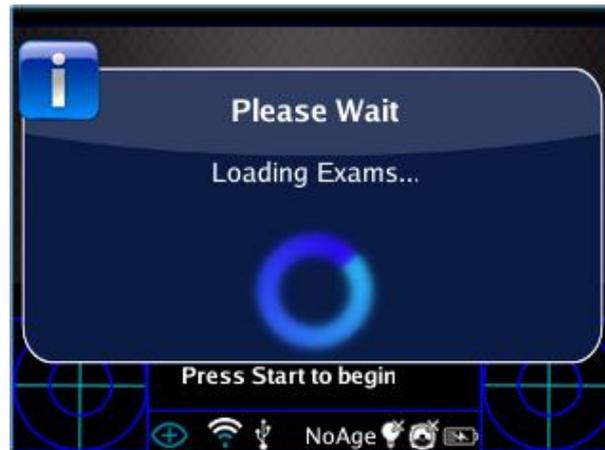
## Measurement with the App activated

When the App is activated, the measurement you will do is the same as a normal 2WIN measurement.



## Activation in Browsing mode

To activate Zoom 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 exams history.

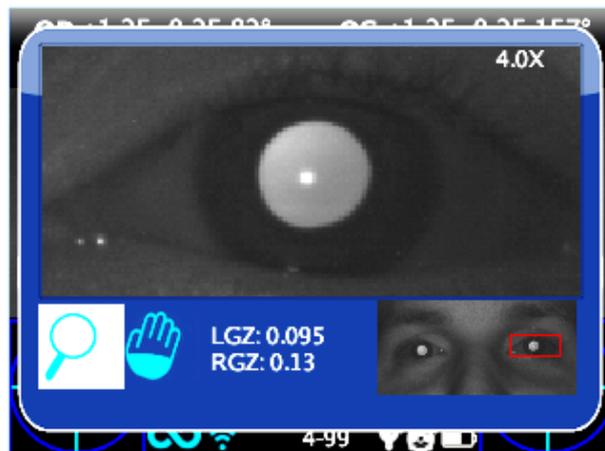


When the exams have been loaded you can browse them by the down and up button of the joystick and select the exam you want.

**N.B: if you want to use Zoom on an exam saved in memory you have to activate the Zoom App before loading the exams in memory.**

## Overview

After you have accomplished the measurement (or loaded from SD memory) you can enter in the Zoom App by clicking the right button of the joystick.



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 the central button of the joystick or by the sound/attention lights button (Button D).

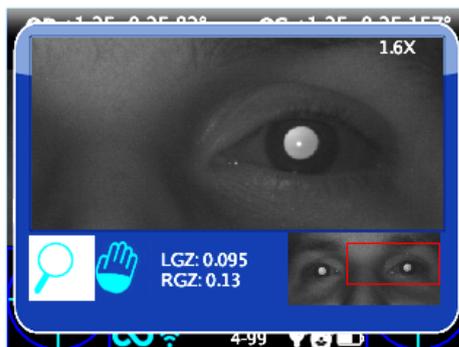
If the measure has been done when the Zoom App was active, the Zoom frame will automatically get in position on the left pupil zoomed to the maximum (4x). If it couldn't identify the pupils (failure measurement or measurement done without Zoom function) maybe the pupils haven't been identified and in this case the Zoom will get in position on the center of the image.

## Zoom Function

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.



## How to activate zoom on other measures

You can use the Zoom App on an image took from another measure by selecting the Zoom function and loading the image.

