VISION-R™ 800

ESSILOR INSTRUMENTS

User manual

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I. Introduction

The complete user manual is available on a web space.

To access other available languages, please scan the QR code available at the end of this user manual > QR Code Chapter (☞ p.94).

1. Main features of the refraction head

Vision-R™ 800 (V01) is an automated phoropter that enables you to perform a refraction test. Its function is to determine optical correction (or compensation), thereby providing examinees with optimal vision conditions.

This part of the eye examination is commonly referred to as **subjective refraction,**because it refers to the patient's responses. In the majority of cases it is performed using preliminary data which may come from:

- The old correction performed using the focimeter,
- From a measurement of the objective refraction using an auto--refractometer, an aberrometer or a skiascope/retinoscope,
- The old correction archived in an patient file,

The results obtained from the patient's responses allow the expert to determine the refraction and prescribe the optical compensation (or another form of assistance) required for the patient's good vision.

Since this is a so-called "automatic" head, its integration into the examination environment also includes the control of the test projection systems from the same control panel.

The patient's subjective refraction is made possible by intercalating an optical correction or a diopter compensation and/or filters in front of the patient's eyes.

It allows measurements to be taken under monocular or binocular vision conditions and allows the binocular vision examination to be performed.

The instrument allows the user to carry out continuous variations of optical characteristics (sphere, cylinder, stem, prism).

2. Instrument classification

Vision-R™ 800 is a class I and B-type medical instrument without measuring functions in accordance with directive 93/42/CEE, amended by directive 2007/47/CE. The design and manufacture of this instrument have meticulously taken care of in terms of ease of use, patient safety and reliability.

It is marked CE.

Date of first marking 2018. Its estimated minimum lifetime is 7 years.

For a safer, more effective use, however, follow the instructions outlines in this handbook.

This instrument is intended for medical use and can only be used with the instruction of visual health expert authorized by the laws in force in the country concerned.

This device complies with the restrictions imposed by section 15 of the FCC regulation. Its use meets the following conditions: (1) this device must not cause interference and (2) must accept interference from external sources, notably that are liable to cause malfunctions.

Those limits are set so as to ensure reasonable protection against interference in a residential environment. This device generates, uses and can emit radio frequency energy, which may interfere with radio communications if the device is not installed and used in strict conformity with manufacturer instructions. However, there is no guarantee that there will be no interference in certain conditions. You can confirm that this device is the source of interferences with radio or television reception by turning the device on and off.

In accordance with the requirements of FCC rules, any modification made to this equipment which is not expressly approved by the manufacturer would nullify the user's right to use this device.

3. Symbols used

On the instrument

	Performing an improper operation due to non-compliance with this information could result in serious injury.
	Failure to heed this symbol may result in personal injury and injury.
	Indicates a general prohibition.
	Obligation to refer to the operating manual.
	Important and/or useful information related to the text in this manual.
	Alternate current
	D.C. current
	Applied, type b parts.
	Manufacturer
	Manufacturing date (year).
	Compliant with FCC standards
	Waste disposal symbol in accordance with Directives 2012/19/EU and 2011/65/EU
I	ON = Turned-on (power supply connected to the mains)
O	OFF = Turned-off (power supply disconnected from the mains)

On the packaging

	Handle carefully.
	This way up.
	Maximum stacking of 4 products above market product.
	Fragile
	Keep dry
	CE Marking (European regulation relating to medical devices).
	Indicate the thermal limits to which the medical device can be exposed in complete safety.
	Indicate the humidity limits to which the medical device can be exposed in complete safety.
	Indicate the limits of atmospheric pressure to which the medical device can be exposed in complete safety.

4. Copyright

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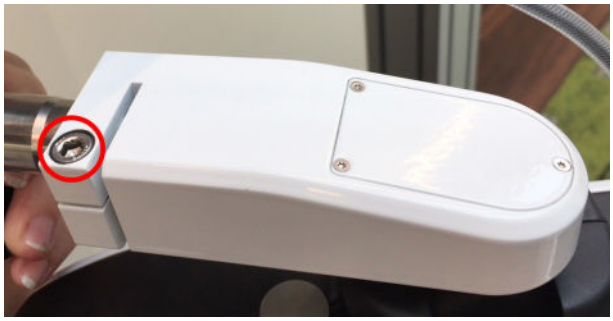
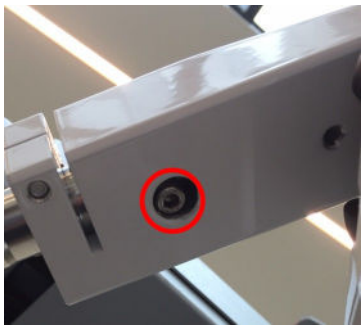
5. Confidentiality of patient data

The instrument is a system that can save, store and share relative information with the patient such as refraction measurements, name or photo. It is the device user’s responsibility to comply with patient data confidentiality regulations, applicable on their site.

II. Instrument

1. Instrument inspection

- Regularly inspect the instrument to ensure that it is assembled correctly and the console is properly connected from the head to the power module.
- Check the tightening of the M6 screw that attaches the head to the phoropter arm.
- Check the tightening of the M5 safety screw (through screw in the phoropter arm).
- If the cover is dirty, gently wipe it with a soft, slightly damp cloth. Wipe any stubborn stains with a little water or neutral detergent.

M6 screw (located above)	M5 screw (located below)
	

2. Checking the accessories

While unpacking, check that the following standard accessories are included.

Standard accessories

- Communication cables:
  - 1 electric cable running to the refraction head (2 m) with 1 extension (3 m)
  - 1 electric cable running to the console (7 m), attached to the console
  - 1 CBOX cable network running to the local area network
- Power cable (2 m)
- Face shield (x2)
- Forehead rest (x1)
- Near vision test chart (x1)
- Near vision chart support bracket (x1)
- Screw attachment of the head M6 (x1) and screw of safety M5 (x1)
- 6 side Allen wrenches M4 (x1) and M5 (x1)
- 2 protective covers (refraction head and console)
- 16 Gb USB key
- Quick start guide (x1)

Optional accessories

- Printer
- Printer paper (x5)
- C-Plug

Vision-R™ 800 is entirely compatible and designed to work with the CSPOLA600 and the CBOX test presentation screens (with an Ethernet adaptor).

3. Installation and connection

This instrument must be installed by a specialized technician. To install the instrument or to change its connection, please contact your Essilor dealer.

Installation precautions

Respect the precautions below:

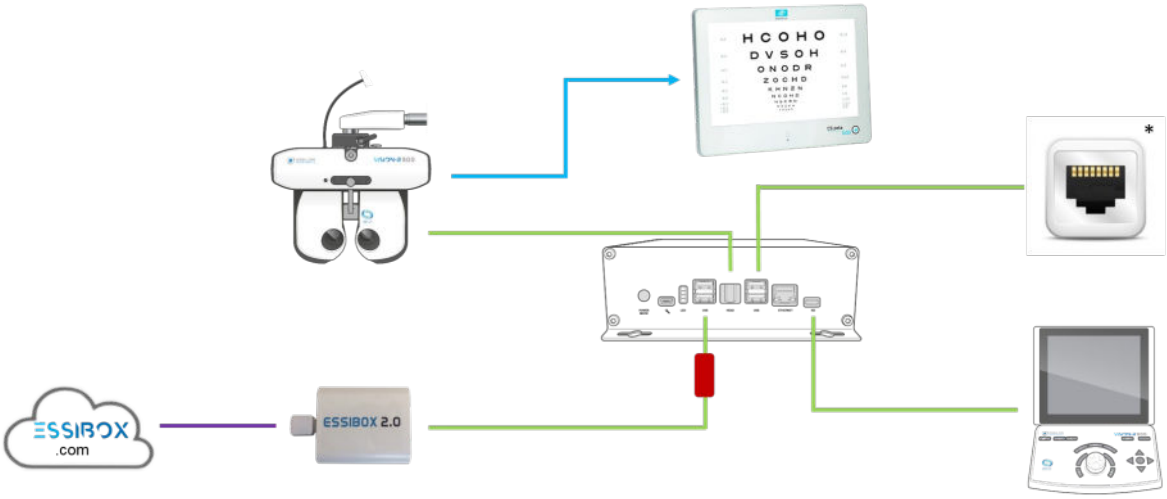
- Do not install the instrument in a place:
  - where dust or dirt accumulates,
  - directly exposed to the light rays,
  - oxygen rich,
  - displaying extreme temperatures and humidity levels,
  - likely to undergo strong oscillations or sudden shocks.
- The instrument of should not be used with flammable anaesthetic products or inflammable products.
- The instrument should not fall; that would likely cause malfunctions. If it does fall, the instrument could also crush your body or feet.
- Do not place your hand between the mounting arm and the instrument. You could get your hand wedged.
- To avoid any risk of injury, be careful when installing or using the near-vision support bracket.
- To avoid any risk of electrocution, do not open the cover. Consult your dealer for all repairs.

a. Installation

1 Position the mounting arm to the phoropter head and attach it using the fixing screw (6-sided key).

To prevent the phoropter head from falling, fasten it with the screw located below the arm of the head.

b. Connection



With:

- Cable connection
- Infra-red connection
- Web connection
- Adapter
- * Wall plug RJ-45

4. Transport

1 Unplug the instrument.

2 Remove the support and near-vision card from the head.

3 Put the forehead rest as close to the refraction head side as possible.

4 Place the arm in the same orientation as the phoropter head.

5 Place the instrument in far vision (convergence to 0).

6 Loosen the M5 screw (safety screw) then the M6 screw (attachment screw).

5. Identification and locating of the elements

a. Complete unit

The main components that make up the Vision-R unit™ 800 are:

- A refraction head
- A console
- A power supply unit,

b. Refraction head

1. *Tilt blocking lever*

Used to adjust the tilt angle (near vision position) and block it.

2. *Near vision test support rod hook*

Used to position the near vision test chart support rod.

3. *Near vision camera*

4. *Horizontal adjustment knob*

Used to adjust the horizontality of the refraction head.

5. *LED panel*

Used for:

- Adjust the horizontality of the head and to illuminate the near-vision card.
- Call up the tests display on the screen.

6. *Forehead rest adjustment knob*

Used to adjust the vertex distance by advancing or moving back the forehead rest.

7. *User-side observation windows*

Patient eyes observation side.

8. *Patient side observation windows*

Patient side: front area where the patient is positioned and through which he or she looks during the eye test.

9. *Forehead rest*

Area on which the patient's forehead must rest during the test.

Applied part.

10. *Movable face shield*

Area which may be in contact with the patient's cheeks.

Applied part.

11. *Measurement cameras for lens-eye distance*

Used to measure the lens-eye distance of the patient and to light up their eyes if necessary during the pupillary distance adjustment.

12. *Rotation axis*

360° rotation movement, during the handling of the instrument.

c. Console

1. *Touch screen*

2. *Touch [Clear]*

Used for:

- Resetting the current session (quick press).
- Turning the instrument on or off (long press).

3. *Keys [Import/export]*

Used for importing and exporting the patient's refraction data.

4. *Touch [Far vision/Near vision]*

Used for changing to far-vision mode or near-vision mode .

5. *Touch [Bluetouch]*

Used for comparing different refraction measurements and rendering the data.

A LED blue around the key helps to visualize it better .

6. *Buttons [R/BINO/L]*

Used for selecting the vision condition:

- Monocular right eye (R) by de-selecting and blocking out the left eye.
- Monocular left eye (L) by de-selecting and blocking out the right eye.
- Binocular (Bino)

7. *Keys [+/-]*

Used for increasing or decreasing the power values.

- Key "+": allows you to increment the positive power values.
- Key "-": allows you to increment the negative power values.

8. *Keys [Position 1/Position 2]*

Used for:

- Navigating through the list of variation steps of the selected optical setting
- Introducing one of the two positions of the cross cylinder while performing the cross-cylinder test

9. *Central button*

Used for:

- Modifying (+), the power values via rotation of the central button
- Navigating through the controlled settings (e.g. S, C, A) by pressing the central button

10. *Acuity navigation buttons*

Used for:

- Navigating through the acuity charts (changing the size of the letters, charts, lines or columns) and saving the answers.
- Navigating in the answers of the dissociated tests
- Confirming the answers of the dissociated tests with the middle button

There are two USB ports located on the side of the console.

To avoid pinching injuries when moving the monitor, please do not put your hand between the monitor and the main unit.

d. Power supply box

1. *Start-up mode*

- Position 1: turning on the refraction head by pressing on On/Off with the console.
- Position 2: turning on the phoropter head using the ON/OFF switch on the power supply box.

2. *Service technician socket*

3. *Information indicator lights*

4. *USB port*

5. *Refraction head connection port*

Used for the connection to the phoropter head.

6. *USB port*

7. *Ethernet port*

8. *Console connection port*

Used for the connection to the console

9. *On/off switch*

Network isolation switch.

10. *Power cable socket*

To avoid any risk of electrocution, do not open the cover. Consult your dealer for all repairs.

e. Main screen

1. *Access to the main menu*

Permits access to the instrument configuration screens.

2. *Optotypes, tests*

Used to display the various categories of types of tests (manual or automatic), associated optotypes and programs.

3. *Configuration for the set up of the patient*

Used to check and manage:

- The inter-pupillary distance.
- The lens-eye distance.
- The far vision or near vision mode.
- To apply filters or masks to the eyes of the patient.
- To modify the steps of the current setting.
- To lock an eye.

4. *Controlled parameters*

Used to select and modify the values of the presented optical settings.

5. *Visualization of the current test.*

Used to visualize, personalize the test in progress and to include the answers of the patient.

6. *Management of the patient data and user help display*

Allows you to:

- Manage the patient data.
- Display and call up memorized data.
- Display the contextual assistance.

III. Basic settings for performing an examination

1. Adjustments before the examination

a. Configure the instrument

Turn on the instrument

1 During the first power up of the instrument, press on the ON/OFF key on the power supply unit.

For future instrument use, the power unit can stay turned on.

In this case, go directly to step 2.

2 Press on the ON/OFF key [Clear] on the console keyboard.

> The system is initialized (refraction head and console).

This may take up to one minute.

3 Then, press the ON/OFF button on the presentation screen.

> The instrument is ready to be used.

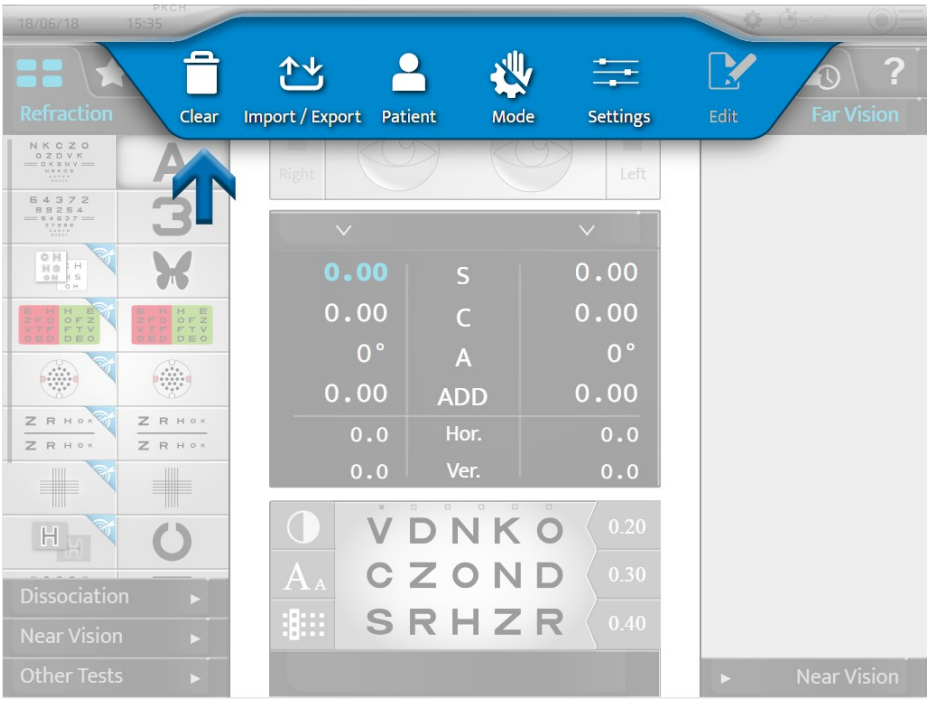
Set the instrument data to zero

At the end of each examination, it is possible to set the instrument data to zero. The expert can then start a new session with a new patient.

Restoring the instrument data can be carried out:

- On the console keyboard, by quickly pressing on the key [Clear].

- On the touch screen, by pressing on > .



The restoring of the patient data does not cause the instrument to turn off.

<u>Pass from the manual mode to the automatic mode</u>

Passing from manual mode to automatic mode can be carried out on the touch screen by pressing on:

- > or,
- (displayed by default).

Once the mode is chosen, the display of the upper strip changes:

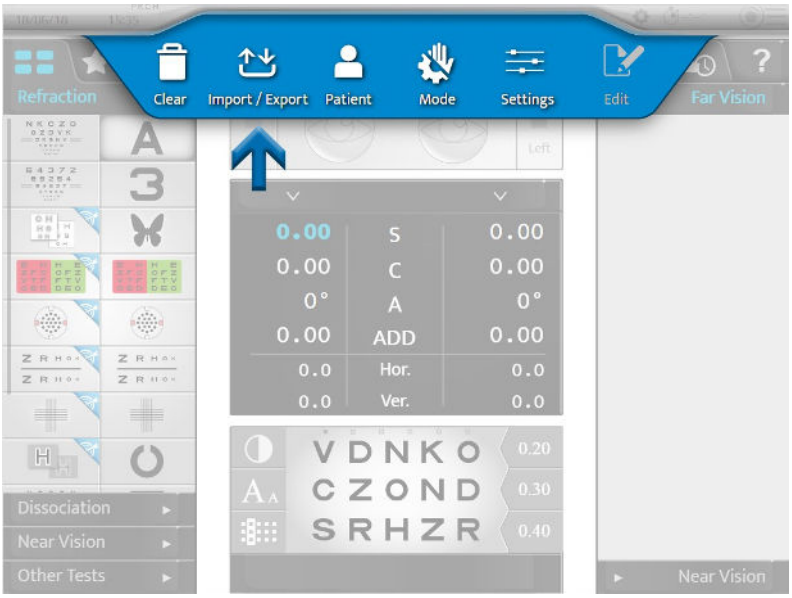
- for manual mode.
- for automatic mode.

