VisuScience

User Manual

Perimeter

Model: IFA-960, IFA-950, IFA-900, IVS-201A, IVS-20B

Please be sure to read this manual carefully
before using the instrument and keep it handy
for ready reference.

Copyright

© 2006-2019 IRC Medical Equipment Co., Ltd. All rights reserved.

Trademarks

VisuScience is a registered trademark of Shanghai VisuScience Meditech Co., Ltd.

HISA is a registered trademark of IRC Medical Equipment Co., Ltd. in China and/or other countries. ARM is a registered trademark of ARM Limited (or its subsidiaries) in the EU and/or elsewhere. All other trademarks used in this document are the property of their respective owners.

All product names mentioned in this manual and other documentation are used for identification purposes only and may be trademarks or registered trademarks of their respective companies. Registered and unregistered trademarks used herein are the exclusive property of their respective owners. IRC Medical Equipment co., Ltd. makes no claim to any such marks, nor willingly or knowingly misused or misapplied such marks.

Notice

	Caution, consult accompanying documents. Note: There are important operating and maintenance instructions found in the manual.
	User manual, technical instructions and software instructions are merged. When a failure happens on the machine, please try to solve in accordance with the appendix “Troubleshooting”; if not, please feel free to contact with the service department of our company for more help. The functions vary depending on the product model. The product you purchase may not include all the features described in this manual.

Document Applicability

This document is applicable to the perimeter, software version 2.0 or higher.

Purpose of this User Manual

IRC Medical Equipment Co., Ltd. as manufacturer designed this User Manual to serve as a training, usage and reference guide. While we/our distributor offer training in the use of the perimeter, we do not offer instruction in diagnostic interpretation. This manual does not attempt to do so.

To fully appreciate the capabilities of the perimeter and to develop good testing techniques, we recommend that you rely on this User's Manual as your training and reference guide. It has been designed to make learning easy. The concise step-by-step instructions and accompanying illustrations help you get started quickly and with more confidence.

1	Read your User Manual in the order written.
2	Read it while sitting at the instrument.
3	Practice using the perimeter by first testing staff members, before using it with patients.

CONTENT

1. Introduction & Instrument Setup

1.1 Intended Use

The IFA/IVS series perimeter is an automatic perimeter which is intended to be used to measure the visual field of human eye.

The IFA/IVS series perimeter is an automated perimeter intended to identify visual field defects for the purposes of screening, monitoring and assisting in the diagnosis and management of ocular diseases such as glaucoma, and related neurological disorders.

	Note
	These perimeter results are an aid to interpretation, not a diagnosis. The doctor's judgment is still the most important element in determining the clinical significance of the results, including considering the limitations of the statistical package.

1.2 Instrument Disposition

When it comes time to upgrade the perimeter, please contact VisuScience or authorized distributor to inquire about trade-in. Should you not wish to trade in the instrument, please see the disposal section below.

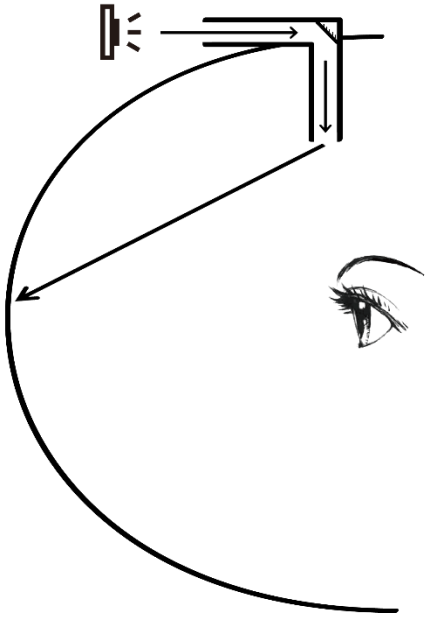
	Disposal
	This product contains electronic components. At the end of its lifetime, the product should be disposed of in accordance with the relevant national regulations.

	Disposal of the Product within the European Union (EU)
	In accordance with applicable EU guidelines at the time at which the product was brought onto the market, the product specified on the consignment note is not to be disposed of via the domestic waste disposal system or communal waste disposal facilities. For further information on disposal of this product, please contact your local dealer or the manufacturer or its legal successor company. Please read the latest web information provided by the manufacturer.

1.3 Working Principle

Under determined background illumination, stimulus points with different contrast and size are presented on the inner surface of the bowl, the subject respond if he/she observed the stimulus point while keeping fixation.

For IFA series, the stimulus point is generated by a front-projection rotating optic system.



For IVS series, the stimulus point is generated by hidden LED array under the surface of the bowl.

The embedded computer and its software control the presentation of stimulus point and record all the subject responses, then the visual field test results are computed automatically. The test result can be used to evaluate the visual sensitivity at different locations and field range of the subject.

1.4 Instrument Installation

Care in Handling

Use extreme care when handling and transporting the perimeter shipping boxes. The instrument contains fragile optics that have been precisely aligned at the factory.

Installation Requirements

a. The perimeter should operate on a dedicated power outlet. The unit has universal power supply of AC 100-240V, 50/60 Hz.

b. An isolation transformer is required when connecting peripheral devices that are not Medical Device approved (i.e., printer, USB drive, etc.) within 1.5 meters (4.9 feet) away from the patient, such that the patient cannot touch a peripheral device with any part of his or her body while being examined.

Mainframe

Patient Responder

Ports on the Rear

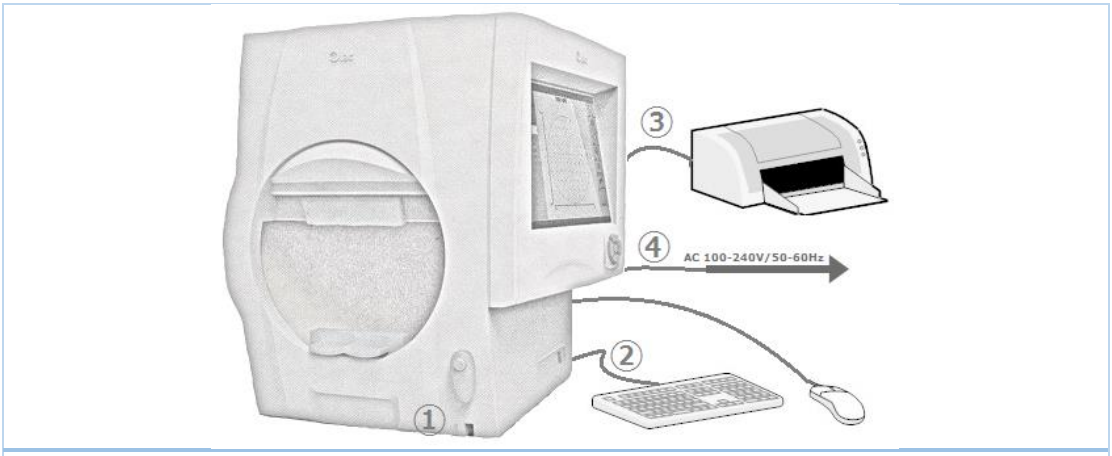


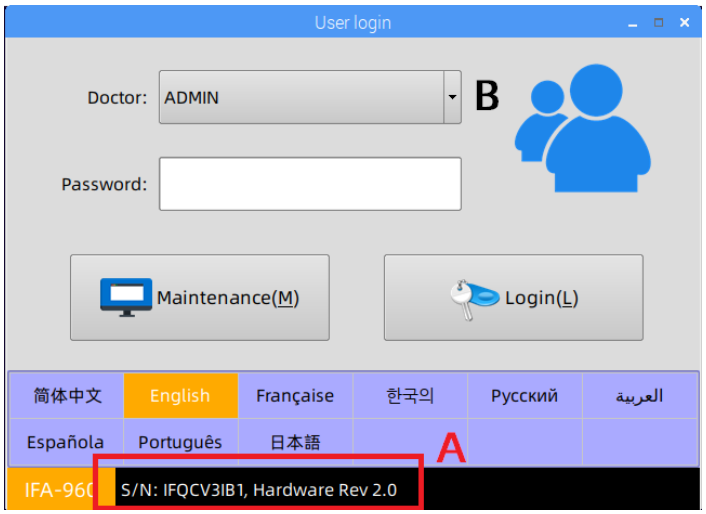
Illustration for Wire Connection

①	Patient responder shall be connected to the port of patient responder in mainframe.
②	Connect the external USB mouse and keyboard to the USB ports of the mainframe, this is not mandatory because the touch screen is enough for routine use.
③	Connect the external printer to the USB 2.0 port of the mainframe. This is not mandatory too. As an option, you can access the shared reports through a PC in LAN, or simply upload your report to DICOM system.
④	The power input shall be connected to AC 100V-240V, 50/60Hz power supply through dedicated power cord.

1.5 Startup

The perimeter shall be used in a totally dark room. The startup procedures of the system are as follow:

①	Turn on the power switch on the side of the perimeter.
②	When the startup of the system is finished, the login page will automatically appear and relevant software languages can be chosen.
③	Select your account and input password, and login into the system.



Users is classified into: the system administrator (ADMIN) and common user (Non-Admin) subject to the permission. The Admin user can change the default parameter and all users' passwords, and edit the program configuration and other key information, while the non-admin user does not have the permission to change any built-in parameters of the system.

➡	The initial password of ADMIN user is "admin". The ADMIN user can change the password of ADMIN and other users in SETUP window.
B	Click on the triangle for dropdown list of users.
A	The S/N of main electronic board is displayed, also the version number. If the embedded computer failed to communicate with the main electronic board, "No device connected" will be shown here.
➡	Under the peculiar circumstances such as instrument repair or software upgrade, click the "Maintenance" button to enter the background operation system with the password "611608".

1.6 Self-Test

This feature only applied to IFA series.

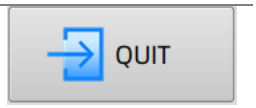
After login in, the system will do a self-test for ensuring the accuracy of test. The projection sub-system, light source, background illumination will be checked one by one.

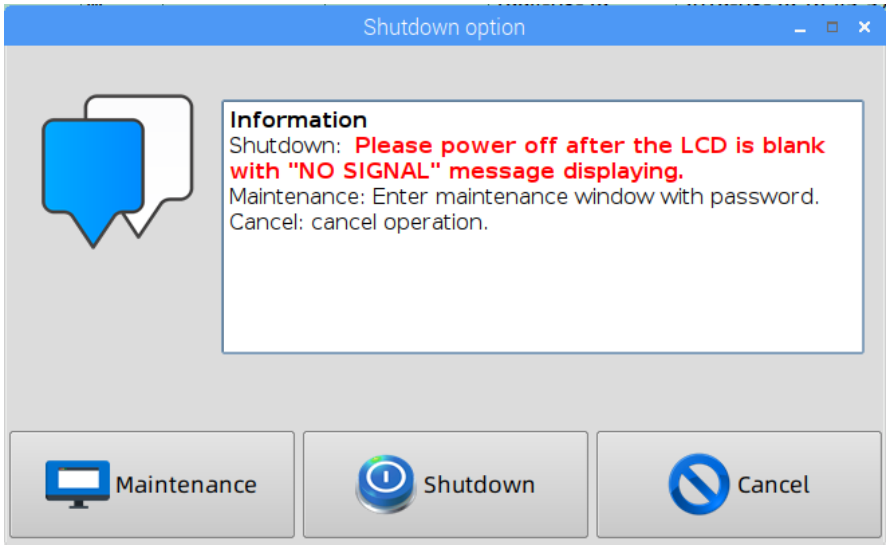
If there is anything wrong, the error message will be displayed on the self-test window. If self-test is failed, please contact manufacturer or authorized distributor and report these error messages.

➡	Too bright indoor illumination can cause failed self-test background light or stimuli. Make sure that the room lighting is dark enough before restarting the device.

1.7 Shut Down

Before powering off the perimeter, the program and perimeter must be shut down in the right order. If not, it may lead to **data loss or device damage**.

a	Make sure that the current test result has been saved, and then go back to the home window.	
b	Click the "QUIT" button on the right side of the main window, and the shutdown confirm window will appear, and then click the "Shutdown" to exit system or click "Cancel" to go back to the home window.	
c	Wait for the shutdown of the unit until the monitor turns blank with "NO SIGNAL" message displaying, and then turn off the power switch.	



	Under the peculiar circumstances such as instrument repair or software upgrade, click the "Maintenance" button to enter the background operation system with the password "611608".

2. Patient Management

2.1 Home Window

After login in, the home window shows as follows.

The upper part of this window shows the patient list with 7 columns. If the patient record is selected by clicking, this record will be highlighted in orange background.

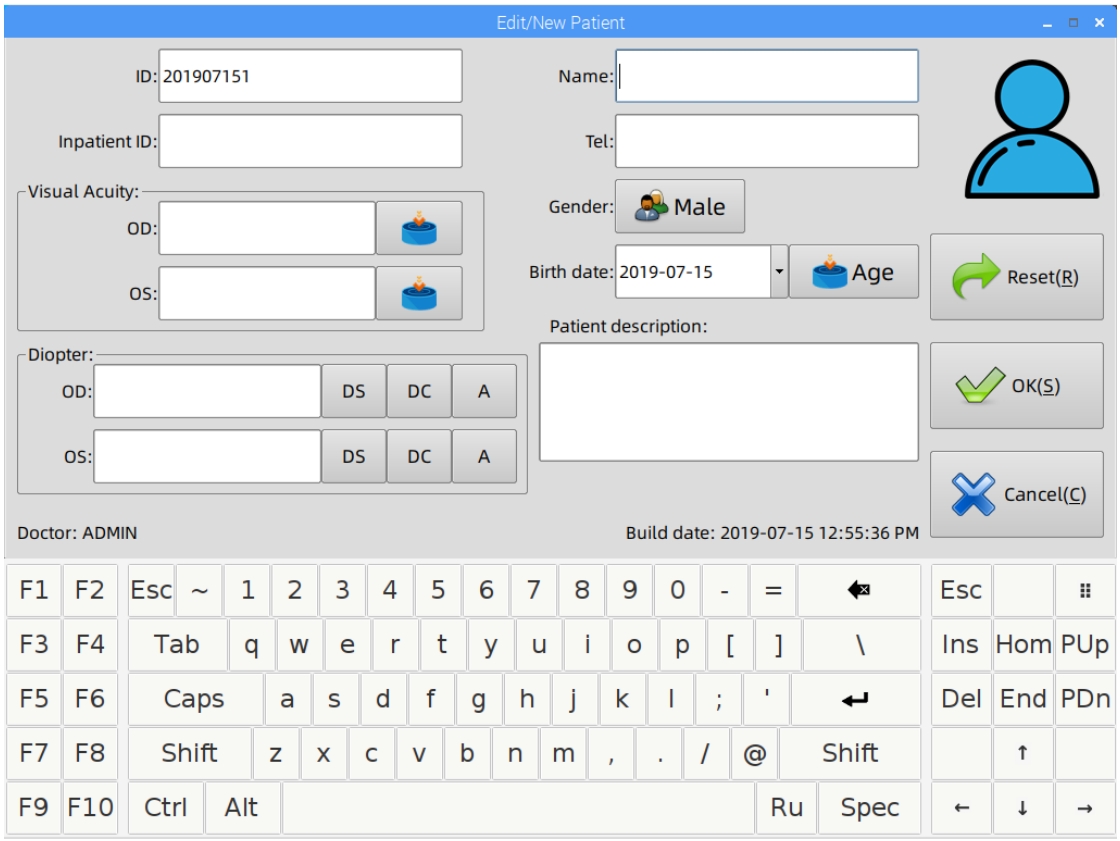
Buttons related to patient management:

BUTTON	Function
SEARCH	Search patient with patient ID or name.
NEW	Create new patient.
EDIT	Edit current selected patient.
DEL	Delete current selected patient with his/her test data.
OPEN	Open tested results of current selected patient.
PREV	Scroll up the patient list.
NEXT	Scroll down the patient list.

2.2 New/Edit Patient

Click "NEW" in home window, following “Edit/New Patient” window will appear.

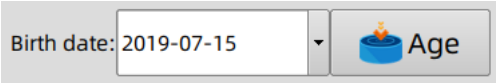
Click "EDIT" in home window, same window will appear with current selected patient information displayed.



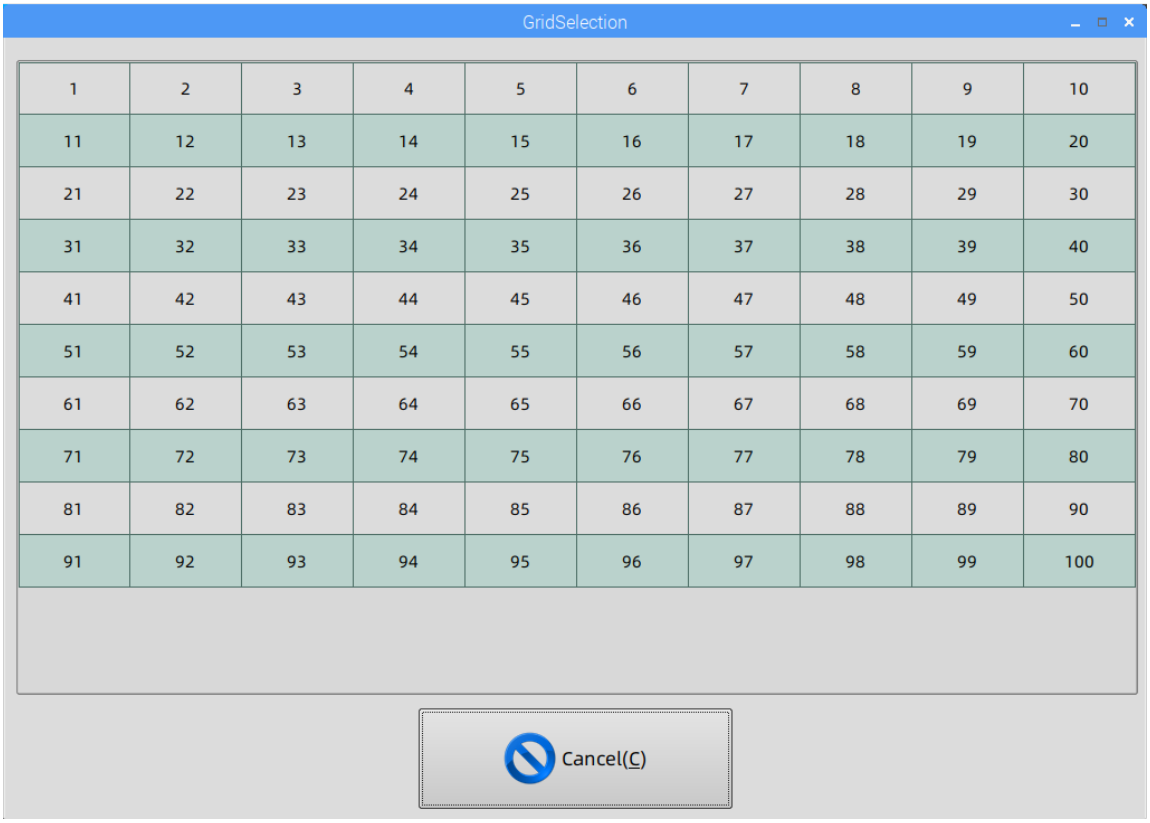
Name and Patient ID are mandatory, can’t leave blank. And each patient's ID shall be unique.

Male/Female	Click to change patient’s gender.
Reset	Clear all filled information, then input again.
OK	Click to confirm and save the change.
Cancel	Click to abort any modification.

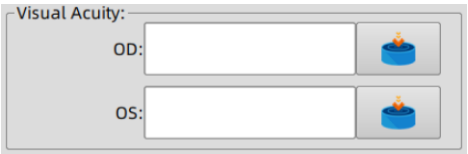
- Birth date/Age



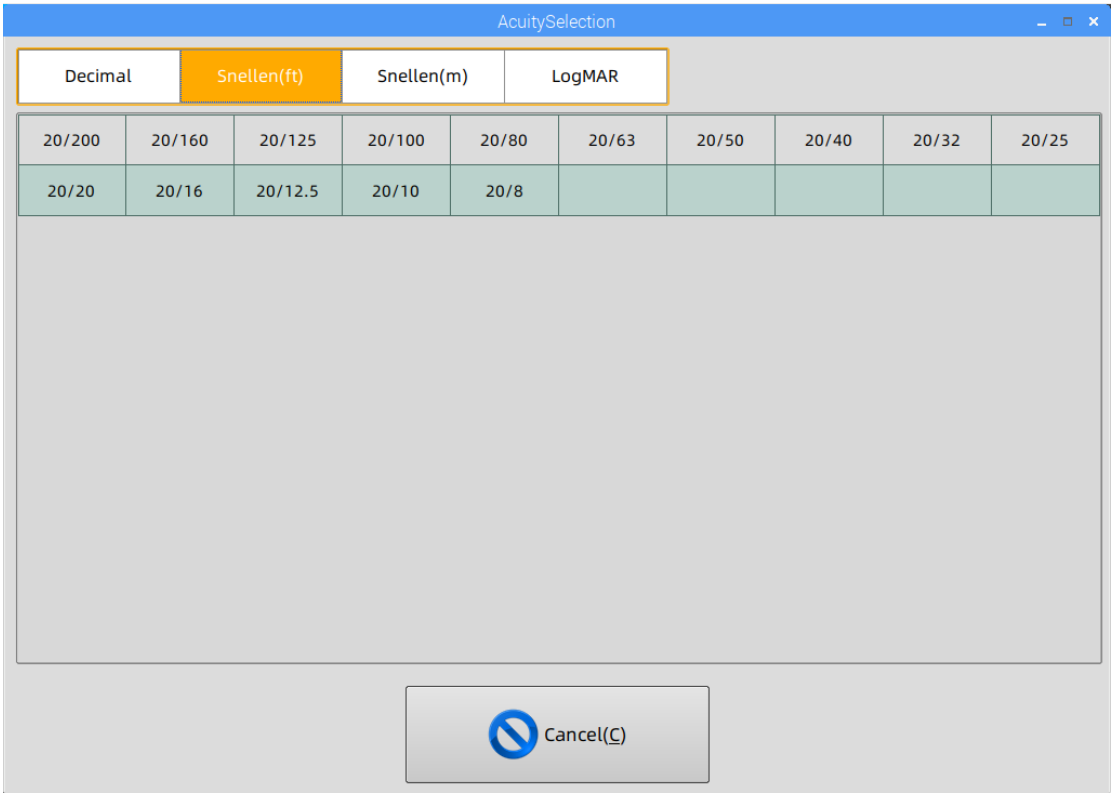
User can input accurate birth date of the patient by click drop down button, or click the "Age" button to select the age of that patient, then his/her birth date will be computed by the software.



- Visual Acuity

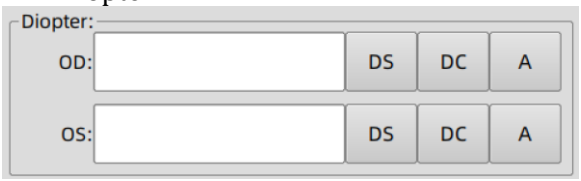


User can input the visual acuity through keyboard or click the button beside the input box to open "Acuity Selection" window for quick visual acuity selection.

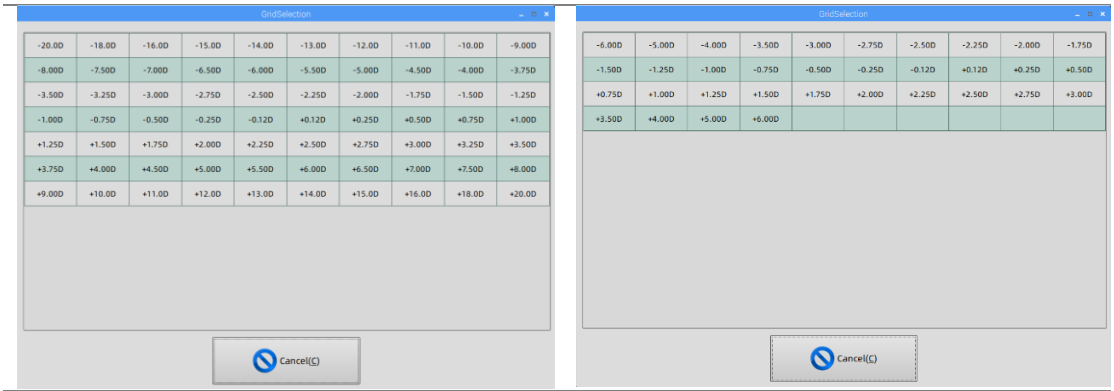


Four type of visual acuity are available in “Acuity Selection” window: Decimal, Snellen(ft), Snellen(m), LogMAR. Click the type and then select the value.

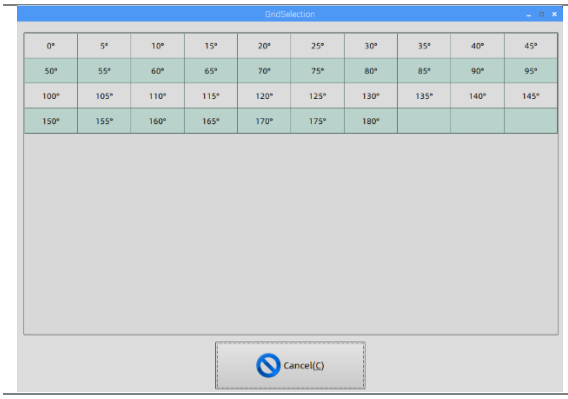
- Diopter



The diopter power can be input directly or select the value after clicking the “DS”, “DC”, “A” button respectively beside the input box.



DS **DC**

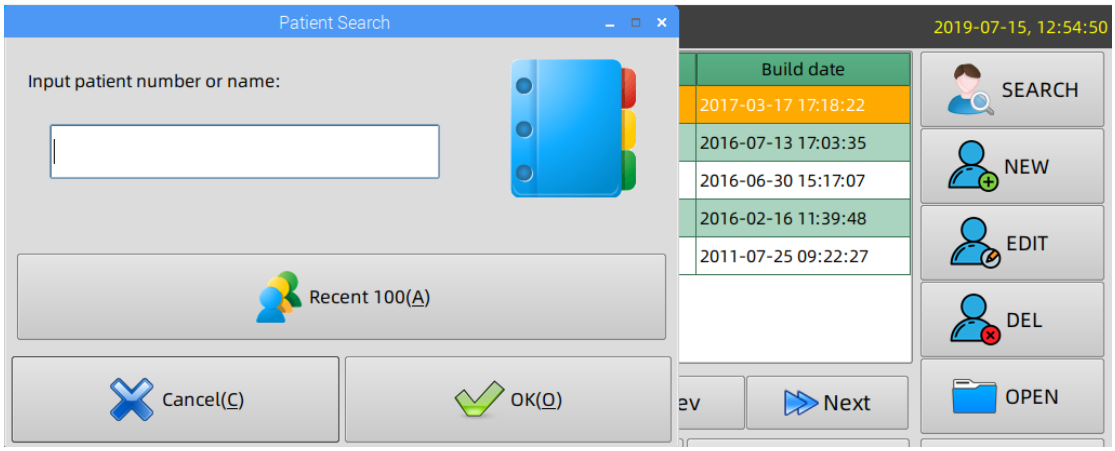


A

2.3 Search Patient

Click "SEARCH" in home window to open “Patient Search” window.

Please input patient ID or patient name in input box, then click "OK" to search the patient record. Precise search or fuzzy search are available. For example, if input “Bill” in searching box, all patients whose name includes “Bill” will be shown in the patient list.