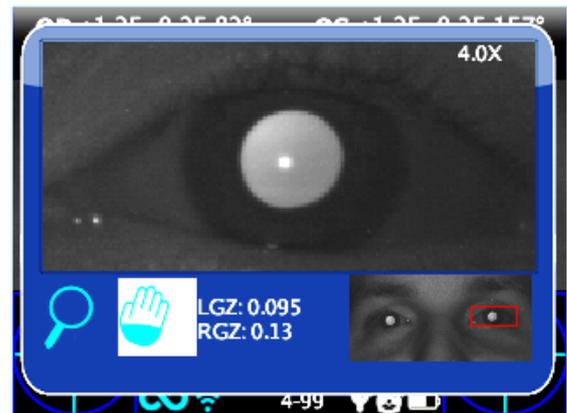
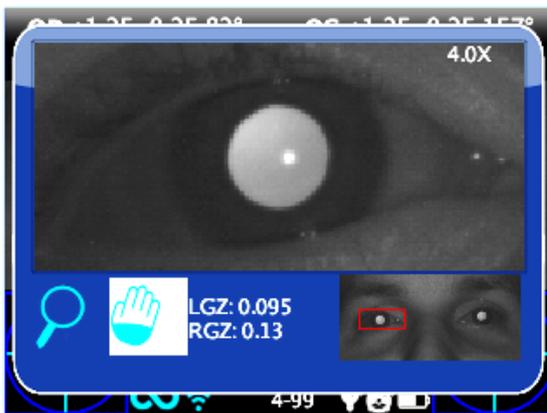
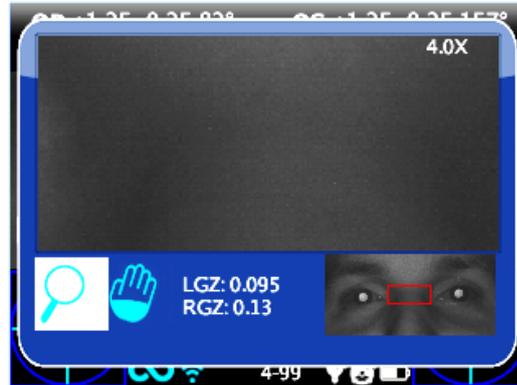
The Zoom App sometimes does not automatically identify the pupils.

## 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 none pupil has been identified in the image and you have to go forward with the manual positioning.

## Manual research of pupils

If the zoom will get in position on the center of the image (if the pupils haven't been recognized or you used a measuring without Zoom App)



you can position the pupils by the pan function and then save their positions after reaching it by pressing the pupil button to memorize its position, both right and left.

After selecting the two pupils you have to return to the main screen by clicking 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.

## **Dynamic pupillometry application**

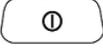
**This function can provide information regarding the pupils response (diameter during time) when the eyes of the patient are illuminated with a known visible and programmable white light created by the 2WIN.**

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 numbers showing the estimation of pupil response time, reaction time and slopes of the change in diameters versus time.

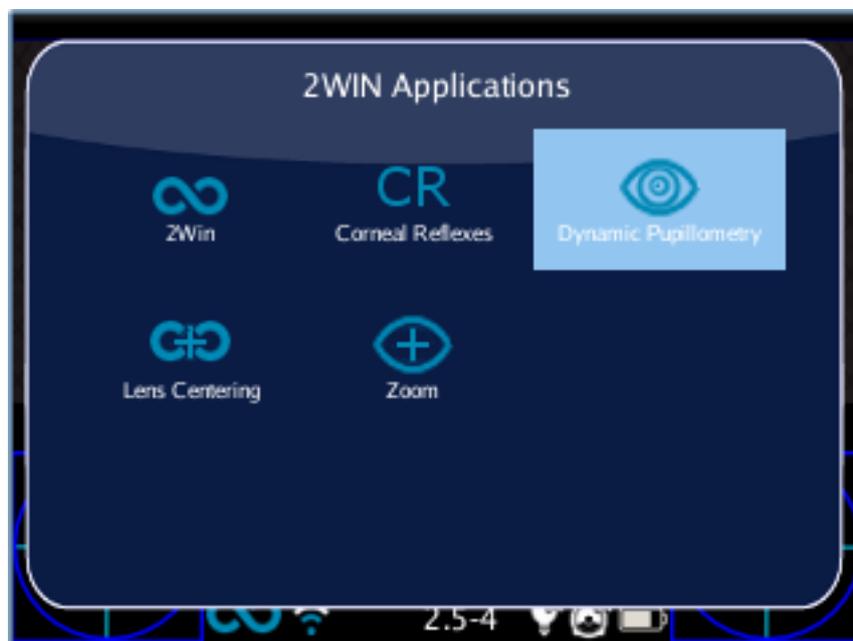
## Dynamic pupillometry application activation

After the installation this package 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 installed packages 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 modes

## Exam

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: 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 it's not present in the 2WIN SD card the right configuration file or if this file is not edited in the proper way. 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 and NOT 2).