Import and export data

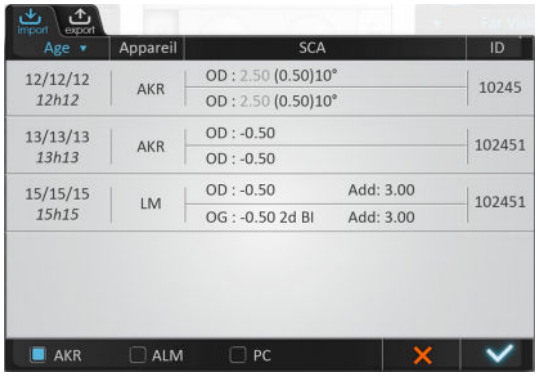
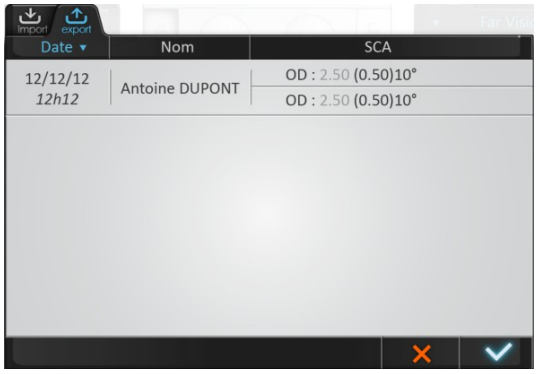
The importing and exporting of the instrument data can be carried out:

- On the console keyboard, by pressing on the [Import] or [Export] keys.

- On the touch screen, by pressing on > .



Once import or export has been selected, the corresponding windows open:

Import	Export
	

It is possible to choose to display the data coming from a:

- AKR (Auto-kerato-refractometer)
- ALM (Focimeter)
- PC (Computer)

The data is saved automatically in the corresponding memory.

Press:

- to confirm the importing or the export of the data.
- to cancel the importing or the export of the data.

You can select several types of products.

b. Setting up the patient

Adjusting the inter-pupillary distances

Before adjusting the distances, position the refraction head in front of the patient's eyes and ensure that the patient is comfortably seated. The test projection screen must be in the middle of his/her field of vision.

The adjustment of the inter-pupillary distances is carried out via the console touch screen by pressing on .

> The reticles are placed in front of the patient's eyes and the right and left distance values are displayed.

It is possible to regulate the pupillary distances in far vision and near vision.

The value:

- Of an eye corresponds to monocular half PD,
- Of the two eyes corresponds to the total binocular distance.

By default the step is 1 mm for the total distance.

The adjustment of the inter-pupillary distances can be carried out on the console:

- By turning the central button clockwise or counterclockwise.

- By pressing on the keys [+/-].

Adjusting the horizontality of the refraction head

Horizontality adjustments are performed manually by using the knob located on the top of the refraction head.

In pupillary distance mode , the LEDs placed on the front of the head provide an indication of its horizontality. If:

• when both LEDs are lit up, the adjustment is correct.	
• when only one of the LEDs flickers or if a LED is not lit up, it is necessary to adjust the horizontality by using the adjustment knob.	

Regulate the forehead rest

The forehead rest adjustment is performed manually thanks to the knob located on the front of the head of refraction.

Correct installation must:

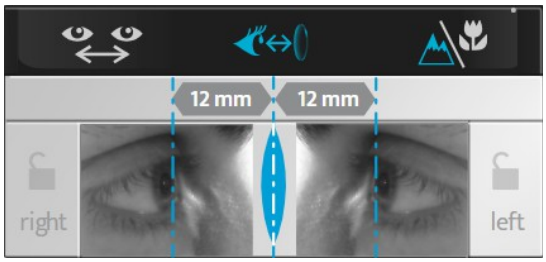
- Allow the patient to have a comfortable posture which guarantees his or her stability throughout the examination.
- Preventing the patient from being in contact with optics (lashes for example).

Adjustment of the forehead rest affects the lens-eye distance. So, it is better to place the refraction head as close as possible to the patient's eyes.

Check the lens-eye distance

The inspection of the lens-eye distance is performed on the touch screen by pressing on .

> Images of the patient's right eye and the left eye appear at the top of the console screen.



> Adjust the position of the vertical lines on the corneal apex of each eye using the central button or the incrementation keys (+/-) on the console keyboard.

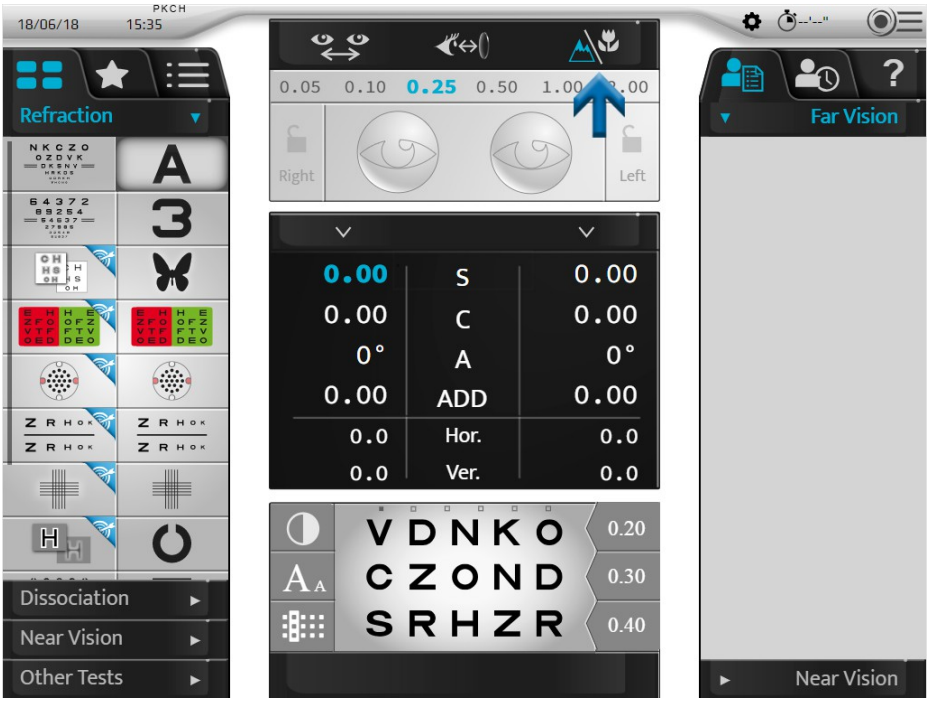
The lens-eye distance can be modified by adjusting the forehead rest using the knob located on the front of the refraction head.

Going from far-vision mode to near-vision mode

Going from far-vision mode to near-vision mode can be performed:

- On the console keyboard, by pressing on the key [NV/FV].

- On the touch screen, by pressing on .



The icon corresponding to the selected mode is displayed in blue on the interface:

- for far-vision mode.
- for near-vision mode.

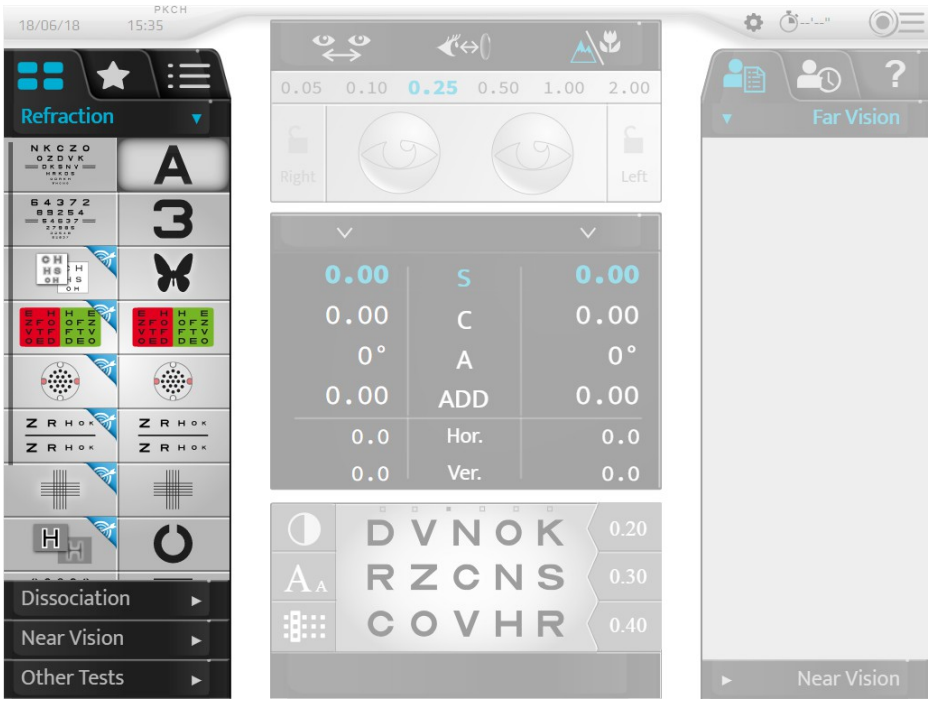
Far vision	Near vision

Switching to near vision mode modifies, the inter-pupillary distances, the convergence of the refraction head and the lighting up of the LEDs.

2. Basic functions for performing a refraction examination

a. Choose a test

The choice of the tests is done on the left part of the main screen.



Several test formats are available. You can press on:

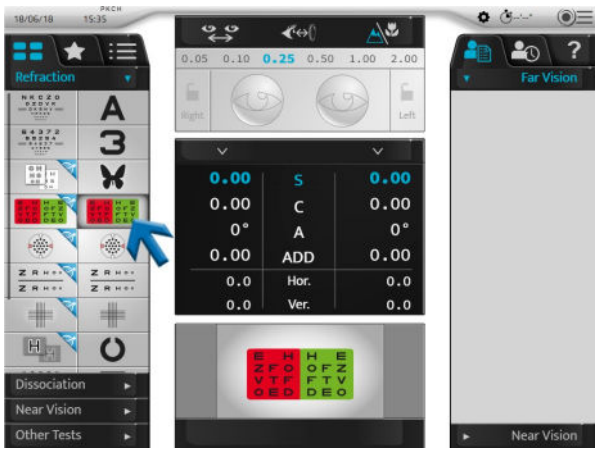
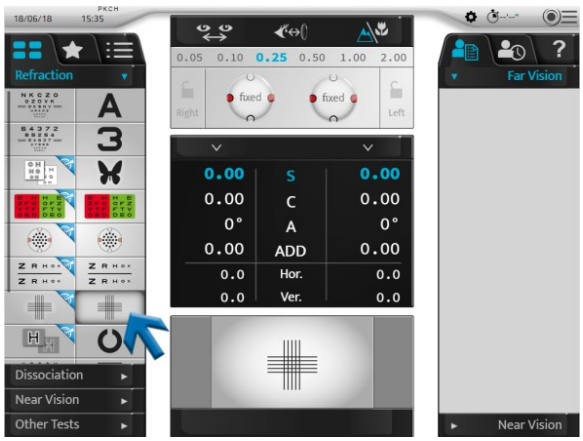
- to access the list of tests available,
- to access the pre-selected favourite tests,
- to access the standard or personalized test programs.

<u>Select a test</u>

Press on the icon of the test that you want to start. A visualization of the test is displayed at the bottom of the main screen.

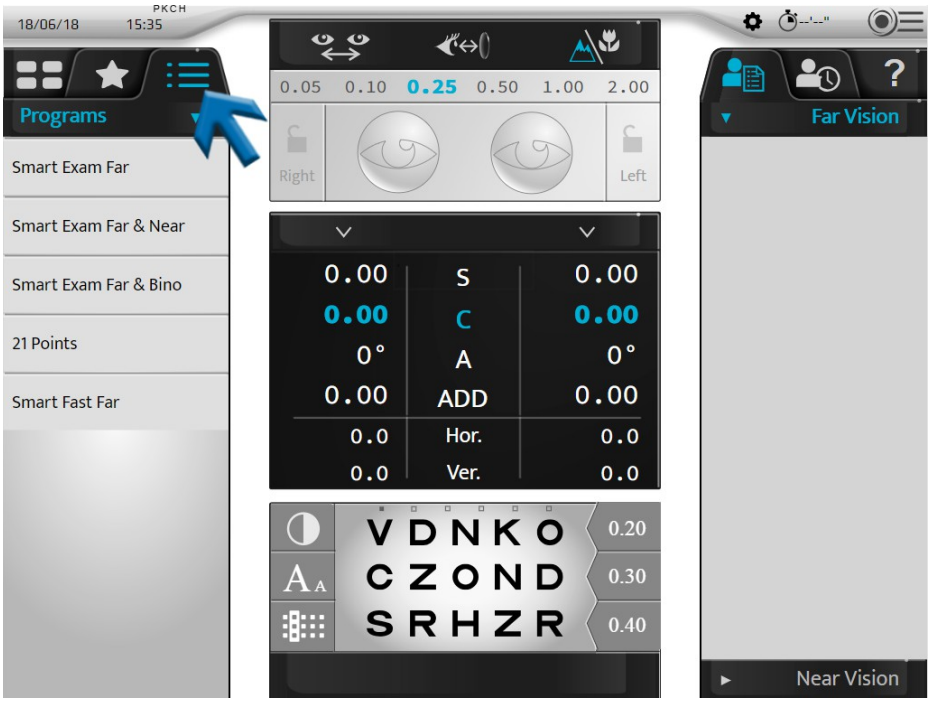
When you select a test, the controlled settings as well as the applied filters are automatically modified. If you wish to deactivate this function, go into manual mode on the touch screen by pressing on:

- > or,
- (displayed by default).

Red/Green test example	Acuity test example
	

Start an existing test program

1 Press on the icon of the test program .



> The list of available test programs is displayed.

2 Select the program that you wish to use.

> The test program is displayed and the first test is set up automatically.

You can: • Follow the program's progression on the progression bar. • Leave the program at any time by clicking on [STOP]. • Go to the following test by pressing on: ◦ the associated icon, ◦ on [NEXT] in the case of smart tests.	

If you wish to select a test outside the program in progress, press on the test list or favorite tests icons.

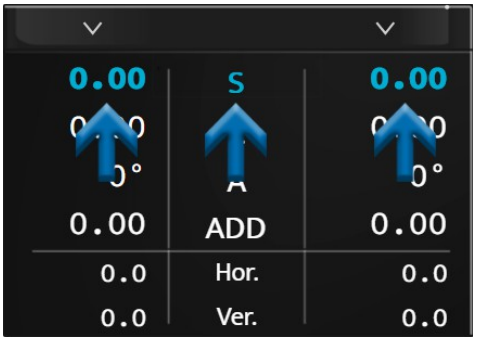
It is possible to return to the running program by pressing on the corresponding icon.

b. Checking the optical module

Changing the checked eye

Selecting the examined eye can be done:

- On the touch screen by selecting:
  - the power of the right eye or the left eye, for the separate inspection of each eye or,
  - on the settings (S, C, A, ADD, Hor., Ver.) for the simultaneous inspection of both eyes.

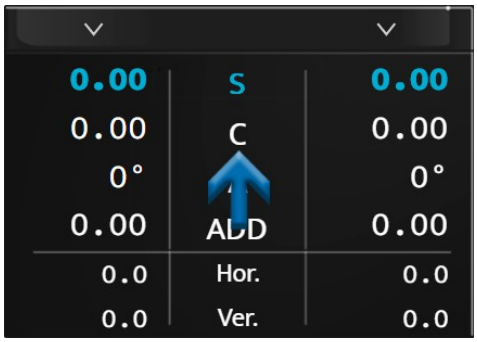


- On the console keyboard, by pressing on the keys [R, BINO, L].

Change the controlled settings

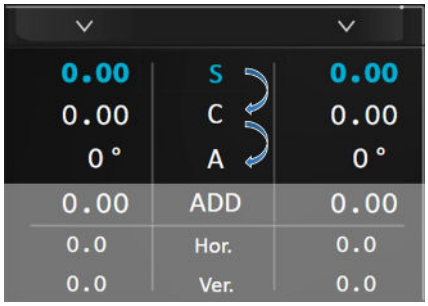
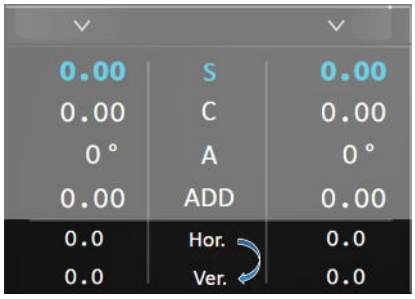
Moving from one controlled setting (S, C, A, ADD, Hor., Ver.) to another can be carried out:

- On the touch screen, by pressing on the setting that you wish to check (on the value of the right eye or the left eye or on the setting).



- On the console keyboard, by pressing on the central button.

Depending on the instrument's status, the operation can be carried out in various ways:

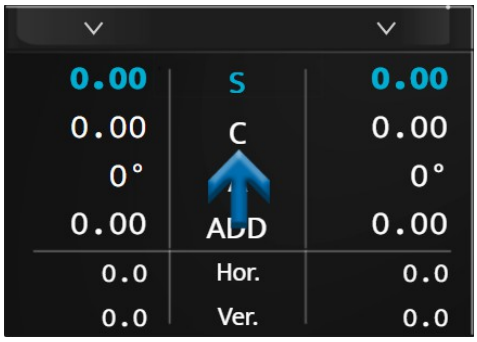
Far vision	Near vision	Prism
		

Modify the power and the incrementation steps

Modify the power

The modification of the power can be carried out:

- On the touch screen, by pressing a second time on the desired controlled setting.



