

EYEVIZ 300



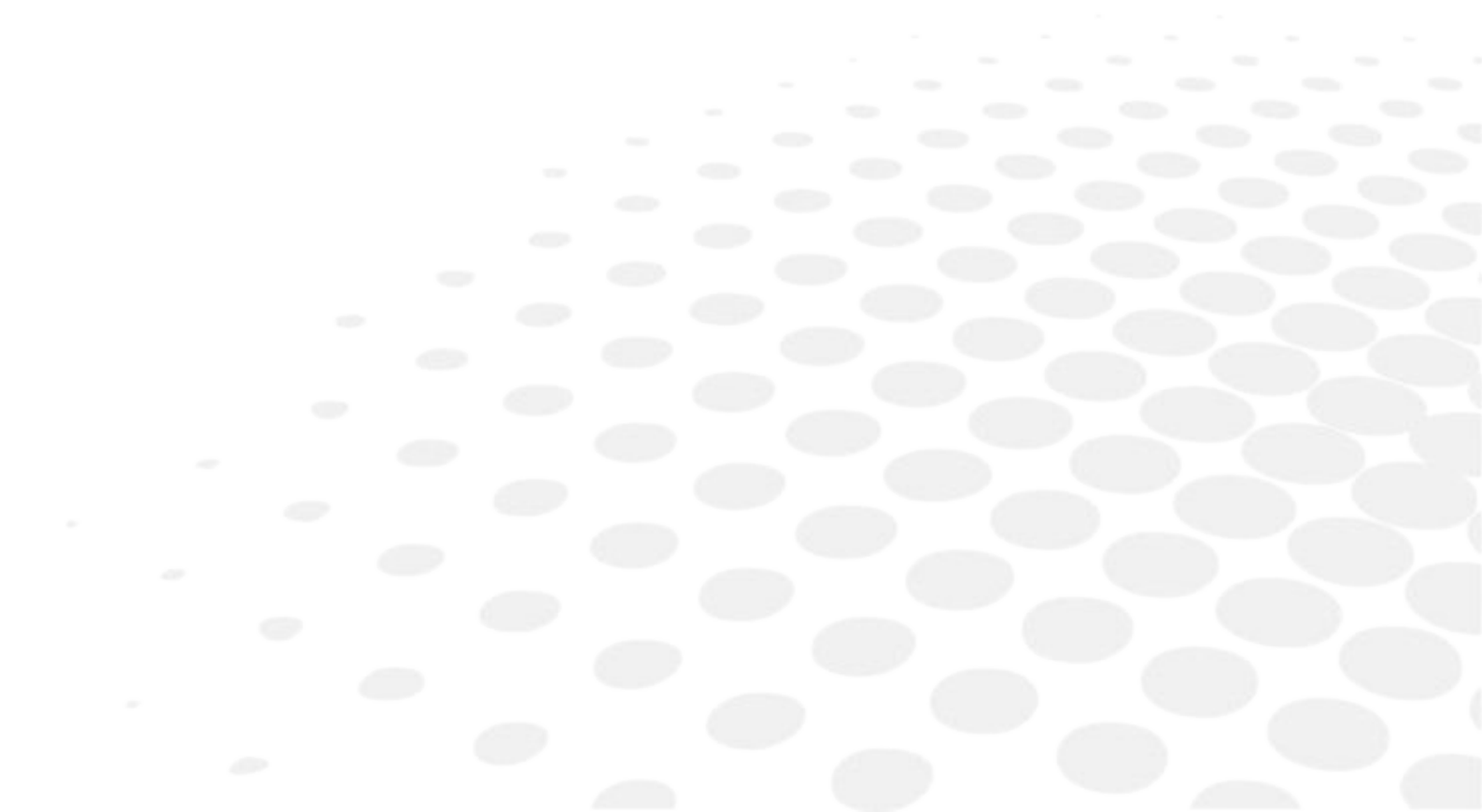
User manual

CONTENTS

I. INTRODUCTION	5
II. GENERAL WARNINGS	7
1. About this manual	8
2. Description of device	8
3. Types of warnings, cautions and notes	8
4. List of abbreviations	9
5. Symbols & Label	10
a. Symbols marked on the instrument	10
III. CONDITIONS FOR USE	11
1. Use	12
a. Intended use	12
b. Indications for use	12
c. Limitations of use	12
d. Contraindications	12
2. Safety	13
a. Electrical safety	13
b. EMC Compliance	13
c. Safety instructions	13
IV. SET UP THE SYSTEM	15
1. Power on and login to system	18
2. Shut down the system	19
3. Position the patient	20
4. Put on the glasses	21
5. Main menu	22
6. Settings screen	22
a. [Facility name]	24
b. [Date and zone time]	25
c. [Change password]	26
d. [Default mandatory subject info]	27
e. [Set modes]	28
f. [Categories]	29
g. [Language configuration]	31
h. [User logo settings]	33
i. [Visual acuity units settings]	34
V. SET UP THE TESTS	37
1. Overview of initial setup screen	38
2. Patient information	39
3. Tests to run	40
4. Tests settings	43
VI. RUN THE TESTS	45
1. Verify correct operation	46


2. Start the tests	48
VII. TESTS RESULTS	49
1. Results	51
2. CT and ACT results key	53
VIII. MAINTENANCE & SERVICE	55
1. Maintenance	56
a. Determining the battery state	56
b. Led low battery indicator	56
c. Indicator on the lenses for low battery	56
d. Charging the battery	56
2. Clean and Disinfect	57
3. Service and repair policy	57
4. Warranty	57
IX. TROUBLESHOOTING	59
1. Error conditions	60
2. Error messages	61
X. SPECIFICATIONS	63
XI. QR CODE	65

I. INTRODUCTION

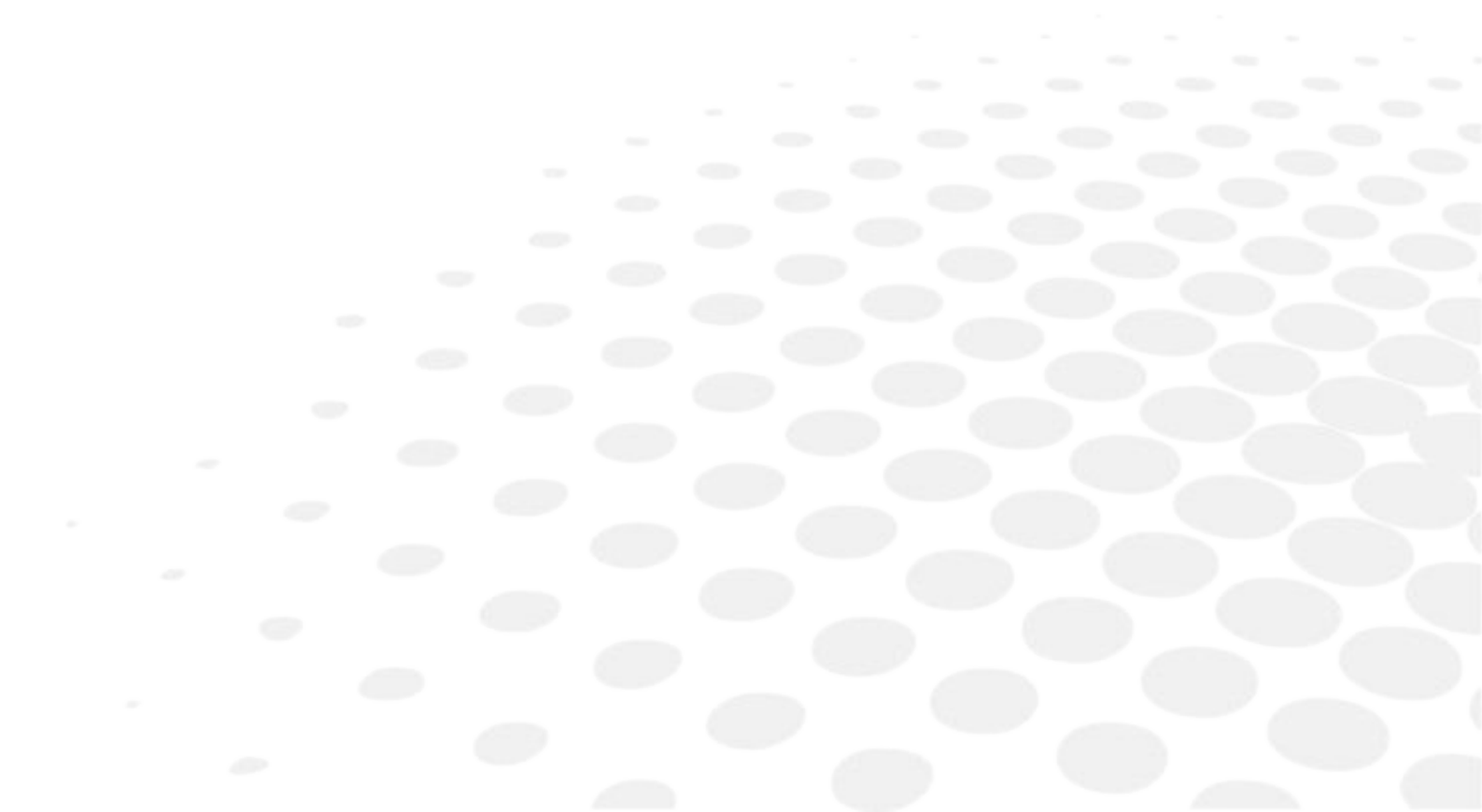




The complete user manual is available on a web space.

To access other available languages, please scan the QR code at the end of this user manual > Chapter QR code ( p.66).

II. GENERAL WARNINGS



1. ABOUT THIS MANUAL

This user manual provides the information necessary to operate and maintain the EyeViz300 assessment system.

Please read this user manual before operating the system. If any part of this user manual requires further explanation, contact customer support for assistance.

Please retain this user manual for future reference.

2. DESCRIPTION OF DEVICE

The product is intended for use by a health care professional and requires no special training to operate other than reading the user manual, which includes comprehensive explanations regarding system operation and handling of various errors and warnings.

The system is based on eye tracking technology, which provides constant information regarding the position of the patient's eyes. Near-infrared illumination is used to create reflection patterns on the cornea (glint) and pupil of the eye of the patient, and these reflections are detected by capturing images using an infrared camera.

Following detection, a vector formed by the angle between the cornea and pupil reflections is calculated—the direction of this vector, combined with other geometrical features of the reflections, is then used to calculate the gaze direction. Advanced image-processing algorithms and a physiological 3D model of the eye are then used to estimate the position of the eye in space and the point of gaze with high accuracy.

To perform the deviation tests, a special pair of glasses is used which, when controlled via the EyeViz300 software, can enable alternating covering and uncovering of each eye similarly to the traditional cover test. For the tests where a 3D image appearance is required, or where a dichoptic test is used, red-cyan anaglyph glasses are used. The physician interacts with the system through the EyeViz300 user interface. The patient puts on the testing glasses and follows a visually stimulating target on the screen. No language or verbal skills are needed in order to perform the test. Once the test is completed, the test results are provided and can be recorded for future reference.

Product regulatory reference : EVZ1IN

3. TYPES OF WARNINGS, CAUTIONS AND NOTES

Three types of special message appear in this user manual:



Warning

A warning indicates precautions to avoid the possibility of personal injury or death.



Caution

A caution indicates a condition that may lead to damage to equipment, or a lower quality of treatment.



Note








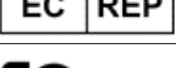









A note provides other important information.

4. LIST OF ABBREVIATIONS

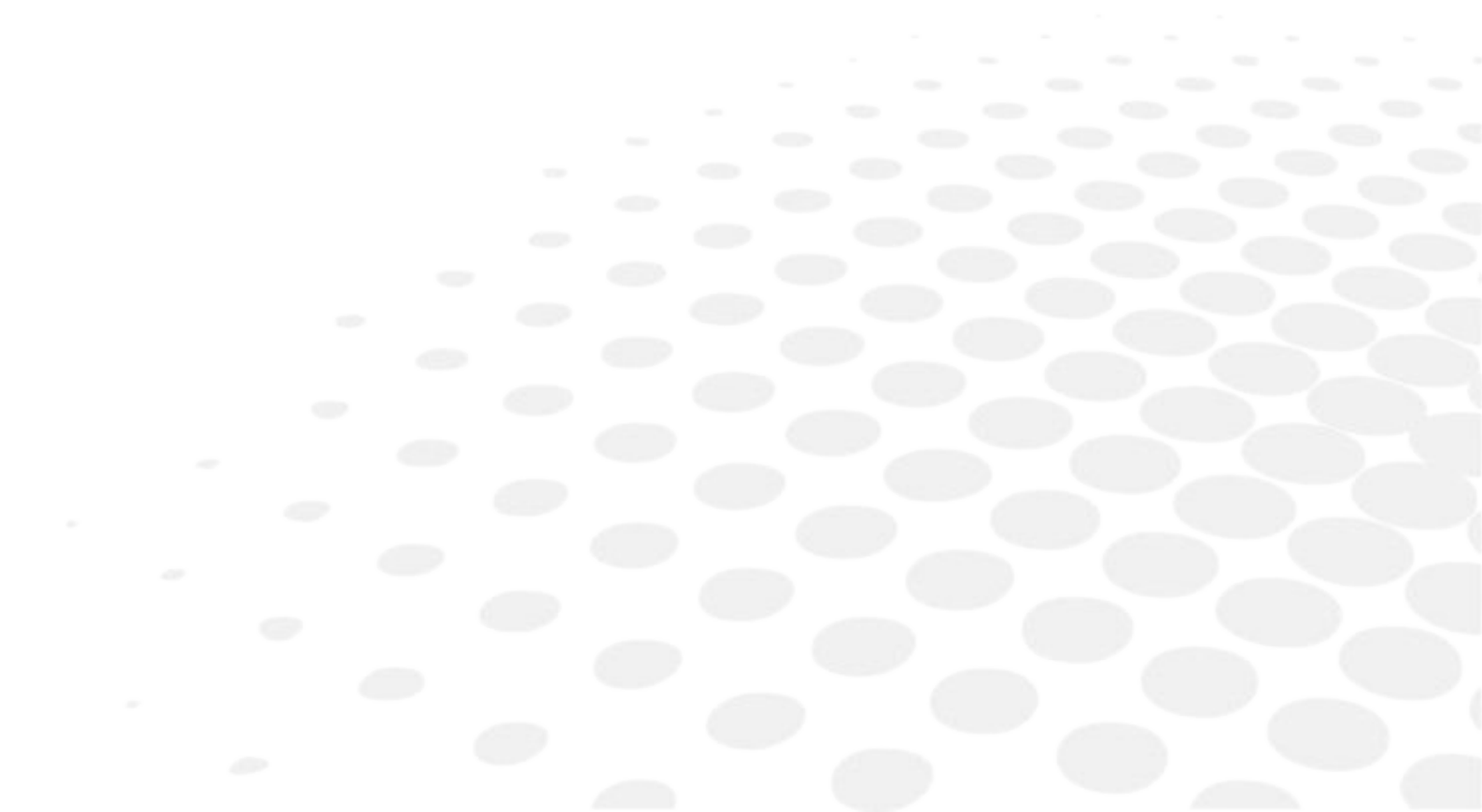
User	Test operator
Dev. eye/ Deviating/ DE	Deviating eye (in strabismus measurement)
R	Right
L	Left
A	Alternating
CT	Cover Test
ACT	Alternating Cover Test
H	Horizontal
V	Vertical
Dist.	Distance
ID	Identification
SC	Sans Correction (no refractive correction)
CC	Con Correction (with refractive correction)
OD	Oculus Dexter (Right Eye)
OS	Oculus Sinister (Left Eye)
PD	Pupillary Distance
DOB	Date of Birth
VA	Visual Acuity
CS	Contrast Sensitivity
S	Small
M	Medium
L	Large
Eso	Towards the nose
Exo	Outwards from the nose
Hypo	Too low
Hyper	Too high

5. SYMBOLS & LABEL

a. Symbols marked on the instrument

	Refer to operation manual It means that, for safety reasons, you need to consult the instruction manual before using the device
	"CE marking" that attests to product compliance with European Union Directive 93/42/EEC (Medical Devices) and following amendments
	Indicates the obligation to collect and separate disposal of electrical and electronic equipment, at the end of their useful life, according to 2012/19/EU
	Manufacturer serial number
	Manufacturer catalogue number
	Date of manufacturing
	Manufacturer
	Authorized Representative Information
	FCC symbol
	QR code
	RoHS compliance
	Warning
	This side up
	Fragile
	Keep dry
	Recyclable
	Type BF (B = Body, F = Floating applied part) applied part

III. CONDITIONS FOR USE



1. USE

a. Intended use

The EyeViz300 is intended for the automated and manual detection of parameters related to ocular and visual function and is intended to be used by a health care professional.

b. Indications for use

The EyeViz300 is indicated for:

1. Detection of a deviating eye
2. Automated assessment of heterophoria and heterotropia in the primary eye position at near and far
3. Automated detection and assessment of fusional divergence and convergence
4. Automated detection of pupillary distance
5. Automated assessment of visual acuity at near and far
6. Manual detection of visual acuity at near and far
7. Presentation of a Worth 4-dot test
8. Manual detection of color vision impairments
9. Manual measurement of stereoacuity
10. Automated analysis of reading patterns

The EyeViz300 is indicated for use in patients over the age of 6 months who are responsive to taking direction and who can pay attention for at least 3 minutes as part of an evaluation in a professional eye care setting.

c. Limitations of use

Clinical situations potentially affecting device accuracy or performance include the following:

- Testing is not recommended for babies under the age of 6 months
- Testing while patient wears glasses with high refractive index may cause assessment difficulties, leading to increased assessment time
- If the patient is wearing bifocals, instruct them to use the appropriate part of the bifocal glasses, the near segment of the bifocals for the near tests, and the distance segment for the far tests
- Multifocal glasses may cause issues with eye detection by the eye tracker

Patient movement and fidgeting may lead to difficulty in completing testing.

d. Contraindications

- Significant neurological or behavioral problems
- Patients with only one eye
- Patients whose binocular visual system has not yet fully developed

2. SAFETY

a. Electrical safety

The device complies with requirements of IEC/EN 60601-1 for general requirements for safety of medical electrical equipment:

- Class I Equipment BF type applied part
- Mode of operation: continuous assessment
- Degree of mobility: portable

b. EMC Compliance

The unit has Class B compliance.

c. Safety instructions



Warnings

- Do not use before reading and understanding this user manual.
- The product's system is intended for indoor operation.
- Do not use the product beyond the declared environmental conditions. Operation outside of these limits can lead to incorrect assessment.

