Operator's Manual

VISIONFIT SC

Wearable Adaptive Refractor

VISIONFIT

Revision notes

Revision number	8_EN
Publication date	21/12/2021
Hardware version	From 1.0 and greater
Software configuration version	1.8.1

Summary

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	CE mark: this device complies the base requirements of the Medical Device directive 93/42/CEE
===	Direct current (DC)
	Read manual
	Applied part – type B
	Warning: necessary information for safety
	Important information

3. Glossary

Astigmatism	A condition in which the optical (or outer) surfaces of the eye are distorted so that light rays are not sharply focused on the retina for near or distant vision.
Auto Shutdown	A procedure whereby VisionFit SC stops working and switches off automatically.
Binocular vision	The use of both eyes simultaneously in such a manner that each retinal image contributes to the final perception of a single image.
Jackson Cross Cylinder JCC XCY	The combination of two cylinders whose powers are numerically equal and of opposite sign (+/-) and whose axis are perpendicular to one another. This is used to search/optimize astigmatism.
Diopter	The refractive power of a lens. It is used as a unit of measurement in refraction.
Esophoria	A tendency for the eyes to turn inward, when fusion is suspended.
Esotropia	Marked turning inward of an eye; crossed eyes.
Exophoria	A tendency for the eyes to turn outward, when fusion is suspended.
Exotropia	Divergent strabismus; abnormal turning outward of one or both eyes.
Focal point	The point to which rays are converged after passing through a lens.
Heterophoria	A tendency for deviation of the eyes, when fusion is suspended.
Heterotropia	A manifest deviation of the eyes resulting from the absence of binocular equilibrium.
Hypermetropia	Hyperopia.
Hyperopia	Farsightedness is a refractive error in which the image comes into focus beyond the retina in the relaxed eye. Accommodation may be used to overcome small amounts of hyperopia.
Monocular	Involving the use of a single eye.
Myopia	Near-sightedness is a refractive error in which the point of focus for light rays is in front of the retina, resulting in blurred distant vision.

Occlusion	Obscuring the vision of one eye to test the vision or force the use of the other eye.
Orthophoria	The parallelism of visual axes, the normal eye muscle balance.
Pantoscopic tilt	It refers to the frame alignment in the up and down position of the frame.
Refraction	When referred to the human eye, this term, or the term refractometry, are used to indicate the measurement of the refractive error that is the error in focusing light by the eye.
Refractive Error	Equivalent to ametropia, it is usually made up of a spherical error and a cylindrical error. Types of ametropia include myopia, hyperopia, and astigmatism.
Spherical error	Occurs when the optical power of the eye is either too large or too small to focus light on the retina.
Strabismus	Failure of the two eyes to direct their gaze at the same object because of inappropriate neuromuscular control or because of fibrosis or paralysis of one or more extraocular muscles, as in crossed eyes or wall-eyes.

4. Intended use of the device

The VisionFit SC is an innovative electronic solid-state drive system of adaptive lenses that is mobile and wearable. It is a human eye refractive corrector used to perform subjective tests in order to prescribe glasses, using two main modules.

The first module is able to correct **myopia** or **hyperopia** by adjusting the defocus optical power of a focusable lens in the range of +20, -20 D manually or electrically.

A second module is able to perform a variable **astigmatism** correction of the human eye in the range of +10 and -10 D.

In order to evaluate phorias, prism data can be obtained through the use of free prisms lenses (used in every trial lens set).

The medical device can be used in place of the standard medical phoropter in a user-friendly procedure, with at least equivalent, or even better, usability.

5. Indications for Use

VisionFit SC is designed for:

- Subjective measurement of the refractive error of the eye.
- Identification of corrective data for refraction anomalies and binocular functions as the basis for manufacturing glasses and contact lenses.
- Use in refraction rooms in clinics, physicians', optometrists' or opticians' practices.
- Operation by physicians, optometrists, opticians or properly trained clinical personnel.
- Installation under medical equipment conditions.

6. Classification and Applied Standards

Classification according MDD 93/42/EEC, Annex IX

Class I

Class and type of applied parts according to EN 60601-1

Class I, Type B

IP classification

IP X0

Electromagnetic compatibility

This device has been classified as class B according to EN 60601-1-2.

Applied standards

- EN 14971 Medical devices - Application of risk management to medical devices
- EN 60601-1 Medical electrical equipment
  Part 1: General requirements for safety
- EN 60601-1-2 Medical electrical equipment
  Part 1-2: General requirements for safety - Collateral standard: Electromagnetic compatibility - Requirements and tests;
  Part 1-6: General requirements for safety - Collateral standard: Usability
- EN 13485 Medical devices - Quality management systems - Requirements for regulatory purposes
- ISO 15223: 2012 Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied
- UNI EN ISO 12867 - 2010: Trial frames limited to §4.2.10, 4.3, 5, 6
- UNI EN ISO 9801 - 2010: Trial case lenses limited to §4.2, 4.4.1, 5.2, 5.3.
- UNI EN ISO 12867 - 2010: Trial frames limited to §4.2.3, 4.2.6, 4.2.8, 4.2.9 (limited to IP distance and minimal lens rotation), 5.
- UNI EN ISO 10341 2013: Refractor heads limited to §4.2, 4.3, 4.4a, 4.4b, 4.4d, 4.4g.

7. Description of the device

VisionFit SC is made of a **wearable trial frame** including two stacks of tunable lenses. Each stack is made of 3 elements:

- o Adaptive Spherical Lens
- o Adaptive Cylindrical Lens
- o Additional Lens Support

The adaptive lenses of the stack are electronically tuned by a tablet without any other operator action. VisionFit SC is powered by a battery pack and it communicates by means of an LE Bluetooth connection.

VisionFit SC can be paired with AQUID CHART optotypes in order to have a complete tablet-controlled system for subjective refraction. For futher information about AQUID CHART please refer to paragraph 12.6 of this manual and to AQUID CHART User Manual.

The goggles

VisionFit SC goggles are a system of tunable lenses that provides the correction requested by the eye care professional. The spherical and cylindrical optics are changed remotely without any direct interaction of the operator with the goggles.

The optics system is designed with one free slot, for each eye, intended to insert any auxiliary lens/filter.

Measurement by means of this device takes place as follows:

- The patient wears the VisionFit SC lens frame like a regular trial frame and looks through it at an eye chart – or any other near or far target.
- The patient can be sitting, standing or in any other desired position and/or environment.
- The eye chart and/or target can be placed at different distances, depending on the type of exam.
- The operator adjusts the device in order to change the position and configuration of the optics, asking the patient for subjective feedback.
- The operator selects the output values for both glasses and contact lens prescriptions.
- VisionFit SC provides versatile prescription printing options.

Adjustable parts include:

- bridge height adjustment
- pantoscopic tilt

- vertex distance. VD is the distance between the back surface of a corrective lens and the front of the cornea)
- pupil distance adjustment (PD) – these knobs on each side of the trial frame move the trial frame apertures closer or further away from each other. They should be adjusted to a patient's PD so that their eyes are in the center of the trial frame apertures

i **ADD-ONs**: Any standard lens (such as red or green filters, polarizing filters and Maddox rod) can be manually added to the VisionFit SC's dedicated track during the examination.
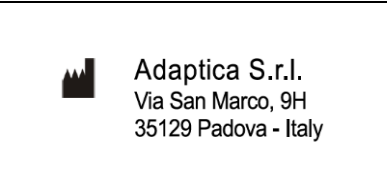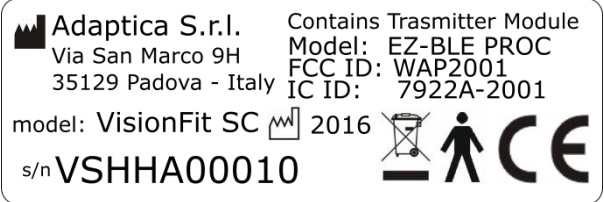
i **STORAGE**: it is possible to store patient data in the internal memory of the tablet. The data can also be copied or moved into a micro SD external storage.

i **WIRELESS**: it is possible to connect the tablet to a WI-FI network in order to share its data with other devices.

Bridge height adjustment

Vertex distance adjustment

Pantoscopic tilt

Pupil distance adjustment
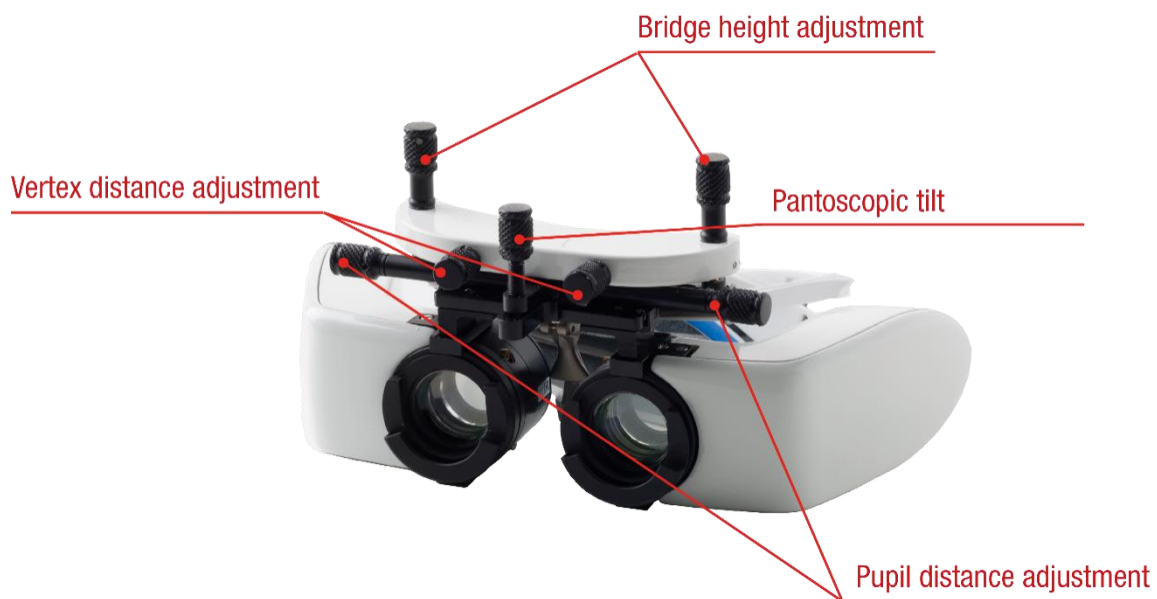
8. Labels

Label	Detail	Explanation
Adaptica S.r.l. Via San Marco 9H 35129 Padova - Italy model: VisionFit SC 2016 s/n VSCHA00010	Adaptica S.r.l. Via San Marco, 9H 35129 Padova - Italy	Manufacturer identification Data: name and address
	model: VisionFit SC	Model name
	s/n VSHHA00010	Serial number, including manufacturing date: VFIT = model code X= year (G=2015 H=2016 I=2017) A = lot 00001 = unique serial number
	CE	CE mark
	(WEEE symbol)	Electrical / electronic device subject to the WEEE Directive on waste disposal
	(person symbol)	Applied part – type B
Adaptica S.r.l. Via San Marco 9H 35129 Padova - Italy Contains Trasmitter Module Model: EZ-BLE PROC FCC ID: WAP2001 IC ID: 7922A-2001 model: VisionFit SC 2016 s/n VSHHA00010	Model FCC ID IC ID	Identifies the WiFi transmitter module
Adaptica S.r.l. Via San Marco 9H 35129 Padova - Italy 2016 INPUT: 24V 2.5A OUTPUT: 14.4V 1.5A model: VisionFit SC s/n VSBHA00010	INPUT: 24V 2.5A	Input Voltage
	OUTPUT: 14.4V 1.5A	Output Voltage
	(connector polarity symbol)	Connector Polarity

9. Precautions

Electromagnetic compatibility

This device has been tested and found to comply with 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 on and off, 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
• if the device is charging, connect the system to an outlet on a different circuit from that to which the other devices are connected
• consult the manufacturer or field service technician for help

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

⚠️ The device must NOT be used in oxygen-rich environments or in the presence of flammable materials.

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

Precautions and general warnings

⚠️ CAUTION – United States Federal law restricts this device to sale by or on the order of a physician.

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

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

⚠ A prescription based on the subjective results obtained by means of the VisionFit SC device shall not be used for a laser intervention prescription: a double check with fixed trial lenses plus an objective type of test are required.

Device-specific training is required for any operator to be able to use the system.
For the correct use of the device, it is mandatory to carefully read the instructions in operative information.

⚠ Do not open the device: this could lead to electric shocks or damage to the system.

No modification of this equipment is allowed.
Do not use the instrument if the cover or other parts of the device have been removed.
Only technicians authorized by the manufacturer may service the device. The manufacturer cannot be held responsible for system safety, should the device be opened, repairs carried out, third parties' software been installed, or parts been replaced by unauthorized persons.
Patient's data is stored on the device's SD memory card. This data can contain personal information such as name/surname/age. Information management is the

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

⚠ Do not replace the original power supply with another one.

⚠ Do not turn on the device during a flight.

Unit damage and accidental oil leakage from the lens group

First aid is indispensable for the treatment of symptoms:

- Inhalation

In the case of exposure to high concentrations of vapors and mists, distance the person from the contaminated air and carry them to a well-ventilated place. If necessary, seek immediate medical care. If you suspect aspiration has occurred, take the person to the hospital.

- Contact with skin

In the case of skin or mucosal contact, wash the exposed skin immediately with large amounts of soap and water. If skin irritation continues seek medical attention.

- Contact with eyes

If accidental eye exposure occurs, flush the eyes immediately with clean water, holding the eyelids open to ensure complete contact with water and seek medical attention.

- Ingestion

Do not induce vomiting to avoid the risk of aspiration. Seek medical attention.

10. Operative information

Unpacking

The box contains (default configuration):

- The electronic version of the operating manual
- Additional lenses (two white negative lenses and two blue positive lenses)
- Occluder
- Wearable Goggles
- Power supply (Meanwell GSM60A24-P1J)
- Case
- Headband
- The battery packs
- Spare cushioning for the helmet - goggles

Before use

Before measuring a new patient, always clean the patient's contact area with the VisionFit SC using alcohol.

11. Using VisionFit SC for the first time

Coupling the optical system to wearable support

The adaptive lens system (goggles) has a female dovetail joint (see figure) in which the two system options can be hooked by following these instructions:
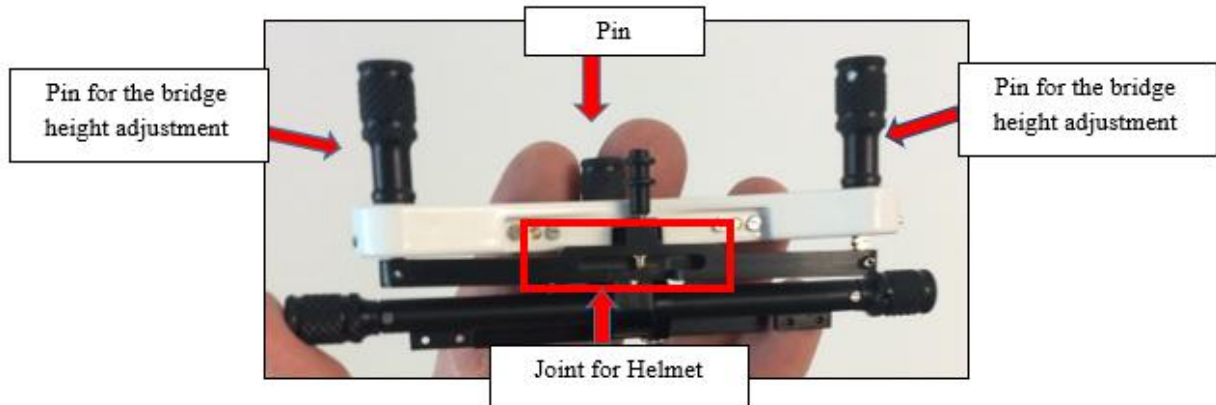
• use the knob of the pin to unscrew it completely (see figures), making sure the tip of the pin disappears from the housing dovetail;
• to facilitate the grab of the pin, it is suggested to screw totally the Pins for the bridge height adjustment;
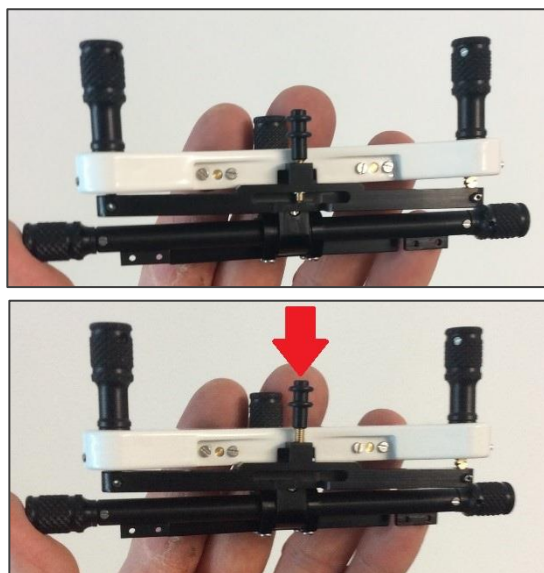
• insert the hook of the media into the female dovetail joint, by motion scrolling. With the helmet, make sure that the mobile part of the attachment is folded down (see figure);

• After inserting the male dovetail joint, screw the knob of the pin until the two sides are completely engaged.

• Before inserting the battery, charge it totally.

• To plug the battery pack you just need to match it with the corresponding track (keeping the battery connector oriented upwards), insert the slot and move it through the track.

• Then press the rear button and keep on moving the battery pack until the end of the stroke.
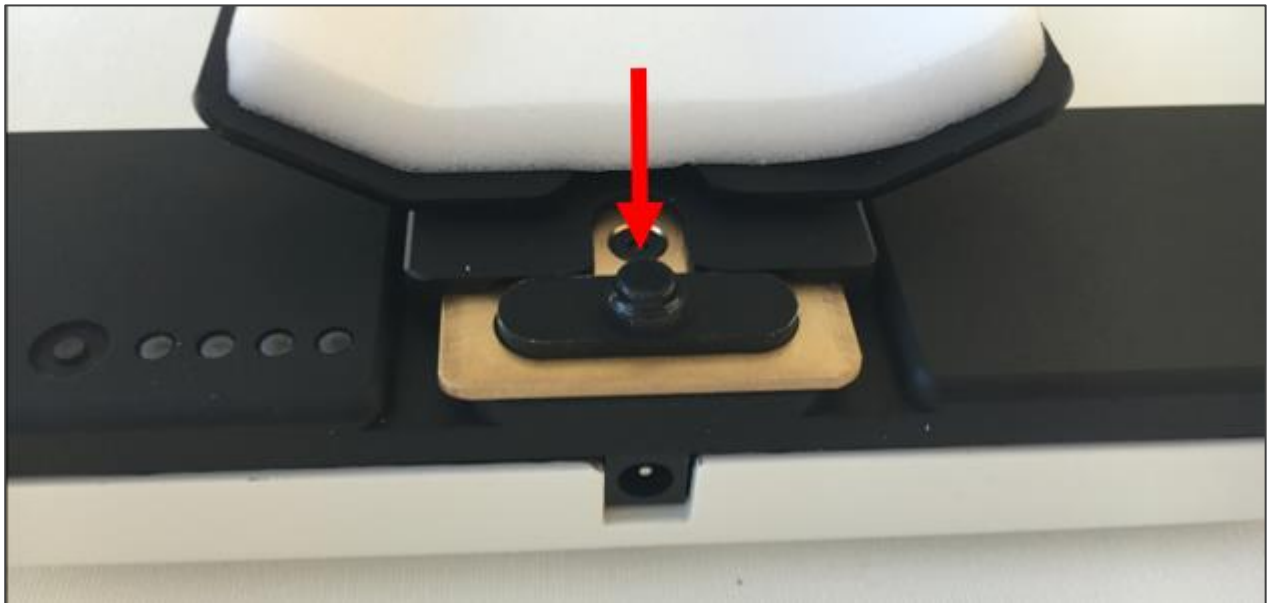
•Suggested cables position:
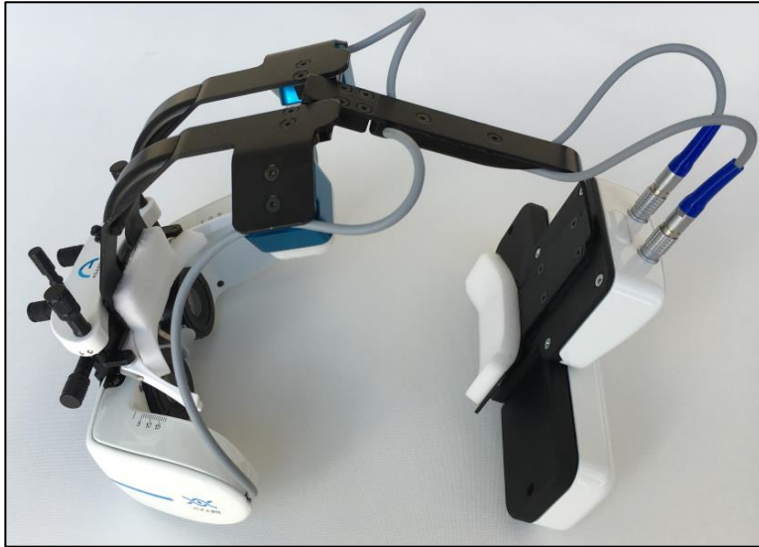
Corneal Vertex Distance

VD, vertex distance, or the distance from the cornea to the spectacle trial lens, can be estimated by a graduated ruler positioned laterally on the device.

Pupillary Distance

The pupillary distance (PD) can be set thanks to a graduated ruler positioned frontally on the device.

12. Starting to work

12.1. Important tablet recommendation

IMPORTANT

This application works perfectly on this recommended tablet model:

Samsung Galaxy Tab A SM-T580

Huawei MediaPad T5

You can use any other tablet as long as it has these basic features:

1. Android 8.0, 8.1, or 9
2. Screen Size: 10 inches or more
3. Bluetooth: 4.0 Low Energy or newer
4. Processor: ARMv7

In case that it is used a different tablet, Adaptica cannot assure a proper functioning

of the system.