> In this case a numeric keypad is displayed. Enter the desired value and confirm .

Once input is complete, do not forget to save the initial prescription in the memory of your choice.

- On the console keyboard:
  - by turning the central button clockwise or counterclockwise, or

  - by pressing on the keys [+/-].

Example:

If you wish to modify the sphere (S), it is possible to modify the values of the right eye or the left eye independently, or both at the same time by selecting "S" directly.

<u>Modify the incrementation steps</u>

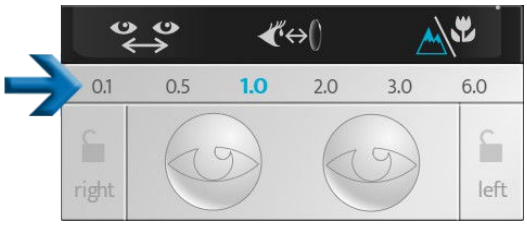
Three step variation choices are configurable:

1. Sphere and cylinder variation step
2. Axis variation step
3. Prim variation step

The value is displayed in the upper blue strip and depends on the active setting.

The unit and the step value depend on this setting. The modification of the incrementation step can be carried out:

- On the touch screen, by selecting the desired step value.



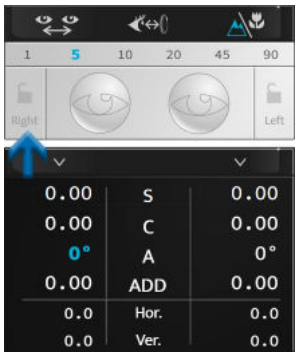
- On the console keyboard, by pressing on the keys [1 and 2].

According to the controlled settings, the values are not the same:

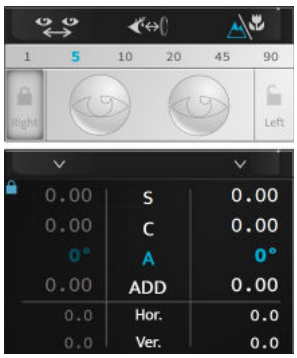
- The sphere (S), the cylinder (C) and additions (ADD) are displayed in diopters and are adjustable to 0.05, 0.10, 0.25, 0.50, 1.00 or 2.00 R.
  > By default, the step is 0.25 R.
- The axes (A) are displayed in degrees and are adjustable to 1°, 5°, 10°, 20°, 45° or 90°.
  > By default, the step is 5°.
- The prisms (Hor. and Vert.) are displayed in prismatic diopters and are adjustable to 0.1, 0.5, 1.0, 2.0, 3.0 or 6.0 R.
  > By default, the step is 1 R.

Value locking function

The value locking function is useful if you wish to lock in different values. To do this, press on the lock icon.



The icon of a closed lock is displayed, the values are grayed and cannot be modified any more.



To unlock the values, press on the lock icon again.

c. Mask an eye and check the filters

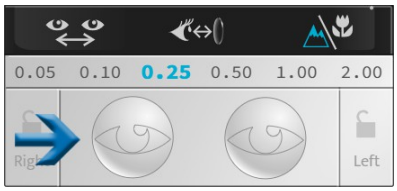
Check the masks

Press on the eye which you wish to mask.

> The mask is applied automatically in front of the eye of the patient.

The mask can be:

- A black mask.
- A spherical power, in this case a lens of this power is applied in front of the eye of the patient.
  > The value of this is displayed on the selected eye.

Selecting the eye to be masked	Example of black mask	Example of power mask
		

The mask set up is automatic during the automated refraction tests, contrary to the dissociated tests.

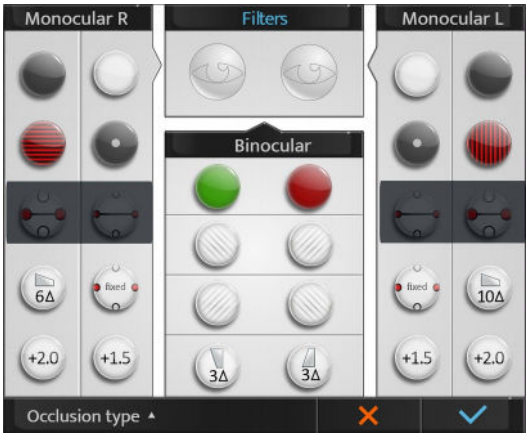
If you wish to deactivate this function, go into manual mode on the touch screen by pressing on:

- > or,
- (displayed by default).

Check and modify the filters

To personalize the filters to be applied in front of the eyes of the patient, press and hold on one of the two eyes.

A window opens:



You can select the different filters:

- Monocular, separate right eye and left eye,
- Binocular with filter couples.

The action is manual. If filters are applied for a test, the adjustment is temporary up to the start of a new session.

The selected filters are displayed in the top part of the window.

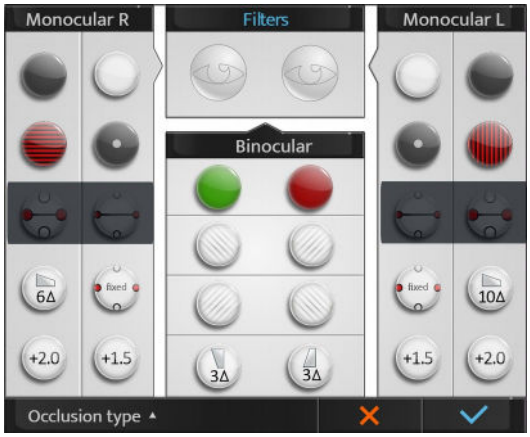
Once this is done, press on:

- to confirm the selection.
- to cancel.

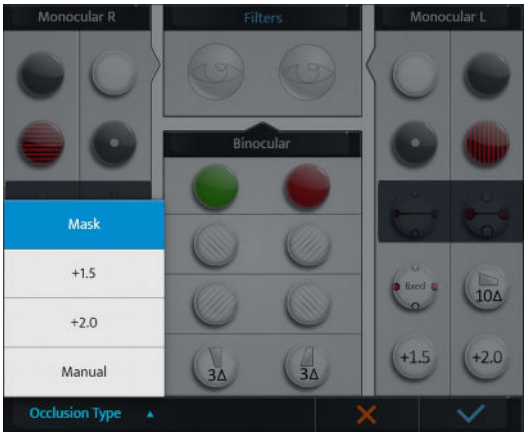
Modify the type of occlusion

To personalize the type of occlusion to be applied in front of the unchecked eye, press and hold on one of the two eyes.

A window opens:



Press on [Occlusion type] and select the desired type of occlusion from the list:

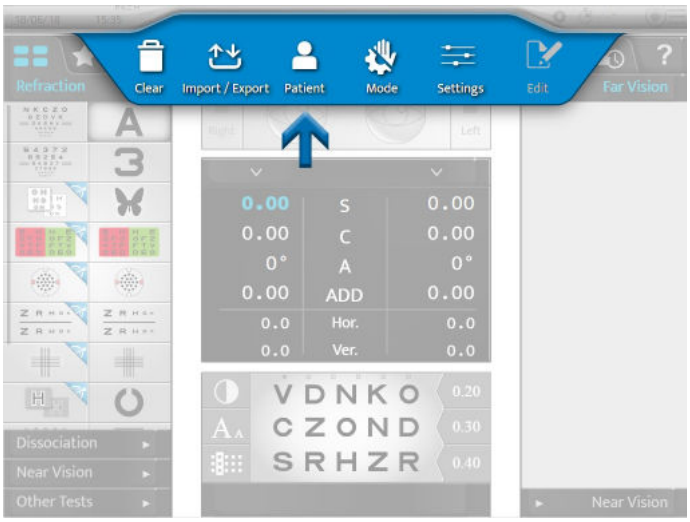


The action is manual. If a type of occlusion is applied, the adjustment is temporary up to the start of a new session.

d. Manage the patient data

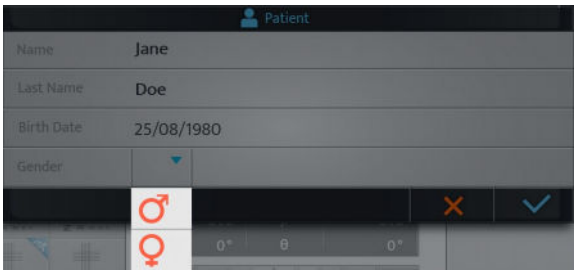
Add a patient folder

To create a patient folder press on > .



> The patient folder creation page is displayed:

Fill in the required fields:



Reminders

- ♂ : male
- ♀ : female

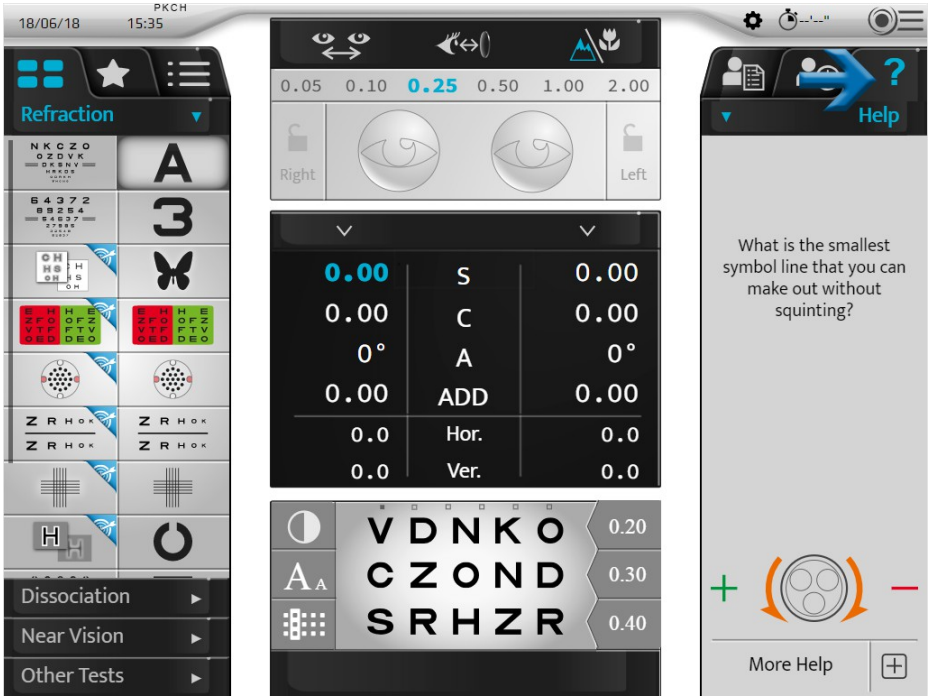
Once the folder in filled in, press on:

- ✓ to confirm.
- ✗ to cancel.

e. Access with contextual assistance

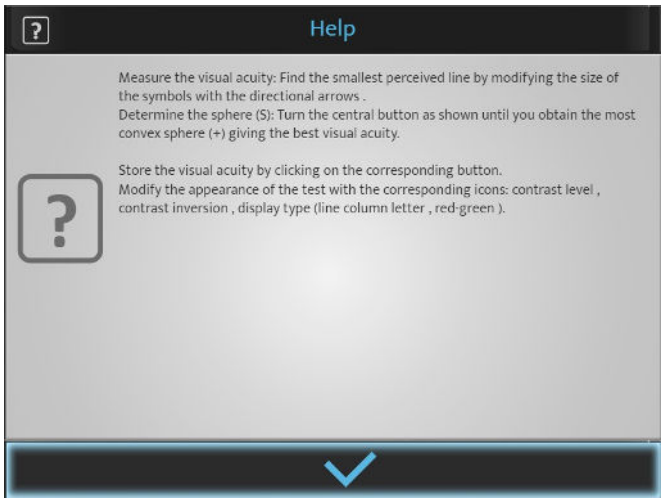
To access with contextual assistance, press on .

The phraseology of the tests as well as actions to be performed on the console are displayed on the right part of the screen.



If you wish to display more information on the test, press on [More help] .

An additional help page is displayed:



Press on to close the page.

IV. Performance of specific tests during a refraction examination

1. Patient refraction data input

a. Objective

Before performing the refraction tests, it is necessary to first enter the data of patient's initial refraction into the instrument.

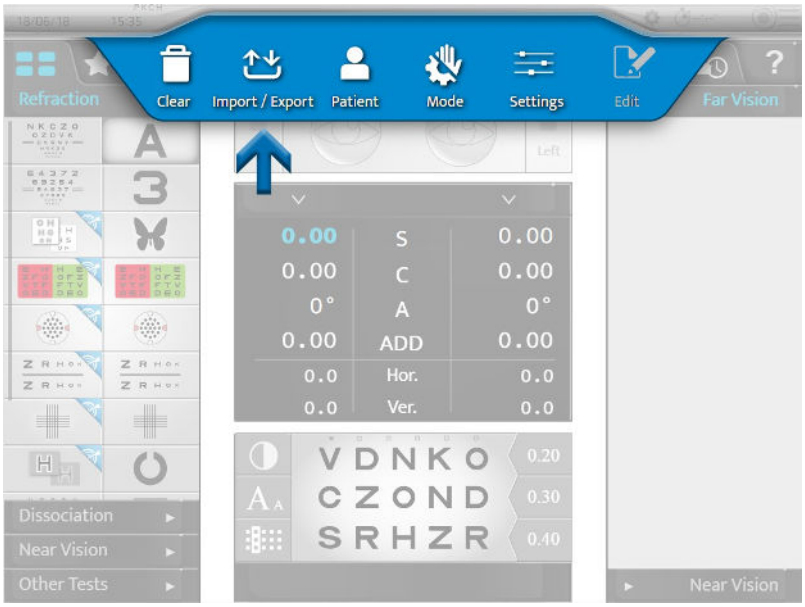
These data can come from:

1. The previous measured refraction on the glasses of the patient,
2. The objective refraction:
   - measured with the auto-refractometer or a skiascope/retinoscope,
   - determined by an aberrometer.
3. The patient folder.

b. Data importing from Essibox.com

The patient refraction data importing from Essibox.com can be done:

- On the touch screen, by pressing on > .



- On the console keyboard, by pressing on the [Import] key .

According to imported information and the phoropter settings, the refraction data is automatically placed in one of the memories of the phoropter:

- Lensmeter: preceding correction
- Autorefractor: objective refraction measured with the auto--refractometer or the aberrometer
- Retinoscopy: refraction measured by skiascope/retinoscope
- Computer: refraction from the patient folder
- Memory 1
- Memory 2
- Memory 3

7 memories are available in all.

It is possible to rename the memories.

c. Manual entry

The entry of the starting refraction can be performed either:

- Eye by eye
- Two eyes at the same time

You can manually enter the patient's refraction data into the phoropter in two different ways:

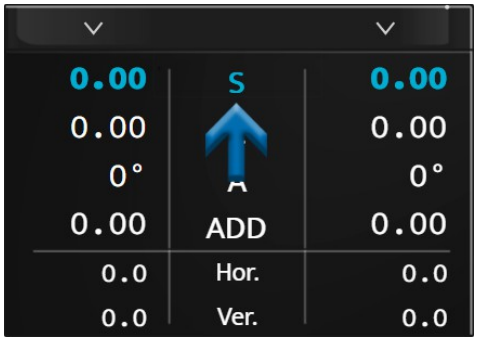
1. By using the console touch screen, or
2. By using the console keyboard.

1 - Using the console touch screen

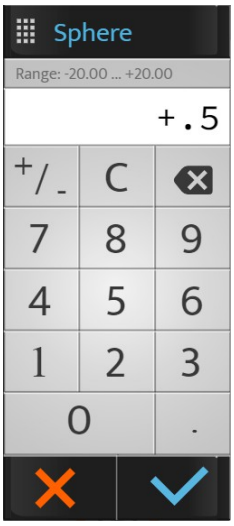
1 Press on the setting which you wish to enter.

- Sphere (S),
- Cylinder (C)
- Axis (A).

The selection can be done independently for the right eye, the left eye or in binocular.



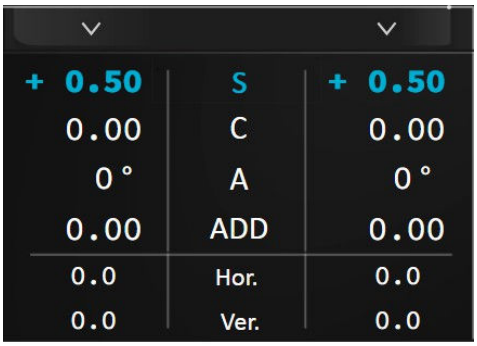
> The line of the selected setting is displayed in blue. By pressing a second time on the selected setting, a numeric keypad is displayed.



2 Enter the desired value, then press

- to confirm.
- to cancel.

> The data is displayed on the screen and is applied in front of the eye or the eyes of the patient.



3 Then press on other settings if necessary.

2 - Using of the console keyboard

1 Press on the keys [R, BINO or L].

2 Turn the console keyboard central button clockwise or anticlockwise.

The direction of rotation is configurable.

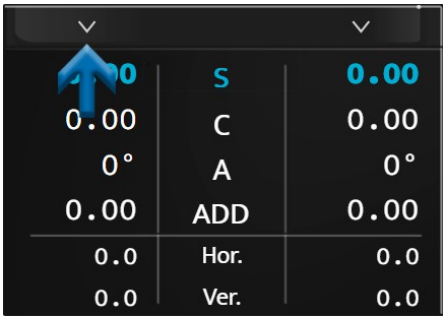
> The values of the selected setting change.

3 Press on the central button on the keyboard to change the setting if necessary.

Do not forget to save the data entered in one of the available memories.

