QUICK REFERENCE CARD

CAUTION

US Federal law restricts **this device to sale by or on the order of a physician**.
Before use **read the precautions** section in the 2WIN Operator Manual.

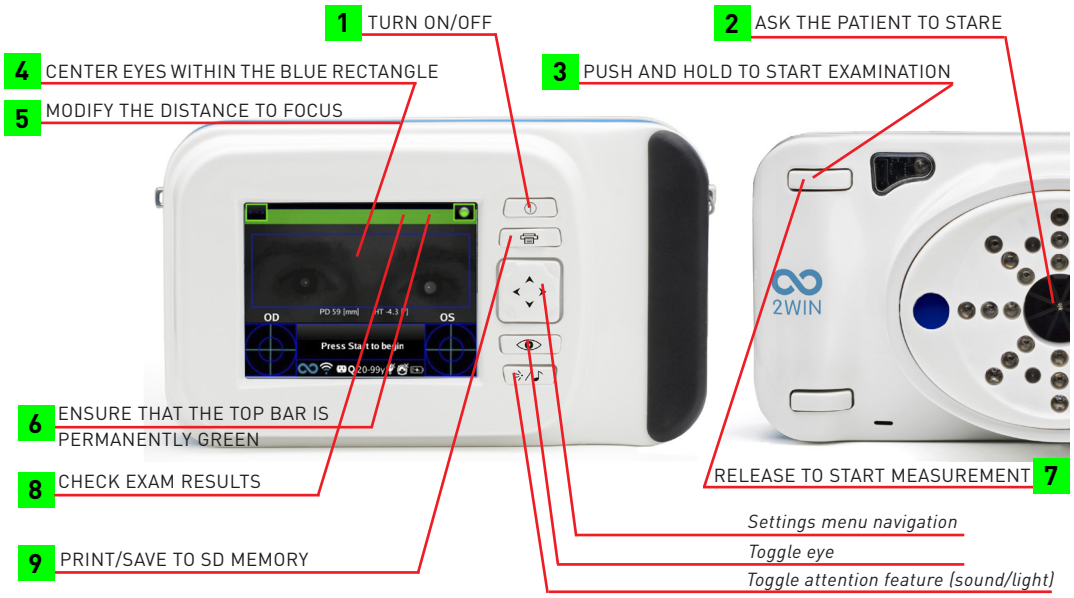
IMPORTANT

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.

- It is **hand-held**, **battery operated**, **very light**, **non-invasive**, **fast** and **easy to use**.
- 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 **accomodative balance/unbalance** between the 2 eyes in the most natural environment conditions.
- For both Sph and Cyl, measurement accuracy is ± 0.25 D in the range of ±5 D. The cylinder axis is calculated between 1° and 180° (step 1°) with precision of ±5°. 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 (N.A., not accessed measurement), we suggest using a 10 D trial lens to offset refraction within the measurement range.
- 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!
- It must be **operated in a dim light environment** to ensure sufficient pupil size and reduce accomodation.
- Please familiarize yourself with the measurement conditions and techniques of the 2WIN in order to exploit its full potential.
- For accurate over-refraction with glasses, please make sure that no stray reflexes disturb the pupil detection; should such reflexes be present, please slightly tilt the glasses down.

MEASUREMENT TIPS

Make sure the cylinder notation (minus or plus) is set to your preference.
Pay attention to half-closed eyes, eyelids or eyelashes masking pupils and to Strabismus inhibiting binocular fixation.
During the measurement mode, please make sure that both eyes appear within the "live" window; if necessary slightly tilt the 2WIN.
To refract infants, young children and any non-cooperative patients, please 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, please repeat the measurement, if possible.
Please remember that free space, non-cyclopegic refraction can vary depending on several conditions and parameters pertaining to the binocular visual function; in some specific patients, including accomodating children, the 2WIN measurements may vary.



EXAM PROCEDURE

***Refer to the Operator Manual for all functions**

The patient shall sit comfortably in a suitable exam room; infants should sit in an adult's lap. A uniform dim light enviroment is necessary. A stable measurement distance of 1 meter is also important.

1 Turn the 2WIN on by pressing the ON/OFF button for 1 sec. and wait until the stand-by screen appears.

2 Instruct the patient to keep his/her eyes wide open, clear of eyelids or eyelashes, and to fixate the center of the camera (a small central LED). Hold the 2WIN horizontally with both hands, approximately at the same height of the patient's eyes, and at a distance of 1 meter.

3 4 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) - the message "FOCUSING" will appear.

5 6 7 Adjust the distance to focus the image until the top bar is green. When the top bar is PERMANENTLY green release the BUTTON S1/S2 – the message "MEASURING" will appear. Stay firmly in the condition in which the upper bar is green until the message DATA PROCESSING appears on the display.

8 After Data Processing measurement results will be displayed.

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ADAPTICA

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;
- 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.

Environment

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, 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 90 cm.

Precautions and general warnings

CAUTION – US Federal law restricts this device to sale by or on the order of a physician.
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 the Operator Manual.
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.
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.