### **Manual mode**

In order to activate this 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 raws or different kind of characters, 2WIN will use the standard measurement mode in this case.

## Calibration mode

In this mode is again necessary to edit a file “pupilresponse.txt” and write 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 on of the above conditional pupil reaction (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

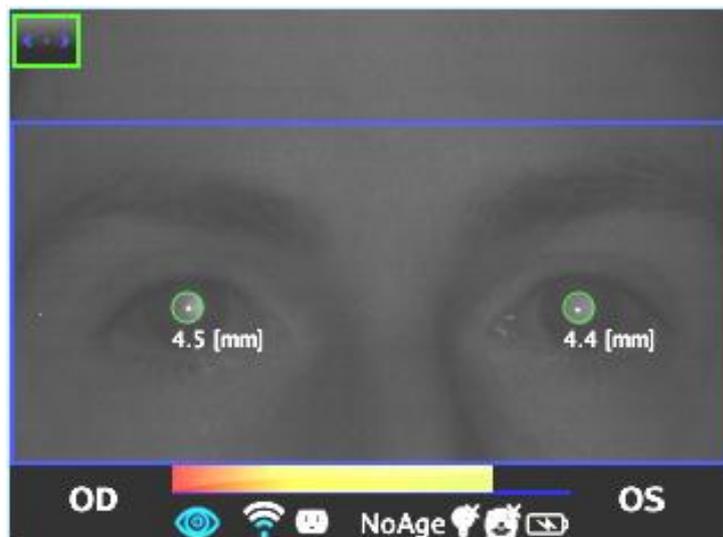
In this example the 4 light intensities at the beginning of the measurement will be 8%, 16%, 32% and finally 64% of the maximum light intensity. At the end of the measurement it will be used a final light impulse that will cause a pupil diameter lower than 4.2 mm or will create a percentage pupil variation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

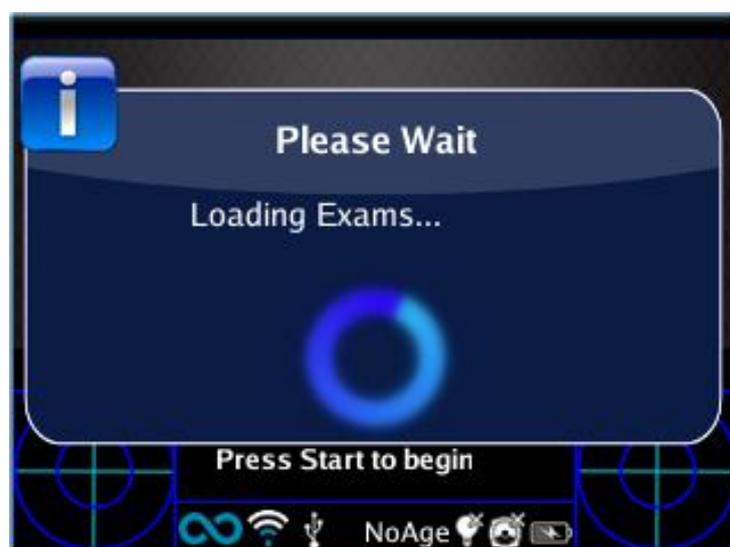


In the following image an example of the auxiliary window showing the full analysis of the examination.