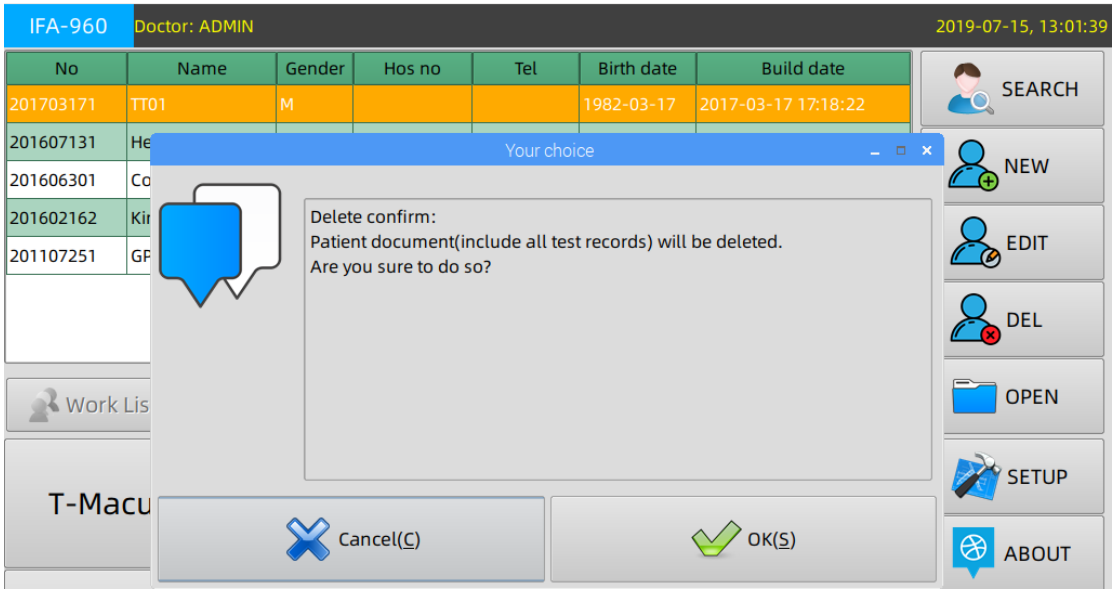
Click "Recent 100" will show all the most recent 100 patients in patient list.

Click "Cancel" to cancel the search.

2.4 Delete Patient

Click "DEL" in home window will delete current selected/highlighted patient in patient list. Before deleting the patient record including all tests, system will request user’s confirmation: "OK" to confirm to delete, "Cancel" to cancel deleting and back to home window.

Warning: The deleted patient can't be recovered.



3. Test Preparation

3.1 New/Select Patient

For new patient, please click the "NEW" button on the right side to input the patient's information.

For returning patient, please click the "SEARCH" button on the right side to locate that patient.

➡	If the patient has been tested by the same instrument for several times, it is better to conduct all his/her test under the same patient record. Since in this way, the patient's progressive visual field loss is available with the "**Glaucoma Progression Analysis**" function. (refer to chapter 5.7 GPA)

3.2 Select Test Pattern

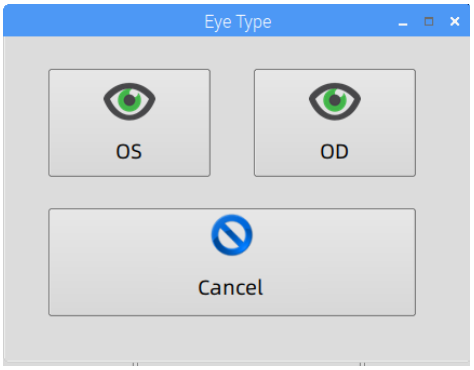
After selecting the patient (the selected patient record will be highlighted), select the test pattern according to needs. Standard programs of the test library are displayed in the bottom of the home window. Click the corresponding button to enter the test pattern.

The test pattern library may be different between different models. For more test patterns, click "…" button.

	T30-2 is the most widely used visual field test program, and it will conduct threshold test for 76 spots within the 30 degrees visual scope. These test spots are carefully set up in the sensitive spots of optic nerve tracts.
	T24-2 is a common choice for quick test.
	T-Macula and **T10-2** can help precisely evaluate the function of macular region.
	Early glaucoma rarely happened beyond the 30 degrees visual scope. The test pattern with the spots beyond the 30 degrees visual scope is seldomly used for early glaucoma test.

3.3 Select Eye Type

After selecting test pattern, the "EyeType" selection window will appear. Click the eye type, or click "Cancel" to go back to the home window.



After selecting the eye type, the software will automatically enter the test window.

3.4 Preparation of the Patient

①	Cover the other eye which is not being tested.
②	If the upper eyelid is severely ptosis, then it should be rectified.
③	Dim the room illumination.
④	Conduct test instruction for patients, including how to keep fixation during the test; If the patient is tired, he/she can long press the responder button to relax. Before releasing the responder button, the test is paused.
⑤	Adjust the seat to proper height, and make sure the patient is seated in comfort. This is the key for reliable test result.

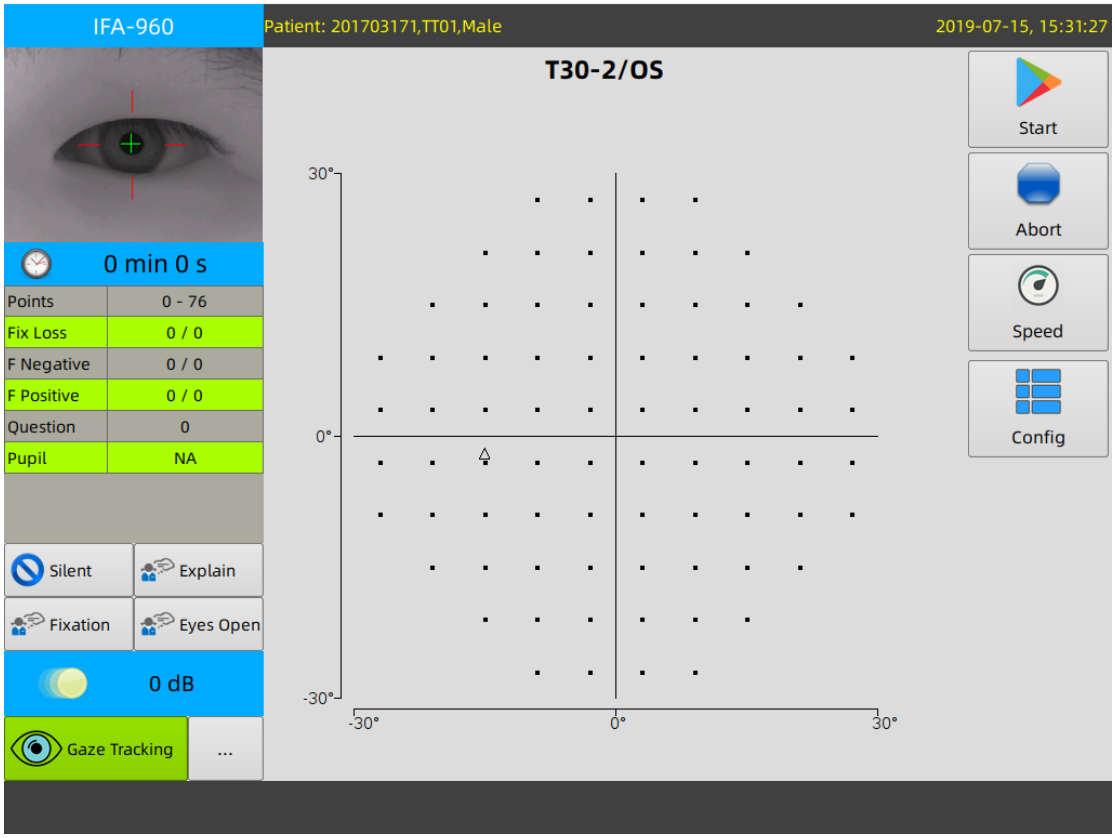
When the patient is ready, let the patient seated in front of the instrument, and guide the patient to put his/her chin on the chin supporter. The left supporter is used to check the right eye, while the right supporter is for the left eye. The patient's forehead should lean on the forehead supporter.

Guide or help the patient to adjust the up-down table to the comfortable height, which is very important since the improper height may result in tiredness of the patient, and may affect the reliability of the test result.

	Warning
	The examination shall be done in a quiet dark room. The bright room will lead to inaccurate test result. The noisy environment will possibly affect patient's cooperation. The materials used to cover patient's eye must meet medical biocompatibility standards. The mental retardation or the young child who is unable to cooperate is not suitable for the examination.

	Trial Lenses
	Only use trial lenses with metal rim. Only use trial lenses in inspections not exceeding 30 degrees; Under the premise of ensuring comfort (eyelashes do not touch the lens), the distance between eye and trial lenses should be as close as possible. Otherwise, the visual field might be affected by the trial lenses.

3.5 Eye Position Adjustment



User can observe the eye position monitoring video in the test window, and adjust the chin and forehead supporter to make sure that the pupil is in the center of the target.

The eye position can be adjusted by five buttons in the bottom right of the monitor.
Control the movement of chin and forehead supporter by pressing corresponding button with arrow. The movement will stop when the button is released.
The central button is used for eye position alignment automatically.

Eye Position Alignment Automatically

When the gaze tracking is started, if the center of the pupil is marked with a green cross, then it indicates that the eye position is in the recognition zone of the picture. At this point, press the central round button in the bottom right of the monitor, and the software will caculate the horizental and vertical distance between the eye position and the center of the fixation, and lead chin and forehead supporter to the target positon in order to align the eye position automatically.

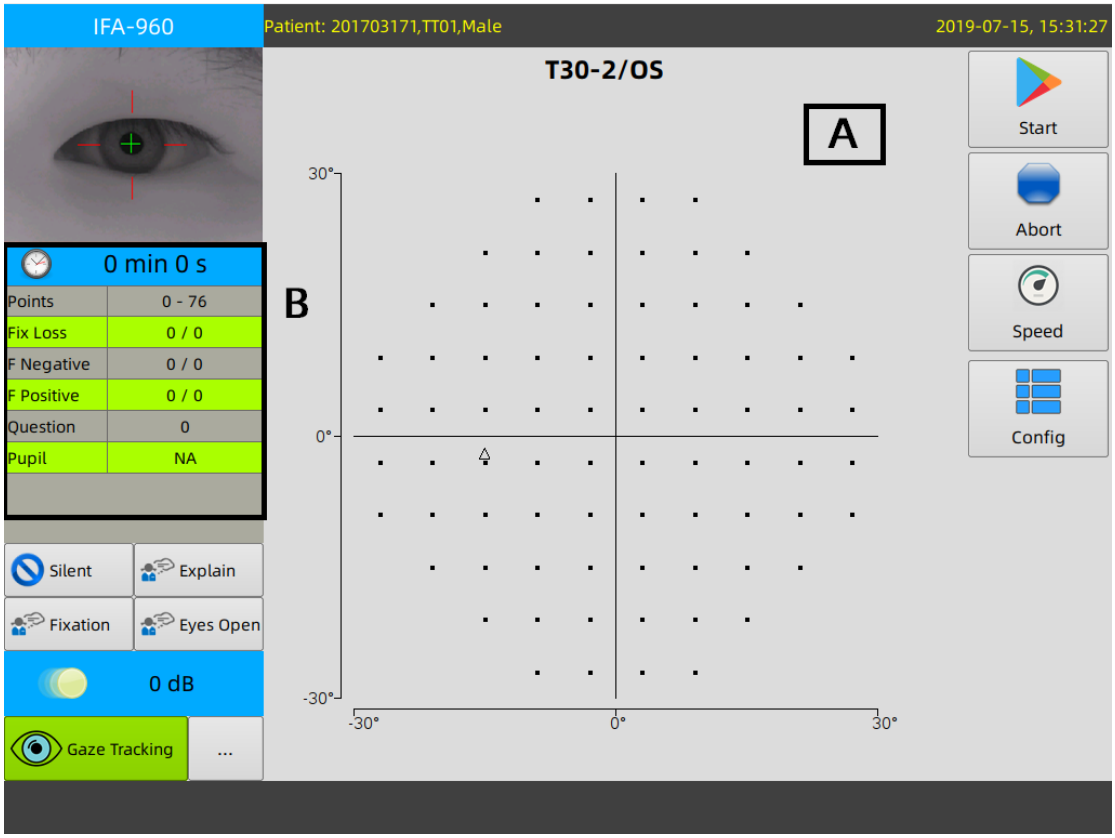
During the test, if the eye postion deviated, press the central button to regain the proper eye position.

During the whole test process, the pupil size may change during time. The central button also help to re-measure size of the pupil by short pressing.

4. Test

4.1 Test Window

After selecting eye type, following test window will appear.

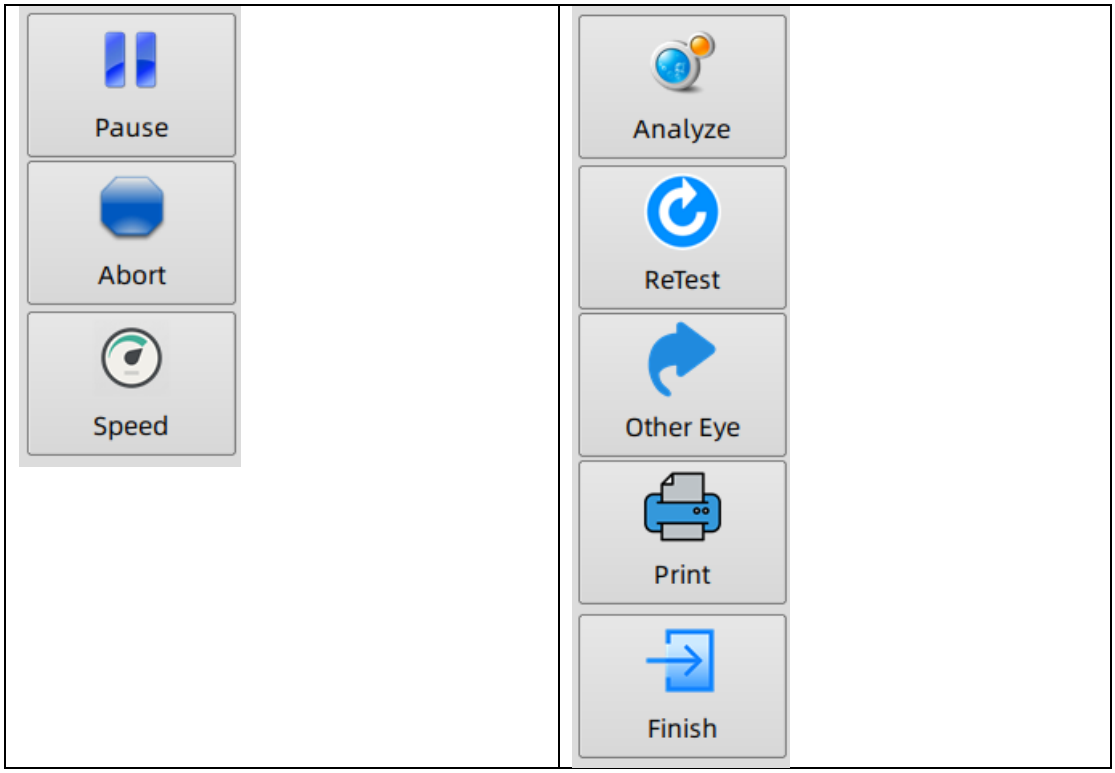


Area A displays all the test points and their testing progress.

Area B displays the summary information of this test. The pupil size can be measured by pressing the central round button in the bottom right of the monitor.

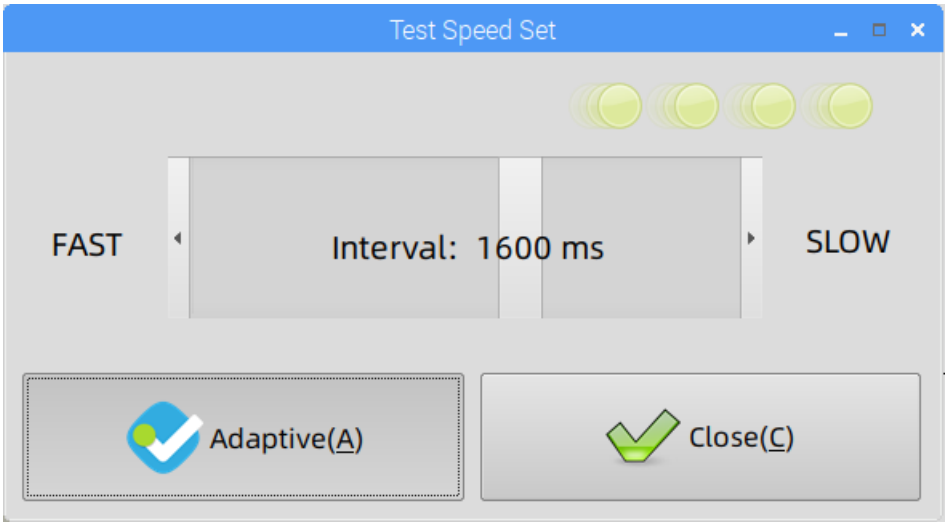
Start	Start the test.
Abort	Abort the test, and return to the home window.
Pause	Pause the test, the test can be resumed after pause.
ReTest	Test the same eye with same test pattern and configuration again.
Other Eye	Test the other eye with same test pattern and configuration.
Analyze	Go to analyze window.

The visibility of buttons is depending on the stage and state of the program. Below picture shows tool buttons on different stage.



4.2 Speed

Click “Speed” button in test window to enter “Test Speed Set”.



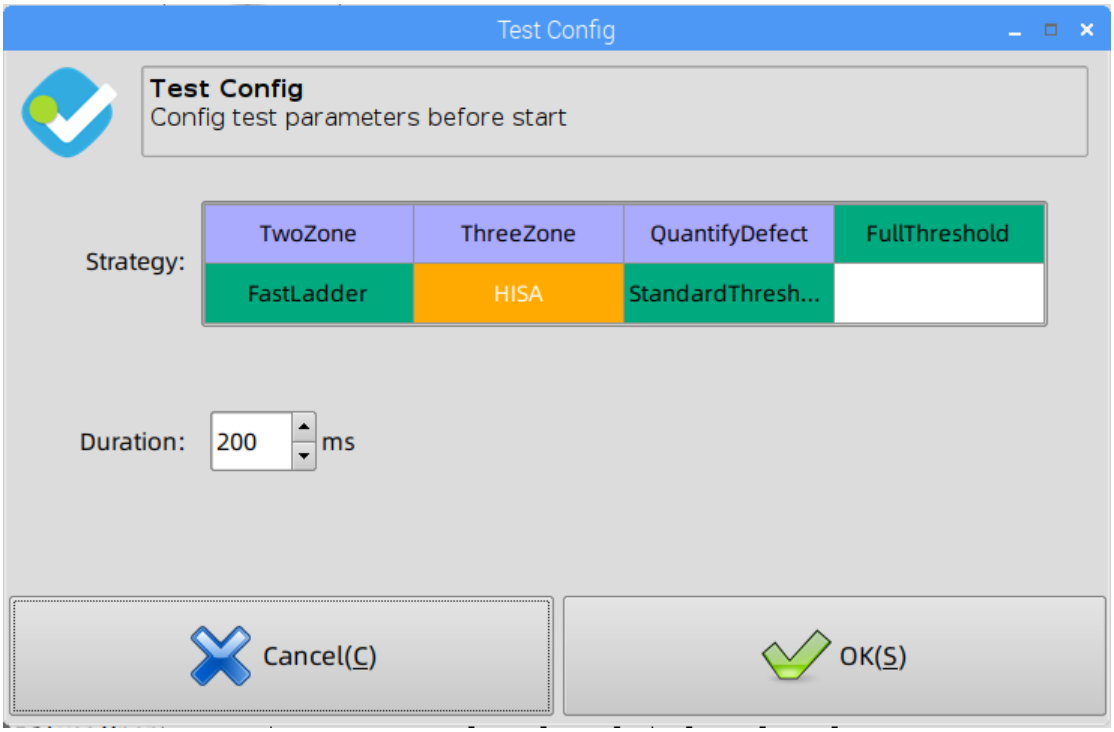
If “Adaptive” button is checked, the test is under adaptive speed mode. In the adaptive mode, the interval between stimuli is intelligently modified according to the response speed of patient. If patient responds quickly, the stimulation interval will be short. If the patient responds slowly, the stimulation interval will be longer, leave enough time for the

patient to respond. The program starts with a very slow speed, then will change based on the response speed of patient.

"Adaptive" mode as default setting is suggested.

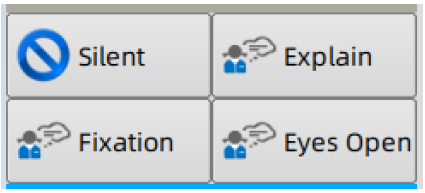
4.3 Config

Click "Config" button in test window to enter "TestConfig".



User can change the test strategy and stimuli duration on "TestConfig" window according to needs.

4.4 Audio



There are 4 buttons related to audio guide in the test window.

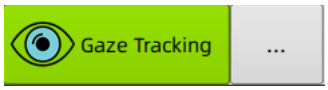
When the test starts or ends, audio guide will be played automatically. If you want to shut down the audio, please click “Silent”.

“Explain” – Audio guides the patient during test. After starting the audio guide, the button will become to “…”, press it again will stop the audio guide.

“Fixation” – Audio guides the patient to keep staring at the fixation.

“Eyes Open” – Audio guides the patient to keep his/her eyes open.

4.5 Gaze Tracking

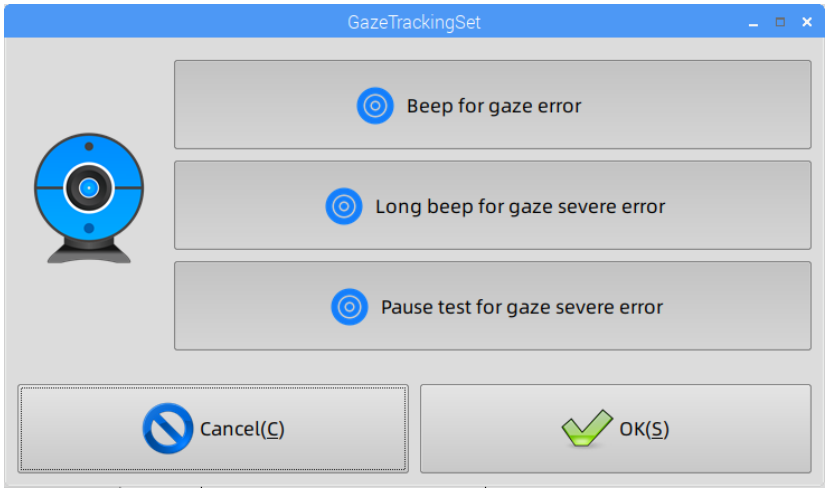


Click the “Gaze Tracking” button, and the eye position auto tracking function will start (the default state is closed). This function will automatically check the pupil center and mark a green cross in the monitor window. When the pupil center deviates from the central position and exceeds the auto tracking range, the instrument will alarm to inform the patient to adjust the eye position in time.

If the pupil center deviates from the central position too much, the software will pause and require the interference from the operator.

Please note that when the upper eyelid of the patient is ptosis, refractive medium turbidity or wear a pair of tinted lenses, the software may not identify the pupil and its central position correctly.

Click “…” button after “Gaze Tracking” to enter “GazeTrackingSet” window.



System will response subject to the gaze error. Keep these 3 options always selected is suggested.

4.6 Monitoring Inspection Process

During test, the operator needs to observe the fixation situation of the patient through monitor window. Additional interference may be required if needed.

If false positive responses increase abnormally, the operator should remind the patient.

Click “Pause” to pause the test if needed. The pause of test may improve the test result for the patient who is easily get tired. Before continuing to start the test, remember to re-adjust the position of the patient’s pupil in order to maintain the good fixation.

	Rest of the Patient
	Besides the manually “pause” by operator, the patient can keep the responder button pressed to pause the test. During test pause, the patient can close eyes, adjust the eye pouch position, etc. The test will continue when the button is released.

4.7 Go to Analyze Window

The program will automatically stop with an audio guide when the test is ended. The operator can click “Analyze” button to enter the analysis window.

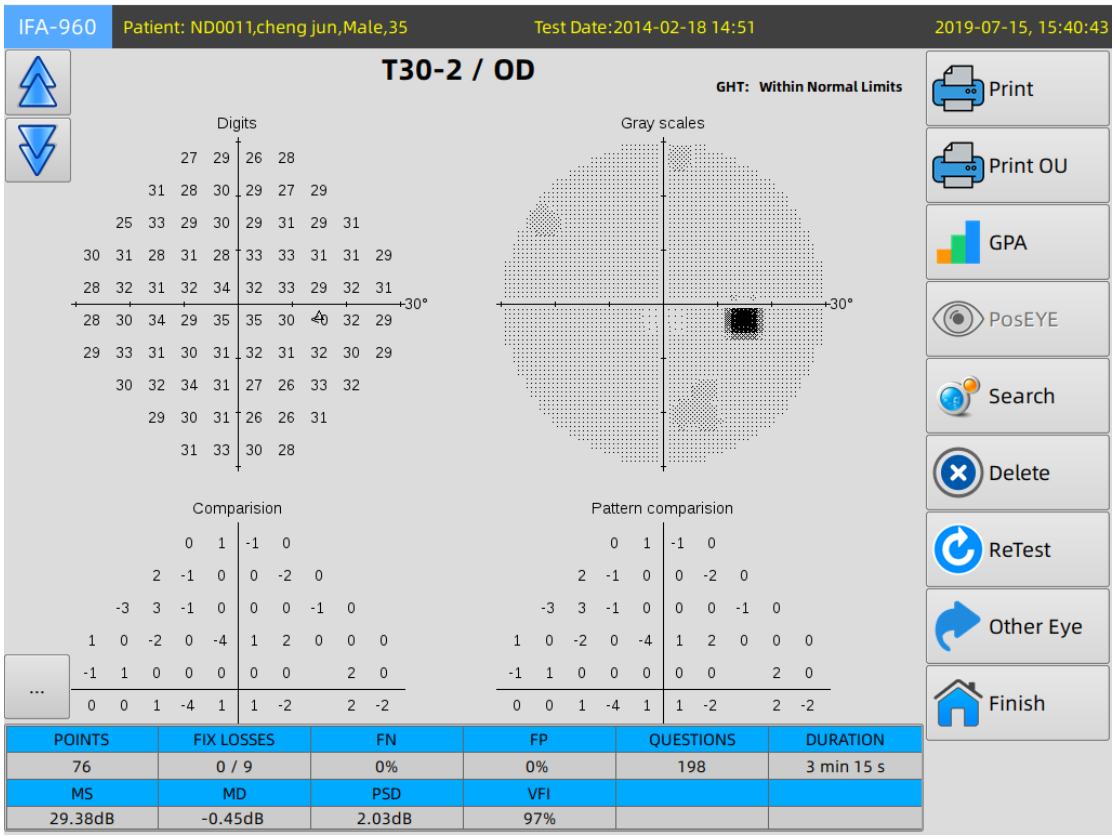
If the test result is doubted, the retest can be made by clicking “ReTest” button.

Click “Other Eye” can start the test of fellow eye directly with the same test pattern and configuration.

5. Analysis & Print

5.1 Analysis Window

In home window, click “Open” button, software will load the most recent test record of current selected patient.



There are many graphs displayed in the window. Please press up/down buttons to scroll up/down to navigate the graphs.