12.2. VisionFit SC Application installation procedure

1. Please connect the tablet to a Wi-Fi network and make sure the internet connection is working properly.

2. Click on "Apps" icon then click on "Settings" menu of your tablet.
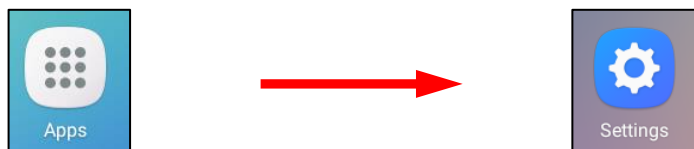
3. Scroll down to the "Lock screen and security" panel, enable the "Unknown sources" and then click "OK" to accept. This feature will allow you to download VisionFit SC application.
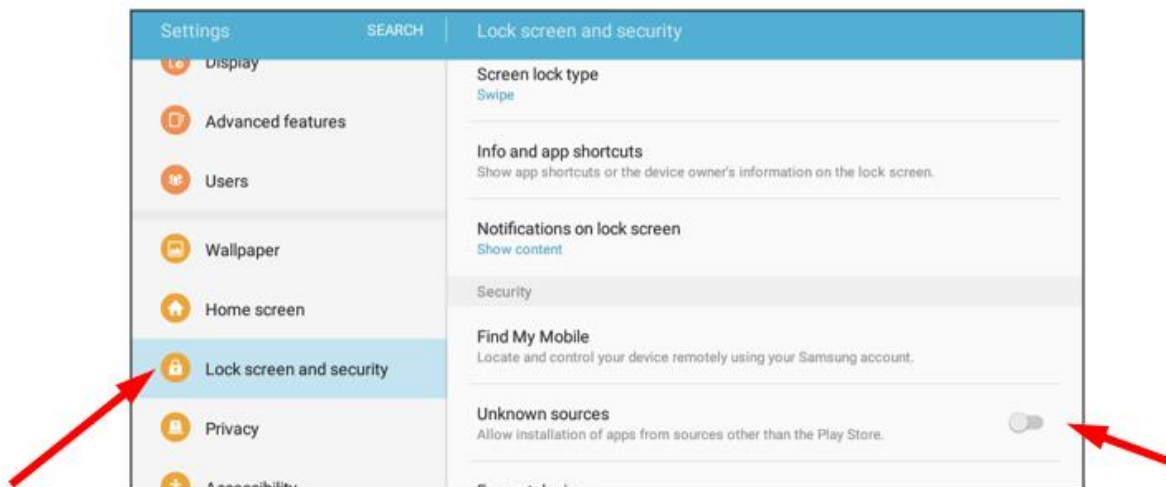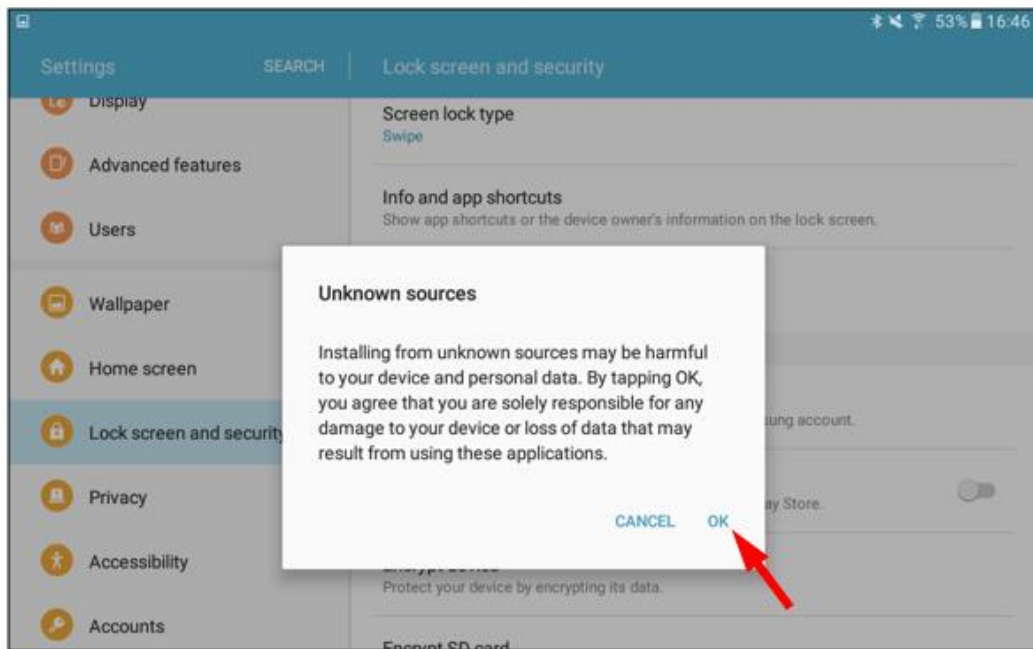
4. Exit from the "Settings" menu and open your internet browser
5. Then go to this link:

https://www.adaptica.com/WP/wp-content/uploads/2019/11/APK_SC_RELOAD_V1_8_Official.apk

6. The download should start automatically (see the download icon on the upper left part of the screen for completion)

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7. When the download is completed, exit from the browser, slide down the "Notification settings" and click on the downloaded file:
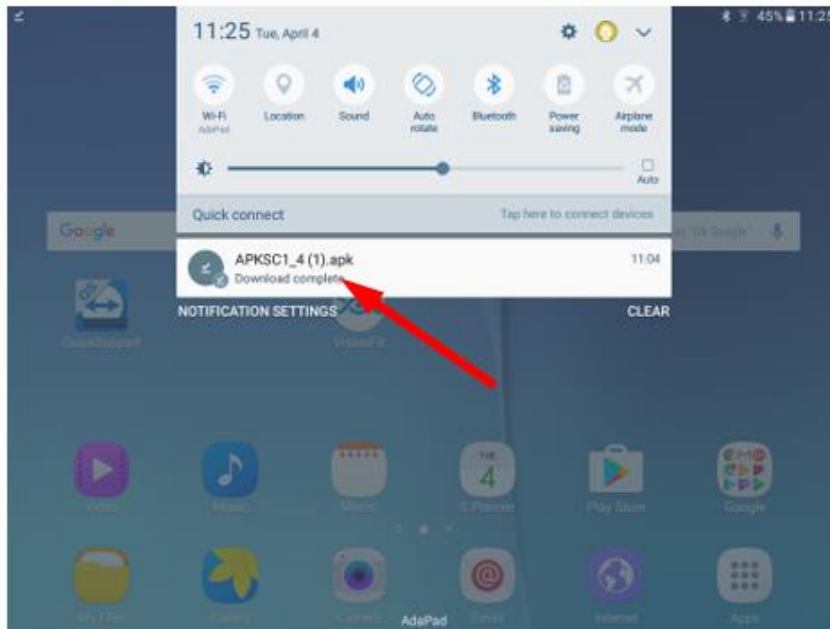
8. Leave default settings as they are and click on "INSTALL" to start the installation of the VisionFit SC application.
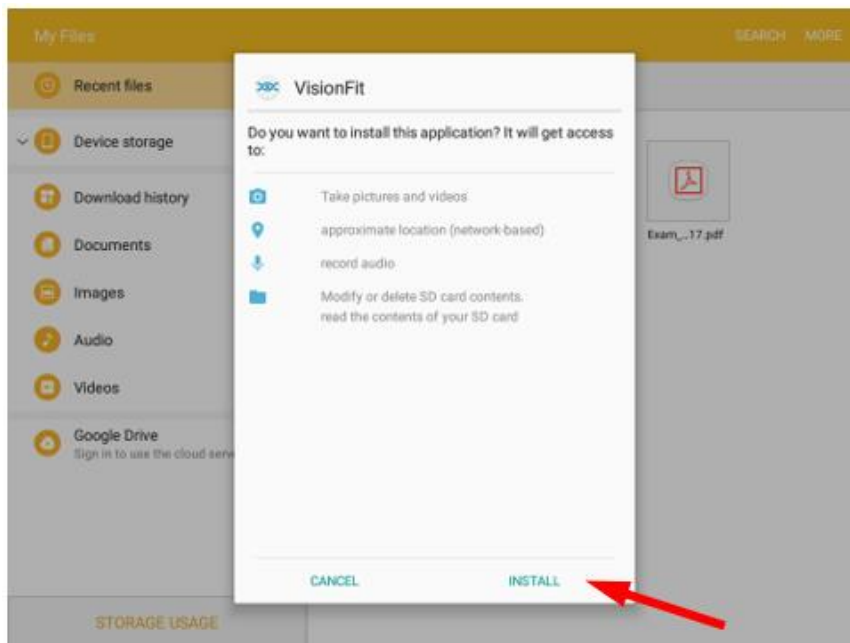
9. Wait for the "App installed" message and click on "OPEN" as in the figure below.
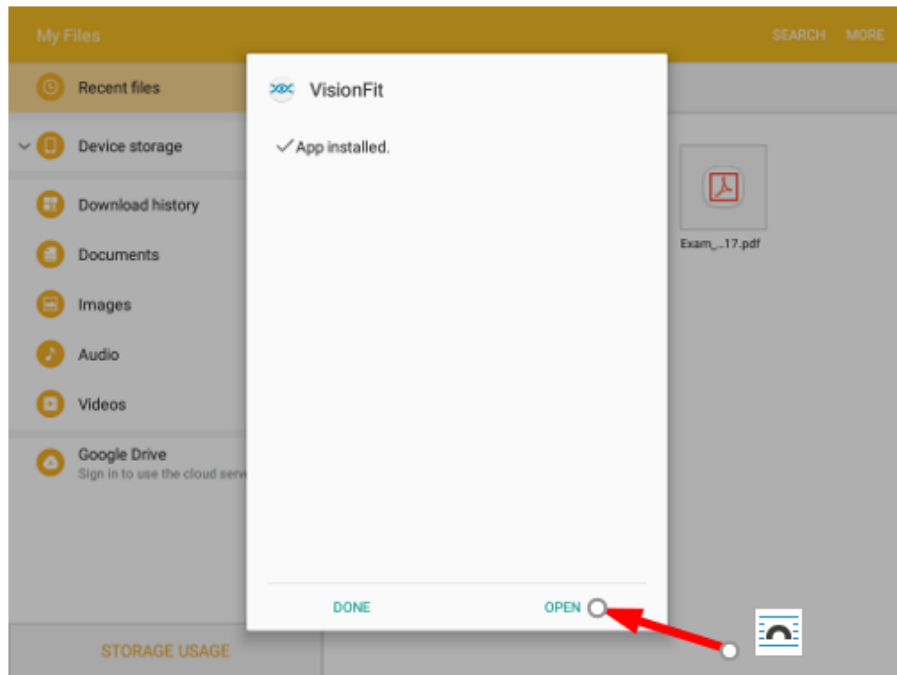
Starting from the software version 1.4, any available new software update may be automatically detected by your VisionFit SC application (you must be connected to the Internet).

Also, starting from the software version 1.4, any time that a new software update will be released by Adaptica, you will find an icon in your app, that will notify you of this.

By tapping that icon, you will easily start the update process as above.

During this procedure, make sure that both the tablet and the VisionFit SC are connected to the main power and that the tablet is connected to the Internet.

10. To launch the application, you just need to go to the Application Menu, click on the VisionFit icon and wait for the loading, then click "OK".

11. In case that for the connected goggles there is a new firmware upgrade available, the following window for a firmware mismatch message will appear. Accept the update by clicking OK.
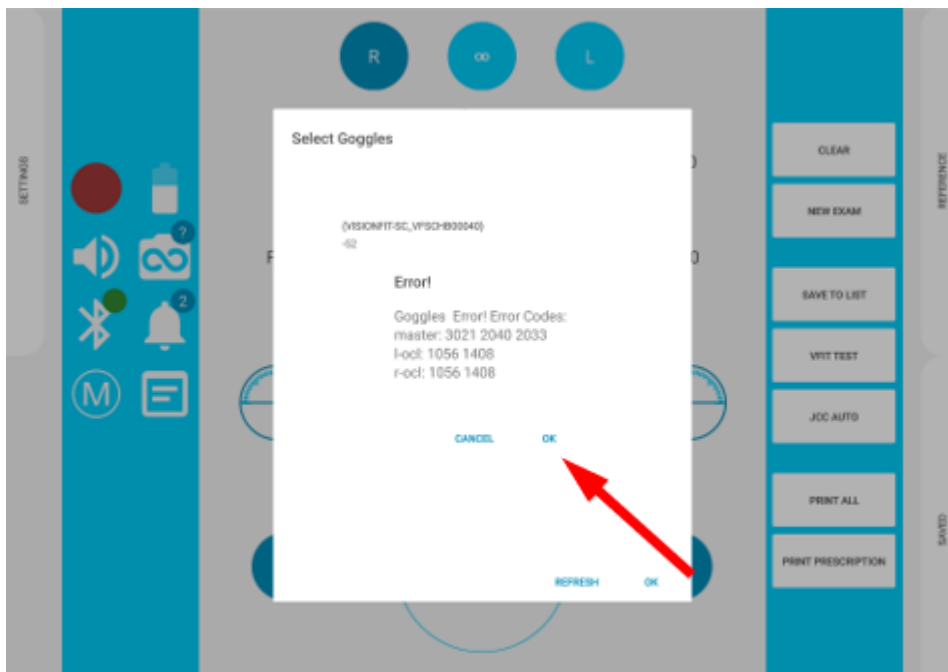
12. The "Update Manager" window will appear. Click on "INSTALL" to upgrade the VisionFit SC firmware.
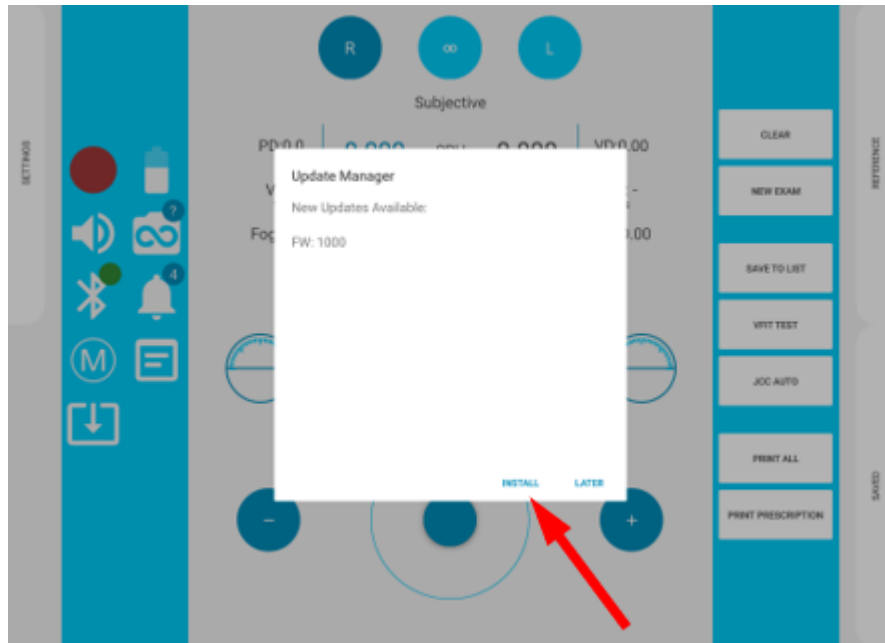
![info icon] WARNING: Do not change the application, wait for the procedure to be completed

13. The system will then reboot, the first led on the main unit will turn to orange, indicating that the firmware upgrade is in progress. It will turn back to green once the update is completed.

12.3. Main Graphical User Interface (Tablet Application)

VisionFit APP allows to control VisionFit SC and Aquid Charts in order to perform subjective sight examination. The following image shows VisionFit APP's user interface:

ADAPTICA

Right Eye Indicator
Both Eye Indicator
Left Eye Indicator

Settings
Sliding Panel

References
Sliding Panel

SETTINGS
REFERENCE

Sphere Values
Pupil Distance

Subjective

Cylinder Values

PD:0.0

0.000   SPH   0.000

VD:0.00

VA: -
Dec

0.00   CYL   0.00

VA: -
Dec

Visual Acuity

Fog:0.00

0   AXIS   0

Fog:0.00

Fogging

Axis values

0.000   ADD   0.000

Addition values

STEP:0.125

Status Icons

CLEAR

NEW EXAM

SAVE TO LIST

VFIT TEST

JCC AUTO

PRINT ALL

PRINT PRESCRIPTION

SAVE
Sliding Panel

SAVED

Axis Display and
Cross Cylinder
Function

KNOB

Aquid Chart
Sliding Panel

AOC Chart

–

Knob BUTTON

+

Decrease Value

Increase Value

Action Buttons

Adjust Value

VISIONFIT

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Legend of the User Interface

Status Icons

⬤ = Adaptive lenses status flag

🔋 = Battery Status

🔊 = Sound

♾️ = 2WIN Connection

✳️ = Bluetooth Goggles Connection

🔔 = Notification Center

Ⓜ = Memory

⬭ =Lens Mode

⤓ =Update available

Actions Buttons

CLEAR = clear the displayed values

NEW EXAM = clear all the temporarily saved values and start a new exam

SAVE TO LIST = save the current measure in one position of the VisionFit SC memory

VFIT TEST = Activate the VisionFit TEST program (see next paragraphs)

JCC AUTO = Activate the Jackson Cross Cylinder Procedure

PRINT ALL = Save in the memory all the subjective and reference values in a PDF format in the VisionFit Memory

PRINT PRESCRIPTION = Save in the memory of the VisionFit SC in a PDF format the final prescription of the patient.

12.4. VisionFit SC Application data management disclaimer

The VisionFit APP may ask the operator to read the application data management disclaimer. At the end of the document the VisionFit APP will ask to tag or not the acceptance of the document and, in case of acceptance, it will enable the use of the system/application.

12.5. VisionFit SC Application First Configuration

- To launch the application, you need to go to the Application Menu, press the VisionFit SC and wait for the loading to complete, then click "Ok"

- Turn the VisionFit SC on by clicking on the button on the side of the main unit above of the battery pack.

- After pressing on the button, the first led from the top will flash orange and then turn to green: it means the electronic system is powered on.
- At the same time the middle led will start flashing in orange until the tablet isn't correctly connected to the VisionFit SC and it will then turn to green.

- Turn on the Bluetooth of your Tablet and then go to the main screen of the VisionFit SC application. Press the Bluetooth icon (a window will appear on the screen) choose "VISIONFIT-SC_VFSCHA#####".
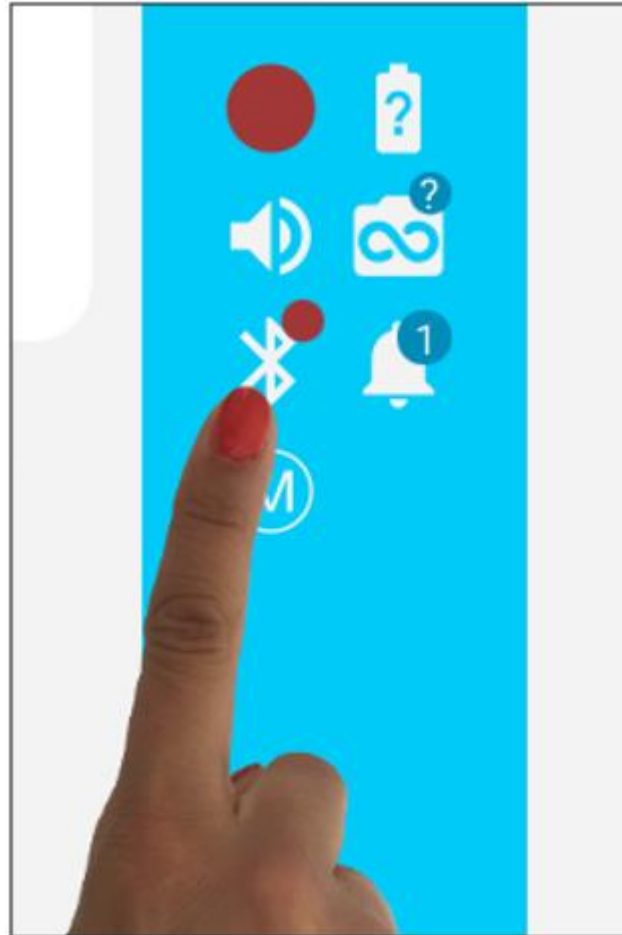
- After connecting the VisionFit SC to the Tablet, the second led should turn to green and then your System is ready to use.
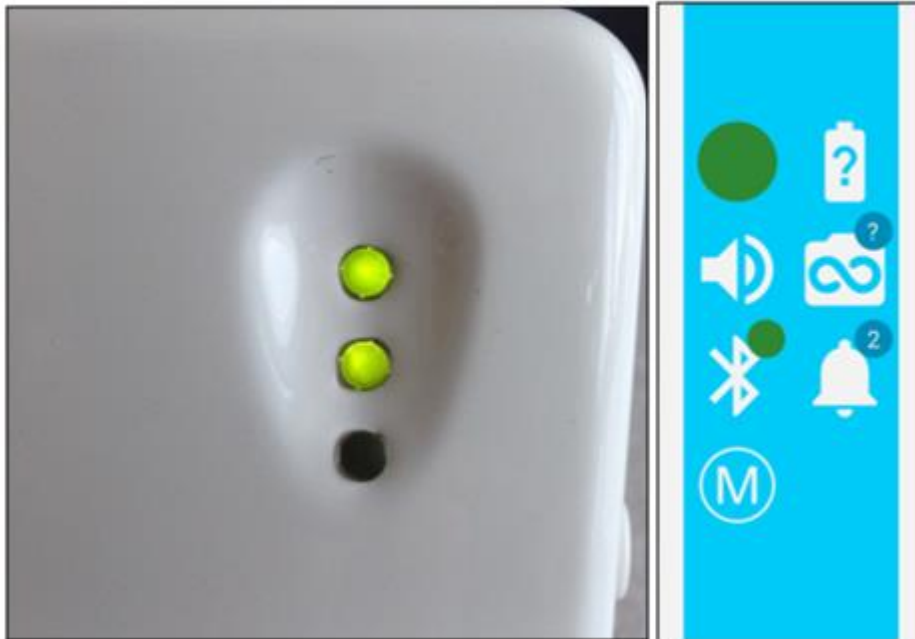
- If, during an examination, the Connection icon turns to red, the Bluetooth icon starts circling and the second led on the VisionFit SC is flashing orange, it possible could be because the VisionFit SC has lost connection with the tablet.
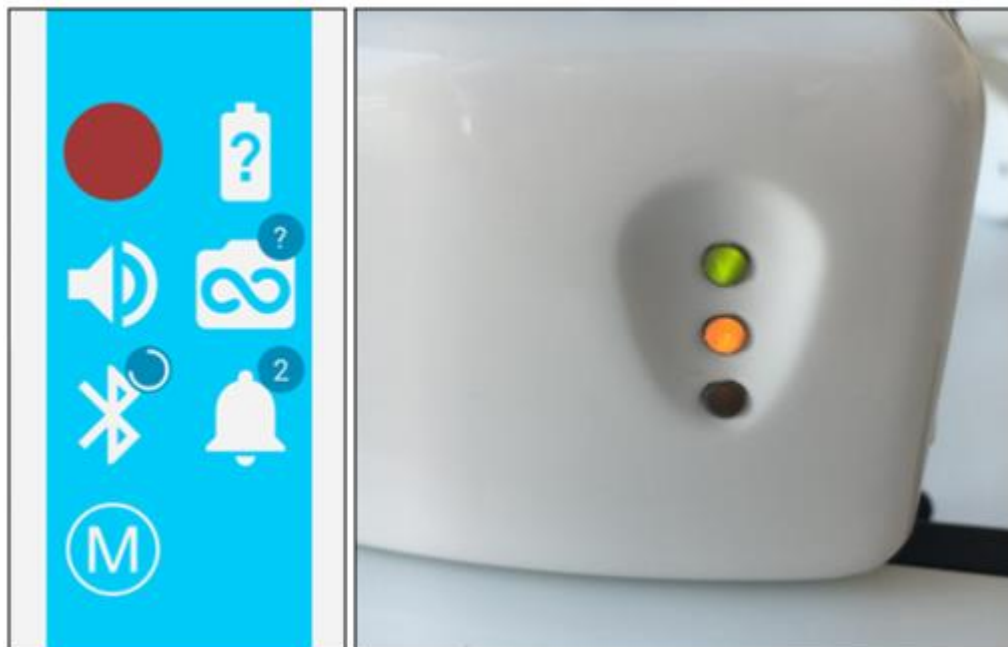
- The tablet and the VisionFit SC will try to connect automatically and a message will appear on the tablet's display showing that the instruments are trying to reconnect.