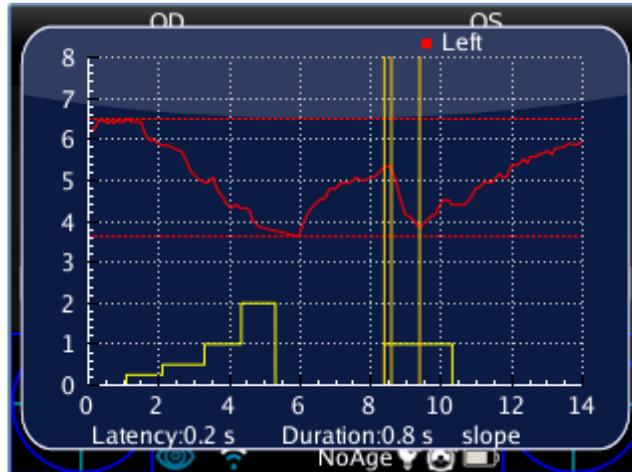
### Browsing mode

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

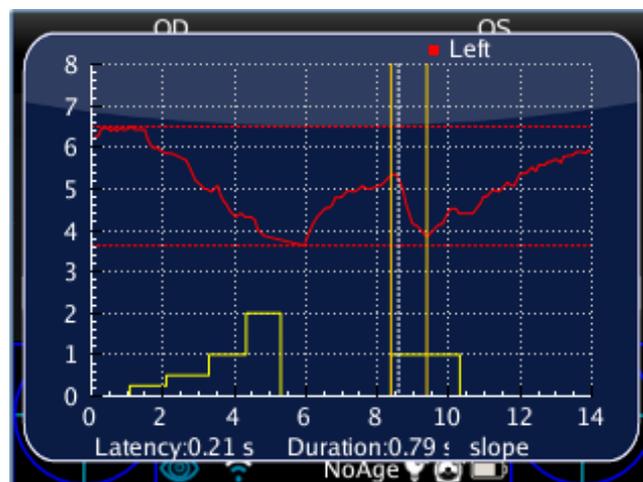
It's possible to measure some details of the final result of the Dynamic Pupillometry Application. In order to start this post exam analysis the operator must press the EYE button in the 2WIN when in the auxiliary window (after pressing the RIGHT button). The system will automatically discover a transition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



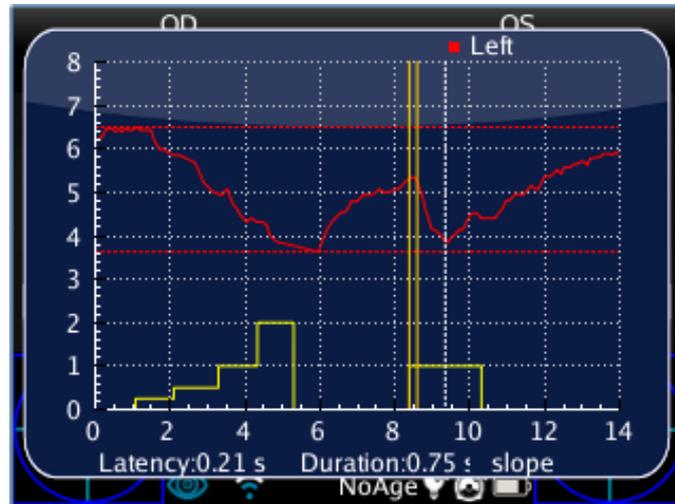
NOTE: if the application is in the DEFAULT or CALIBRATION mode, 2WIN will recognize automatically the calibration pulses. In this case it will be possible to measure only the last pulse (not calibration one).

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 in the pupil dimension (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 start to react to light stimulus. In the following figure an example of the second line positioning.