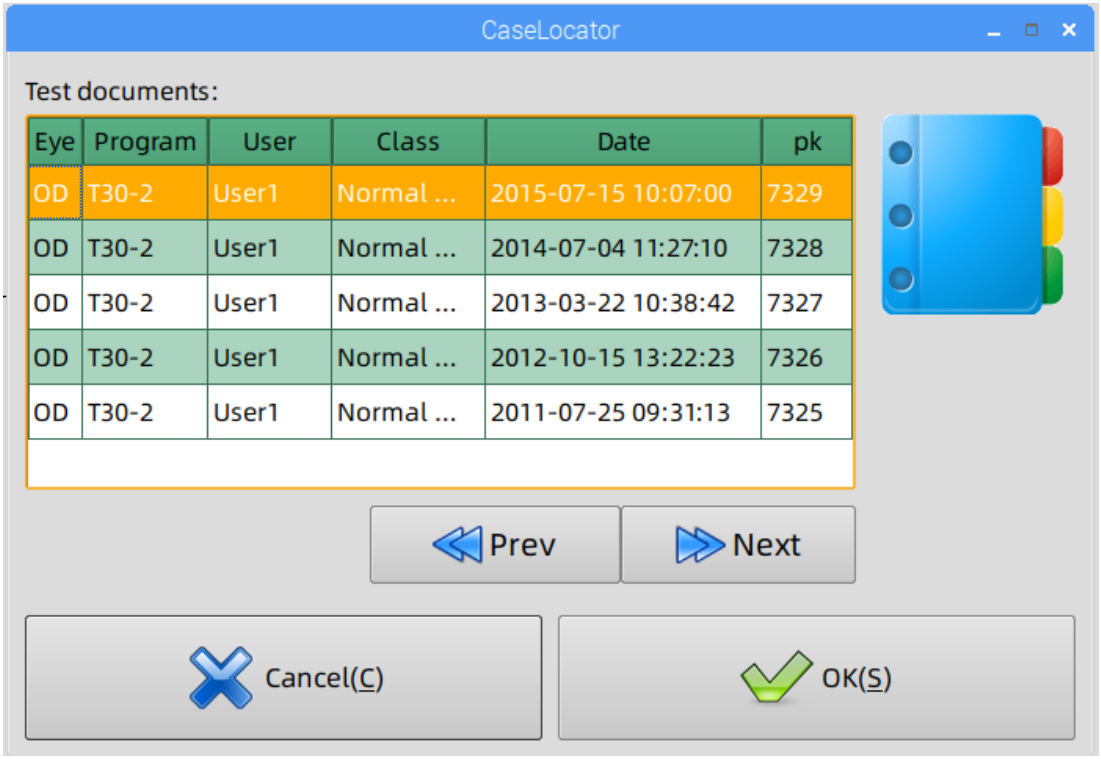
- **Buttons**

Print	Print out test report. Usually, a single test is launched to test one eye
Print OU	Print out test report of both eyes in a single page. After clicking “Print OU” button, the operator can select the test records for both eyes.
GPA	Do glaucoma progression analysis.

PosEYE	Review eye position of patient at the moment of stimuli. The disabled button means that offline video data have been cleared. The offline video data is in huge size, the software will only keep it for 30 days by default.
Search	Load other test case/record of the patient.
Delete	Delete current loaded test case/record.
ReTest	Test the same eye with same test pattern and configuration.
Other Eye	Test the other eye with same test pattern and configuration.
Finish	Return to the home window.
...	Test result transfer.

5.2 Search Test Record

Click “Search” in analyze window to enter “CaseLocator” window.

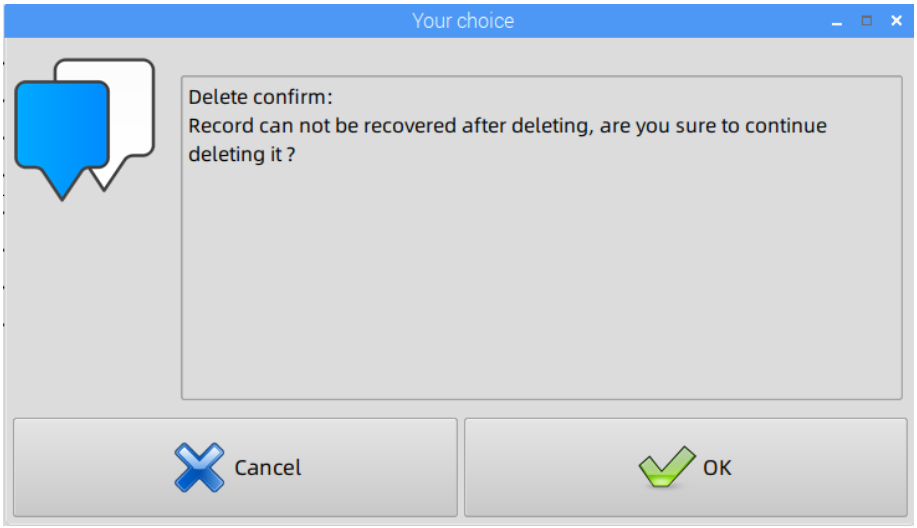


All test records are listed in the order of test time from the latest to the earliest. Select the test record by clicking the corresponding row to be highlighted, and then click “OK” to open the test record window.

5.3 Delete Test Record

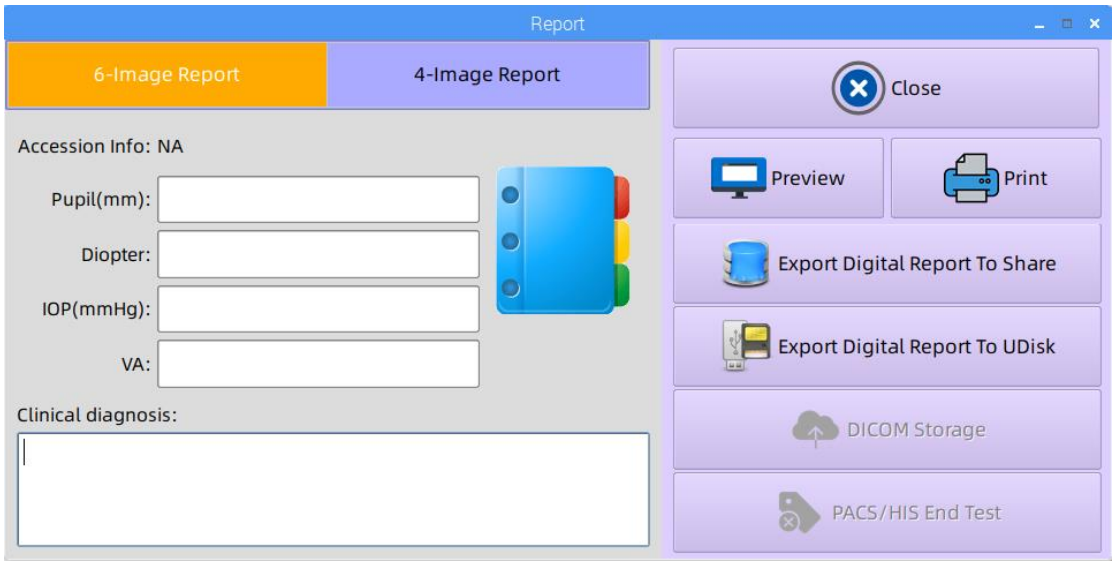
Click the “Delete” button on the right of analysis window to delete the displayed test record. Other test records remain unchanged.

Test record cannot be recovered after deleting. Before deleting, the software will require your confirmation.



5.4 Print the Report

Click the “Print” button on the upper right of analysis window to enter the “Report” window.



Before printing, you can input the patient’s other information which will be displayed on the report, such as the pupil diameter, refraction, intraocular pressure, visual acuity, etc.

Click the “Print” button to print report after confirmation. If a laser printer is connected, it probably need to wait a few seconds for preheating the printer after clicking the “Print” button.

6-image Report: Test report display 6 graphs of Digits/Gray Scales/Comparison/Pattern Comparison/Probability/Pattern Probability.

4-image Report: Test report display 4 graphs of Digits/Gray Scales/Comparison/ /Probability.

Preview: preview report before printing

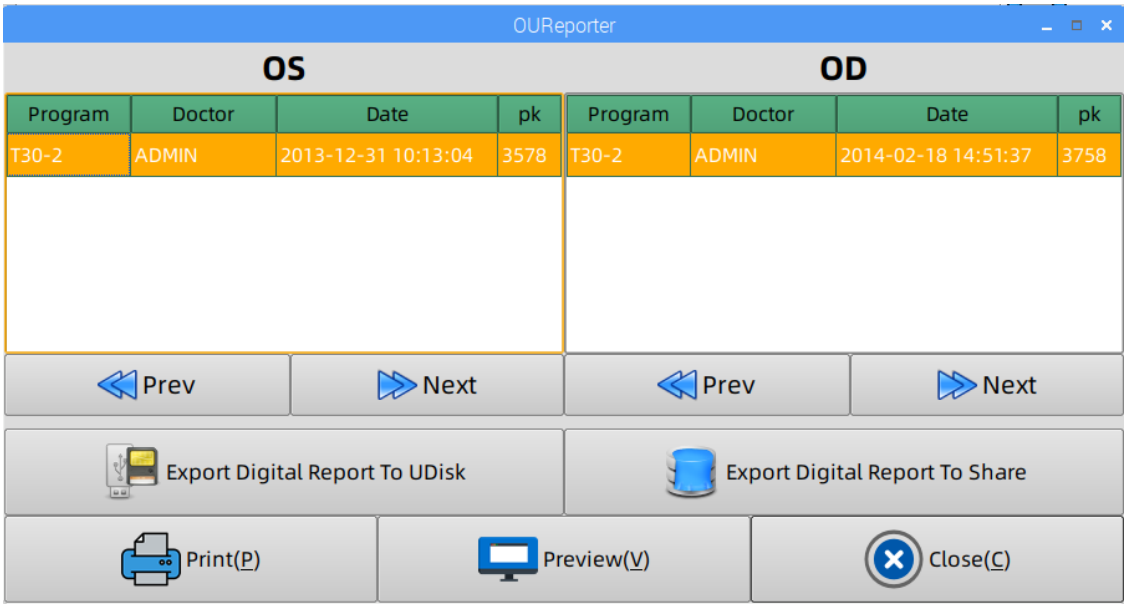
Export Digital Report to Share: Export report in PDF and/or JPG format into share folder, which can be accessed by another PC in the same LAN.

Export Digital report to UDisk: Export report in PDF and/or JPG format into USB flash memory disk.

DICOM Storage: Refer to the chapter 9.6.3

5.5 Print OU Report

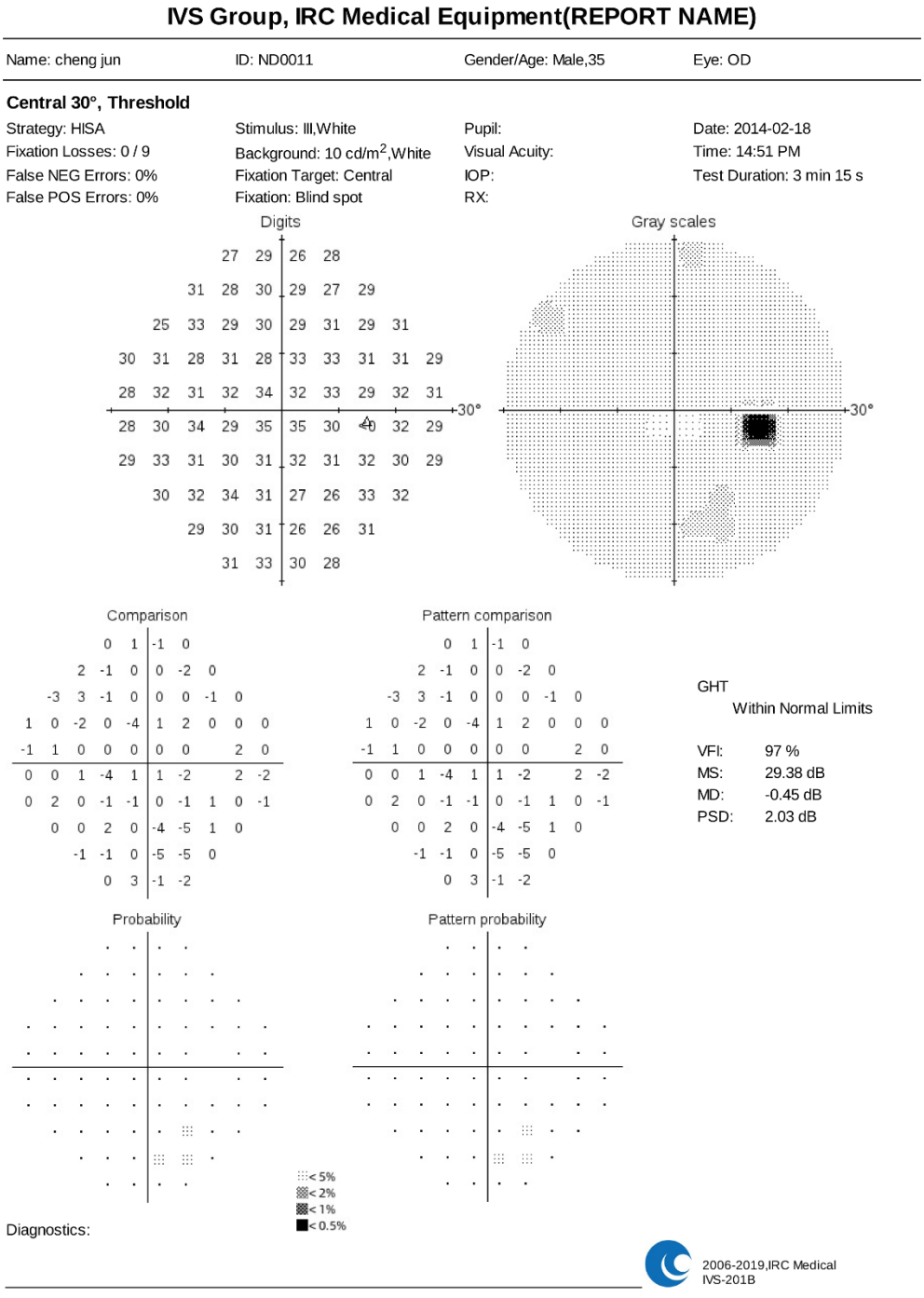
Click “Print OU” in analysis window to enter “OUReporter” window.



The OU Report will display test results of both eyes in a single page. Compared with one eye report, it is requested to select the test record for OS and OD separately.

The OU report is useful for the test result comparison between eyes.

5.6 Read the Report



The graphs and the most majority parameter showed on report are in accordance with international standards.

- **Test type**

The test type is either Threshold test or Screening test, and this term is also noted with the scope of the test. For example, the most commonly used program is T30-2, which means the scope of the test is central 30 degrees.

- **Test strategy**

The program supports the following threshold strategies: full threshold, standard threshold, fast ladder and HISA. HISA is the unique heuristic intelligent threshold search algorithm owned by IRC Medical Equipment Co., Ltd. Under this algorithm, for most of patients, it only takes 3-4 minutes to complete the threshold test of T30-2.

- **Refractive correction**

Let the patient undertake the test under the best-corrected near vision acuity (30cm), which is the primary condition. Here, the power of sphere and cylinder used to get the best-corrected near vision acuity will be recorded.

- **Pupil diameter**

The pupil diameter of the patient should be at least 3mm or more to avoid wrong results—especially for the patients applied miotic. For retesting patient, try to maintain the same pupil diameter wider than 3mm.

- **Reliability index**

The reliability index contains the following three parameters: fixation loss, false negative error and false positive error. In order to identify the reliability of test results, these three indexes are expressed with X/Y format, X shows the time of error, and Y shows the total test time.

Fixation loss

Fixation loss indicates whether the patient can stare at the fixation point steadily. During test, approximately 5% of the stimulated light is projected to the physiologic scotoma region of the patient. If the patient can see those points, it means the fixation of the patient is not well. The perimeter will alarm to remind the operator to require the patients to concentrate. In order to ensure the reliable test request, the fixation loss should be not more than 20%.

False negative error

The perimeter periodically utilizes the light, which is 9dB higher than threshold value, to test the locus which has already been tested the sensitiveness of threshold value. If the patient fails to respond to this stimulate point—always led by the tiredness and less of focus, the perimeter will record this as false negative. False negative error will not affect the visual field defect as false positive error.

Besides, there is a gaze tracking curve on the bottom on some reports. In this curve, the upward offset demonstrates the degree that the observation direction of eye deviates from the right fixation direction, while the downward offset

demonstrates the observation direction has not been captured (commonly means that the patient blinks eyes during test).

False positive error

Perimeter catches errors of this type through generating electrical machine moving sound but does not project stimulated points. False positive mainly affects the index of the visual field result, and can be commonly found in:

a. Euphoria patient always presses the responder button before seeing the cursor.
b. The patient expect to see the cursor but presses the responder button before seeing it.

- **Digit graph**

The cursor brightness value visible by patient is shown on the test points, and the unit is dB. The larger the value is, the stronger the patient's visual sensitiveness for this point is, otherwise, the weaker.

Note: The value in the bracket on the digit graph demonstrates that the system consider this point result is suspicious and conduct automatically retest. The value in the bracket is the test result before retesting.

- **Grayscales**

The different levels of light sensitiveness will be shown as different grey scale. The region of relatively high light sensitiveness is shown in relatively bright grey scale, while region of relatively low light sensitiveness is shown in relatively dark grey scale. The grey-scale graph is rather straightforward, and makes the defected region quite clear, especially those with medium or severe visual field defect. However, though the grey-scale graph has some clinic significance, it is quite rough and hard to identify the rather superficial visual field defect from the grey-scale graph.

- **Comparison and probability graph**

Comparison value graph shows that the different value (dB) of the results of each monitoring point compared with standard value at the same age group, and negative number indicates that the test result of the point is worse than the standard value at the same age group. Probability graph transforms the value in comparison value graph into shadow symbol, which demonstrates the statistics significance of each different value. The probability symbols explain each different value. For example, P<1 indicates that the test result of the locus belongs to the worst 1% among the healthy people at the same age group, in other words, worse than the 99% healthy people at the same age group. The darker the shadow symbol is, the less possibility that the visual field in this locus is normal.

- **Pattern comparison and probability**

This is the most significant analysis in the visual field report. Pattern comparison value and pattern probability graph shows the existing loss of sensitiveness except for the decline of general sensitiveness after adjustment. Pattern comparison value graph and pattern probability graph try to reinforce the significant local visual field defect, except for those declines of diffuse sensitiveness led by cataract, small pupil, etc.

The comparison between comparison value graph and pattern comparison value graph: If the distinction between the two is not so obvious, then it indicates that there's almost no visual field defect or extensive visual field defect; a comparison value graph with a decline of general sensitiveness pluses a seemingly normal pattern comparison value graph may suggest "cataract"; on the contrary, a normal comparison value graph and an abnormal pattern comparison value graph usually suggest that the client is a patient of "euphoria".

- **Glaucoma Hemifield Test**

In the programs of T24-2 and T30-2, GHT compares the test results of five regions in upper half vision with the mirror image region in the bottom half. GHT assesses the seriousness of sensitiveness distinction of each corresponding region, and prints one of the following reminders: within normal limit, outside normal limit, borderline, general reduction of sensitivity and abnormal high sensitivity.

- **Perimetry indices**

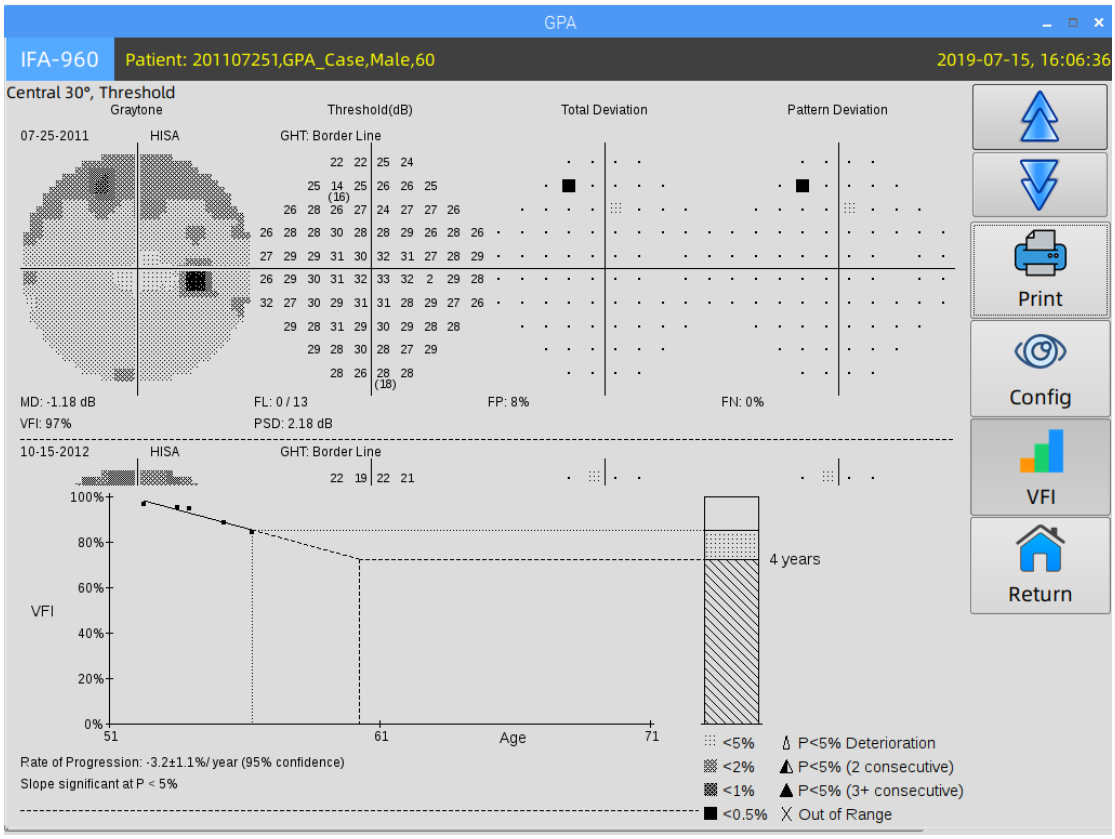
Visual Field Index (VFI): VFI is the standard to measure the overall eyesight of the patient (equivalent to the average normal people at the same age). That VFI equals to 100% means that the distinction of client's visual field pattern deviation with normal average level is less than 5%. That VFI equals to 0% means no light perception.

Mean Deviation (MD): MD shows the average deviation to normal value of the entire visual field. Positive value means patient's average visual sensitivity is better than normal, while negative value means patient's average visual sensitivity is worse than normal.

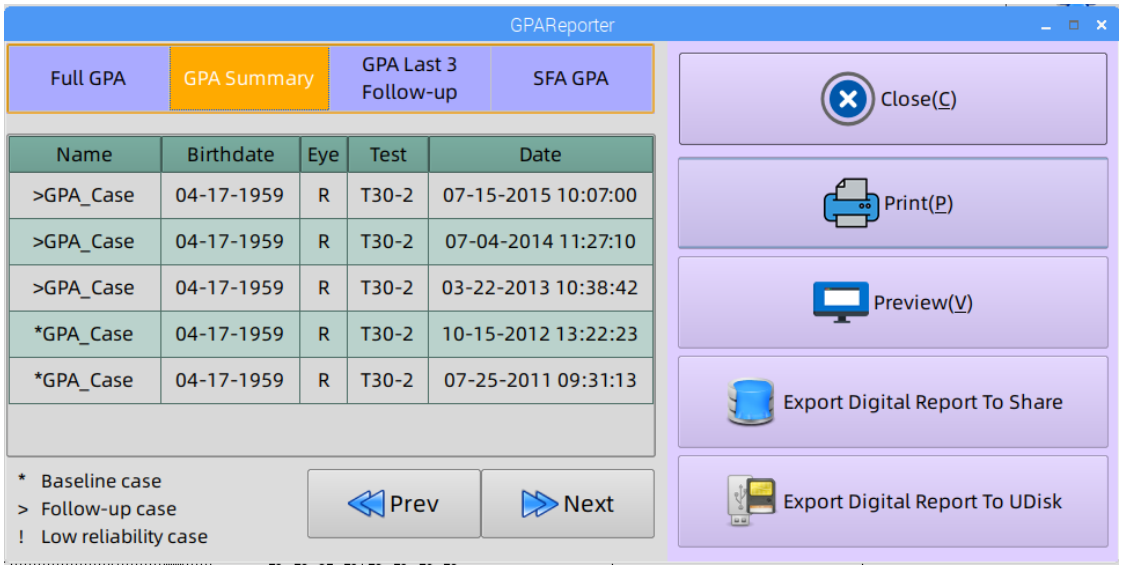
Pattern Standard Deviation (PSD): PSD indicates the irregularity of visual field caused by local visual field defect. The larger the value is, the more severe the local visual field defect is. If the client only suffers from "well-distributed" diffusible defect, then the value will be small, even if the disease is quite severe.

5.7 GPA

Click “GPA” button in analysis window to enter ”GPA” window.

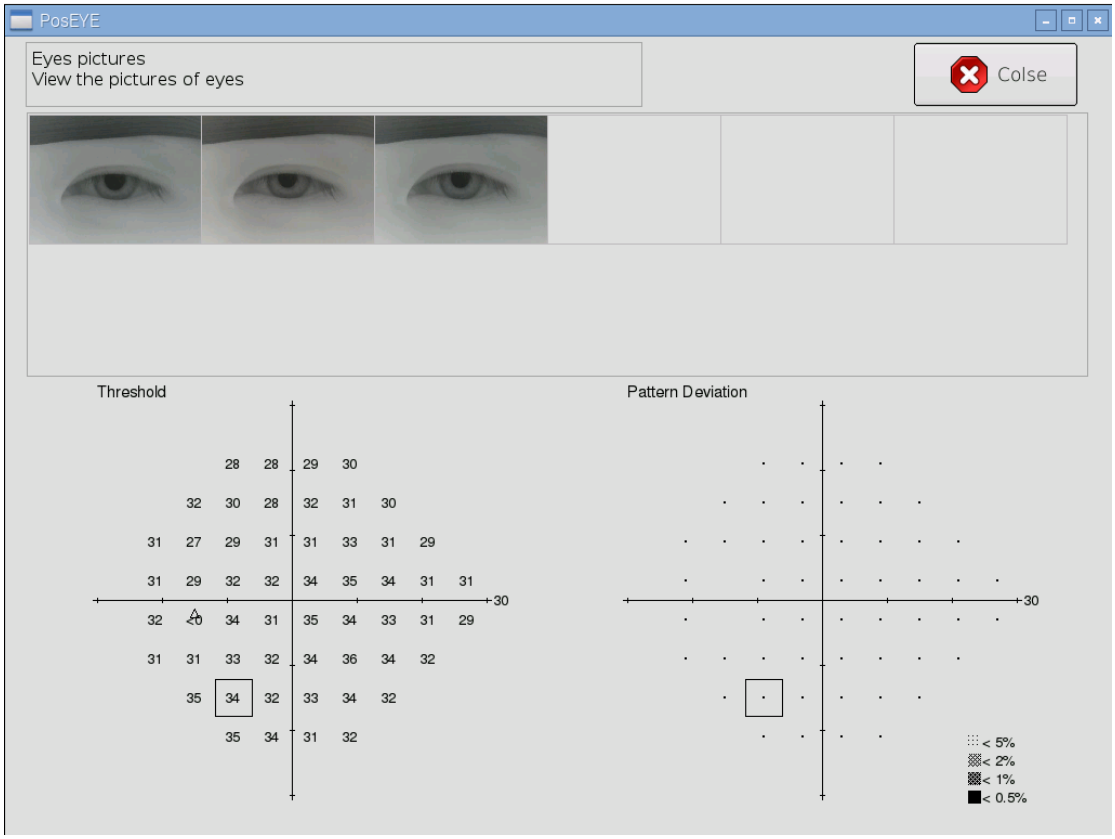


The GPA analyze the glaucoma progression by series of T30-2/T24-2 test. Click “VFI” button to show VFI change over years. After clicking “Print” button, several formats of GPA report can be generated.