- When the connection is restored, the Connection icon, the Bluetooth icon and the second led will turn to green again. The tablet will advise you that it is connected with the VisionFit SC and you can resume your work.

NOTE: when the tablet and the VisionFit SC are not connected, if you change the values on the tablet, they will not change on the VisionFit SC. When the instruments will reconnect, you just need to wait few seconds and the values will get back to the real settings.

- To turn off the VisionFit SC you just to keep the button pressed till the first led starts flashing orange, release the button and the VisionFit SC will turn off.

12.6. AQUID CHART First Configuration

VisionFit SC can be paired to Aquid Chart 24" or to Aquid Chart Mobile. Aquid Charts can be remotely controlled using VisionFit APP "AOC Chart" menu.

The pairing istructions are the same for Aquid Chart 24" and Aquid Chart Mobile.

Pairing procedure:

- Run VisionFit APP and tap "Allow" on the popup message asking to make the tablet visible to Bluetooth devices for 300 seconds.
- Enter Aquid Chart setup window, select the 2nd icon and press OK button on the IR remote control.
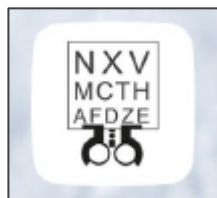
- Press the right arrow button until the option PHOROPTER PAIRING (6/6) is displayed.
- Press START button on the IR remote control to start the pairing with VisionFit SC.
- When the pairing is done Aquid Chart status icon becomes green on VisionFit APP:

- Control Aquid Chart using the buttons in "AOC Chart" sliding panel of VisionFit APP:
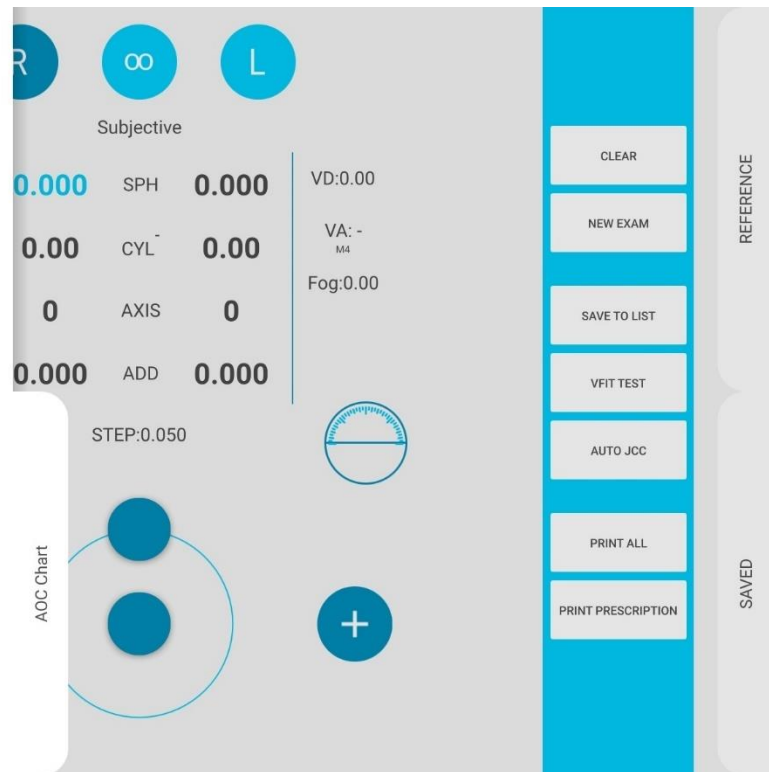
NOTE: Please refer to AQUID CHART User Manual for any information regarding Aquid Chart 24" and Aquid Chart Mobile.

13. How to upgrade the VisionFit APP

Once installed in the tablet, the VisionFit APP will automatically check the presence of a new version of the APP itself. In order to check if a new version of the APP is present and to upgrade the APP, we recommend to connect time to time the VisionFit tablet to a WiFi connected to the Internet and start the VisionFit APP. Doing so, the VisionFit APP will automatically contact Adaptica's server and understand if a new version is present and ready to be installed in the Tablet.

14. The meaning of the LEDs

The first LED:

- Green: means that the electronic system is powered on.
- Flashing Orange: means that the VisionFit SC is turning off or during firmware update.

The second LED:

- Green: means that the VisionFit SC is correctly connected to the Tablet
- Flashing Orange: means that the VisionFit SC is trying to connect to the Tablet

The third LED:

- Red: means that there is an error in the electronic system or the goggles are not correctly connected.

15.   Measurement

Following the specific operator's procedure, the system VisionFit SC allows to perform a subjective test, controlling electronically VisionFit SC tunable trail lenses.

An example of a standard operating sequence:
- Measure the patient's objective refraction (performed with 2WIN or Autorefractometer)
- In case a 2WIN has been used transfer the data automatically to the VisionFit SC by pressing the DOWN button of the 2WIN Joystick (or manually enter setup data). To do so 2WIN and VisionFit SC must be connected (paired), follow the instructions in this manual or the same instructions in the 2WIN manual.
- Measure the uncorrected visual acuity
- Measure the corrected visual acuity
- Measure with the cross cylinder by the JCC procedure that is embedded in the VisionFit SC
- Perform the subjective refinement sequence for each eye:

Measure the cylinder axis

Measure the cylinder power

Refine the spherical power with the red-green test

Refine the spherical power at the best to achieve the BCVA (Best Corrected Visual Acuity)

- Perform the binocular balance test
- Perform the stereo test
- Check the corrected visual acuity
- Measure the addition powers
- Check the near visual acuity

15.1.   Eye selection

Press the **Right** icon to select the right eye, press **Left** icon to select the left eye or the icon between the **Left and Right icon** to select both eyes.

| Right | Binocular icon | Left |
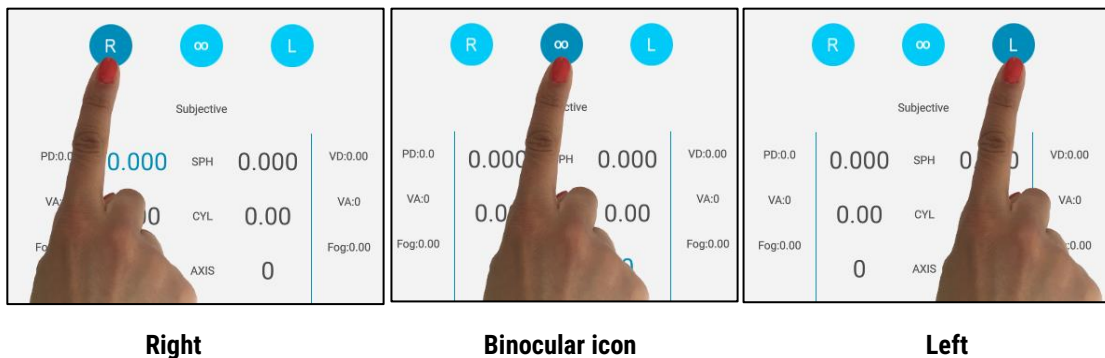
NOTE: If L or R is pressed, VisionFit SC does not occlude physically the other eye. Use the provided trial lens occluder if a physical occlusion is needed or use Fogging instead.

15.2.   The knob and the knob button

Turning the external knob changes the numerical values and the selection of fields as follows (DEFAULT configuration):

VISION**FIT**
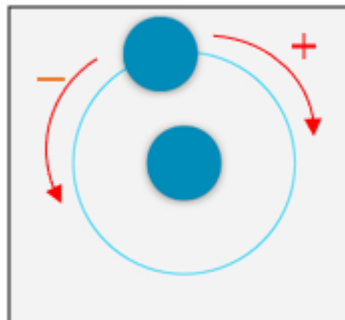
- **Clockwise rotation**: positive changes to value
- **Counterclockwise rotation**: negative changes to value

Pressing the knob button in the center:
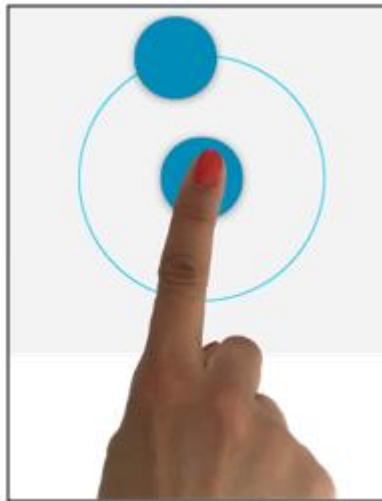
Moves on to the next step/field (e.g. from Sphere to Cylinder, from Cylinder to Axis).

Tapping rapidly twice the knob button you will enter into "sliding mode". You will be able to change the values by sliding your finger towards the right or the left as shown in the following figure. Sliding mode can be either full screen or not, according to the menu setting.
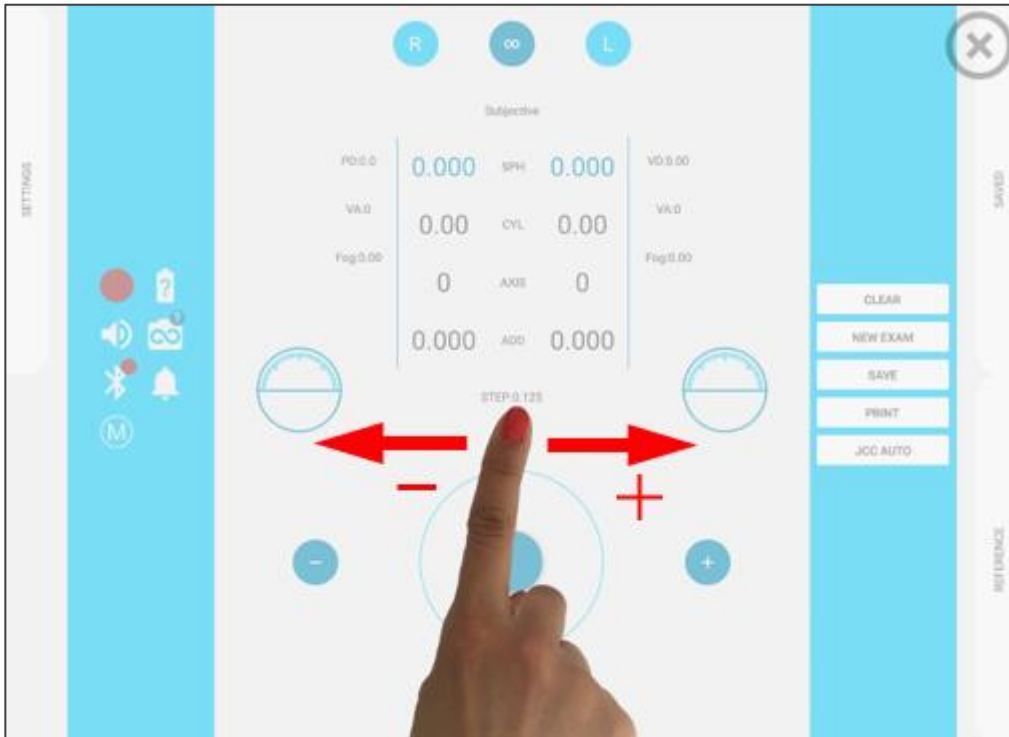
If you set "Global Refraction Control" option in Settings sliding panel to "Normal" a swipe window appears:

- To switch between steps, you just need to swiftly slide your finger upwards or downwards.
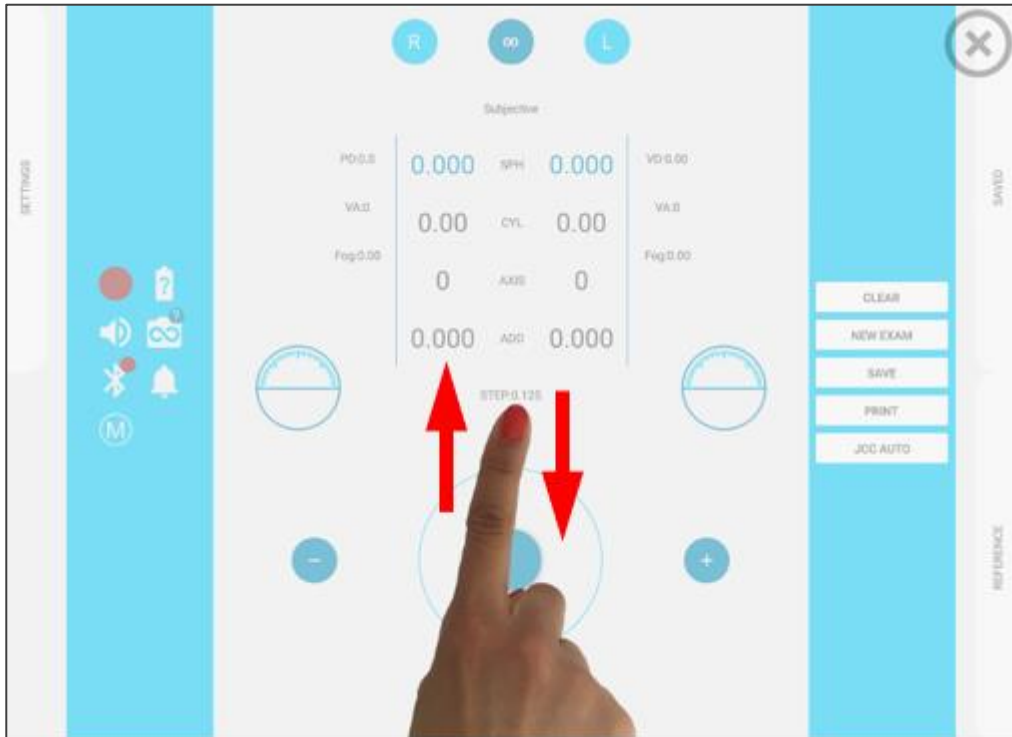
15.3. Selection of values for Sphere, Cylinder, and Axis.

For each eye, you can select the angle and the power of the lens there are a few ways to this:

Rotate the knob.

Tap on the "−" icon button on the left of the central knob button or on the "+" icon button on the right, to decrease and increase the selected values respectively.

Double tap on the center of the knob button. This will activate the "sliding mode" function on your screen so that only by sliding your finger from left to the right or from right to the left, you can increase or decrease the values (diopters or degrees) respectively.

The size of the sensitive pad can vary, it can be configured to be only a rectangle in the bottom center of the display or full screen, by selecting "normal" or "full screen" in Global Refraction Control setting, in the left sliding "settings" panel.

By double tapping each value for Sphere, Cylinder, and Axis you can enter in the "Trial lenses box" mode.

Here you can select a boxed value associated with the power of the lens. Reds are negative, while blacks are positive values (see the next picture).
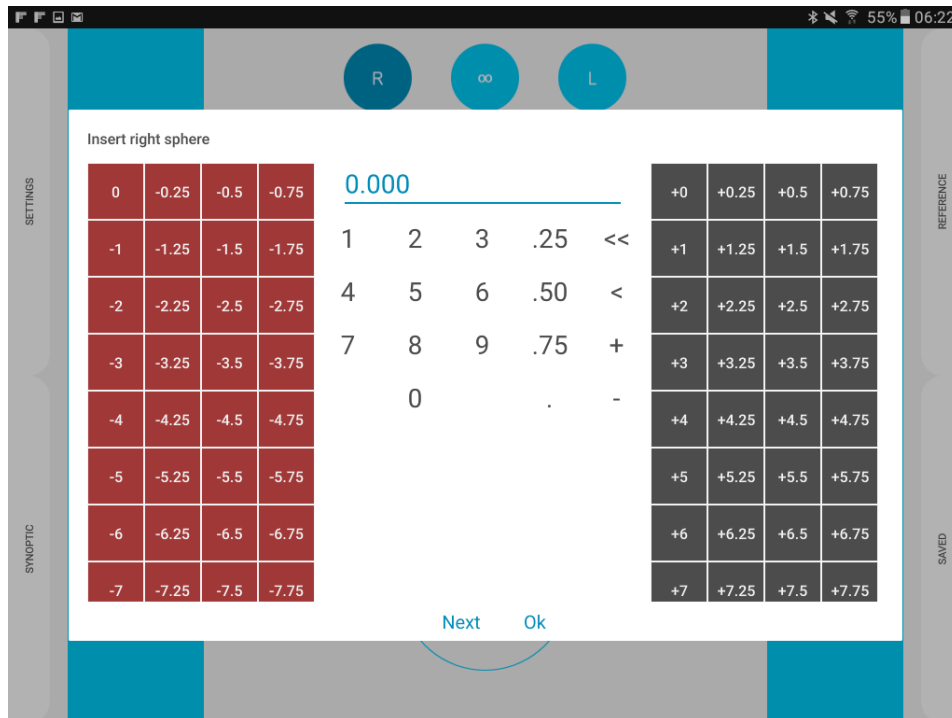
Alternatively, you can enter directly the values through the numeric touchpad in the middle of the screen.

If you prefer on the right-hand side, you can choose to add 0.25/0.50/0.75 diopters to the selected values.

For the axis, you will have also the possibility to directly change the angle by tapping and rotating on a graduated circle on the right-hand side or entering directly the values from the numeric touchpad.

If you prefer on the right-hand side, you can choose to add 45/90/135 degrees to the selected values (see next figure).
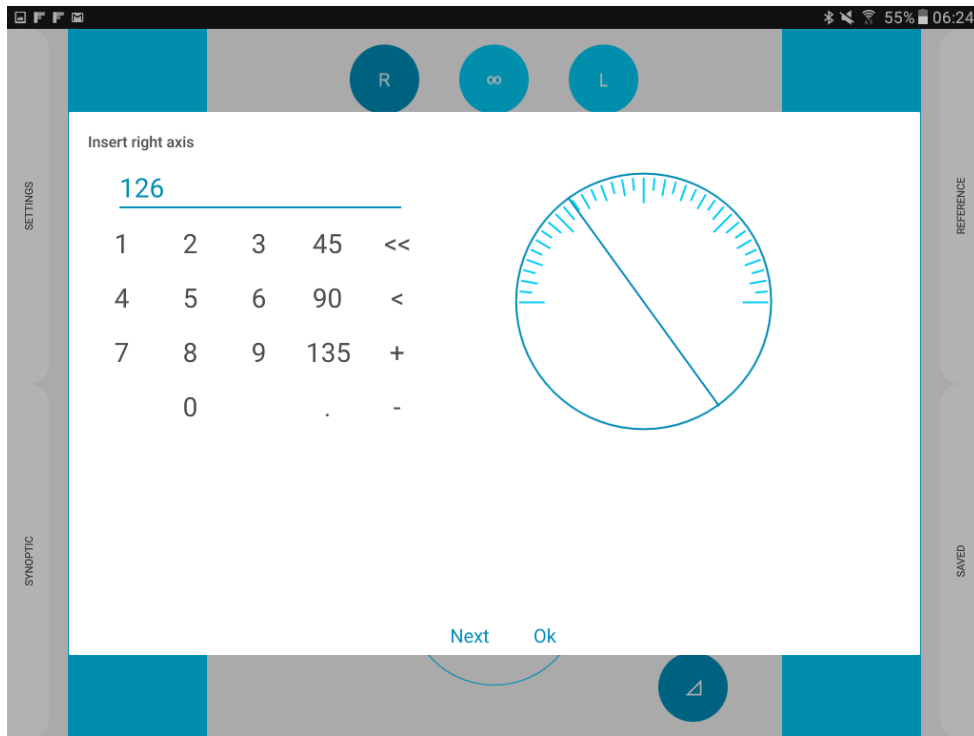
Using the "Next" button at the bottom of the window, you can save the selected current value and directly go to input the next field value. In this manner, you can toggle between the values in the following order:

Sphere (Right) / Cylinder (Right) / Axis (Right) / Addition (Right) / Sphere (Left) / Cylinder (Left) / Axis (Left) / Addition (Left) / Sphere (Right) / etc.

