

2WIN-S

2WIN-S *Plus*

OPERATOR MANUAL



Revision notes

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	KALEIDOS App	1.4.0.0
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General notes

Family: 2WIN VISION ANALYZER

Family intended use: Portable instruments for the measurement of binocular and monocular refraction based on infrared photorefracton

Models: 2WIN, 2WIN-S, 2WIN-S PLUS

Summary

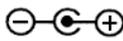
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1 Manufacturer identification

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

2 Legend of symbols

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

3 Intended use of the device

Instrument for the measurement of binocular and monocular refraction based on infrared (IR) photorefraction.

4 Classification and Applied Standards

Classification according to MDD 93/42/EEC, Annex IX, rule 10

Class IIa.

Type of applied part according to EN 60601-1, rules *c* and *d*

Type B.

Classification of power supply according to EN 60601-1

Class I.

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 standard IEC 60601-1-2.

Applied standards

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

5 Precautions

Electromagnetic compatibility



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

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



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



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



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



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



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



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



This device is not to be used during a flight.

Light radiation



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.

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 carefully read the instructions in *Chapter 8 - Operative information*.



The patient applied part, i.e., the face cushion, shall be disinfected before each patient change, to avoid patient contamination by infectious agents. Please follow instructions provided on *Chapter 15 - Disinfection and Cleaning* of present 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 if the cover or other parts of the device have been removed.

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

Inside the remote controller's (tablet) internal memory is stored the patient data. This information can contain personal information such as name/surname/age. This information management is responsibility of the operator.



Only the power adapter provided by Adaptica with the system can be used to charge the 2WIN-S' battery pack, for safety reasons.



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



The battery cells of 2WIN-S cannot be replaced by the user, only by authorized service personnel.



Do not use different configurations of 2WIN and KALEIDOS to compose the 2WIN-S. The serial numbers of 2WIN and KALEIDOS are matched to create the 2WIN-S, for manufacturing and warranty reasons.



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



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



Do not remove the 2WIN camera from the KALEIDOS tube: the calibration and alignment of the device could be compromised.

6 Quick user guide

6.1 Important

- Carefully read *Chapter 5 – Precautions* of the present manual before operating the device.
- The 2WIN-S is a stand-alone binocular vision analyzer. It measures refraction of both eyes at the same time.
- The 2WIN-S 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 familiarize yourself with the measurement conditions and techniques of the 2WIN-S in order to exploit its full potential.

6.2 Main Applications

- The 2WIN-S is a stand-alone binocular vision analyzer. It detects a patient's real-time refraction.
- It is a binocular instrument that measures refraction on the basis of eccentric infrared (IR) photo-refraction (also photo-retinoscopy). Both eyes are measured at the same time, while fixating at 1 meter.
- It is battery operated, non-invasive, fast, and easy to use.
- It automatically measures binocular refraction, pupil distance, pupil size, direction of gaze, and fixation abnormalities.
- Binocular refraction of children from 3 years of age to seniors.
- Early detection and documentation of multiple amblyogenic factors.
- Over-refraction of contact lenses.
- OPTIONAL (APP), CR-App: phoria/tropia measurements.
- PLUS package (2WIN-S *Plus*):
 - CR-App: phoria/tropia measurements;
 - AI-App: anterior segment screening warning customers of possible pathologies of the anterior segment;
 - Personalized tablet;
 - EMR connection.

6.3 Exam conditions

The device should be paired with a tablet through Wi-Fi or Bluetooth connection, depending on the model.

6.4 Measurement tips

- For sphere and cylinder, measurement precision is ± 0.25 D or ± 0.50 D depending on the range. The cylinder axis is calculated between 1° and 180° (step 1°) with precision of $\pm 5^\circ$. For high refractive errors (above +7 D and below -7 D), the 2WIN displays “high M” (myopia) or “high H” (hyperopia) in the upper part of the display. For higher refractive errors (above +15 D and below -15 D), the 2WIN still displays “high M” or “high H”: in this case, the 2WIN will not display a numerical result, but it will write “N.A.” (Not Accessible 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 between ± 15 D. Refer to Section 18.1 for further information.
- Make sure the cylinder notation (minus or plus) is set to your preference.
- Make sure the Reliability Index of the measurement is higher than 6 (max. is 9). In case it’s lower than 6 a message with a hint will be displayed, for the repetition of the measurement.
- Remember that non-cycloplegic refraction can vary depending on several conditions pertaining to the binocular visual function; in some specific patients, including accommodating children, the 2WIN-S measurements may vary.

7 Description of the device

7.1 2WIN and 2WIN-S

2WIN-S comprises the 2WIN and the accessory tube KALEIDOS.

 A number of additional features of the 2WIN-S could be handled only approaching the 2WIN device. Please, refer to the *2WIN Operator Manual* for these options. This manual could be found in the MicroSD inside 2WIN as well as downloaded at our [website: adaptica.com](https://www.adaptica.com) > **Products** > **2WIN** > **Manuals Download**.

 Do not remove the 2WIN camera from the KALEIDOS tube: the calibration and alignment of the device could be compromised.

7.2 2WIN-S

The measuring principle of the 2WIN-S is based on infrared photorefraction. In this technique, infrared light is projected through the pupils of the patient onto the retina. Depending on the refractive error, the reflected light forms a specific crescent-shaped brightness pattern within the pupil. The spherical refraction is calculated based on this crescent pattern. Cylinder and axis measurements are based on the same kind of calculation, repeated on four meridians.

The 2WIN-S performs the measurement 1 meter (3 feet 3 inches) away from the patient’s eyes, with continuous tracking of the corneal reflex, for the analysis of the binocular alignment. The device works as a portable darkroom and allows a contact-less measurement between the patient and the operator.

The 2WIN-S accepts a pupil diameter between 4 and 7 mm and it is compatible with the measure both in mydriasis (dilation of the pupil) and in miosis (constriction of the pupil). It is possible to measure down to 3.5 and up to 11 mm, but this depends on several conditions. Outside the 4-7 mm range the overall precision could decrease. Note that KALEIDOS tube helps inducing a mild mydriasis.

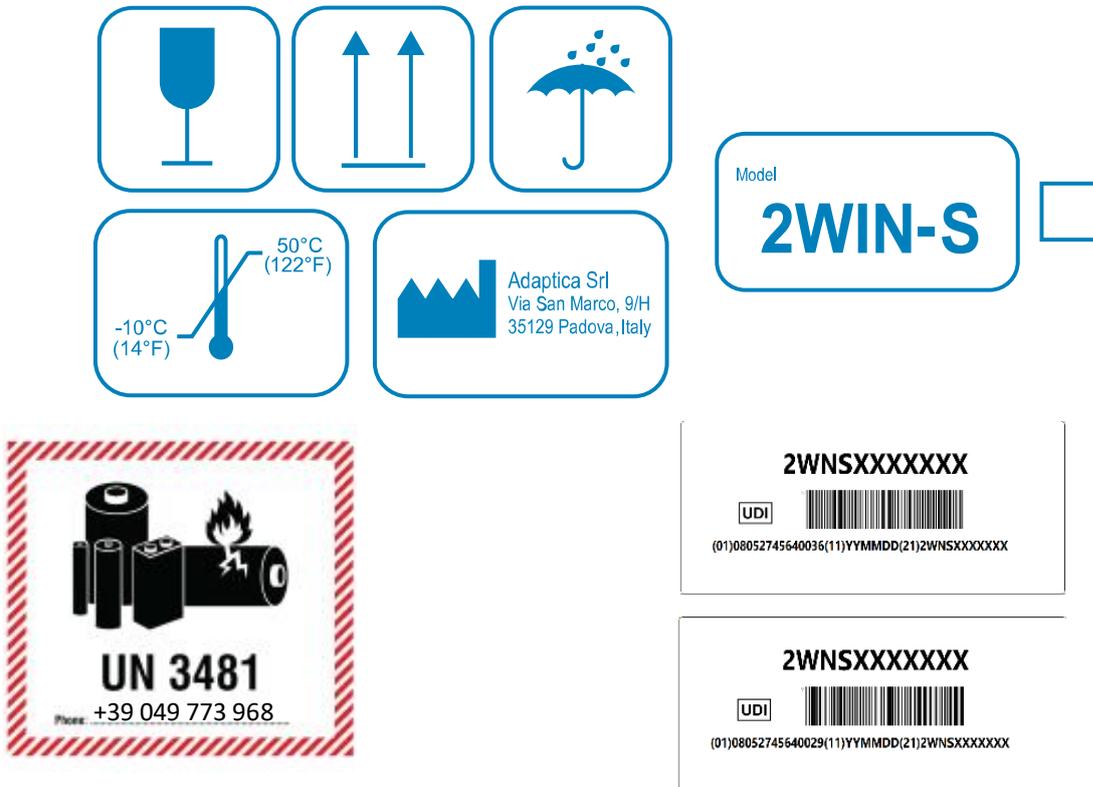
The 2WIN-S, moreover, is able to detect the refraction only of patients which eyes permit good Purkinje images. Anomalies in such images, due for example to eye-surgery interventions or intraocular lenses (IOL), do not allow an accurate measurement.

The 2WIN-S is portable, battery powered, equipped with a computing integrated unit and controlled through an Android tablet.

2WIN-S data is saved inside “KALEIDOS App”, used to control the device, and it can be shared through the sharing services provided by the tablet in use. Moreover, the data is saved in the MicroSD card of the 2WIN inside 2WIN-S.

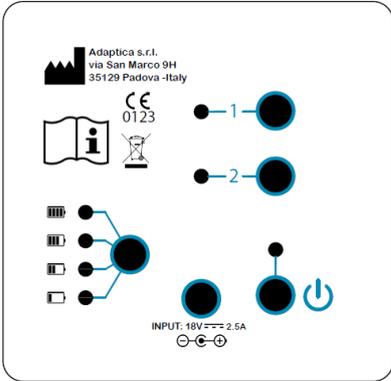


7.3 Package labelling



Label	Detail	Explanation
	Adaptica S.r.l. Via San Marco, 9H 35129 Padova - Italy	Manufacturer identification Data: name and address
		Fragile - handle with care
		This side up - do not reverse
		Keep dry
		Storage minimum and maximum temperature
		Lithium ion batteries contained or packed with device Call +39 049 773 968 for more information

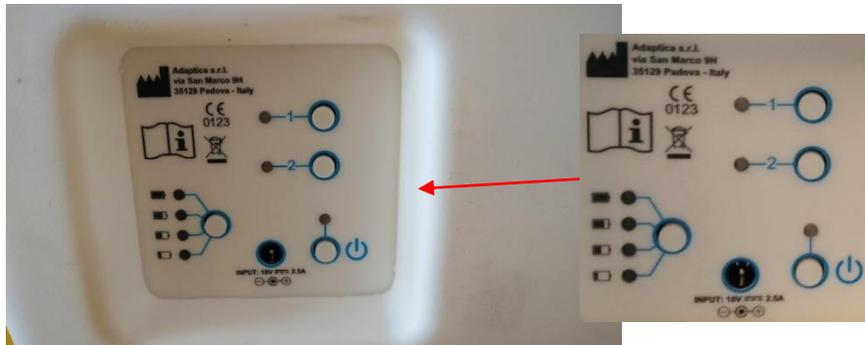
7.4 2WIN-S labeling

Label	Detail	Explanation
	 Adaptica S.r.l. Via San Marco, 9H 35129 Padova - Italy	Manufacturer identification data: name and address
		Connector polarity
	18V 2.5A	Input C.C. voltage and current
		CE mark and Notified Body identification code
		Electrical / electronic device subject to the WEEE Directive on waste disposal
		Read manual strictly before operation
		Turn on device
	1	Button 1 (see Section 9.1)
	2	Button 2 (see Section 9.1)
		Battery fully charged
	Battery discharged	
	:serial number	Serial number
		UDI code (expressed as GS1 Data Matrix and in human readable format)
	Model: 2WIN-S	Model name
	Model: 2WIN-S Plus	
		Applied part type B

BACK INDOOR



CONTROL PANEL



UPPER SIDE



7.5 Interfaces

2WIN-S

The customer can operate the 2WIN-S from the control panel depicted in figure. The buttons' role is described in the following, and also in Section 9.1.

A: BUTTON 1 - "Measurement"

Press for 2 sec to start a new measurement

B: BUTTON 2 - "Connection"

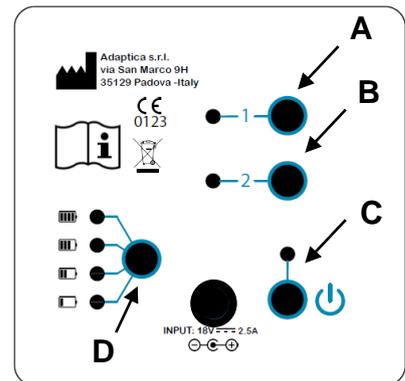
- Press for 2 sec to reset Wi-Fi and Bluetooth connection
- Press for 4 sec to prepare the system to be paired with 2WIN App: this is a deprecated legacy feature.

C: POWER BUTTON

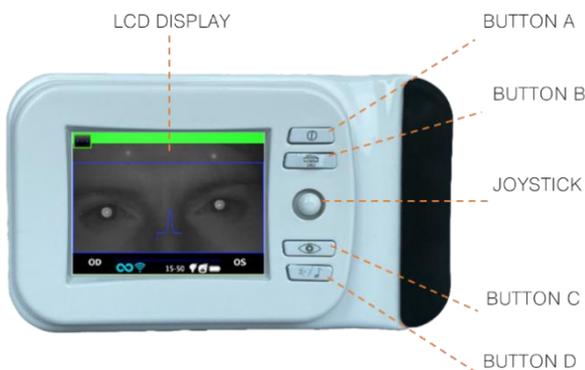
- Short press to switch the system on
- Press for 2 sec to switch the system off
- Long press the button to force the power off

D: BATTERY LEVEL BUTTON

Short press to see the 2WIN-S battery level



2WIN

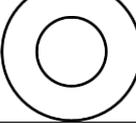


Inside the USB & SD connection door there are a Micro-USB port, which connect the 2WIN camera to the KALEIDOS tube, and a MicroSD card holder.

For a summary of the functions of the buttons, refer to the following, and also to *2WIN Operator Manual*.



Please, note that operator can have access to 2WIN menu if, and only if, the KALEIDOS App is not connected to the 2WIN-S device.