5.8 PosEYE

Click “PosEYE” in analysis window to enter “PosEye” window.

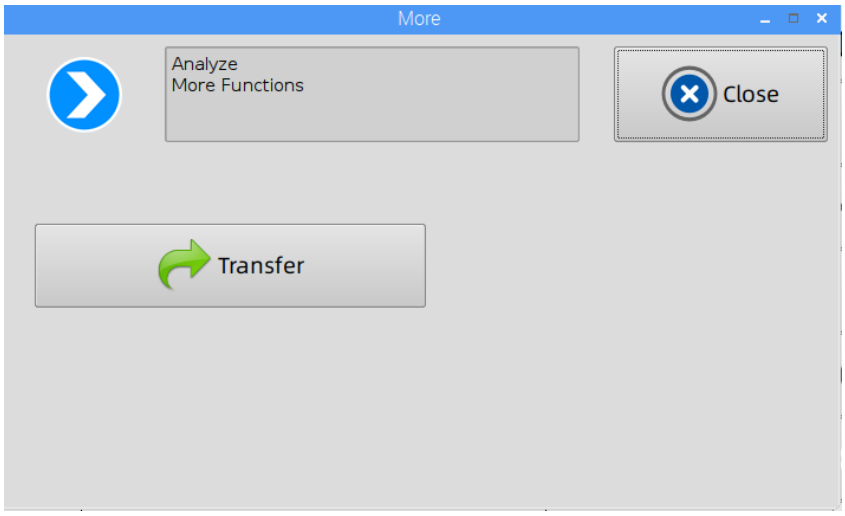


Click test point in Threshold/Pattern Deviation graph, eye pictures on the stimuli time for that test point will be shown. Doctors can assess the reliability of each test point through this way after the test.

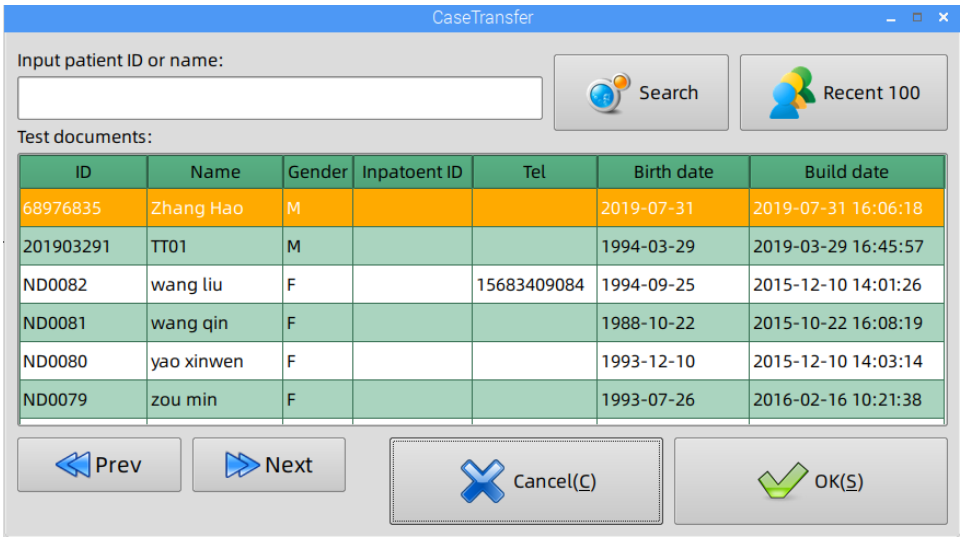
The offline eye monitoring video occupies huge size of storage. The system keeps these videos in 30 days after the test and will delete them after.

5.9 Test Result Transfer

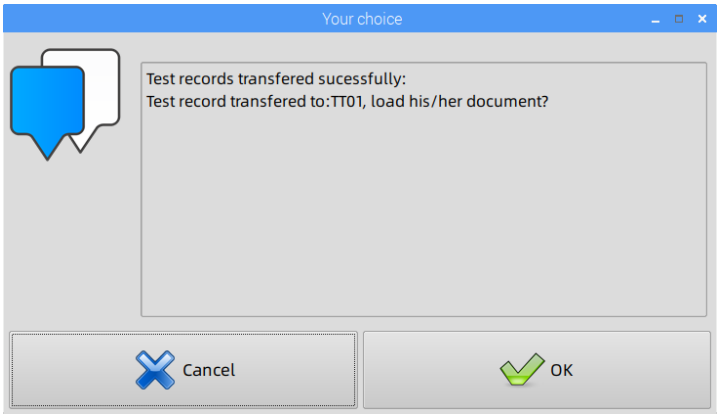
	Test Result Transfer
	If you accidentally test the B patient under the A patient file, you can correct it with “Test Result Transfer” function. Click the “…” button in lower-left corner in analysis window to enter the “More” window.



Click “Transfer” button to select the target patient in following window, then click “OK” button to start the test record transfer process.



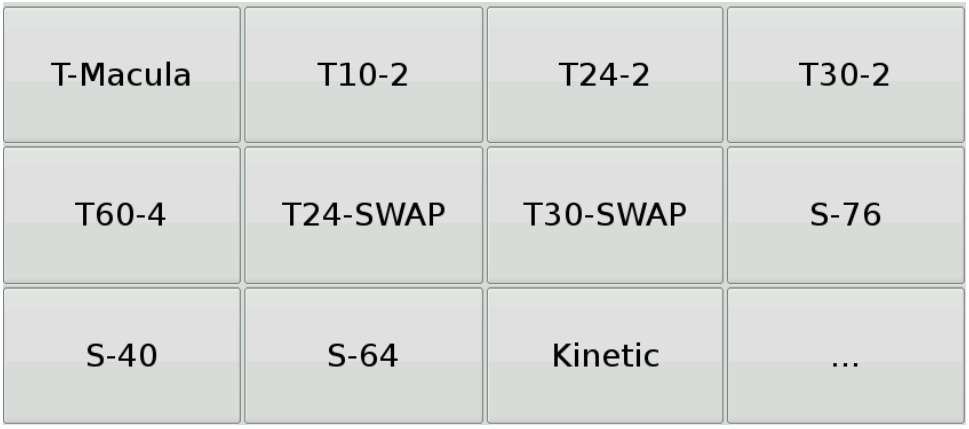
A message box will be shown after transfer process:



6. Kinetic Test

This feature is applicable to model IFA-960 only.

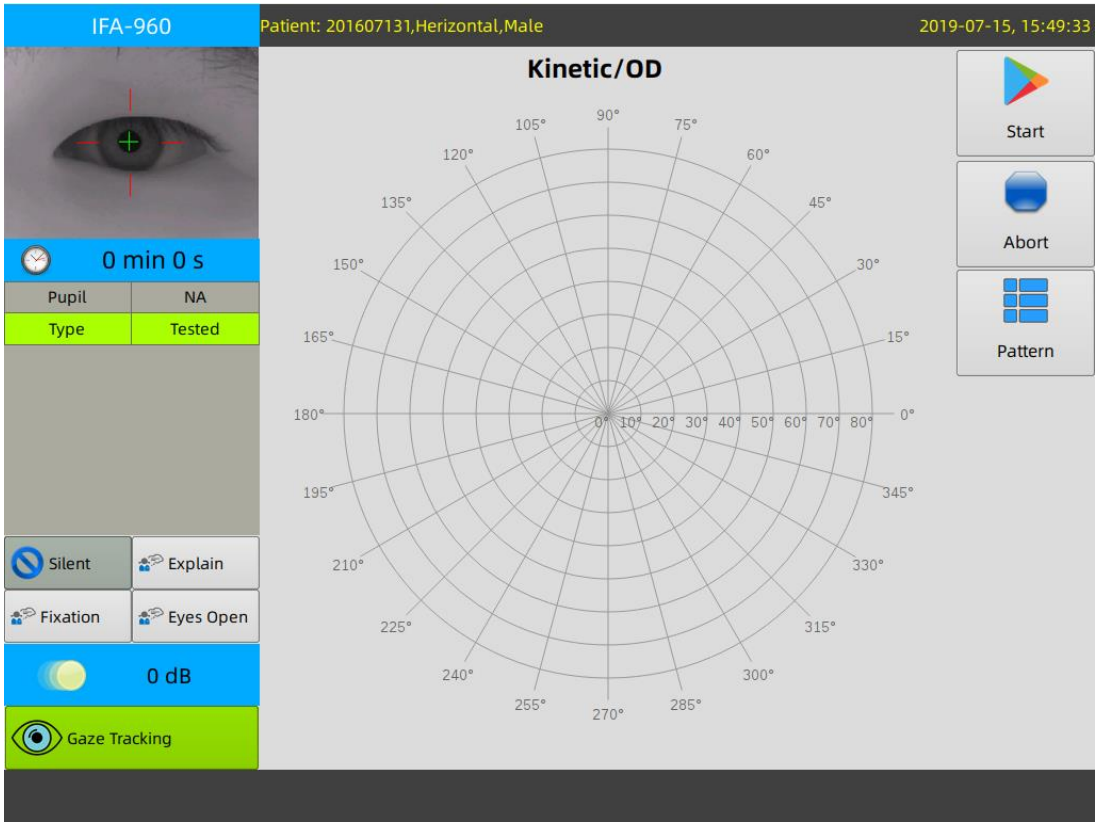
6.1 Select Kinetic Pattern



Select “Kinetic” test pattern to enter Kinetic Test.

	Gaze Tracking during Kinetic Test
	There are no False Negative, False Positive test, and fixation test by giving stimulus inside blind spot during kinetic test. We recommend using gaze tracking or pay close attention to patient’s eye movement during examination.

6.2 Test Window



Click “Pattern” button on right side, you can choose and configure the test parameters like “Cursor Size”, “Cursor Intensity”, “Theta Interval” etc.

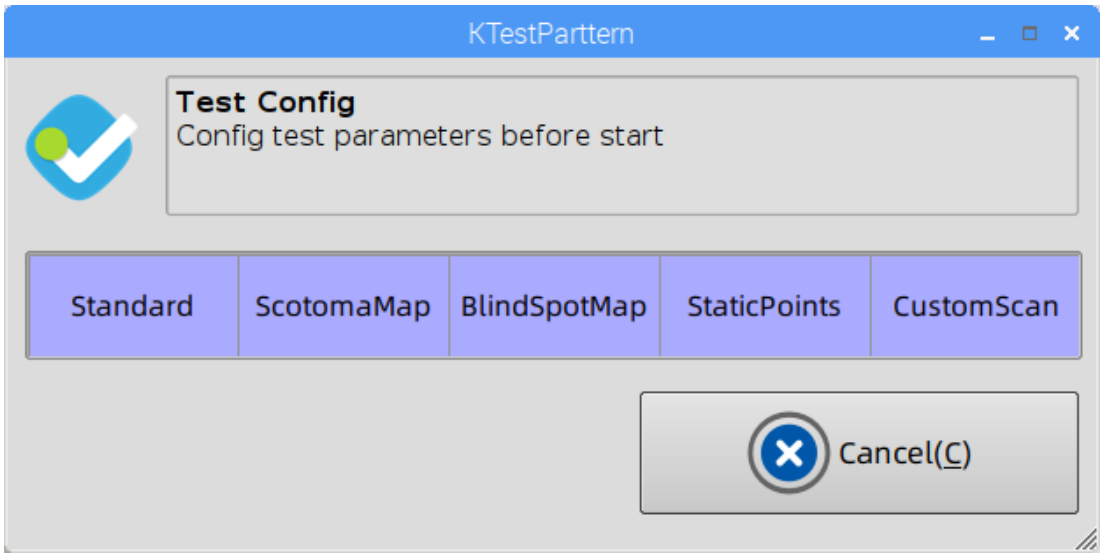
Before Kinetic test, please get the patient prepared and keep his/her eye in the center of monitor window. Click “Start” button to start test.

During the test, operator shall pay close attention to patient’s fixation, and interfere if necessary. If the eye movements are too frequent, click "Pause". Suspension testing can improve test results for patients who are prone to fatigue. The patient is required to make a good fixation before continuing test. And then click “Start” button to continue test.

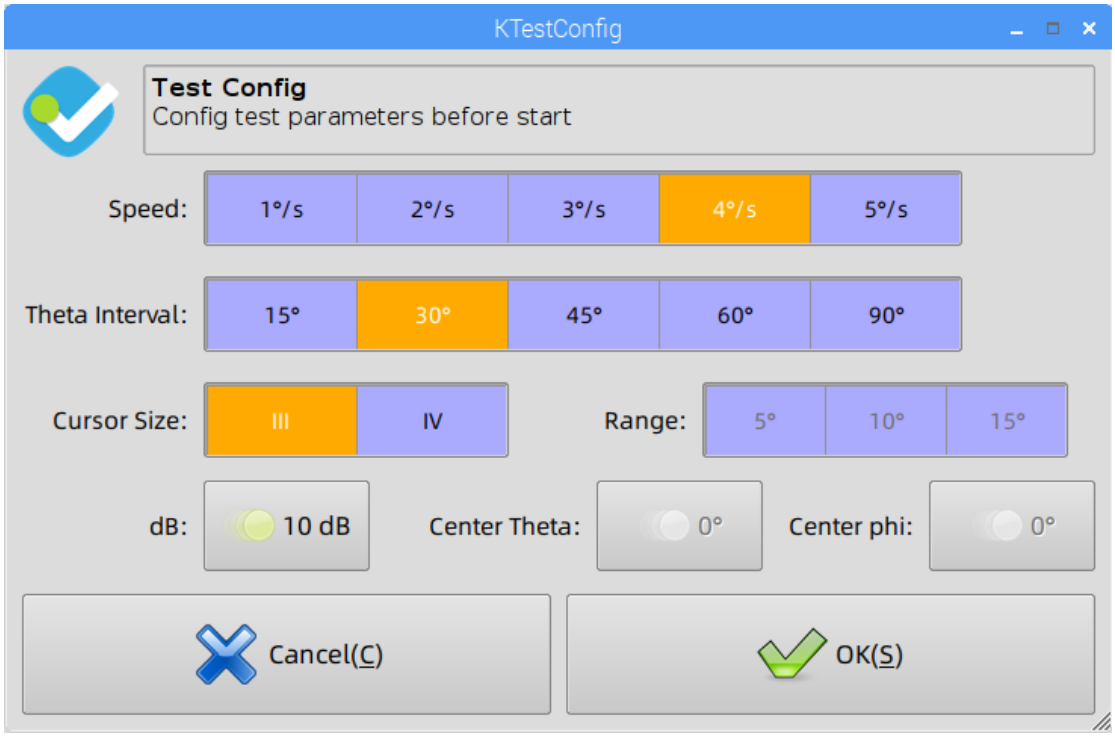
	Pause
	Pausing test during kinetic test will cause partial test result loss for current visual isopter. All visual isopeters that have been tested before will not be affected.

6.3 Pattern

Click “Pattern” in test window to enter in “KTestPattern” window.

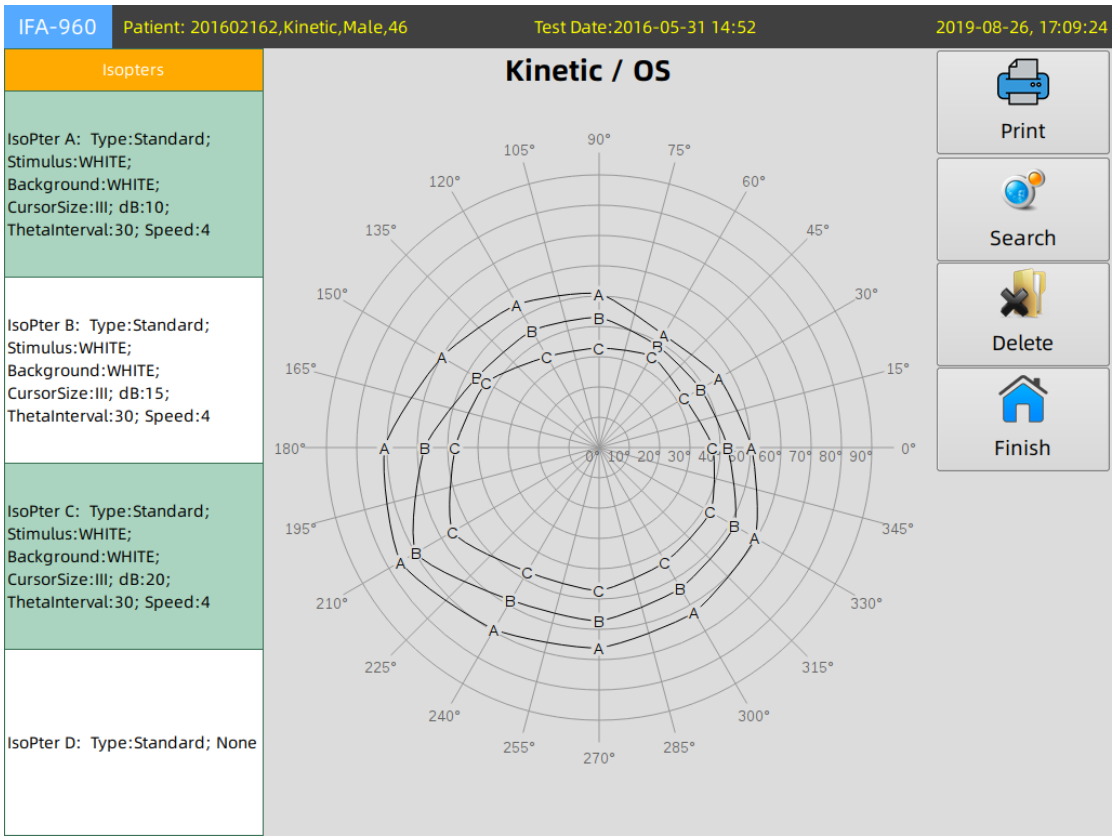


There are 5 test patterns available in Kinetic test. Click either pattern to enter detailed configuration setting window. Following window is for "Standard" Test Pattern setting.

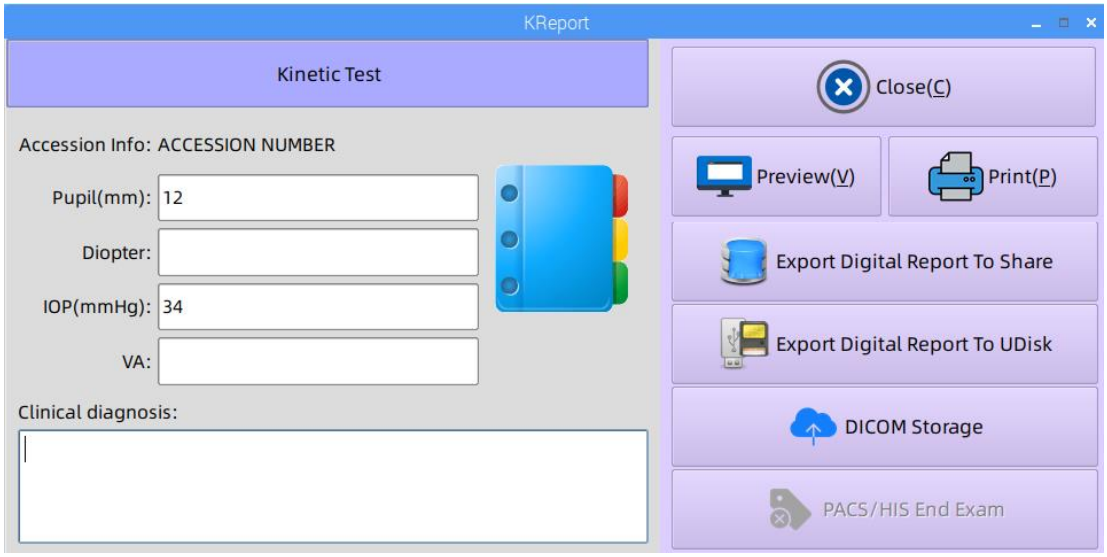


6.4 Analyze & Print

When the test is finished, the program will stop automatically with audio guide. The operator can click the "Analyze" button to enter the analysis window.



The multiple isopters are displayed on the same report. Click “Print” to enter print window. For more information on print window, please refer to chapter 5.4



IRC Medical Equipment

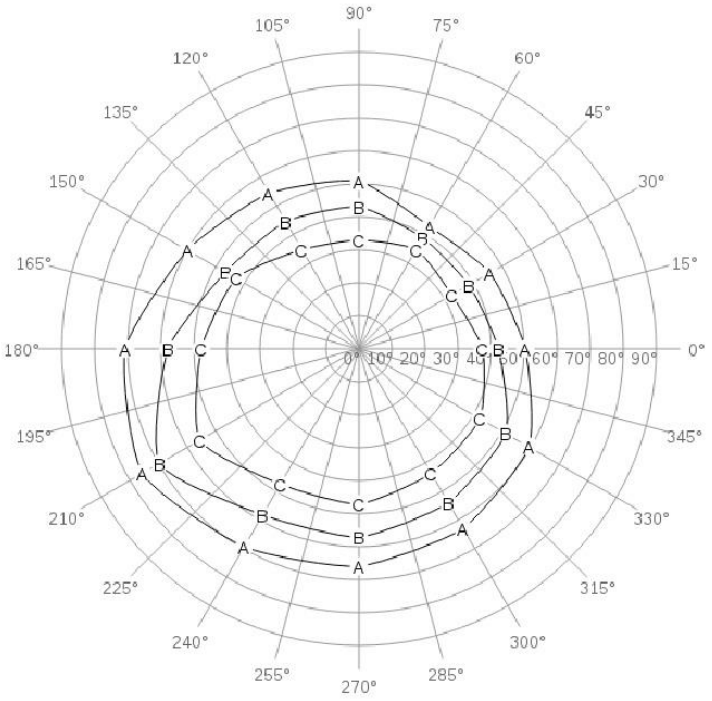
Name: Kinetic	No: 201602162	Eye: OS	Gender/Age: Male,46

Kinetic Test

Pupil: 12 mm	Visual Acuity:	IOP: 34 mmHg	RX:
Stimulus: White; III	Fixation Target: Central	Background: White; 10cd/m²	Range: 90°
Date: 2016-05-31	Time: 14:52 PM	Test Duration: 1 min 52 s	

IsoPter A: Type:Standard; Stimulus:WHITE; Background:WHITE; CursorSize:III; dB:10; ThetaInterval:30; Speed:4
IsoPter B: Type:Standard; Stimulus:WHITE; Background:WHITE; CursorSize:III; dB:15; ThetaInterval:30; Speed:4
IsoPter C: Type:Standard; Stimulus:WHITE; Background:WHITE; CursorSize:III; dB:20; ThetaInterval:30; Speed:4

Kinetic Graph



Diagnostics:

2006-2019,IRC Medical
IFA-960 Made in China

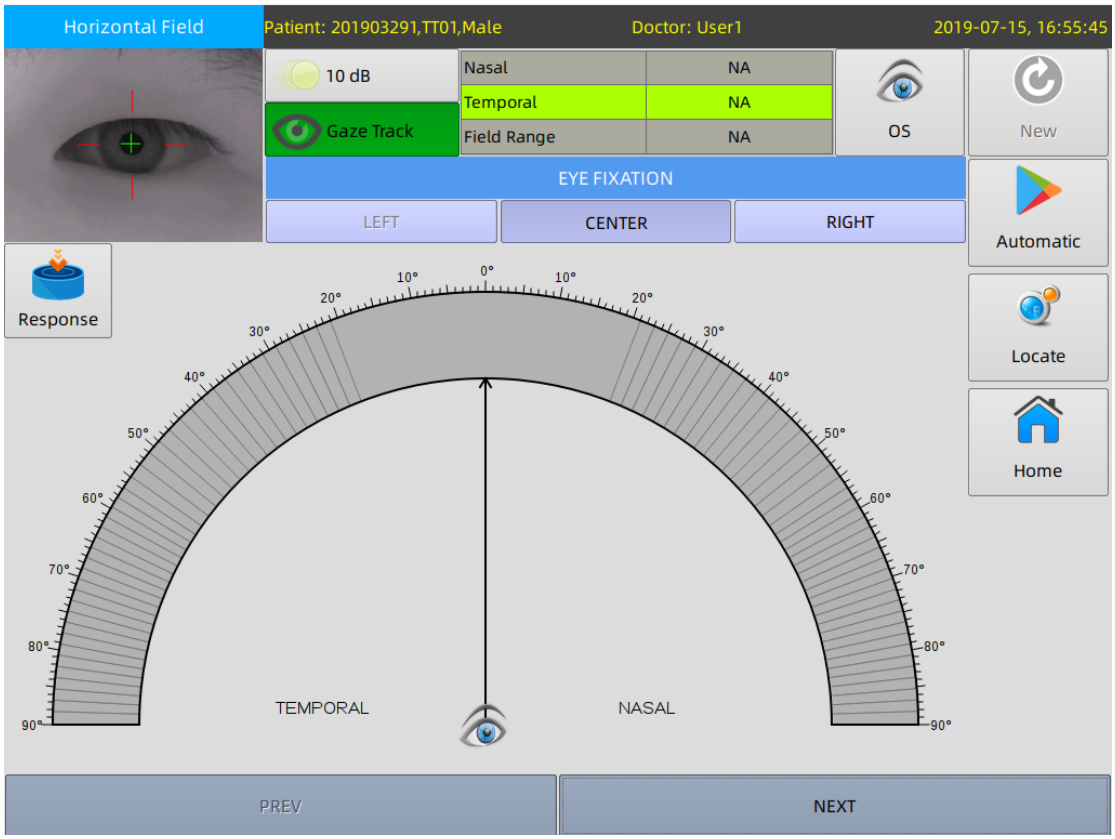
7. Horizontal Field

This feature is applicable to model IVS-201B only.

The horizontal field test is applied to evaluate the range of patient's horizontal field. In some countries/regions, seafarers, pilots, and drivers are required to measure horizontal field.

7.1 Test Window

Select "Horizontal" test pattern in home window to enter horizontal field test window.



Click "OS/OD" button to change the eye type.

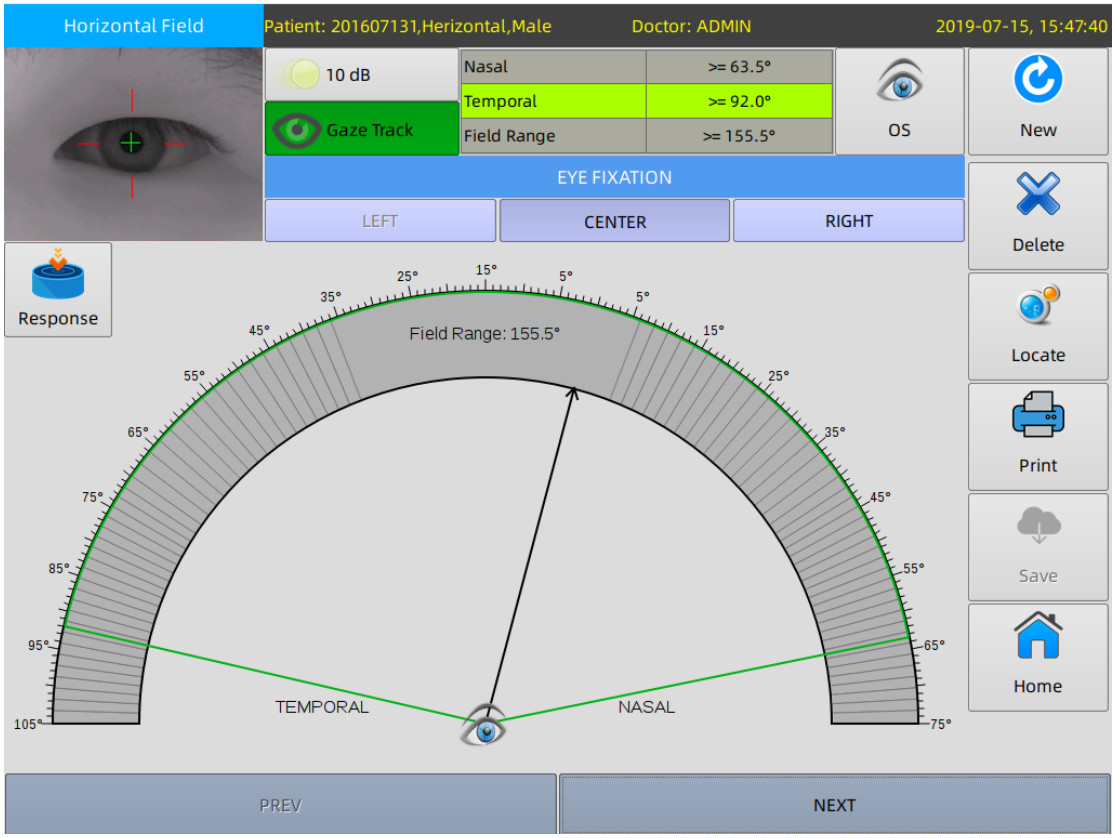
Please refer to above picture. When measure horizontal field of OS, there are 2 fixation options: center, right(15°). When center fixation is applied, the test range is -90° to +90°; when right fixation is applied, the test range is -105° to +75°.