3 - Data memorization

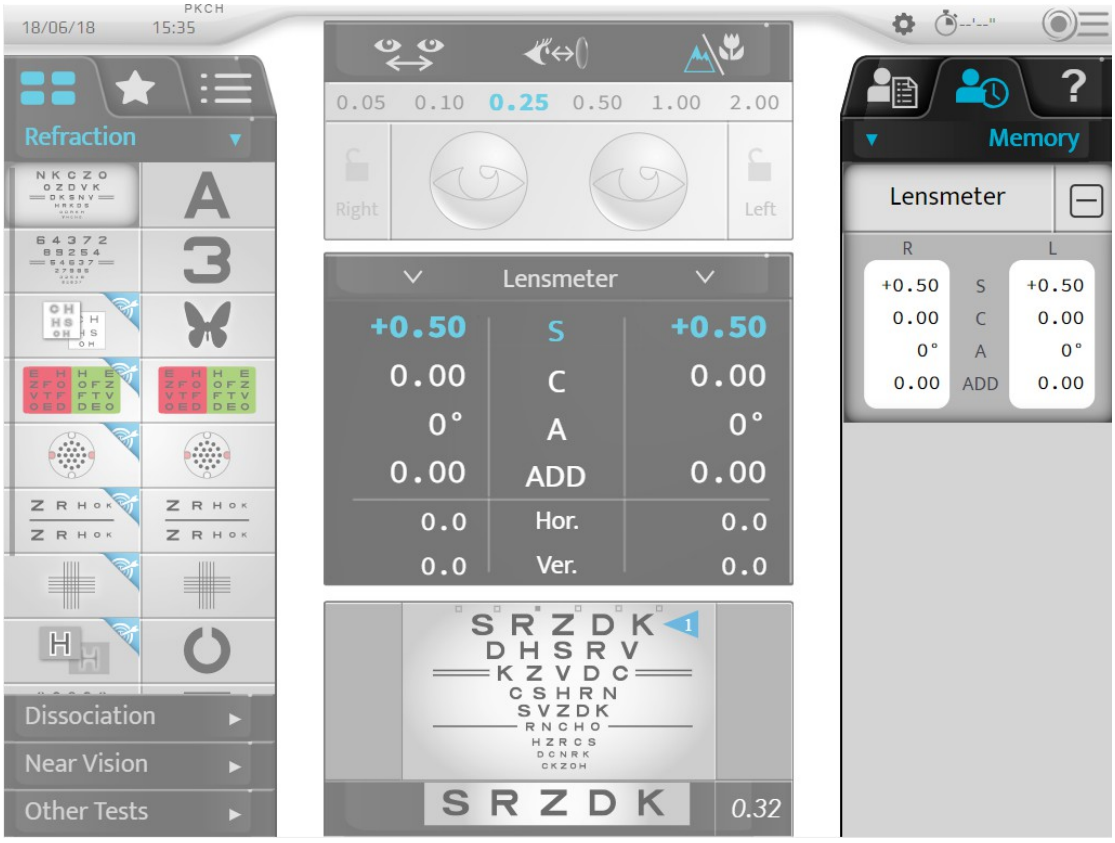
1 Press:



> The list of the available memories is displayed.

2 Choose the desired memory.

> The saved data is displayed on the right part of the screen.



2. Standard tests

There are three types of standard tests:

1. The far-vision refraction tests
2. The binocular-vision tests
3. The near-vision tests

a. Refraction tests

The following refraction tests will be detailed:

- Visual acuity
- Red/Green or Duochrome
- Fixed cross cylinders (Jackson cross)

This list is not exhaustive.

Some main tests are only detailed here to help understand operation of the instrument.

For each test, a contextual "in situation" help is available by pressing on .

User is prompted to refer to this.

Reminder

Before performing the refraction tests, it is necessary to first enter the data of patient's initial refraction into the instrument.

These data can come from:

1. The previous measured refraction on the glasses of the patient,
2. The objective refraction:
   - measured with the auto--refractometer or a skiascope,
   - determined by an aberrometer.
3. The patient folder.

Visual acuity

Objective

Measure the visual acuity of the patient with and/or without correction in:

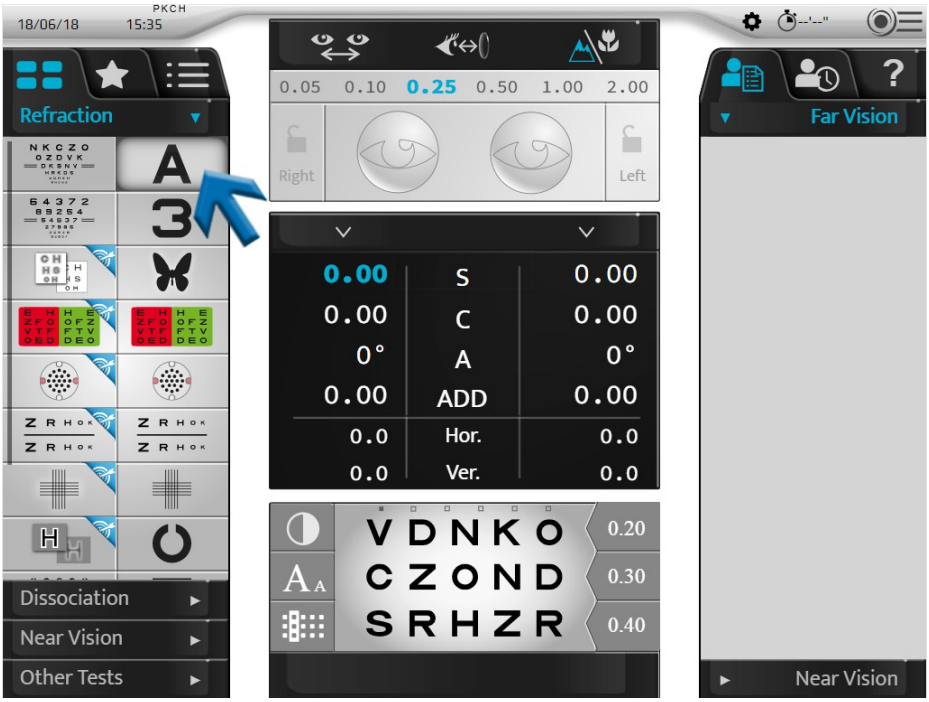
- Far vision,
- Monocular vision condition:
  - right eye OD,
  - left eye OG,
- Binocular vision condition (RLE i.e. RE and LE simultaneously).

Choice of optotypes scale

It is possible to choose two types of optotypes scales:

1. Rational progression scale (in opposite and decimal acuity)
   - letters
   - numbers
   - C of Landolt
   - E of Snellen
   - stylized figures
2. Logarithmic progression scale
   - letters
   - numbers
   - C of Landolt
   - E of Snellen

Once you have made your choice, press on the icon of the desired test. The visualization of the test is then displayed at the bottom of the main screen:



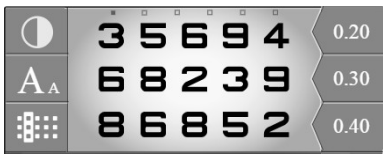
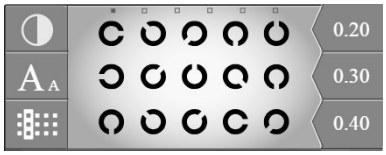
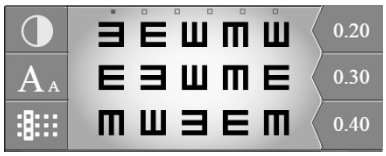
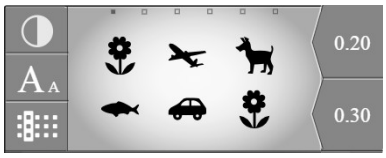
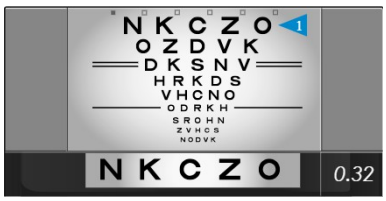
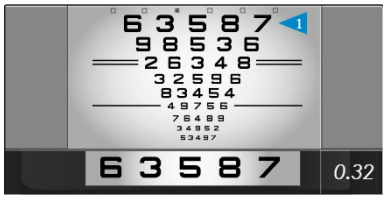
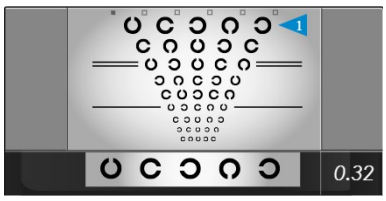
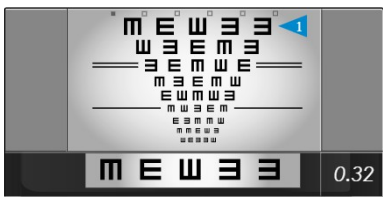
The test display area allows you to:

- Visualize the optotypes presented.
- Display the acuity values in the unit chosen during configuration:
  - decimal acuity (x/10)
  - Snellen acuity in meters (6/x)
  - Snellen acuity in feet (20/x)

The table of optotypes allows you to:

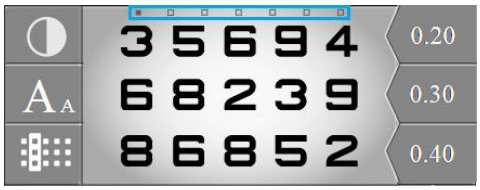
- Display the value of corresponding acuity,
- Display the unit of acuity.

Choice of optotypes scale

Scales of acuity	Types	Icons	Display zone at the bottom of the screen
Rational progression scale	letters		
	numbers		
	C of Landolt		
	E of Snellen		
	stylized figures		
Logarithmic progression scale	letters		
	numbers		
	C of Landolt		
	E of Snellen		

So that the patient does not memorize the series, for each scale of acuity, six series of optotypes are available. You can change the series while maintaining the same letter size:

- On the touch screen, by pressing on the points above the optotypes.

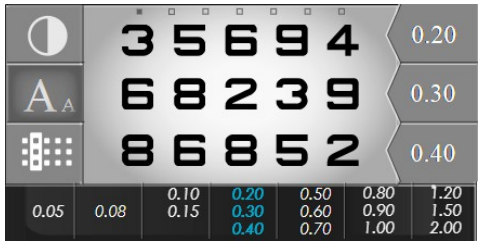


- On the console keyboard, by pressing on the horizontal keys.

Display of the visual acuity values

To display acuity values, press on .

The acuity values are displayed below the table with the visual acuity value(s) currently being presented highlighted in blue.



You can change the visual acuity values on the console keyboard by pressing on the vertical keys:

Confirm your choice by pressing on:

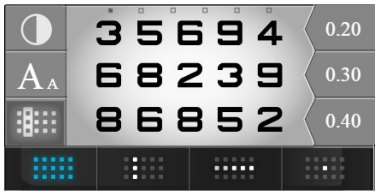
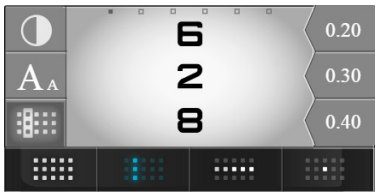
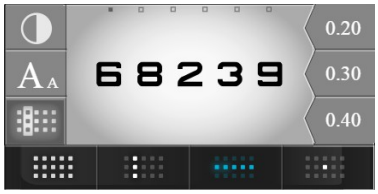
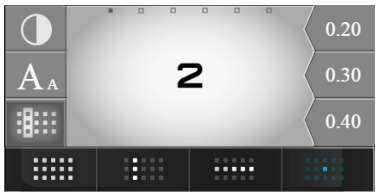
Choice of optotype table display

To choose a kind of display press on .

It is possible to choose four display types of optotypes:

1. In table
2. In column
3. In line
4. In isolated optotype

Only available for rational progression scales (letters, figures, C of Landolt, E of Snellen, stylized figures).

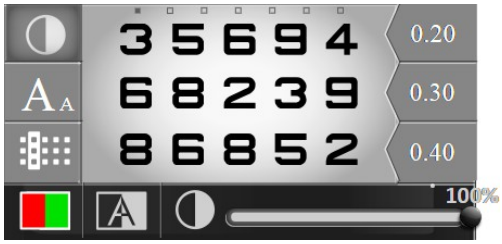
Display types	Display in zone at the bottom of the screen
Table	
Column	
Line	
Isolated optotype	

Choice of contrast type

To choose a type of contrast, press on .

It is possible to choose three types of contrasts:

1. Red-green, in 100% contrast,
2. White on black background
3. Black on white background, with choice of contrasts from 0 to 100%.



Procedure - Determine the visual acuity of the patient

1 Select the optotypes on the touch screen.

Check that the optotypes that appear correctly on the test presentation screen.

2 Select the right eye, the left eye or both eyes by using the keys [R, L or BINO] on the console keyboard.

3 Scroll through the acuity tests using the vertical arrows on the console keyboard.

4 Ask the patient the following question:

"*Look at the test, tell me what the small characters are that you can make out, and read them aloud (or describe them)*."

> If the patient manages to make out 3 out of 5 optotypes on the same line of acuity, the level of acuity is considered as achieved.

5 Save the visual acuity value. You can save this value:

- On the console keyboard, by pressing on the key located in the middle of the 4 arrows.

Only for the logarithmic scales and rational scale if a line or a symbol is isolated.

- On the touch screen, by pressing on the acuity value appearing in the display area.

> The value of the visual acuity of patient (OD, OG or BINO) changes into blue and is saved in the section "Patient Data", in the memory "Visual Acuity".

> It appears in the dial on the right of the screen.

RED/GREEN or DUOCHROME

Objective

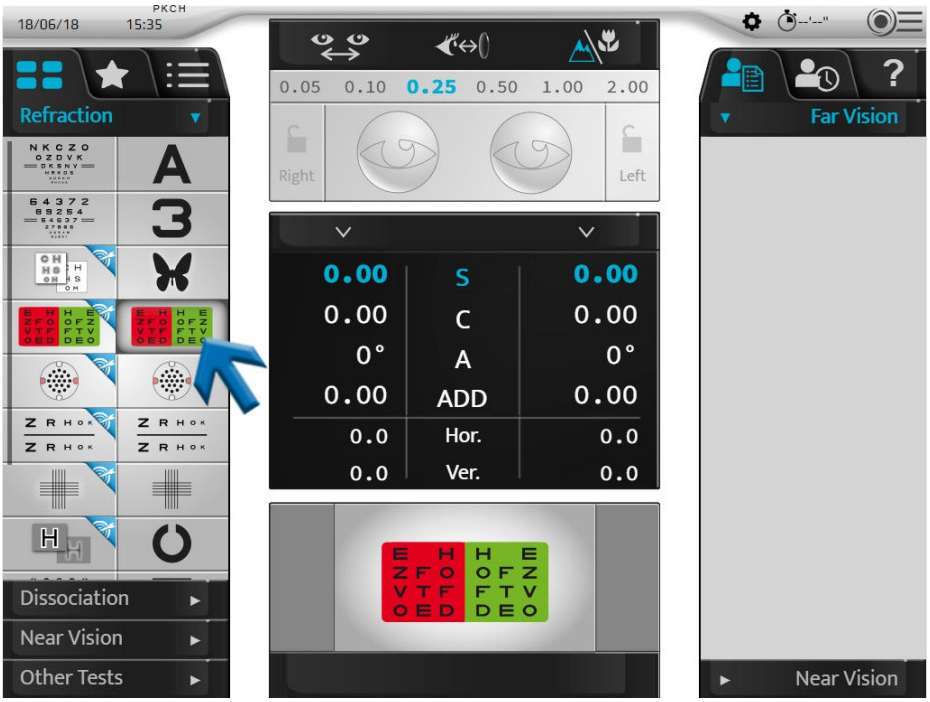
Adjust the patient's spherical correction value in:

- Far vision,
- Monocular vision condition:
  - right eye OD,
  - left eye OG,
- Binocular vision condition (ODG i.e. OD and OG simultaneously).

Procedure - Performing the test

1 Press .

> The Red/Green test is displayed in the display area in the bottom of the touch screen of the console.



> The corresponding table of optotypes is displayed on the test presentation screen.

To perform this test in the best conditions, a soft atmosphere is advised.

2 Ask the patient the following question:

"Look at the test and tell me if the characters appear darker to you or more contrasted on the red background, on the green background or if they seem identical to you."

If the answer is:

> **- darker on the red background** add -0.25 R* to the value of the sphere. Either:

- On the console keyboard, by pressing on the key " - ".

- On the console keyboard, by turning the central button clockwise*.

> Start the test again until you obtain the equal blackness for the characters on the red background and the green background or you achieve the preference for the green background.

> **- darker on the green background** add +0.25 R* to the value of the sphere. Either:

- On the console keyboard, by pressing on the key "+".

- On the console keyboard, by turning the central button anticlockwise*.

> Start the test again until you obtain the equal blackness for the characters on the red background and the green background or you achieve the preference for the red background.

> **- identical on the red background and the green background**retain this sphere value.

In the event of preferred red and green inversion between two sphere steps, retain the last values:

- "**red**" for a patient **with myopia**
- "**green**" for a patient **with hypermetropia**

Notes

- To avoid the disturbing effects of the accommodation of the patient (which can make him prefer the red), it is possible to:
  - ask the patient to lock on the green background before proceeding to the red/green comparison,
  - lightly scramble by adding a power of +0.50 R in order to obtain a preference for the red and to then clear it up until obtaining the balance between the red and the green.
- Several successive preferred answers for the red can indicate that the patient unintentionally involves his accommodation.
  This can occur in particular with young patients who can be sometimes appear short-sighted by the excessive inclusion of their accommodation. It is thus important to make sure not to let it result in a too concave (or negative) sphere value.

*

This information corresponds to the phoropter default settings:

- The variation step of the sphere is by default 025 R, but it can be adjusted in the settings.