MAIN FUNCTION		Short press	Long press
	BUTTON A	Switch-on; Open Applications Menu	Switch-off
	BUTTON B	Zoom after exam	Print and Save
	JOYSTICK	Navigate in the menu	CENTER: contextual help
	BUTTON C	Toggle eye	Notification center
	BUTTON D	Start a new exam *	

 *: This function is operating only if the “KALEIDOS mode” is switched on (default in 2WIN-S configuration); otherwise, the functionality of BUTTON D will be different. Refer to Section 7.4 and 9.7 of *2WIN Operator Manual* for further information.

The JOYSTICK features contextual functions:

- push CENTER to enter menu or to say OK
- the other four direction allow operator to navigate in the menu

 Please, refer to the *2WIN Operator manual* for further information.

8 Operative information

8.1 Operating conditions

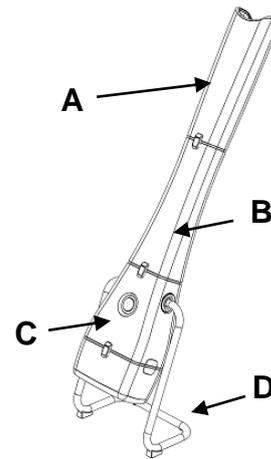
The device needs to be operated under the following environmental conditions:

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

8.2 Unpacking

The box contains (default configuration):

- the 2WIN-S device, divided in:
 - Top (Part A)
 - Middle (Part B)
 - Bottom (Part C)
 - Base-support, cradle (Part D)
- the 2WIN-S battery charger
- EU/US AC wall adapter
- 2WIN accessories (refer to *2WIN Operator Manual*):
 - a MicroSD memory card (containing the electronic version of the Operator Manuals)
- SD card filesystem must be FAT32
 - a USB cable (Micro-USB to USB-A)
 - an occluder (infrared patient's eye occlusion system)



- ⓘ The MicroSD memory card, besides containing the electronic version of the manuals, it contains also presentations and further instructions on how to operate the device.
- ⓘ For further information regarding 2WIN and its Applications, please refer to video tutorials that can be found in the Adaptica's YouTube channel: <https://www.youtube.com/user/AdapticaSrl>.

8.3 Access to 2WIN

- ⓘ To have access to the 2WIN device, the rear hinged lid of the KALEIDOS tube has to be opened.

Removing the MicroSD memory card

First remove the USB cable from the 2WIN device, and then remove the MicroSD card from the device

Navigating in the 2WIN menu

- ⓘ Please, note that operator can have access to 2WIN menu if, and only if, the KALEIDOS App is not connected to the 2WIN-S device. Refer to *Chapter 12 - Remote control: KALEIDOS App* of the manual.

The Menu is activated by pressing the center of the JOYSTICK. To exit the Menu, push left on the main Menu page, or by pressing the BUTTON A.

To navigate in the Menu, use the four directions of the JOYSTICK: up and down will move up and down the highlighted choice, right will select the highlighted choice navigating deeper by one level in the menu, left will step back to the previous menu level.

 For further details, please refer to *2WIN Operator manual > Section 9.7 - Menu*

8.4 Before operation

After completely charging the device, be sure to set up date and time. Current date and time will be also used into the measurement exam's report.

The 2WIN device has an automatic hardware self-test procedure that can be activated as an option from the 2WIN inside KALEIDOS, as follows: **Menu > Functions > Aux > Auto test**. This procedure may be executed any time to verify hardware integrity.

8.5 Data management disclaimer

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

8.6 Important notes on Battery

 The device must be charged at least once every 30 days.

 **When using 2WIN-S, the 2WIN is connected to the KALEIDOS battery pack through the USB cable: 2WIN's internal battery must be removed, whether the battery was inserted for using the 2WIN separately.**

 Detaching the USB cable, the 2WIN will switch off in 3 seconds.

9 Operative instructions

To power on the 2WIN-S, push the ON/OFF BUTTON on the Control Panel of the KALEIDOS (refer to Section 7.5).

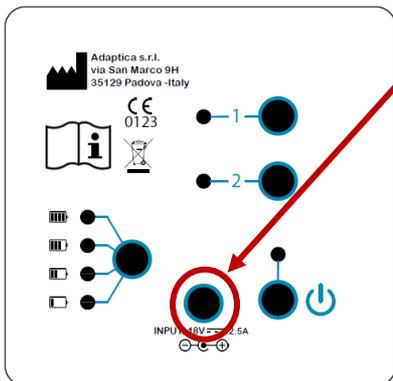
To turn OFF the device, long press the ON/OFF BUTTON. Alternatively, you can turn off the device from the KALEIDOS App as follows: **Settings > General > System > Shut Down**.

 2WIN-S has no auto-shutdown timer.

To operate correctly the instrument, it's important to carry out the following main steps:

1. **Device setup**
2. **Preparation of the patient**
3. **Measurement**

9.1 Device setup



To charge the system:

1. Connect the provided power supply cable to the INPUT 18V - 25A, depicted in figure.
2. Connect the other end of the power supply to the line.
3. In order to monitor the battery charge level, press the battery charge button.

Configuration steps

Refer to Chapter 11 of this Operator Manual for 2WIN-S configuration using the Wi-Fi tablet application (deprecated legacy feature).

The 2WIN-S configuration using the Bluetooth tablet application (KALEIDOS App) is briefly described in the following.

At first use, it is necessary to pair the 2WIN-S to the tablet, following these instructions:

- Install the KALEIDOS App on your tablet
- Check that Bluetooth is enabled on the tablet
- Switch the 2WIN-S on
- Run KALEIDOS App on tablet
- Tap on the Bluetooth icon on the KALEIDOS App to start available Bluetooth devices search. A window showing all the available 2WIN-S will appear.
- Connect to the desired 2WIN-S. When the pairing is complete a confirmation message will appear.

- ⓘ Refer to *Chapter 12* for further information.
- ⓘ In the 2WIN-S *Plus* configuration, the provided tablet is already paired with the device.
- ⓘ For the 2WIN-S configuration and how to assembly the instrument, refer to the *2WIN-S Quick Start Guide* provided with the system.

Patient age

2WIN-S uses the patient's birthdate / age range as a corrective parameter to determine the refraction. This information is used in particular to compensate accommodation in young patients with hyperopia-based refraction error. Take care of selecting the right birthdate / age range before taking the measurement. Take into consideration that the default age range is 0-2 years.

Control Panel functionalities

		Button		
		Power	1 – Measure	2 – Connection
State	Flashing Green	The system is booting up	Exam ongoing	-
	Fixed Green	The system has successfully started. There is a blinking when the activity is normal	Measure well done	2WIN-S correctly connected to the application
	Fixed Red	Error: please shut down the system and power it on again	Measure error: repeat the measurement	2WIN-S not connected: check connections' settings
	Flashing Yellow	The system is shutting down	-	Connection ongoing (Wi-Fi/BT)
	Fixed Yellow	Firmware updating	-	2WIN-S not connected to the application
	Flashing blue			Pairing ongoing with application

		Button		
		Power	1 – Measure	2 – Connection
Function	Short press	System power up	-	-
	Long press	2 sec: system shut down More: force power off	2 sec: start/stop a measurement; the exam is automatically saved	2 sec, until flashing yellow: WiFi\BT connection reset 4 sec, until flashing blue: start application pairing

9.2 Preparation of the patient

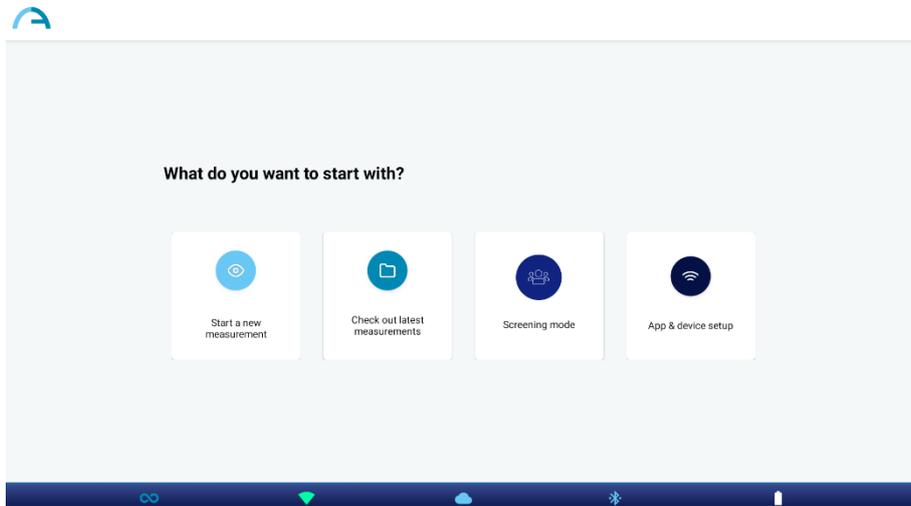
The operator shall instruct the patient to look inside the tube and to try to open wide his eyes so to avoid eyelashes covering the pupils.

The operator shall instruct the patient to look, during the measurement, at the fixation target positioned at the bottom of the device: three white dots in the shape of a triangle. Most importantly, the patient must not follow with his eyes the moving red lights that turn on during the exam but concentrate on the fixation target.

In case of monocular measurement, ask the patient to cover his/her other eye with the provided occluder.

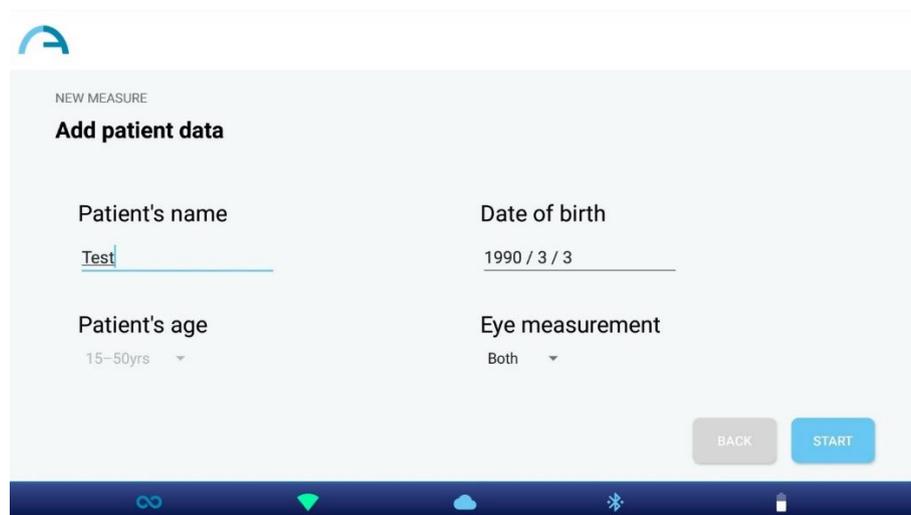
9.3 Measurement

Turn the 2WIN-S ON by pressing the ON/OFF button for 1 sec. A beep sound stands for 2WIN-S turning ON. Select “Start a new measurement” from the KALEIDOS App’s main page.



Insert the patient’s name and date of birth. When the date of birth is set, the age range is automatically selected. Then set the type of the measurement: right eye, left eye or both eyes. As alternative, you can just select the patient age range, without the patient’s personal data.

Choose what kind of “Eye measurement” you want to perform: binocular (“both”) or monocular (“left” or “right”).

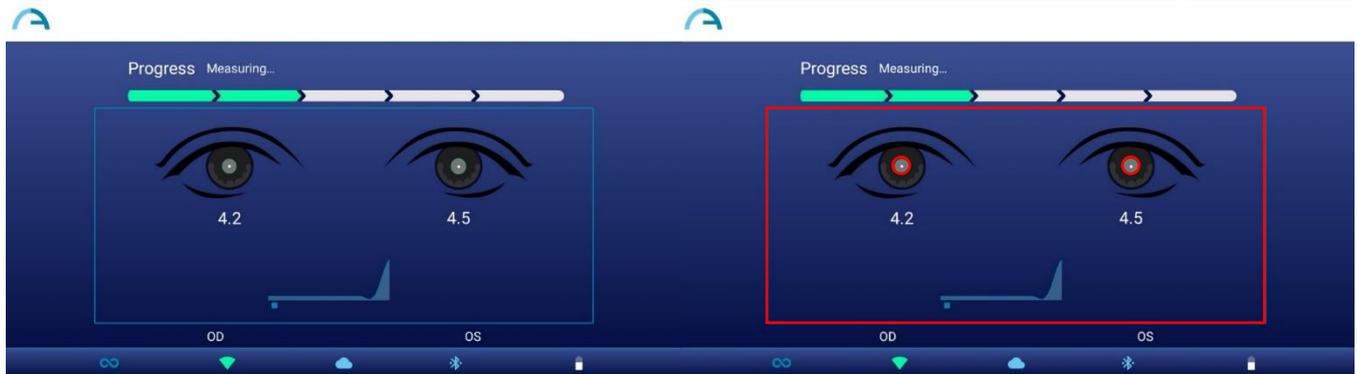


Press the START button. The measurement starts and a progress bar is displayed. This step will last at least 3 seconds.

From the start of the examination, the patient's pupils are circled in green (left figure). If the patient's pupils are circled in red the conditions for the measurement are not met and it shall be repeated (right figure). Pupil diameters are displayed below the eyes' image during the measurement phase.

If the patient is not positioned correctly during the examination, the rectangle that frames the eyes' image becomes red. In this case, the operator must ask to the patient to position himself/herself correctly.

The graph on the bottom of the window is the focusing meter. Maximizing the value of the graph will lead to a better measurement: this is done automatically by the system.



A one-beep sound indicates that the measurement was taken, while a two-beep sound indicates that the measurement has been correctly processed (this is an option selectable from the 2WIN inside 2WIN-S, in **Menu > Measurement > Sound > Alerts > Ending Beep**).

If an error occurs during the measurement and the message appears, the causes could be the following:

- Pupil/s too small or large.
- High IR noise.
- Unstable conditions of the data due to other eye problems.
- Other unexpected facts.

If an error message persists after repeating the measurement several times, suggest the patient to have an ocular examination with a licensed doctor.

For any problems during operation, please refer to *Chapter 17 – Troubleshooting*.

At the end of the measurement, the following results are displayed (from top to bottom):

- Spherical Equivalent (SE);
- Refraction results (Sphere, Cylinder, and Axis);
- Reliability index, calculated independently for right eye and for left eye;
- Pupil size (PS).

Axis angles are expressed according to TABO system.

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



 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 2WIN's diagram.

The Reliability Index is a number between R1 and R9 (the higher the index, the more reliable the measure). A measure with a low reliability index (less than R6) should be repeated.

If “N.A.” is displayed, it indicates that the refraction is outside the range of the 2WIN-S measurement range.