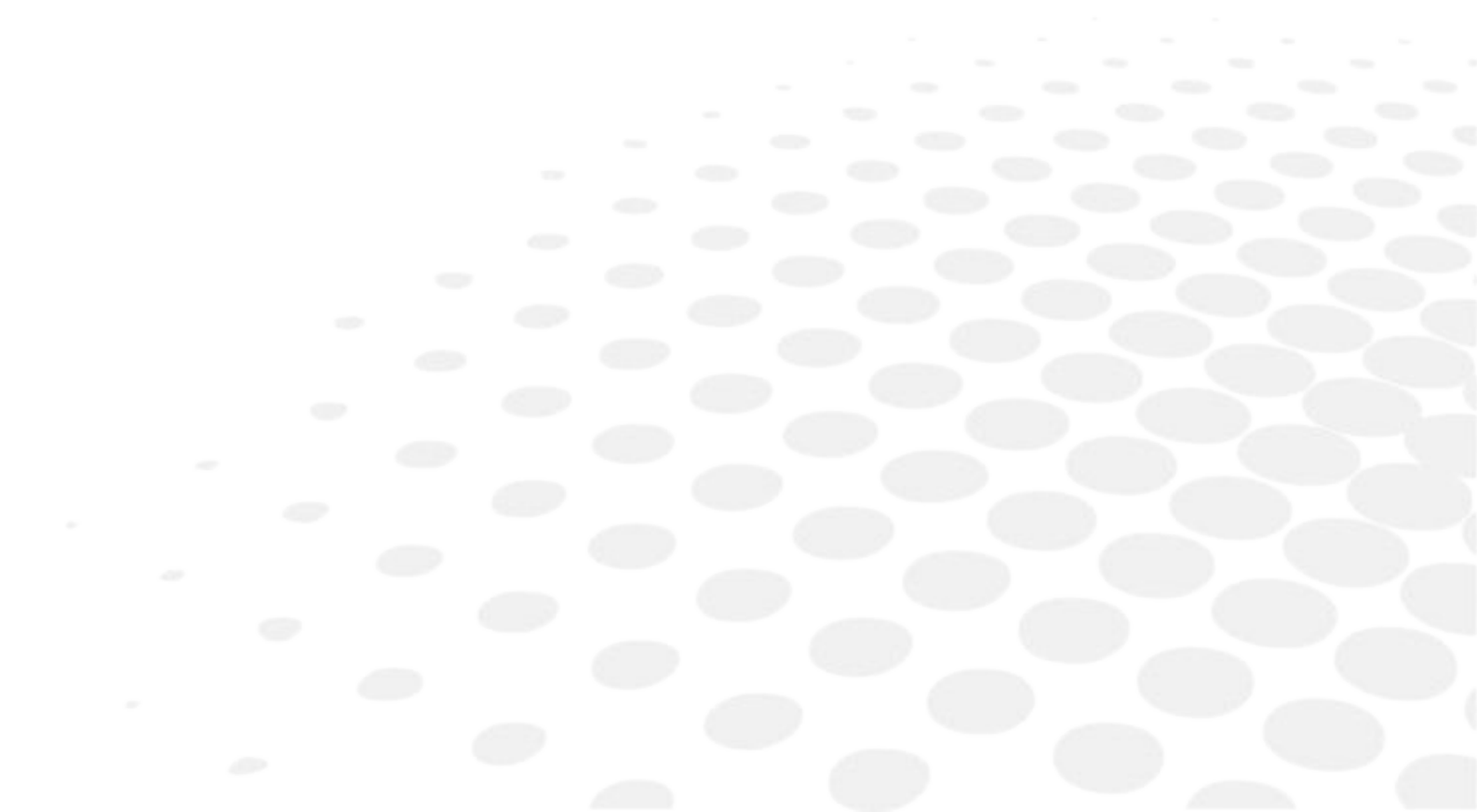


Cautions




Factors that may affect the accuracy of the assessment include the following:

- Eyeglasses with high refractive index
- Extraneous movements or excessive fidgeting of patient
- Clean the device before applying it to a new patient.
- The system should be placed on a stable surface in order to avoid any risk of harm or damage to the patient
- Do not sterilize, autoclave, or immerse this device in liquid. Do not pour or spray any liquids into the device.
- If the system overheats, contact customer service.
- Do not expose the product to excessive moisture such as direct exposure to rain. Excessive moisture can cause the device to perform inaccurately or fail.
- Do not expose the product to temperatures outside of the normal operating range, as this may cause the device to perform inaccurately or fail.
- This device is a precision electronic instrument and must be repaired by Essilor qualified technical professionals. Field repair of the device is not possible. Do not attempt to open the case or repair the electronics. Opening the case may damage the device and void the warranty.
- Follow relevant government regulations regarding disposal or recycling of the device and device components, including batteries.
- In compliance with the European Directive on Waste Electrical and Electronic equipment (WEEE) 2012/19/EU, do not dispose of this product as unsorted municipal waste.
- This device contains WEEE materials. Please contact your distributor regarding return or recycling of the device. If you are unsure how to reach your distributor, please call Essilor for your distributor's contact information.
- Do not disassemble any part from the device.
- This device is not user-serviceable.

IV. SET UP THE SYSTEM



The components of the EyeViz300 system are shown below.

	<p>EyeViz300 system with:</p> <ul style="list-style-type: none"> • Tablet PC: displays user interface and displays targets to patient during tests • Eye tracker: records eye position • Infra-red emitter: controls lens shutters of the glasses
	<p>IR glasses (worn by patient)</p>
	<p>Anaglyph glasses (worn by patient)</p>

Before using the system, please check that the following components are properly prepared and connected.

- 1 Connect the power adaptor to AC power.



- 2 Make sure that the system display is clean.



Wipe if necessary with a damp cloth.

- 3 Check the glasses.

Check that the glasses are clean and in proper working order.



Disinfect the glasses between patients, as described in section [Clean and Disinfect].

Please see section [Service and Maintenance] for instructions to check that the battery is properly charged.



Do not remove or tamper with the red stickers found on the front of the glasses.

These stickers are important for the correct functioning of the internal distance correction system.



4 Turn on the glasses.

There is no need to turn on the glasses. The glasses will wake automatically when the system loads.

On wake up the glasses will display three fast blinks and the LED will turn on for several seconds.

If the glasses do not signal wakeup, press the button (1) once. The red LED will turn on.



5 Turn off the glasses.

There is no need to shut down the glasses. The glasses will shut down automatically when the system is not in use.

If you do wish to manually shut down the glasses, press the button (1) until the red LED will flash for a moment and then turn off. The glasses will then shut down.

In addition to the LED indicator, when powering down the glasses, the glasses will display a long blink and open both lenses.





Low battery indication: The following indications are shown in case of low battery. The LED will blink on and off.

If the glasses are in sleep mode, the lenses will also blink open and closed.

6 Prepare the IR front panel.

Check that the front IR panel is clean and unobstructed.



Wipe if necessary with a lens cleaning cloth.



1. POWER ON AND LOGIN TO SYSTEM

1 To start the system, press the power on button on the top of the system.



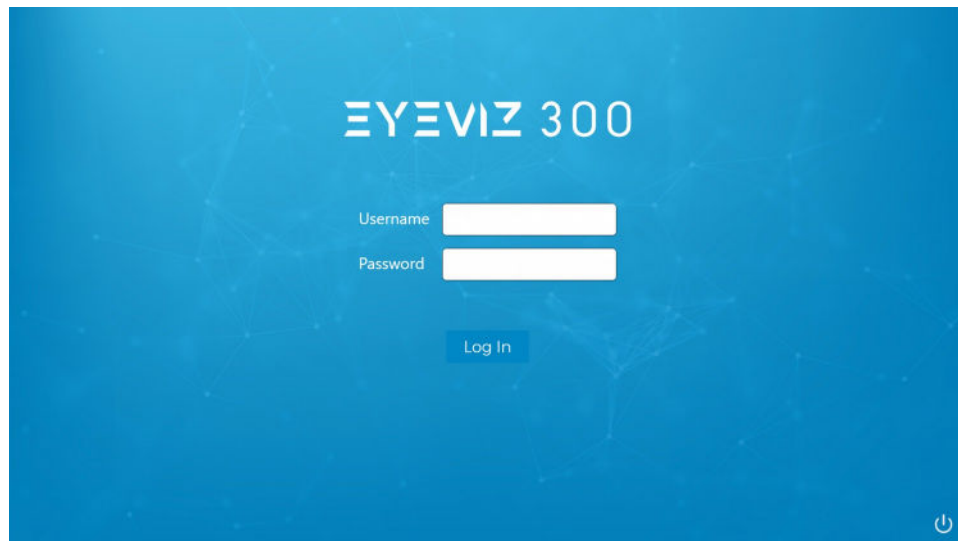
Contact customer service if the system does not turn on after the power supply has been checked.

> The login screen will be displayed.

2 Please enter the user name and password that are defined for your system.



- The default user name is [Admin].
- The default password is [1234].



If the system does not display this screen, or if other errors occur during system startup, check that the system components are connected properly.

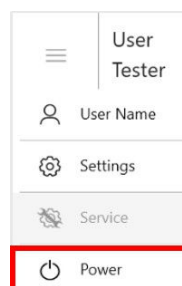
If the system still does not work properly, please contact customer service.



If the touch-screen or other functionality does not work properly, please contact customer service.

2. SHUT DOWN THE SYSTEM

After you have run the desired tests and viewed the results, you may shutdown the system by pressing [Power] on the main menu:



The program will close and the system will shut down.



Contact customer service if the system does not turn off.

3. POSITION THE PATIENT





It is very important to assure that the patient maintains the correct head position for the duration of the test. Improper head position may lead to incorrect results.

The patient's head must be maintained in the primary position. If the patient cannot maintain this position independently, the operator should correct the head position and maintain it for the duration of the test.

The patient must be at the correct height and centered in front of the screen.

This can be confirmed by observing the indicators on the top right of the screen. When correctly positioned, the indicators should appear as follows:

Centered and correct height	Correct distance
	



Small children can be seated on their mother's lap.

Correct placement of device, with the patient sitting directly in-front of the system at a distance between 50 and 80 cms.



4. PUT ON THE GLASSES



Make sure the glasses have sufficient battery before wearing.

Then, turn on the glasses by pressing the on/off switch, as shown below:




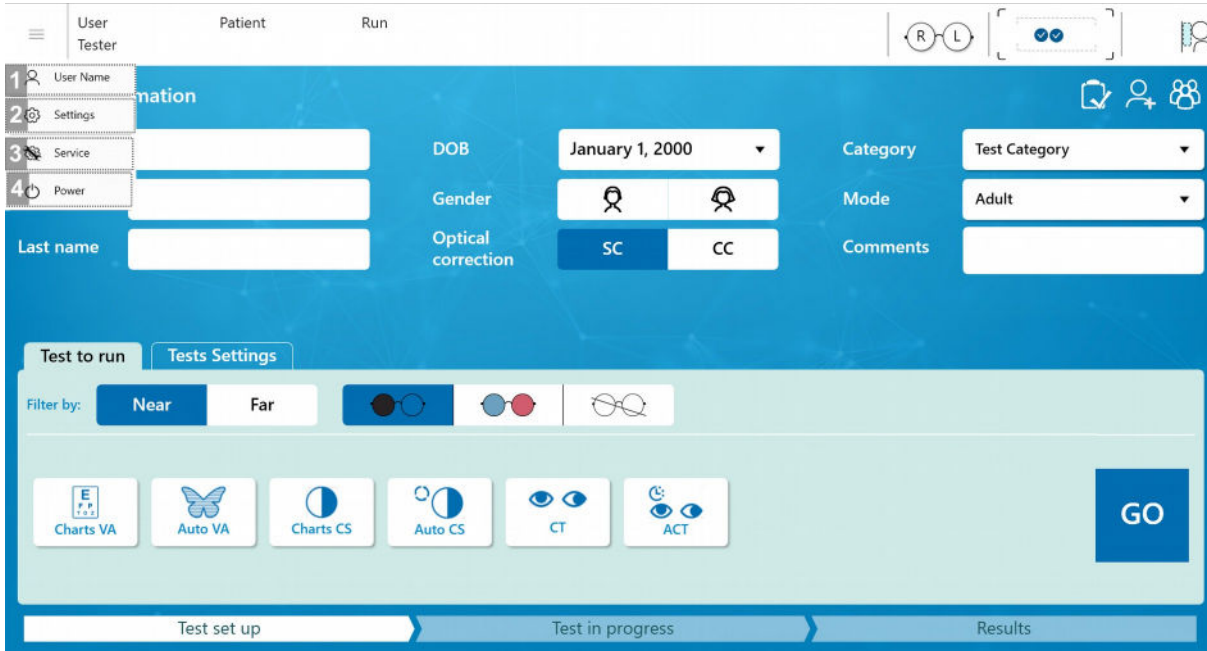
Proper placement of the glasses

Glasses should be placed on top of the patient's prescription glasses. When putting on the glasses, make sure that the glasses do not slip down the nose.



5. MAIN MENU

Press on the  icon to view the main menu:



1. [User Name]

Enter the user name that will identify this session.

2. [Settings]

View and change the settings.

3. [Service]

Enables the support team to analyze and fix issues with the system.

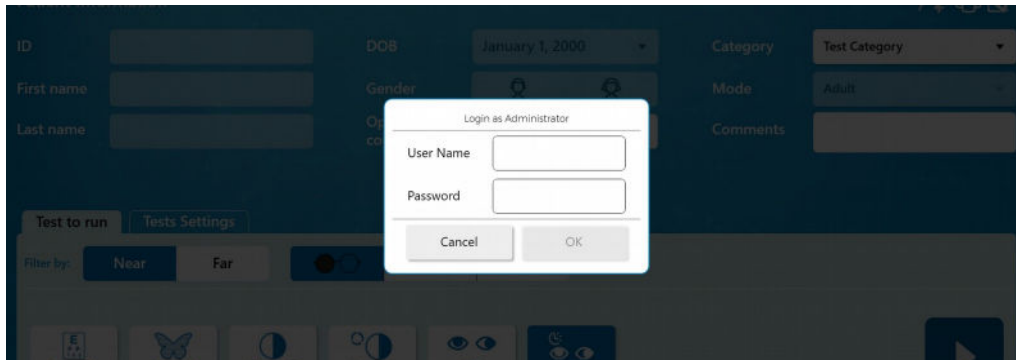
4. [Power]

End the session and shut down the system.