Click "Automatic", software will start the test and control the whole test process. But sometimes, the patient may click the responder without seeing the stimuli point. To avoid this, the operator can click specific angle in the sector ring, then observe the patient's

response. If the patient responses to a stimulus point that is impossible to be seen, for example, nasal 90°, then, he/she is false negative.

7.2 Analyze & Print

When the test is finished, the test results will be displayed in below window.



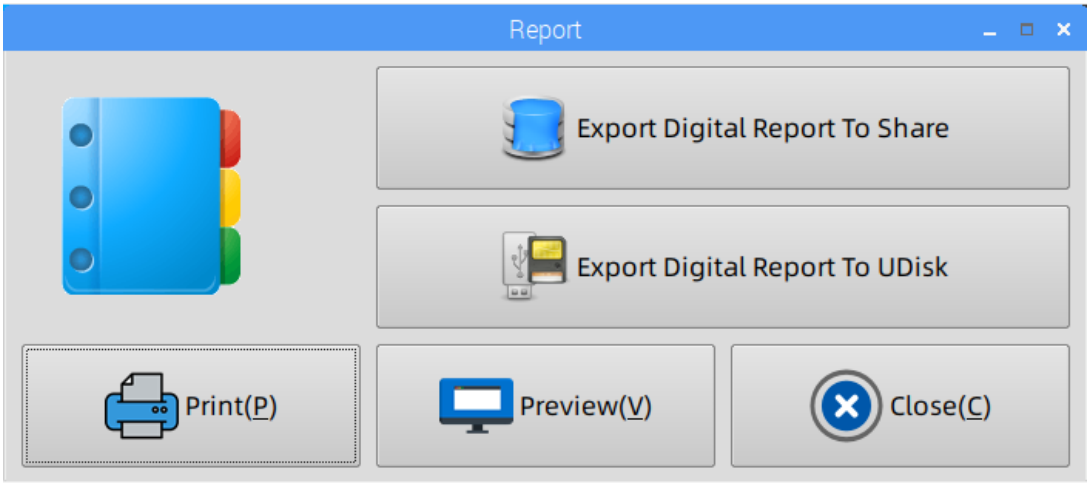
Click “New” to start a new test.

Click “Delete” to delete this test record.

Click “Locate” to search other horizontal test record.

Click “Print” to enter print window.

Click “Save” to save this test record. When the test is finished, it is required to save the test result in horizontal filed test manually by clicking “Save” button.



The horizontal test report looks like below:

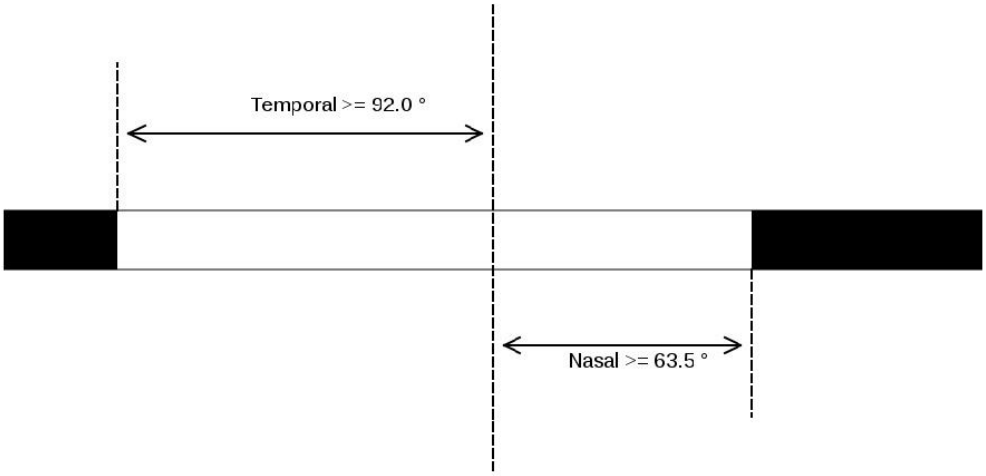
IRC Medical Equipment

Name: Herizontal No: 201607131 Hos No: Gender/Age: Male,35

Horizontal Field For Driver

Stimulus: Goldmann III, 0dB Background: 10 cd/m^2 Date: 2016-07-13

Eye: OS



(Normal Horizontal Field Range >= 150°)

Active Horizontal Field Range >= 155.5 °

Diagnostics:

2006-2019,IRC Medical IFA-960

(Remarks:This report only reflect the situation of the subject at that time.)

8. Regional Condensed Test

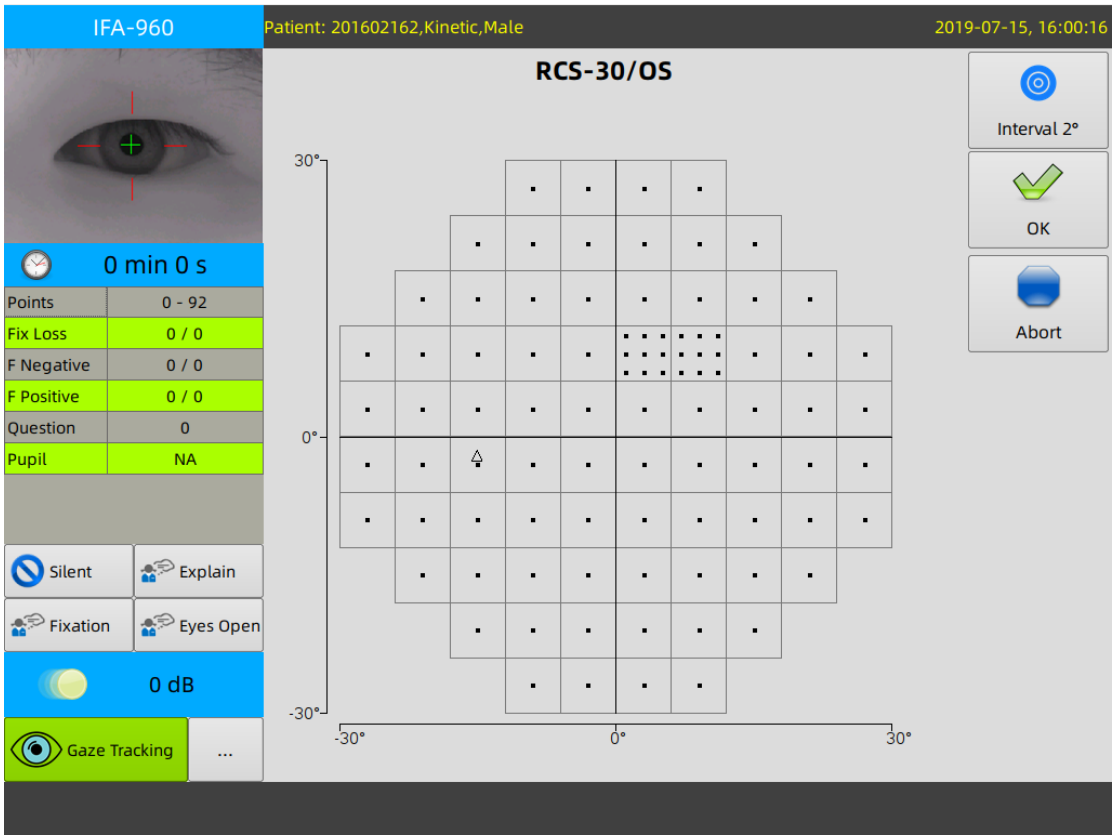
This feature is applicable to model IFA-960 only.

The pitch between stimuli points in T30-2 and T24-2 is 6°. For early glaucoma, the pitch is too big. Sometimes, a very regional sensitivity reduction may be missed by standard T30-2 or T24-2 test.

If doctor find clue of glaucoma damage in OCT or other imaging examination, he/she may want to add additional stimuli points in order to proof the glaucoma damage in visual field test. This is the purpose of regional condensed test.

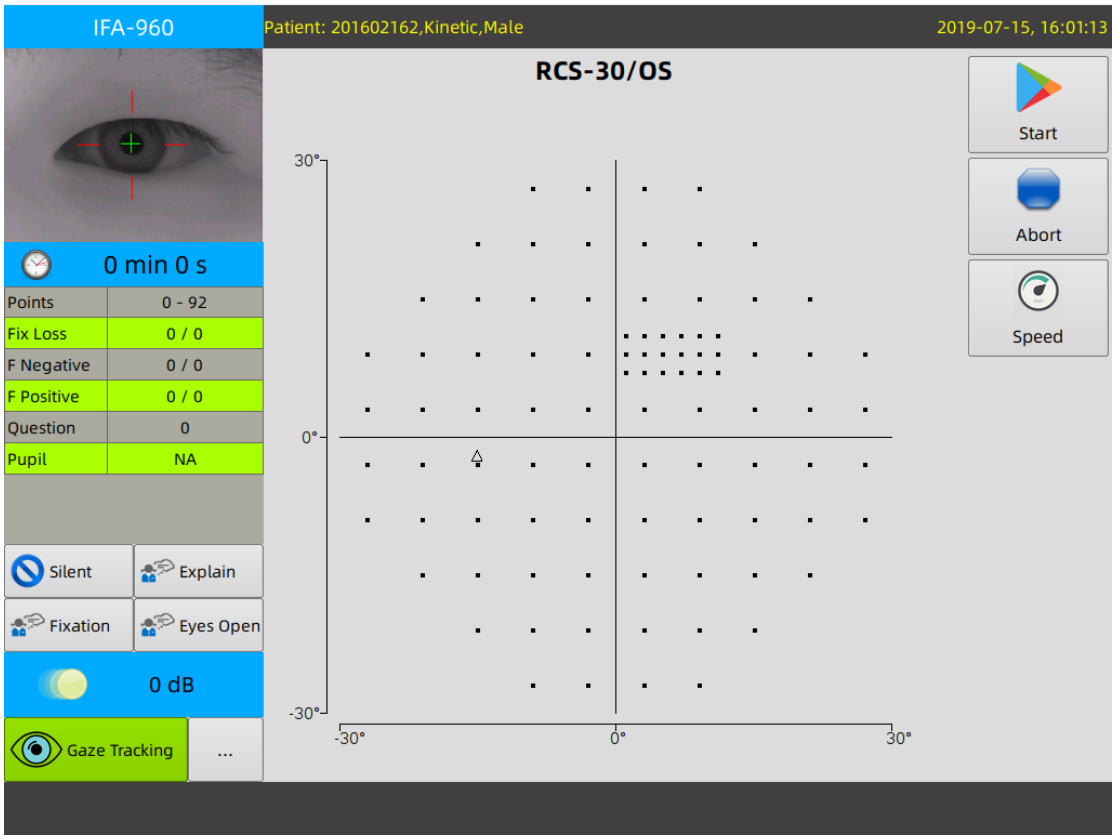
8.1 Test Window

Select “RCS-24” or “RCS-30” test pattern in home window to enter regional condensed test window.



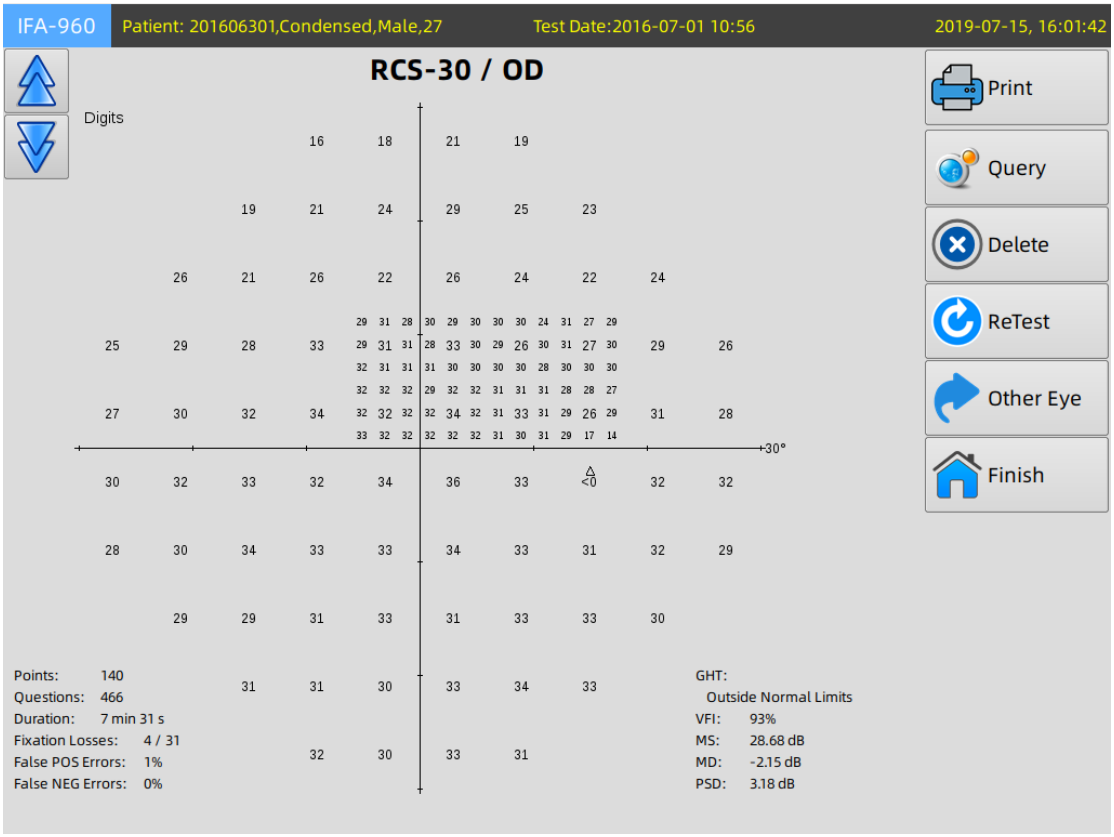
Test points in RCS-30 is same as T30-2; Test points in RCS-24 is same as T24-2.

Click “Interval 2°” to switch density of additional test points. Each rectangle in above picture represents a test region. Please click the test regions that you want to add additional test points. Re-click selected test region can remove additional test points. When configuration is set, click “OK” to start the test.



8.2 Analyze & Print

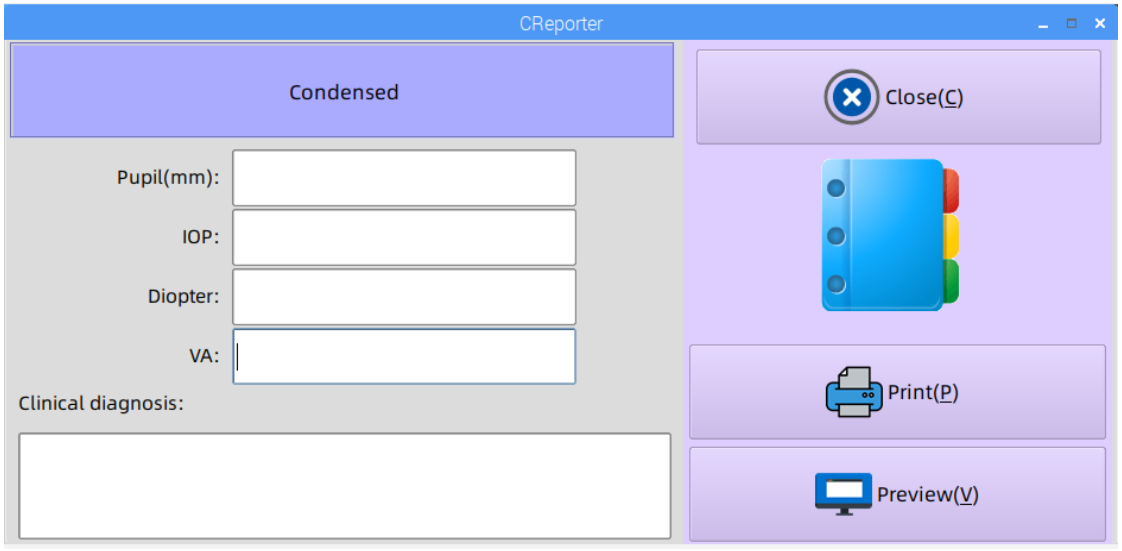
When the test is finished, test result is displayed in analysis window.



Click “ReTest” to test the same eye with same test pattern and configuration again.

Click “Query” to search another test record.

Click “Print” to enter the print window.



The regional condensed test report looks like below.

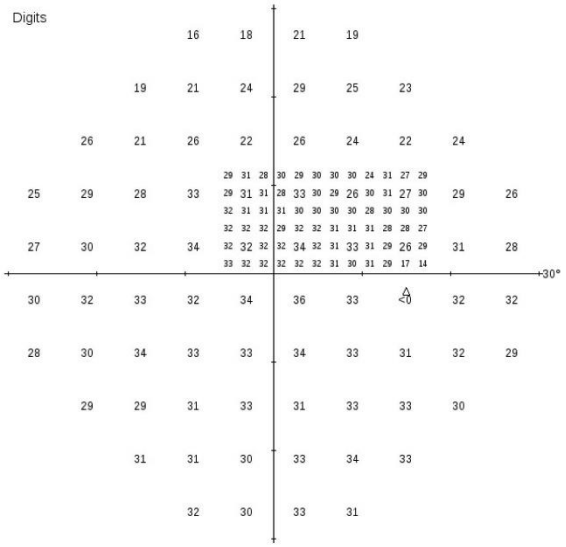
IRC Medical Equipment

Name: Condensed	No: 201606301	Eye: OD	Gender/Age: Male,27

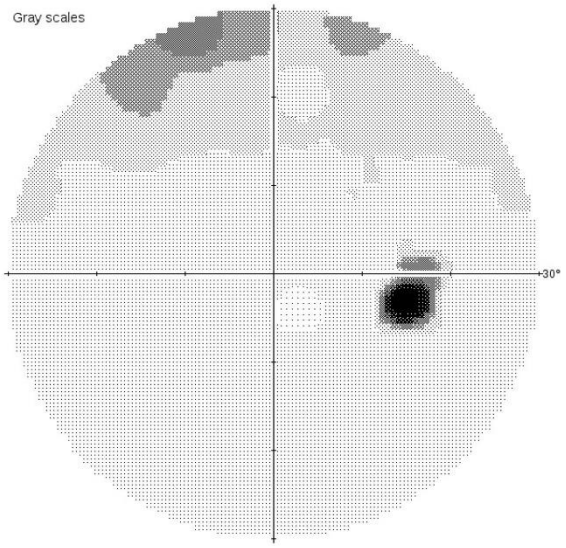
Central 30°, Threshold

Strategy: HISA	Stimulus: III,White	Pupil:	Date: 2016-07-01
Fixation Losses: 4 / 31	Background: 10 cd/m^2,White	Visual Acuity:	Time: 10:56 AM
False NEG Errors: 0%	Fixation Target: Central	IOP:	Test Duration: 7 min 31 s
False POS Errors: 1%	Fixation: Blind spot	RX:	

Digits



Gray scales



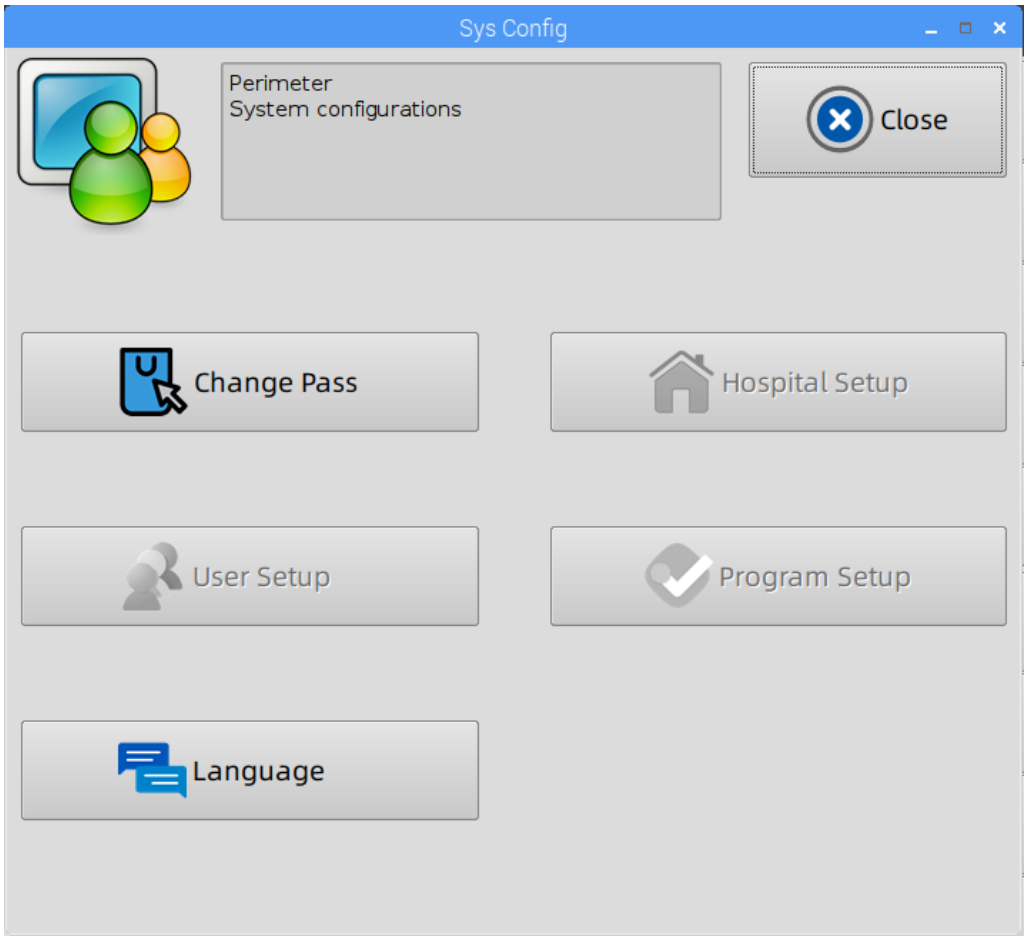
Diagnostics:

2006-2019,IRC Medical
IFA-960

9. System Setup

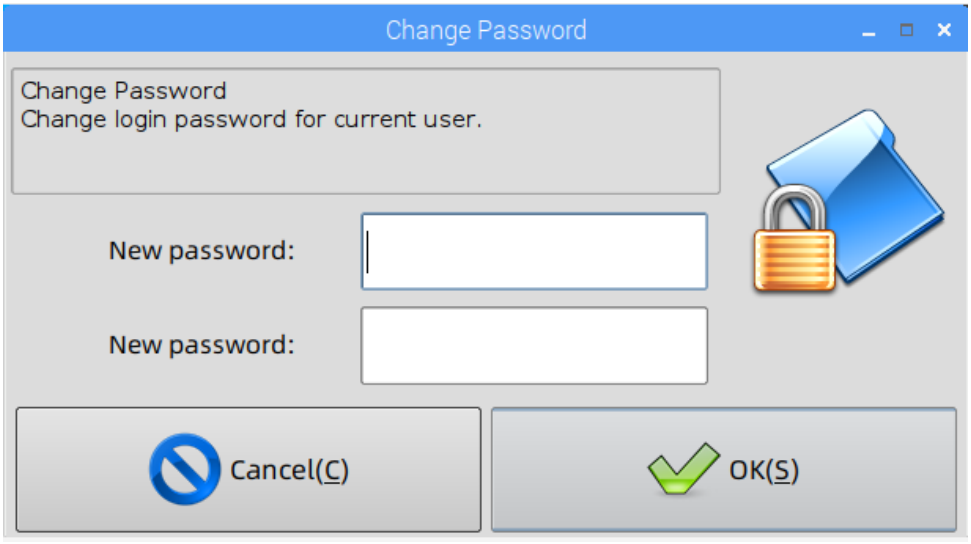
Click the “Setup” in the home window to enter the setup window.

Note: some buttons on this window might be disabled subject to product type, user’s permission.



9.1 Change Password

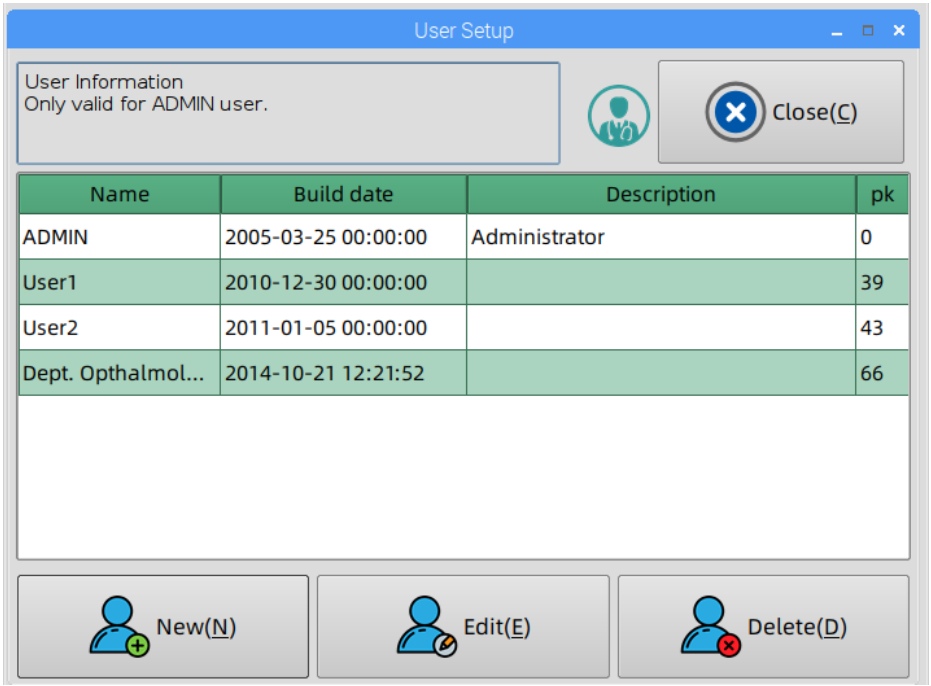
Non-admin user can change his login password. The new password will be valid in next login.