Numbers for “Pupil” and for “Gaze” represent, for OD and OS respectively, pupil diameters, 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.

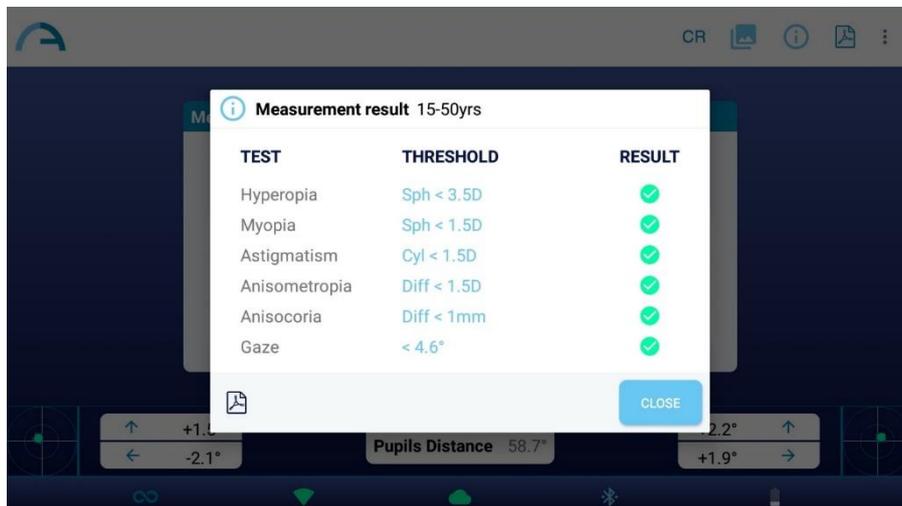
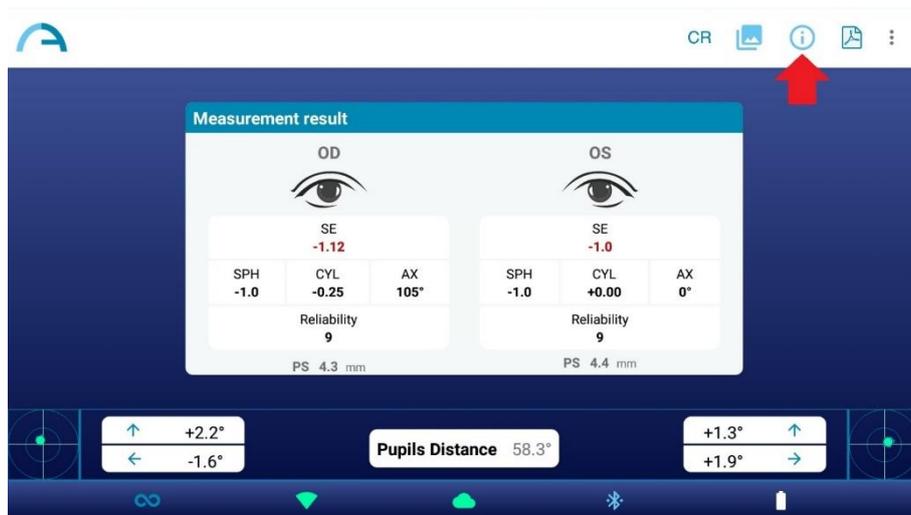
The Gaze is also graphically depicted for each eye in the two bottom corners of the display in the form of a cloud of dots and an averaging cross inside two concentric blue circles.

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.

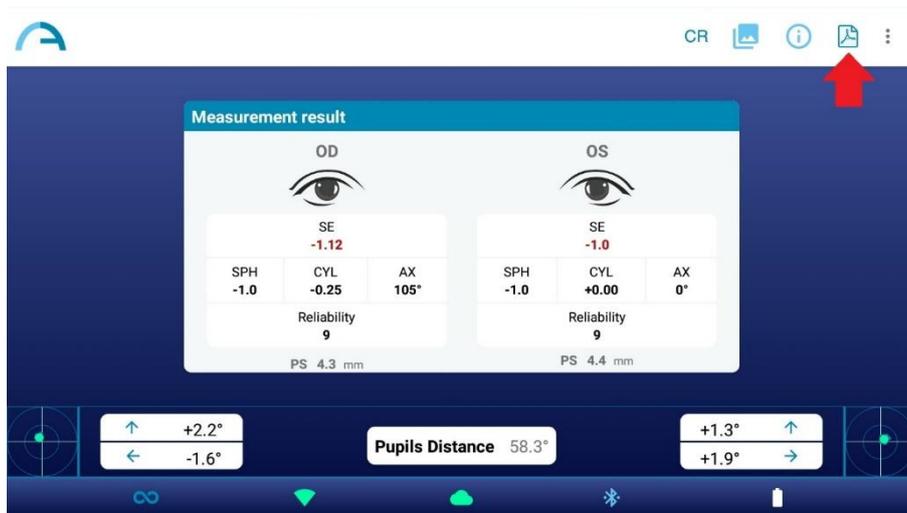
 For further information on the features present on the *Plus* configuration of 2WIN-S, please refer to *Chapter 13*.

2. To see the “Screening Table” results, press on the “Info” button on the top right:



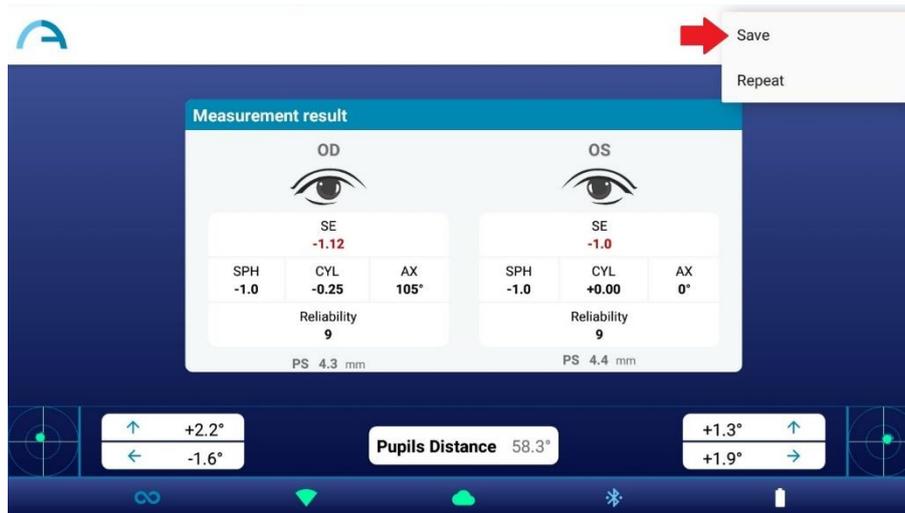
The Screening Table is a set of thresholds that are used by the 2WIN-S to determine if a patient is inside or outside the guidelines (AAPOS) for amblyopia detection screening.

3. Tap on the PDF icon below the screening results table to generate the PDF report of the exam. As an alternative, tap on the PDF icon on measurement results window:



4. Click on the three dots on the top right corner to save or repeat the measurement (a dropdown menu appears). If you repeat the measurement, current patient data will be kept:





① Pressing 'Save', the exam is automatically saved both in the tablet and in the 2WIN's MicroSD card (inside 2WIN-S). The PDF report is saved only in the tablet.

① The path in which the PDF reports are saved is: Internal Storage\Documents\Adaptica.

9.4 Save exam

The saved exams could be re-opened by clicking "Check out latest measurement" on the main screen of KALEIDOS App. A list of all the saved exams will appear, from which you can select the exam of interest.

The PDF report of the exams when saved will be filed in the Internal storage of the tablet: Documents > Adaptica. The file is named "ExamNumber_ *number* _*date*", where *date* is the current date and *number* is a sequential number.

Below is the description of the PDF report:

Exam Report

PATIENT NAME	Patient Name: _____ Date of birth: _____	EXAM DATE	Exam Date: Tue Jul 19 2022																																
	DATE OF BIRTH		Exam N: 111																																
			EXAM NUMBER																																
RIGHT EYE	OD	LEFT EYE	OS																																
SPHERE	Sph	Cyl	Ax																																
CYLINDER	+1.00	-3.0	21°																																
	SE: -0.5	Reliability: 7	Info: N.A.																																
SPHERICAL EQUIVALENT			SE: -1.37																																
			Reliability: 6																																
GAZE	Pupil Size: 5.4 mm Gaze: -2.8° ← +0.8° ↑		Pupil Size: 5.3 mm Gaze: +6.4° → +1.1° ↑																																
GAZE GRAPH	Pupil Distance : 59.0 mm Error Measure : -		Head Tilt: 0.8°																																
AI-App HINT	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 20%;">Criteria for:</th> <th style="width: 40%;">15-50yrs</th> <th style="width: 20%;"></th> <th style="width: 20%;">Outcome</th> </tr> </thead> <tbody> <tr> <td>Hyperopia:</td> <td>Sph < 3.5D</td> <td></td> <td style="text-align: center;">✔</td> </tr> <tr> <td>Myopia:</td> <td>Sph < 1.5D</td> <td></td> <td style="text-align: center;">✔</td> </tr> <tr> <td>Astigmatism:</td> <td>Cyl < 1.5D</td> <td></td> <td style="text-align: center;">✘</td> </tr> <tr> <td>Anisometropia:</td> <td>Diff < 1.5D</td> <td></td> <td style="text-align: center;">✘</td> </tr> <tr> <td>Anisocoria:</td> <td>Diff < 1mm</td> <td></td> <td style="text-align: center;">✔</td> </tr> <tr> <td>Gaze:</td> <td>< 4.6°</td> <td></td> <td style="text-align: center;">✔</td> </tr> <tr> <td colspan="2">Signature: _____</td> <td colspan="2" style="text-align: right;">Screening Result: Refer</td> </tr> </tbody> </table>			Criteria for:	15-50yrs		Outcome	Hyperopia:	Sph < 3.5D		✔	Myopia:	Sph < 1.5D		✔	Astigmatism:	Cyl < 1.5D		✘	Anisometropia:	Diff < 1.5D		✘	Anisocoria:	Diff < 1mm		✔	Gaze:	< 4.6°		✔	Signature: _____		Screening Result: Refer	
Criteria for:	15-50yrs		Outcome																																
Hyperopia:	Sph < 3.5D		✔																																
Myopia:	Sph < 1.5D		✔																																
Astigmatism:	Cyl < 1.5D		✘																																
Anisometropia:	Diff < 1.5D		✘																																
Anisocoria:	Diff < 1mm		✔																																
Gaze:	< 4.6°		✔																																
Signature: _____		Screening Result: Refer																																	
CUSTOMIZABLE FOOTPRINT																																			

The number of prints before the device starts rewriting the oldest files is 1000.

Moreover, if the SD card is inserted in the 2WIN, a set of 3 files for each examination are saved in it, into the folder "2WIN Exams". A subfolder named "Exam #number date" is created.

The subfolder contains at least 3 files, with the same name of the folder, but different extensions:

- *.pdf = examination results in A4 size paper; other PDF can be written by specific functions.
- *.xml = xml file version of the measurement results.
- *.json = internal file (for service purposes only).

CSV Exporter Tool

The 2WIN-S permits to export all the exams stored in the MicroSD card of 2WIN in a CSV file, by selecting **Menu > Print > Export Patients** from 2WIN inside 2WIN-S.

Once activated, the 2WIN-S creates in the root of the MicroSD memory card the CSV file with the following name-format: *Resume_Date_Hour*.

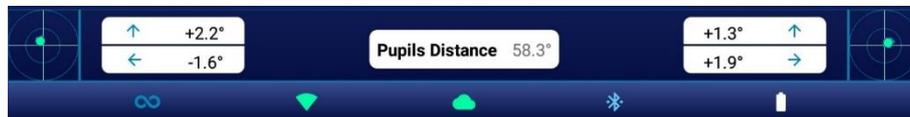
 For a detailed description of the CSV file, please refer to the 2WIN Operator Manual.

9.5 Gaze

The maps on the two bottom corners of the results screen indicate the eye position (Gaze). This is calculated based on the corneal reflex positions, but compensated because the light is not centered, and the direction of eye movement is opposite compared to the movement of the reflex.

The Gaze shows the displacement of the visual axis with respect to the pupil center. This displacement can be related to strabismus, but it normally corresponds to the *K* angle. This indication could be confirmed with the CR Application, which allows to identify the Gaze independently from the *K* angle.

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



 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.

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

This graphical representation suggests the presence of tropias and stability/instability of fixation.

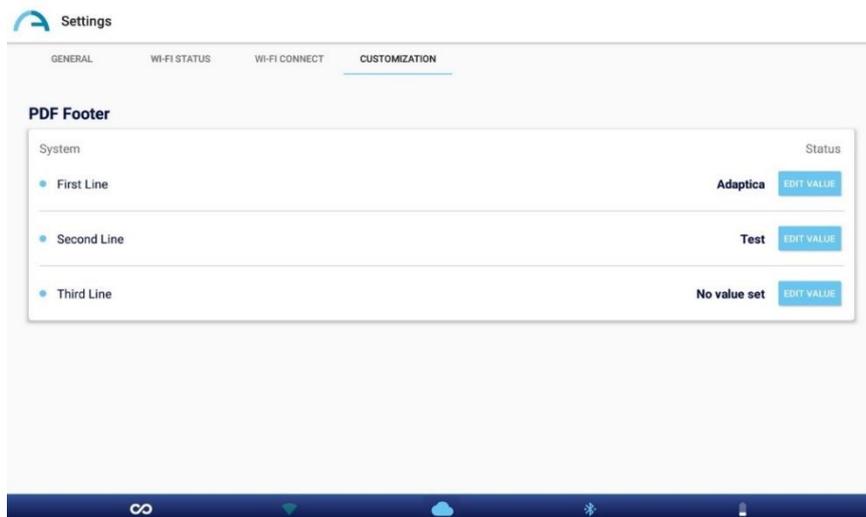
9.6 Customization

Some features of the device can be customized by the user.

Custom printouts

From the KALEIDOS App, in **Settings > Customization** it's possible to customize the PDF report's footer.

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



Other customizations

For a list and description of other customization options, please refer to *2 WIN Operator Manual > Section 9.15 – Customization*.