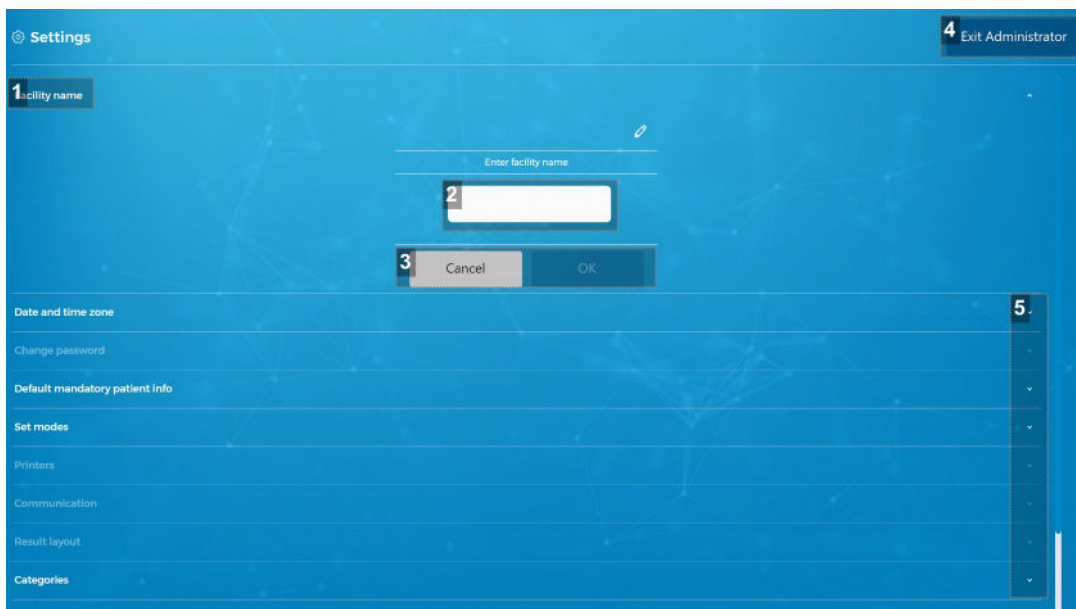
6. SETTINGS SCREEN

To access the settings screen, you must select settings from the menu on the top panel. A dialog box will open where you are required to enter the admin user name and password.

- The default user name is [Admin].
- The default password is [1234].



When you press on one of the settings, the screen will expand the section and allow you to enter its details. Press [OK] or [Cancel] will collapse that setting but keep you in the settings screen. Press on [Exit Administrator] to exit from the settings screen.



1. [Facility name]

Press to open the [Facility name] section.

2. [Enter facility name]

Press to edit the facility name.

3. [Cancel] / [OK]

Press [Cancel] or [OK] to collapse this section.

4. [Exit Administrator]

Press to exit from the [Settings] screen.

5. Arrows

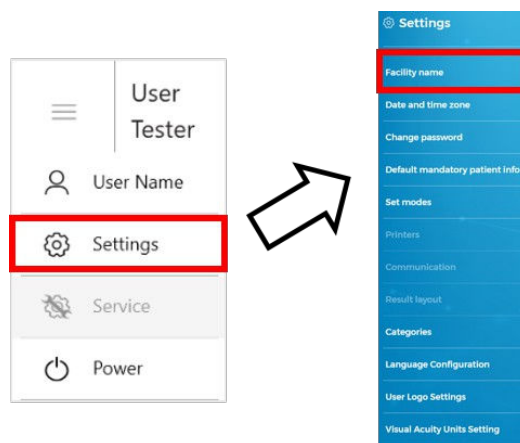
Press to open or close a setting.

MENU ITEM FOR SETTINGS	DESCRIPTION
Facility name	Name of the hospital or other medical facility.
Date and time zone	Must be maintained by user.
Change password	Maintain the user and administrator passwords.
Default mandatory patient info	Change which subject information is required before a test may be run.
Set modes	Change the 'mode' settings for each age group. This will change the default settings applied when a patient belonging to the age group is run. The settings for each individual patient may still be changed for the regular settings on the [Test Setup] tab.
Categories	Enables setting of different patient categories, in case there is a need to stratify the patient population.
Language configuration	Change the system language.
User logo settings	Upload the facility logo from an external USB drive. The logo will appear on the output report. Logo dimensions must be 80x20 pixels.
Visual acuity units setting	Set the units for the visual acuity tests.

a. [Facility name]

The facility name is the name of the hospital, clinic or other organization that is using the system.

From the main menu, choose [Settings > Facility name]:



The [Facility name] screen will display:

The screenshot shows the 'Settings' screen with a blue background. At the top right is an 'Exit Administrator' button. The 'Facility name' section is highlighted, showing a text input field with a placeholder 'Enter facility name' and a pencil icon. Below the input field are 'Cancel' and 'OK' buttons. A list of other settings options is visible below: 'Date and time zone', 'Change password', 'Default mandatory patient info', 'Set modes', 'Printers', 'Communication', 'Result layout', and 'Categories'.

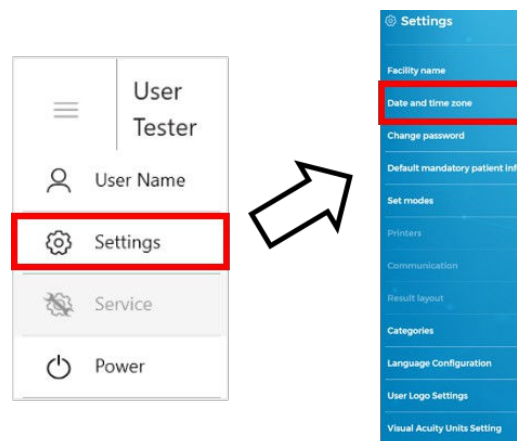
Enter the facility name, and press:

- [OK] to accept the change
- [Cancel] to ignore the change

b. [Date and zone time]

If the system is connected to the internet, there is no need to manually alter the date and time zone. If no internet connection is available, the system date and time must be maintained by the user.

From the main menu, choose [Settings > Date and zone time]:



The [Date and zone time] screen will display:

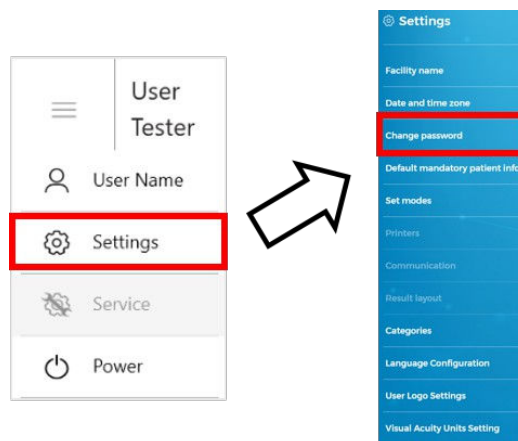
Enter correct date and time, and press:

- [OK] to accept the change
- [Cancel] to ignore the change

c. [Change password]

This screen allows you to change the administrator and user passwords.

From the main menu, choose [Settings > Change password]:



The [Passwords] screen will display:

Enter the old (current) password, and new values for passwords that you wish to change, and press:

- [OK] to accept the change
- [Cancel] to ignore the change

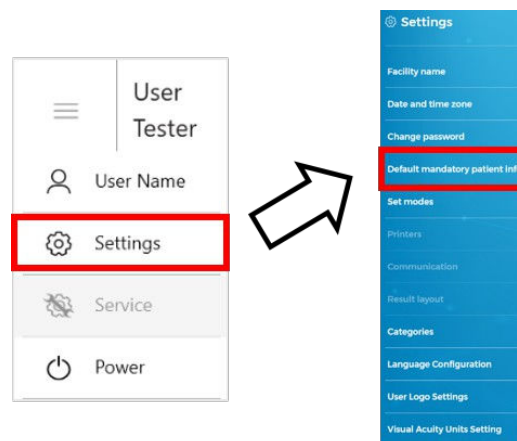


This screen requires that you know the current password (old password), before you can change it. The initial user/password for the user is [Tester/1234], and for the administrator is [Admin/1234]. If you forget the current password, contact Essilor service for assistance.

d. [Default mandatory subject info]

This screen allows you to change the default subject info.

From the main menu, choose [Settings > Default mandatory subject info]:



The [Default mandatory subject info] screen will display:

Settings Exit Administrator

Facility name

Date and time zone

Change password

Default mandatory patient info

ID First name Last name DOB Comments

Gender Mode Category

Set modes

Printers

Communication

Result layout

Categories

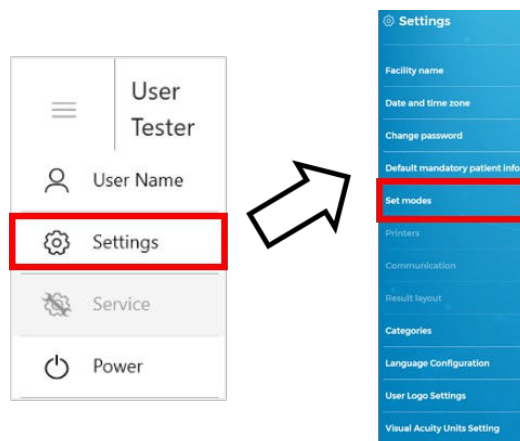
Select which input fields should be mandatory, and press:

- [OK] to accept the change
- [Cancel] to ignore the change

e. [Set modes]

This screen allows you to change the modes (baby, toddler, child, adult) settings.

From the main menu, choose [Settings > Set modes]:



The [Set modes] screen will display:

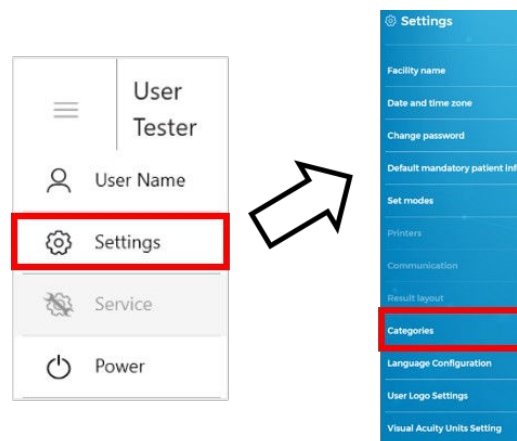
Change any default settings for any of the modes you wish, and press:

- [OK] to accept the change
- [Cancel] to ignore the change

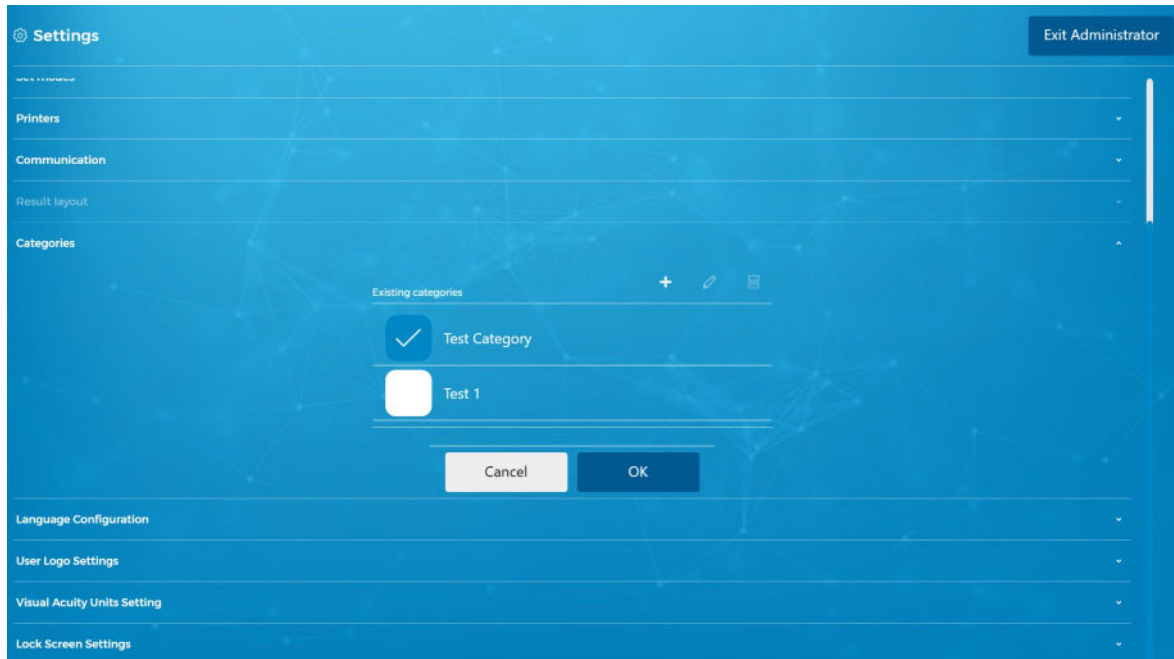
f. [Categories]

This screen allows you to change the patient categories.

From the main menu, choose [Settings > Set Categories]:

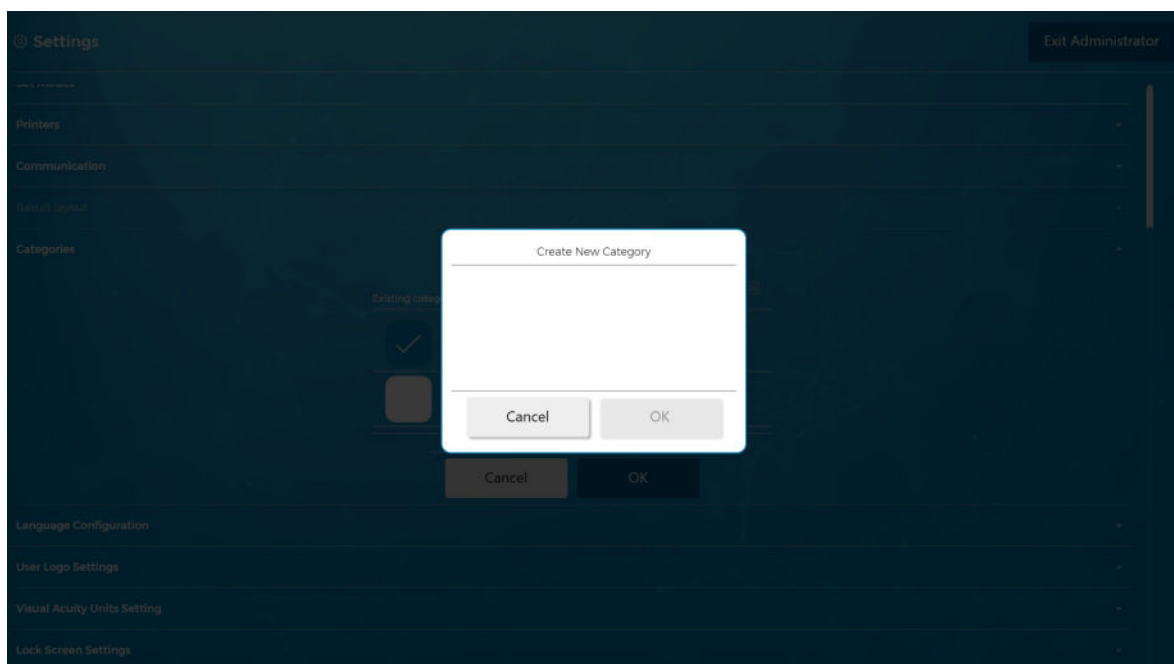


The [Categories] screen will display:



Select the [+] sign to add a new category.

> A popup will display.



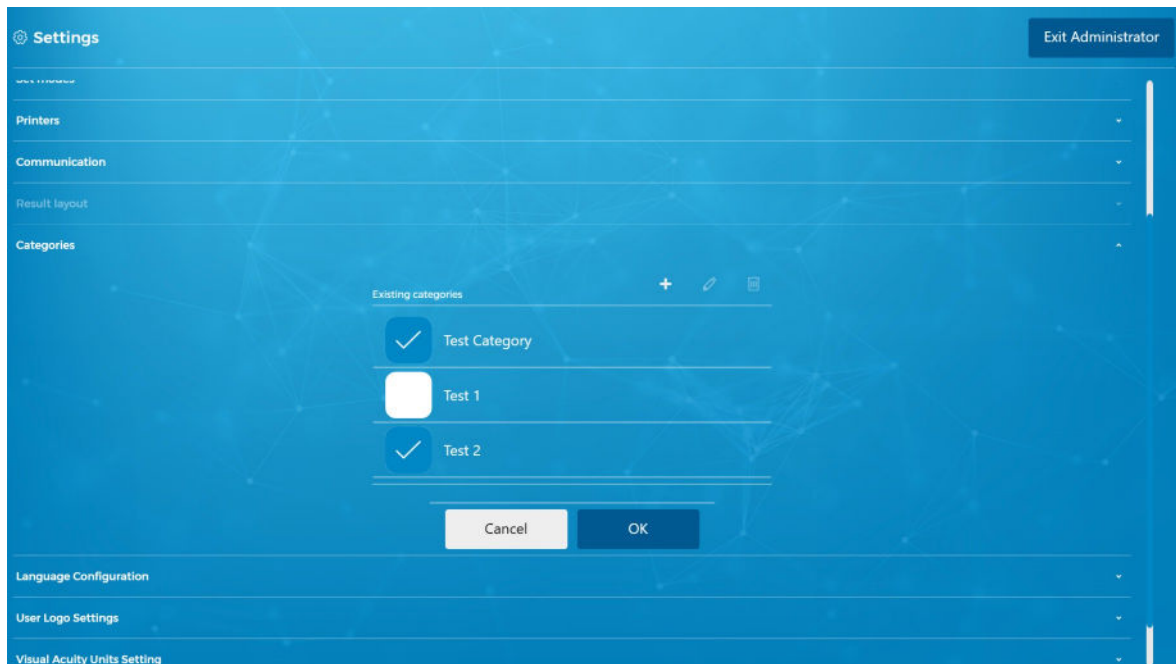
Enter the new category text and press:

- [OK] to accept the change
- [Cancel] to ignore the change

Select which categories should be displayed on the category list.