Fixed cross cylinders (Jackson cross)

Objective

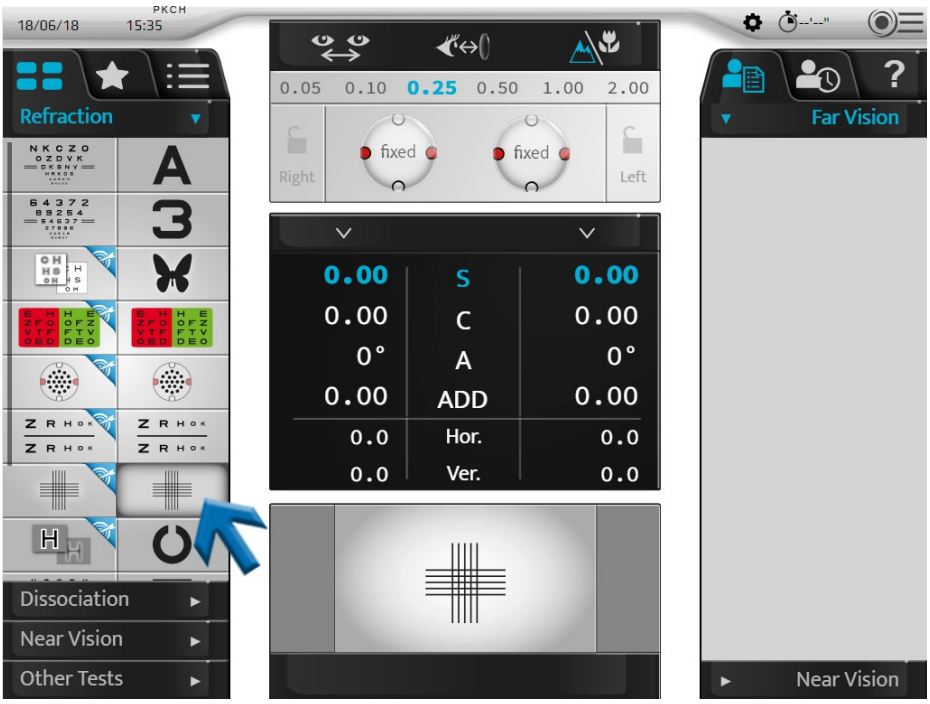
Adjust the patient's spherical correction value in:

- Far vision,
- Monocular vision condition:
  - right eye OD,
  - left eye OG,
- Binocular vision condition (ODG i.e. OD and OG simultaneously).

Procedure - Performing the test

1 Press .

> The Jackson cross, made up of black horizontal and vertical lines on a white background is displayed in the display area at the bottom of the touch screen on the console.



> The Jackson cross is displayed on the test presentation screen.

> A fixed cross cylinder with a "+0.50 (- 1.00) 90°" formula is added to the patient's correction (on the right eye, the left eye or both eyes).

This cylinder is **automatically** generated by the optical module through combination with the patient's correction.

It is not an additional lens added in front of the correction of the patient.

2 Ask the patient the following question:

"*Look at the cross. Tell me if the horizontal or vertical lines appear clearer to you or darker or if they have the same darkness*."

If the answer is:

> **- clearer vertical lines**add -0.25 R* to the value of the sphere. Either:

- On the console keyboard, by pressing on the key " - ".

- On the console keyboard, by turning the central button clockwise*.

> Start the test again until you obtain equal clearness between the horizontal and vertical lines or a greater clearness for the horizontal ones.

> **- clearer horizontal lines** add +0.25 R* to the value of the sphere. Either:

- On the console keyboard, by pressing on the key "+".

- On the console keyboard, by turning the central button anticlockwise*.

> Start the test again until you obtain equal clearness between the horizontal and vertical lines or a greater clearness for the vertical ones.

> **- equality of darkness between the horizontal and vertical ones**retain this sphere value.

In the event of preferred inversion between the horizontal and vertical lines between two sphere steps, retain the last values:

- "**vertical**" for a patient **with myopia**
- " **horizontal**" for a patient **with hypermetropia**

Notes

- To avoid the disturbing effects of accommodation, it is possible to scramble the patient (with a convex power) until you obtain the preference for the vertical lines and to then clear up it until you achieve a balance between the horizontal and vertical lines.
- The test of the fixed cross cylinders supposes an exact correction of the astigmatism of the eye. The result can be distorted if a direct astigmatism (cylinder axis further from 0°) or the opposite (cylinder axis further from 90°) is over or under-corrected.
- At the end of the test, the horizontal and vertical lines are slightly fuzzy (because the patient looks through a cylinder of 1.00 D). The important thing is that the blurring is identical on the horizontal and vertical lines.

(*)

This information corresponds to the phoropter default settings:

- The variation step of the sphere is by default 025 R, but it can be adjusted in the settings.

3. Smart tests

A smart test is a semi-automatic test using an algorithm that can determine more precisely the subjective refraction of the patient. At the time of a smart test, all the answers are saved and integrated automatically in order to prescribe the best possible correction.

The smarts tests are identifiable through a pictogram located on the right of the icon .

a. Refraction tests

Smart RED/GREEB or DUOCHROME

Objective

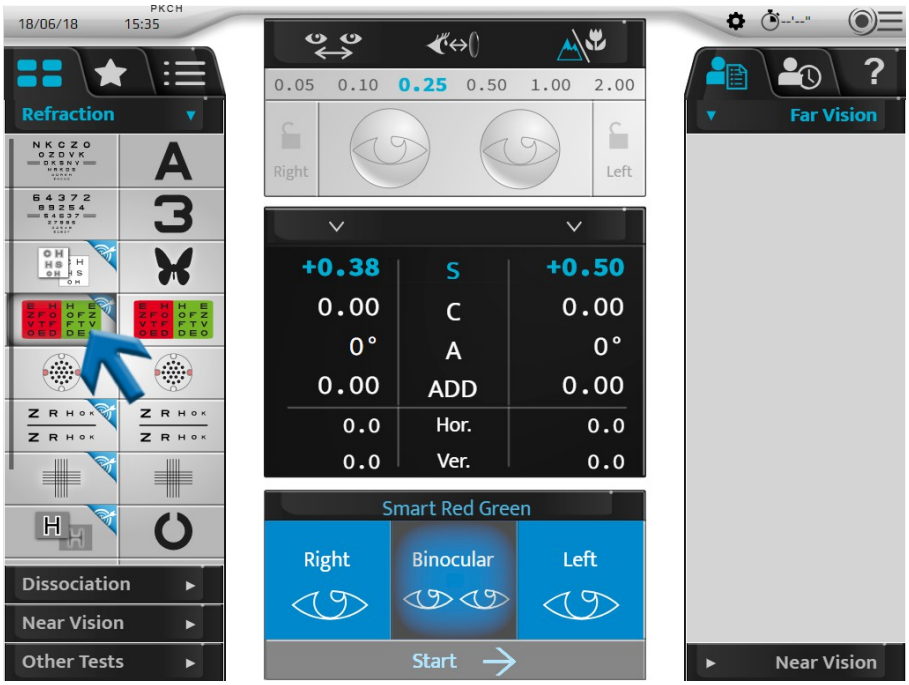
Refine the patient's spherical correction value in:

- Far vision,
- Monocular vision condition:
  - right eye OD,
  - left eye OG,
- Binocular vision condition (ODG i.e. OD and OG simultaneously).

Procedure - Performing the test

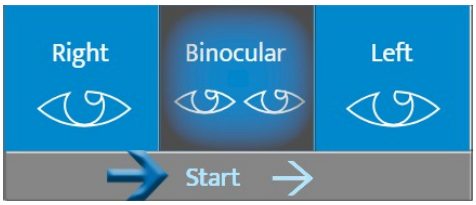
1 Press .

> The test view window in the bottom of the touch screen of the console allows you to choose under which conditions the test will be performed (OD, OG, ODG).



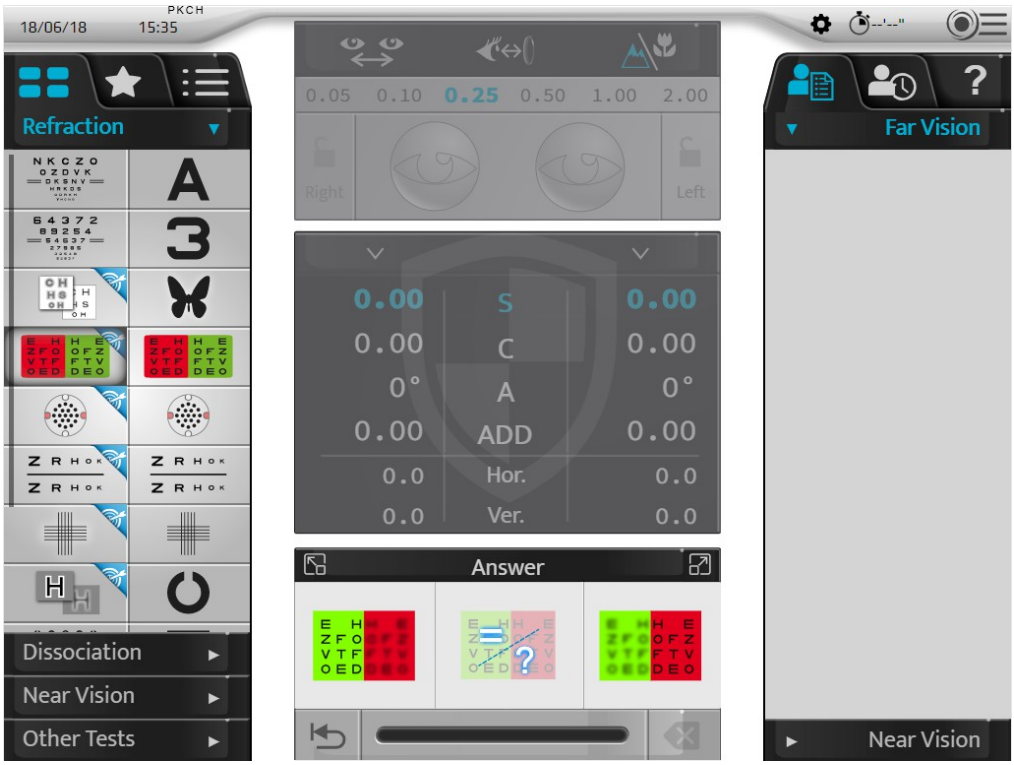
2 Once the condition is selected, start the test.

- On the touch screen by pressing on [Start].



- On the console keyboard, by pressing on the central button.

> The Red/Green smart test is shown in the display area in the bottom of the console's touch screen.



It is no longer possible to modify the values of controlled settings, the masks, the filters or the adjustments of the instrument.

> The corresponding table of optotypes is displayed on the test presentation screen.

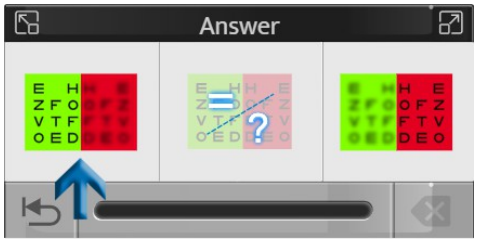
3 Ask the patient the following question:

"Look at the test and tell me if the characters appear darker to you or more contrasted on the red background, on the green background or if they seem identical to you."

If the answer is:

> **- darker on the green background.** Select the answer by either:

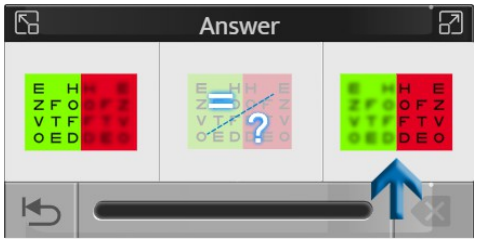
- Pressing on the corresponding answer on the touch screen.



- On the console keyboard, by pressing on the key "+".

> **- darker on the red background**. Select the answer by either:

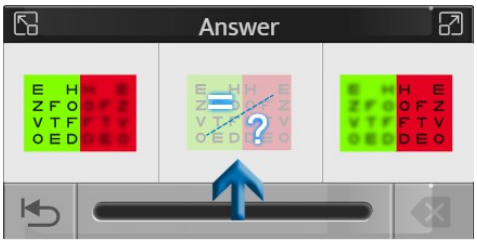
- Pressing on the corresponding answer on the touch screen.



- On the console keyboard, by pressing on the key " - ".

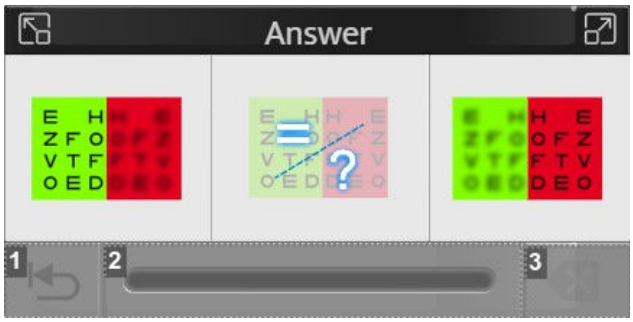
> **- no preference, doesn't know**. Select the answer by either:

- Pressing on the corresponding answer on the touch screen.



- On the console keyboard, by pressing on the central button.

The response window also allows for:



1. *Return to the beginning of the test*

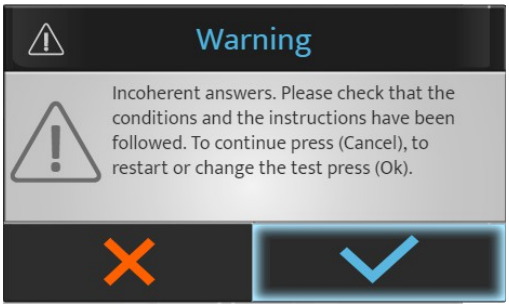
2. *Visualize the progress of the test*

Three status indications on the progression bar are available.

3. *Cancel the last answer*

An error message may appear, if there is an anomaly during the test.

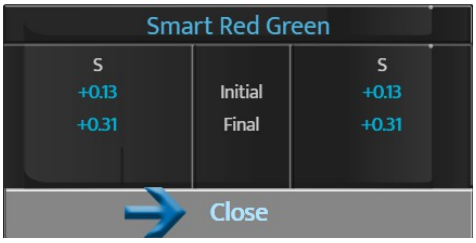
EXAMPLE:



Press:

- to continue the test.
- to stop or start the test again.

4 At the end of the sequence, close the test by pressing on [Closed].



5 Select the following test on the touch screen by pressing on the desired test in the available list.

In the case of a test program, moving to the following test is done:

- On the touch screen by pressing on [Next].

- On the console keyboard, by pressing on the central button.

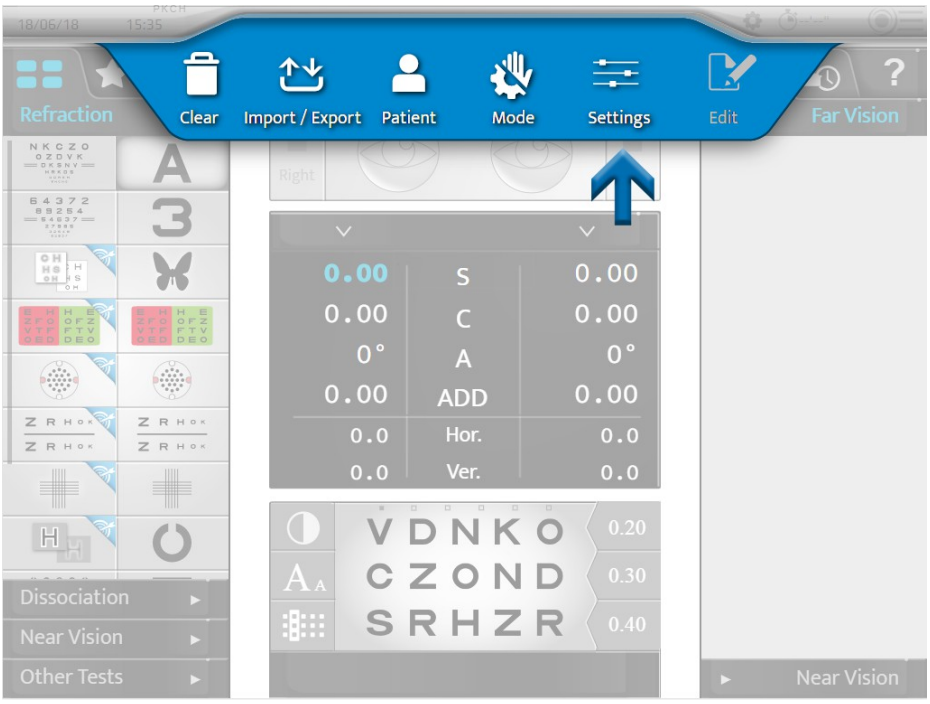
All the smart tests function based on the principle of inputting patient answers and the progression of the algorithm to determine the checked setting. And this, until the right value is found.

For each test, a contextual “in situation” help is available by pressing on .

User is prompted to refer to this.

V. Instrument settings

It is possible to modify the default settings of the instrument by pressing on > .



> The instrument settings page is displayed.