To memorize the selected value and to return back to the main page, you can tap on "Ok" or anywhere else outside of the current window.

| Sphere | Cylinder | Axis |
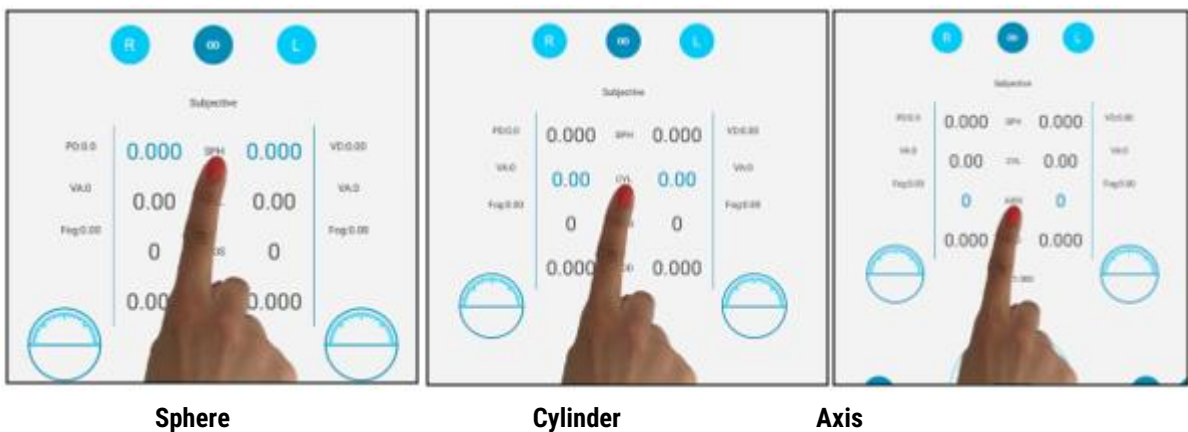
15.4. Additional Value and Fog

Press **Add** to activate an additional value for the preferred eye.

Press **Fog** to activate the fogging. Fog is added in according to a preset value: you can choose the fogging value 0.25 D, 1.5 D, 2 D in the settings window.

15.5. Equi Spherical Equivalent (Constant Spherical Equivalent)

Once inserted a set of refraction values, with this option enabled, you will change the power of the cylinder maintaining constant the spherical equivalent. Please notice that the knob will turn white to remind you that you are in a different modality (see also direct angle control). The knob instead is blue, when you select and change the values for sphere and axis.

For example, if you insert:

SPHERE: +1
CYLINDER: -1

and then you enable this option, by changing the cylinder, you will see that also the sphere will change, as in the following examples:

SPHERE: 0
CYLINDER: +1

SPHERE: -2
CYLINDER: +5

SPHERE: +0.5
CYLINDER: 0

In all these cases, the equivalent sphere is constantly fixed at +0.5 diopters.

15.6.   Choosing sphere, cylinder and addition steps

You can change the sphere, cylinder and addition steps by clicking on the "STEP" option (see figure).

a) Choose the step out of the four available steps for spherical correction:
0.05 D – 0.125 D – 0.250 D – 0.500 D

b) Choose the step out of the two available steps for cylindrical correction:
0.08 D – 0.250 D

c) Choose the step out of the four available steps for addition correction:
0.05 D – 0.125 D – 0.250 D – 0.500 D
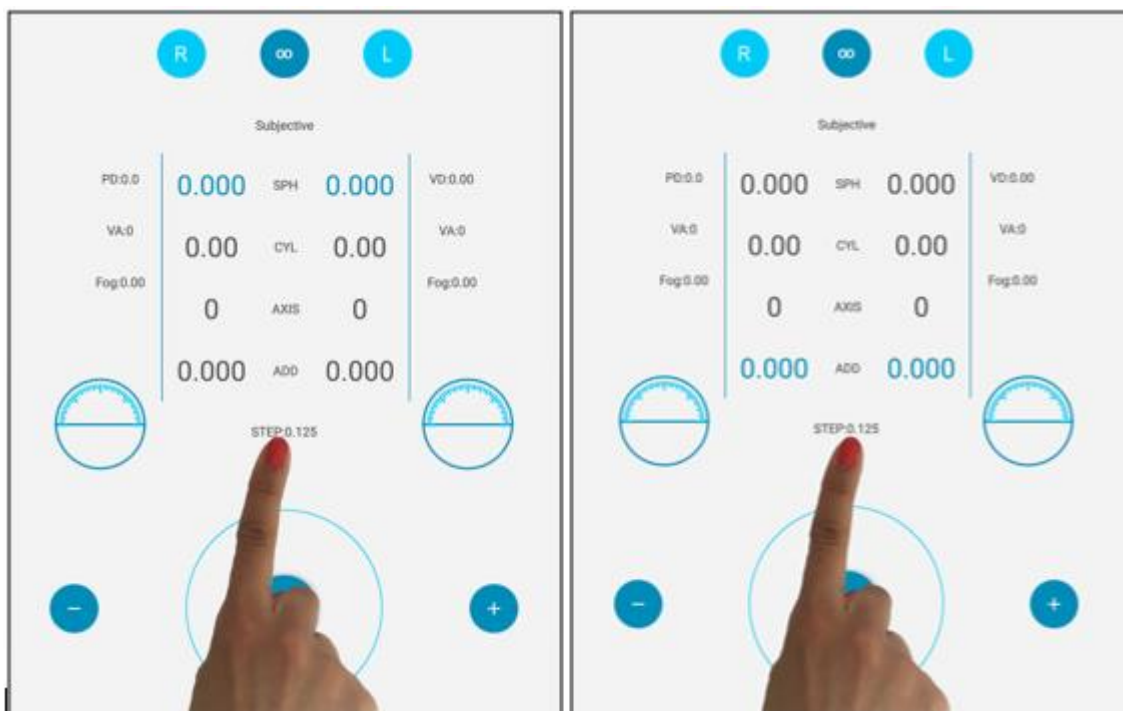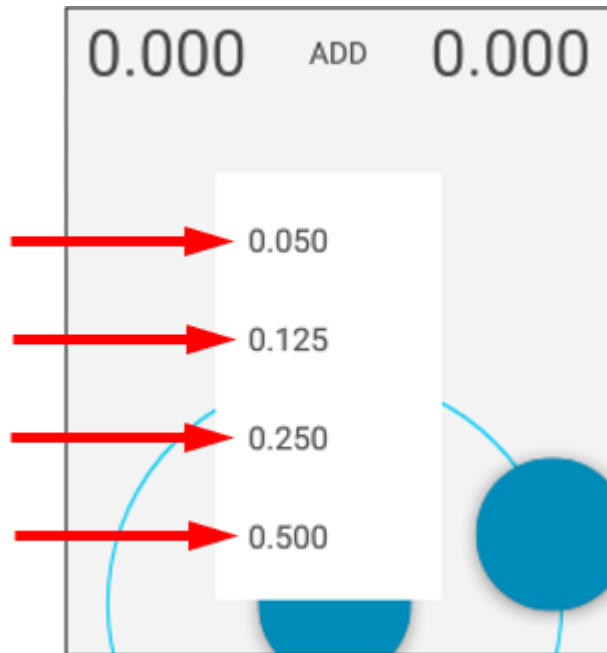
ℹ️ **NOTE**: When the step is changed, the value is rounded up to an absolute value.

ℹ️ **NOTE**: Tap on the **Phoropter** button to adjust currently set values for sphere, cylinder and addition according to a 0.25 D step.
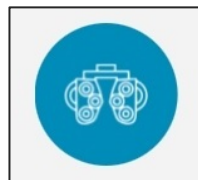
15.7. How to quickly deactivate the Addition value

You can enable or disable the power you have inserted in the addition by simply tapping on the middle of the display the item "ADD". In this manner, you can easily demonstrate to your patient, the effect of inserting or removing of the selected addition value.

15.8. Choosing axis steps

You can change the axis steps by clicking on the voice "STEP" (look at the image).
Choose the step you want three steps are available for axis correction: 1.000 – 5.000 – 10.000 degrees
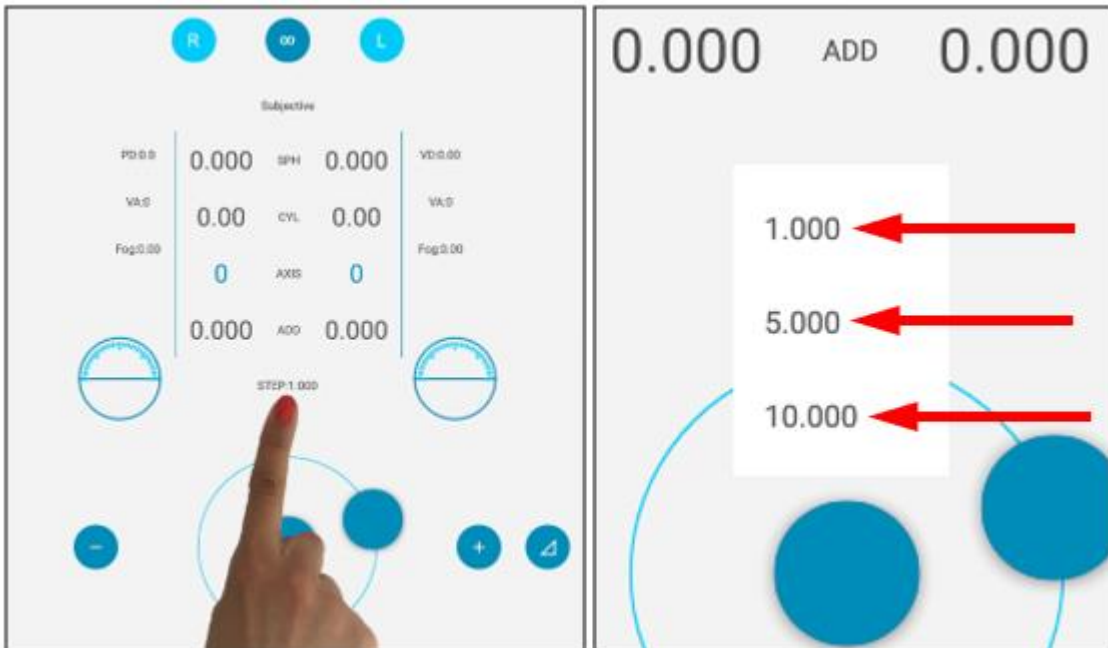
15.9.   Positive/negative cylinder

There is the possibility to select or switch between positive, negative or mixed cylinder. You can select the preferred mode by selecting "CYL" and then by pressing it again.

VisionFit SC automatically calculates the changes in Refraction Data Window.

15.10. Specifying PD (pupillary distance), VD (Vertex distance), VA (Visual acuity for left and right eye)

You can insert and specify the PD, VD, VA fields by clicking 2 times the corresponding icons.

- **PD** (Pupillary Distance)
- **VD** (Vertex Distance)
- **left VA** (Visual Acuity for Left Eye), insert **right VA** (Visual Acuity for Right Eye)
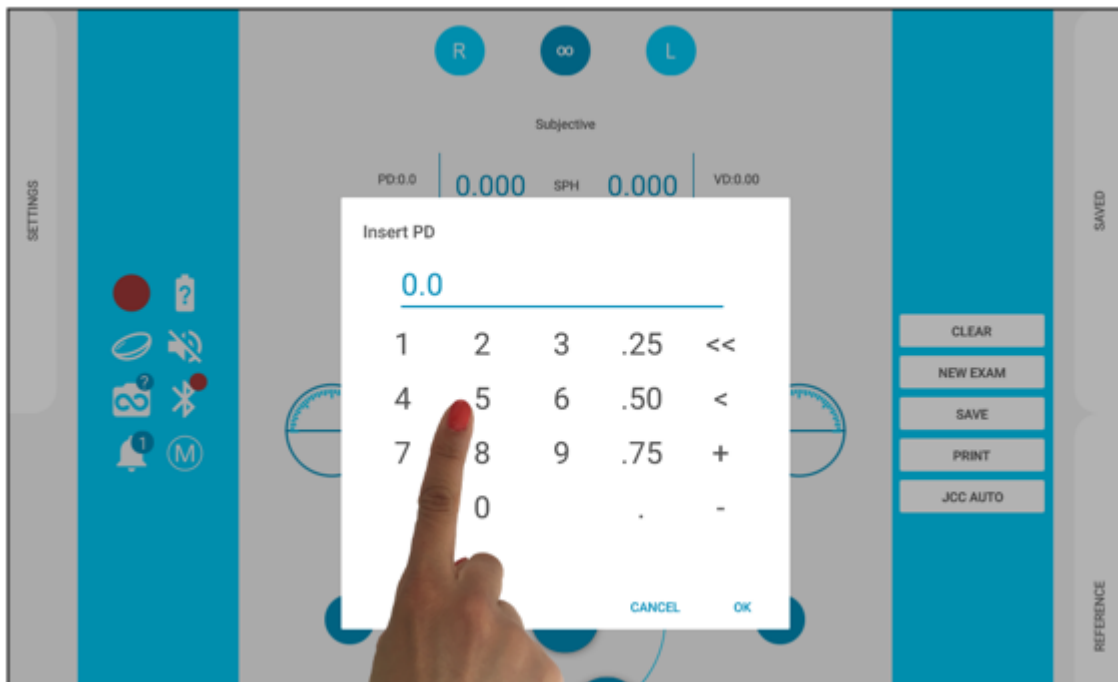
You can use this insertion method also in standard refraction.

15.11 How to use AQUID CHART

AQUID CHART can be remotely controlled from VisionFit APP "AOC Chart" sliding panel.

On the top part of the panel there is a mirroring of the selected line on the Chart. If one only line is visible in the Chart, that line is mirrored. If more lines are displayed on the Chart, the highlighted line is mirrored.
Visual acuity is also displayed, on the right side of the panel. Visual acuity is always displayed in US 20/20 notation.

Tap on Visual acuity value to assign it to the current examination on the VisionFit SC. A message prompt will appear to select which eye you want to assign the VA:
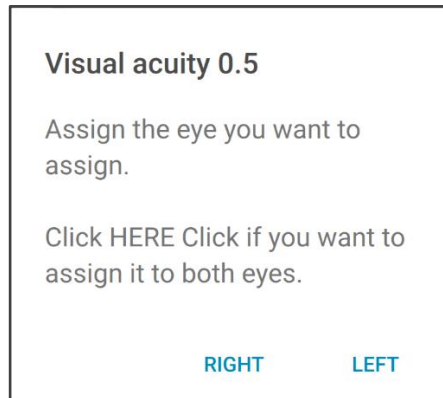
Tap on "LEFT" to assign selected Visual acuity to the left eye; tap on "RIGHT" to assign it to the right eye.

Tap on the popup message to assign selected Visual acuity to both eyes.

Selected Visual acuity value is then displayed on VisionFit SC main window:

NOTE: if the Visual acuity notation settings are different between the AQUID CHART and the VisionFit SC a message will prompt to alert a change the VisionFit SC notation in accordance with the Chart.

16. Managing Data and Exams

In this section we outline how it is possible to manage the objective/subjective refraction measurements of a patient with the VisionFit SC and how it is possible to save them permanently in the tablet's memory (save data in PDF printable format).

As a general information please pay attention that you can operate the VisionFit SC in two different ways:

- **VisionFit Test** - During the refraction exam the operator will insert in the memory of the VisionFit 4 different set of lens values representing four different exams and subjective conditions (e.g. actual lens prescription, autorefractor reading, best corrected visual acuity and another possible subjective refraction). These four sets of values will be presented to the patient at the end of the examination. Since these four conditions are clearly displayed in four different large sectors of the tablet display and since VisionFit control algorithm are very smooth and quick, it's really easy to toggle repeatedly between the four conditions. With this the patient, himself can compare the different conditions and choose the best one simply walking around the room and changing the values with the tablet.

- **Normal Test** - the operator will manually find the best subjective condition and will decide the prescription directly saving (PDF printing) it in the tablet's memory.

16.1. SAVE TO LIST

This selection allows you to save the data you have on the display. After tapping on "SAVE TO LIST" a "Measurement Save" window will be displayed. Here there are two options:

by simply tapping on "SAVE" button all data will be stored and be available under the "SAVED" right slide panel.

choosing one of the four available boxes for the VisionFit test.

By default, the 4 selectable items are Lens Meter/2WIN/BCVA/SUBJ. Once you have selected one of the four boxes, a small white dot will show that the selection is completed.
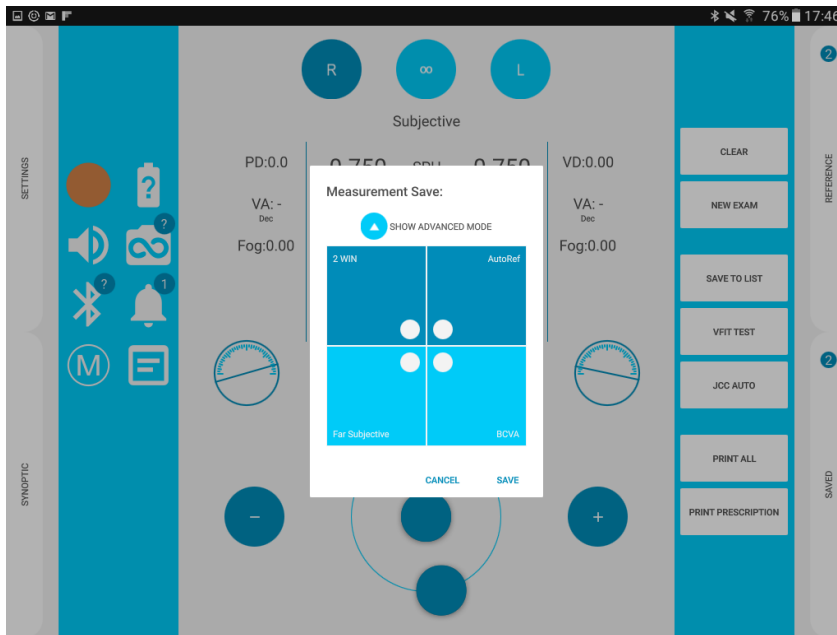
You can also overwrite the boxes many times and it's possible to change the 4 items, in the ADVANCED MODE.

By tapping "SHOW ADVANCED MODE", you will see a set of suggested items, such as the Autoref, LensInUse, FarVision, NearVision, etc. They are dark or light blue in color, depending on the type (see paragraph 17.1 - Reference / Saved).

You can select one of them and then select the box where you want to save the type of exams. Consider that the light/dark blue items can be positioned only in the light/dark blue boxes respectively.

A warning popup message will appear in case of error.

To save another item different from the suggested, you can customize an entry by inserting your preferred name in the name line field (only in the ADVANCED MODE). All the new exams will report the 4 items selected in the ADVANCED mode, even after you have exited. To change the selection, you can enter in ADVANCED MODE again.
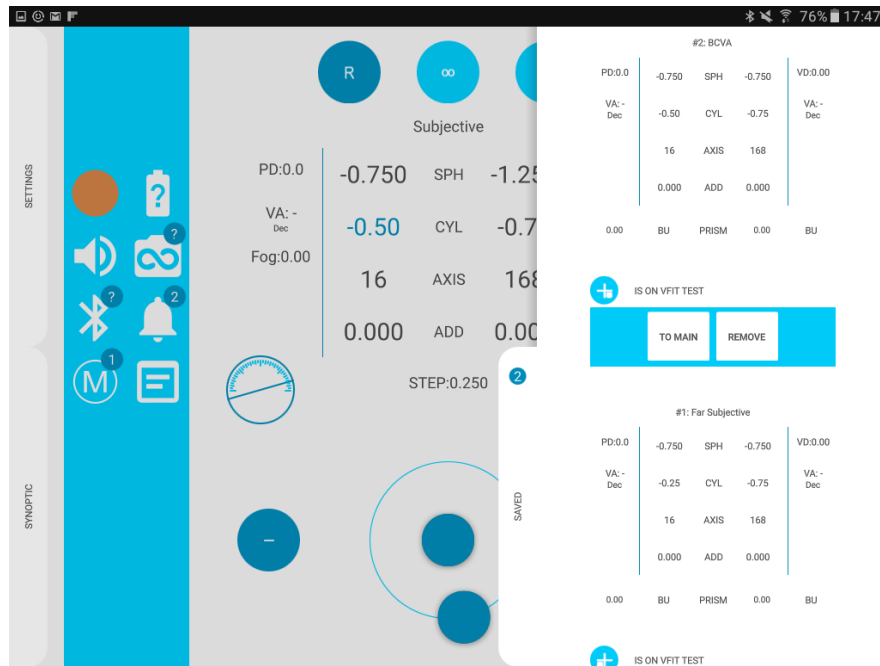
NOTE: All data not saved permanently on the device, will not be stored in its memory at shutdown. To permanently save data and to generate a PDF, please refer to "Print to PDF".

16.2.   Reading a test using the temporary memory

You can temporarily store a refraction value by pressing (M) button selecting "Add Current". Your values will be memorized there and they can be used for that exam session.
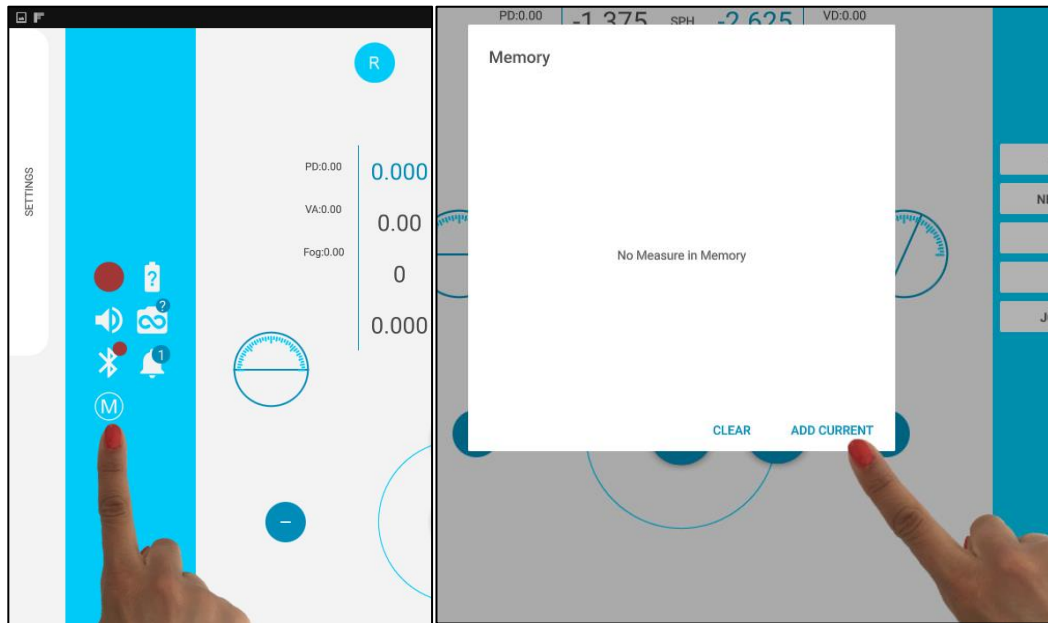
Then if you press that icon again you can choose between the positions stored (measure 1 and measure 2…). The patient can choose the best refraction between the proposals.