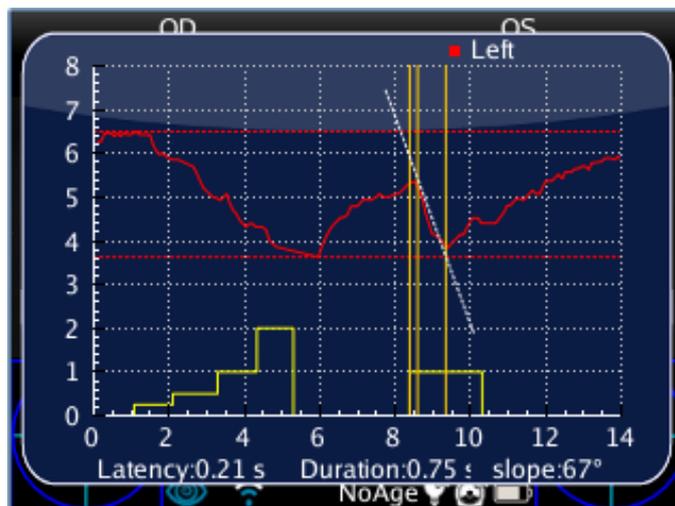


When the second axis (line) is positioned, automatically the response time of the pupil (in seconds) will appear in the lower part of the display of the auxiliary window of the 2WIN. On the next pressing of the MENU button the selected (and editable) line will be the third, showing the exact time the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



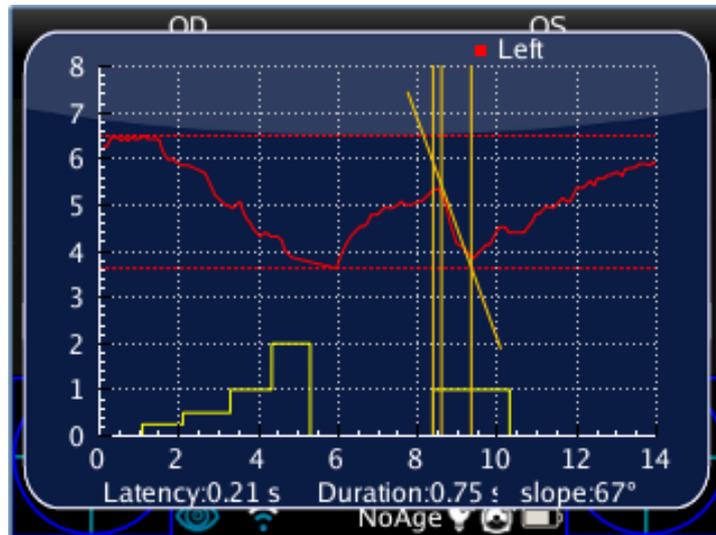
When the third axis (line) is positioned, automatically the overall time reaction time of the pupil (in seconds) will appear in the lower part of the display of the auxiliary window of the 2WIN.

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).

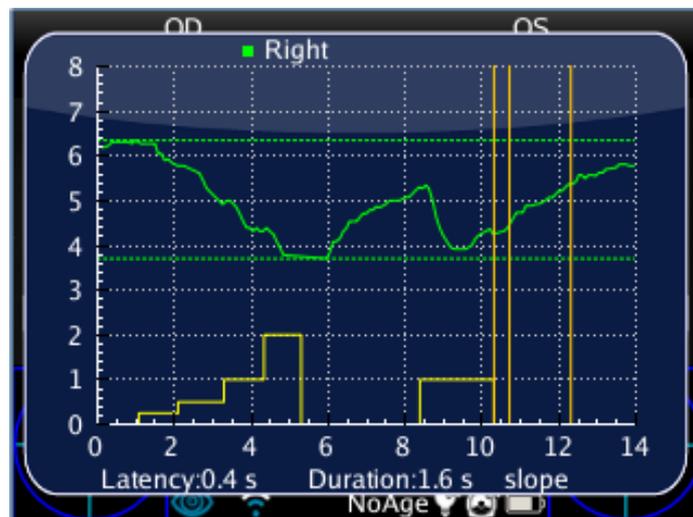


When the slope axis (line) is positioned, automatically the slope angle value will appear in the lower part of the display of the auxiliary window of the 2WIN. This last line will be white if it is related to a decrease in the pupil diameter, while it will be black if it is related to an increase.

If the operator presses again the MENU button, it will be possible to edit the numerical values of the exam on the lower part of the display.