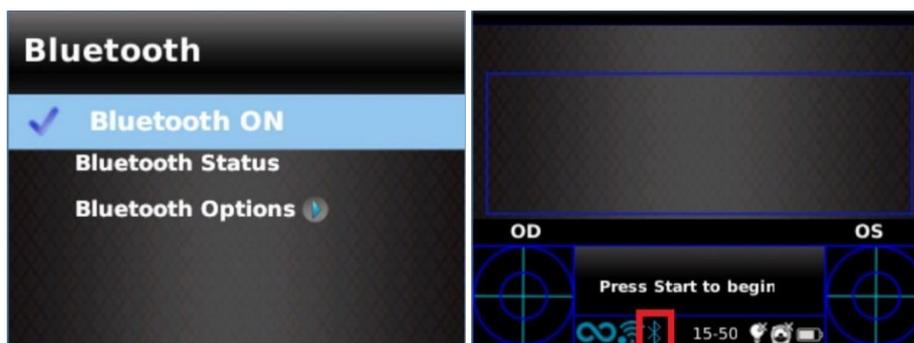
10 Wireless Connections

10.1 Bluetooth connectivity

2WIN-S devices that are equipped with the Bluetooth module, allow:

- the transmission of 2WIN-S' refraction results to the VisionFit SC; only from 2WIN/2WIN-S' software version 5.4 (refer to Section 10.3 for the pairing instructions);
- remote control of the 2WIN-S through the KALEIDOS App BT, running on Android tablets (refer to Chapter 12 for the pairing instructions).

The Bluetooth connectivity can be enabled from the 2WIN inside 2WIN-S in **Menu > Settings > Bluetooth**. The Bluetooth icon is shown on 2WIN's display:



ⓘ Bluetooth connectivity is enabled by default on the device.

ⓘ Refer to Section 10.1 of *2WIN Operator Manual* for further information.

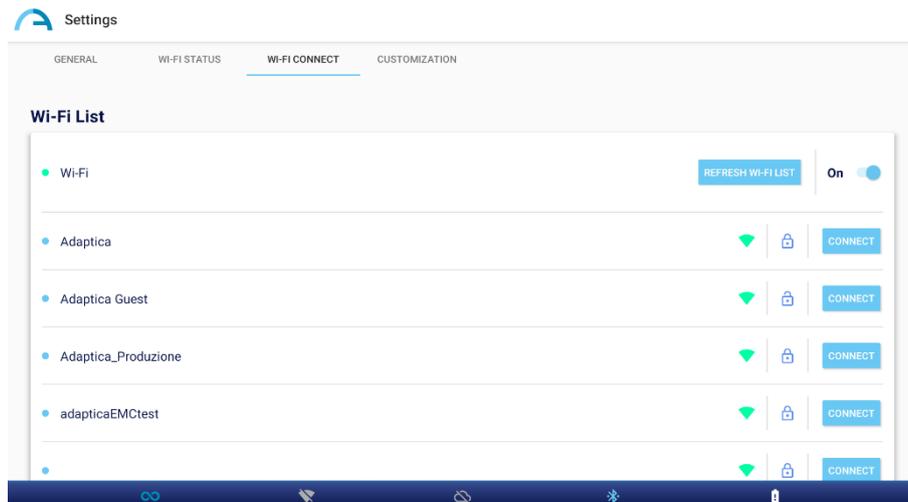
10.2 Wi-Fi connectivity

A 2WIN-S device that is equipped only with the Wi-Fi module can be connected to a Wi-Fi network, for the following tasks:

- control remotely the 2WIN-S through the 2WIN App-Connection Wi-Fi, running on Android tablets: this is an unsupported legacy feature, reported only for backwards compatibility;
- remote control for Remote Service and Support;
- download the latest software update.

The Wi-Fi connectivity can be enabled in the 2WIN-S as follows:

- Click on **“App & device setup”** in the KALEIDOS App.
- Select **“Wi-Fi Connect”** and choose your favorite network. When clicking on **“Connect”**, the password insertion window will appear. Insert the **Password**, then click on the option **“Confirm”**.



- Click on **“Wi-Fi Status”** to (1) **check if the 2WIN-S is connected to your network** and to (2) **determine the IP address of 2WIN-S**.

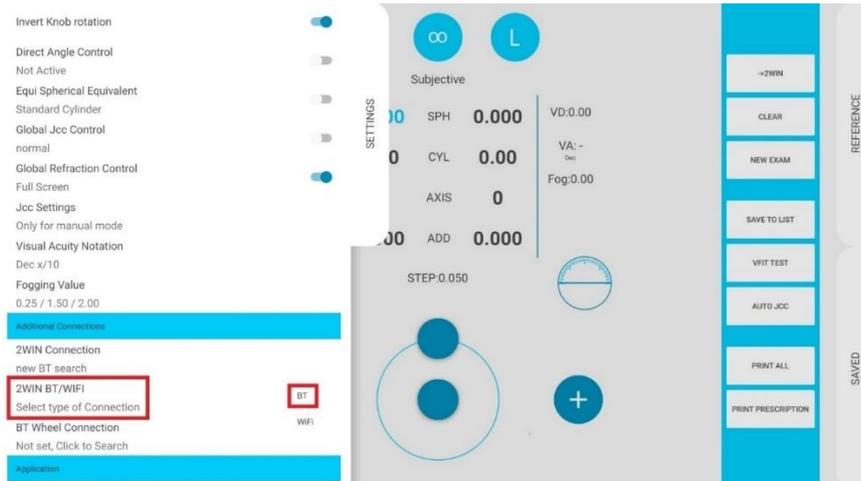
10.3 Pairing and transferring a 2WIN-S exam to VisionFit SC

ⓘ In the following, it will be described the pairing procedure between 2WIN-S and VisionFit SC. This is a deprecated legacy feature, described only for backwards compatibility.

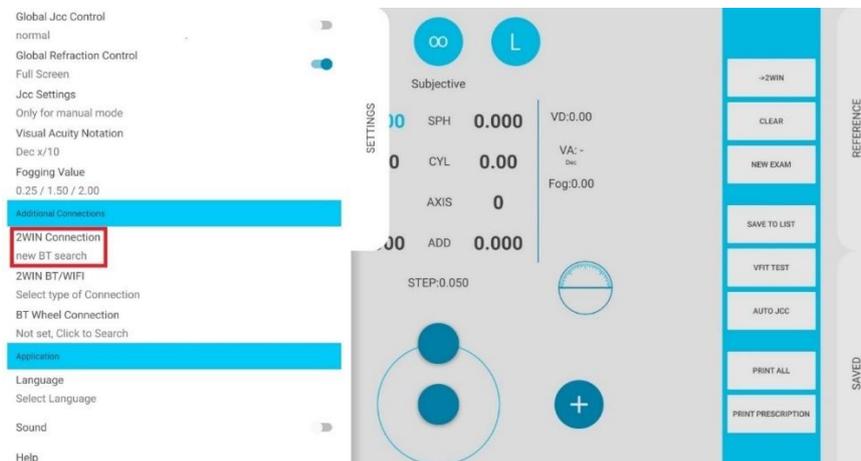
VisionFit SC is a mobile and wearable subjective refractor which can be used in combination with 2WIN-S. Once 2WIN-S is paired it is possible to transmit its objective refraction results to VisionFit SC, to speed up the subjective refraction measurement.

The first time transferring an exam to VisionFit SC, the pairing needs to be performed as follows:

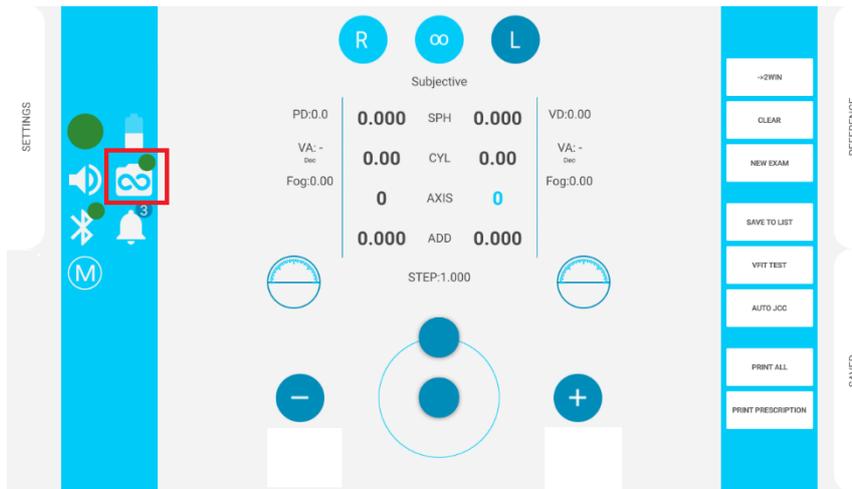
1. Enable **“Bluetooth”** on 2WIN-S from **Menu > Settings**.
2. From VisionFit SC’s tablet application, enter **Settings** and set **2WIN Connection type: BT**



3. Afterwards, select **2WIN Connection**. The pairing starts automatically.



4. Press on 2WIN icon to see a list of available devices: select the desired 2WIN. When the pairing is complete, a green circle appears on 2WIN's icon.



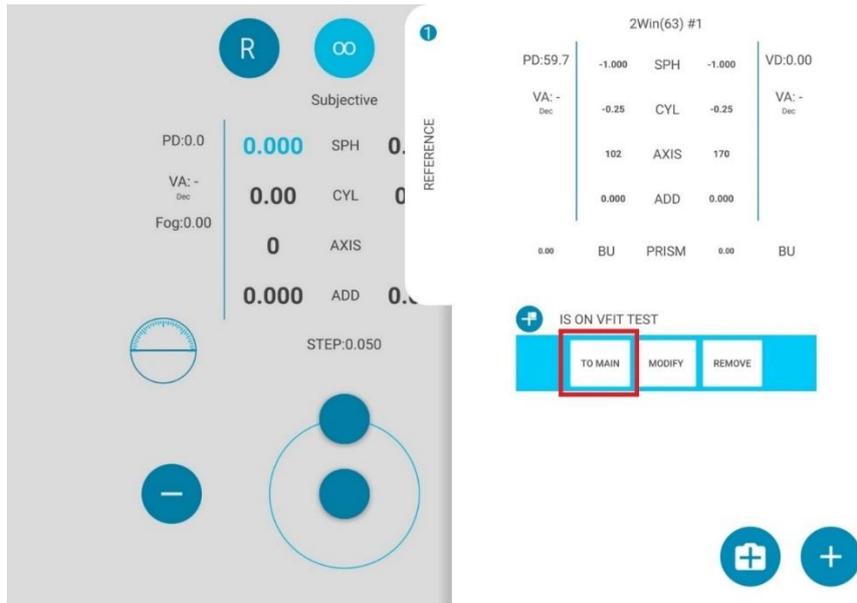
To transfer a 2WIN-S measurement to VisionFit SC follow the steps below:

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



3. 2WIN-S data will appear instantly on the Reference area in VisionFit SC's application.

4. Press **TO MAIN** button on VisionFit SC's application to add data to the Subjective Area.



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

 Not available measurements from 2WIN-S can't be transferred on VisionFit SC.

11 Remote control: 2WIN App-Connection Wi-Fi

 The 2WIN App-Connection Wi-Fi allows to remotely control the 2WIN-S, from an Android tablet through Wi-Fi connection. However, it is an unsupported legacy feature, reported only for backwards compatibility. Further information could be found in our website at Products > 2WIN-S > Manuals Download. Otherwise, feel free to contact support@adaptica.com.

12 Remote control: KALEIDOS App

The KALEIDOS App allows to remotely control a 2WIN-S, from an Android tablet through Bluetooth connectivity.

 You can download KALEIDOS App on your device from Google Play Store ([here](#)). Otherwise, you can download the installation file on your tablet from Adaptica's [website](#) in the section **Technical Information > Downloads > KALEIDOS App: installation file**.

The tablet shall satisfy the following requirements:

- Android version: 8.0, 8.1, 9, 10, 11, 12, 13
- Bluetooth Version: 2.0 Low energy
- Display size: 10 inches or more
- Processor type: ARMv7

These are recommended tablet models which were intensively tested with KALEIDOS App:

- Huawei MediaPad T5 (AGS2-W09)
- Samsung Tab A6 (SM-T580)
- Lenovo Tab M10 2nd and 3rd Gen (TB-X605L and TB-328XU)
- Lenovo Tab M10 HD (TB-X306X)
- Lenovo Tab M10 Plus 3rd and 4th Gen (TB-125FU and TB128FU)

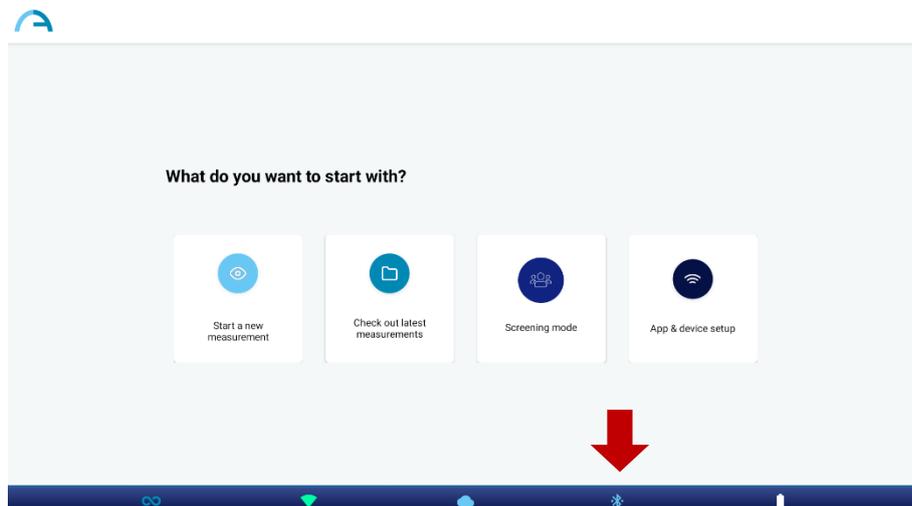


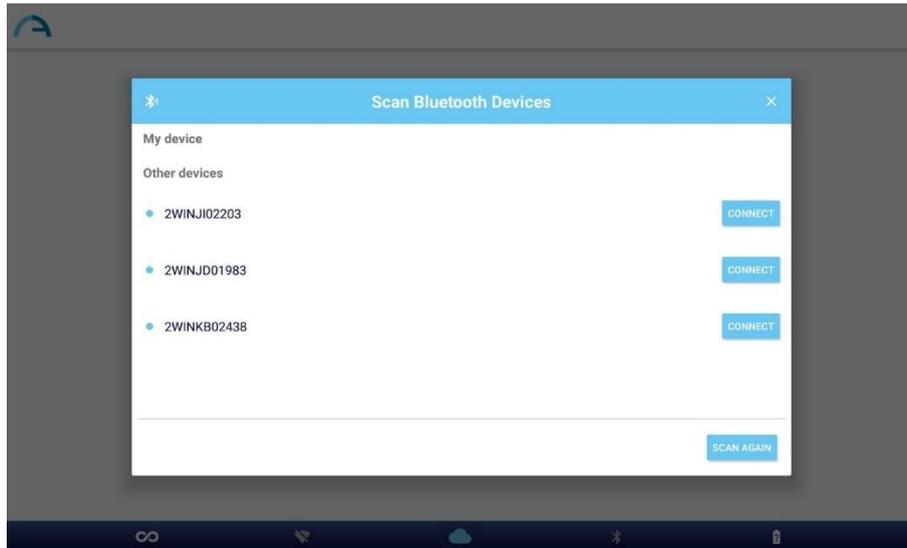
Tablet's operating system updates are forbidden. They could compromise the KALEIDOS App's functioning.