Memory

Measure 1
-1.375 0.000 | 2.625 2.000@66

Measure 2
-1.750 0.000 | 3.125 1.500@66

Measure 3
-1.250 0.000 | 1.750 1.500@72

NOTE: All the positions saved in the temporary memory will not be saved permanently. When you will press "New Exam" or when you will turn off the VisionFit SC Application, the values will disappear.

CLEAR   ADD CURRENT

17. Inserting values from external devices

17.1.   Reference / Saved (and add to list option)

There are 2 different kinds of exams. The first, is a REFERENCE exam, i.e. all the exams (Sphere, Cylinder, Axis, Addition, VD, PD, …) coming from other instruments, such as Autorefractor, Lens Meter, Lens in use, 2Win, etc.

They will be stored under the upper right sliding panel, dark blue in color.

If you are using a 2WIN, paired with a VisionFit SC, and you transfer the data wirelessly, this 2WIN exam will be automatically recognized and saved in the correct position.
The second is a SAVED exam, i.e. all sets of values (Sphere, Cylinder, Axis, Addition, VD, PD, …) obtained through the examination done with a VisionFit SC, such as BCVA, Lens Prescription, Subjective exam, etc.

They will be stored under the bottom right sliding panel, light blue in color.

It is also possible to create a new REFERENCE exam, by tapping on the + button, in the bottom part of the right REFERENCE panel. A pop-up will appear, in which you can enter all the values with the numpad and the "Trial lenses box" that appears when you double-click a field value (see paragraph 30 "Inserting values from external devices").

This is not possible for the SAVED values because only exams obtained using the VisionFit are expected to be saved here.

Each exam in the right panels can be moved to the main prescription, by tapping the button "TO MAIN". It can also be removed with "REMOVE".

In each exam in the right sliding panel, there is a small icon "add to VFIT Test" where you can easily add or move the position of the exam in the set of 4 exams saved for the VisionFit SC test.

Pressing on this small icon it enables to select where to position the REFERENCE (or SAVED) exam in the first or second box of the dark (or light) blue positions.

To insert values from an external source you just need to open the "Reference window" by sliding it towards left.

Then press "+", another window will appear where you will be able to
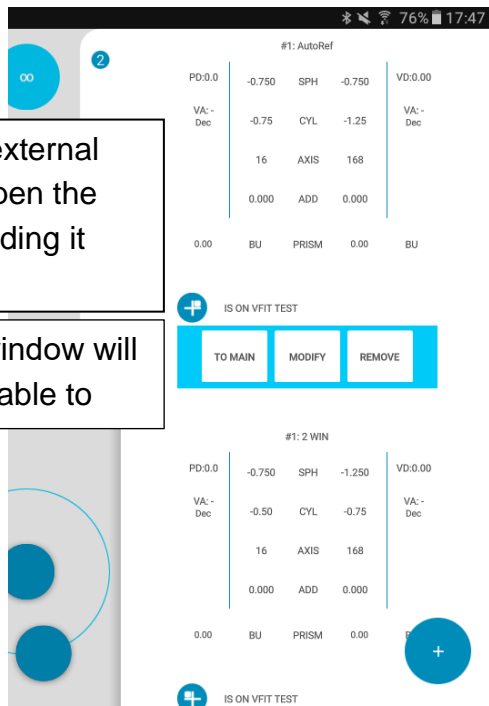
Click twice on the field where you want to insert the value, a keyboard will appear. Insert all the values in the corresponding fields and then press "OK".

DOUBLE CLICK!
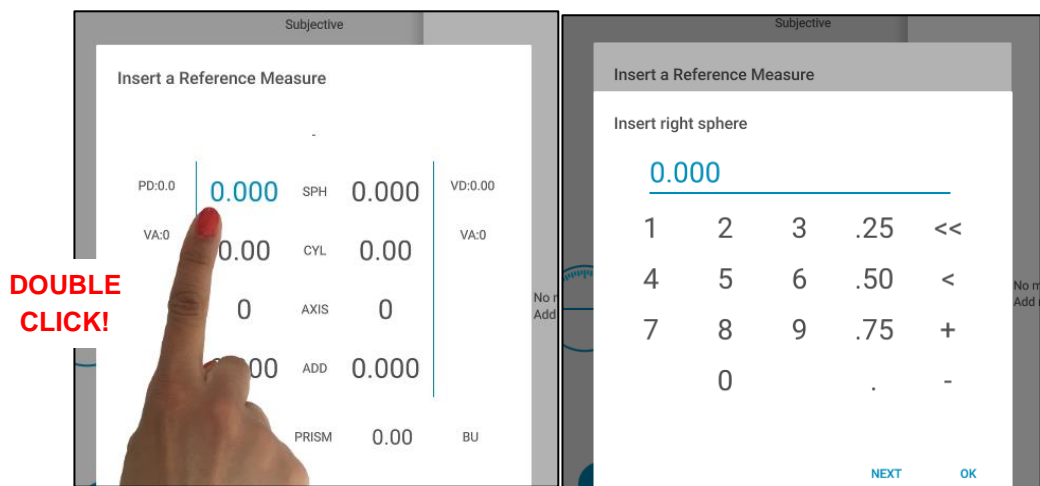
Your reference measure will be stored and you will be able to:
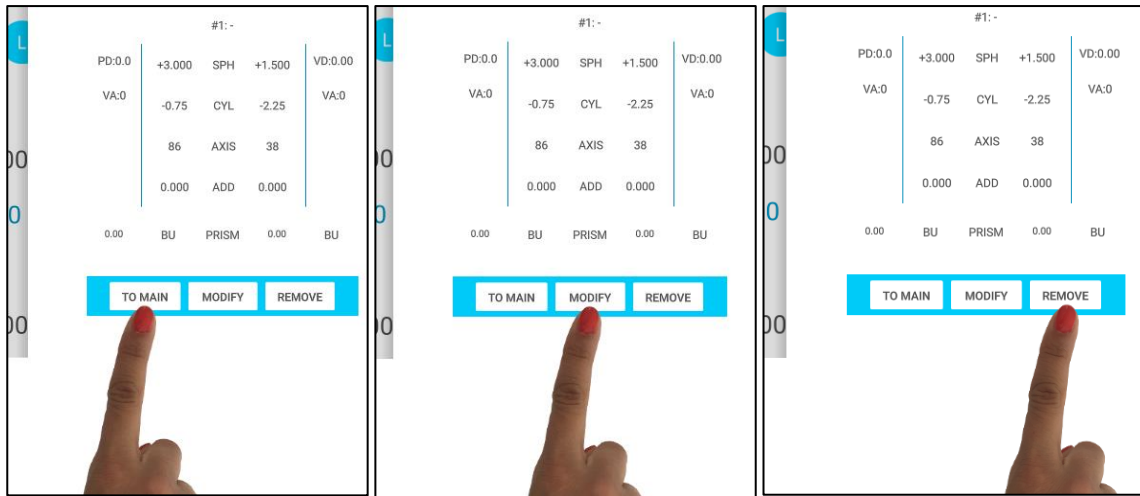
Bring the values of the reference measure to the main screen by using the "TO MAIN" button.

Modify the values of the reference measure by clicking the MODIFY" button.

Delete the reference measure by pressing the "REMOVE" button.

17.2. Clear / New Exam

Select "CLEAR" each time you want to delete the displayed values. The reference and saved values will remain in the system's memory and you will find them under the right sliding panel "SAVED". Select "NEW EXAM" when you want to start a new exam and delete all the references and saved values. e.g. with a different patient.

- To perform a test with a new patient, or simply if the operator wants to delete the data entered, press the "NEW EXAM" button and click "Ok". All the data inserted will be reset (including the reference and the saved measures).
- You can clear the values of the screen by pressing the "CLEAR" button and click "Ok". The reference and the saved measure will not be deleted.

17.3. VFIT TEST

VisionFit test is intended to let patients test a combination of 4 lens configurations. Patients will be asked to move, maintaining their heads in a horizontal position, while looking around the room. Switching via tablet between the 4 selected VFIT-TEST exams by the doctor or the patient himself. In this way, a patient's feeling will be closer to the feeling they will have when wearing the final lenses prescription obtained.

First save a combination of 4 types of configurations, 2 per type "REFERENCE" and "SAVED". In alternative, it will be possible to insert them later, using the exams from the REFERENCE/SAVED sliding panels (see paragraph 17. "Inserting values from external devices").

The "VFIT TEST" button, will display, in full-screen mode, the 4 selected exams. Once the preferred one is selected, exit by tapping on the "X" in the middle of the screen. The selected exam is the one contained in the white highlighted box (see the next picture).
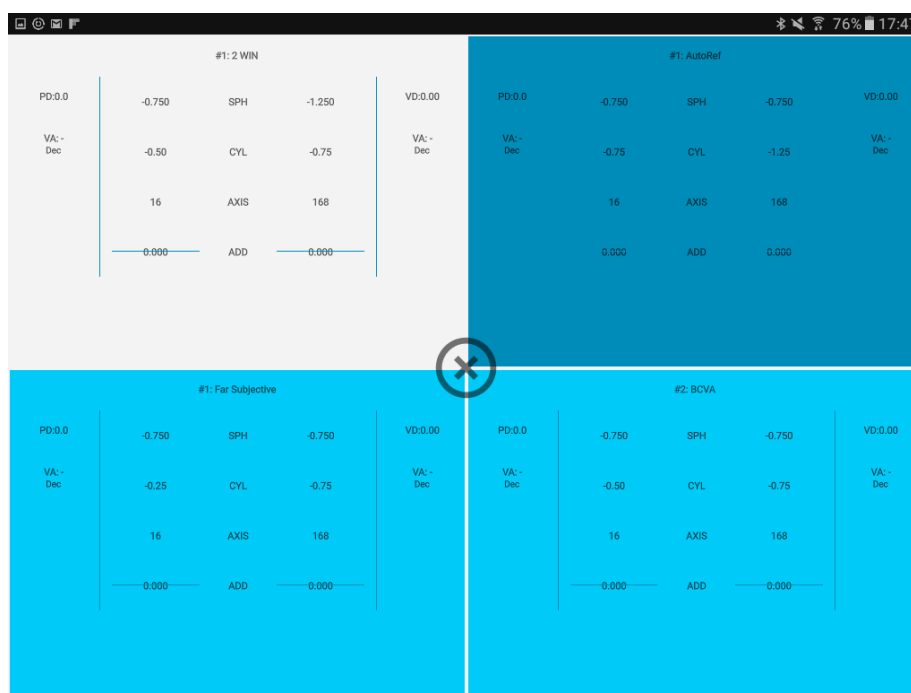
The selected exam will appear on the display, and now it's possible to print your prescription by tapping PRINT PRESCRIPTION.

17.4. PRINT PRESCRIPTION

This selection will create a PDF file only with the final prescription. You are supposed to

select this, only at the end of the VisionFit test, when the patient has chosen his preferred combination. As part of the procedure, you will be asked to remove the helmet from the patient's head.
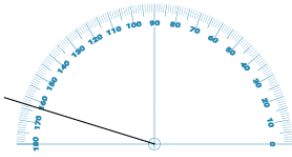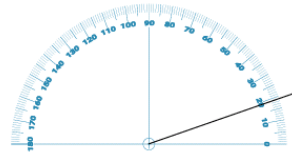
The system will then make a final check to control the correct calibration of the lenses. Finally, if no errors are present, you will obtain the prescription. In case of an error message, reset system and repeat the exam.

The data will be saved into the internal mass storage of the device, inside the **EXAMS** folder.

The EXAMS folder will be saved in folders with the following structure "Exam_Number_Date". The folder and the PDF file can be copied from the SD memory card by connecting the VisionFit SC device to a PC via a USB cable (**USB-A, PC** to **USB-B, VisionFit SC**) The VisionFit SC device will be seen as an external memory.

Lenses

Name:				Prescription Date: Mon Apr 3 07:05:51 2017			
Date of birth:							

OD			OS		
Sph	Cyl	Ax	Sph	Cyl	Ax
FAR					
-1.500	-0.75	163	-1.000	-1.00	19
NEAR					
-1.500	-0.75	163	-1.000	-1.00	19

InterPupillary Distance: 0

Vertex Distance: 0

Note:

Signature:

17.5. PRINT ALL

This selection will create a PDF with all the exams that have been saved under your REFERENCE and SAVED right sliding panels.

VISION FIT REPORT

VISIONFIT

Exam Date: Thu Mar 30 2017

Exam N: 51

SUBJECTIVE EXAMINATIONS:

EXAM CODE:#3: Last Subjective　　　　Examination Date:Thu Mar 30 17:48:50 2017

OD					**OS**			
Sph	**Cyl**	**Ax**	**Add**		**Sph**	**Cyl**	**Ax**	**Add**
-0.750	-0.500	16	0.000		-1.250	-0.750	168	0.000

　　　Prism:0.0 BU　　　Acuity:-　　　　　　　　Prism:0.0 BU　　　Acuity:-
　　　　　PD:0.0　　　　　　　　　　　　　　　　　　VD:0.0

EXAM CODE:#2: BCVA　　　　Examination Date:Thu Mar 30 17:46:21 2017

OD					**OS**			
Sph	**Cyl**	**Ax**	**Add**		**Sph**	**Cyl**	**Ax**	**Add**
-0.750	-0.500	16	0.000		-0.750	-0.750	168	0.000

　　　Prism:0.0 BU　　　Acuity:-　　　　　　　　Prism:0.0 BU　　　Acuity:-
　　　　　PD:0.0　　　　　　　　　　　　　　　　　　VD:0.0

18. JCC AUTO

The automatic JCC auto procedure allows to get a faster and smoother change of the lenses between 2 selected positions. It's also possible, to toggle between them, during the fine-tuning procedure, by tapping always on the same arrow button, it will toggle from position 1 to position 2, another tap will toggle back to position 1 again.

The cross cylinder examination (JCC) is embedded in the VisionFit SC. It's possible to use the cross cylinder test in two possible ways:
AUTOMATIC JCC:
- Automatic procedure for power of the cylinder
- Automatic procedure for axis of the cylinder
- Automatic discovery of both power and axis of the cylinder

VISIONFIT

MANUAL JCC: a manual way of operating with the cross cylinder.

18.1 Automatic Cross Cylinder (Automatic JCC)

When the objective refraction of the patient cylinder is known it's possible to better refine the power and the axis of that cylinder by means of this automatic procedure, which helps the productivity/speed of the examination. Before starting the automatic procedures, the operator must set in the VisionFit SC the known power/axis of the cylinder.
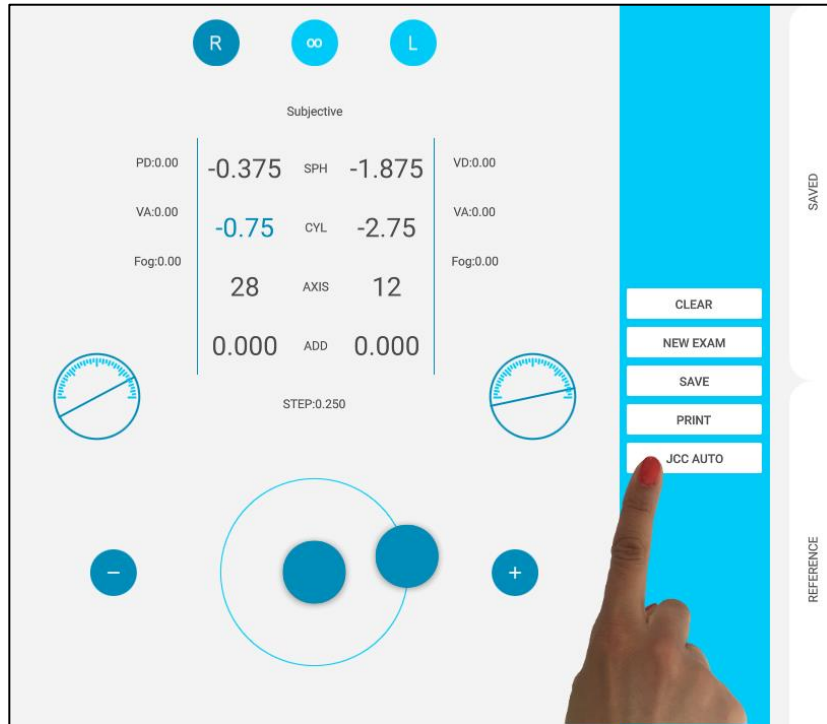
a) Automatic procedure for the POWER of the CYLINDER

Steps of the procedure:

1. Get in position on the power of the known (and already set) Cylinder to optimize it. If you want to refine the astigmatism power of the right eye you just need to get in position on the corresponding box. If you want to refine the astigmatism power of the left eye you just need to get in position on the corresponding box (left eye).
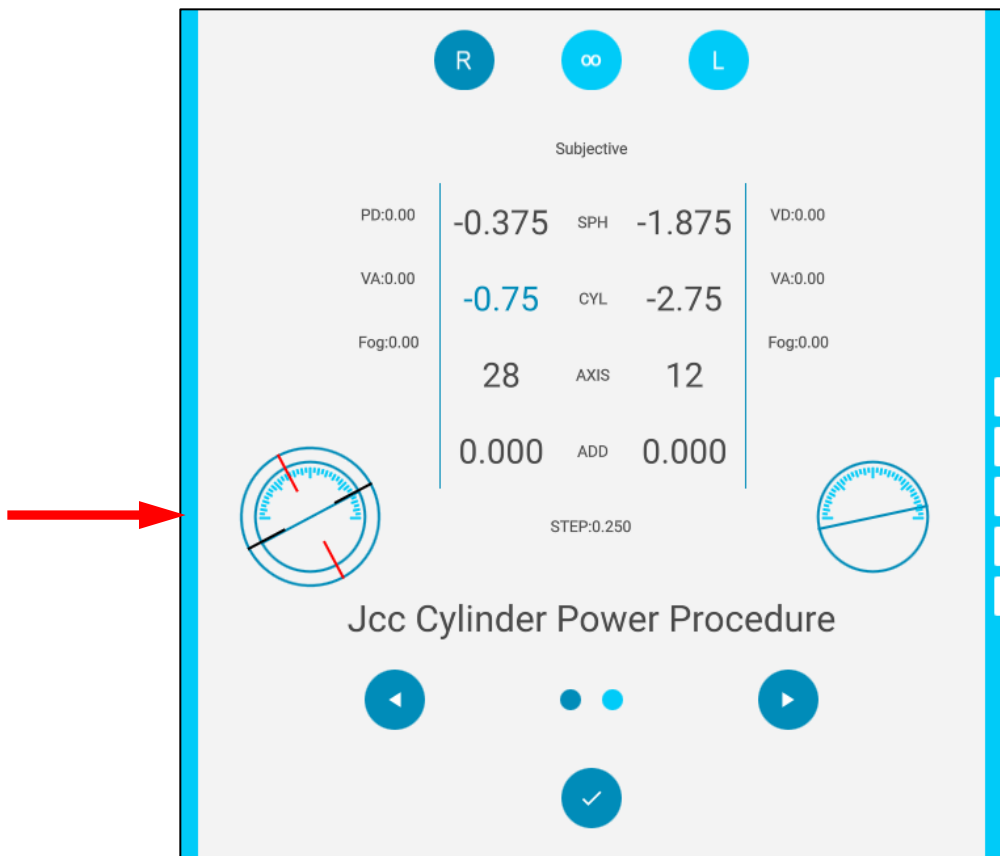
2. Press the JCC AUTO Button (the function will begin), then the JCC screen will appear on the display. Doing this, the VisionFit SC introduces the cross cylinder for the test of the power of the cylinder in the selected eye of the patient.