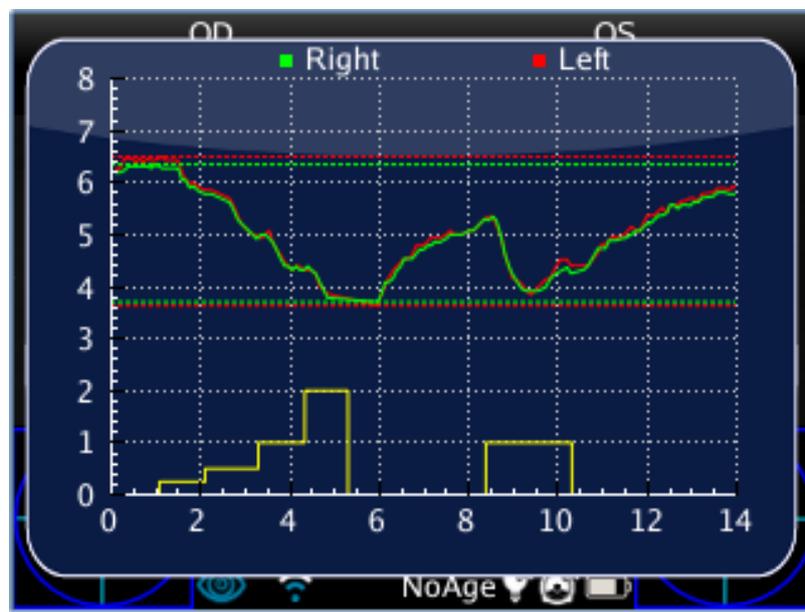


By pressing the EYE (Button D) button in the 2WIN, the system of four lines will be displayed on the following event of transition in the pupil diameter. Then if the EYE button is pressed again the overall measurement procedure will be started in the DX eye.



## 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).



## Lens Centering Application

### Lens Centering Application activating

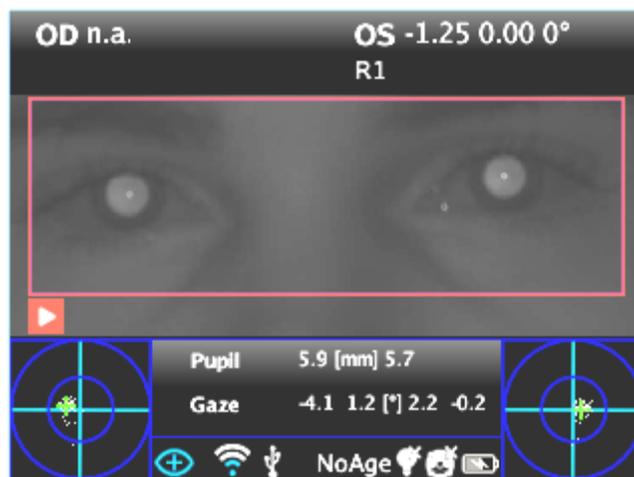
To activate Lens Centering Application you have to press the Button A, and select the right Application by moving by the arrows of the joystick.

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



## Measurement with the App activated

When the App is activated, the measurement you will do is the same as a normal 2WIN measurement.



## Activation in Browsing mode

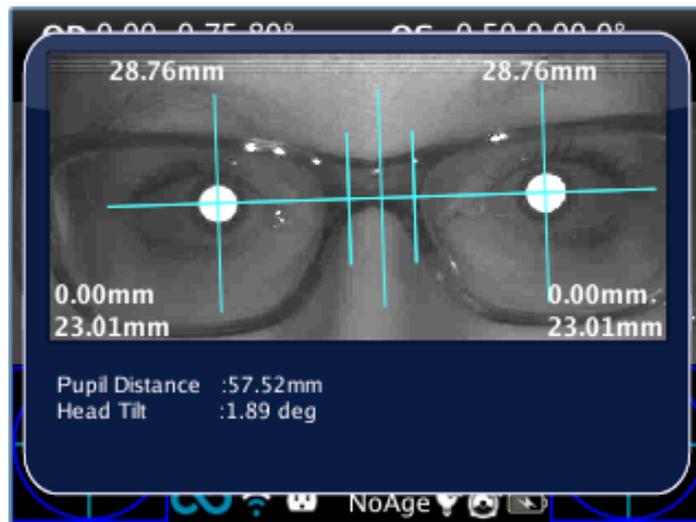
To activate Lens Centering App in a measurement already saved you have to enter in the browsing mode by holding the down button of the joystick till the loading of the exams history.