> The selected categories will be marked with a checkmark.

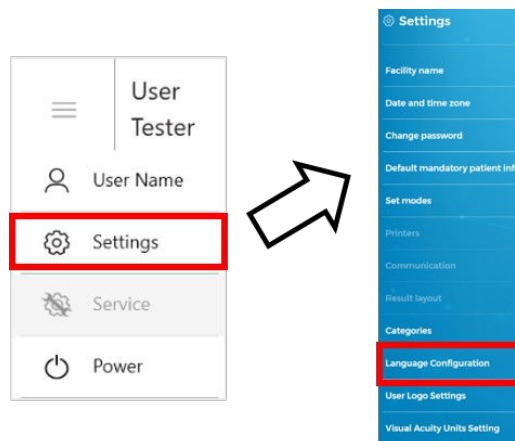
You may edit a category by selecting the pencil icon, or deselect categories by selecting the trash bin symbol.



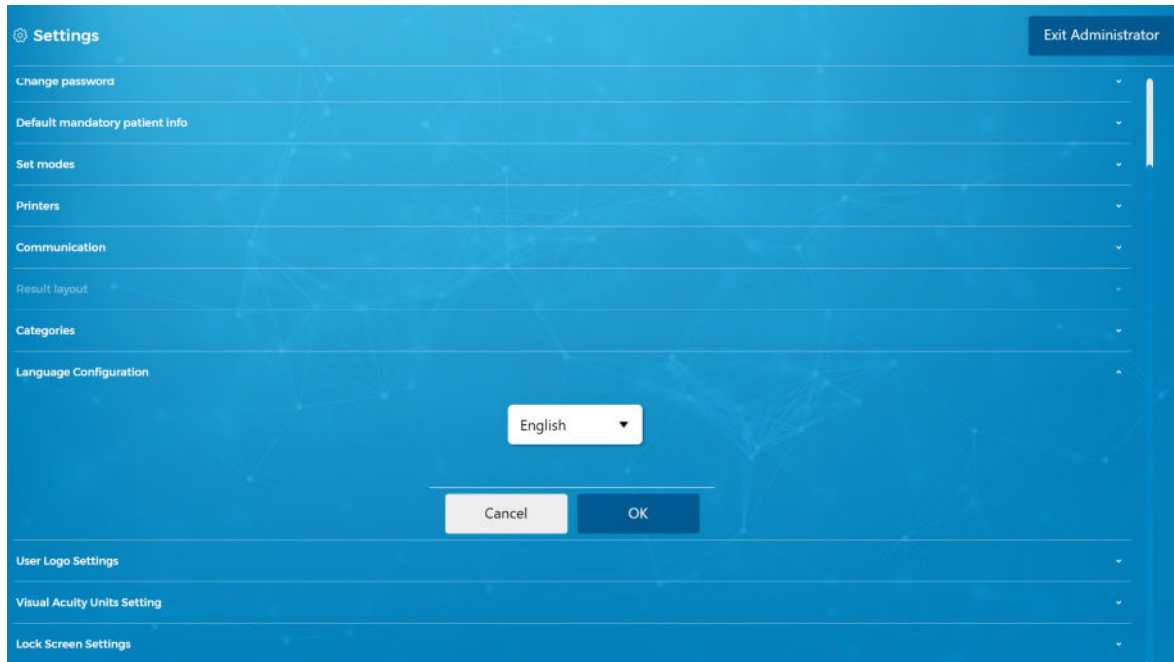
g. [Language configuration]

This screen allows you to change the language system.

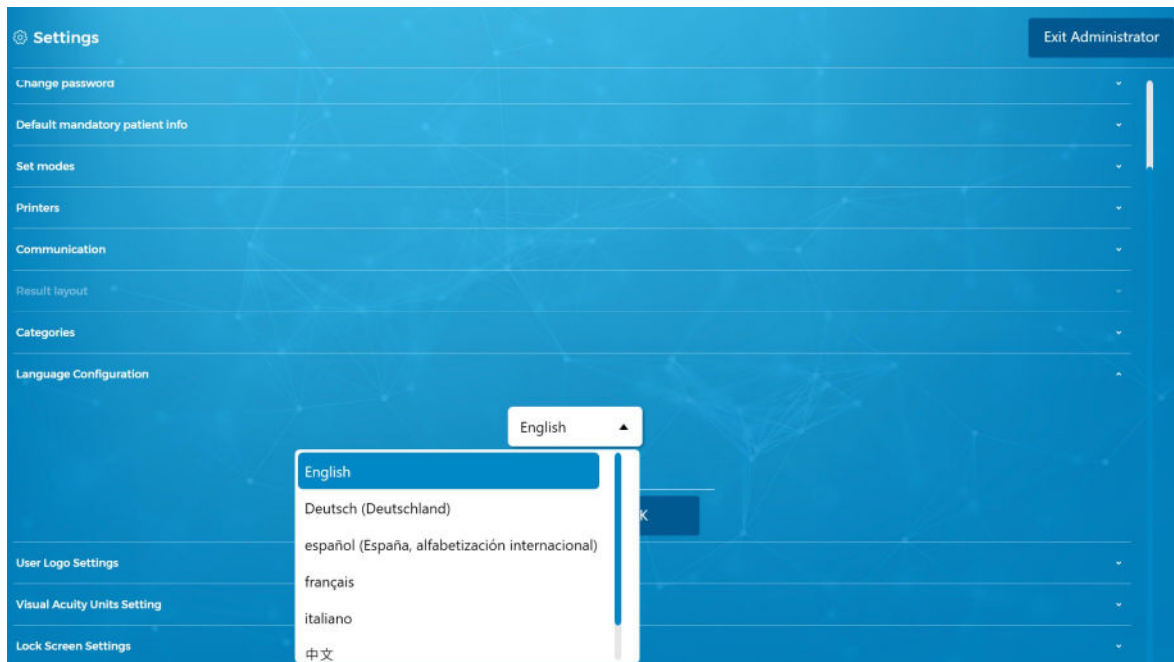
From the main menu, choose [Settings > Language configuration]:



The [Language configuration] screen will display:



Select the marker to view the list of available languages.



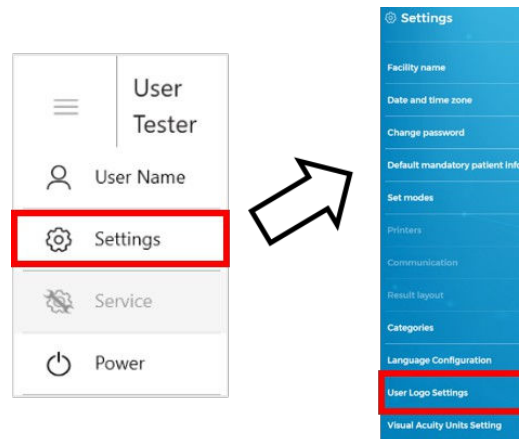
Select the desired language, and press:

- [OK] to accept the change
- [Cancel] to ignore the change

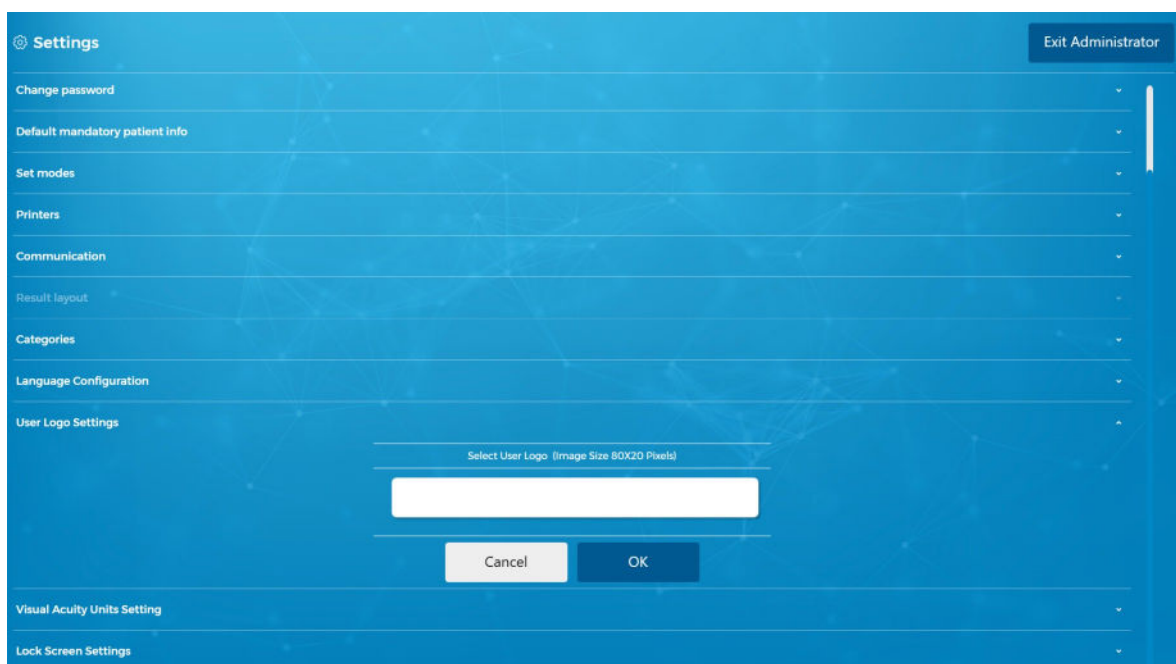
h. [User logo settings]

This screen allows you to change the user logo which be shown on the output report.

From the main menu, choose [Settings > User logo settings]:



The [User logo settings] screen will display:



Select the dialog box and a popup will appear with access to the USB drive directory. You must connect a USB drive in order to load a logo.

Select the desired logo, and press:

- [OK] to accept the change
- [Cancel] to ignore the change

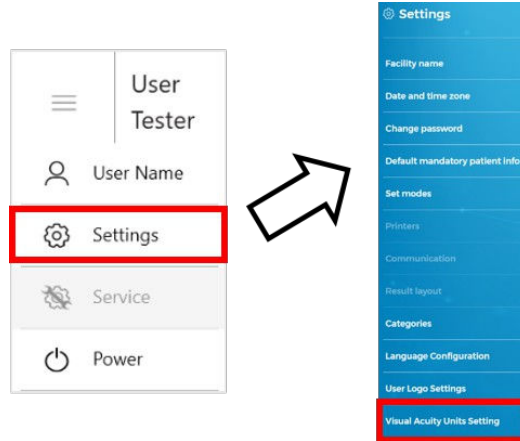


The logo must be 80x20 pixels in order to fit the report formatting properly.

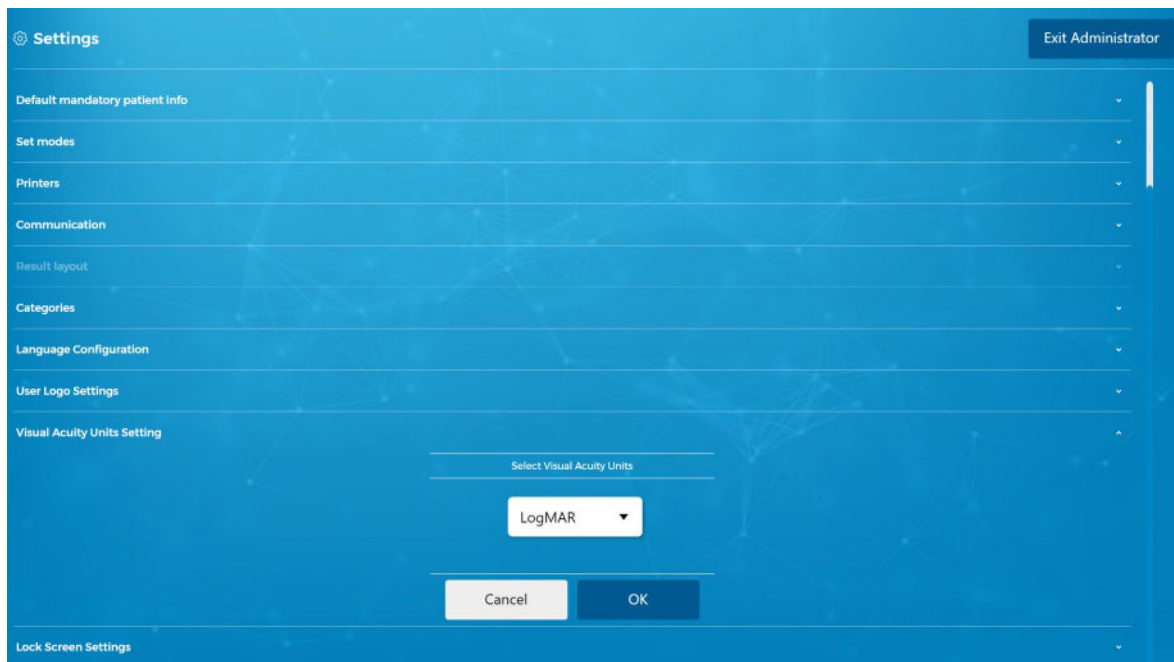
i. [Visual acuity units settings]

This screen allows you to select which units are used for displaying the visual acuity and contrast sensitivity test results

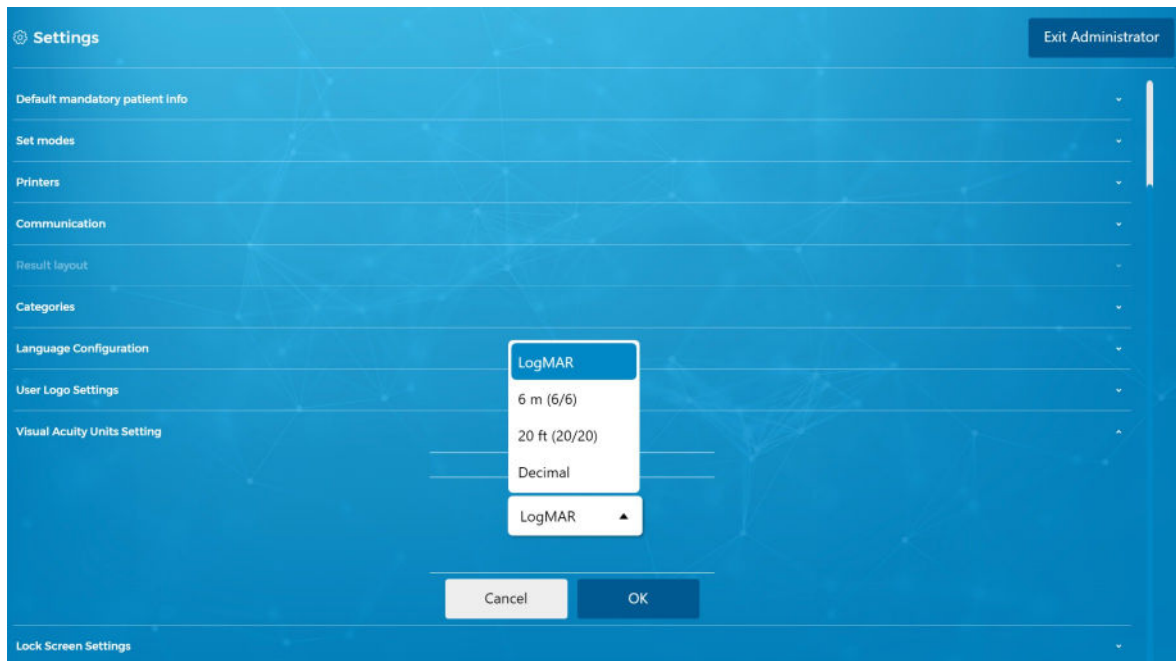
From the main menu, choose [Settings > Visual acuity units settings]:



The [Visual acuity units settings] screen will display:



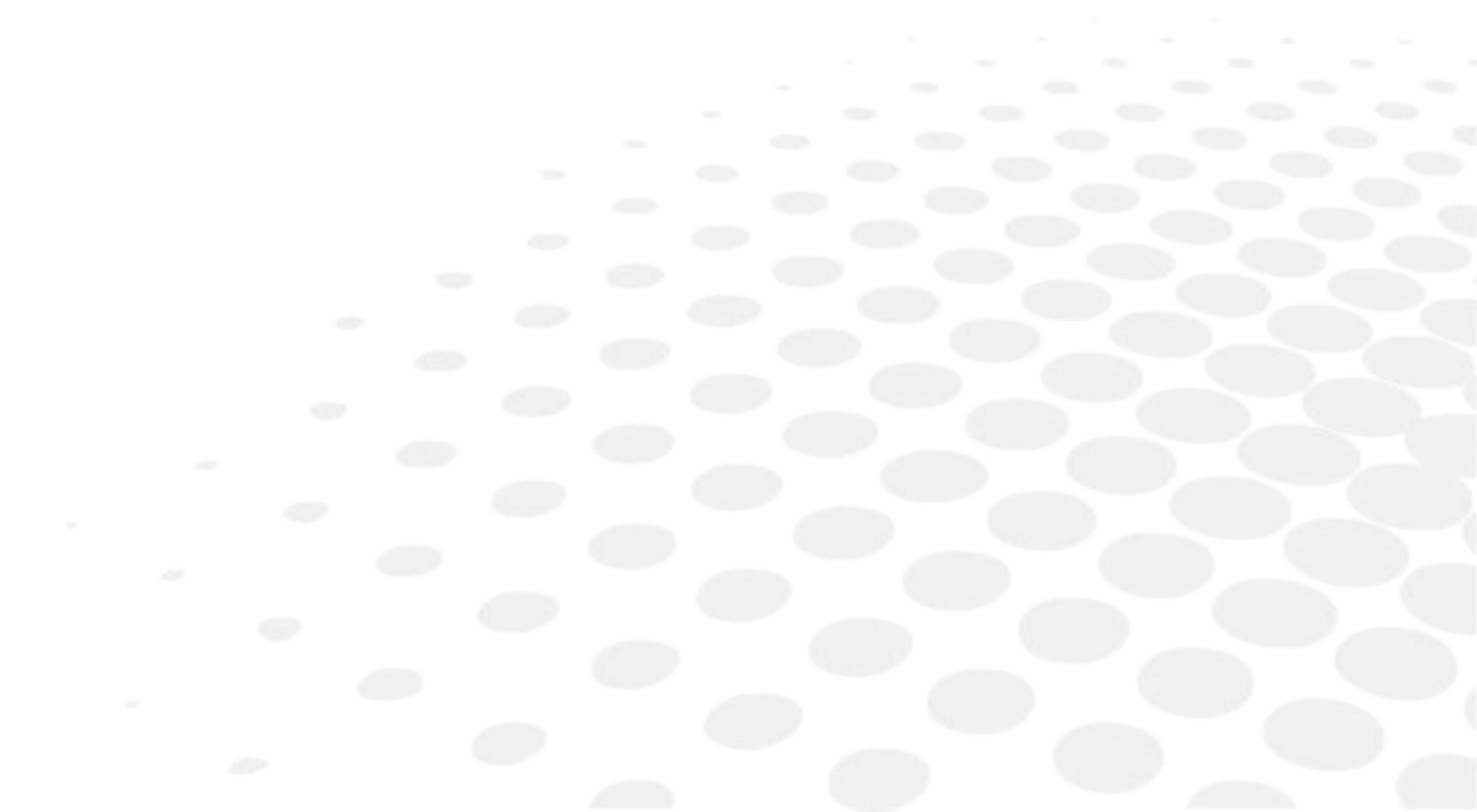
Press the arrow indicator and the list of available units will appear.