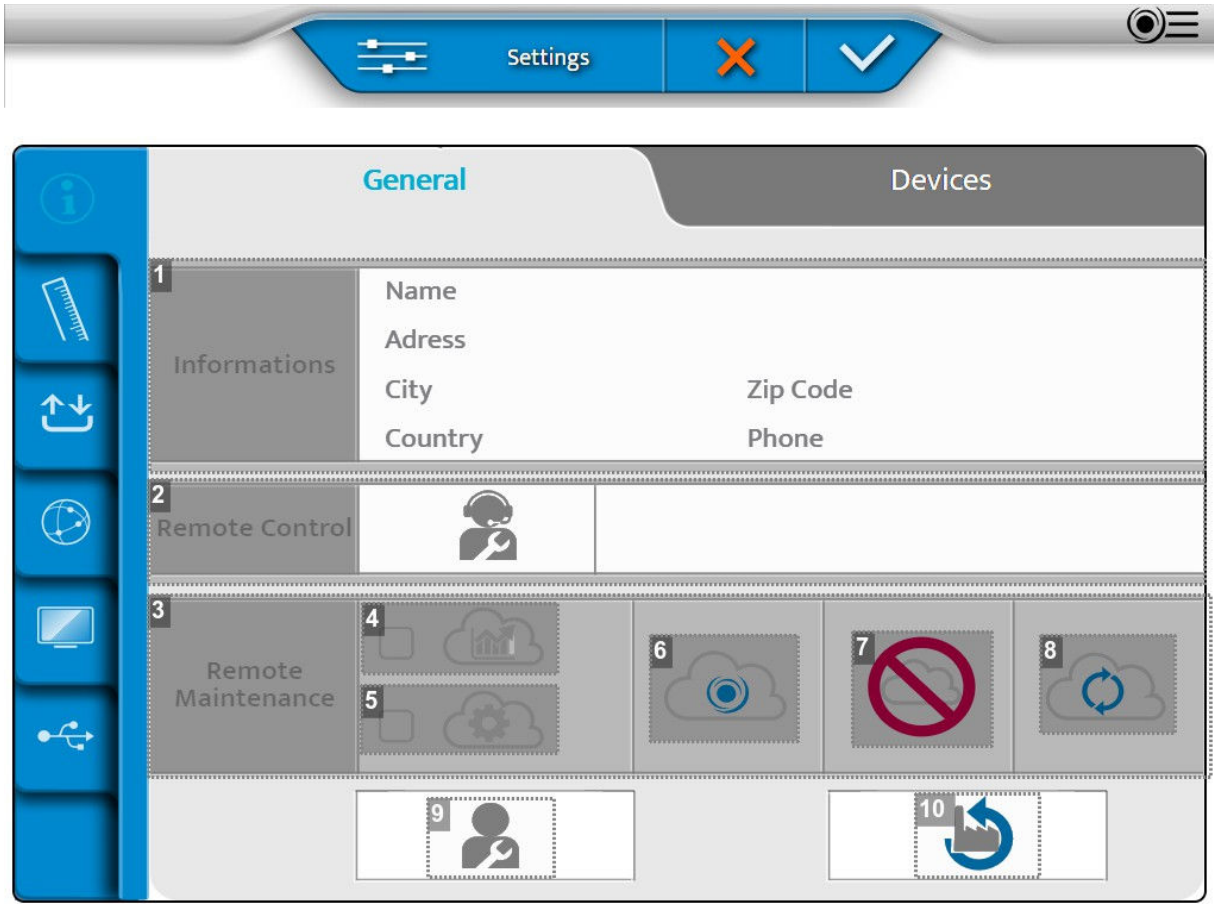
1. Description of the settings menus

a. General information

The general information menu has two pages:

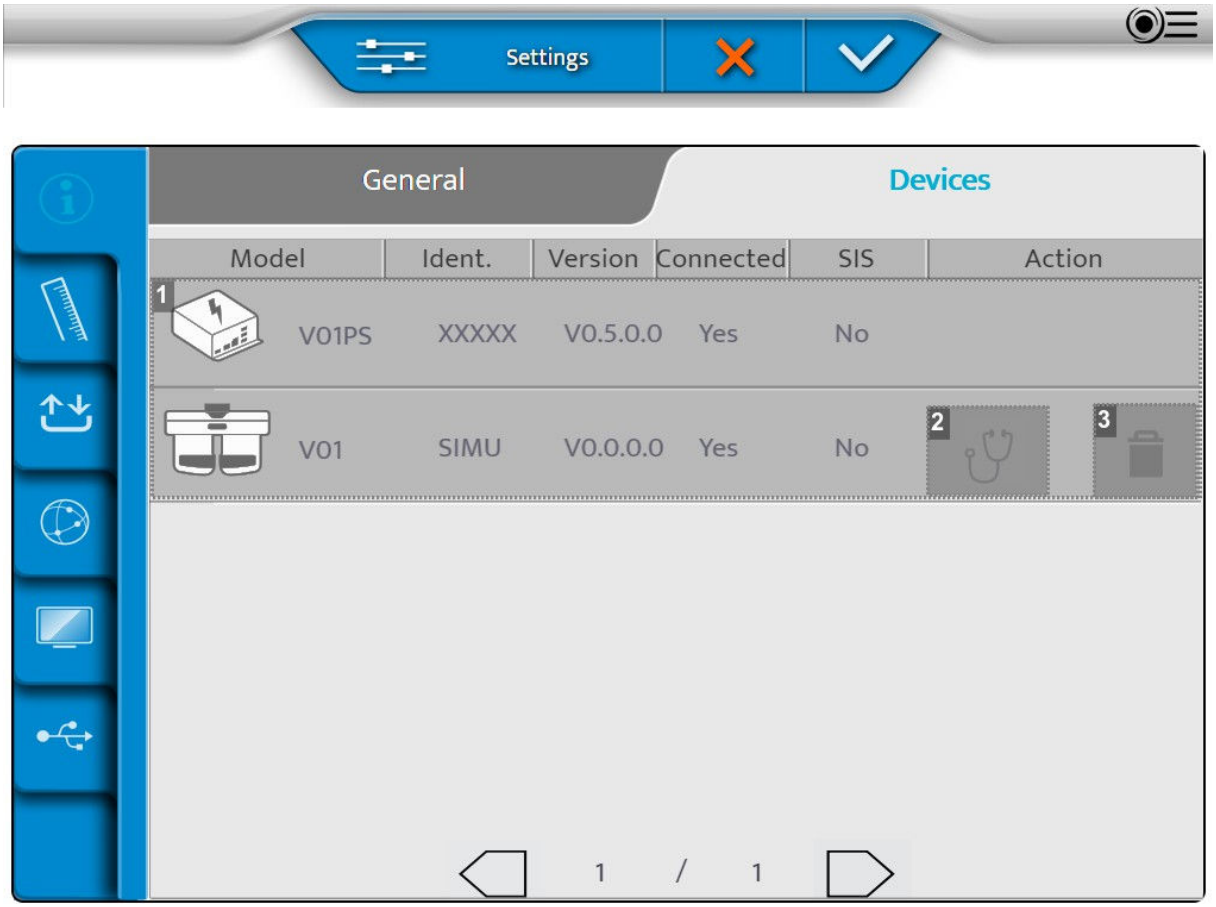
1. "General"
2. Devices

1 - Page "General"



1. *Instrument inspection*
2. *Remote access,*
3. *Access to the remote maintenance*
4. *Access to the statistics and the log files*
5. *Access to the adjustments*
6. *Recording on SIS*
7. *Deletion of recording*
8. *Connection refreshing*
9. *After-sales service*
10. *Restoration of the default settings*

2 - Page "Devices"



1. *Information concerning the various components of the instrument*
2. *Carry out autotests*
3. *Removal of the component*

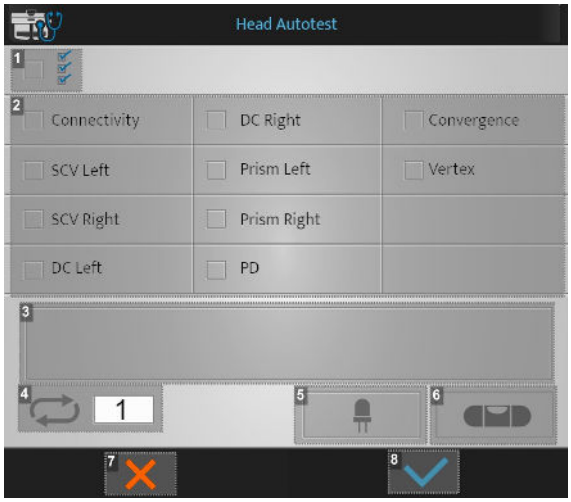
Once the adjustments are made, pres on:

- to confirm.
- to cancel.

Carrying out the autotests

1 On the "Device" page, press on .

> The following page appears:



1. *Launch of all the self-tests*
2. *List of available self-tests*
3. *Display*
4. *Number of self-test launch*
5. *Test of LEDs in near-vision mode*
6. *LED panel test for horizontal adjustment*
7. *Launch cancellation*
8. *Launch confirmation*

2 Choose the self-test which you wish to perform and press on .

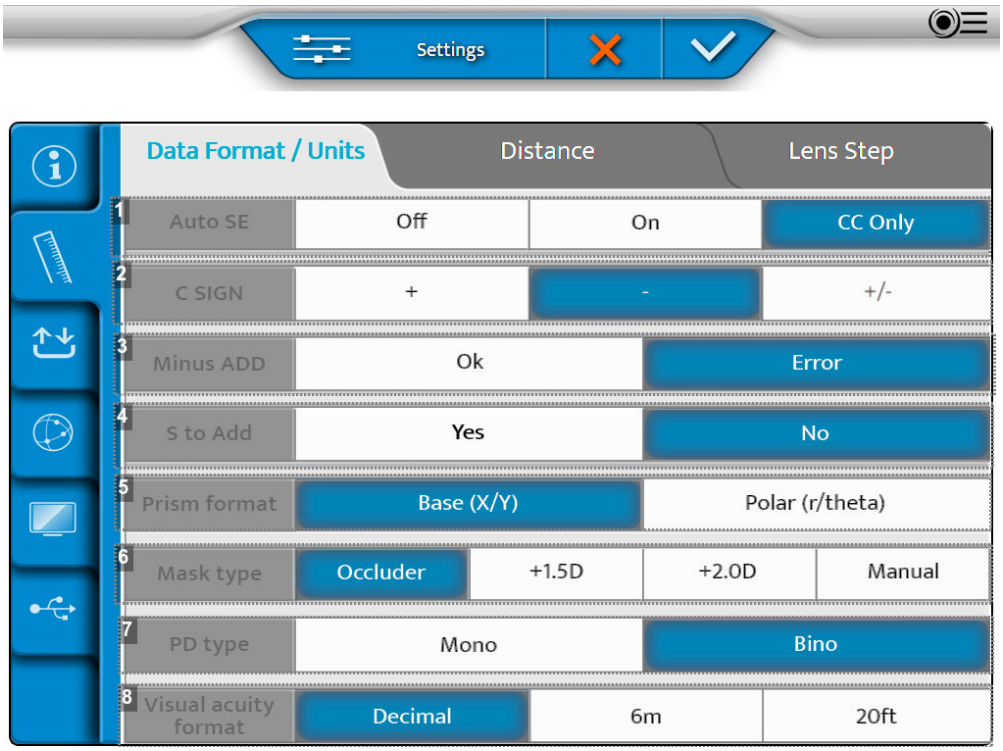
> The self-test starts.

b. Measurement data

The measurement data menu has three pages:

1. Dated Format/Units
2. Distance
3. Lens Step

1 - Page "Dated Formats/Units"



1. *Auto ES*

Automatic maintenance of the equivalent sphere during introduction of the cylinder.

2. *C Sign*

Define the sign of the cylindrical power (C).

3. *Minus ADD*

Allows for the addition of a negative addition.

- OK: authorizes the negative addition for specific tests
- Error: only a positive addition can be taken into account

4. *S to Add*

Allows user to combine or separate the addition of the near vision from/to the far-vision sphere.

5. *Prism format*

6. *Template type*

The choice of the type of mask during a test in monocular vision.

7. *PD type*

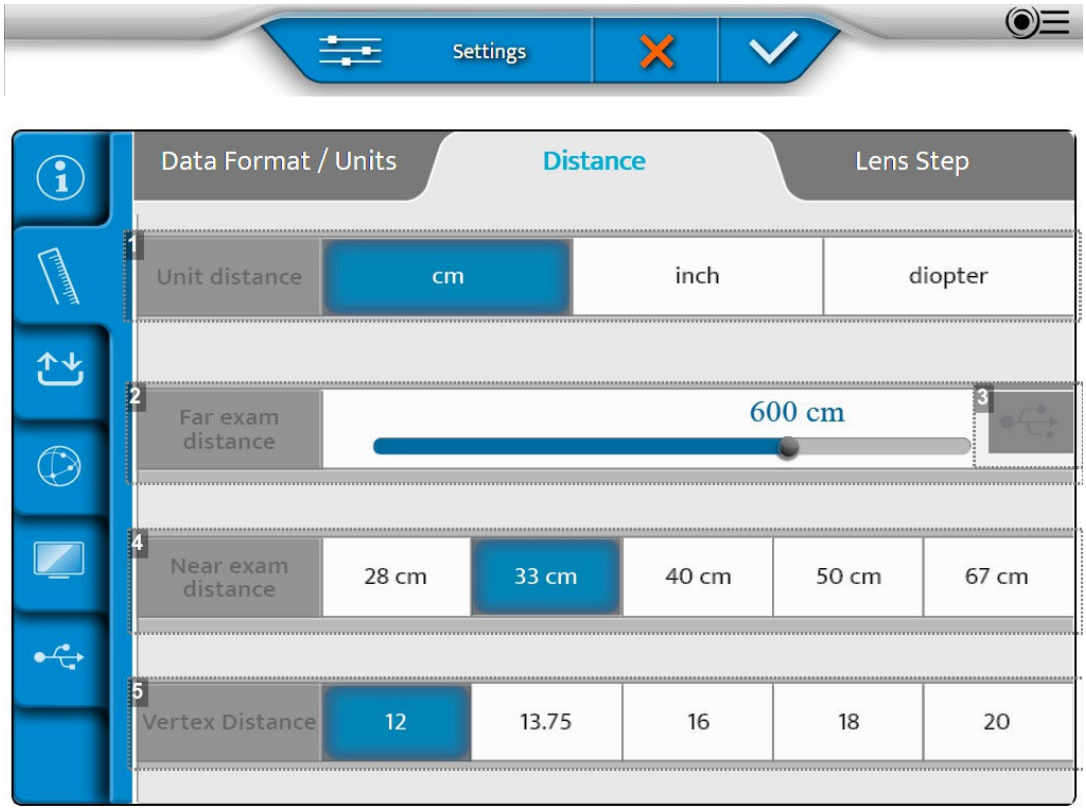
Define the type of monocular or binocular pupillary distance.

8. *Visual acuity format*

Defines the visual acuity unit, notation:

- Decimal (x/10)
- Snellen in meters (6/x)
- Snellen in feet (20/x)

2 - Page "Distance"



1. *Unit distance*

Define the default distance unit:

- in cm
- in inches
- in diopters

2. *Far exam distance*

Define the test presentation screen distance.

To modify this distance move the cursor to the left or the right (steps from 25 cm to 3m to 8m).

3. *Generation of personalized optotypes*

4. *Near exam distance*

Defines the distance of the near-vision test.

> The values indicated correspond to a default setting in cm.

5. *Vertex Distance (in mm)*

Sets the lens-eye distance by default taken into account for the conversion of the refraction value of a standard reference distance.

3 - Page "Lens step"

1. *Spherical Step*

Define the default variation step of the sphere.

2. *Cylinder Step*

Define the default variation step of the cylinder.

3. *Axis Step*

Define the default variation step of the axis.

4. *Prism Step*

Define the default variation step of the prism.

5. *PD Step*

Define the default variation step of the pupillary distance.

6. *Cross Cylinder Lens*

Sets the default value of the cross cylinder, used for finding the cylinder in manual mode.

Once the adjustments are made, pres on:

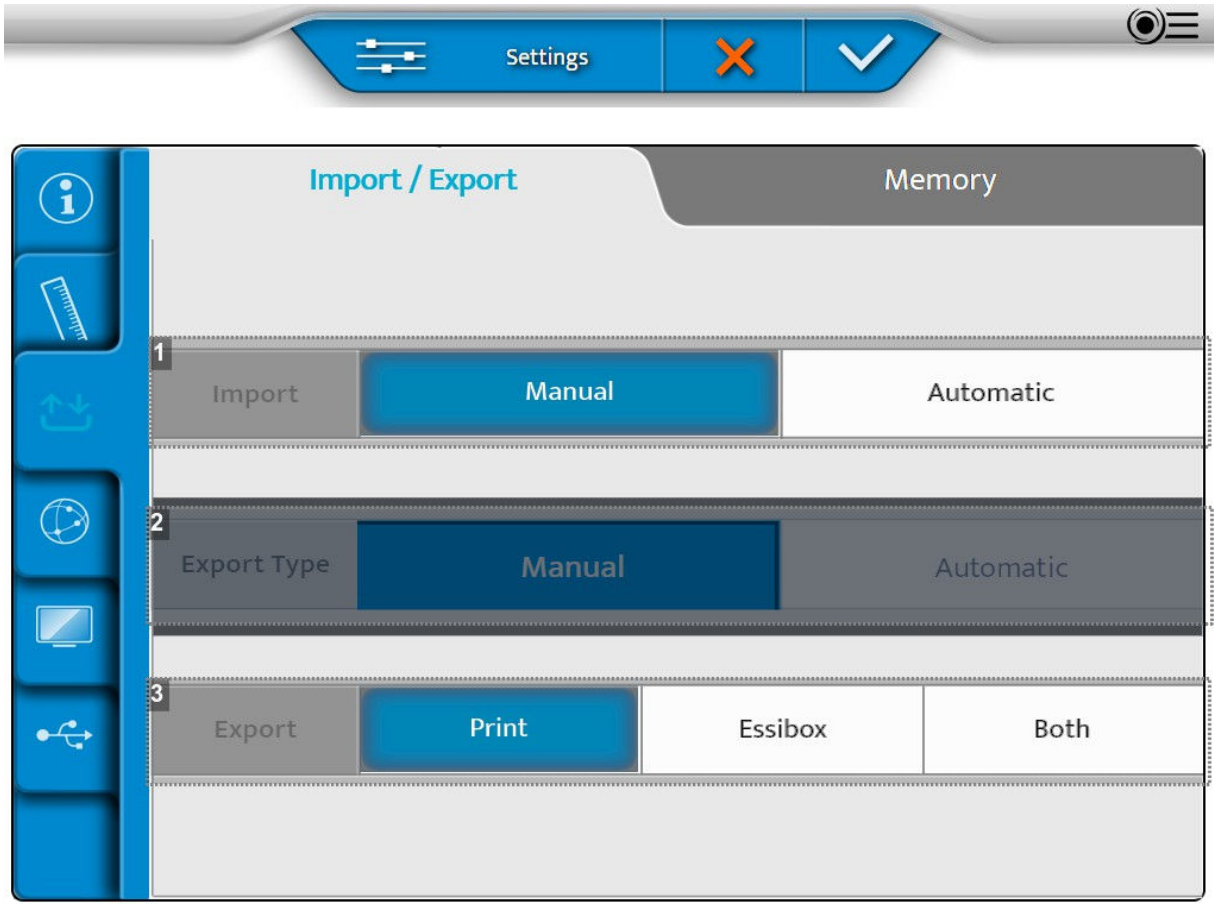
- to confirm.
- to cancel.