12.1 KALEIDOS App: installation and configuration

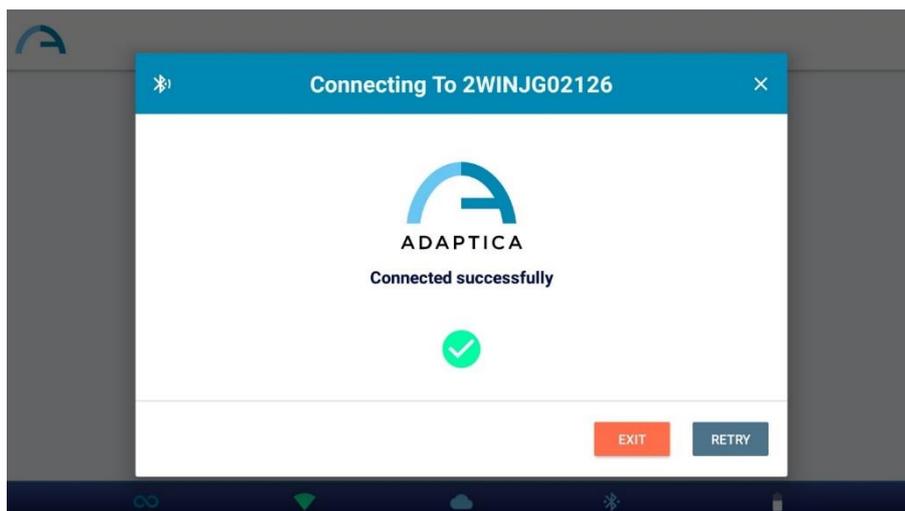
To use the KALEIDOS App, the device and the application must be paired for the first time as follows:

1. Install the KALEIDOS App on your tablet.
2. Check that Bluetooth is enabled on the tablet.
3. Switch the 2WIN-S on.
4. Run the KALEIDOS App.
5. Tap on the Bluetooth icon on the KALEIDOS App to start the available Bluetooth devices search. A window showing all the available 2WIN-S will open.





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



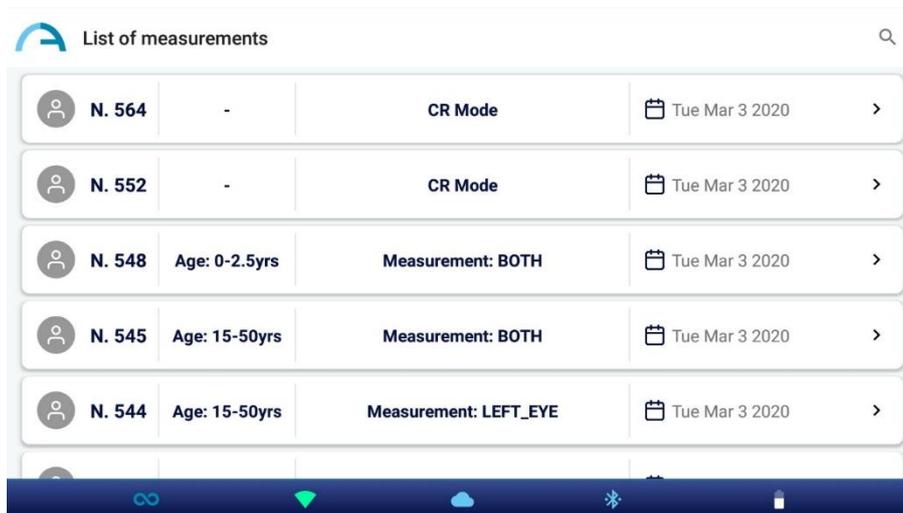
-  At the next launch, KALEIDOS App will automatically reconnect to the paired 2WIN-S unless the user disconnects it.
-  KALEIDOS App is intended to be used to control 2WIN-S and it does not allow 2WIN remote control.
-  KALEIDOS App is compatible with 2WIN-S having software version 5.4.2 or higher, and hardware version 29.1 or higher.
-  In the 2WIN-S *Plus* configuration, the provided tablet is already paired with the device.



Respecting the 'General Data Protection Regulation' (GDPR), to use the KALEIDOS App, a screen lock mechanism must be enabled on the tablet. If such mechanism is not active, the application will not start.

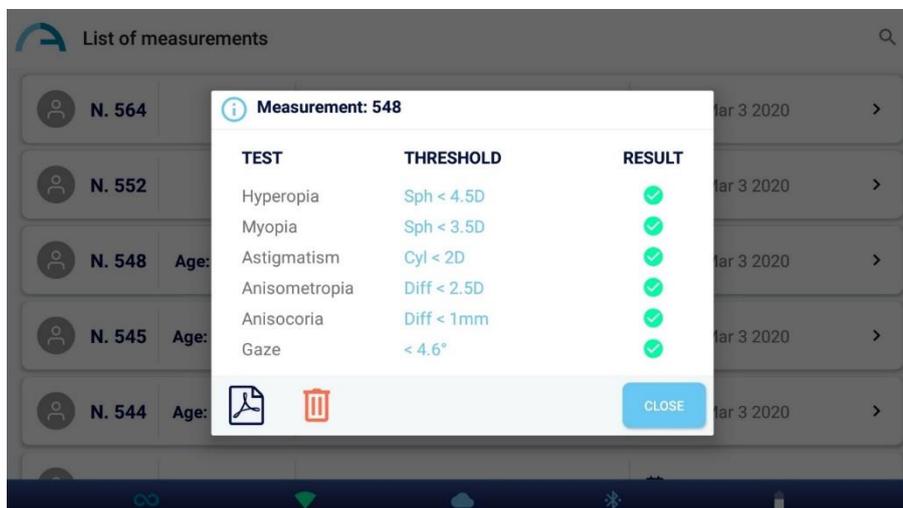
12.2 Review exams using KALEIDOS App

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



Exams acquired in Refraction mode report the indication of the examined eye: both eyes, left eye, or right eye. Corneal Reflexes exams, instead, are marked with a “CR Mode” label. Refer to *Chapter 13 – 2WIN-S Plus* for further information on the Corneal Reflexes exam.

Clicking on Refraction exams it is possible to review the exam’s Screening Table and to open, share and print the PDF report.



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

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

12.3 Screening Mode

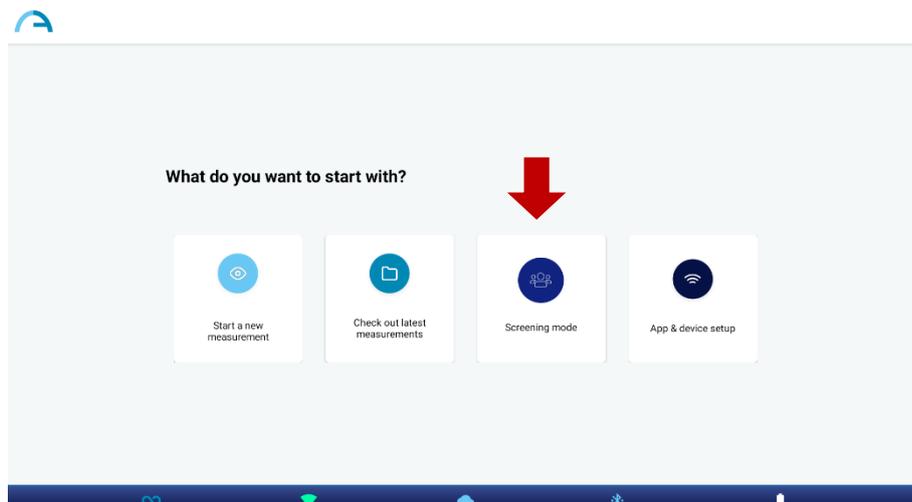
KALEIDOS App allows to handle mass screening process. Follow the below instructions in order to perform screening sections.

1. A list of patients can be prepared ahead of time in a laptop or PC, using the “SCREENING_IN.csv” template file available in our [website](#), **Technical Information > Downloads > Screening file**. This file can be easily read and modified by using Microsoft® Excel or similar programs: please, add users’ information in the related columns.

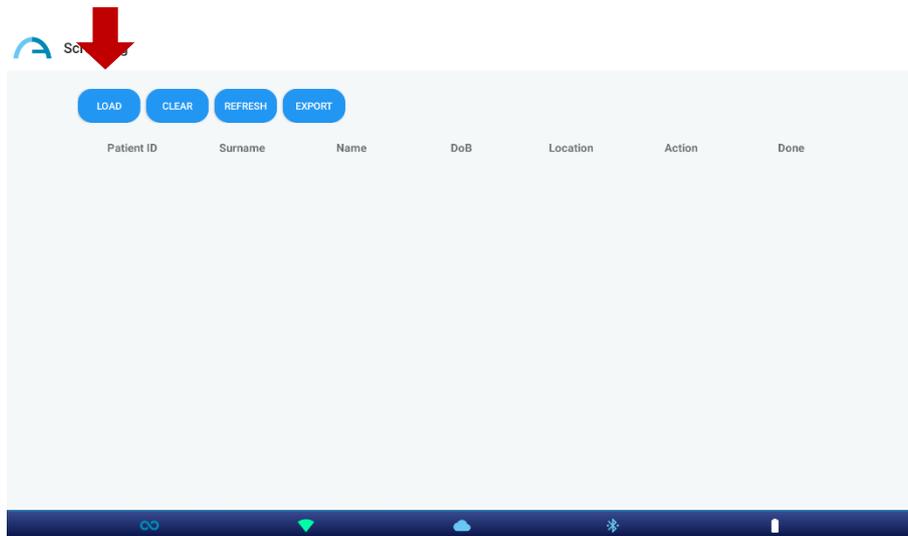
Field	Meaning	Format
<i>surname</i>	Patient’s surname	String
<i>name</i>	Patient’s name	String
<i>dob</i>	Patient’s Date of Birth (mandatory)	Date format
<i>patientId</i>	Patient’s Identification Number	Number
<i>location</i>	Patient’s location (e.g., city or state)	String
<i>email</i>	Patient’s email	String

-  Note that the “Date of Birth” item must be in one of the following formats, otherwise the measurement cannot be correctly performed: “YYYY-MM-DD”, “MM-DD-YYYY”, “DD-MM-YYYY”, “YYYY/MM/DD”, “MM/DD/YYYY”, or “DD/MM/YYYY”.
-  The first row of the input file, containing the header information, should not be changed in any way: conversely, the KALEIDOS App will not be able to run the screening mode.

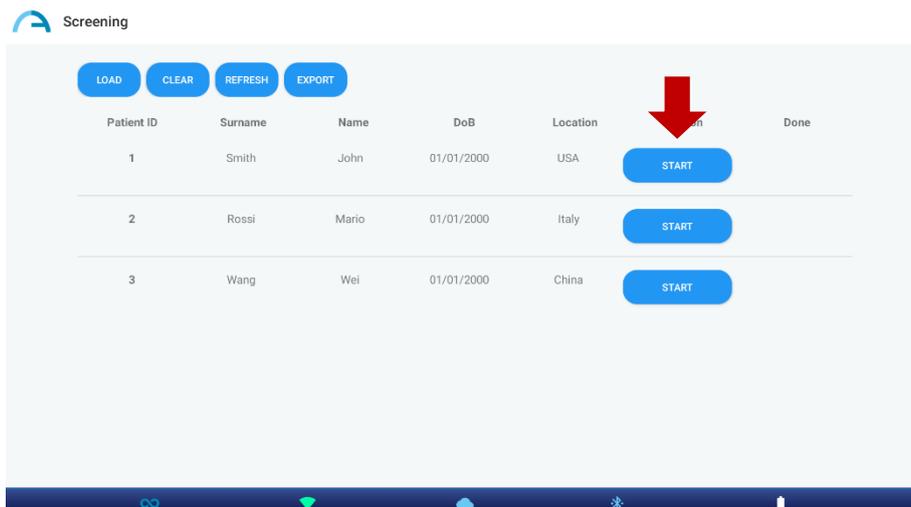
2. Connect the tablet with a PC/laptop using a USB cable. Create a new folder named “SCREENING” within the tablet in the path *Internal Storage > Documents > Adaptica*. In this new folder, then copy the correctly compiled “SCREENING_IN.csv” file.
3. Open the KALEIDOS App and enter into the “Screening mode”, by pressing the related button.



4. Press the “Load” button in order to import patients’ information: navigate into *Internal Storage > Documents > Adaptica > SCREENING* and select the “SCREENING_IN.csv” file.



5. Select the patient that will perform the next measurement by pressing the “Start” button.

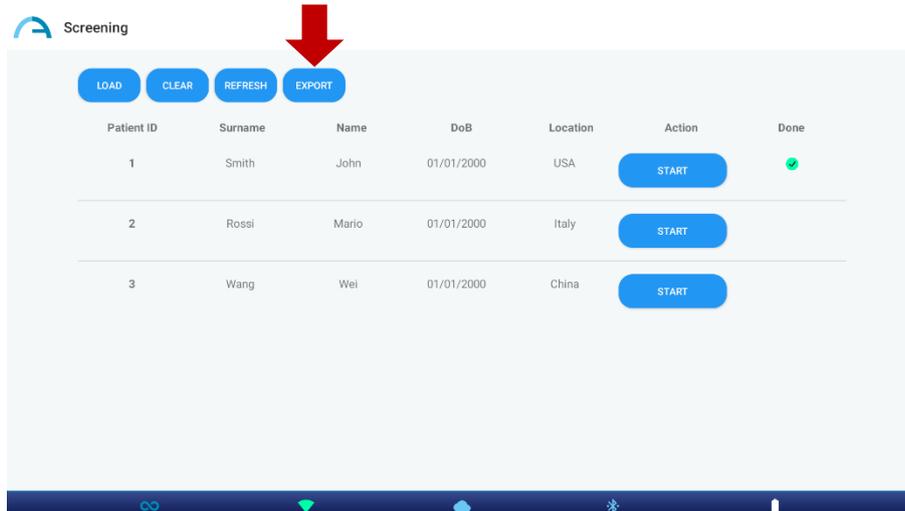


After having performed the exam, press the application icon (top left corner of KALEIDOS App) or the tablet behind arrow in order to continue the screening.