9.2 User Setup

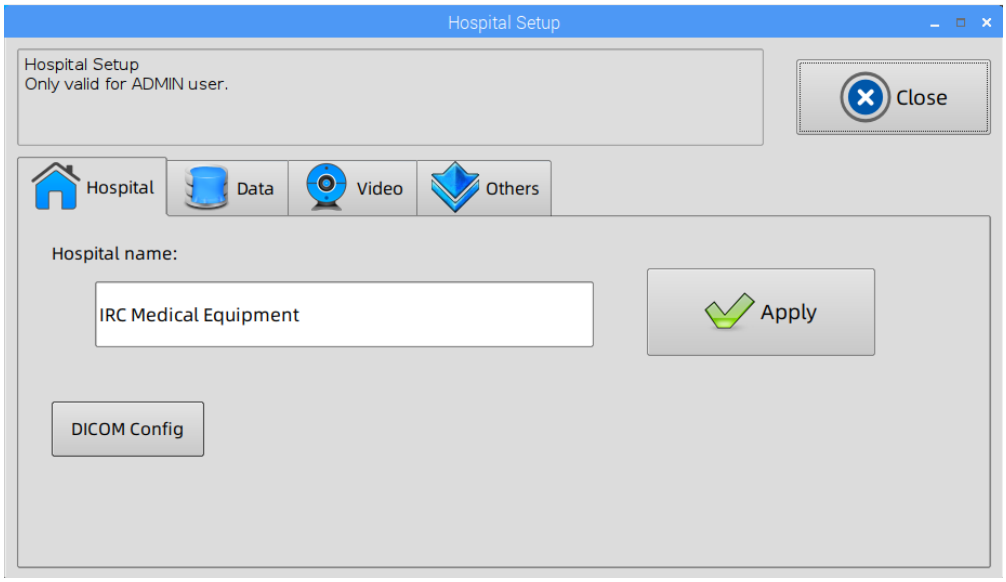
Admin user can add, delete and edit non-admin user's file. If any user forgets his password, he can log in ADMIN account and change the password accordingly. Only the ADMIN has the permission to utilize this function.

Click the "Setup" button on the right of the home window, and then click "User Setup" button to enter the "User Setup" window. ADMIN user can create, edit and delete the admin or non-admin user account.



9.3 Hospital setup

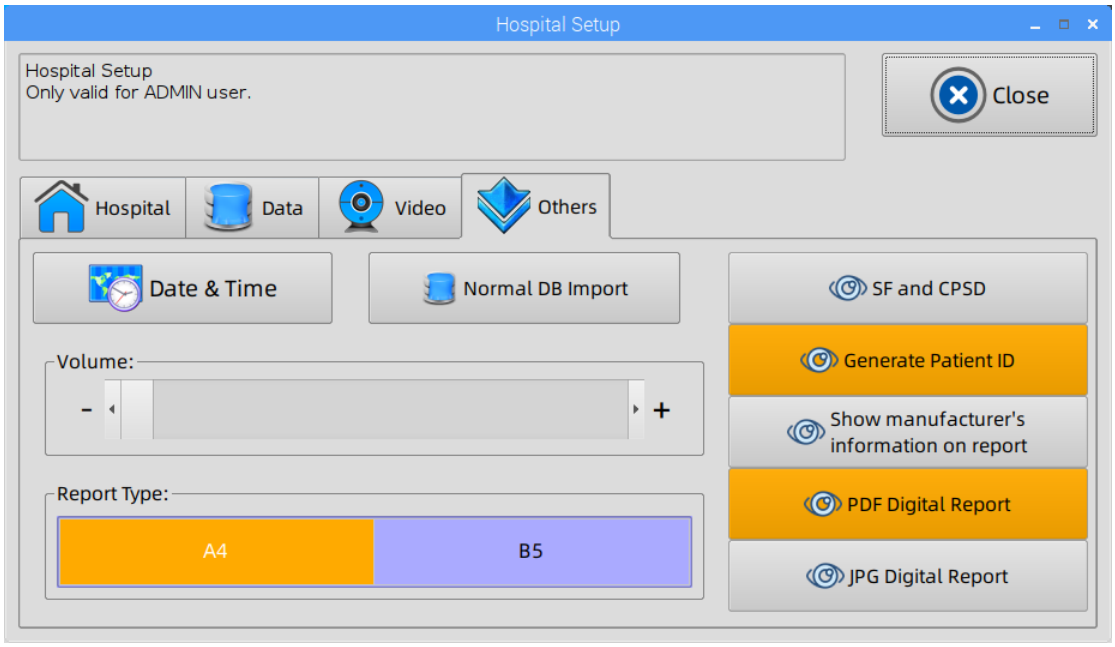
Hospital page: The hospital name input on this page will be displayed on the top of the test report.



Data page: All test data can be backup into a USB flash disk on this page. Data backup once a month is strongly suggested.

Others page: Change the system date & time by clicking “Date & Time”. The volume of audio guide can be adjusted here.

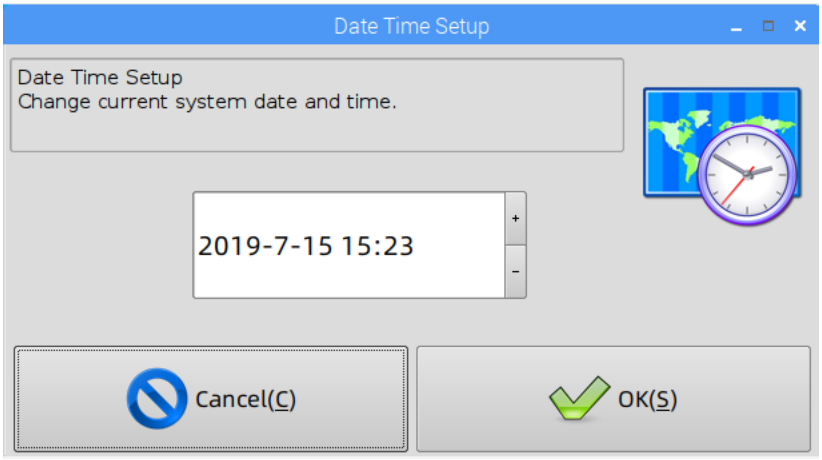
Some features on this page may be disable subject to the user’s permission.



Normal DB Import	Manufacturer continue to collect data on normal populations. When new version of normal database published, the user can import new normal database through this button.
SF and CPSD	SF – Short Term Fluctuation CPSD – Corrected Pattern Standard Deviation If option checked, SF & CPSD will be shown in the report
Generate Patient ID	If option checked, software will automatically generate a ID for new patient
Show manufacturer's information on report	If option checked, manufacturer's information will be shown in the report
PDF Digital Report	If option checked, PDF report will be exported in "Export Digital Report…"
JPG Digital Report	If option checked, JPG report will be exported in "Export Digital Report…"

9.4 Date & Time Setup

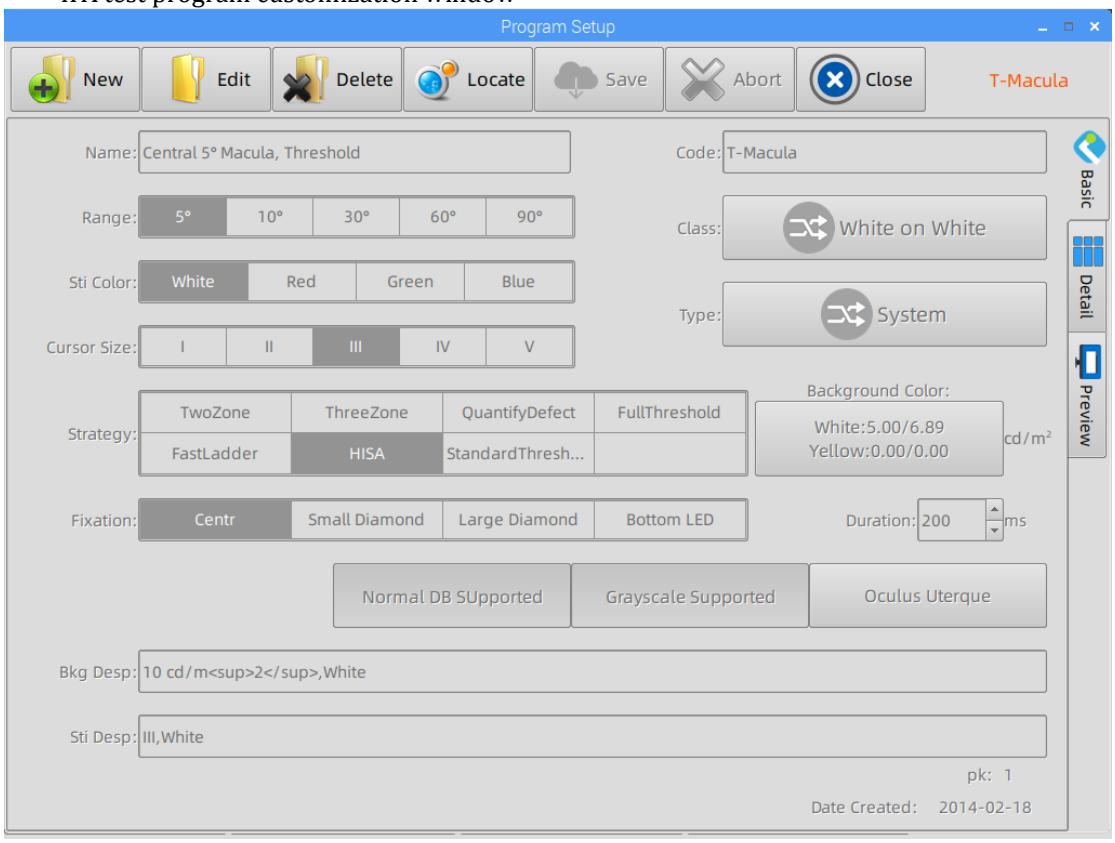
Click "Date & Time" button on Hospital Setup to enter "Date Time Setup" window.



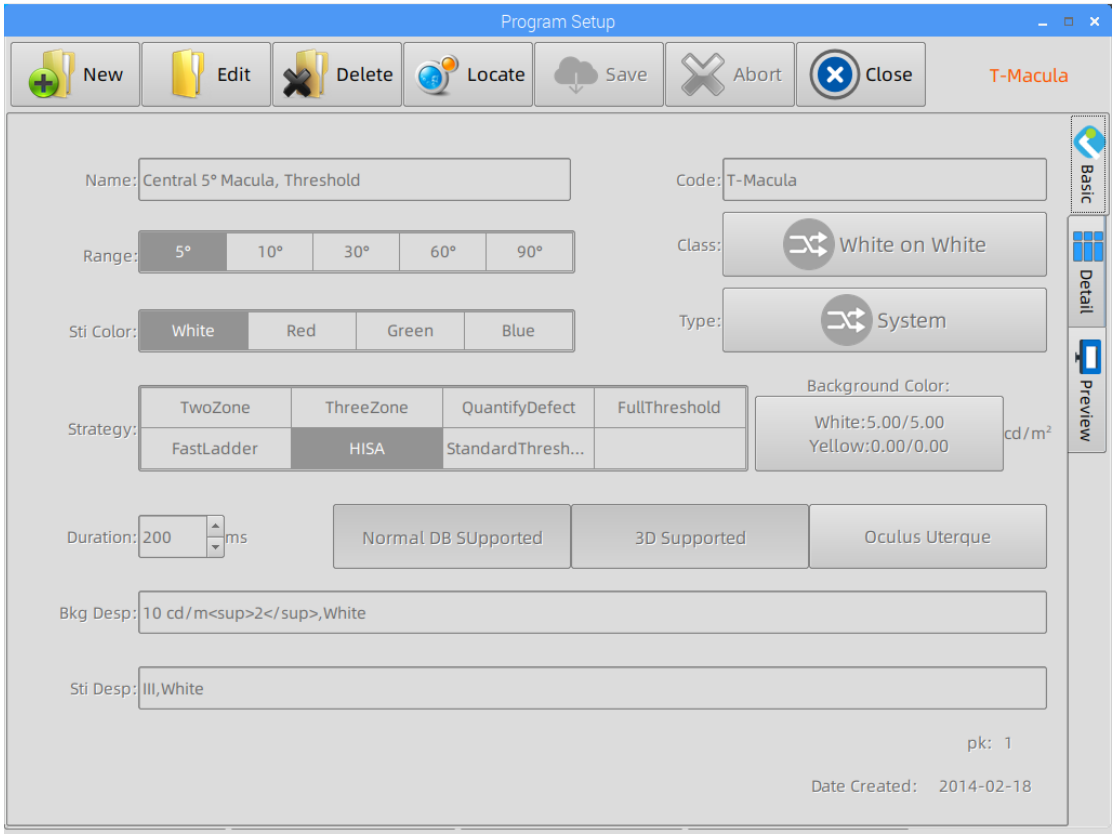
If you connect the perimeter with Internet, the operating system will synchronize with an internet date and time server. It is requested to configure time zone option in operating system configuration. The operating system is Linux, please refer to Linux Manual for detail.

9.5 Program Setup

✓ IFA test program customization window

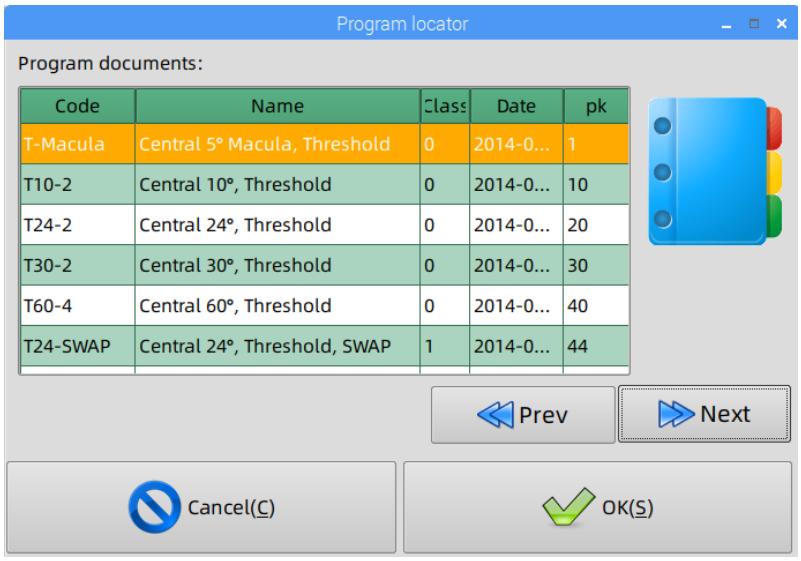


✓ IVS test program customization window

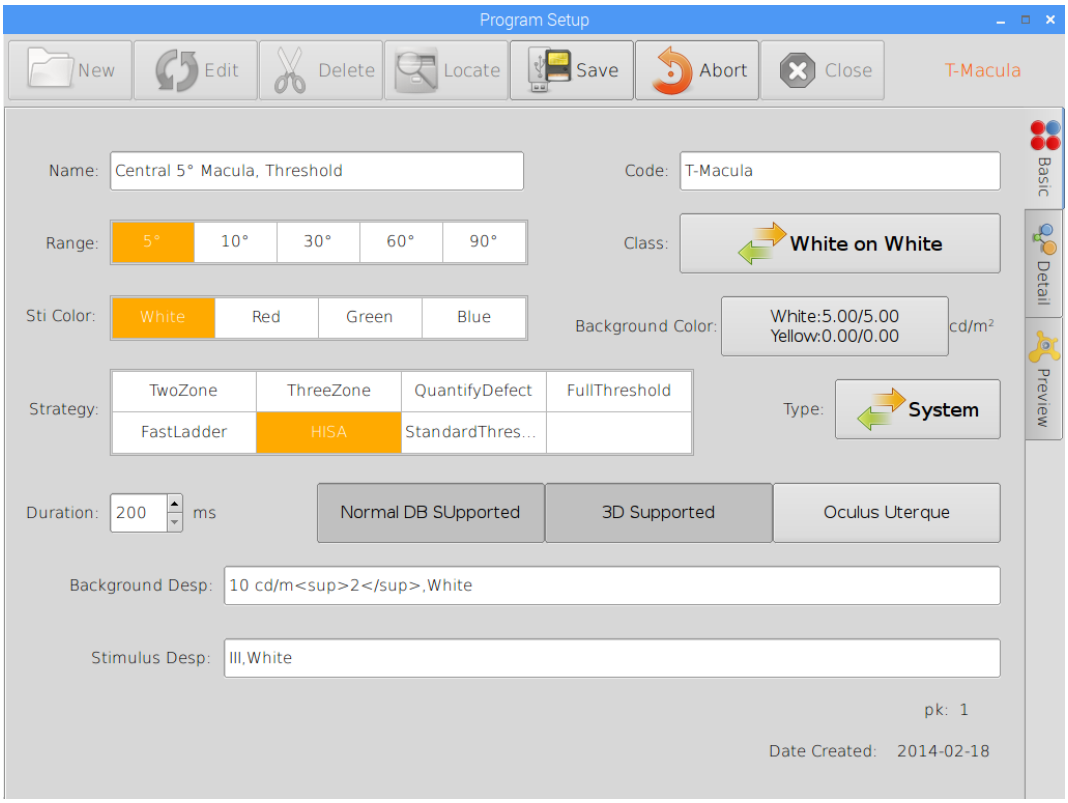


Admin user can customize test parameter and stimulus point locations of each test pattern, including edit, delete and search. But the system defined test patterns, like T30-2, T-Macular, etc., cannot be edited.

By clicking “Locate” button to enter threshold pattern locator window. Select a pattern, and then click “OK”.



Click “Edit” button to begin program edit. Test control parameters like background illumination, strategy, stimulus color, stimulus duration etc. can be edited on basic page.

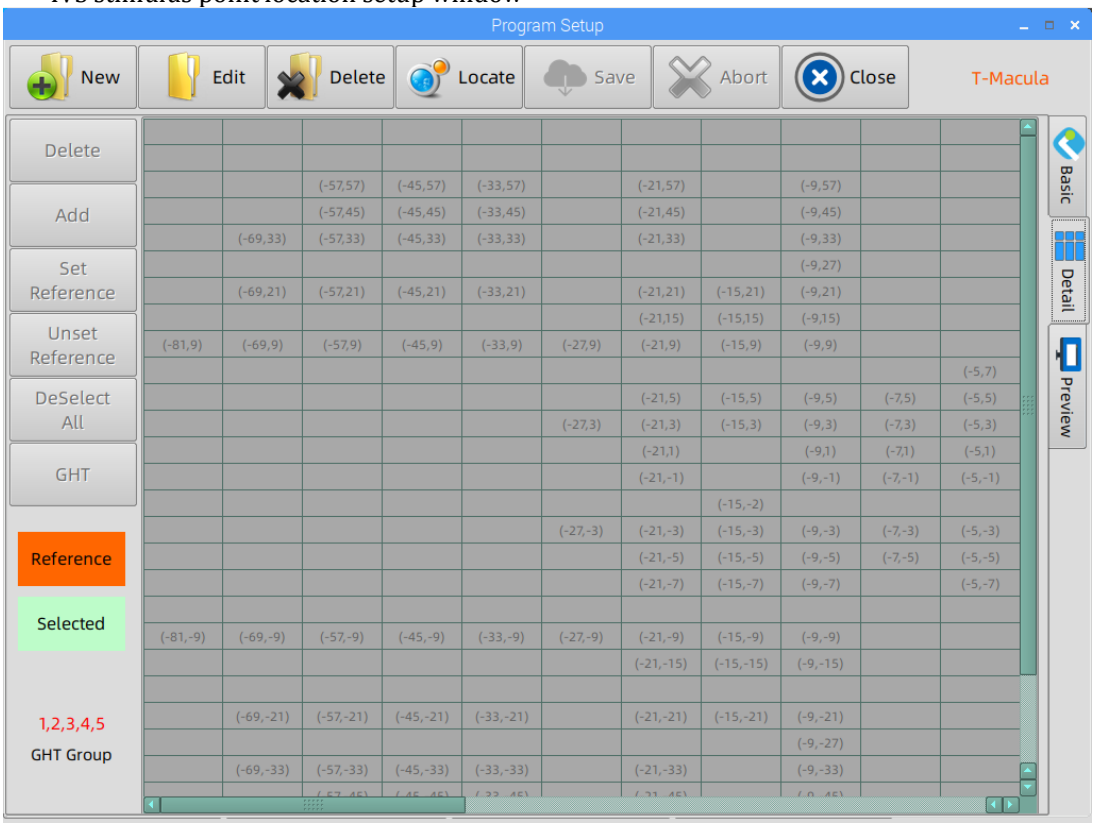


	Warning
	Do not set background & stimulus intensity too bright if it is not needed, which will be uncomfortable to the patient.

The stimulus point locations can be edited on detail page.

✓ IFA stimulus point location setup window

✓ IVS stimulus point location setup window



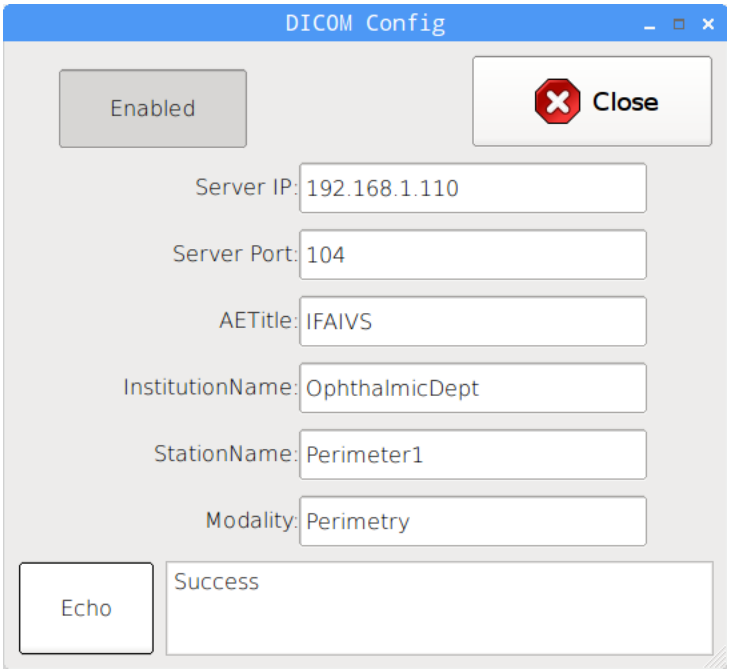
The test pattern can be previewed on Preview page. Click “Save” to save the edited program or “Abort” to cancel all edits.

9.6 DICOM

The perimeter is controlled by an embedded computer running Linux. It is available to be connected with LAN through RJ45 port or WIFI. After necessary parameter setting up, the perimeter can upload PDF encapsulated DCM file to DICOM Storage, and also get work list from HIS, or send “end exam” information to HIS.

9.6.1 Connections

Please login in with ADMIN (password is admin), then click “Setup -> Hospital Setup -> DICOM Config”.



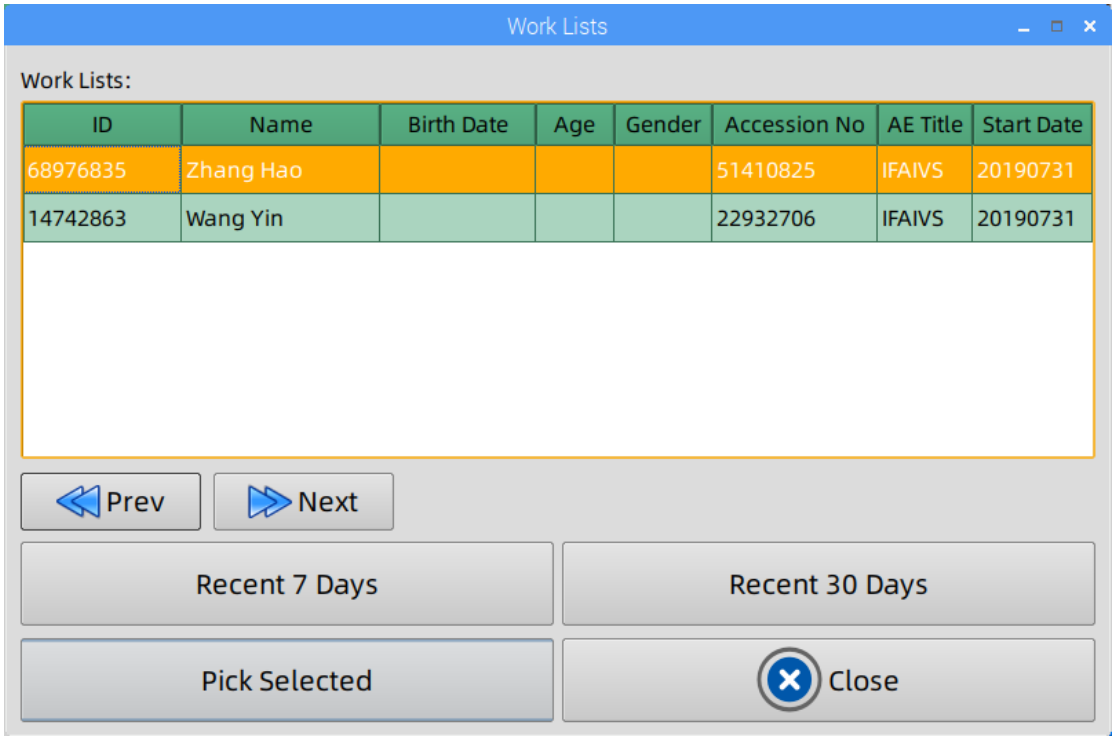
In DICOM Config window, it is requested to input following information. For any assistance needed during DICOM configuration setting up, please contact PACS administrator.

AETitle here means the **local** AE title, Modality means diagnostic type. Please contact HIS/PACS administrator about modality for perimetry test.

After configuration setting up, please click “Echo” button to test the connection with HIS/PACS. Description of "Success" means the correct connection. Or else, the error information will be displayed.

9.6.2 Work List

The work list is available from HIS/PACS system by clicking "Work List" in the wizard. By default, system will get the work list with configured "Modality", and scheduled current date. Please be noted that the “Work List” button will not be shown in wizard window unless the DICOM parameter is set up successfully.

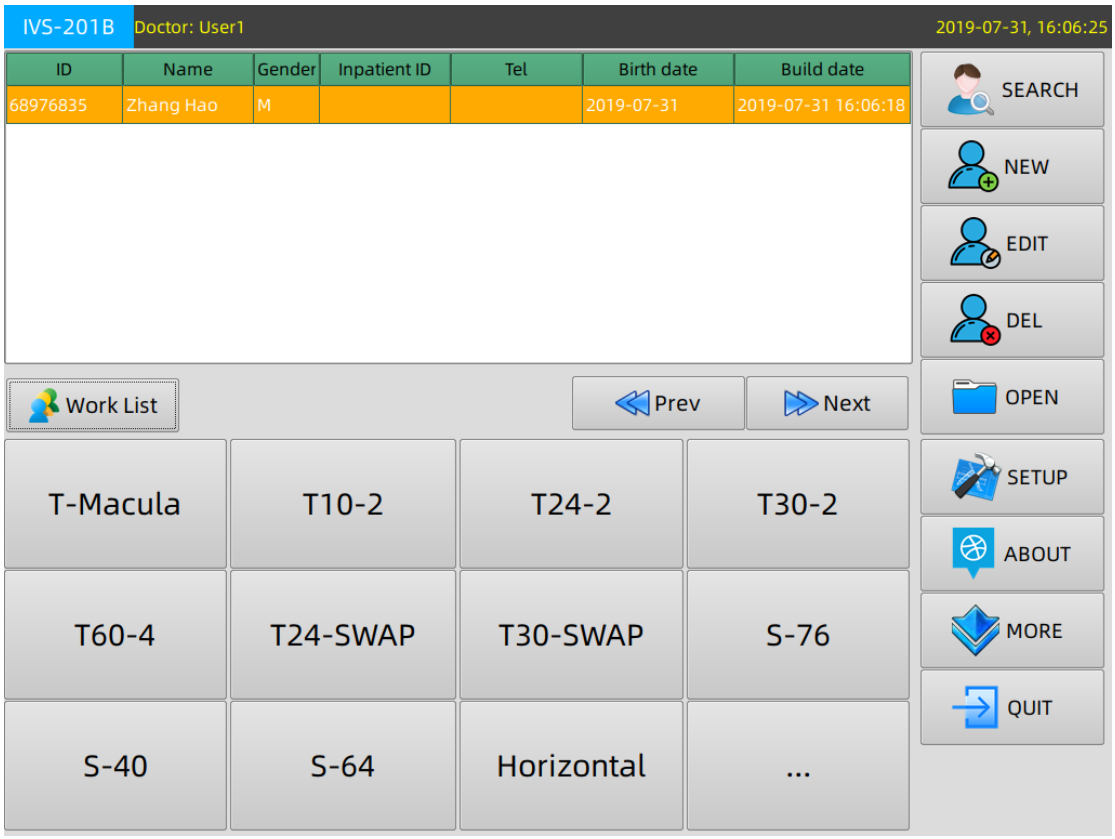


"Recent 7 Days": download work list of designated "Modality" for recent 7 days;

"Recent 30 Days": download work list of designated "Modality" for recent 30 days.