Select the desired units, and press:

- [OK] to accept the change
- [Cancel] to ignore the change

V. SET UP THE TESTS

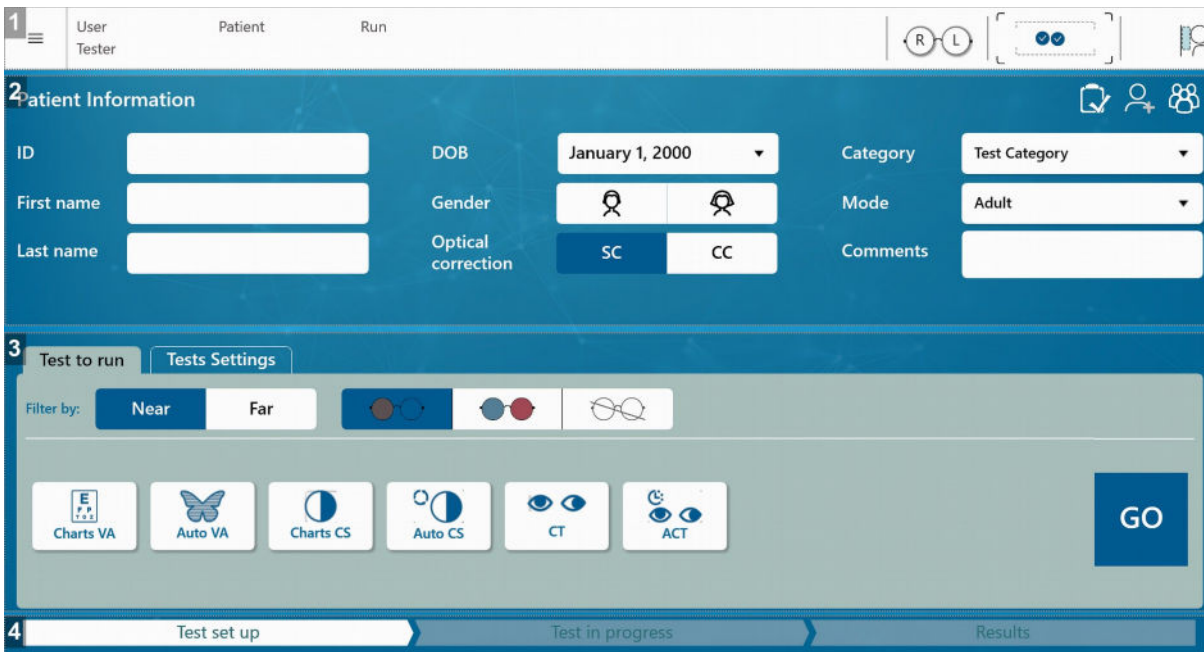


To prepare for a test, the initial [Setup] screen asks you to identify and describe the patient, specify which tests to run, and specify settings for the tests. The system also keeps you informed about which stage you are in the process:

- Test set up
- Test in progress
- Results

The initial [Setup] screen is divided into four sections, which are summarized below. Each section is described in more detail in the following pages.

1. OVERVIEW OF INITIAL SETUP SCREEN



The screenshot displays the initial setup screen with the following sections:

- 1. Top Panel:** Includes tabs for 'User' (Tester), 'Patient', and 'Run'. On the right, there are icons for eye position and a dynamic display of occlusion glasses.
- 2. Patient Information:** Contains input fields for ID, First name, Last name, DOB (January 1, 2000), Gender (Male/Female), Optical correction (SC/CC), Category (Test Category), Mode (Adult), and a Comments field.
- 3. Test to run / Tests Settings:** Features a 'Filter by' section with 'Near' and 'Far' options, and a row of test icons: Charts VA, Auto VA, Charts CS, Auto CS, CT, and ACT. A 'GO' button is located on the right.
- 4. Progress Indicators:** A horizontal bar at the bottom shows three stages: 'Test set up' (active), 'Test in progress', and 'Results'.

1. User identification and device status

The upper portion of the top panel shows the current software version, date and battery state.

The user name (Tester in this example) is entered via the user name option of the main menu.

The right side of the screen shows a dynamic display of the occlusion glasses, the current eye position, and the positioning of the patient relative to the screen.

Caution: Please verify correct operation before running tests

2. [Patient information]

Patient name and other identifying information.

3. [Test to run / Tests Settings]

List of which tests to run, and the detailed settings for each test. In this section, you can filter the available tests based on glasses type and testing distance. Filtering by each of these will change the list of available tests.

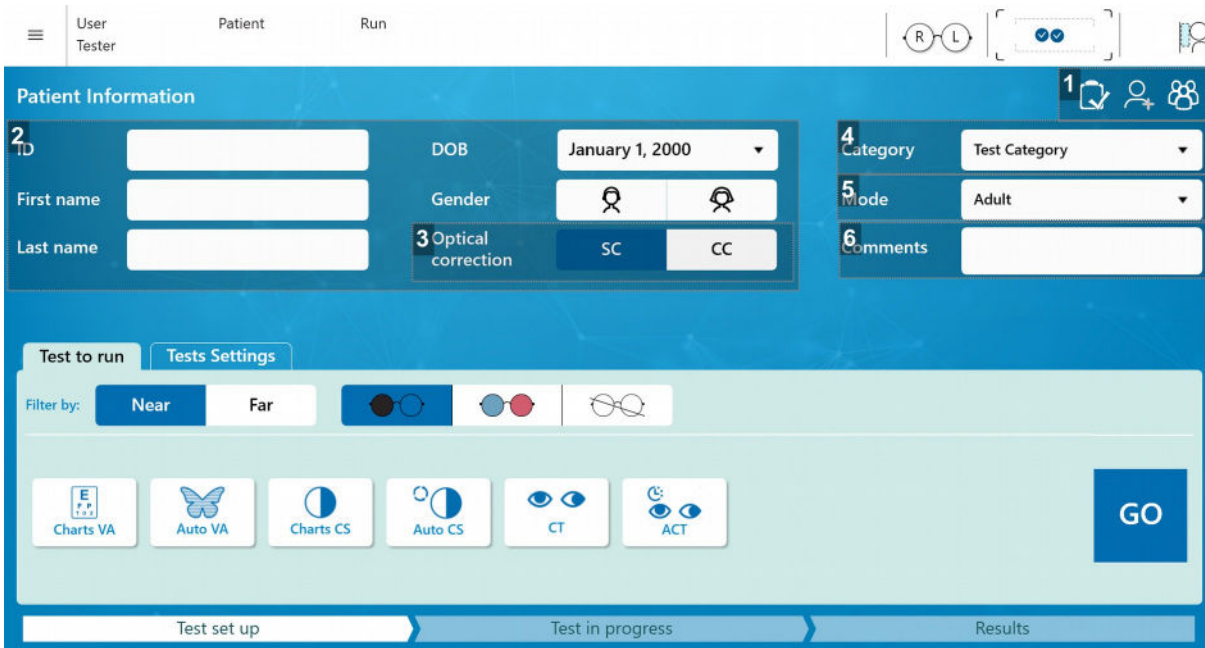
4. Progress bar

Where we are in the:




- [Test setup]
- [Test in progress]
- [Results process]

2. PATIENT INFORMATION

This section of the screen identifies the patient and provides details relevant to the test procedure.



1. Patient

-  Results: If tests have already been run in the current session, use this button to toggle back to the results screen to continue viewing.
-  New patient: Clear all data. When you are entering data for a new patient, you usually do not need to press this button.
-  Load patient: Search for an existing patient, using the entered fields as search criteria. This allows previous patient information to be loaded, instead of having to manually reenter the information. In addition, the patient database may be accessed to review previous test results and trends over time.

2. Basic identifying information

- Patient's ID
- First name
- Last name
- Gender
- Date of birth (DOB)

3. [Optical correction]

Specify whether the patient is currently using optical correction.

4. [Category]

Set the category of the patient if part of a study group.

5. [Mode]

Initial assessment of eye deviation. If there is no initial assessment, do not press on any of the buttons.

6. [Comments]

Any additional notes or comments that you wish to enter for the patient.

3. TESTS TO RUN

This section of the screen allows you to identify which tests will run in the near and far procedures.

1. Test selection

This tab indicates that you are selecting which tests to run.

Press on each test that you wish to run. The button will change to green to indicate that the test has been selected:



2. [Near / Far]

Based on the selected toggle, the tests will be run in near or far mode. This toggle will also change the available tests view.

3. Glasses toggle

Based on the selected toggle, the available test selection will change in order to indicate which tests may be run with each type of glasses.

Toggle when occlusion glasses is selected, tests which may be run:

- Charts VA
- Auto VA
- Charts CS
- Auto CS
- CT
- ACT

The screenshot shows the software interface with the 'Glasses toggle' set to 'Near' (occlusion glasses). The 'Test to run' section displays icons for Charts VA, Auto VA, Charts CS, Auto CS, CT, and ACT. The 'Tests Settings' section shows 'Near' selected under 'Filter by:'. The 'GO' button is visible.

Toggle when anaglyph glasses is selected, tests which may be run:

- Worth 4-dot
- Fusional Vergence
- Stereo Test

The screenshot shows the software interface with the 'Glasses toggle' set to 'Far' (anaglyph glasses). The 'Test to run' section displays icons for Worth 4-dot, Fusional, and Stereo Test. The 'Tests Settings' section shows 'Far' selected under 'Filter by:'. The 'GO' button is visible.

Toggle when no glasses is selected, tests which may be run:

- Reading test
- Color test

4. Go

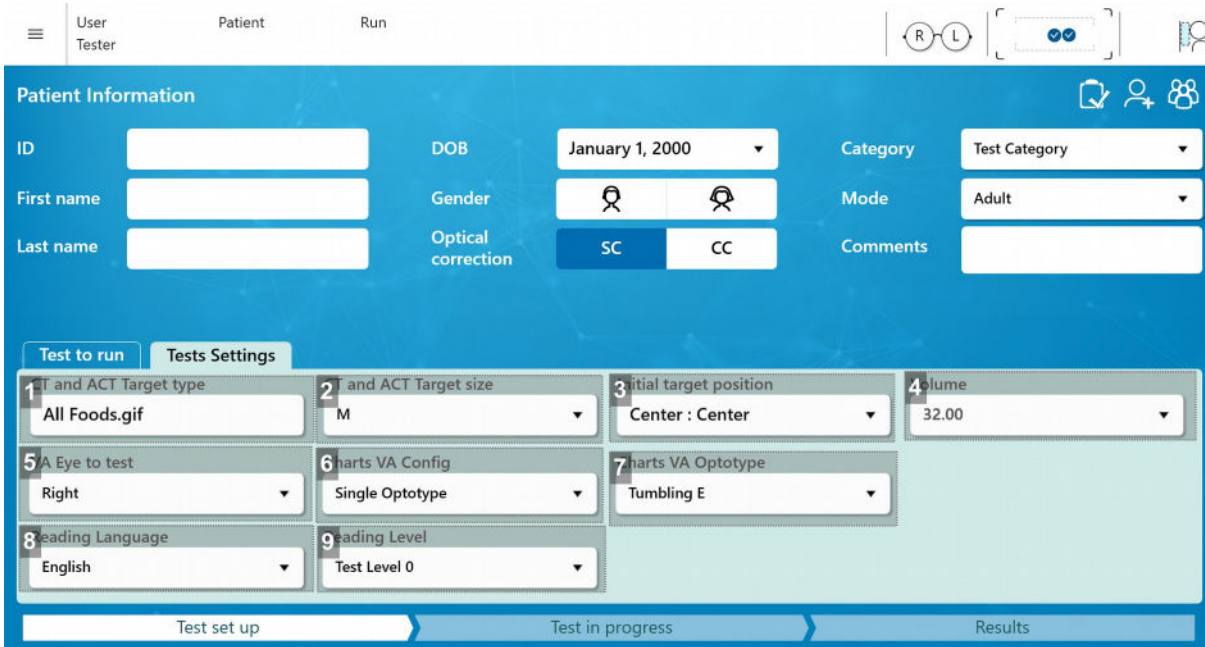
Select the play button **GO** when you are ready to begin the test.



The fusional, Worth 4-dot and reading tests can only be performed for the near procedure.
Only the CT and ACT may be performed using far procedure.

4. TESTS SETTINGS

Specify the detailed settings for the tests.



1. [CT and ACT Target type]

- **Description:** The image that will be displayed on the screen. The default image is a panda bear eating fruits.
- **Possible values:** Choose from a list of images displayed on the screen.

2. [CT and ACT Target size]

- **Description:** The size of the target that is shown during the test. Choose the smallest target size for which the patient can clearly see the target details.
Note: Use the manual glasses shuttering to occlude the dominant eye and change the target size until the patient sees it clearly using the eye with poorer vision.
- **Possible values:** S, M, L.

3. [Initial target position]

- **Description:** The position on the screen where the target will first display. In case of difficulty with detecting both eyes by the eye tracker, proceed as follows before beginning the test:
> Move the target on the screen until, with the patient looking at the target, both eyes are detected at least intermittently by the eye tracker.
- **Possible values:** Choose a position from the grid.



4. [Volume]

- **Description:** Enables setting of the sounds which are emitted from the system, including during the tests.
- **Possible values:** 0 to 100.

5. [VA Eye to test]

- **Description:** Sets which eyes will be tested during each run. The non-tested eye will be occluded by the occlusion glasses. If multiple setups are selected, they will be run concurrently.
- **Possible values:** Right, left, binocular, monocular, all.

6. [Charts VA Config]

- **Description:** Sets the type of optotype organization for each level.
- **Possible values:** Single optotype, Single crowded, optotype, Single line, 3 row chart, Single line crowded, 4 surrounding optotypes.

7. [Charts VA Optotype]

- **Description:** Sets the type of optotype used during the test.
- **Possible values:** Tumbling E, Letters, Numbers.

8. [Reading Language]

- **Description:** Enables selection of the text language for the reading test.
- **Possible values:** English, French.