c. Import/Export data

The Import/export menu has two pages:

1. Import/export
2. Memory

1 - Page "Import/export"



1. *Import*

Describe the type of importing:

- Manual
- Automatic

2. *Export type*

Describe the type of export:

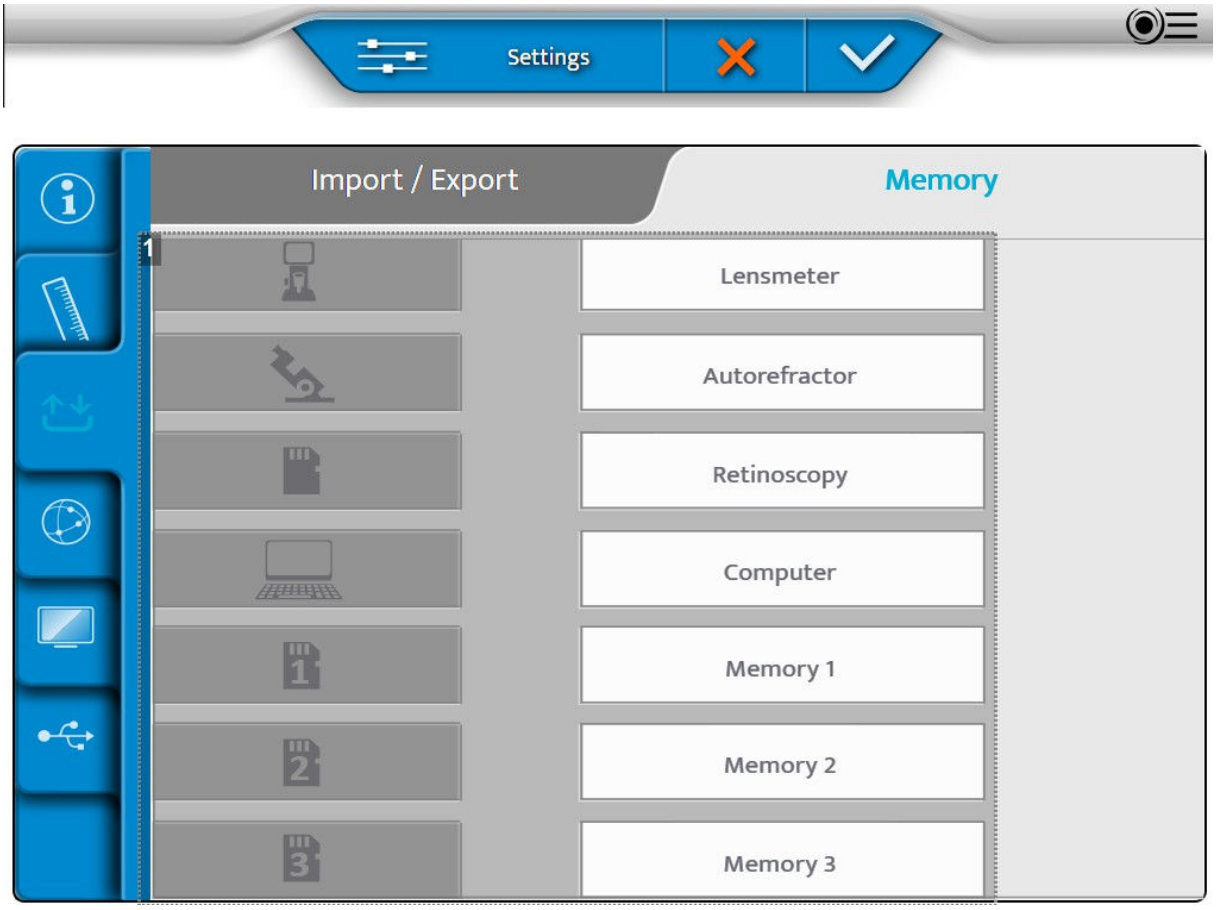
- Manual
- Automatic

3. *Export*

Defines the way data is processed during export:

- Sent to the printer
- Sent to the Essibox
- Both

2 - Page "Memory"



1. *List of available memories*

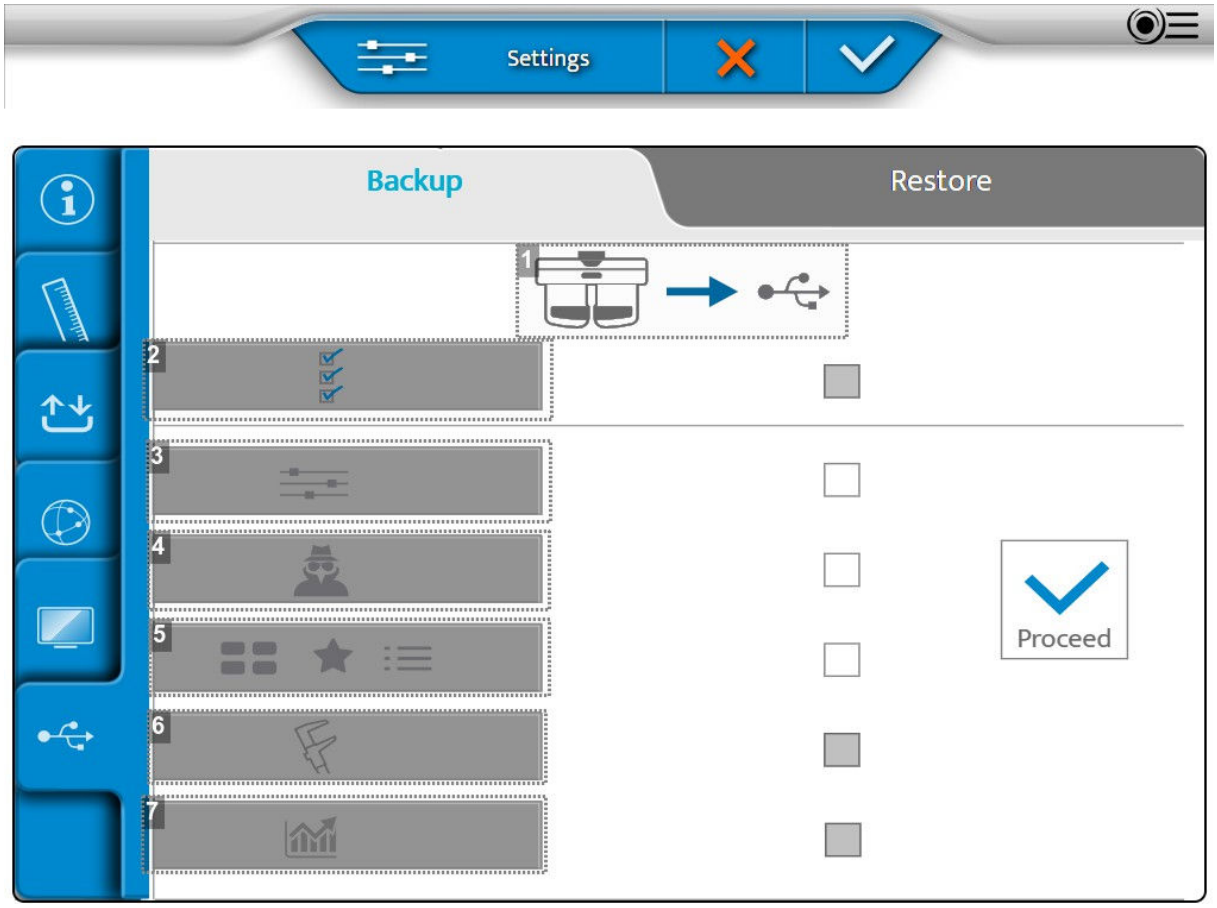
It is possible to rename the memories (long press on name).

d. Backups and memory

The backups and memory menu has two pages:

1. Backup
2. Restore

1 - Page "Backup"



1. *Export of refraction head data to an USB key*

2. *Export of all the instrument data*

3. *Settings export*

4. *Export of the technician data*

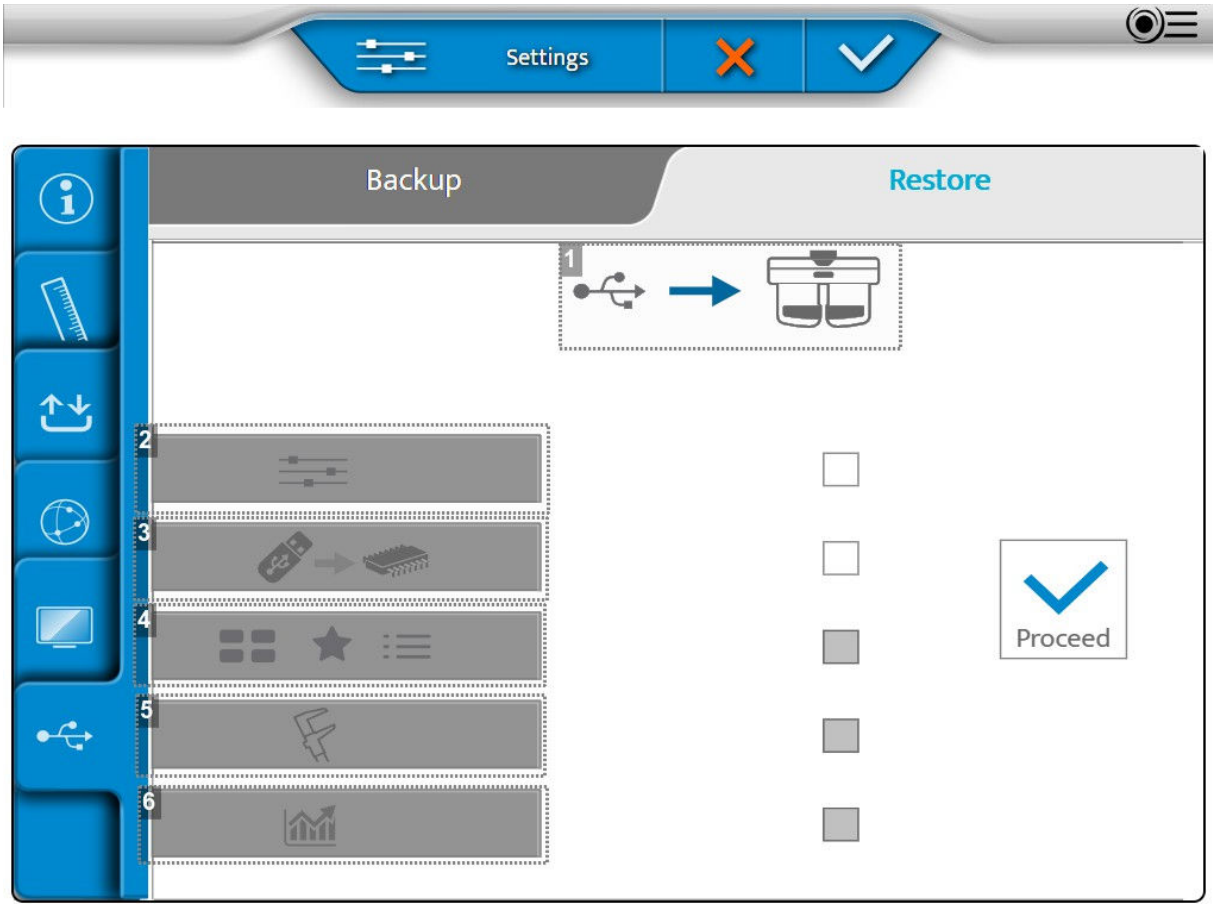
5. *Export of tests, favorites and test programs*

6. *Calibrations export*

Not available

7. *Statistics exportation*

2 - Page "Restore"



1. *Importing of data from an USB key to the refraction head*

2. *Settings importing*

3. *Importing a memory update.*

4. *Importing new tests, favorites and test programs*

5. *Importing new calibrations*

Not available

6. *Statistics importing*

VI. Breakdown service

If a problem is detected, refer to the table below in order to take the appropriate measures.

Symptoms	**Causes and measurements**
The refraction head does not initialize itself	• No power ◦ Check that the USB cable connected to the power supply is connected (cable + extension) ◦ Check that the power supply block is on
The console does not initialize itself	• No power ◦ Check that the power supply block is on ◦ Check that [Bluetouch] is on ◦ Press on the [Clear] key to start initialization ◦ Check that Red/Green LEDs are on a few minutes after initialization ◦ If the screen remains black, check that the SD card is inserted correctly
No supply to the power supply block	• No power ◦ Check that the [ON/OFF] button is set to ON ◦ Check that the first LED on the power supply block is on
Frozen console screen	• No power ◦ Check mains lead is connected ◦ Turn the console off with the [Clear] key and restart the product
Rainbow on the screen	• Video cable error Check that the console cable is plugged into the power supply block

If the problem has not been resolved after taking the measures listed above, contact your local distributor immediately.

VII. Technical data

Centering

- Pupillary distance: 48.0 to 80.0 millimeters for far; 44.0 to 76.0 millimeters for near; by steps of 0.1 millimeter. Binocular and monocular settings
- Convergence: automatic, compared to the position of the target for near vision and to the patient's pupillary distance.
- Eye-lense distance 8.0 to 30.0 millimeters by steps of 0.1 millimeter, monocular, measured by cameras.

Measurement range

- Sphere: from -20.00 D to +20.00 D
- Cylinder: up to 8.00 D for the sphere and the cylinder
  - In "standard" mode: increments of 0.05 D with adjustable steps.
  - In "Intelligent" mode: increments of 0.01 D, rounded to 0.05 D or 0.25 D.
- Axis: 0° to 180° by increments of 1°, with adjustable steps.
- Prism: 0 to 20 Δ by increments of 0.1 Δ, with adjustable steps.

Auxiliary lenses

- Eye masks: dark and translucent.
- Pin Hole: yes
- Retinoscopic lenses: +1.50 D, +2.00 D (powered by the optical module).
- Blurring lenses: +1.50 D, +2.00 D and handbook (powered by the optical module).
- Jackson cross cylinders: +/- 0.25 D, + 0.50 D (powered by the optical module).
- Fixed cross cylinders: +/- 0.50 D (powered by the optical modules).
- Prisms: 3 Δ upper base/3 Δ lower base, 6 Δ upper base, 10 Δ internal base (powered by alternating prisms/diasporameters).
- Maddox rods: red, horizontal and vertical.
- Red/green filter: red on the right eye, green on the left eye.
- Polarised filter: linear and circular.

Dimensions and weight

- Head of the phoropter:
  - width = 29.6 cm at the top - 21.9 cm at the base /Height = 22.2 cm
  - Depth = 8.4 cm at the top - 6.5 at the base
  - Weight = total 3.5 kg
- Console (keyboard + screen):
  - Keyboard: 28 X 22 cm
  - Display screen: 10.4"
  - Total weight = 3.0 kg
- Power block: L = 16.3 cm, l = 12.5 cm, P = 5.8 cm, weight = 1.0 kg.
  - AC input: 100 V-240 V, 50/60 Hz
  - DC output: 24V
  - Power output: 48VA

LEDs

- Lighting near vision:
  - Colour: white, neutral
  - Chromaticity CCT: 4000 K
  - Flow: 93.9 lm
  - Category: NC
- Visible white LED (lens-eye distance):
  - Colour: sunrise
  - Chromaticity CCT: 2700 K
  - Flow: 7 lm
  - Category: NC
- Infra-red LED:
  - Color: IR
  - Wavelength: 850 nm
  - Energy intensity: 35mW/Sr
  - Category: NC

VIII. General warnings

1. Exclusion of liability clause

- Each instrument constructed, marketed and/or put on the market directly and/or indirectly by Essilor is designed according to the provisions and the regulations in force. It contains the necessary information to ensure the intended use and permitting the identification of the manufacturer, taking into account the training, experience and knowledge of the intended user.
- This information, including that contained in the accompanying product manuals and the technical advice provided, whether oral, written or communicated during a demonstration, is provided on the basis of best knowledge. However, it must be considered as information without any binding effect, including third-party industrial property rights. It does not exempt the customer from checking current versions, communicated advice and suggestions, particularly the technical safety data sheets, instructions and technical information, as well as assessing the capacity of the instruments to ensure the intended use during delivery.
- The application, use and handling of these instruments as well as the products developed by the customer on the basis of technical consulting and/or maintenance activities are not under the control of Essilor. They are therefore the sole responsibility of the customer. Essilor declines any responsibility in the matter, as indicated below.
- The results and/or technical data resulting from the handling or use of instruments must be analyzed by professionals experienced in various fields of application of the instrument in order to avoid any risk of misreading or incorrect analysis of the data.
- The sale of products is governed by the general conditions of sale and delivery as modified.
- Diagnostics are carried out under the responsibility of the user and Essilor declines any responsibility for the results of these diagnostics.

2. Warning

Respect the operating and storage conditions noted below:

	Temperature	Humidity	Atmospheric pressure
Use	[+15°C; +30°C]	[30 %; 90 %]	[800 hPA; 1060 hPA]
Storage	[- 10°C; + 55°C]	[10 %; 95 %]	[700 hPA; 1060 hPA]
Transport	[- 40°C; + 70°C]	[10 %; 95 %]	[700 hPA; 1060 hPA]

Avoid condensation conditions.

- Do not install the instrument next to wireless devices (TV, radio, etc.). The instrument may cause interference.
- Never attempt to dismantle the instrument. This may cause a malfunction or fire.
- Do not try to repair or modify the instrument.
- Never try to perform any repairs inside the instrument yourself. In the event of malfunctions, consult your dealer.
- If the instrument does not work properly, do not touch the inside. Disconnect the plug from the outlet and consult your dealer.
- If liquid spills onto the instrument or foreign objects get inside, unplug the plug from the outlet and consult your dealer.
- If any abnormalities occur (noise, smoke, etc.), unplug the plug from the outlet and consult your dealer. Continued use may result in fire or personal injury.