"Prev" and "Next": move up and down the work list.

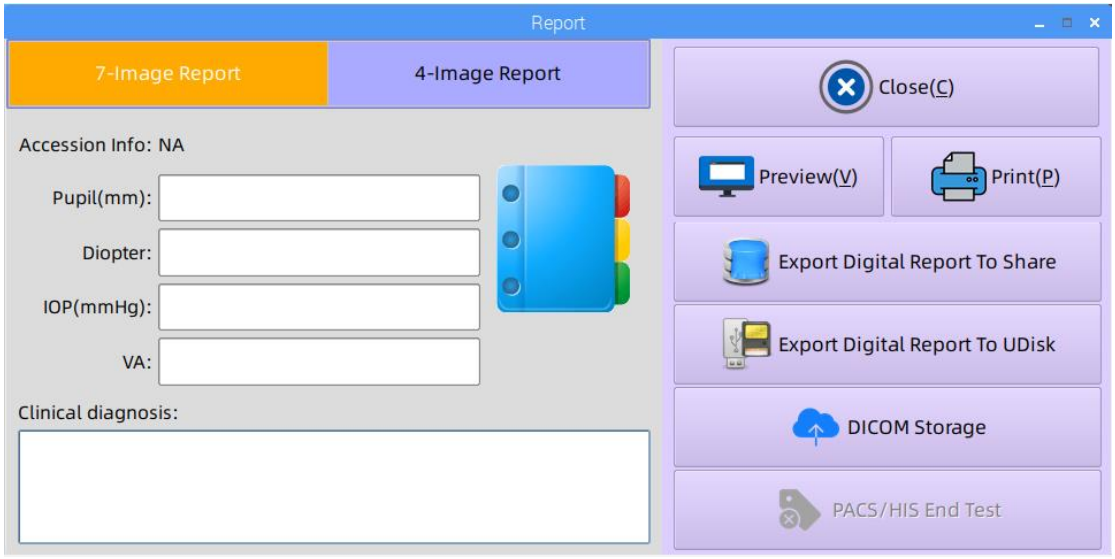
“Pick Selected”: Select one patient record in work list and click "Pick Selected", system will create a new patient or locate an earlier patient record by the ID. The basic patient information like gender, birth date and patient name is automatically filled out.



In the meantime, system will do a "MPPS In Progress" to inform the HIS that the test is started. Now, you can do the test for the picked patient.

9.6.3 DICOM Storage

If the test is finished, click "Print" to enter the “Report” window.



"DICOM Storage" will upload a PDF encapsulated DCM file to PACS. The button will be disabled if the uploading is finished. System ensures that one test report can only upload one time.

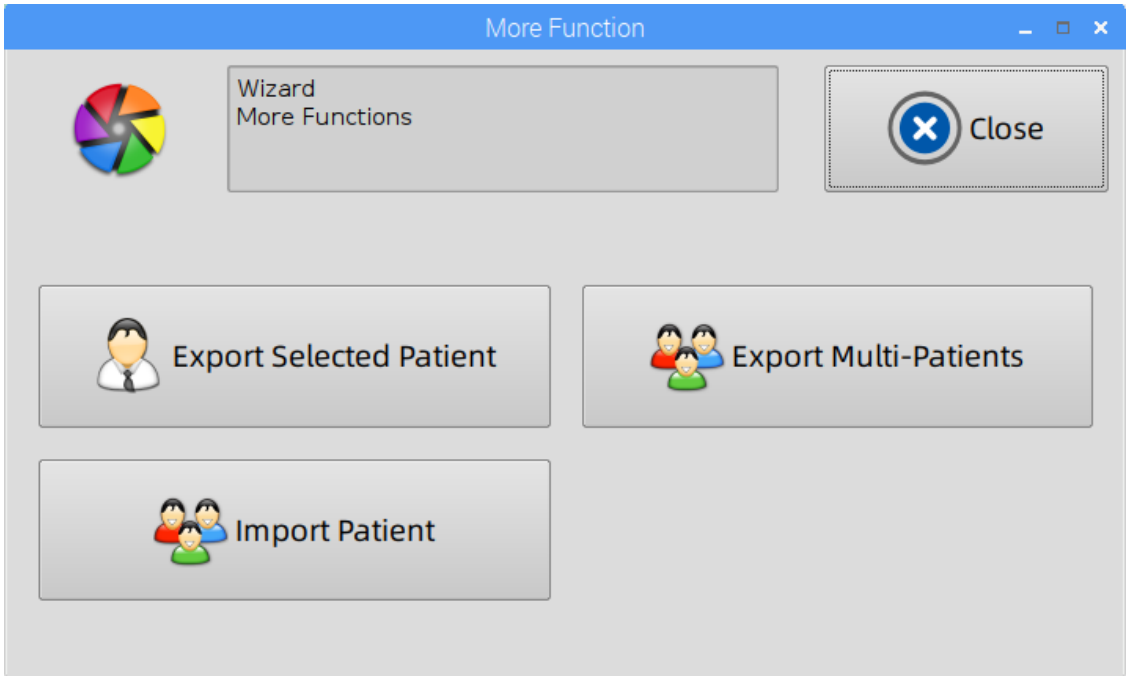
9.6.4 End Exam

"PACS/HIS End Exam" do a "MPPS Completed" process to inform the HIS that the test is finished. The button will be disabled after successful operation.

10. Miscellaneous

10.1 More Function

Click “More” in home window to open the following window for patient’s record import and export.

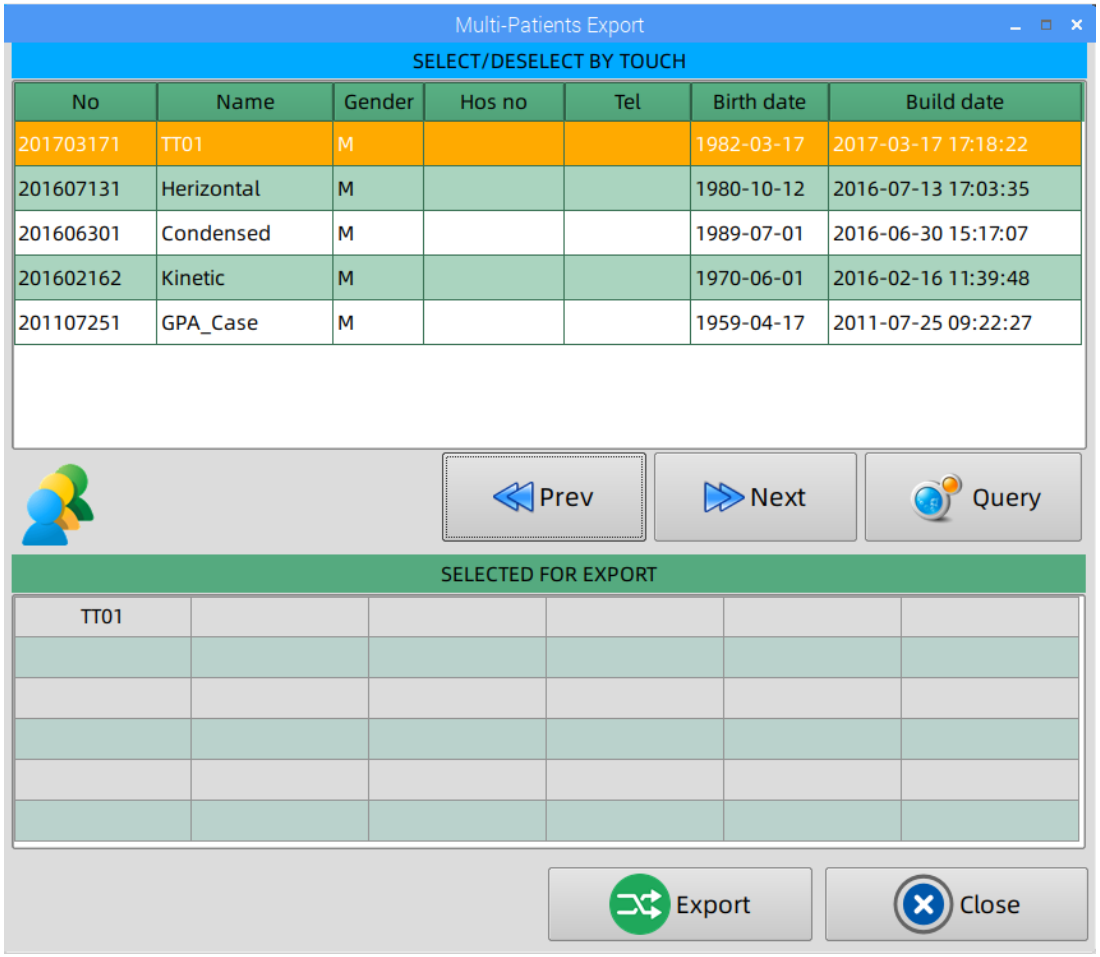


10.2 Patient Export / Import

Export Selected Patient: Select one patient record to be exported in home window, and then click “more -> Export Selected Patient”. The patient’s information and test data will be saved in .ptData file.

Export Multi-Patients: Click “Export Multi-Patients” button to open the patient list. Click the patient record to select the record to be exported. Re-click to remove the selected patient record from selected list. One or more patients’ information and test data will be saved in one .ptData file after clicking “Export” button.

Import Patient: Import the patient’s information and test data with .ptData file.


Multi-Patients Export
SELECT/DESELECT BY TOUCH
No
Name
Gender
Hos no
Tel
Birth date
Build date
201703171
TT01
M
1982-03-17
2017-03-17 17:18:22
201607131
Herizontal
M
1980-10-12
2016-07-13 17:03:35
201606301
Condensed
M
1989-07-01
2016-06-30 15:17:07
201602162
Kinetic
M
1970-06-01
2016-02-16 11:39:48
201107251
GPA_Case
M
1959-04-17
2011-07-25 09:22:27
Prev
Next
Query
SELECTED FOR EXPORT
TT01
Export
Close

11. Care & Cleaning

11.1 General Use Principles

①	The perimeter is designed for daily operation. Please power it off when it is not used in a period and covered with the dust cover.
②	Avoid turning the instrument on and off frequently in a day.
③	The perimeter should be used in a cool, dry and dust-free condition.
④	Do NOT connect or disconnect cables while power is on.
⑤	Do NOT place any container holding liquid near the instrument.
⑥	Do NOT place objects on top of the instrument.

11.2 Cleaning

The perimeter should be kept clean and maintained for proper operation. Please follow the methods and cleaners in below table to clean the indicated surfaces. Clean as often as is necessary.

Surface	Cleaner	Method
Exterior Panels	Mild detergent or appliance cleaner or glass cleaner containing no ammonia	Dampen a soft cloth with cleaner and gently wipe the surfaces. Never spray the cleaner directly on the exterior surfaces.
Bowl(Please review the two cautionary notes that follow this table)	Dust cloth	Remove accumulated dust from the bowl periodically. Wipe the bowl gently with a clean, dry, soft cotton cloth. Use downward strokes that move the dust toward the front edge of the bottom of the bowl, where there is a small opening around the base of the lens holder.

	Distilled water	If dusting the bowl is inadequate, slightly moisten the cloth with distilled water. Whether using a dry or a dampened cloth, always avoid excessive rubbing in one area, as this can create shiny spots or wear through the specially painted surface of the bowl.
	70% Isopropyl alcohol in H2O(Rubbing alcohol)	For small spots on the bowl surface caused by sneezing or coughing during a test, slightly dampen a cotton-tipped applicator with isopropyl alcohol and gently remove the spot. It is best to wet the spot with the tip of the dampened swab first and let it soak briefly. Then, use the swab very gently to remove the deposit.
Touch Screen	Mild glass cleaner containing no ammonia.	Turn OFF the perimeter before cleaning the touch screen. Wipe gently with a moistened cloth. Do not spray cleaner directly on the touch screen.

	Note
	Always be cautious to avoid scratching, discoloring, or staining the bowl surface. Prior to cleaning the bowl surface, remove all jewelry as it can permanently scratch or damage the painted surface. Be especially careful of long fingernails and fingernail polish contacting the bowl surface, as these can mark or damage the painted surface permanently.

	Note
	During cleaning the bowl, please be cautious to avoid getting either the distilled water or isopropyl alcohol cleaning liquid inside of the fixation target openings or on mirrored surfaces.

	Attention

⚠	The chin/forehead supporter of the perimeter contact with patient's skin during examination. It should be cleaned & disinfected by 75% medical alcohol with cotton wool. These parts can be isolated from patient's skin with disposable protective film materials. These isolation materials could be medical gauze or other materials that meet medical biocompatibility standards.

11.3 Maintenance

1	If the machine is not used for a long time, the mainframe should be powered 1 hour once a week.
2	To avoid data loss, it is suggested to back up the test data once a month.
3	Check the power cord for safe connection every 6 months.
4	For the IFA series, pay attention to the operating noise of the projection system. If you hear harsh noise, stop using it and ask the supplier for support.
5	If it is possible, the brightness should be calibrated for every 2 years. The calibration should be carried out by the manufacturer's or its authorized distributor with professional tools.
6	Any changes or updates to the software shall be performed by the authorized distributor.

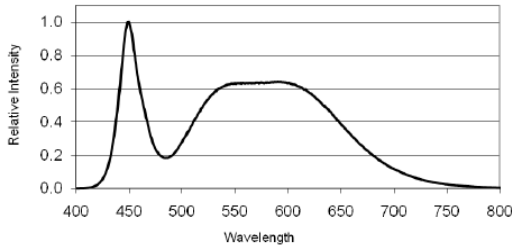
A. Technical Specifications

■ Model List

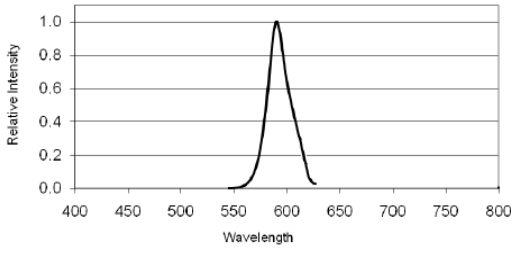
Model	Function & Structure					
	Back-ground	**Stimuli**	**Combination**	**Stimuli Size**	**Static Perimeter**	**Kinetic Perimeter**
IFA-900	White	White	/	Ⅲ	√	---
IFA-950	White, Yellow	White, Blue	White on White Blue on Yellow	Ⅰ - Ⅴ	√	---
IFA-960	White, Yellow	White, Red, Green, Blue	White on White Red on White Green on White Blue on Yellow	Ⅰ - Ⅴ	√	√
IVS-201A	White, Yellow	White, Blue	White on White Blue on Yellow	Ⅲ	√	---
IVS-201B	White	White	/	Ⅲ	√	---
Software Component: Type - PERI Release Version - V2.2 Remark: "√" – feature included, "---" – feature not included.						

■ Spectral distribution(s) of the background and the test stimuli

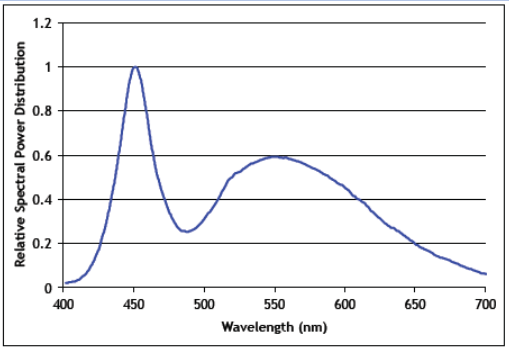
Spectrum of White Background



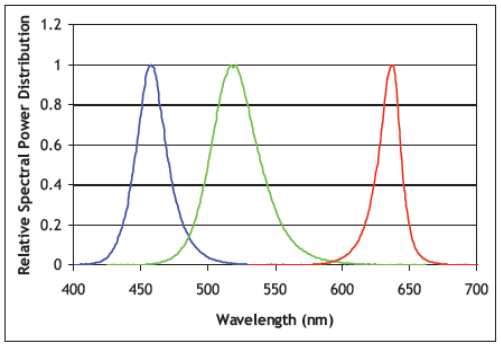
Spectrum of Yellow Background



Spectrum of White Stimuli



Spectrum of Blue,Green,Red Stimuli



■ The test stimuli be presented within the tolerances specified in following table.

No.	Criteria	Tolerances
1	Background luminance, L_B	+25%, -20%
2	Contrast, $\Delta L/L_B$	+25%, -20%
3	Stimulus location	0°～10°: ≤0.5°
		10°～30°: ≤1°
		＞30°: ≤2°
4	Stimulus size	Converted to solid angle: +20%，-15%
5	Stimulus duration	±20%
6	Extent of background	Not less than 2° beyond the edge of the most peripheral stimulus
7	Shape of stimulus	Shall conforms to accommodating files

- Chin & forehead supporter movable distance

Item	Distance
Chin&forehead supporter left-right movable distance	≥30 mm
Chin supporter up-down movable distance	≥50 mm

- The luminance of the background and test stimuli shall be specified in candela per square meter (cd/m^2), measured at the designated position of the center of the entrance pupil of the patient's eye.

- Standard stimulus size

Standard Stimulus Size

(Applicable to model IFA-900, IFA-950, IFA-960)

Azimuth θ	**Eccentricity Φ**		**b/a**	**Solid angle Ω**
0°	15°		>0.7	6.7×10^{-5}
	40°		>0.6	9.8×10^{-5}
45°	15°		>0.7	6.4×10^{-5}
	40°		>0.6	1.3×10^{-4}
90°	2°	Ⅰ	>0.7	6.9×10^{-6}
		Ⅱ	>0.7	2.4×10^{-5}
		Ⅲ	>0.7	7.9×10^{-5}
		Ⅳ	>0.7	2.2×10^{-4}
		Ⅴ	>0.7	5.0×10^{-4}
	15°		>0.7	8.4×10^{-5}
	40°		>0.6	1.4×10^{-4}
135°	15°		>0.7	6.7×10^{-5}
	40°		>0.6	1.3×10^{-4}
180°	15°		>0.7	6.2×10^{-5}
	40°		>0.6	7.2×10^{-5}

225°	15°	>0.7	7.4×10^{-5}
	40°	>0.6	8.0×10^{-5}
270°	15°	>0.7	7.1×10^{-5}
	40°	>0.6	1.1×10^{-4}
315°	15°	>0.7	7.4×10^{-5}
	40°	>0.6	8.7×10^{-5}

Standard Stimulus Size

(Applicable to model IVS-201A, IVS-201B, White Stimulus)

Azimuth θ	**Eccentricity Φ**	**b/a**	**Solid angle Ω**
0°	15°	>0.8	4.6×10^{-5}
14°	34°	>0.8	5.5×10^{-5}
45°	13°	>0.8	4.5×10^{-5}
40°	45°	>0.8	6.5×10^{-5}
108°	3°	>0.8	4.4×10^{-5}
103°	15°	>0.8	4.5×10^{-5}
107°	34°	>0.8	5.5×10^{-5}
137°	13°	>0.8	4.6×10^{-5}
140°	45°	>0.8	6.5×10^{-5}
182°	15°	>0.8	4.6×10^{-5}
194°	34°	>0.8	5.5×10^{-5}
225°	13°	>0.8	4.5×10^{-5}
222°	45°	>0.8	6.5×10^{-5}
283°	15°	>0.8	4.6×10^{-5}
288°	34°	>0.8	5.5×10^{-5}
315°	13°	>0.8	4.5×10^{-5}
315°	45°	>0.8	6.5×10^{-5}

Standard Stimulus Size

(Applicable to model IVS-201A, Blue Stimulus)

Azimuth θ	**Eccentricity Φ**	**b/a**	**Solid angle Ω**
12°	16°	>0.8	4.5×10^{-5}
18°	29°	>0.8	5.5×10^{-5}
45°	13°	>0.8	4.5×10^{-5}
45°	21°	>0.8	5.0×10^{-5}
133°	5°	>0.8	4.5×10^{-5}
105°	16°	>0.8	4.5×10^{-5}
112°	29°	>0.8	5.5×10^{-5}
139°	13°	>0.8	4.5×10^{-5}
139°	21°	>0.8	5.0×10^{-5}
191°	16°	>0.8	4.5×10^{-5}
197°	29°	>0.8	5.5×10^{-5}
225°	13°	>0.8	4.5×10^{-5}
225°	21°	>0.8	5.0×10^{-5}
286°	16°	>0.8	4.5×10^{-5}
283°	29°	>0.8	5.5×10^{-5}
310°	13°	>0.8	4.5×10^{-5}
310°	21°	>0.8	5.0×10^{-5}

- The viewing distance between patient pupil and fixation target is 300mm±20mm.
- If the patient has more than 1D refractive power that causes a change in the visual distance from the fixation target, please wear glasses or use trial lens for test.
- The fixation of the eye is monitored by an infrared camera. During the test, the operator should pay attention to monitoring the eye position deviation on the monitoring window.
- The differential light sensitivity was measured at fixation.

- Kinetic perimeter: the standard stimuli point color is white, and the point is moving along the semi-mesis of the polar coordinate. Its standard speed is 4º/s.

- Static perimeter: the standard stimulus duration is 200ms, and can be adjusted between 200ms – 1000ms.

- Nominal luminance of white background: 10cd/m^2; Nominal luminance of yellow background: 100cd/m^2.

- Standard stimulus contrast

Standard Contrast for White, Red, Green Stimulus on White Background

dB	Stimulus luminance $L_s - L_B$ $\mathbf{cd/m^2}$	Luminance L_s $\mathbf{cd/m^2}$	Contrast $(\mathbf{L_s - L_B})/\boldsymbol{L_B}$
0	3183.10	3193.10	318.310
1	2528.43	2538.43	252.843
2	2008.40	2018.40	200.840
3	1595.33	1605.33	159.533
4	1267.21	1277.21	126.721
5	1006.58	1016.58	100.658
6	799.56	809.56	79.956
7	635.11	645.11	63.511
8	504.49	514.49	50.449
9	400.73	410.73	40.073
10	318.31	328.31	31.831
11	252.84	262.84	25.284
12	200.84	210.84	20.084
13	159.53	169.53	15.953
14	126.72	136.72	12.672
15	100.66	110.66	10.066

16	79.96	89.96	7.996
17	63.51	73.51	6.351
18	50.45	60.45	5.045
19	40.07	50.07	4.007
20	31.83	41.83	3.183
21	25.28	35.28	2.528
22	20.08	30.08	2.008
23	15.95	25.95	1.595
24	12.67	22.67	1.267
25	10.07	20.07	1.007
26	8.00	18.00	0.800
27	6.35	16.35	0.635
28	5.04	15.04	0.504
29	4.01	14.01	0.401
30	3.18	13.18	0.318
31	2.53	12.53	0.253
32	2.01	12.01	0.201
33	1.60	11.60	0.160
34	1.27	11.27	0.127
35	1.01	11.01	0.101
36	0.80 < 0.1 L_B	10.80	0.080
Remark: Nominal white background luminance = 10cd/m^2			

Standard Contrast for Blue Stimulus on Yellow Background

dB	Stimulus luminance $L_s - L_B$ **cd/m^2**	Luminance L_s **cd/m^2**	Contrast **$(L_s - L_B)/L_B$**
0	400.00	500.00	4.0000

1	317.73	417.73	3.1773
2	252.38	352.38	2.5238
3	200.47	300.47	2.0047
4	159.24	259.24	1.5924
5	126.49	226.49	1.2649
6	100.48	200.48	1.0048
7	79.81	179.81	0.7981
8	63.40	163.40	0.6340
9	50.36	150.36	0.5036
10	40.00	140.00	0.4000
11	31.77	131.77	0.3177
12	25.24	125.24	0.2524
13	20.05	120.05	0.2005
14	15.92	115.92	0.1592
15	12.65	112.65	0.1265
16	10.05	110.05	0.1005
17	7.98	107.98	0.0798
18	6.34	106.34	0.0634
19	5.04	105.04	0.0504
20	4.00	104.00	0.0400
21	3.18	103.18	0.0318
22	2.52	102.52	0.0252
23	2.00	102.00	0.0200
24	1.59	101.59	0.0159
25	1.26	101.26	0.0126
26	1.00	101.00	0.0100
27	0.80	100.80	0.0080
28	0.63	100.63	0.0063

29	0.50	100.50	0.0050
30	0.40	100.40	0.0040
Remark: Nominal yellow background luminance = 100cd/m^2			

■ Minimum test stimulus pattern extension

	Stimulus point eccentricity Φ
Nasal	45°
Temporal	70°
Superior	45°
Inferior	60°

■ Minimum total number of potential stimulus locations

Eccentricity Φ	Minimum number
0°～25°	60
＞25°～50°	30
＞50°～70°	15
Total locations	105

B. Test Strategies

Screening Strategy

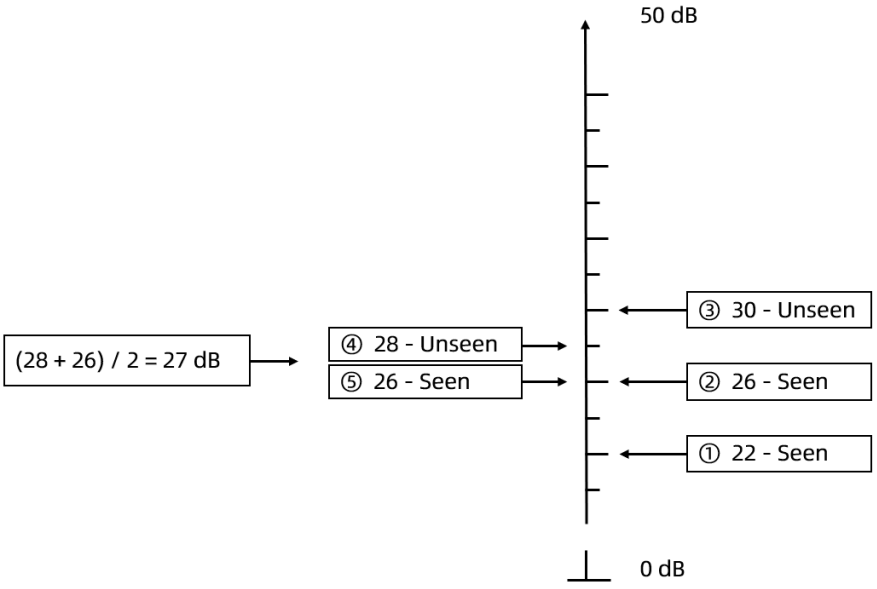
ASN - averaged sensitivity of age-related normal database of specific test point.