9. [Reading Level]

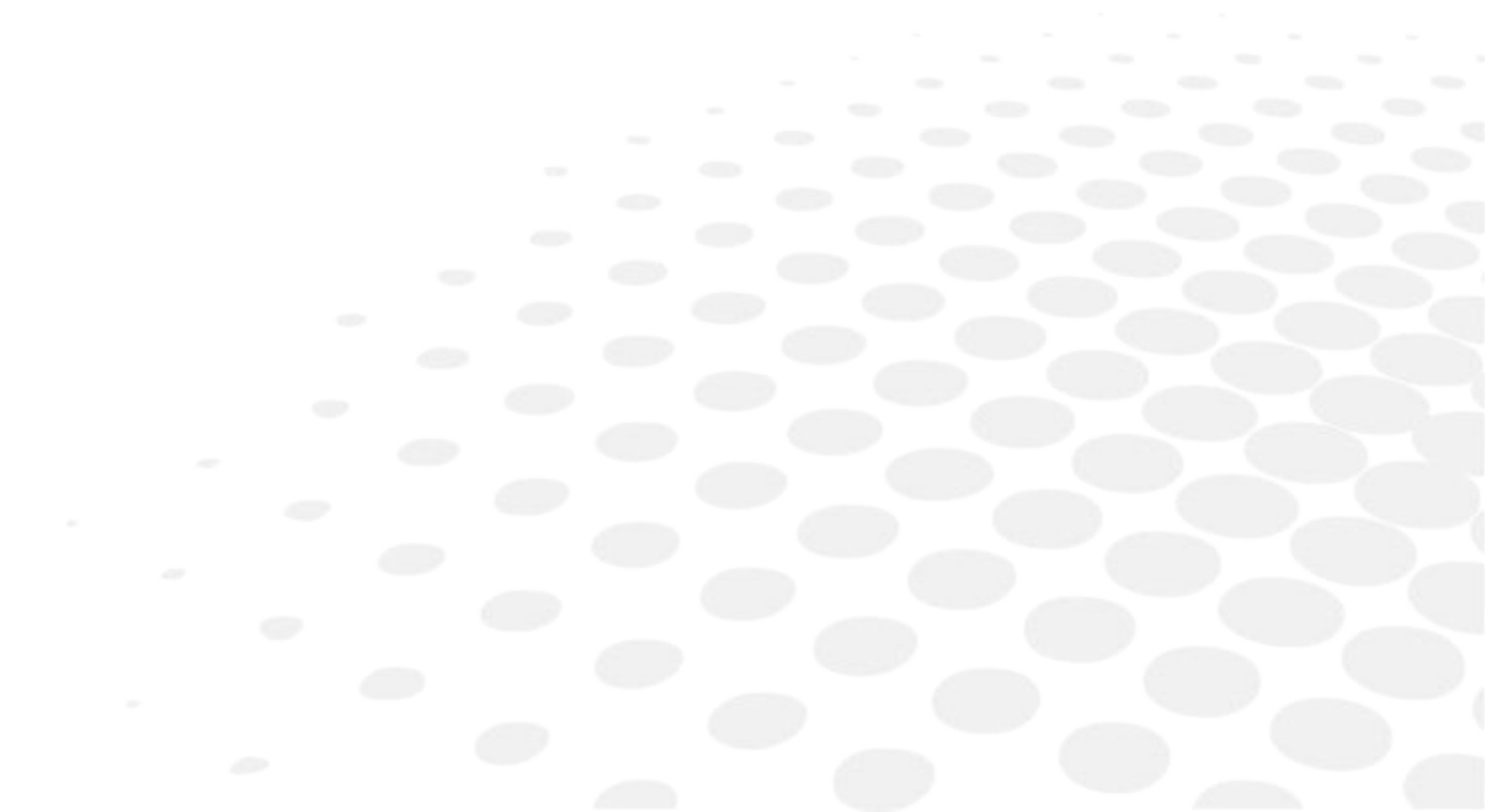
- **Description:** Enables setting the level of the displayed reading text.
- **Possible values:** /



The default values in this screen are set by the [Settings/Set Mode] screen.

If you find that you are often changing these values, you may wish to change the default values.

VI. RUN THE TESTS



After you have entered the patient information, indicated which tests you wish to run, and specified the test settings, you are ready to check the system operation and perform the tests.

Before running the tests, turn on the glasses and place them on the patient. Only run the tests when the glasses are positioned properly. (For further information you can consult the chapter [Position the patient]).

Ensure that the target size allows the user to see it comfortably with the weakest eye. If necessary, increase the target size before running the tests.


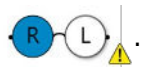




Check also that there is no obstruction of light to the patient's eyes, such as dirty or blocked glasses, or a physical barrier such as hair, swollen eyes, or ptosis.

**Caution**

Tests must be performed only under standard room lighting conditions. Do not run the tests when the room is illuminated by direct sunlight, or in a completely dark room.

1. VERIFY CORRECT OPERATION

The system must be checked for correct operation before running tests, as shown in the table below. It is required to correct any error condition before proceeding with the tests.

STATUS CHECK	TEST	CORRECTION
Shutter operation	<p>Press on the R or L buttons to shutter (darken) each lens. The lenses should darken or lighten accordingly.</p> <p>The yellow triangle () shown in this illustration should not be present – it indicates a failure in communication with the glasses.</p> 	<p>If the glasses fail to shutter, make sure the battery is charged and that the glasses are turned on.</p>
Eye tracker operation	<p>The eye tracker status should show green check marks, not red X's. X's indicate that the eye tracker is not accurately detecting the eyes.</p> <div style="display: flex; align-items: center;"> <div style="margin-right: 10px;"> <ul style="list-style-type: none">  : OK  : NOK </div> </div> <p>Note:</p> <ul style="list-style-type: none"> The dotted lines indicate the optimal positioning. <p>Caution:</p> <ul style="list-style-type: none"> If a recurring eye detection error persists, contact customer service. Recheck the eye tracker positioning before each test and check that it is clean and unobstructed. Instruct anyone who is positioned behind the patient (for example, a parent whose child is sitting on their lap) to look away from the screen. 	<p>Direct the patient's vision toward the eye tracker.</p>
Distance of patient	<p>The system should detect that the patient is the correct distance from the eye tracker (approximately 20 inches/50 cm).</p> <p>A red outline and an arrow indicate that the patient is either too close or too far from the eye tracker.</p> <p>An arrow pointing to the left means that the patient is too far from the eye tracker. An arrow pointing to the right means that the patient is too close.</p> <div style="display: flex; align-items: center;"> <ul style="list-style-type: none">  : OK  : NOK (patient too close to Eye Tracker) </div>	<p>Move the patient closer or further from the eye tracker.</p>

2. START THE TESTS

Press the start button, highlighted below, to begin the tests.

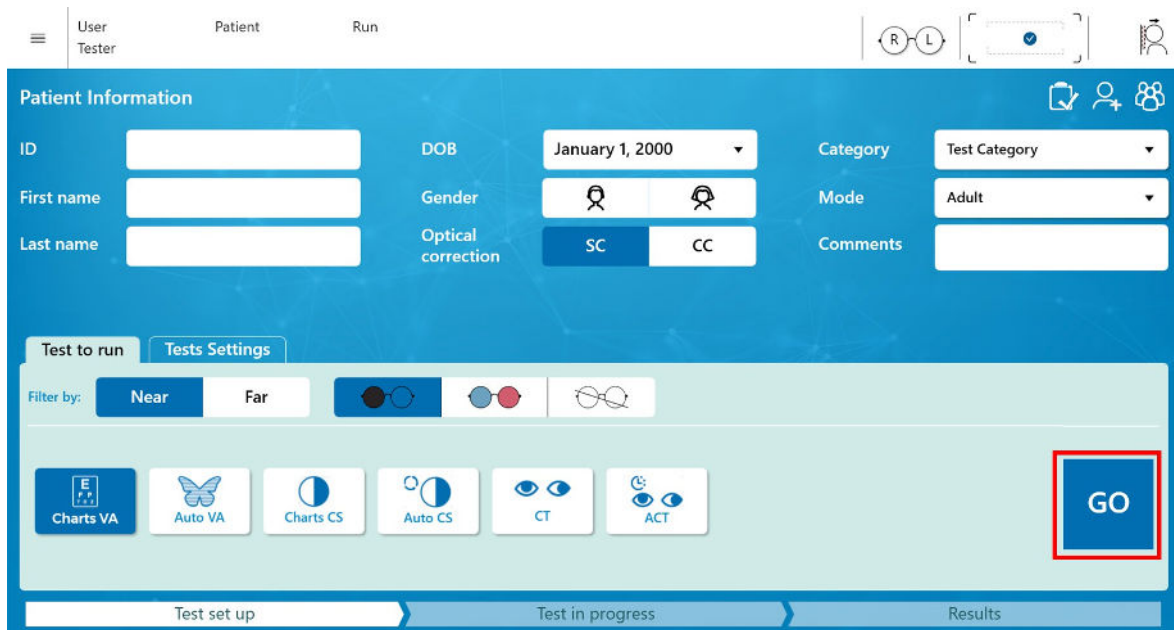


Caution

If a power outage occurs during a test, restart the system and run the test again.



- Check that the screen is working properly before beginning the tests.
- Instruct the patient to concentrate on the target during the test.



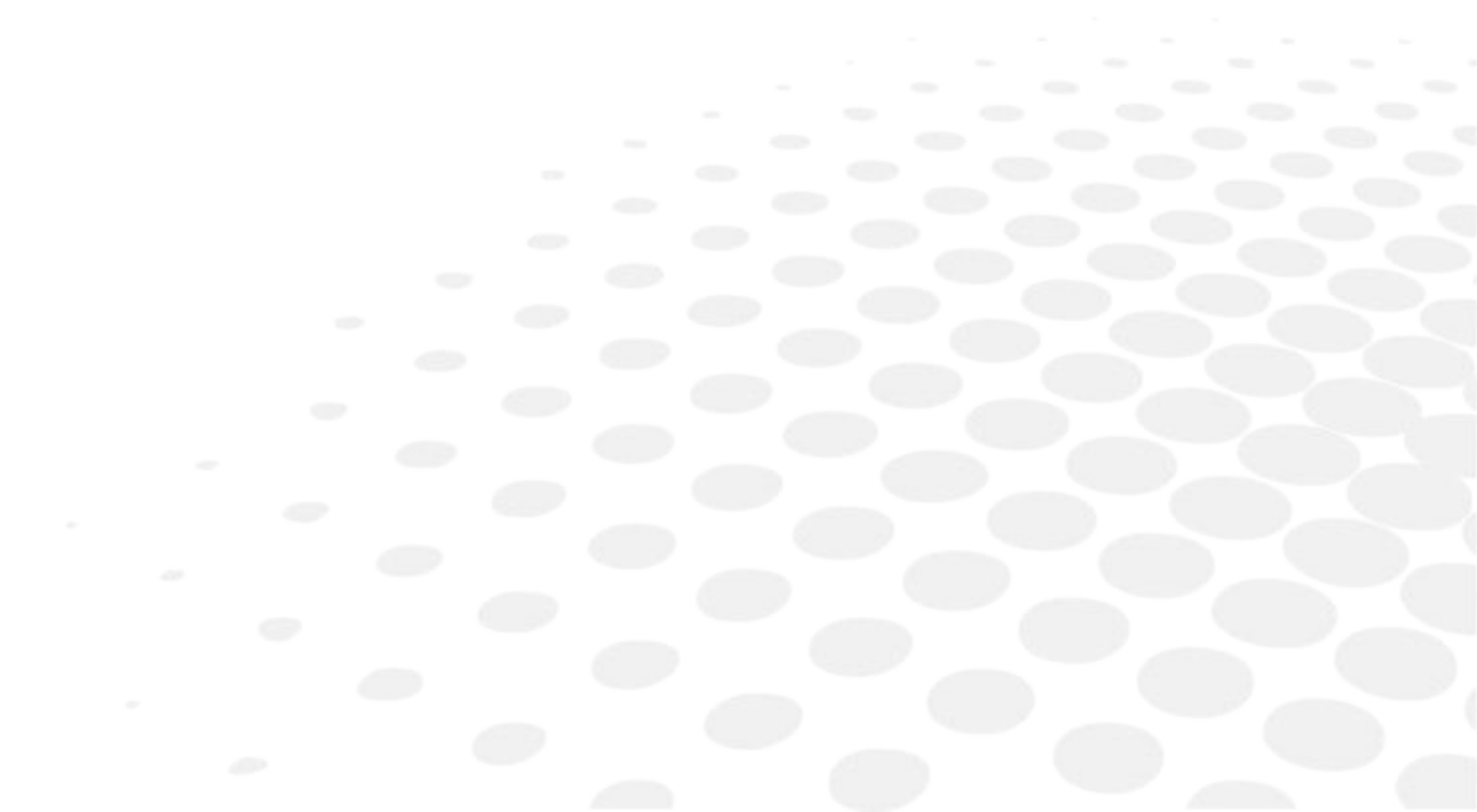
The screenshot shows the EyeViz 300 software interface. At the top, there are tabs for 'User Tester', 'Patient', and 'Run'. Below these are icons for 'R' and 'L' eyes, a 'GO' button, and a 'TEST' button. The main section is titled 'Patient Information' and contains fields for ID, First name, Last name, DOB (January 1, 2000), Gender (Male/Female), Category (Test Category), Mode (Adult), Optical correction (SC/CC), and Comments. Below this is a 'Test to run' section with 'Near' and 'Far' filters, and icons for 'Charts VA', 'Auto VA', 'Charts CS', 'Auto CS', 'CT', and 'ACT'. A large blue 'GO' button is highlighted with a red box. At the bottom, there is a progress bar with three stages: 'Test set up', 'Test in progress', and 'Results'.



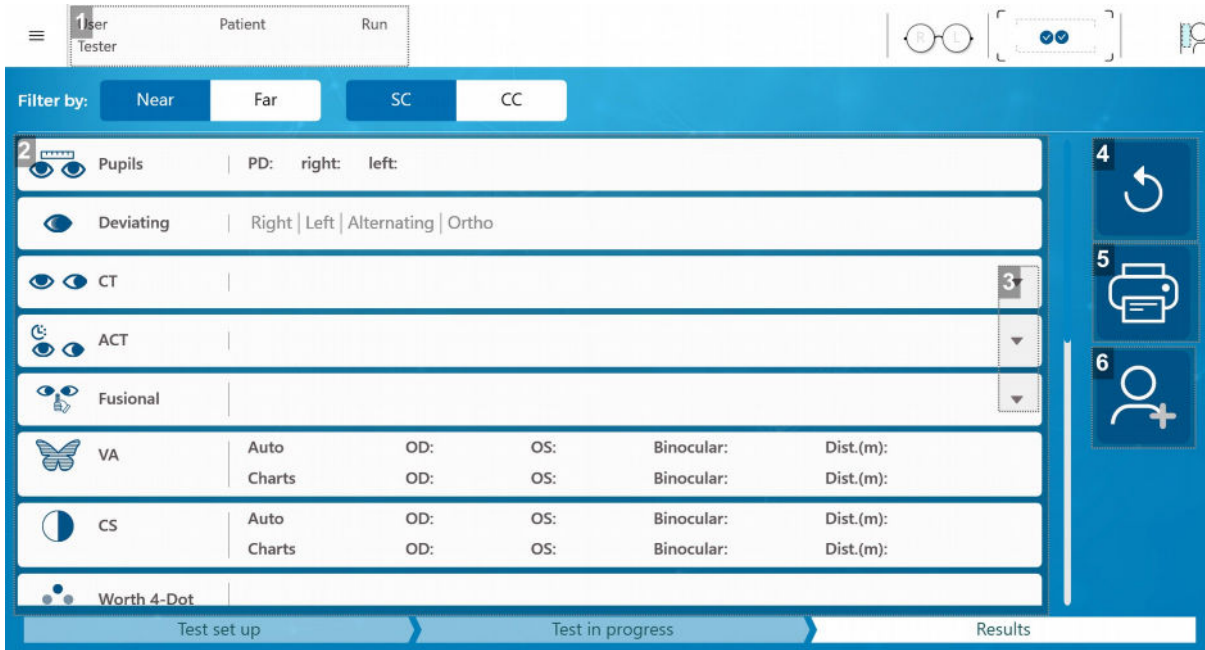
Following are the approximate times required for each test:

- [CT]: 30 seconds
- [ACT]: 40 seconds
- [Far CT]: 25 seconds
- [Far ACT]: 35 seconds
- [Charts VA/ Chart CS]: 45 seconds
- [Auto VA/ Auto CS]: 60 seconds
- [Fusional Vergence]: 90 seconds
- [Worth 4 dot]: 20 seconds
- [Reading]: 40 seconds
- [Color Test]: 30 seconds for short test, 2 minutes for full test (if suspected non-normal color vision)
- [Stereo Test]: 30 seconds

VII. TESTS RESULTS



The [Test Results] screen shows an interactive summary of the tests that were run and provides an indication whether strabismus was detected.