- The presence of fingerprints or dust on the optical parts, for example on the observation windows, affects the accuracy of measurements. It is therefore recommended not to handle them with your fingers and to keep them away from dust. If there are fingerprints or dust on the optical parts, gently wipe them with a soft cloth.
- The covers are fragile, handling them while wearing jewelery or having long nails can lead to scratches.
- The white covers may yellow over time when exposed to ultraviolet light for an extended period.
- When the instrument is not in use, protect it using the cover provided.
- The continuous time of usage should not exceed 70 mins.
- No contraindications.

a. Power supply.

WARNING

To prevent risk of electric shock this device must be only connected to a supply fitted with a protective grounding system.

- Do not use multi-socket power strips, adapters or extension cords to connect the instrument to the mains.
- Take care to use the power cord grounding cable when connecting to the ground terminal.
- Do not damage the power cord (by bending it, pulling it or placing heavy objects on top of it, etc.). Do not modify it either. If the cord is damaged (loose contact, damaged sheath, etc.), replace it with a new cord. Continued use may result in an electric shock or fire.
- Make sure the power cord is fully inserted into both the plug and the instrument Failure to insert it properly may result in a fire or electric shock.
- Clean the power cord regularly to avoid dust buildup. If the cord is dirty, it may cause a malfunction or fire.
- If the power cord becomes hot after using the instrument, check that it is not dirty. If it is not, replace the power cord with a new one. Continued use may cause malfunction or personal injury.
- Use the instrument with the appropriate supply voltage. Continued use with a supply voltage greater than the rated power may cause malfunction or fire.
- Hold the plug when you insert or remove the power cord.
- Do not touch the power plug with wet hands. This may cause an electric shock.
- If you do not use the instrument for an extended period, disconnect the power cord from the outlet.

b. Computer network

- This instrument can transfer data to a computer or other devices via a USB or RJ45 interface. These devices must comply with standard IEC 62368-1.
- Connecting this instrument to a computer network that includes other equipment may result in safety and data protection risks.
- The responsible organization is expected to identify, analyze, evaluate and control these risks.
- Any subsequent changes to the computer network may cause risks and require further analysis.
- These changes include:
  - changing the configuration of the computer network;
  - connecting additional items to the computer network;
  - disconnecting computer network elements;
  - updating the equipment connected to the computer network;
  - upgrading the equipment connected to the computer network.
- Please contact your distributor for detailed information on this instrument.

c. Disposal

	Instructions for the disposal of the instrument in accordance with Directives 2012/19/EU and 2011/65/EU regarding the limitation of dangerous substances in electrical and electronic equipment and the disposal of electrical and electronic waste. When it reaches the end of its lifetime, the instrument should not be thrown out with the household refuse. It can be disposed of at a waste management center operated by the municipality or the retailers who offer this service. The separate disposal of an electrical device avoids any damage to the environment or health that could result from a non-compliant disposal, and also allows the materials it is composed of to be recycled in order to save energy and resources. The pictogram of the wheeled container appears on the label of the instrument. It indicates the obligation for separate collection and disposal of end-of-life/out-of-use electrical and electronic equipment.

The user must take into account the potentially harmful effects on the environment and human health that could result from the non-compliant disposal of the instrument in its entirety or some of its components.

To avoid the release of dangerous substances into the environment and to encourage the preservation of natural resources, the manufacturer facilitates, in the event that the user wishes to dispose of the instrument at the end of its lifespace, the reuse, recovery and recycling of the instrument and its components. Before disposing of the instrument, the requirements of European and national regulations must be taken into consideration.

- Do not dispose of the instrument with household waste, but dispose of it separately by giving it in a company specialized in the disposal of electrical and electronic equipment or at the local administrative services in charge of waste collection.
- The supplier or manufacturer is required to recover the old equipment.
- By joining a consortium for the waste of technological equipment, the manufacturer covers the treatment and recycling costs of the used instrument.

The manufacturer undertakes to provide the user with all the information relating to the dangerous substances contained in the device and the methods of recycling these substances, and to inform them of the existence of recycling of the used equipment.

The law provides for severe penalties in case of infringement.

3. ELECTROMAGNETIC COMPATIBILITY

This instrument complies with the electromagnetic compatibility standard (IEC 60601-1-2 Ed. 4.0:2014).

1. This instrument requires special precautions regarding Electromagnetic Compatibility (EMC) and must be installed and put into service according to the EMC information provided in this operating manual.
2. The portable and mobile RF communications equipment (Radio Frequency) may affect medical electrical equipment.
3. The use of accessories, transducers and cables other than those specified, with the exception of transducers and cables sold by the hardware or system manufacturer as replacement parts for internal components, may result in increased emissions or a decrease in the immunity of the equipment or system.

4. The equipment or system should not be used next to or placed on top of another device. If use in the vicinity of another device or with the device installed on top of another device is required, it must be checked for proper operation in the exact configuration where it will be used.
5. Essential performances : Product integrity is as described on the leaflet after immunity tests. The device is designed according to ISO 10341
6. Appliance shall fulfill these essential performances for all Immunity tests (ESD, Radiated RF disturbance, Fast transient, Surge, Conducted RF disturbance, Magnetic field).

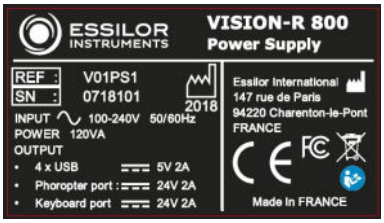
Manufacturer guidelines and declaration - Electromagnetic emissions		
Vision-R™ 800 is intended to be used in the electromagnetic environment specified below. It is up to the customer or the user to verify that the instrument is used in this environment.		
Emissions test	**Compliance**	**Electromagnetic environment – Guidelines**
RF emissions CISPR 11	Group 1	Vision-R™ 800 uses RF energy only for its internal functions. Therefore, its RF emissions are very low and are not likely to generate any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	Vision-R™ 800 can be used in all sites, including domestic sites and those that are directly connected to the public low-voltage power supply network that supplies private residential buildings.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/Flicker emissions IEC 61000-3-3	Complies	

Manufacturer guidelines and declaration - Electromagnetic immunity			
Vision-R™ 800 is intended to be used in the electromagnetic environment specified below. It is up to the customer or the user to verify that the instrument is used in this environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – Guidelines**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	The floor must be out of wood, concrete or ceramic tiling. If the floor is covered with a synthetic material, the relative humidity must be at least 30%.
Fast transients/Electric bursts IEC 61000-4-4	± 2 KV (repetition frequency 100 KHz)	± 2 KV (repetition frequency 100 KHz)	The quality of the power supply must be that of a typical hospital or commercial environment.
Surge IEC 61000-4-5	± 1 KV in differential mode ± 2 KV in current mode	± 1 KV in differential mode ± 2 KV in current mode	
Immunity to the magnetic field at frequency (50/60 Hz) IEC 61000-4-8	30 A/m		Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% U_T (0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° for 0.5 cycle) 0% U_T for 1 cycle 70% U_T phase with 0° for 25/30 cycles 0% U_T for 250/300 cycles	0% U_T (0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° for 0.5 cycle) 0% U_T for 1 cycle 70% U_T phase with 0° for 25/30 cycles 0% U_T for 250/300 cycles	The quality of the power supply must be that of a typical hospital or commercial environment. If the user of the instrument needs uninterrupted use in the event of a power failure, it is recommended to power the instrument using an uninterruptible power supply or battery.
NOTE: U_T is the AC mains voltage before applying the test level.			

Manufacturer guidelines and declaration - Electromagnetic immunity			
Vision-R™ 800 is intended to be used in the electromagnetic environment specified below. It is up to the customer or the user to verify that the instrument is used in this environment.			
Immunity test	**Test level IEC 60601**	**Compliance level**	**Electromagnetic environment – Guidelines**
Conducted RF disturbances IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 0.15 KHz to 80 MHZ 3 V/m 80 MHZ to 2.7 GHZ	3 Vrms 0.15 KHz to 80 MHZ 3 V/m 80 MHZ to 2.7 GHZ	Portable and mobile RF communications equipment should not be used any closer to any part of the instrument, including cables, than the recommended separation distance calculated according to the equation applicable to the frequency of the transmitter. Recommended separation distance d= 1.2 √P d= 1.2 √P 80 MHZ to 800 MHZ d= 2.3 √P 800 MHZ to 2.7 GHZ knowing that (P) represents the maximum rated output power of the transmitter in watts (W) according to the manufacturer of the transmitter, and (d) is the recommended separation distance in meters (m). The field strength emitted by RF transmitters, as determined by an electromagnetic study[i] should be less than the compliance level in each frequency range [b]. Interference may occur near equipment marked with the following symbol:
NOTE 1: At 80 MHZ and 800 MHZ, the higher frequency range applies. NOTE 2: These indications may not apply to all the situations. Electromagnetic propagation is affected by absorption and reflections of structures, objects and people.			
[i] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcasting, and TV broadcasting, cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength at the location where the instrument is used exceeds the applicable RF compliance level stated above, please check to ensure the instrument is operating normally. If abnormal performance is observed, additional measures may be necessary, for example the reorientation or movement of the instrument. [b] On the frequency range ranging between 150 KHz and 80 MHZ, field strengths must be less than 3 V/m.			

Recommended separation distance between the mobile and portable RF communications equipment and Vision-R 800™			
Vision-R™ 800 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the instrument can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the product by following the recommendations below, based on the maximum power output of the communication equipment.			
Maximum nominal power output of the transmitter (W)	**Separation distance depending on the frequency of transmitter (m)**		
	150 Khz to 80 MHZ d= 1.2 √P	80 MHz to 800 MHz d= 1.2 √P	800 MHZ to 2.5 GHZ d= 2.3 √P
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters whose maximum rated power is not mentioned above, the recommended separation distance (d) in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where (p) is the maximum rated power output of the transmitter in Watts (W) according to the manufacturer of the transmitter. NOTE 1: At 80 MHZ and 800 MHZ, the separation distance of the higher frequency range applies. NOTE 2: These indications may not apply to all the situations. Electromagnetic propagation is affected by absorption and reflections of structures, objects and people.			

4. Device's registration plate

Device's registration plate	Power block registration plate	Console's registration plate
		

5. MAINTENANCE

In order to ensure safety and the performance of the instrument, all maintenance operations, unless otherwise specified in this manual, must be carried out by qualified maintenance technicians.

- This instrument is a high precision optical device. Handle it carefully at all times.
- Take care to handle the instrument carefully in order to avoid any scratches (covers for example).
- Always handle the refraction head by the upper part, do not hold it or never move it by its moving parts (lower).
- Do not touch the optical parts (the observation window for example) with your fingers, and take care to clean off any dust buildup which would be likely to distort the result of measurements.
- Unplug the instrument before cleaning.

Do not use benzene, thinners, organic solvents, ether or gasoline to clean the instrument.

a. Cleaning the head

Always use a slightly damp soft cloth (microfiber, silicone), to clean the elements of the head:

- The face shields by removing them beforehand
- The forehead rest
- The optics
  - patient side (only if a trace is identified)
  - practitioner side
- The camera window for near-vision distance measurements
- The camera windows for lens-eye distance measurements
- The LED panel

To disinfect the areas likely to be in contact with the patient (face shields and forehead rest), use disinfectant wipes for medical use or ethanol. Clean these areas between testing each patient.

Disinfectant ethanol contains from 76.9 to 81.4% of ethanol (C_2H_6O. 46.07) with 15°C (specific gravity).

Do not clean the observation windows (patient side) with liquid, nor with a compress held in a clamp or a screwdriver to prevent damage of the optical surfaces.

b. Cleaning the console

Always use a slightly damp soft cloth (microfiber, silicone), to clean the elements of the console:

- The touch screen
- The keyboard

Do not squirt liquids of any kind on the touch screen or on the console keyboard, to prevent damage to the electronic boards.

IX. QR Code

The complete user manual is available on a web space. To access, please scan the QR codes below using a dedicated application.

The complete user manual is available on a web space. To access, please scan the QR codes below using has dedicated application.

Die vollständige Bedienungsanleitung STI auf einem Speicherplatz verfügbar: Für den Zugriff darauf scannen Sie bollard untenstehenden QR-Code mittels einer dafür vorgesehenen Anwendung.

العربية الأدبية

إن الدليل الكامل للمستخدم متاح على استضافة ويب. لتتمكن من الوصول إليه, يُرجى مسح رمز الاستجابة السريعة أدناه باستخدام تطبيق مخصص لذلك.

O manual C usuário completo está disponível Na área Web C customers. Para acessar, scanear O código QR abaixo usando has respetiva aplicação.

Пълното ръководство за потребителя е достъпно на уеб пространство. За достъп, моля, сканирайте QR кода по-долу с помощта на специално предназначено приложение.

操作手册全文可在一个网络空间内查询。如要访问该空间, 请使用一个专门的应用软件扫描 QR 条码。

완전한 사용자 매뉴얼이 웹사이트에 있습니다. 전용 앱을 사용해 아래의 QR 코드를 스캔하면 접근할 수 있습니다.

Potpuni korisnički priručnik dostupan I Na webu. Da bist driven pristupili, skenirajte QR-kod U nastavku namjenskom aplikacijom.

Den komplette brugermanual findes på and websted. Får adgang T it den ved At scans QR-koden nedenfor ved hjælp af in dertil beregnet applikation.

El manual of uso completo está available in the Web. Para to access, escanee el código QR that will encuentra itself has continuación idiot the ayuda of una aplicación.

Täielik kasutusjuhend one saadaval veebis. Juurdepääsuks palun skannige allolevat QR-koodi, kasutades selleks spetsiaalset rakendust.

Täydellinen käyttöohje one käytettävissä verkossa. Avaa käyttöohje skannaamalla QR-koodi asianmukaisella sovelluksella.

Το πλήρες εγχειρίδιο χρήσης διατίθεται σε έναν ιστοχώρο. Για να μεταβείτε σε αυτόν, σαρώστε τον παρακάτω κωδικό QR μέσω μιας ειδικής εφαρμογής.

With teljes használati útmutató megtalálható has webes felületen. A hozzáféréshez, kérjük, olvassa has it lenti QR-kódot has megfelelő alkalmazás használatával.

Panduan pengguna yang lengkap tersedia di Web space. Untuk mengaksesnya, silakan pindai kode QR berikut dengan menggunakan aplikasi khusus.

It manuale utente completo è disponibile known uno spazio Web. Per accedervi, scansionare it codice QR seguente mediant un' applicazione dedicata.

ユーザーマニュアル完全版はウェブサイト内で閲覧いただけます。そちらにアクセスするには、 以下の専用アプリケーションを使用して QR コードをスキャンしてください。

Pilnā lietotāja instrukcija ir pieejama tīmeklī. Lay tai piekļūtu, lūdzu, noskenējiet tālāk redzamo QR kodu, izmantojot tam paredzētu lietojumprogrammu.

Išsamaus naudotojo vadovo ieškokite interneto svetainėje. Kad jį atvertumėte, specialia programėlę nuskaitykite toliau pateiktą QR kodą.

Manual pengguna yang lengkap boleh didapati di ruangan Web. Untuk akses, sila imbas kod QR di bawah menggunakan aplikasi yang berkenaan.

Den komplette brukerhåndboken er tilgjengelig på and webområde. For å få tilgang, må of the skanne QR-koden nedenfor ved front hjelp in dedikert applikasjon.

Of volledige gebruikershandleiding is beschikbaar op een website. U kunt of handleiding bereiken door of QR-code hiernaast you scannen puts een geschikte applicatie.

Kompletna instrukcja użytkownika jest dostępna Na stronie internetowej. Aby uzyskać dostęp, zeskanuj poniższy kod QR przy użyciu dedykowanej aplikacji.

O manual C utilizador completo está disponível num espaço Web. Para aceder, will queira digitalizar O QR codes seguinte COM has ajuda uma aplicação dedicada.

Celá uživatelská příručka I K dispozici Na webu. Pro přístup K ní oskenujte níže uvedený QR kód pomocí specializované aplikace.

Versiunea integrală has manualului utilizare este disponibilă EP a Web site. Pentru a-l accesa, scanați codul QR of May jos Cu ajutorul unei aplicații dedicate.

Полное руководство пользователя доступно на сайте. Чтобы получить к нему доступ, сканируйте QR-код ниже с помощью специального приложения.

Potpuno korisničko uputstvo I dostupno Na vebu. Da bist driven pristupili, skenirajte QR kôd U nastavku pomoću namenske aplikacije.

Celý používateľský manuál I dostupný Na internete. Aby ste its K nemu dostali, naskenujte QR kód nižšie pomocou Na to určenej aplikácie.

Celoten uporabniški priročnik I Na voljo Na spletnem mestu. Za dostop C njega skenirajte spodnjo kodo QR Z uporabo namenske aplikacije.

Den fullständiga handboken fine på in dishes på Internet. Skanna QR-koden nedan med in lämplig app för att få åtkomst T it den.

มีคู่มือผู้ใช้ฉบับสมบูรณ์ให้ที่เว็บไซต์ เพื่อเข้าถึงข้อมูล กรุณาสแกนรหัส QR ด้านล่างนี้โดยใช้แอปพลิเคชั่นเฉพาะงาน

Kullanma kılavuzunun tamamı internette bulunmaktadır. Kılavuza erişmek için, drunk amaca yönelik to bir uygulama kullanarak aşağıdaki QR kodunu taratın.

Повний посібник користувача доступний на сайті. Щоб отримати до нього доступ, скануйте QR-код нижче за допомогою спеціального додатку.

Cẩm nang hướng dẫn s dụng hoàn chỉnh hiện có trên không gian Web. Đ truy cập, vui lòng quét m, QR Ben dưới s dụng ứng dụng chuyên dụng.

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