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.

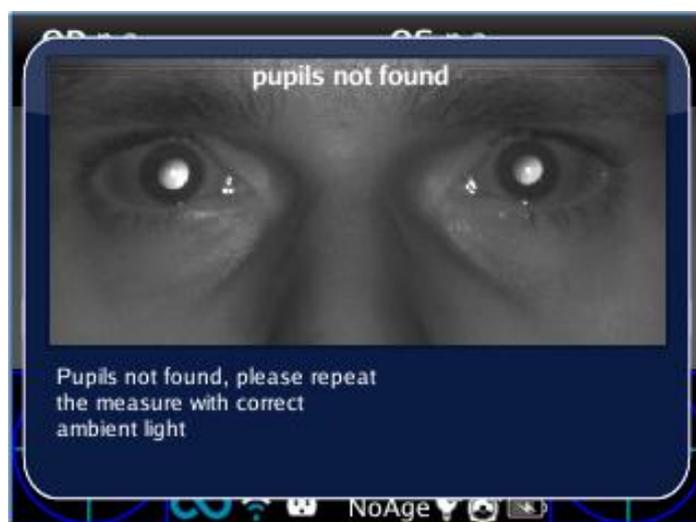
## Overview

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 center.



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 an other 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.

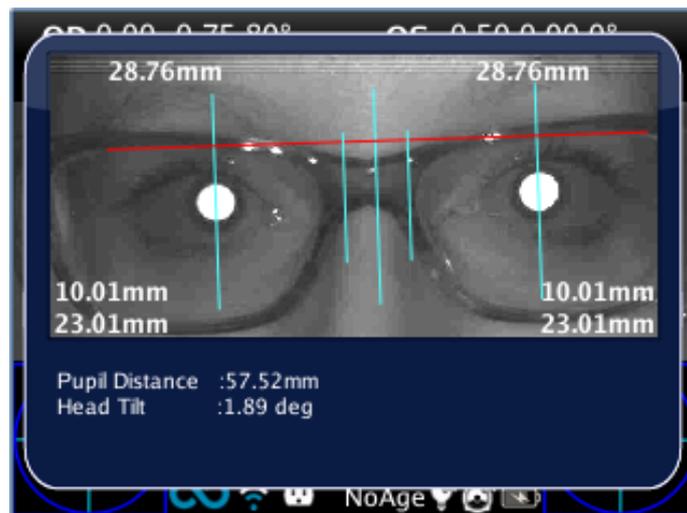


## Navigation

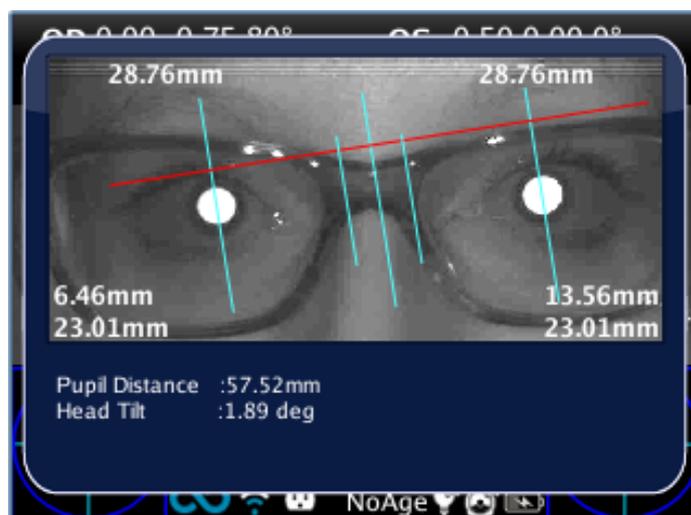
You can select the axis you want to move by pressing the central button of the joystick, it will highlight red the axis allowing the changes. At the first pressing you will see the horizontal axis; at the second pressing you will see the vertical axis on the left; at the third pressing you will see the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