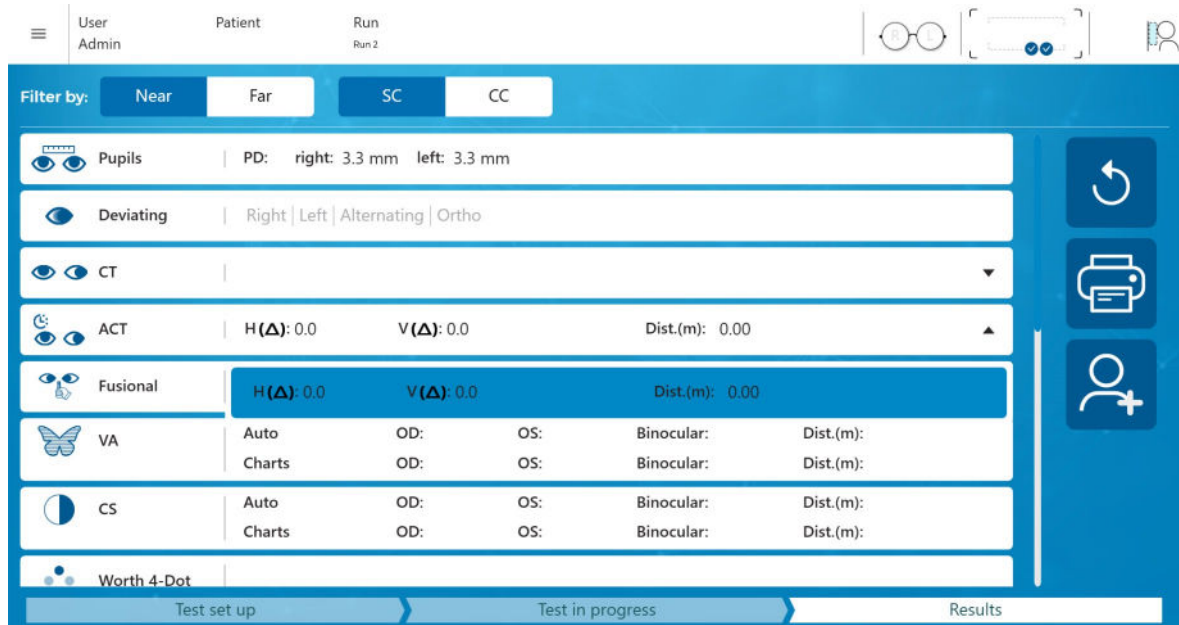


1. Patient information

2. Results fields for all available tests

3. Arrows

If more than one test of a particular-type was run, press on arrow to see test details.



4. Return button

Return to the Patient Information screen, retaining the data for this patient both in the results screen and on the test set up screen. This option would be used to perform more tests on the same patient.

5. Print button

Print results.

6. Save button

Return to the Patient Information screen. Save the data to the database. The patient screen starts off as an empty screen. This option would be used to prepare for a new patient.

1. RESULTS

1 - Deviating

Existence of a deviating eye, and which eye is deviating if exists. Types of deviating eye are: right, left or alternating (where the fixating eye switches between the right and left eyes).

Note: the result for this test is received following a CT test

2 - CT

Horizontal and vertical manifest deviation results of the cover test. Reported in prism diopters. Sitting distance from screen is also reported.

3 - ACT

Horizontal and vertical latent deviation results of the alternate cover test. Reported in prism diopters. Sitting distance from screen is also reported.

4 - Fusional Vergence

Divergence, recovery and convergence are reported in prism diopters. Sitting distance from screen is also reported.

5 - VA/ CS

The results for the automated and charts test are reported. For each test, the results are reported for OD, OS and binocular (if tested).

The actual result and the simulated VA result are reported. Simulated VA result units may be set from "settings" menu- 20/20, 6/6, LogMar and Decimal. Sitting distance from screen is also reported.

6 - Worth 4-dot

The text result is reported based on the patient's response.

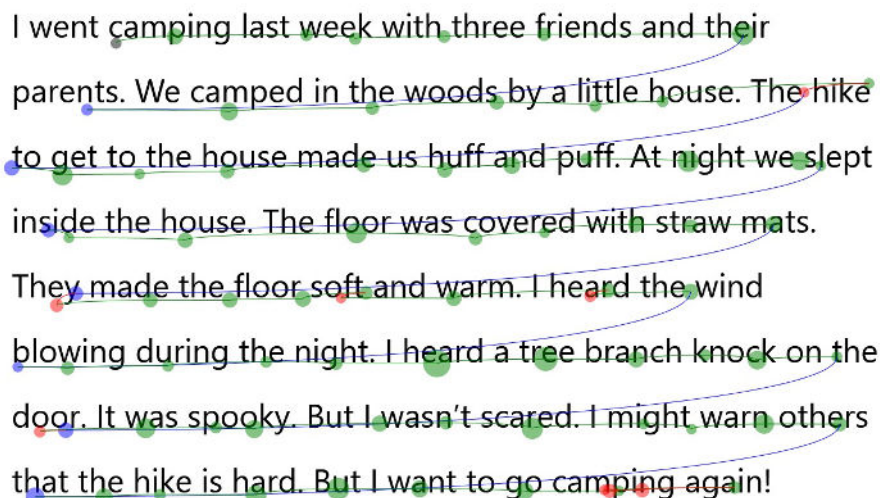
Patient's response	Result
Four	Fusion
Three	Suppressing OS
Two	Suppressing OD
Sometimes three, sometimes two	Alternation
Five	Diplopia
No clear response	Fail

7 - Stereo Test

Stereo results are reported in Arc Sec. Sitting distance from screen is also reported.

8 - Reading

The number of fixations, number of regressions, fixation duration and reading rate (words/ min) are reported. An image showing the reading results is also displayed.



I went camping last week with three friends and their parents. We camped in the woods by a little house. The hike to get to the house made us huff and puff. At night we slept inside the house. The floor was covered with straw mats. They made the floor soft and warm. I heard the wind blowing during the night. I heard a tree branch knock on the door. It was spooky. But I wasn't scared. I might warn others that the hike is hard. But I want to go camping again!

With:

- Green circles > indicate fixations
- Red circles > indicate regressions
- Blue circles > indicate line beginning
- Connecting lines > show direction of reading movement

	Normal reading pattern	Abnormal reading pattern
Visual result	<p>I went camping last week with three friends and their parents. We camped in the woods by a little house. The hike to get to the house made us huff and puff. At night we slept inside the house. The floor was covered with straw mats. They made the floor soft and warm. I heard the wind blowing during the night. I heard a tree branch knock on the door. It was spooky. But I wasn't scared. I might warn others that the hike is hard. But I want to go camping again!</p>	<p>I went camping last week with three friends and their parents. We camped in the woods by a little house. The hike to get to the house made us huff and puff. At night we slept inside the house. The floor was covered with straw mats. They made the floor soft and warm. I heard the wind blowing during the night. I heard a tree branch knock on the door. It was spooky. But I wasn't scared. I might warn others that the hike is hard. But I want to go camping again!</p>
#Fixations	80	88 (more fixations)
Regressions	1 (1%)	19 (22%) (more regressions/higher percentage of regressions)
Fixation duration	0.218 sec	0.285 sec (longer fixation duration)
Reading rate (words/min)	230	78 (lower reading rate)

9 - Color vision

The text result of the color vision test is reported, indicating whether the subject has normal color vision, or deficient color vision.

2. CT AND ACT RESULTS KEY

- 1st letter- deviating eye
- 2nd letter- direction
- 3rd letter- tropia / phoria

Add brackets if intermittent

Deviating eye

Right	R
Left	L
Alternating	A

Direction

Eso	E
Exo	X
Hyper	H
Hypo	Hypo

Type

Tropia	T
Phoria	No letter
Intermittent	No letter, add brackets () around the direction if controlled, or around the T (for tropia) if manifest

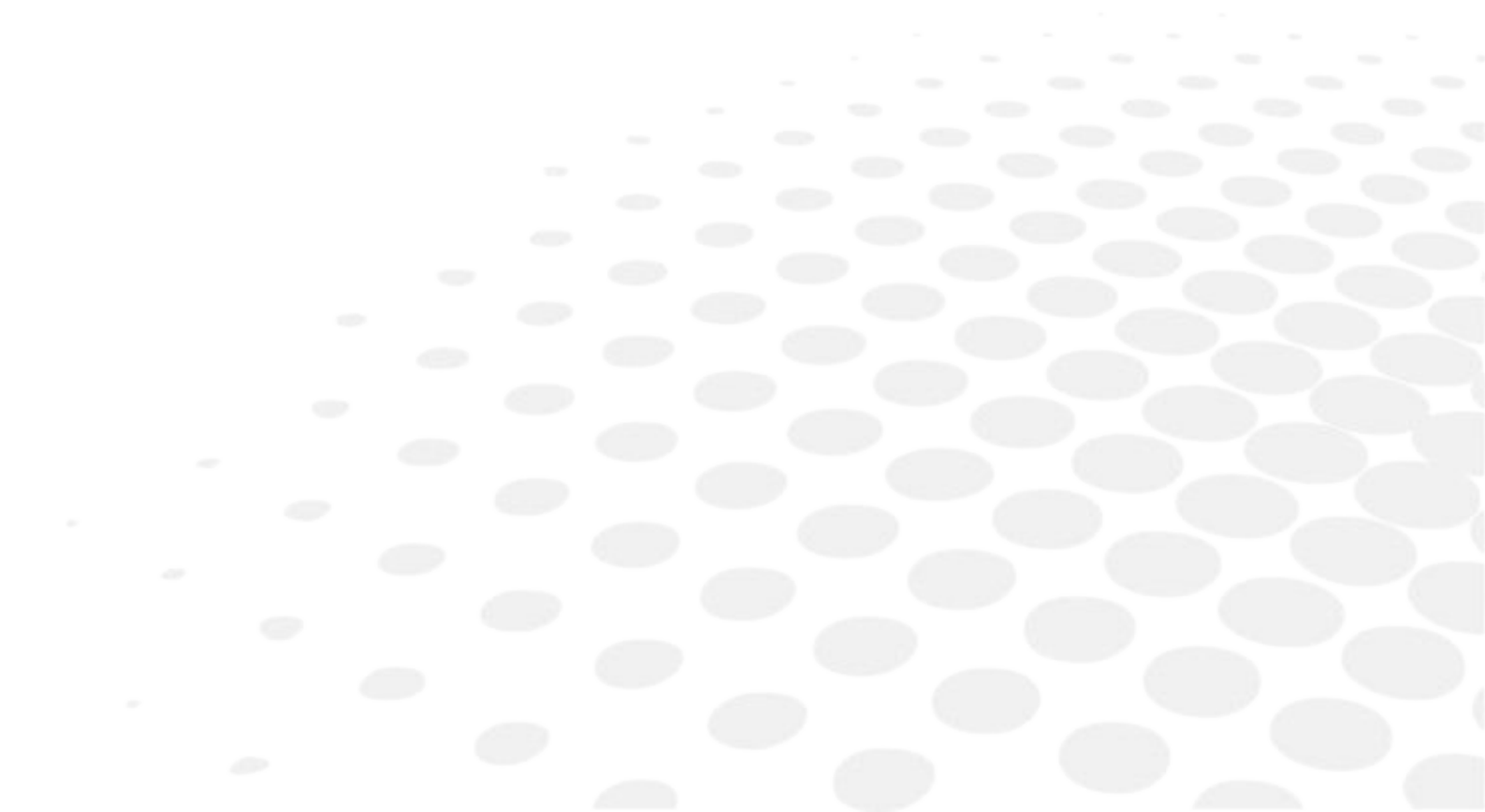
Example (all options for right eye)

DEVIATING EYE	DIRECTION	TROPIA/ PHORIA	ABBREVIATION
Right	Eso	Tropia	RET
Right	Exo	Tropia	RXT
Right	Hyper	Tropia	RHT
Right	Hypo	Tropia	RhypoT
Right	Eso	Phoria	RE
Right	Exo	Phoria	RX
Right	Hyper	Phoria	RH
Right	Hypo	Phoria	Rhypo



For cases where ACT is run without CT being run first, and for cases of alternating deviation, the vertical deviations will not receive a direction (hypo/hyper), but rather a description of which eye is positioned above the other eye- L/R (left higher than right) or R/L (right higher than left).

VIII. MAINTENANCE & SERVICE





The user or any technical personnel who are not formally authorized by Essilor should not open the device under any circumstances. Opening the device could damage the unit and will void the warranty provided by Essilor.

The system does not require maintenance or service on a routine basis, except as suggested in this user manual. Service should only be provided by an authorized Essilor representative.

1. MAINTENANCE

a. Determining the battery state

There are two indicators that indicate the condition of the glasses: the LED, and a separate indicator on the lenses.

b. Led low battery indicator

If the LED flashes every few seconds during operation, this indicates that the battery level is low.

If the LED is continuously lit, the battery is charging.

c. Indicator on the lenses for low battery

In power down mode, the lenses will blink every two seconds to indicate a low battery.

In wake-up mode, the lenses will blink continuously to indicate a low battery.

d. Charging the battery

To charge the battery for the glasses, use the micro USB cable to connect the USB charging port on the glasses to a powered USB port (on a computer or a wall charger with USB compliant output).

The LED will stay brightly lit until charging is completed. Charging usually takes up to two hours.



- The battery should be fully charged the glasses prior to first use.
- The glasses cannot be used while the battery is charging.
- Glasses should be charged at the end of each work day.
- Glasses should be turned off at the end of each patient session in order to maintain maximal battery life.
- The glasses battery is not user-replaceable. If the glasses fail to charge, replace the glasses.

2. CLEAN AND DISINFECT

Between patients, the glasses should be cleaned with an antiseptic wipe, or with a 70% isopropyl alcohol solution.



Caution

- The system is approved for IPX0. To avoid damage to device, be careful of liquid spillage while cleaning.
- Do not sterilize, autoclave, or immerse this device in liquid. Do not pour or spray any liquid into the device.
- Do not use caustic or abrasive cleaning agents, or any cleaning products containing ammonium chloride, isopropyl alcohol, petroleum-based or acetone solutions.
- Do not use cleaning solution other than those recommended here, as permanent damage could result.

3. SERVICE AND REPAIR POLICY

- The device is not user-serviceable.
- The system does not require maintenance or service on a routine basis, except for cleaning and disinfection of the glasses between uses.
- Service should only be provided by an authorized Essilor representative.
- Defective or malfunctioning devices and components should be shipped back to the local vendor for replacement of defective parts.
- Defective parts should be sent for service by the local vendor, as per manufacturer guaranty and warranty.
- A replacement system will be provided while the client's system is being repaired.
- Essilor will provide hotline and e-mail support for errors and device malfunctions.

4. WARRANTY

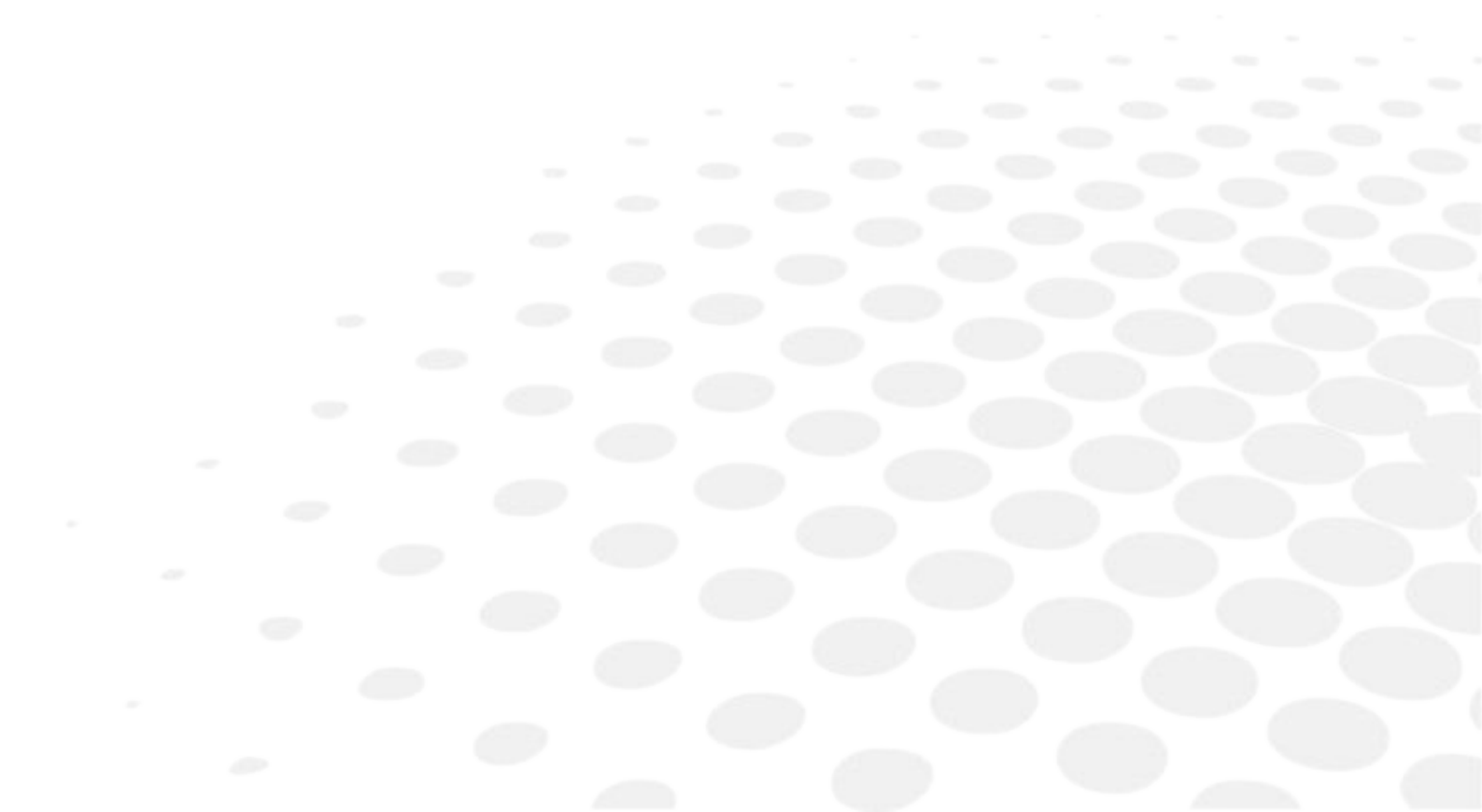
Essilor warrants to the initial purchaser for a period of one (1) year from the date of purchase that: (1) each new product and the software media as delivered are free from defects in workmanship or materials, and (2) the product and software will perform substantially as labeled in the directions for use. Essilor's sole obligation under this warranty is to repair or replace any product or software that is covered under warranty.