Jcc Cylinder Power Procedure

3. Now it is possible to start the optimization. By repeatedly pressing the selecting arrows, the operator is switching between condition-1 and condition-2 (look at the dark spot which switches from right to left). As in a normal cross cylinder procedure, the operator must ask the patient which of the two condition is perceived better. In order to flip/switch between condition-1 and condition-2 you can tap/click the axis degree picture/indicator.
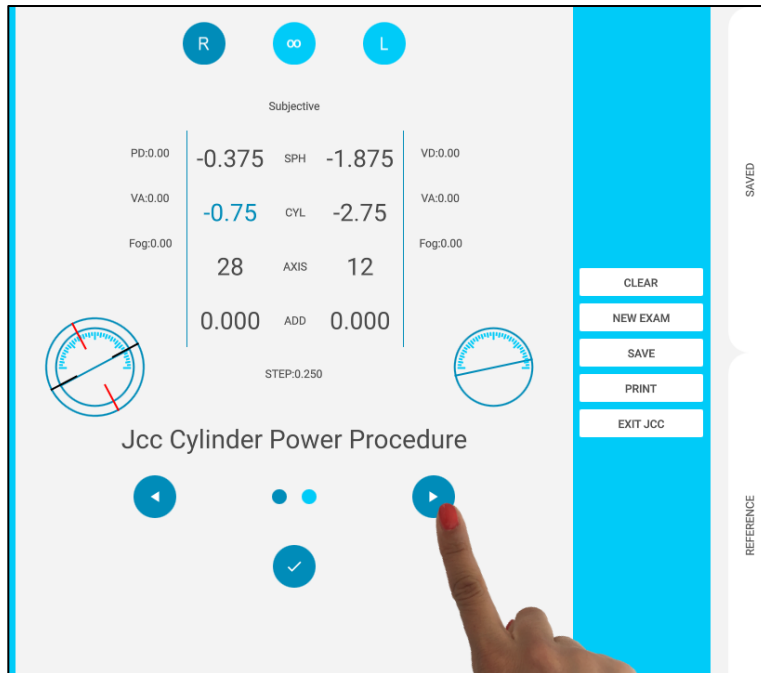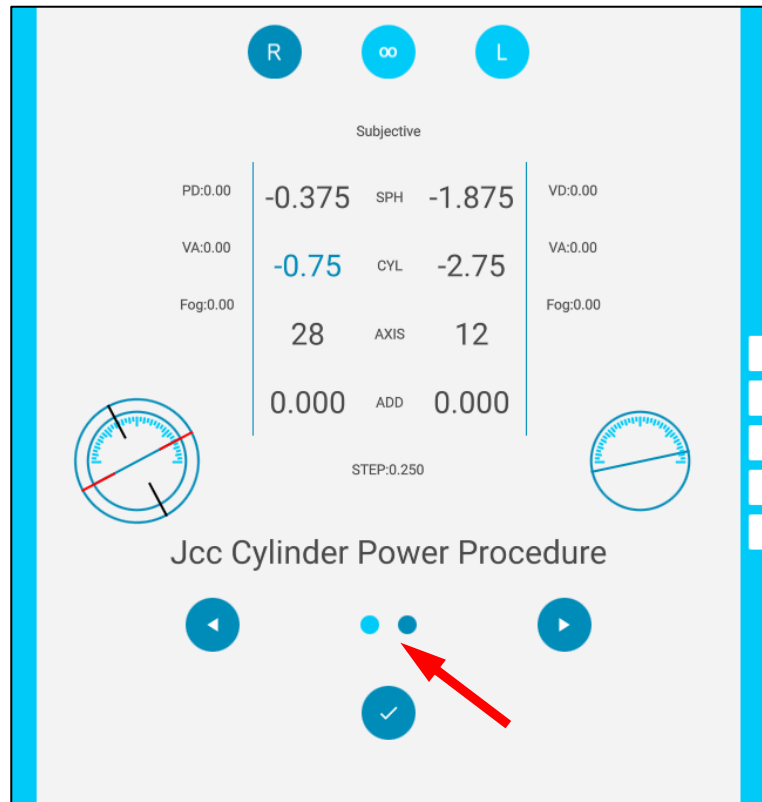
4. To confirm the best patient condition (condition-1 or condition-2) just press the Confirm Button (as shown in the photo). This action creates an automatic correction of the power of the cylinder in accordance to the choice of the patient. At this point is possible to do other (several) iterations just starting from STEP-2 of this procedure list. To stop the procedure, press the EXITJCC button of VisionFit SC.
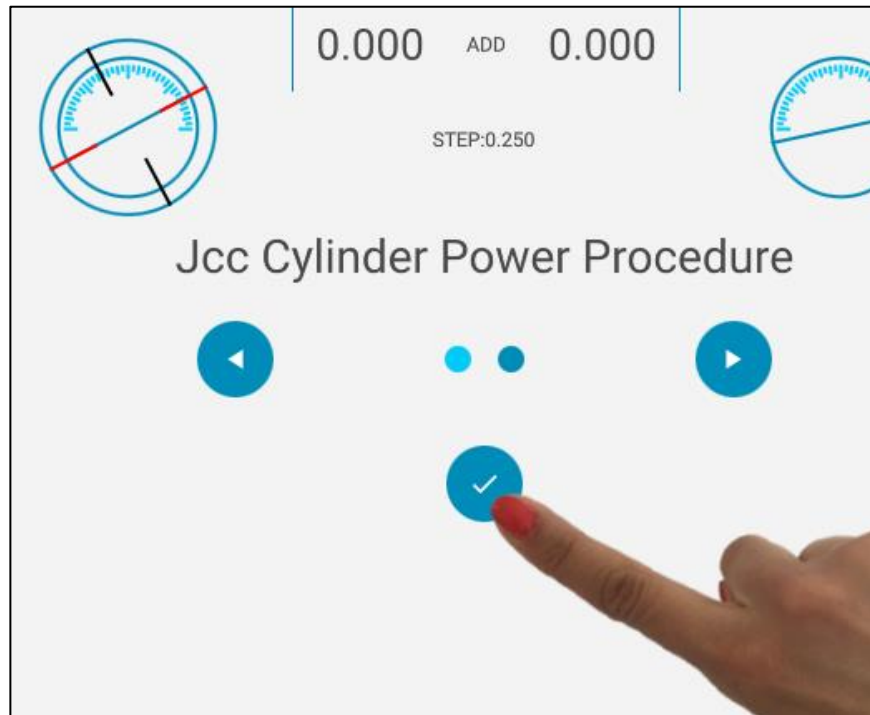
b) Automatic procedure for AXIS of the CYLINDER

Steps of the procedures:

1. Get in position on the axis of the known (and already set) Cylinder to optimize it. If you want to refine the astigmatism axis of the right eye you just need to get in position on the corresponding box. If you want to refine the astigmatism power of the left eye you just need to get in position on the corresponding box (left eye).

2. Press the JCC AUTO Button (the function will begin), then the JCC screen will appear on the display. Doing this, the VisionFit SC introduces the cross cylinder for the test of the axis of the cylinder in the selected eye of the patient.
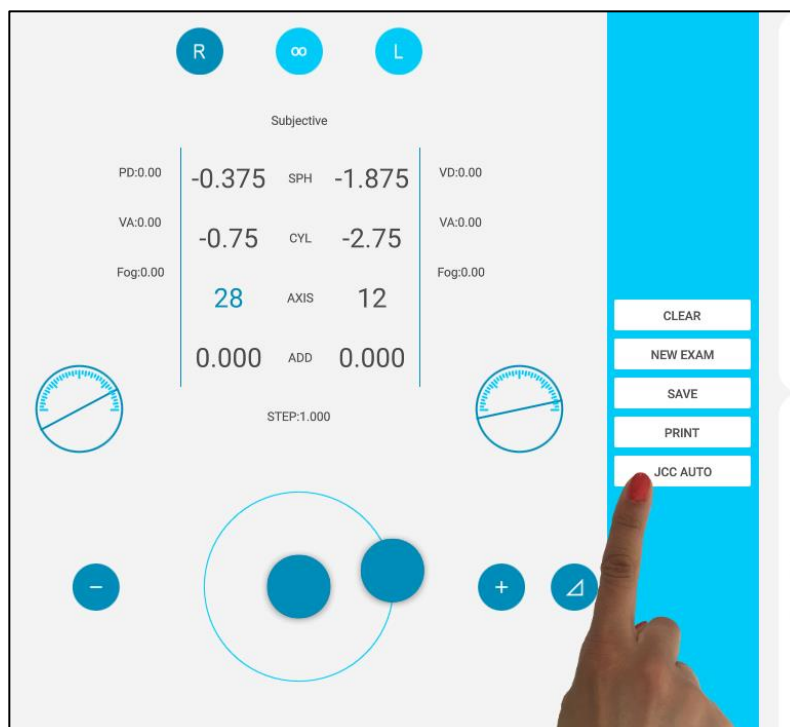
3. Now it is possible to start the optimization. By pressing the selecting arrows, the operator is switching between condition-1 and condition-2 (look at the dark spot which switches from right to left). As in a normal cross cylinder procedure, the operator must ask the patient which of the two condition is perceived better.

70
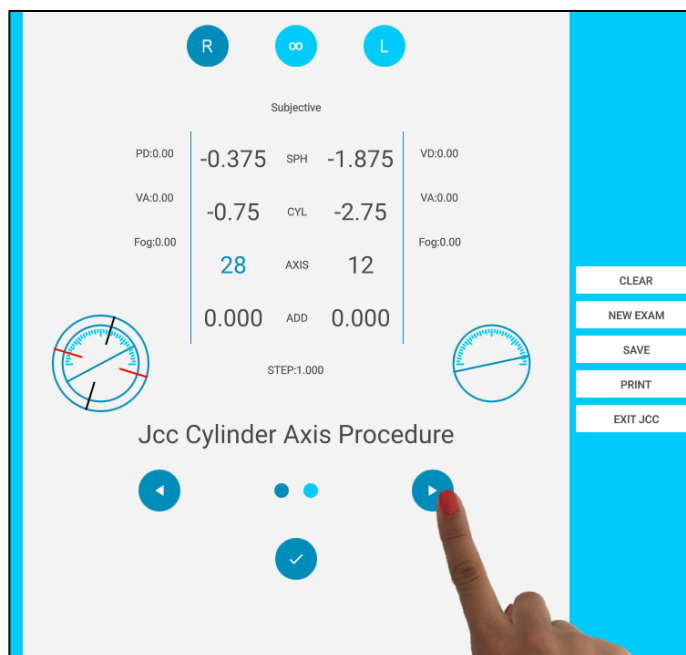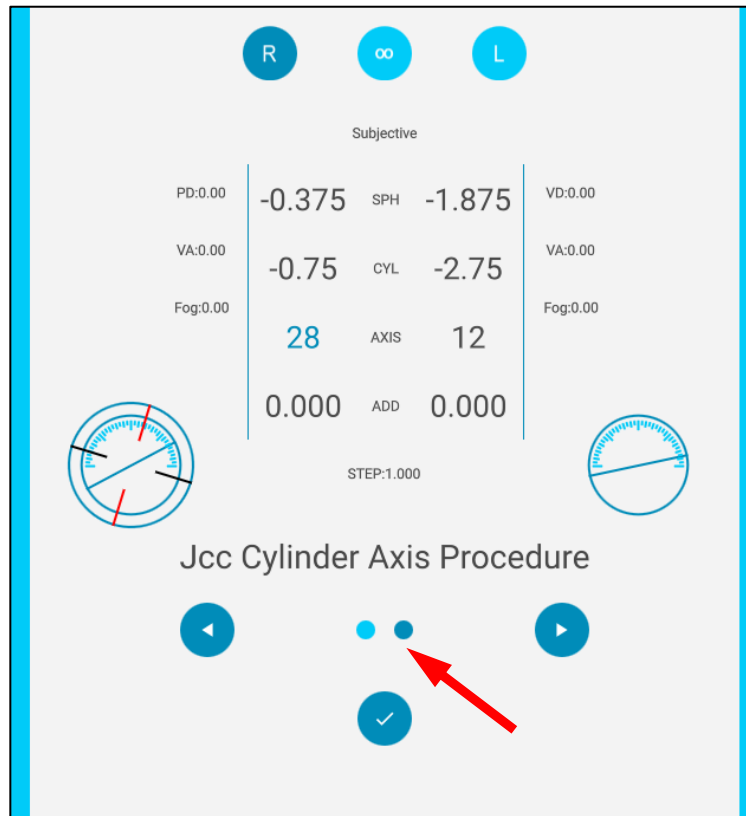
4. To confirm the better patient condition (condition-1 or condition-2) just press the Confirm Button (as shown in the photo). This action creates an automatic correction of the axis of the cylinder in accordance to the choice of the patient. From this point is possible to do other (several) iteration just starting from STEP-2 of this procedure list. To stop the procedure, press the EXIT JCC button of VisionFit SC. If not stopped by the operator, after some iteration the system can find the subjective convergence axis (VisionFit SC will display "Axis Determined" in the right part of the screen).
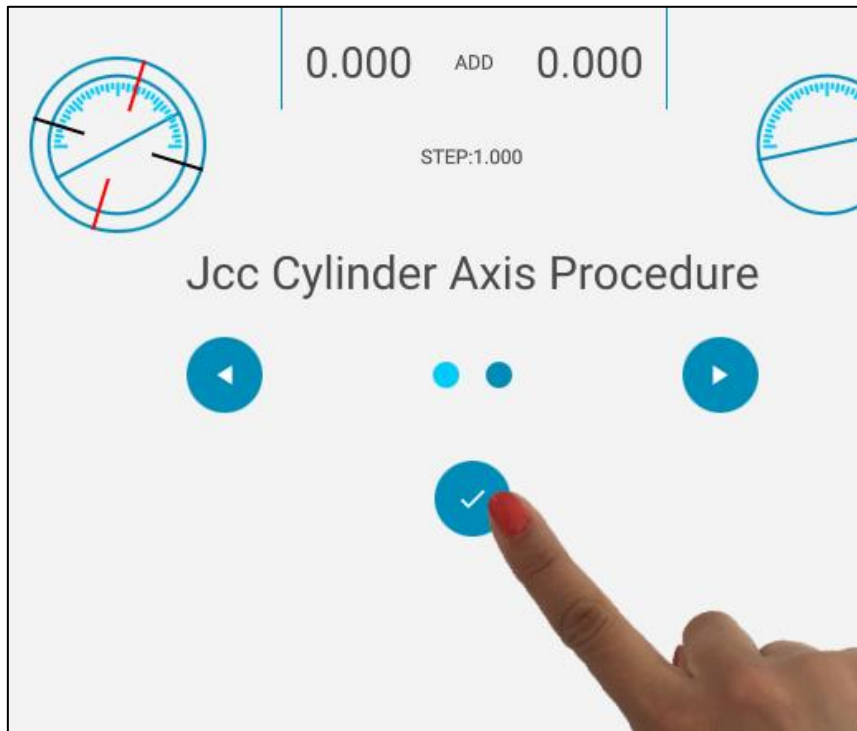
c) Automatic discovery of both POWER and AXIS of the CYLINDER (JCC Discovery)

When the objective astigmatism of the patient is not known it's possible to activate an automatic discovery of the cylinder just following the next steps. After this discovery, it's possible to switch to the axis optimization (first) and then the power of cylinder optimization just pressing the Axis and power of cylinder button.

1. Get in position on the Power of Cylinder to find (the system will automatically find the axis as well). If you want to find the astigmatism details of the right eye you just need to get in position on the corresponding box. If you want to find the astigmatism details of the left eye you just need to get in position on the corresponding box.

2. Press the JCC AUTO Button (the function will begin), then the JCC screen will appear on the right side of the display. Doing this, the VisionFit SC introduces the cross cylinder for the auto-discover of the cylinder in the selected eye of the patient.
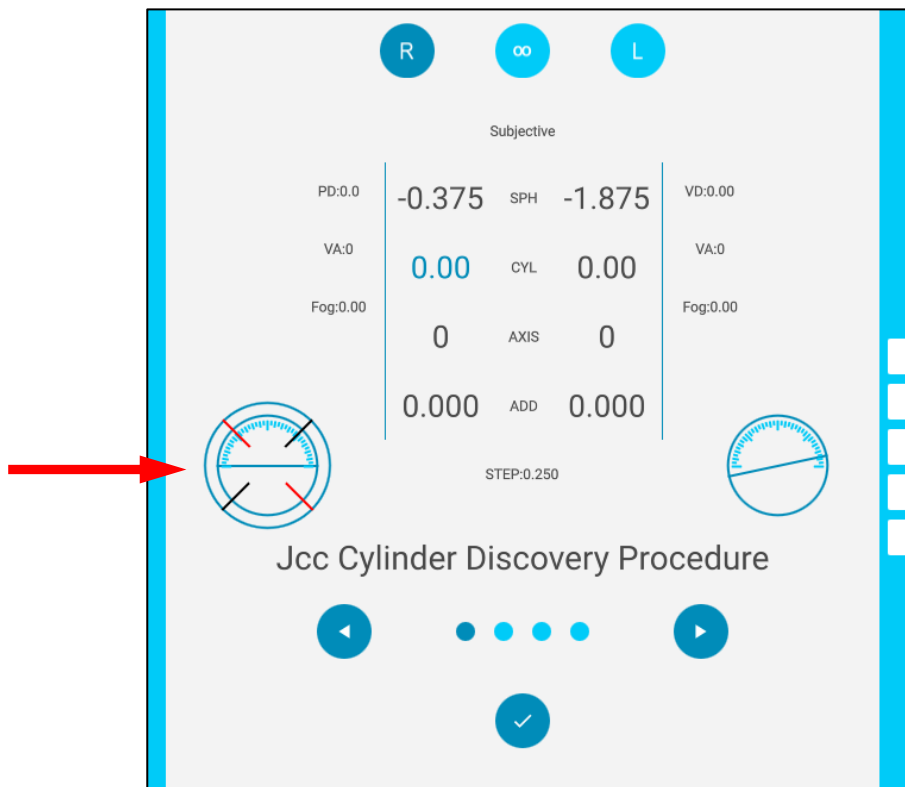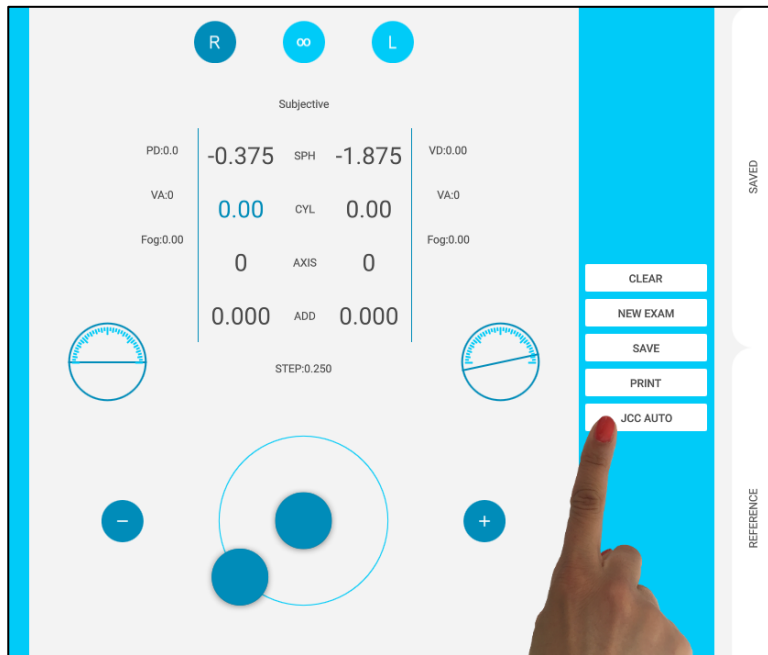
3. Now it is possible to start the automatic discovery. By pressing the selecting arrows, the operator is switching between condition-1 condition-2, condition-3 and condition-4 (look at the dark spot which switches from right to left). As in a

normal cross cylinder procedure, the operator must ask the patient which of the four conditions is perceived better.
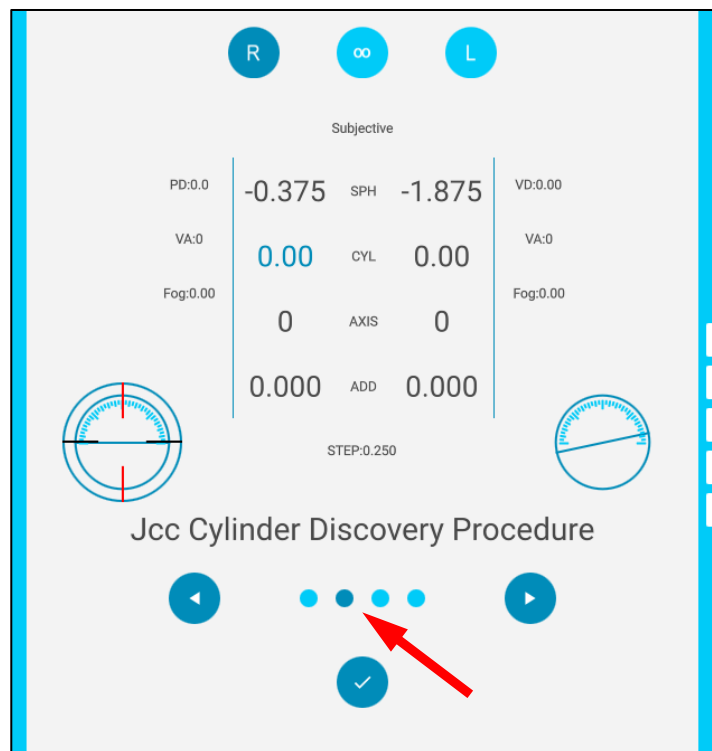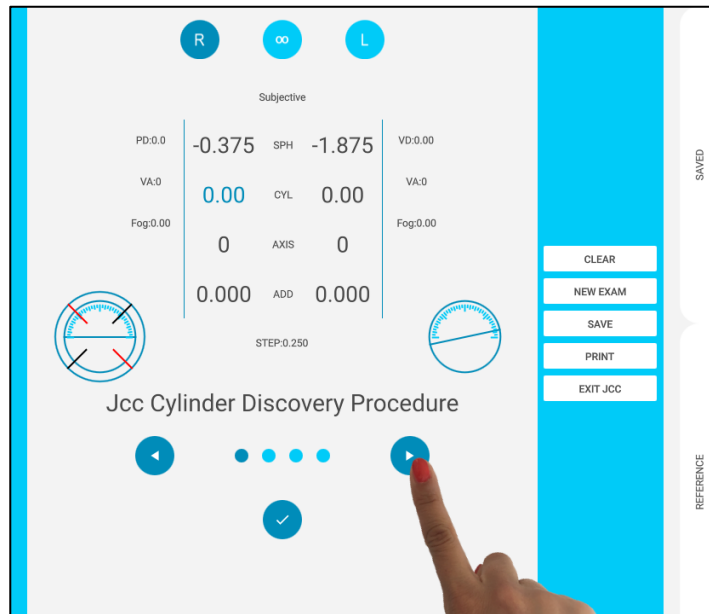
4. To confirm the preferred patient condition (condition-1-2-3-4) just press the Confirm Button (as shown in the photo). This action creates astigmatism in the selected eye of the patient (power and axis).
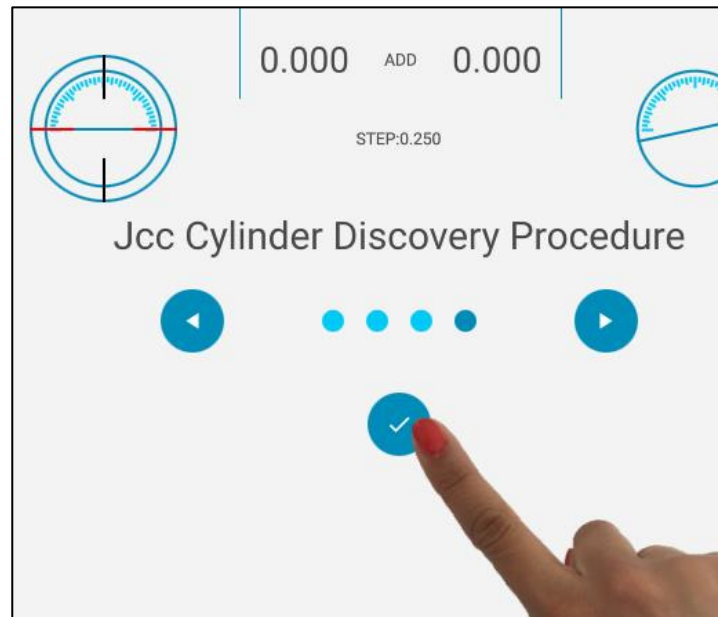
5. At this point a first estimation of the patient's astigmatism is known, it's possible to switch to the axis best determination by pressing the axis button in the VisionFit SC. Moreover, it's possible to better determine the power of the cylinder just pressing the power of cylinder button.

18.2 Manual Cross Cylinder (Manual JCC)

If you want to use the Manual Cross Cylinder mode, you just need to click once on the Axis Indicator, this action increases and decreases values to the cylinder in according to the preset options:

Go to the settings window and press JCC Settings, this will open a window for the configuration options of the JCC (JCC Settings).