① The icon  will appear under “Done” near the patient information row when correctly saved.

① If the icon does not appear immediately after the exam, press the “Refresh” button.

6. When the screening is completed, press the “Export” button.



A “.csv” file will be saved in the folder selected by the user. This file will contain all patients’ information, along with refraction-related data.

Field	Meaning	Unit of measure
<i>sphere_od</i>	Right sphere power	D
<i>cylinder_od</i>	Right cylinder power	D
<i>axis_od</i>	Right axis value	°
<i>ps_od</i>	Right pupil size	mm
<i>reliability_od</i>	Right reliability index	1 to 9
<i>se_od</i>	Right sphere equivalent	D
<i>sphere_os</i>	Left sphere power	D
<i>cylinder_os</i>	Left cylinder power	D
<i>axis_os</i>	Left axis value	°
<i>ps_os</i>	Left pupil size	mm
<i>reliability_os</i>	Left reliability index	1 to 9
<i>se_os</i>	Left sphere equivalent	D
<i>pupil_distance</i>	Pupil distance	mm
<i>gaze_x_od</i>	Right gaze value on X-axis	°
<i>gaze_y_od</i>	Right gaze value on Y-axis	°
<i>gaze_x_os</i>	Left gaze value on X-axis	°
<i>gaze_y_os</i>	Left gaze value on Y-axis	°

 If needed, press the “Clear” button in the Screening mode window in order to eliminate all patients’ information.

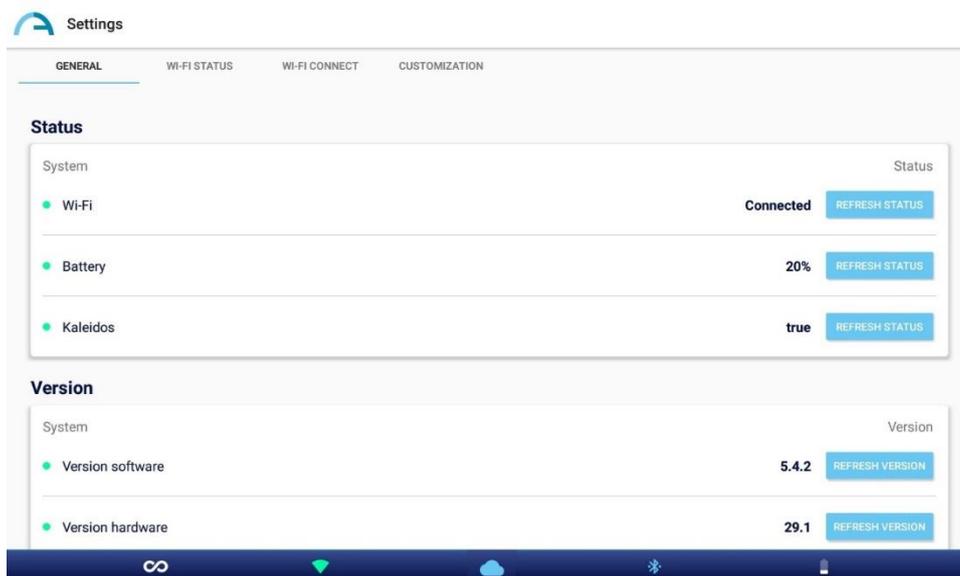
12.4 KALEIDOS App: settings

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

GENERAL

In the GENERAL tab the following information are displayed:

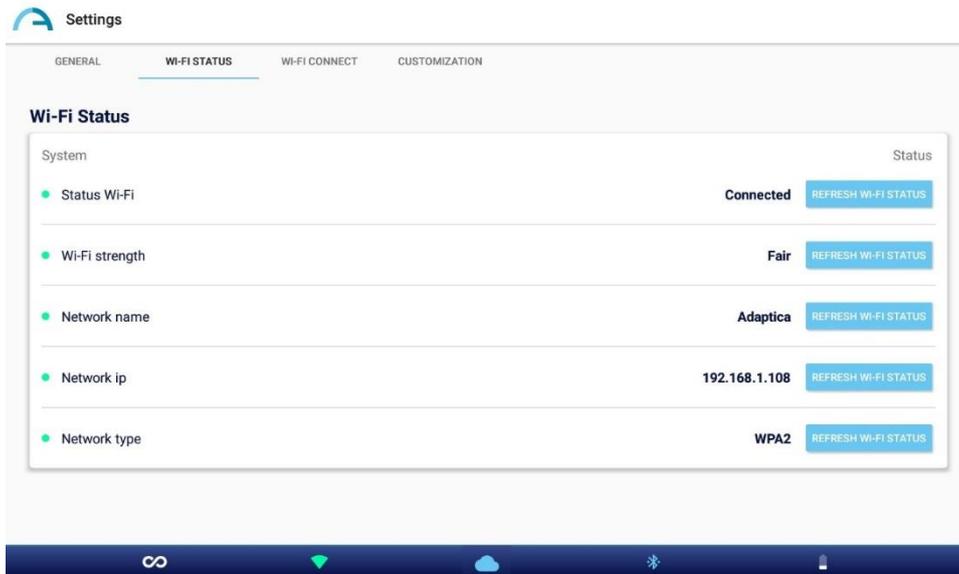
- **Status:** Wi-Fi status, Battery status, KALEIDOS mode.
- **Version:** 2WIN-S’ software version, 2WIN-S’ hardware version, 2WIN-S BT protocol version, 2WIN-S’ serial number.
- **System:** the button SHUT DOWN allows you to switch the 2WIN-S off.



WI-FI STATUS

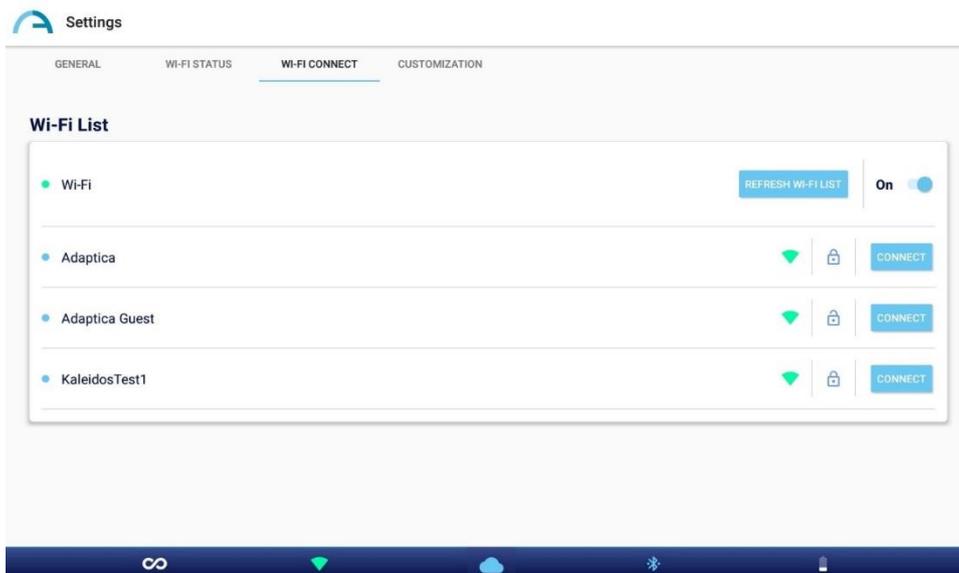
From the WI-FI STATUS tab it is possible to get information about 2WIN-S’ **Wi-Fi connection**:

- Wi-Fi status
- Wi-Fi strength
- Network name
- Network IP
- Network type



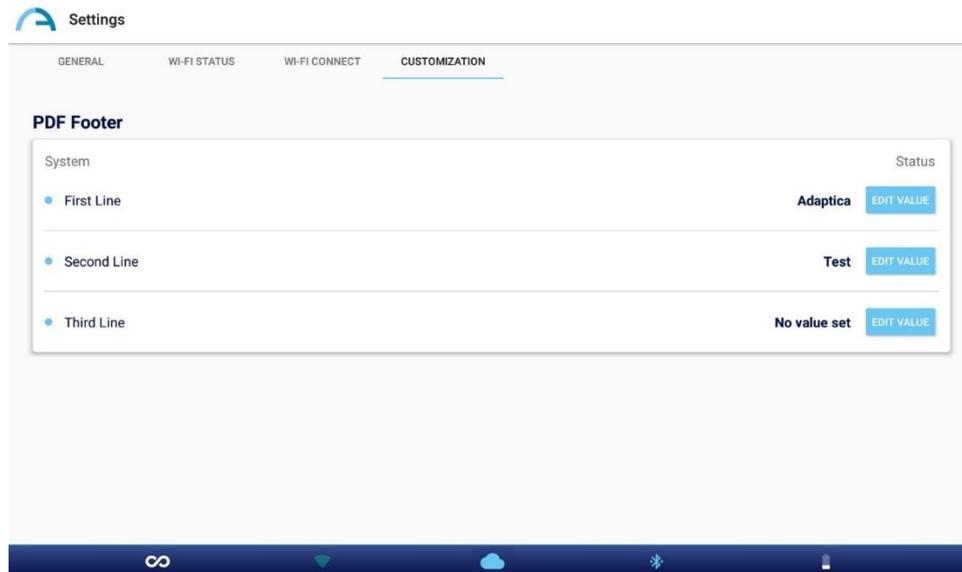
WI-FI CONNECT

From the WI-FI CONNECT tab it is possible to scan for the **available Wi-Fi networks** and to connect to them.



CUSTOMIZATION

From the CUSTOMIZATION tab, it is possible to personalize the PDF report's footer and set up the EMR connection (for the latter refer to Section 13.3).



13 2WIN-S Plus (Package)

2WIN-S (Bluetooth version) is also available in the 2WIN-S *Plus* configuration. The latter has the same characteristics of the standard 2WIN-S, but includes additional software and hardware features such as:

- Personalized Tablet;
- AI-App: anomalies detection hint of Anterior Segment;
- CR-App: corneal reflexes application;
- EMR connection.

 The *Plus* configuration is not available in all countries.

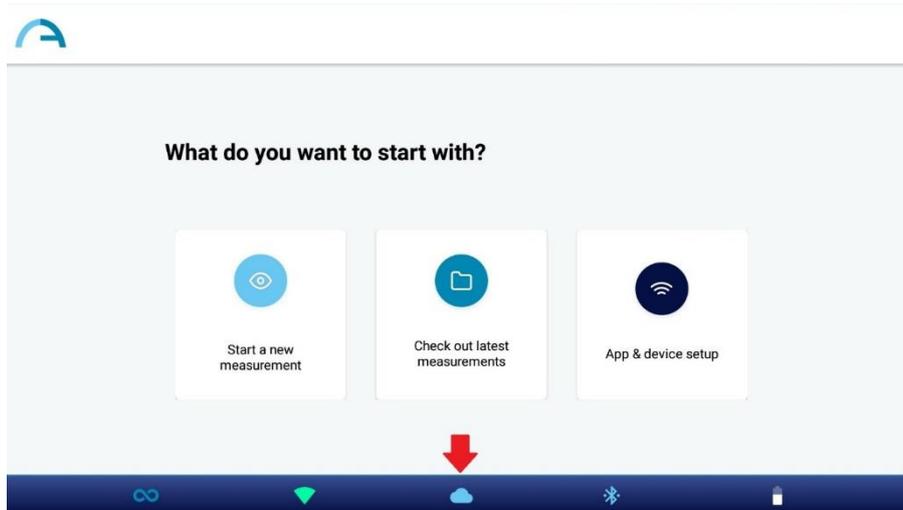
13.1 AI-App: anomalies detection hint of Anterior Segment

Anterior Segment Hint (AI-App) is an innovative Artificial Intelligence (AI) based algorithm running on Adaptica Cloud, developed to give to the user additional information on possible anterior segment anomalies where 2WIN-S is not able to refract the patient.

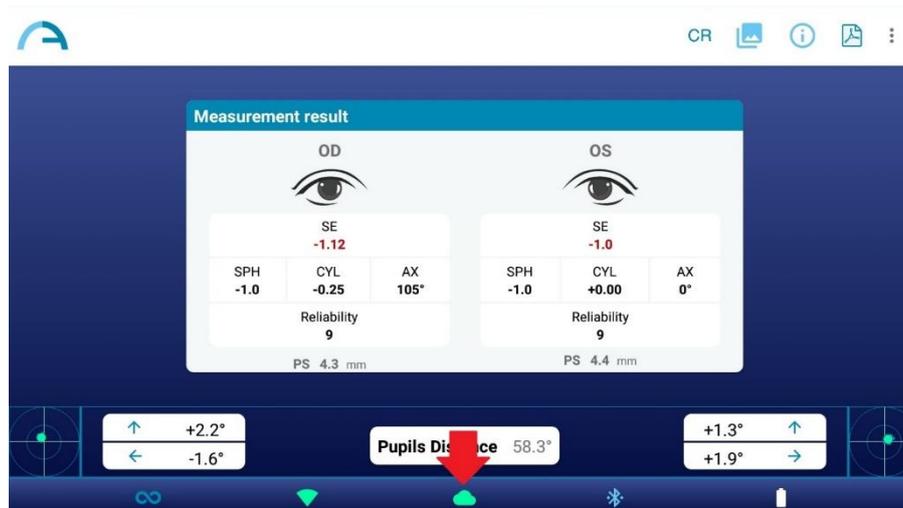
 Anterior Segment Hint is already active if you are using a 2WIN-S *Plus*. To activate the AI-App whether not having the *Plus* configuration, please contact your local distributor to get the update and the activation code.

 To work properly, Anterior Segment Hint needs the tablet to be connected to a Wi-Fi network having internet access.