To request a replacement under warranty, purchaser must contact Essilor for a returned goods authorization. If Essilor determines that a product must be replaced under warranty, it will be replaced, and the cost of shipment covered. All other shipping costs shall be the responsibility of purchaser.

Limited warranty

Essilor warrants that the EyeViz300 system meet their published specifications at the time of shipment from the factory. Essilor further warrants that the product was calibrated at the factory prior to shipment.

IX. TROUBLESHOOTING



1. ERROR CONDITIONS

The following table lists some typical conditions that may occur with the system.

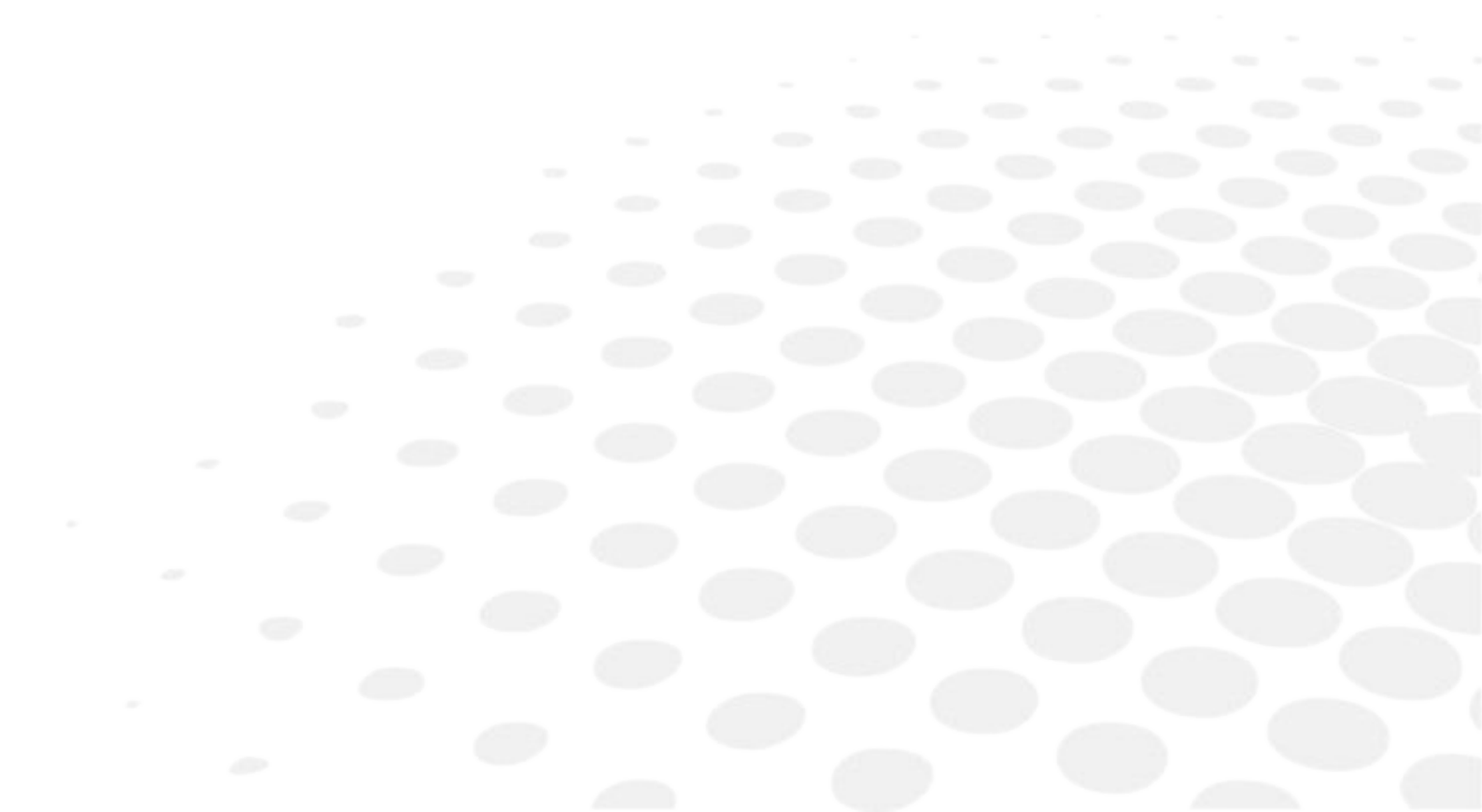
PROBLEM	POSSIBLE CAUSE	SUGGESTED SOLUTIONS
Eye tracker does not detect both eyes	Head position is inaccurate Glasses are improperly positioned.	Instruct the patient to tilt their chin down a bit while still looking at the monitor. Try adjusting the sitting height of the patient to be centered with the monitor. Make sure the glasses are not sitting too low or too high on the nose.
Eye tracker does not detect one eye	Head position is inaccurate Glasses are improperly positioned.	Instruct the patient to tilt their chin down a bit while still looking at the monitor. Try adjusting the sitting height of the patient to be centered with the monitor. Make sure the glasses are not sitting too low or too high on the nose.
Eye tracker detection alternates between detection and non-detection	Head position is inaccurate Glasses are improperly positioned.	Instruct the patient to tilt their chin down a bit while still looking at the monitor. Try adjusting the sitting height of the patient to be centered with the monitor. Make sure the glasses are not sitting too low or too high on the nose.
Test fails due to failed fixations	The patient has difficulty focusing within the required area for the minimal time, or there is a problem with eye detection	Make sure both eyes are clearly detected. Enlarge target size if patient cannot see the target clearly.
The patient cannot see the target clearly	Target size is too small and may have been set for the dominant eye	Use the manual glasses shuttering to occlude the dominant eye, and change the target size until the patient sees it clearly with the eye with poorer vision
I want to begin a test, but the "run" button is not enabled	Required patient info is not entered No tests are selected	Make sure all of the required information is entered and that at least one test has been selected

2. ERROR MESSAGES

The following table lists error messages that may be displayed by the system.

PROBLEM	ERROR MESSAGE
CPU fault	CPU fault. Please contact Essilor service for assistance.
RAM fault	RAM fault. Please contact Essilor service for assistance.
Hard disk filled up	Hard disk full! Please contact Essilor service for assistance.
Eyetracker init. Malfunction/ Not connected	The eyetracker has malfunctioned or is disconnected. Please check eye tracker connection. If connection is valid, please contact Essilor service for assistance.
Eyetracker malfunction during test	The eyetracker has malfunctioned. Please contact Essilor service for assistance.
No eyes identified	The eyetracker cannot see the patient's eyes. Please try to adjust head position and tilt of screen.
No fixations identified	No fixations identified. Please try to adjust head position and tilt of screen. Please instruct patient to focus on target. If issue persists, consider using "easy" fixation parameters.
Eyetracker license is not valid	The eye tracker license is not valid. Please contact Essilor service for assistance.
Unexpected eye movements	Unexpected eye movements detected! Please check that patient is following the target as instructed.
Low quality fixations	Fixation quality is low. Results may be impacted.
Distance from screen	Patient is out of optimal distance range. Please reposition to within the working range.
Glasses controller not connected/ not working	Glasses controller is not connected. Please shutdown then restart, then try again. If the error persists, please contact Essilor for assistance.
Not on patient before test	Glasses are not properly positioned on patient!
Not enough valid data points for result -> switching to eye tracker distance	Not enough valid data points for distance calculation. Eye tracker distance used (note: result accuracy may be reduced)
Crucial setting parameters have been altered- Checksum error	Crucial settings have been altered. Please contact Essilor service for assistance.
Database fault	Database cannot be accessed properly. Please contact Essilor service for assistance.

X. SPECIFICATIONS



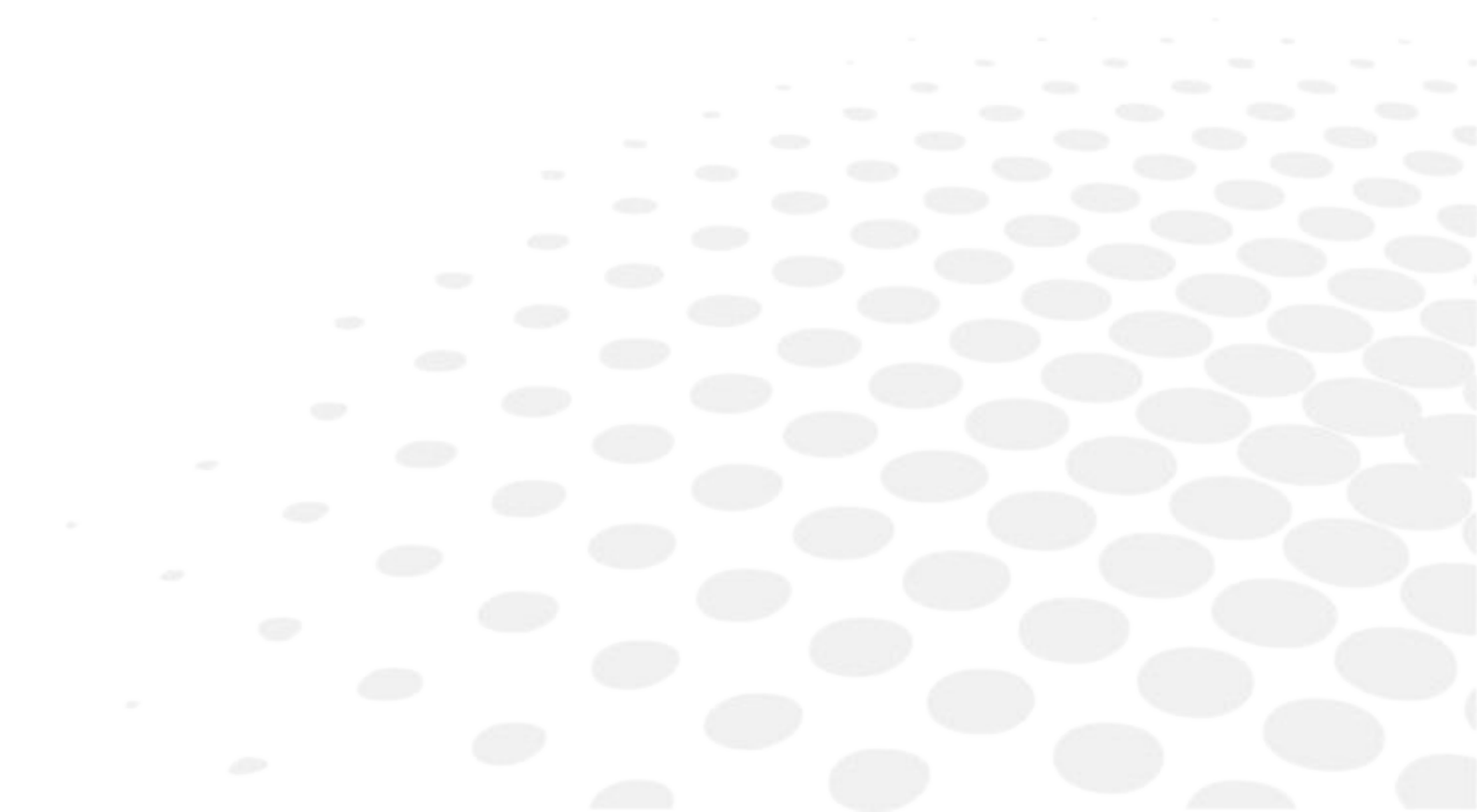
	Temperature	Humidity	Atmospheric pressure	Operating altitude
Use	[10°C ; 35°C]	[30% ; 90%] non-condensing	[700hPa ; 1060hPa]	[-378 ; 3050m]

Electrical	
Tablet PC	
Power Source/Consumption	100-240 V AC, 50/60 Hz, 500mA
Glasses	
Battery Powered	Rechargeable lithium-ion polymer cell
Capacity	Approximately two weeks after full charge
Battery charging time	2 hours when powered off
Charger	Micro USB cable
Emitter	
USB Powered	USB cable
Tablet	
USB Powered	USB cable
Physical Characteristics	
Dimensions	W541.2 x L416.38 x H57.3 [mm]
Weight	7 kg

Compliance

- Equipment Classification: IEC 60601-1
- Type of Protection (battery power): Internally powered
- Degree of Protection – Glasses: Type BF-Applied Part
- Enclosure degree of ingress protection- Glasses: IPX0

XI. QR CODE





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



Le manuel utilisateur complet est disponible sur un espace web. Pour y accéder veuillez scanner le QR code ci-dessous à l'aide d'une application dédiée.



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

الأدبية العربية

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



O manual do usuário completo está disponível na área web do cliente. Para acessar, escaneie o código QR abaixo usando o aplicativo respectivo.



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



可通过网络空间访问操作手册全文。如需访问该空间，请使用专用应用程序扫描QR码。



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



Potpuni korisnički priručnik dostupan je na webu. Da biste mu pristupili, skenirajte QR-kod u nastavku namjenskom aplikacijom.



Den komplette brugermanual findes på et websted. Du får adgang til den ved at scanne QR-koden nedenfor ved hjælp af en dertil beregnet applikation.



El manual de uso completo está disponible en la web. Para acceder, escanee el código QR que se encuentra a continuación con la ayuda de una aplicación.



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



Täydellinen käyttöohje on 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.



A teljes használati útmutató megtalálható a webes felületen. A hozzáféréshez, kérjük, olvassa le a lenti QR-kódot a megfelelő alkalmazás használatával.



Panduan pengguna yang lengkap tersedia di halaman web. Untuk mengaksesnya, silakan pindai kode QR berikut menggunakan aplikasi khusus.



Il manuale utente completo è disponibile su uno spazio Web. Per accedervi, scansionare il codice QR seguente mediante 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、専用アプリケーションを使用して以下のQRコードをスキャンしてください。



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



Išsamaus naudotojo vadovo ieškokite interneto svetainėje. Kad jį atvertumėte, specialia programėle 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 et webområde. For å få tilgang, må du skanne QR-koden nedenfor ved hjelp av en dedikert applikasjon.



De volledige gebruikershandleiding is beschikbaar op een website. U kunt de handleiding bereiken door de QR-code hiernaast te scannen met een geschikte applicatie.



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



O manual do utilizador completo está disponível num espaço web. Para aceder, queira digitalizar o QR code seguinte com a ajuda de uma aplicação dedicada.



Celá uživatelská příručka je k dispozici na webu. Pro přístup k ní oskenujte níže uvedený QR kód pomocí specializované aplikace.



Versiunea integrală a manualului de utilizare este disponibilă pe un site web. Pentru a-l accesa, scanați codul QR de mai jos cu ajutorul unei aplicații dedicate.



Полное руководство пользователя доступно в Интернете. Для доступа просканируйте приведенный ниже QR-код с помощью специального приложения.



Potpuno korisničko uputstvo je dostupno na vebu. Da biste mu pristupili, skenirajte QR kôd u nastavku pomoću namenske aplikacije.



Celý používateľský manuál je dostupný na internete. Aby ste sa k nemu dostali, naskenujte QR kód nižšie pomocou na to určenej aplikácie.



Celoten uporabniški priročnik je na voljo na spletnem mestu. Za dostop do njega skenirajte spodnjo kodo QR z uporabo namenske aplikacije.



Den fullständiga handboken finns på en plats på Internet. Skanna QR-koden nedan med en lämplig app för att få åtkomst till den.



มีคู่มือผู้ใช้นับสมบรูณ์อยู่ในพื้นที่เว็บ เพื่อเข้าถึงข้อมูล กรุณาสแกนรหัส QR ด้านล่างนี้โดยใช้แอปพลิเคชันเฉพาะงาน



Kullanma kılavuzunun tamamı internette bulunmaktadır. Kılavuza erişmek için, QR kodunu uygun bir uygulama kullanarak taratınız.



Повне керівництво користувача доступно в Інтернеті. Для доступу проскануйте наведений нижче QR-код за допомогою спеціального додатку.



Cẩm nang hướng dẫn sử dụng hoàn chỉnh hiện có trên không gian web. Để truy cập, vui lòng quét mã QR bên dưới bằng ứng dụng chuyên dụng.





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