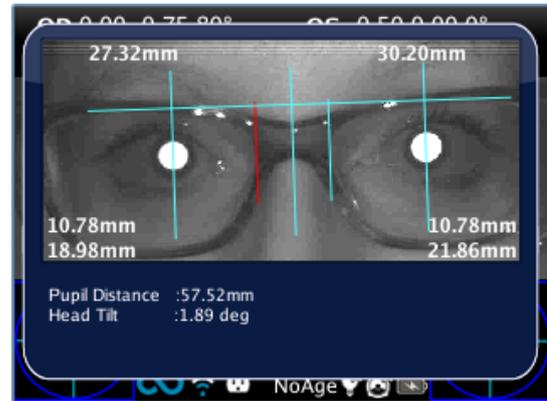
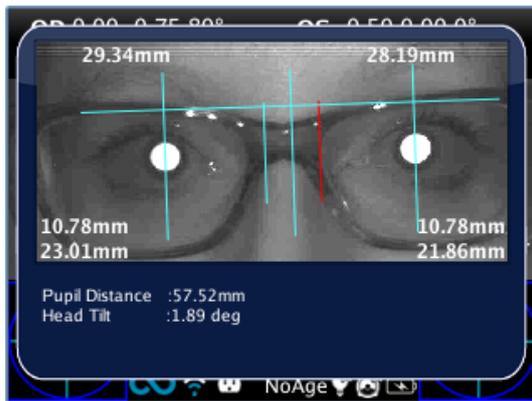


The second positioning allows to tilt the axis. This change implicates an equivalent rotation of all the other axes.



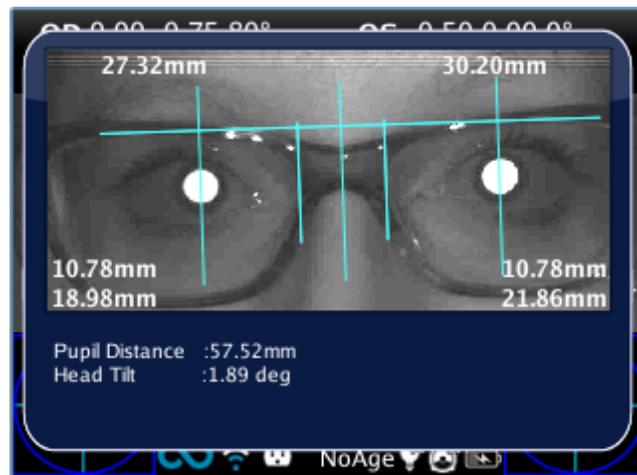
## How to position the vertical axes

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.



The 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:
  - the greatest value and the distance between the center of the optic axis and the horizontal axis (Y).
  - the lower value and the measure between the center of the optic axis and the corresponding stud (X).

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 axes 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.

## 14. 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<br>-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<br>- The printer is not in front of the instrument | -Switch on/recharge the printer<br>- Position the printer in line of sight with the instrument.                   |

## 15. Additional information

### Technical specification

Measuring range for spherical defect: -5,00D +5,00D

Measurement precision for spherical defect: +/- 0,25 D

Measuring range for cylindrical defect: -5,00D +5,00D

Measurement precision for cylindrical defect: +/- 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 – 7 mm, step 0.1 mm

Measurement precision for pupil diameter: +/- 0.2 mm

Measuring range for interpupillary distance: 30 – 120 mm step 1 mm

Measurement precision for interpupillary distance: +/- 1 mm

### 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

### Other specifications

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

Display size: 3.5 inches

Battery charger: 110-220 VAC 0.5 A

Weight: 0,84 kg

Dimensions: 165mm x 130mm x 98mm h

### In flight use

Do not use the device during a flight.

### Device warranty

**The device has one year warranty**

## 16. Analitic index

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## 17. 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