Options displayed: value, JCC comply with axis of astigmatism, offset to axis.

If you want to fine tune the cylinder power, please activate follow axis at 0°.

If you want to fine tune the cylinder axis, activate follow axis at 45°.

For the fused Cross Cylinder technique, please deactivate follow axis option.
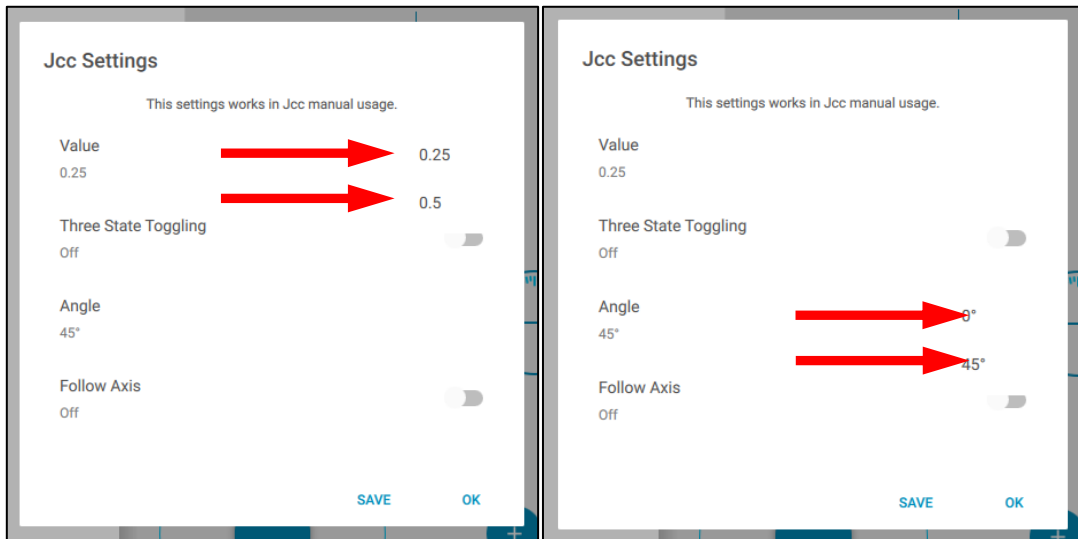
NOTE: Select your preferred setting, then save changes by clicking on "Save" for the current measurement.

To deactivate the cross cylinder function, keep the JCC Axis Indicator button pressed.

If the cross cylinder mode (JCC) is activated you will be prompted to perform:
- Axis Enhancement
- Cylinder Power Enhancement

To perform the examination with cross cylinders, simply click on the **JCC axis indicator** button:
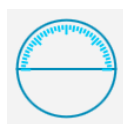
Next, clicking on that button allows the Operator to toggle the JCC cross cylinders in two configurations: JCC1 and JCC2
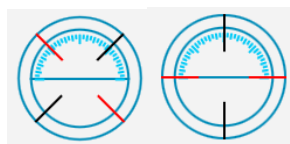
JCC1   JCC2

The red dots are related to negative values of the cross cylinder, while the black dots represent positive values.

19. GLOBAL JCC CONTROL

To change the values, as described in paragraph 16 "Inserting values from external devices", you can double tap on the knob button. In this manner, a sensitive pad, will appear. The size of the sensitive pad can be or a rectangle in the lower part of the screen or full screen, by enabling/disabling the Global Refraction Control (Full Screen) selection on the left sliding panel.
The pad is sensitive to the sliding your finger to the right to increase the values (diopters or degrees) and to the left, to decrease them.

20. Sliding panels settings

In this section we will describe the use of the settings sliding panel in which is possible to configure some of the VisionFit application features. Other specific configuration are described in other part of the manual. The next picture shows part of the Settings sliding panel.
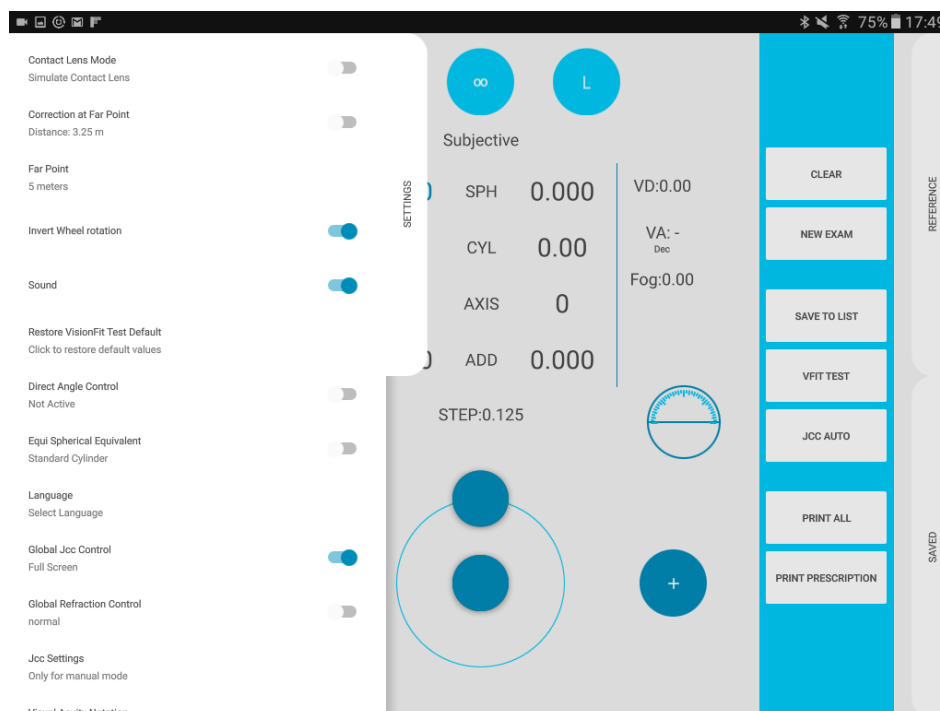
20.1. CONTACT LENS MODE

This modality enables the VisionFit SC to be used for a prescription of a pair of contact lenses. This is possible thanks to the very high resolution of the spherical lens. The procedure is the following:

1. Help the patient to wear the system, paying attention to the correct positioning of the goggles with the proper Vertex Distance. Use the rulers on the side of the goggles as a reference. Typically, a reasonable distance is about 12 mm. This distance is the distance between the vertex of the patient's eye and the surface of the first lens, the one closest to the human eye.
2. First insert the Vertex Distance (VD) in mm, double tap the item VD (on the right of the sphere of Left Eye) of the display
3. Then enable the Contact Lens Mode, setting in the left sliding panel. The icon of a contact lens will appear in the left blue icon bar.
4. All the values on the display are those that will result in the report of the final prescription for contact lenses.

In fact, the lenses are not the values that have been set but have a different value taking into account the distance of the lenses from the human eye (which was provided manually by inserting the VD) and converting it to the needed power considering a pair of contact lenses.
The difference is higher at higher power.

The use of contact lenses is useful for the correction of refractive defects such as myopia, hyperopia and astigmatism.

You can automatically calculate refraction with Vertex Distance to 0 mm (Contact Lens Vertex Distance) and obtain the patient's contact lens prescription.

Perform the subjective measurement. Then slide the Settings window and turn on the Contact Lens Mode.

Refraction values (VD= 0mm) will be recalculated immediately.

The calculation is performed using the Vertex Distance set in the measure. If no vertex distance is set, a warning message will appear requiring for it.
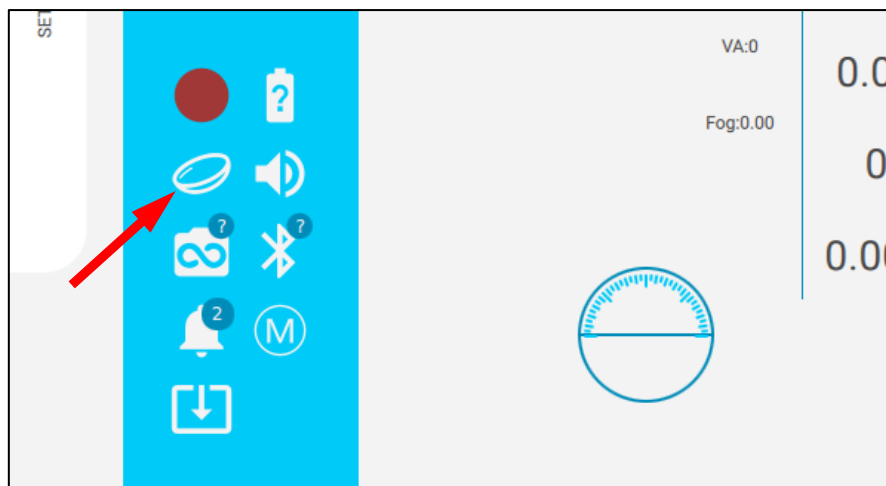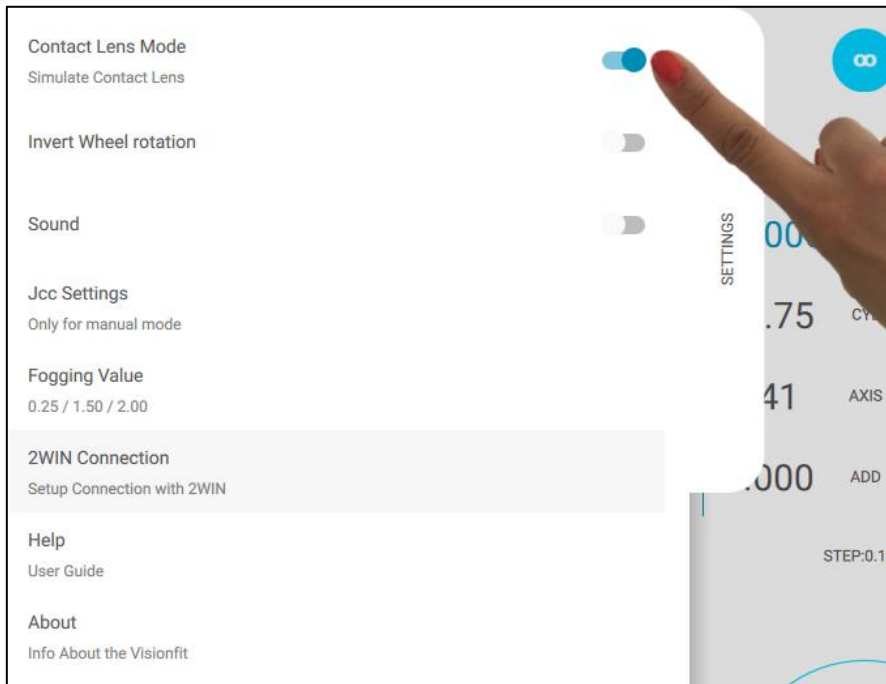
20.2.   CORRECTION AT FAR POINT and FAR POINT setting

This modality is intended for clinics where the distance between a patient and the eye-chart is less than the standard distance considered as the far point. The definition of Far Point may differ from country to country (between 5 to 6 meters).

1. Define your far point and insert it in the selection menu "Far Point" in the left settings sliding panel.

2. Once set this distance, measure the distance between your eye-chart and the human eye.

3. Insert this value in meters, in the selection menu "Correction at far point" on the left Settings sliding panel after enabling it, in the popup window "Set Target Distance"

and click OK to save the value.
The values on the tablet are directly the values for the lens prescription.

Indeed, the VisionFit SC is calculating and applying the conversion of the refraction, given the information of the distance between the eye-chart and the patient.

An example:
NO "CORRECTION AT FAR POINT" ENABLED
1. The standard "Far point" in your country is 5 meters.
2. Your eye-chart is at 3 meters.
3. Let's assume that the patient is finding his best vision on the eye-chart with a refraction correction of 2 diopters.
4. To pass from an eye-chart at 3 meters to an eye-chart at 5 meters, you need a correction of $1/3-1/5 = 0.13$ diopters.
5. You calculate manually that the prescription must be given to 2.13 diopters (and then you approximate it, most probably, to 2.25 diopters)

WITH "CORRECTION AT FAR POINT" ENABLED
1. The standard "Far point" in your country is 5 meters.
2. Your eye-chart is at 3 meters.
3. With the correction at far point enabled, the patient's best vision with the eye-chart at 3 meters will be found.
4. The value is read automatically on the tablet
5. This value has already the needed refraction correction for the best vision at a far point. A value around 2.13 diopters (most probably, in this example, 2.15).

> *i* NOTE: When importing measures and when using VFIT TEST if the measure set to main refraction has LENS MODE or CORRECTION at FAR point different from current settings, the current settings are normally overwritten to become compatible with the measure settings and convert the measure to the actual settings, or to overwrite the current settings.

20.3.   Visual Acuity Notation

It's possible to select from a dropdown list a notation so that the system can automatically convert the Visual Acuity prescription to the most diffused international notations.
In case the VisionFit SC is connected to AQUID CHART the visual acuity settings are mutuated from the chart. Please refer to AQUID CHART User Manual to see how to select the visual acuity on the chart itself.

20.4. Direct Angle Control

Selecting this operational mode, the knob will operate in a more intuitive way. The position of the of the knob will be the same for the axis of the cylinder angle i.e. if the handle is on the upper part of the circle, your axis will be 90 degrees.

20.5. Plus/Minus/Mixed Cylinder

By holding and then releasing the item "CYL" between the cylinder values of the eyes, the selection of the notation for cylinder (Plus, Minus, Mixed) is made available.

20.6 Profiles

It is possible to create custom settings Profiles. The following settings can be included in a Profile:

- Contact Lens Mode
- Correction at Far Point
- Far Point
- Invert Knob rotation
- Direct Angle Control
- Equi Spherical Equivalent
- Global Jcc Control
- Global Refraction Control
- Visual Acuity Notation
- Cylinder Notation: Plus, Minus, Mixed
- Sphere step
- Addition step
- Cylinder step
- Axis step

In order to save a new Profile open the Settings panel and tap on **Profile Actions** button and select **Save Profile**. A window will prompt for naming your new profile.

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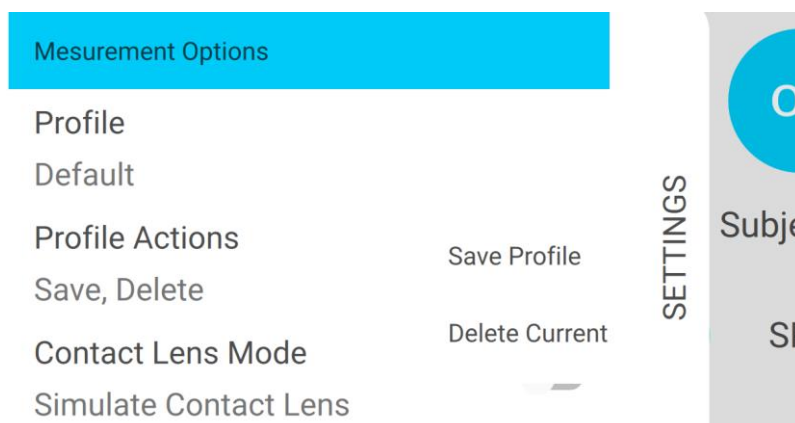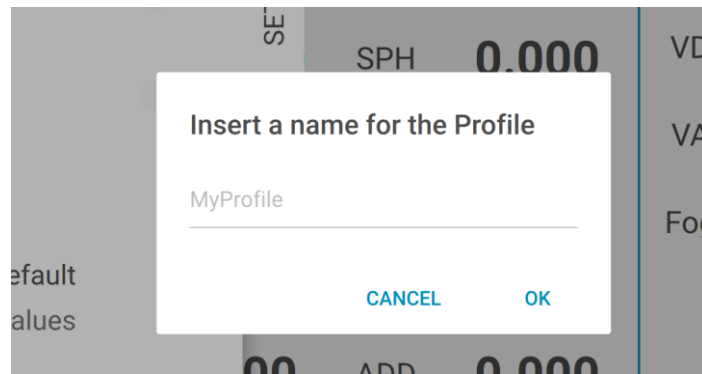
To select the Profile to be used open the Settings panel, tap on **Profile** button and choose the Profile to be loaded from the list of available Profiles.
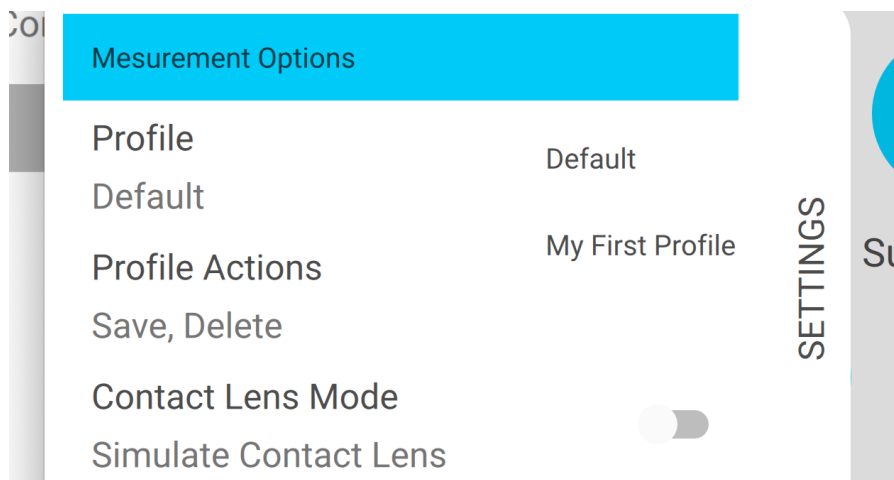
To delete a Profile, select it and then tap on **Profile Actions** button and tap on **Delete Current**.

21. Sleep Mode

If the application is not running or the operator changes application during the measurement, the VisionFit SC will enter into sleep mode: the goggles will enter in the stand-by mode and all the lenses will return to zero.

If the application stands still for more than 5 minutes a message will appear indicating that the lens will go to sleep in 10 seconds even if the application is on and the tablet is not in standby.

22. Pairing a 2WIN with VisionFit SC and transferring a test

22.1. Pairing a 2WIN with VisionFit SC and transferring a test though a Wi-Fi connection

In order to pair a 2WIN with a VisionFit SC using Wi-Fi connection follow these steps:
  a. Activate Wi-Fi on the tablet on which the VisionFit SC application is running
  b. Activate Wi-Fi on 2WIN and choose the same network to which the tablet is connected
  c. In VisionFit SC application select **2WIN Connection** from Settings > *2WINConnection*
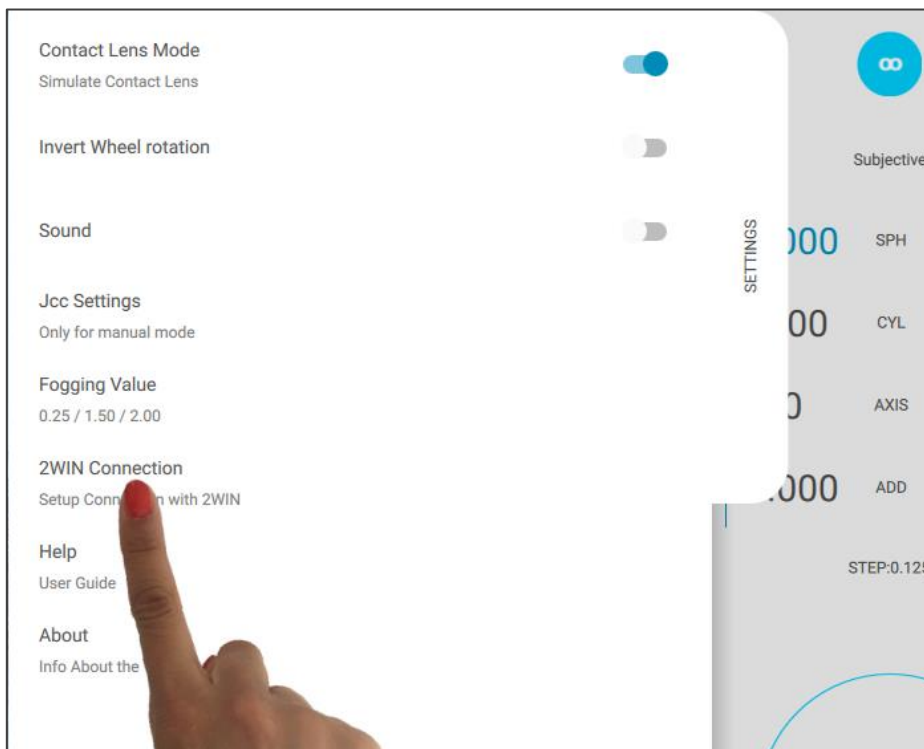
  d. A new window will appear (see the following figure). Keep it open and continue using the 2WIN.
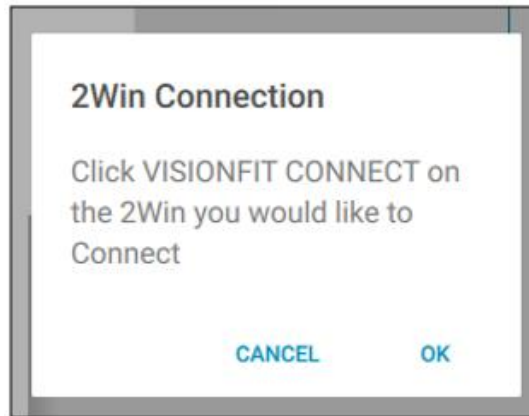
e. In the 2WIN select **VisionFit SC Connection** from Menu > Settings > Wireless > Connections > VisionFit SC Connection.

f. A new window notifying the correct pairing will be displayed.

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

 Pairing must be performed again only if you change devices (2WIN or VisionFit SC) or if you change the Wi-Fi network.

If 2WIN and VisionFit SC are paired using a Wi-Fi connection it is possible to send the objective refraction measurement from 2WIN to VisionFit SC application.

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

a. Perform a test using the 2WIN and save it. Press the joystick down in 2WIN. 2WIN data will appear instantly on the right side in VisionFit SC application (Reference data area). If the 2WIN test has already been performed, browse the 2WIN "Browsing Mode" and hold the joystick down. Data will appear in the Reference area in VisionFit SC application.

b. In VisionFit SC application open Reference area and tap on **To main** button to apply the prescription to VisionFit SC.