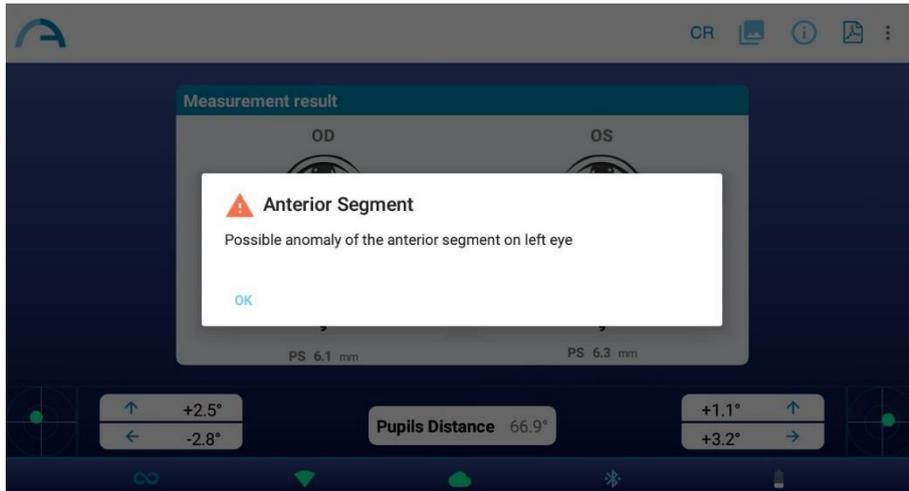
If AI-App is enabled on your 2WIN-S and if the tablet is connected to a Wi-Fi network having internet access, the cloud icon on KALEIDOS App is blue, as shown in the figure below. Otherwise, the cloud icon is grey.



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



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



The message “Possible anomaly of the Anterior Segment” shall not be misunderstood as a diagnosis. The measurement shall in any case be used to refer the patient to an eye-care professional for further evaluation.

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



When the AI-App is active, after performing a measurement please wait that the pop-up message “Upload completed” or “Failure uploading AI data” appears before doing anything else.

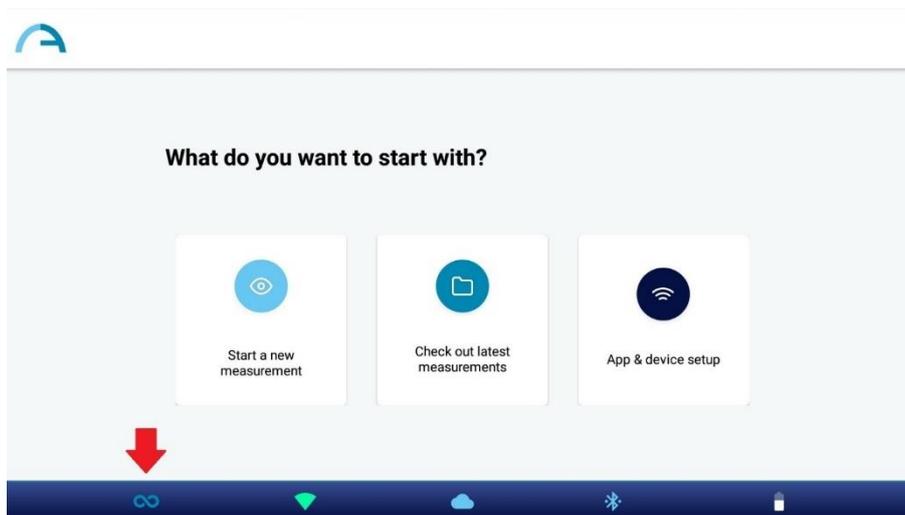
13.2 CR-App: corneal reflexes application

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

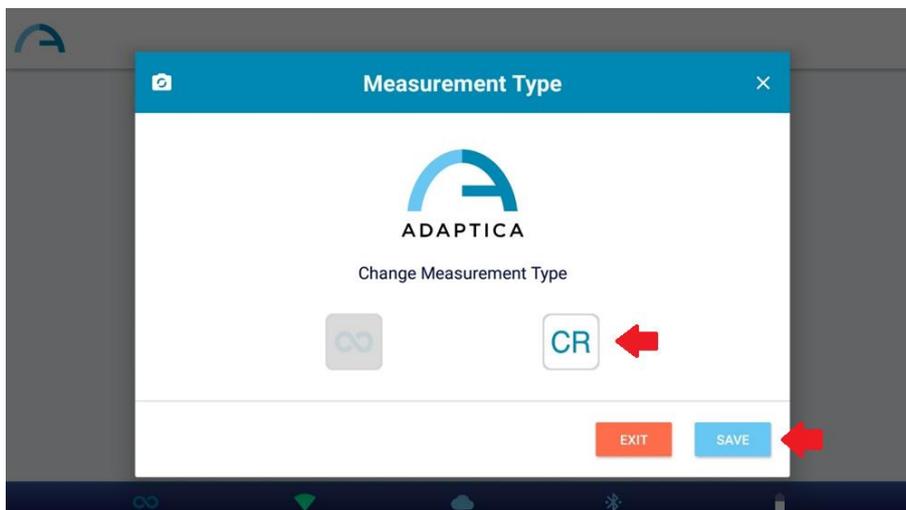
CR measurement mode provides information regarding the corneal reflexes position, giving hints about possible phorias and tropias. The procedure will last 10 second at least.

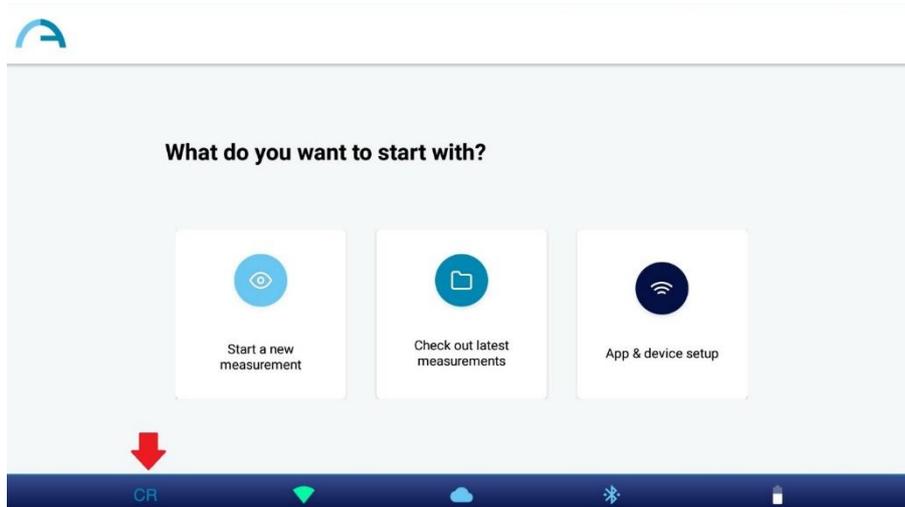
 CR measurement mode is already active if you are using a 2WIN-S *Plus*. Otherwise, whether having only the 2WIN-S, to request the activation code, please contact your local distributor.

To enable Corneal Reflexes measurement mode, tap on the standard measurement mode icon (infinite symbol) on the home page of the application:



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





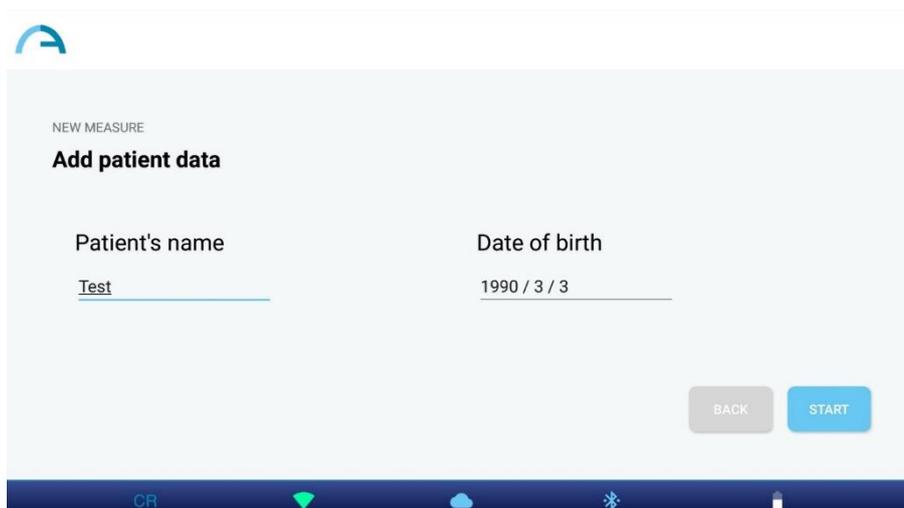
 Default mode is 2WIN-S (Refraction) mode. When KALEIDOS App is restarted 2WIN (Refraction) mode is loaded.

CR Exam Procedure

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

To perform a Corneal Reflexes measurement, follow these steps:

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

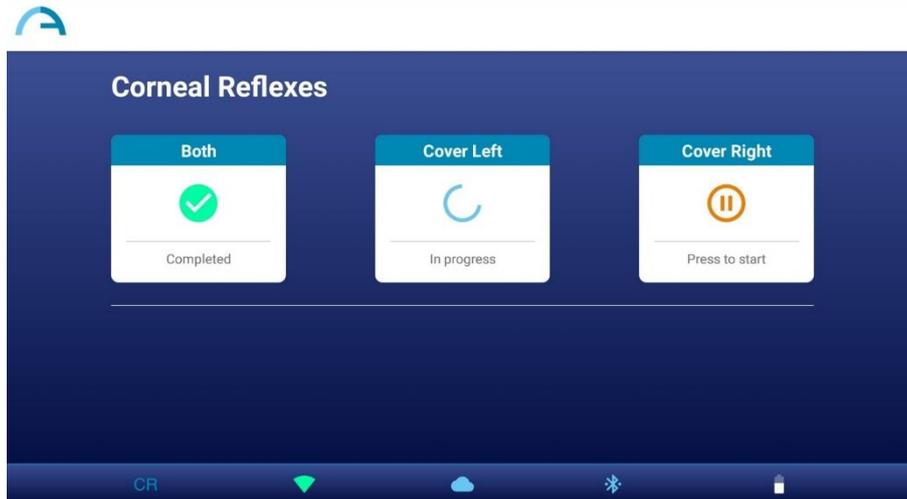


4. Click on “Start” and the Corneal Reflexes measurement window opens.

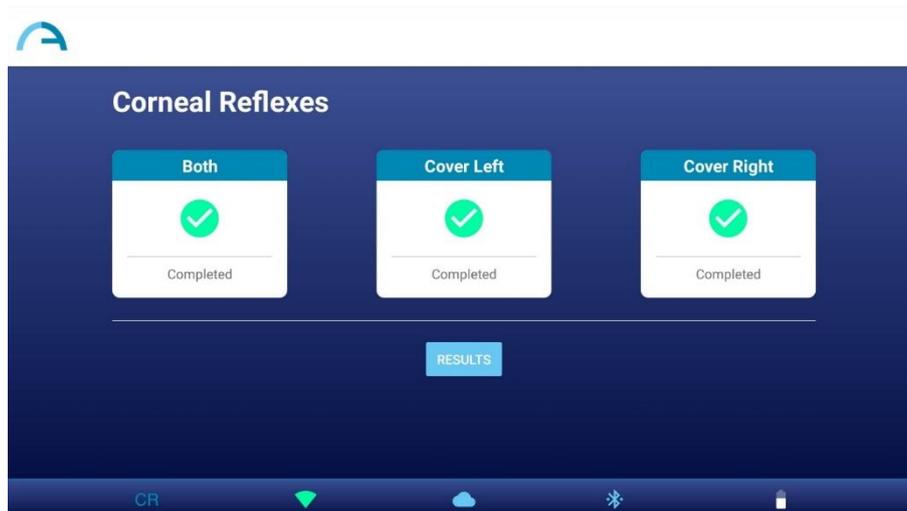
5. Ask the patient to look inside the 2WIN-S and at the white light. Press on one of the 'pause' buttons to start the corresponding exam. You can perform the three measurements in any order.



When you perform any of the cover tests use the IR occluder provided by Adaptica to cover the contralateral eye. Other occluders are forbidden.



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



You can repeat each measurement as many times as you wish, just tapping on the corresponding button. After you press RESULTS, you cannot modify the measurements anymore.

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



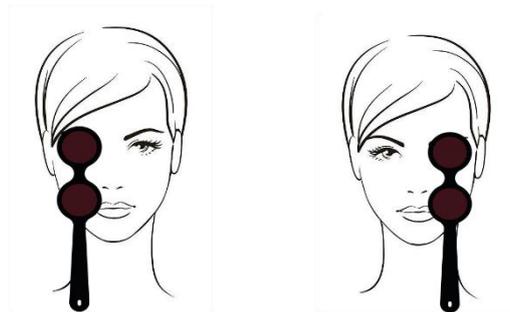
- Create the exam report by pressing on the PDF button on the CR Measurement Result window.
- To save the measurement, press the SAVE button on the CR Measurement Result window. When the saving is complete, a confirmation message appears.

You can also start a CR exam just after a 2WIN-S (Refraction) exam, by tapping on the CR button in exam's Measurement Result window. The CR exam will start with the same patient data.



Follow these instructions for the correct IR occluder positioning:

1. Hold the occluder in a vertical position and with the handle downwards.
2. Hold the occluder using the ipsilateral hand to the covered eye (i.e., hold the occluder with the right hand if you need to cover the right eye, and vice versa).
3. Place the occluder in front of the eye, keeping the edge of the occluder in contact with the side of the nose.
4. Do not press the occluder against the eye: eyelid movements shall be possible and comfortable.
5. Look into 2WIN-S keeping the occluder in the correct position. Pay attention to fit 2WIN-S' aperture: ambient light must not enter the device during the exam.



CR Exam Results

In the CR Measurement Result window, three pairs of pupil images are displayed. The images represent from top to bottom (see point 7 of previous section):

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

 The covered eye is highlighted by a grey square.

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

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

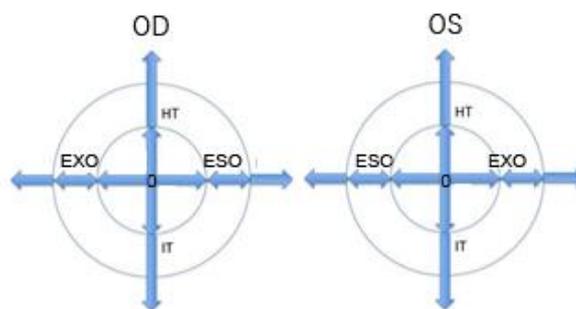
When a manifest asymmetry of the corneal reflexes is detected without cover test the output is: **ET** (esotropia) or **XT** (exotropia).

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

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

The angle of deviation is expressed in Prismatic Diopters.

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



 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.

 **The messages ET, XT, EP, XP, HT, IT, HP, and IP shall not be misunderstood as a diagnosis. The measurement shall in any case be used to refer the patient to an eye-care professional for further evaluation.**

The default output also shows a value for the *K* angle:

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

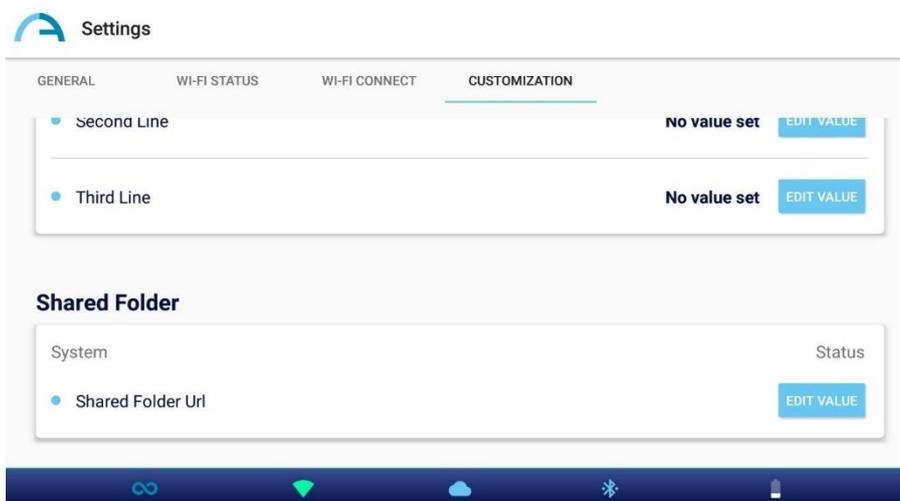
13.3 EMR connection set-up

The EMR connection feature allows to import patient data from an Electronic Medical Record (EMR) system to the KALEIDOS App and to automatically send the exam results from the KALEIDOS App back to the EMR system.

 The EMR connection feature is already active if you are using a 2WIN-S *Plus*. Otherwise, whether having only a 2WIN-S, to request the activation code to enable EMR connection, please contact your local distributor.

To setup the EMR connection follow these steps:

1. Verify that the tablet and the EMR system PC are connected to the same Wi-Fi network.
2. Create a folder on the EMR system PC and share it on the network. This folder will be the Shared Folder. If you create the Shared Folder as a subfolder, you must share the subfolder only.
3. Run the KALEIDOS App and tap on “**App & device setup**”, then select CUSTOMIZATION.



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



Pressing the VALIDATE button you can check if the inserted data are correct.

Pressing the SAVE button you will confirm the Shared Folder configuration.

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

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

1. Select a patient in your EMR system. The CSV input file is instantly created in the Shared Folder.
2. Start a new 2WIN-S (Refraction) measurement from the KALEIDOS App. The app imports the patient data from the CSV input file and displays it. After the import is completed, the app will delete the CSV input file from the Shared Folder.

 KALEIDOS App is checking the Shared Folder approximately every 2 sec. for a new input file.

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

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

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

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

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

14 Software update instructions

14.1 Manual update procedure

When a software update is released, to install it in the 2WIN-S, follow the instructions at adaptica.com > **Products > 2WIN-S > Technical Information > Downloads > Software Installation Instructions.**



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



When the software update procedure is performed, the 2WIN-S' battery must be fully charged.

14.2 Automatic update procedure



To exploit the automatic update, 2WIN-S must be connected to a Wi-Fi network with Internet connection.

An automatic software update procedure is available for 2WIN-S. When a new software version is released, and the 2WIN-S is connected to a Wi-Fi network with internet access, the update is notified on the screen of the 2WIN inside 2WIN-S.

At 2WIN-S' start-up, the system checks if a new update is available. If it is, the new software version and release date are reported on the 2WIN's screen, and the user can decide to download it or not.



The automatic update notification is visible only on the 2WIN screen.



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

Before starting the update, make sure that the MicroSD card is inserted, and that the battery is fully charged.



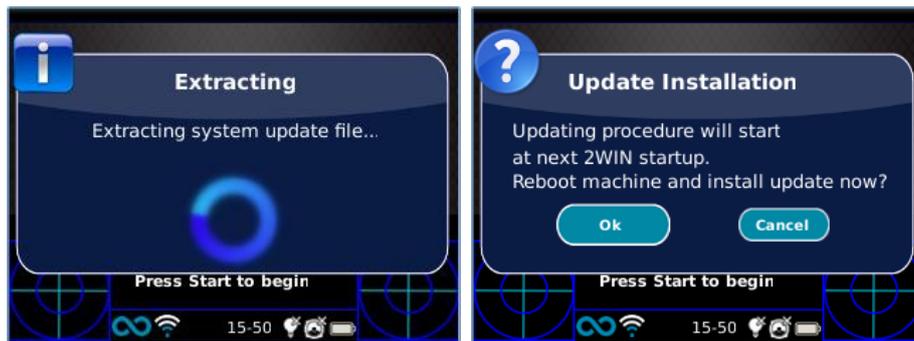
The software update's size is about 120MB; with a standard ADSL/VDSL/FIBER connection the download should take just a few seconds/minutes, depending on the connection's speed.



Do not remove the MicroSD card (or the power supply/battery) during this procedure.



After the download, 2WIN-S will extract the update inside the MicroSD card; this procedure takes less than a minute and the 2WIN will show you a waiting message until the extraction is complete.



After the extraction, 2WIN-S will prompt the request of immediate or delayed installation. If the OK button is pressed, 2WIN-S will restart and run the system update. Press the CANCEL button to delay it (the update will take place at the next 2WIN-S reboot).

15 Disinfection and cleaning

If necessary, it is possible to clean 2WIN-S with a lightly moist microfiber cloth.

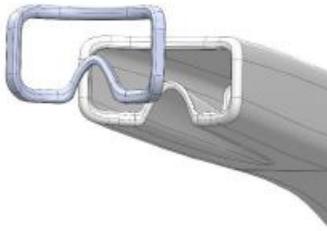
It is always necessary to disinfect the area where the face of the patient will touch the device before any change of patient.

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

The 2WIN-S is equipped with 3 disposable hygienic masks in *Plastazote*[®] to be positioned on the product as shown in the figure. To purchase additional hygienic masks, contact your distributor or write an email to contact@adaptica.com.



Reusable pads are to be avoided.



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

For further indication please check:

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

16 Maintenance instructions

16.1 Storage instructions

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

Temperature: -10 to 50 °C (14 to 122 °F); Humidity (max): 90% not condensing.

16.2 Instructions for the correct disposal of the device

The device is made of different materials, such as plastics, aluminum, electronic parts: in case of disposal, separate the materials and follow the laws and regulations effective in your own country.

16.3 Instructions for correct disposal of 2WIN-S packaging

2WIN-S' packaging is made of expanded polyethylene foam, present inside the device's suitcase and between the suitcase and the shipment box. Such foam is eco-friendly and 100% recyclable.

16.4 Separate collection for electrical and electronic equipment

The European Directive 2002/96/EC establishes the separate collection for Waste of Electrical and Electronic Equipment (WEEE). The users of Electric and Electronic Equipment (EEE) have not to dispose of WEEE as unsorted municipal waste, they have to collect such WEEE separately. The available return and collection system is defined by the local public administration, or in alternative an authorized company can recycle the WEEE. 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 are a few indications of specific dangers of some substances, which may leach in the environment and in the water system.

- Lead: in humans damages the nervous system, 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. Can cause allergic reactions, asthma and it's considered genotoxic (damages the DNA). Highly dangerous when incinerated.
- Brominated flame retardants: widely used to reduce flammability (e.g., cables, connectors, plastic cases).

17 Troubleshooting

#.	Symptom	Possible cause	Solution
1	The KALEIDOS App cannot be installed	An older version is already installed in the tablet	Uninstall the old version, and try again installing the new one
2	The KALEIDOS App cannot find the 2WIN-S	The battery is completely discharged	Charge the battery
3	The KALEIDOS App crashes when opened	The several application's permissions are not allowed	Allow the permissions
4	On the display, an error message appears	Electronic malfunctioning	Contact support@adaptica.com , mentioning the serial number and error message
5	On the display, an error message appears	Software malfunctioning	Contact support@adaptica.com , mentioning the serial number and error message
6	A warning - "Hint check Gaze" - appears on the display	The patient is not looking at the fixation target	If collaborative, ask them to look at the target If not collaborative, activate the central fixation target
7	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
8	A warning - "Possible strong Anisocoria" appears on the display	The two eyes have very different pupil diameters	It is suggested to measure eyes singularly in two different measurements.
9	The measurement never ended correctly or prematurely quit while the pupils are detected	There may be a hardware problem	Run the Self-Test diagnostic through the MENU and contact Support
10	The KALEIDOS App does not start	A screen-lock mechanism is not enabled on the tablet	Enable the screen-lock mechanism
11	The binocular measurement is impossible	Patient underwent eye-surgery or has IOL	It is suggested to measure the eye without issues singularly

18 Additional information

18.1 Technical specifications

Measuring range for spherical defect: $\pm 15 D$, step $0.25 D$ in range $\pm 7 D$, step $0.5 D$ outside

Measurement precision for spherical defect in the range $\pm 5 D$: $\pm 0.25 D$

Measurement precision for spherical defect in the range $-15 D$ to $-5 D$, $5 D$ to $15 D$: $\pm 0.5 D$

Measuring range for cylindrical defect: $\pm 5 D$, step $0.25 D$

Measurement precision for cylindrical defect: $\pm 0.25 D$

Measuring range for cylinder axis: 1 to 180 degrees, step 1 degree

Measurement precision for cylinder axis: ± 5 degrees

Measuring range for pupil diameter: 4 to 11 mm, step 0.1 mm

Measurement precision for pupil diameter: ± 0.2 mm

Measuring range for inter-pupillary distance: 30 to 120 mm, step 0.1 mm

Measurement precision for inter-pupillary distance: ± 1 mm

Gaze range: $\pm 20^\circ$; out of range: $\pm 10^\circ$; resolution: 0.1° ; precision: 0.2° (corneal radius of 7.75 mm)

18.2 Rechargeable batteries specifications

2WIN-S

Type of Cell: Lithium-ion Cylindrical

Cells: 4 x Panasonic NCR18650B

Rated capacity: 4 x 3400 mAh (13600 mAh)

Rated voltage: 4 x 3.7V (14.8V)

Not replaceable by user

Battery Pack Input specification: 18V 2.4A (use provided power adapter only)

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

2WIN

Type of Cell: Sealed Lithium-polymer Prismatic

Battery Pack Model: CS-SP112XL or PSP-110ML; replace No.: Sony PSP-S110

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 (model 1) or 600mA (model 2)

Quick charge current: 1800mA

Charger model 1: Lvsun CPSC110; Input: 90-250Vac, 50/60Hz, 100mA; Output: 4.2-8.4Vdc, 800mA

Charger model 2: C-HE18; Input: 5V, 750mA; Output: 4.2V, 650mA

18.3 Wi-Fi modules / Bluetooth adapters

Actual Model: eyeROBO WB440

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

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

Old Model: LM Technologies LM817

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

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

18.4 Other specifications

Working distance from patient's eyes: 1 m

Weight: 5.5 kg

Dimensions: 1300mm x 320mm x 215mm

18.5 Device warranty

The device has normally 18-month warranty, unless otherwise specified.

18.6 2WIN-S EMC tables

Guidance and manufacturer's declaration – electromagnetic emissions		
The 2WIN-S is intended for use in the electromagnetic environment specified below. The customer or the user of the 2WIN-S should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 2	The 2WIN-S must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF emissions CISPR 11	Class B	The 2WIN-S is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded: Warning: This equipment/system is intended for use by healthcare professionals only. This equipment/ system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the 2WIN-S Battery Charger or shielding the location.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Guidance and manufacturer's declaration – electromagnetic immunity				
The 2WIN-S is intended for use in the electromagnetic environment specified below. The customer or the user of the 2WIN-S should assure that it is used in such an environment.				
Immunity test	IEC test level	60601	Compliance	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air		Complies	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines		Complies	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth		Complies	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s		Complies	Mains power quality should be that of a typical commercial or hospital environment. If the user of the 2WIN-S Battery Charger requires continued operation during power mains interruptions, it is recommended that the 2WIN-S Battery Charger be powered from an uninterruptible power supply or a battery
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m		Not applicable	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.				

Information for assistance

For any service requirement, please contact first your distributor. Nevertheless, you can contact directly Adaptica at: 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 autonomously by service personnel.

Remote control

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



When the “Remote Control” is enabled and used, it’s not possible to access the MicroSD card of 2WIN-S; the device must be rebooted in order to do that.

Telemetry

The telemetry service is used by Adaptica to get information on the status of the 2WIN (refer to APPENDIX A).

Appendix A – Data management disclaimer

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

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

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

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

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

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

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

Place and Date _____

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

Appendix B – EMR input and output files specifications

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

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

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

Definitions

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

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

Use different Shared Folders for different 2WIN-S.

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

Input file specifications

- Patient information must be put in a CSV File, side by side in one single line and without a space after the separator.
- The sequence for patient information must be the following: last name, first name, date of birth (YYYY-MM-DD), patient ID, location, contact, autostart.
- Autostart field can be 0 or 1. If autostart=0, when the input file is created, KALEIDOS App opens patient data window. The user must press START to start the measurement. If autostart=1, when the input file is created, the measurement automatically starts, without pressing the START button.

Example:

Smith,John,2016-02-24,1234567890,Downtown Clinic,johnsmith@e-mail.com,0

is a valid input file.

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

Example:

Smith,John,2016-02-24,,,,0

is a valid input file.

Output file specifications

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

 For refraction, always positive cylinder notation is used.

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

- Date and time stamp, formatted as YYYY-MM-DDThh:mm:ss where T is a separator
- Same last name as provided in input file
- Same first name as provided in input file
- Same date of birth as provided in input file
- Same patient ID as provided in input file
- Same location as provided in input file
- Same contact as provided in input file
- Spherical measurement value of the right eye in diopters [dpt]
- Cylindrical measurement value of the right eye in diopters [dpt]
- Axis measurement value of the right eye in degrees [deg]
- Pupil diameter measurement value of the right eye in millimeters [mm]
- Spherical measurement value of the left eye in diopters [dpt]
- Cylindrical measurement value of the left eye in diopters [dpt]
- Axis measurement value of the left eye in degrees [deg]
- Pupil diameter measurement value of the left eye in millimeters [mm]
- Measurement value of gaze x value for right eye in degrees [deg]
- Measurement value of gaze y value for right eye in degrees [deg]
- Measurement value of gaze x value for left eye in degrees [deg]
- Measurement value of gaze y value for left eye in degrees [deg]
- Distance between left and right pupil in millimeters [mm]
- 2WIN exam number [int]
- 2WIN software version [string]
- Exam ending message in case of inconclusive result [string]
- Exam ending message code [int] (if 0 everything is ok).