ⓘ **VisionFit SC application must be running on the tablet to make the measurement transfer work correctly.**

ⓘ **Not available measurement from 2WIN cannot be transferred to VisionFit SC application.**
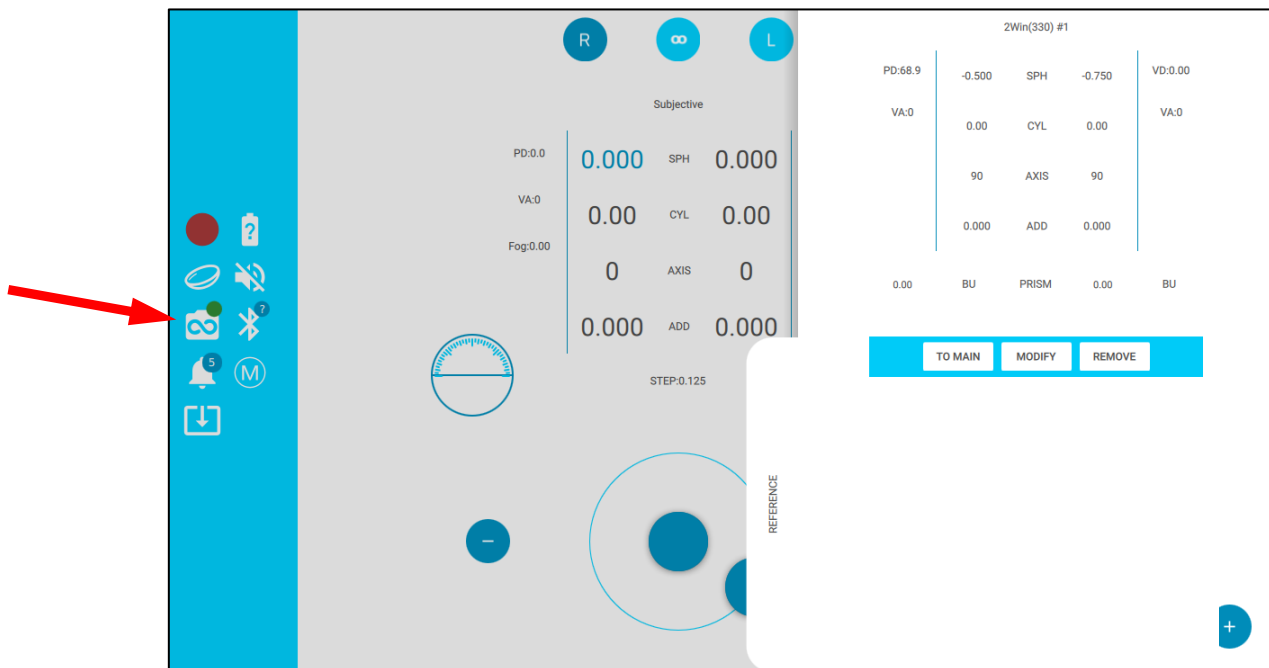
ⓘ **Green circle on the 2WIN symbol in the VisionFit SC application indicates the connection with the 2WIN is working properly.**

22.2. Pairing a 2WIN with VisionFit SC and transferring a test through a Bluetooth connection

In order to pair a 2WIN with a VisionFit SC using Bluetooth connection follow these steps:

a. Activate Bluetooth on the tablet on which the VisionFit SC application is running

b. Activate Bluetooth on 2WIN. Please refer to 2WIN Operator Manual for the istructions.

c. In VisionFit SC application settings tap on **2WIN BT/WIFI** option and set BT connection.
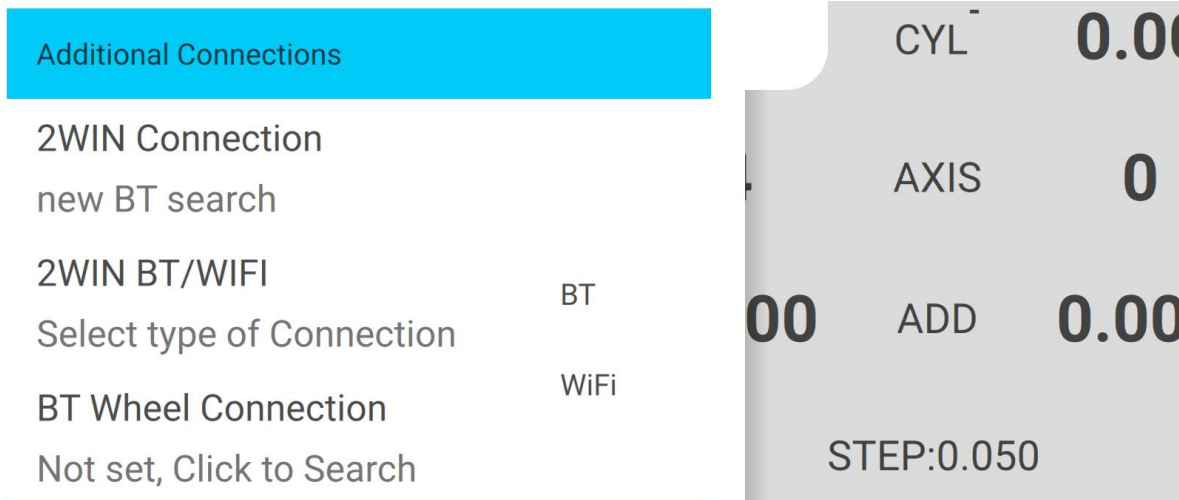
d. In VisionFit SC application settings tap on 2WIN Connection.
e. Wait until the 2WIN Connection icon becomes green.
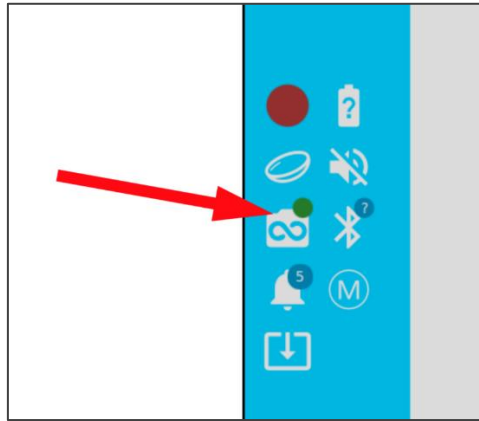
If 2WIN and VisionFit SC are paired using a Bluetooth connection it is possible to send the objective refraction measurement from 2WIN to VisionFit SC application.

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

    a. Perform a test using the 2WIN and save it.

    b. In VisionFit SC application open Reference tab and tap on the **2WIN+** icon (see figure below).
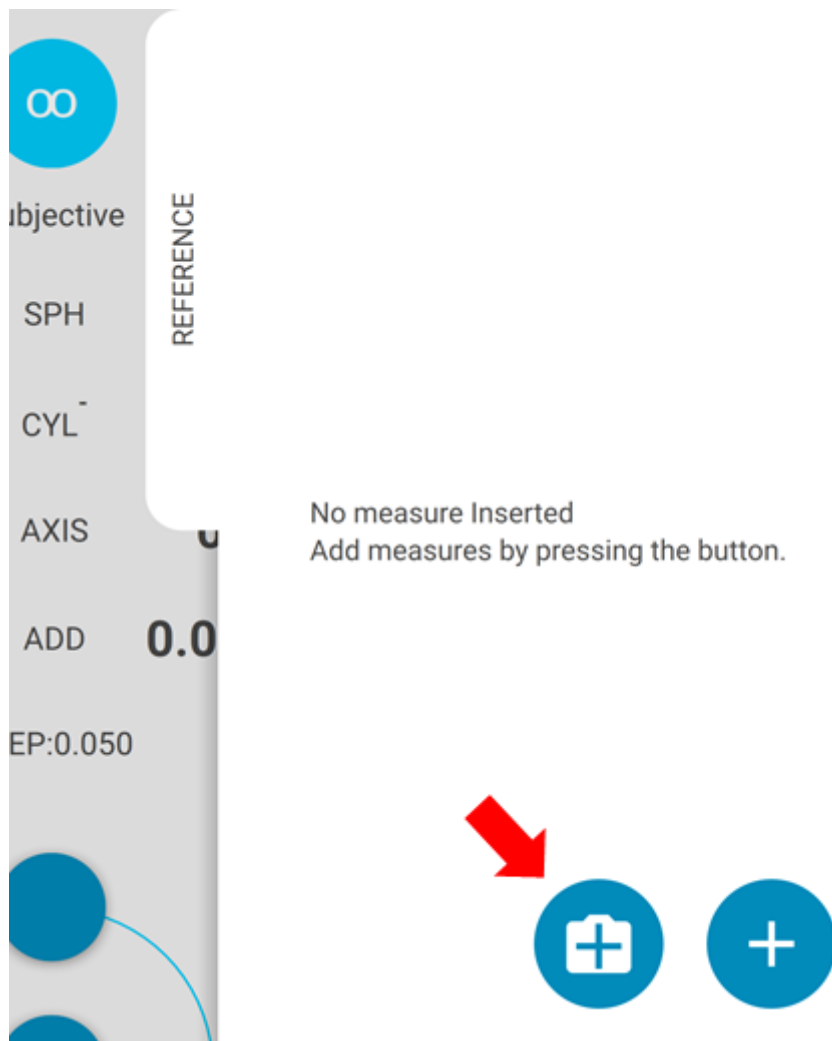
c. The exam displayed on the 2WIN screen will be transferred to the VisionFit SC application.

 VisionFit SC application must be running on the tablet to make the measurement transfer work correctly.

 Not available measurement from 2WIN cannot be transferred to VisionFit SC application.

> **Green circle on the 2WIN symbol in the VisionFit SC application indicates the connection with the 2WIN is working properly.**

23. Notification Center

This feature allows the real time monitoring of VisionFit SC messaging and logs. Two different types of notifications are reported: saved data and information on WiFi networking status and logins (IP, Netwoks, Pairing).

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

In order to see the Notification Center press the 🔔 button you can then consult the list of notifications.
In order to exit from the notification center just press out of the window.

24. Mechanical Stand for VisionFit-SC

It is possible to mount VisionFit SC in an optional mechanical stand. Follow the instructions of the mechanical stand to mount the device.

25. Maintenance

Cleaning instructions

Do not put the device in an autoclave.

Do not submerge the device in water or any other liquid.

Use only alcohol to clean the device. Do not use washing-up liquid diluted in water.

Wipe the trial frame - goggles with a clean and slightly damp microfiber cloth (a towelette is acceptable).

Wipe the cushioning of the helmet – goggles with a clean and slightly damp microfiber cloth alcohol-soaked (a towelette is acceptable). Please be careful not to use too much liquid not to soak the cushioning. When the cushioning is too dirty even after cleaning with alcohol, replace it with the spare cushioning provided in the packaging.

Instructions for correct disposal of the device

The device is made of different materials such as plastics, oil, aluminium and electronic parts. To dispose it, please separate the various materials and follow the laws and regulations regarding waste disposal or recycling for each material in your own country.

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Separate collection for electrical and electronic equipment

The European Directive 2002/96/EC establishes separate collection for Waste of Electrical and Electronic Equipment (WEEE). Users of Electric and Electronic Equipment (EEE) must not dispose of WEEE as unsorted municipal waste. It must be collected separately. The return and collection system is controlled by the local public administration, by an authorized recycling company. Please refer to your public administration about separate collection. If this information is not available, contact the device manufacturer.

Users play a fundamental role in reusing, recycling and recovering WEEE. The potentially dangerous substances contained in WEEE can pollute the environment and cause harmful effects on the human health.

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

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

26. Troubleshooting

If the device does not work correctly, check the problem according to the following table before contacting your authorized distributor.

#.	Problem	Possible cause	Solution
1	The VisionFit SC does not turn on, the LEDs do not light up.	The battery pack is not charged.	Charge the battery pack with the charger included.
2	The VisionFit SC does not turn on, the LEDs do not light up.	The battery pack is not correctly hooked.	Check the position of the battery, try to push it till the end of the stroke.
3	The third LED is red.	System Error Detected	Contact the service center, keeping at hand the serial number and software configuration version.
4	The VisionFit SC does not connect to the tablet, the second LED keeps flashing orange.	Bluetooth error	Turn on and turn off the Bluetooth of the tablet and the VisionFit SC.
5	The device does not respond to commands.	System error.	Force the device to shut down by pressing the On / Off power button for at least 6 seconds. Then turn the device on again.
6	The device does not respond to commands.	The cables are not correctly connected to the electronic box.	Connect the Goggles cables to the electronic box.
7	On the display, led for lenses is permanently red.	System error.	Contact the service center, communicating the serial number and the problem.

8	Tablet does not connect to the Wi-Fi network.	Network password entered incorrectly.	Check the password and enter all characters correctly.
9	After entering the correct Wi-Fi network password, the device still does not connect properly to a Wi-Fi network.	The device is too far away from the network router.	Move the Tablet of VisionFit SC closer to the router.
10	The Tablet and the VisionFit SC disconnect.	The Tablet is too far away from the VisionFit SC.	Move the Tablet closer to the VisionFit SC.

27. Additional information

Operating conditions

The device must be operated under the following environmental conditions:

Temperature	**10 – 35 C°**
Relative humidity	30% to 90%
Pressure	800-1100 hPa

Storage instructions

The device must be stored under the following environmental conditions:

Temperature	**-10°C to +50 C°**
Relative humidity	10% to 95%

Technical specifications

Range for spherical correction	**-10/+10 D and -20/+20 D with the use of an additional lens with prescription steps of 0.125 D and variable fluidity**

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	steps (adjustable from 0.05 to 0.25 D) with the use of the basic spherical lens.
Range for cylindrical correction	0 to 10 D by steps of 0.25 D
Range for axis adjustment	1-180° by steps of 1°
Range for facultative (additional) prismatic lenses	0 to 10 PD, steps 1 PD (add on – no automatic)
Tolerances of lenses according to ISO 10341, §4.3	
Corneal vertex distance range	10-18 mm
Manual and separated pupil distance adjustment range	50-80 mm, steps 0.50 mm, separated right and left
Device free aperture	30°
Display	colour LCD, 3.5 inches
Wi-Fi Module	Radicom- Model: WiFiHU-a
Bluetooth Module	IDATA, USB 2.0 Bluetooth Mini Class 2+EDR
Power requirement	Voltage: 100-240 VAC, 50-60 Hz Power consumption: 60 VA

Weight
Trial frame/Google: 250gr
Headband: 250gr
Battery packs: 300gr
VisionFit SC: 800gr

Dimensions

Trial frame/Goggles: = 200 mm x 120 mm x 120 mm

Headband: 300 mm x 150 mm x 180 mm
VisionFit SC: 300 mm x 200 mm x 200 mm

In flight use

Do not use the device during a flight.

Device warranty

The device has a 1- year warranty.

28. Information for user service requirements

For any service requirements, please contact your distributor, or contact:

Adaptica Srl
Via San Marco 9/H - 35129 - Padova (Italy)
Tel. +39 049 773968
Fax +39 049 097 0901
email: contact@adaptica.com

Note only for service personnel

Adaptica can provide, on request, circuit diagrams, component part lists, descriptions, calibration instructions or other information that will assist service personnel in repairing those parts of the equipment that are designated by Adaptica as repairable by qualified service personnel.

29. Appendix A: Disclaimer

29.1. English Language

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

We hereby inform that the utilisation of the VisionFIT 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 the application that controls it. 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 IP addresses, the geographical position at national level of the instrument, the serial number of the instrument, the registration number, the device's identification code, the software version, the firmware version and the number of observations carried out, The sole purpose of the Telemetry Data processing is to enable Adaptica S.r.l. to constantly monitor the efficiency of the proposed service based on the utilisation of the VisionFIT instrument. Furthermore, Adaptica S.r.l. may, once a temporary session has been activated by the user, connect to the VisionFIT 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**").

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 eyeglass and enable Adaptica S.r.l. to check its functioning and/or carry out particular procedures. The processing of the Telemetry Data and the Remote Control Data will take place mainly through electronic (or in any case automated), IT and telematic instruments, and will be memorised on IT devices, following criteria strictly correlated to the aforementioned purposes, in compliance with the minimum security provisions contemplated by Art. 34 of the Privacy Code and by Schedule B thereof and, in any event, in such a way as to ensure the security and confidentiality of such Telemetry Data and Remote Control Data. If the Telemetry Data are not transferred, it will not be possible to download the software update for the VisionFIT instrument. The autonomous owner ("*titolare autonomo*") of the Telemetry Data and the Remote Control Data is Adaptica S.r.l., a company with its registered office in Padua, Via San Marco 9/H.

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

Finally, Adaptica S.r.l. informs that the law grants all the Parties Concerned the specific rights that are set out in Article 7 of the Privacy Code; purely by way of example and without limitation, these include the right to ask for, and obtain, confirmation of whether or not Telemetry Data of one's own exist and to ascertain their origin; the purposes and

modalities of the processing; and the updating, rectification and, where required, integration of the said Telemetry Data. The Parties Concerned may also, within the limits imposed by the law, ask for any inexact or incomplete data to be corrected, updated or integrated and, for Telemetry Data processed in breach of the law, to be cancelled or blocked, or oppose their utilisation for justified reasons which must be indicated in the request (pursuant to Art. 7 of the Privacy Code).

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

Place and Date

_____

Signature of the declarant (legible and written in full)

_____

29.2.   Italian Language

Informativa di Adaptica S.r.l. ai sensi dell'articolo 13 del decreto legislativo 30 giugno 2003, n. 196 (il "Codice Privacy")

Con la presente si informa che l'utilizzo dello strumento VisionFIT comporterà il trattamento di alcuni dati relativi allo stato operativo del medesimo (i "**Dati di Telemetria**"), che verranno acquisiti dai sistemi informatici e dalle procedure software preposte al funzionamento di questo strumento ogni qual volta esso si connetterà all'applicazione che lo controlla. Si tratta di informazioni non raccolte per essere associate a interessati identificati, ma che per loro stessa natura potrebbero, attraverso elaborazioni e associazioni con dati detenuti da terzi, permettere di identificare gli utenti (di seguito gli "**Interessati**"). Tra i Dati di Telemetria rientrano gli indirizzi IP, la posizione geografica a livello di nazionalità dello strumento, il numero seriale dello strumento, il numero di matricola, il codice identificativo del dispositivo, la versione software, la versione firmware e il numero di rilevazioni effettuate. La finalità del trattamento dei Dati di Telemetria è esclusivamente quella di consentire ad Adaptica S.r.l. di monitorare costantemente l'efficacia del servizio proposto attraverso l'utilizzo dello strumento VisionFIT. Inoltre, Adaptica S.r.l. potrà, previa attivazione da parte dell'utente di una sessione temporanea, connettersi allo strumento VisionFIT e ottenere parametri, di natura prettamente tecnica, relativi alla movimentazione e salute delle parti meccaniche, elettroniche e firmware (i "**Dati di Remote Control**").

Adaptica S.r.l. informa altresì che i Dati di Telemetria e i Dati di Remote Control non contengono informazioni sensibili relative agli utilizzatori, saranno trattati esclusivamente nell'ambito della normale attività, secondo le finalità legate al perseguimento dell'oggetto sociale di Adaptica S.r.l. stessa, e saranno conservati da tale azienda. I Dati di Telemetria saranno utilizzati al solo fine di ricavare informazioni anonime sull'uso dello strumento e per controllarne il corretto funzionamento. I Dati di Remote Control saranno utilizzati al fine di fornire assistenza da remoto all'occhiale e permettere ad Adaptica S.r.l. di controllarne le funzionalità e/o di svolgere determinate procedure. Il trattamento dei Dati di Telemetria e dei Dati di Remote Control avverrà principalmente mediante strumenti elettronici (o comunque automatizzati), informatici e telematici, e saranno memorizzati su supporti informatici, con logiche strettamente correlate alle finalità sopra menzionate, nel rispetto delle misure minime di sicurezza previste dall'art. 34 del Codice Privacy e dall'Allegato B al medesimo e, comunque, in modo da garantire la sicurezza e la riservatezza dei Dati di Telemetria e dei Dati di Remote Control stessi. Il mancato trasferimento dei Dati di Telemetria comporterà l'impossibilità di scaricare l'aggiornamento software per lo strumento VisionFIT. Titolare autonomo del trattamento dei Dati di Telemetria e dei Dati di Remote Control è Adaptica S.r.l., con sede legale in Padova, Via San Marco n. 9/H.

I Dati di Telemetria e i Dati di Remote Control potranno essere comunicati al Garante per la protezione dei dati personali e alle altre autorità governative e regolamentari che eventualmente ne abbiano titolo, in conformità alle norme di legge e/o

regolamentari applicabili, ai consulenti e professionisti, alle società di servizi e a tutti gli altri soggetti cui tali comunicazioni devono essere fatte ai fini dello svolgimento dei servizi e per l'esatto e diligente adempimento degli obblighi contrattuali e imposti dalla normativa vigente. In ogni caso, i Dati di Telemetria e i Dati di Remote Control non saranno oggetto di diffusione. L'elenco completo e aggiornato dei soggetti ai quali i Dati di Telemetria e i Dati di Remote Control possono essere comunicati e di quelli che ne possono venire a conoscenza in qualità di responsabili del trattamento (i "**Responsabili**"), unitamente alla presente informativa, saranno messi a disposizione presso la sede legale di Adaptica S.r.l.

Adaptica S.r.l. informa, infine, che la legge attribuisce a ciascuno degli Interessati gli specifici diritti di cui all'articolo 7 del Codice Privacy; a mero titolo esemplificativo e non esaustivo, il diritto di chiedere e ottenere la conferma dell'esistenza o meno di propri Dati di Telemetria, di conoscere l'origine degli stessi, le finalità e modalità del trattamento, l'aggiornamento, la rettificazione nonché, qualora vi abbiano interesse, l'integrazione dei Dati di Telemetria medesimi. Gli Interessati possono altresì, nei limiti imposti da legge, richiedere la correzione, l'aggiornamento o l'integrazione dei dati inesatti o incompleti, ovvero la cancellazione o il blocco per i Dati di Telemetria trattati in violazione di legge, o ancora opporsi al loro utilizzo per motivi legittimi da evidenziare nella richiesta (ai sensi dell'art. 7 del Codice Privacy).

☐ Dichiaro di aver letto l'informativa privacy riportata sopra e autorizzo espressamente il trattamento dei Dati di Telemetria e dei Dati di Remote Control per le finalità ivi descritte e per l'adempimento degli obblighi contrattuali e di legge, ai sensi del Decreto Legislativo 30 giugno 2003, n. 196 "Codice in materia di protezione dei dati personali"

Luogo, Data

_____

Firma del dichiarante (leggibile e per esteso)

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