Two Zone	For each test point of test pattern, a stimulus of **ASN** – 6 dB is presented to the patient. In result, system print circles(O) for seen and responded stimuli, boxes(■) for missed stimuli. Since screening is done with 6 dB brighter stimuli than expected sensitivity, missed points are known to be at least 6 dB defect. O - ASN – 6 dB was seen and responded by the patient; ■ - ASN – 6 dB was missed by the patient.
Three Zone	Same as Two Zone, except each missed point is measured again at a maximum intensity of 10,000 asb (0 dB) to determine if the defect is absolute. Printouts display circles (O) for seen stimuli, "X's" for relative defects, and boxes (■) for absolute defects. O - ASN – 6 dB was seen and responded by the patient; X - ASN – 6 dB was missed, 0 dB was seen and responded by the patient; ■ - ASN – 6 dB and 0 dB were missed by the patient.
Quantify Defects	For each test point of test pattern, a stimulus of **ASN** – 6 dB is presented to the patient. Circles(O) displayed in printouts for seen stimuli. Otherwise, system will present a sequence of stimulus with step of 3 dB to evaluate the depth of its defect, numbers (in dB) displayed in printouts to indicate the depth of any defects. The greater the number, the lower the retinal sensitivity. O - **ASN** – 6 dB was seen and responded by the patient; Number - depth of defect.

Threshold Strategy

Full Threshold

In full threshold testing, for each test point of test pattern, an initial stimulus is presented at a level the patient is expected to see. If it is seen and responded, the stimulus intensity is decreased in step of 4 dB until the patient no long sees the stimulus; If it is not seen, it is increased in step of 4 dB until it is seen. Then the system changes strategy, the stimulus moves in step of 2 dB until patient responds. The threshold of that point is computed as the average of last seen and unseen intensity.



Above figure gives an example for this full threshold searching process.

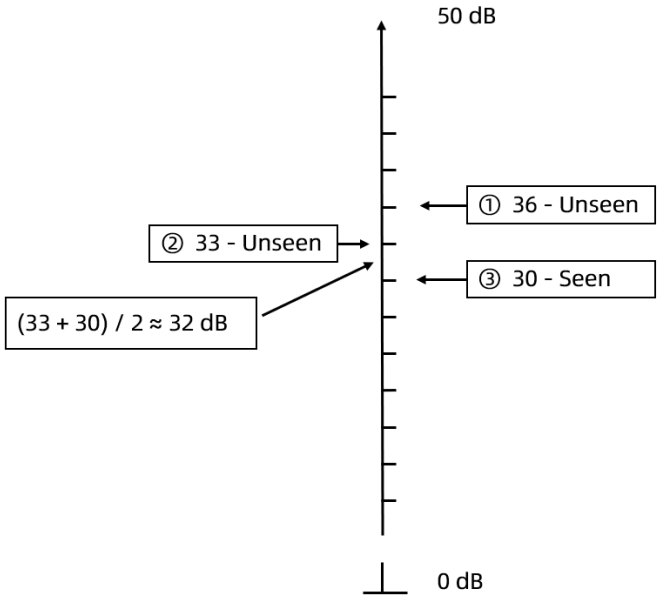
Step	Strategy
1	Initial 22 dB stimulus been presented, seen.
2	26 dB (22 + 4) stimulus been presented, seen.
3	30 dB (26 + 4) stimulus been presented, unseen.
4	Change direction, 28 dB (30 – 2) stimulus been presented, unseen.
5	26 dB (28-2) stimulus been presented, seen.
	Threshold is the average of last seen and unseen intensity = (28 + 26)/2 = 27 dB.

In above process, the intensity of initial stimulus is computed through a mathematical model in which the averaged sensitivity of age-related normal database, the results of tested neighboring test points have been taken into consideration.

In above process, system will automatically insert stimuli from other test points, prevent the stimulus continuously been presented at specific location.

Standard Threshold

The standard threshold follows a similar stair-stepping technique as in Full Threshold, but uses 3 dB increments instead of 4 dB and crosses the threshold only once.



Above figure gives an example for this standard threshold searching process.

Step	Strategy
1	Initial 36 dB stimulus been presented, unseen.
2	33 dB (36 - 3) stimulus been presented, unseen.
3	30 dB (33 - 3) stimulus been presented, seen.
	Threshold is the average of last seen and unseen intensity = (33 + 30)/2≈32 dB.

Fast Ladder

The fast ladder follows a similar stair-stepping technique as standard threshold, but uses 5 dB increments instead of 3 dB. Please be aware that even the subject never makes a mistake, the error of the fast ladder strategy is 5 / 2 = 2.5 dB.

HISA

HISA is initial abbreviation of **H**euristic **I**nteractive Threshold **S**earching **A**lgorithm. With HISA, every test is done through several mathematical models.

It forecasts initial threshold for new point through a complex mathematical model, which takes neighboring tested results and age-related normal values into consideration. Then unnecessary search will consequently be avoided. During test process, HISA intelligently skips those "undoubted" questions regarding the change of neighboring point's value.

HISA is not likely to initiate all points but do a sample survey from some specific location. Subsequently, time will be saved for patients with serious reduction of sensitivity by skipping those high-sensitivity questions.

HISA will adjust the stimuli interval adaptively according to the patient's response lag. With HISA, young, quick patients will experience a happier, faster and more reliable test. And older, sluggish patients will not miss the response in long stimuli intervals.

With HISA, an information index for each test point is computed through a mathematical model. When the system believes that the collected information is sufficient, it will stop asking questions for that test point.

HISA will evaluate the reliability of the tested points through a complex reliability function. Besides, HISA will automatically retest the suspected result.

C. Test Patterns

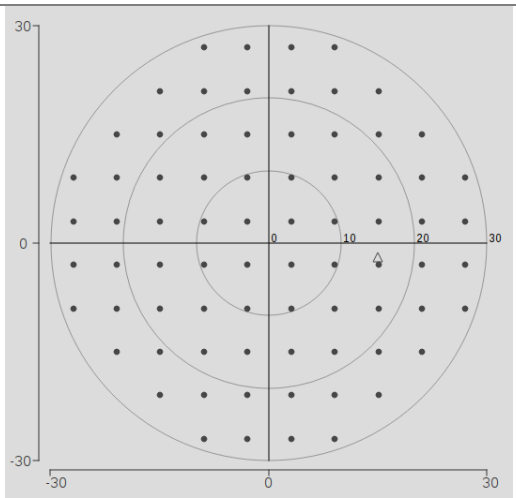
This appendix describes Threshold and Screen test patterns. Please be reminded that test patterns are different between different models, not all showed test patterns in this manual are available on your unit.

C.1 Threshold Test Patterns

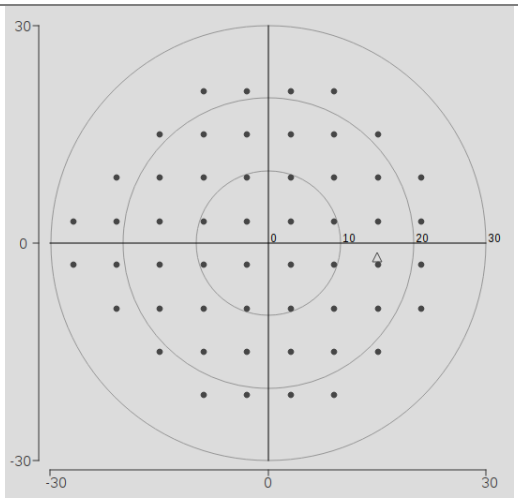
Test Pattern	Extent of Visual Field Tested/ Number of Test Points	Application
T30-2 / Central 30-2	30 degrees / 76 points	Glaucoma, Retinal, Neurological, General
T24-2 / Central 24-2	24 degrees / 54 points	Glaucoma, Neurological, General
T10-2 / Central 10-2	10 degrees / 68 points	Macula, Retinal, Neurological, Advanced Glaucoma
T-Macula / Macula	5 degrees / 16 points	Macula
T-NS / Nasal Step	50 degrees / 14 points	Glaucoma
T60-4 / Peripheral 60-4	30 – 60 degrees / 60 points	Retinal, Glaucoma
T30-SWAP / Central 30 SWAP	30 degrees / 76 points	Glaucoma
T24 – SWAP / Central 24 SWAP	24 degrees / 54 points	Glaucoma
T30V-2 /Central 30-2, Size V test points	30 degrees / 76 points	Low Vision
T60-2 / Central 60-2,	60 degrees/ 76 points for IFA, 72 points for IVS	Glaucoma, Research Purpose
GT30-2 /Central 30-2, Green Test Points	30 degrees / 76 points	Research Purpose
RT30-2 /Central 30-2, Red Test Points	30 degrees / 76 points	Research Purpose
D-30 / Driver Test 30	30 degrees / 32 points	Special occupational medical examination
D – 60 / Driver Test 60	60 degrees / 32 points	Special occupational medical examination

- **Layout of Test Points**

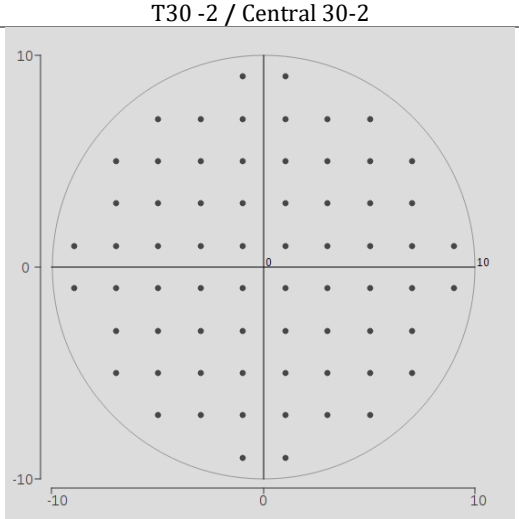
All the patterns are shown for Right Eye.



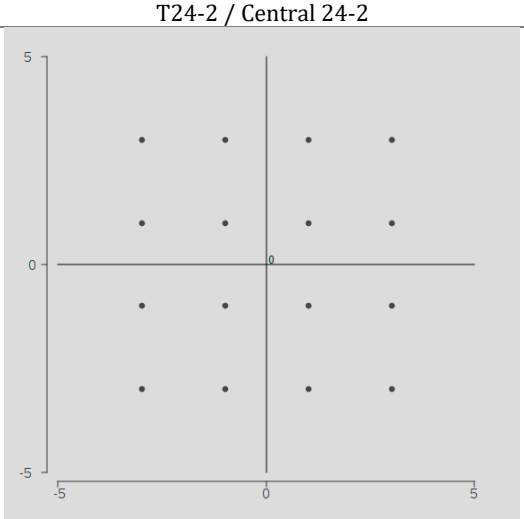
T30 -2 / Central 30-2



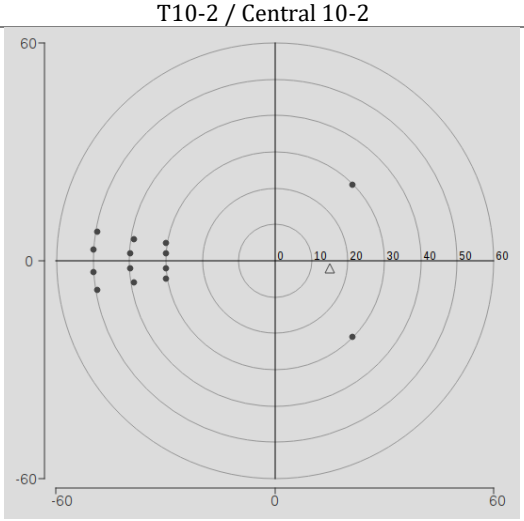
T24-2 / Central 24-2



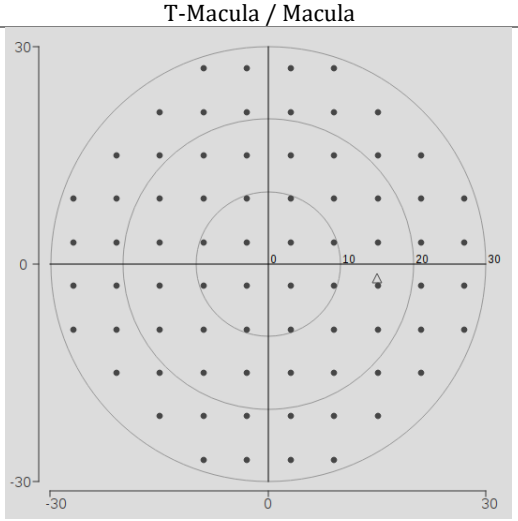
T10-2 / Central 10-2



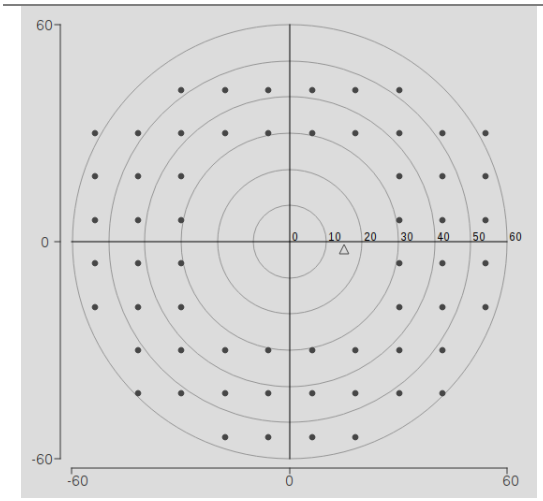
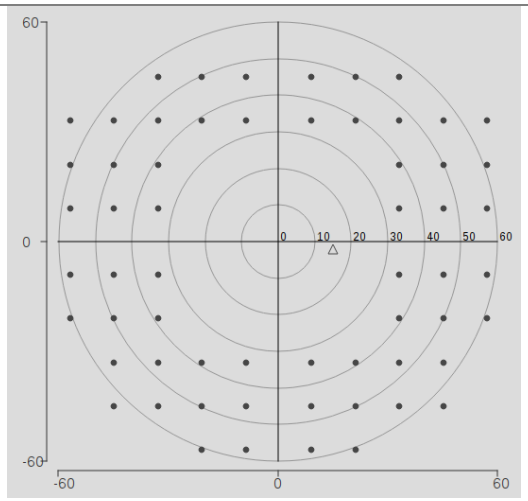
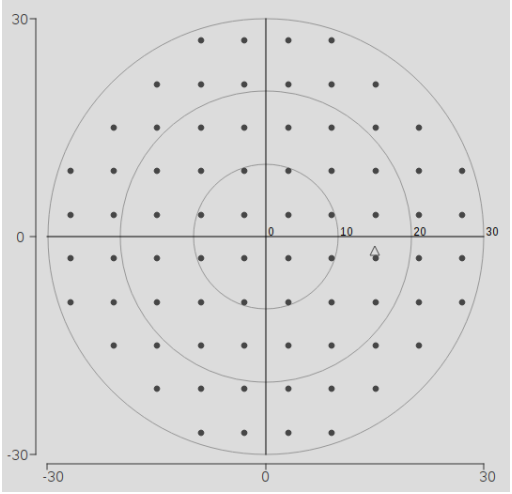
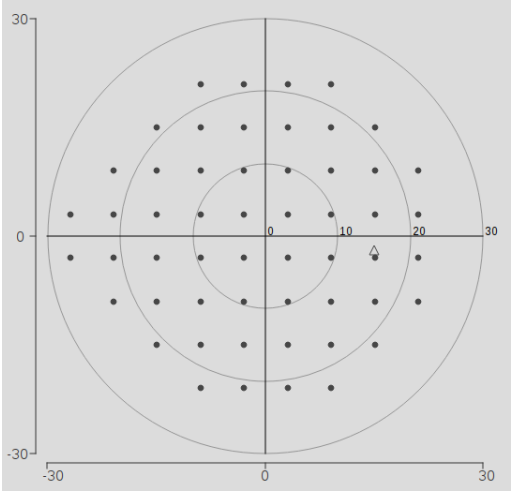
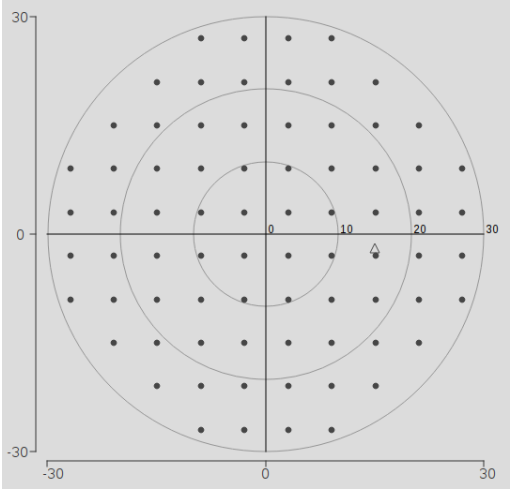
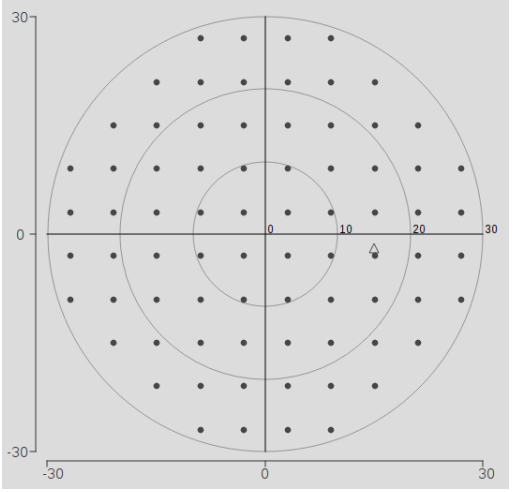
T-Macula / Macula

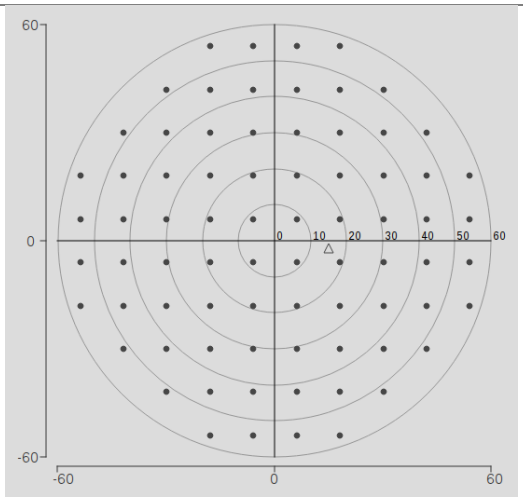


T-NS / Nasal Step

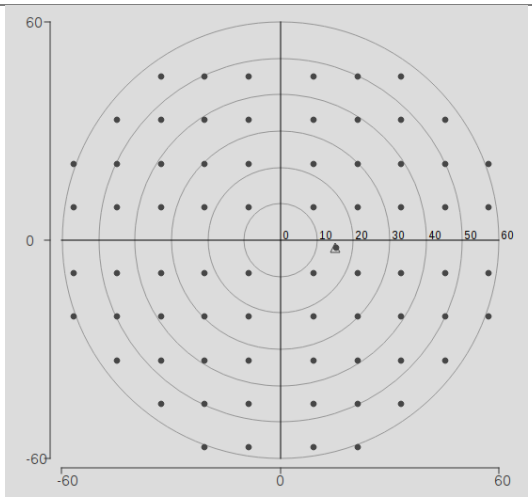


RT30-2 / Central 30-2, Red Test Points

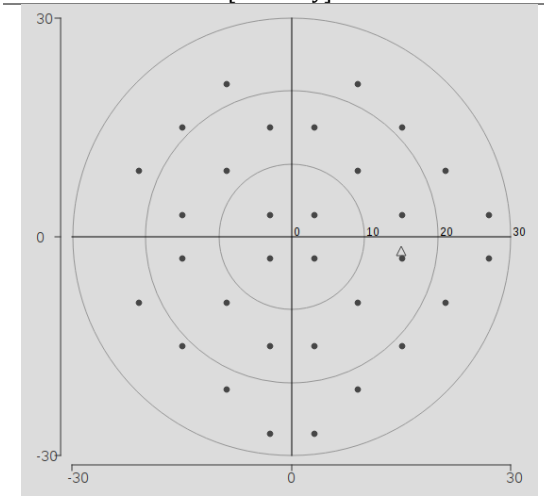
[IFA Only]	[IFA-960 Only]
	
T60-4 / Peripheral 60-4 [IFA Only]	T60-4 / Peripheral 60-4 [IVS Only]
	
T30-SWAP / Central 30 SWAP [IVS-201A, IFA-950, IFA-960 Only]	T24-SWAP / Central 24 SWAP [IVS-201A, IFA-950, IFA-960 Only]
	
T30V-2 / Central 30-2, Size V Test Points [IFA-950, IFA-960 Only]	GT30-2 / Central 30-2, Green Test Points [IFA-960 Only]



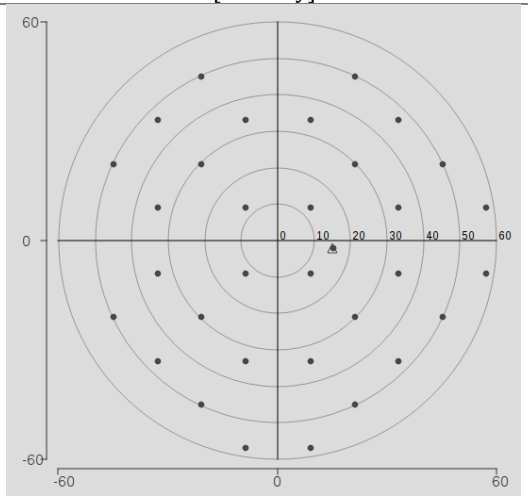
T60-2 / Central 60-2
[IFA Only]



T60-2 / Central 60-2
[IVS Only]



D-30 / Driver Test 30
[IVS Only]



D-60 / Driver Test 60
[IVS Only]

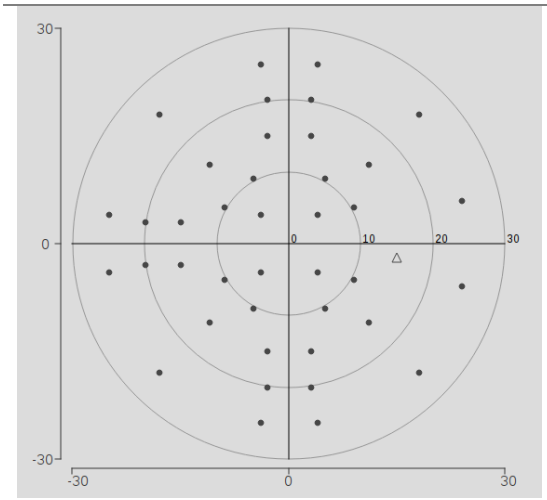
C.2 Screen Test Patterns

Test Pattern	Extent of Visual Field Tested/ Number of Test Points	Application
S-40 / Central 40 Points	30 degrees / 40 points	General Screening
S-64 / Central 64 Points	30 degrees / 64 points	General, Glaucoma, Neurological
S-76 / Central 76 Points	30 degrees / 76 points	General, Glaucoma, Neurological
S-80 / Central 80 Points	30 degrees / 80 points	General Screening
S-Armaly / Armaly Central	30 degrees / 88 points	Glaucoma
S-NS / Nasal Step	50 degrees / 14 points	Glaucoma
S-60 / Peripheral 60 Points	30 – 60 degrees / 60 points	General, Neurological with central exam, Retinal, Glaucoma
SF-81 / Full Field 81 Points	60 degrees / 81 points	General, Retinal, Glaucoma, Neurological

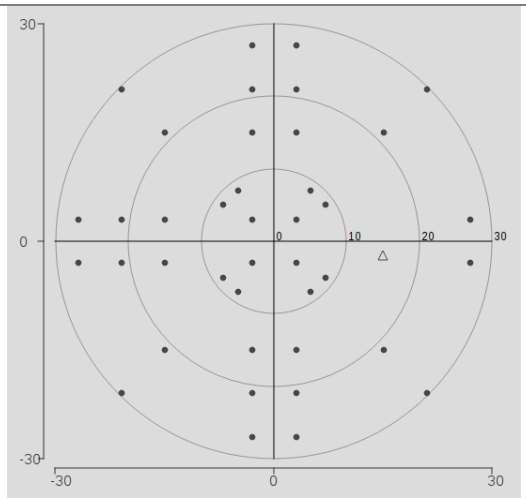
SF-120 / Full Field 120 Points	60 degrees / 120 points	General, Retinal, Glaucoma, Neurological
SF-135 / Full Field 135 Points	87 degrees / 135 points 87 degrees temporally	Full Field Screening
SF-246 / Full Field 246 Points	60 degrees / 246 points	Full Field Screening
SS-36 / Superior 36 Points	60 degrees, superior hemifield / 36 points	Superior Field Screening, Ptosis
SS-64 / Superior 64 Points	60 degrees, superior hemifield / 64 points	Superior Field Screening, Ptosis
EM-M / Esterman Monocular	75 degrees temporal 60 degrees nasal / 100 points for IFA, 86 points for IVS	Functional disability
EM-B / Esterman Binocular	150 degrees bitemporal / 120 points for IFA, 106 points for IVS	Functional disability
SF-Armaly / Armaly Full Field	50 degrees / 98 points	Full Field Screening

- **Layout of Test Points**

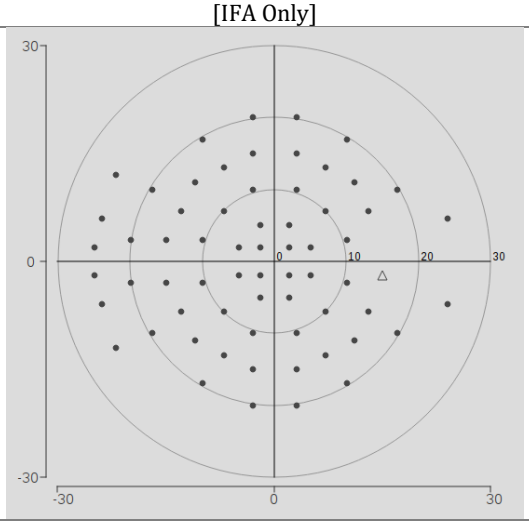
All the patterns are shown for Right Eye unless specified.

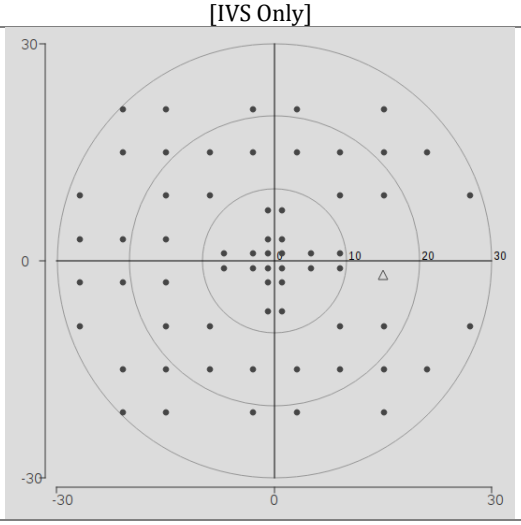


S-40 / Central 40 Points
[IFA Only]

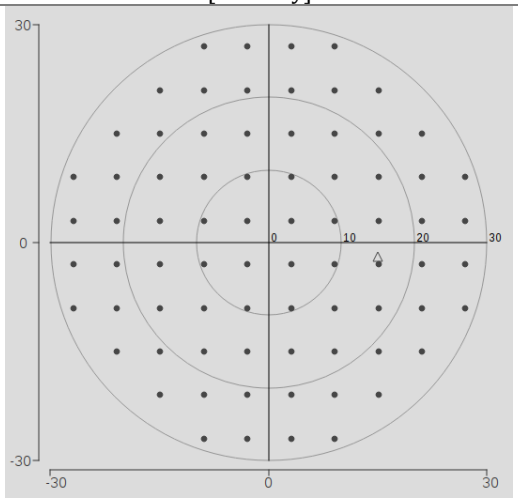


S-40 / Central 40 Points
[IVS Only]

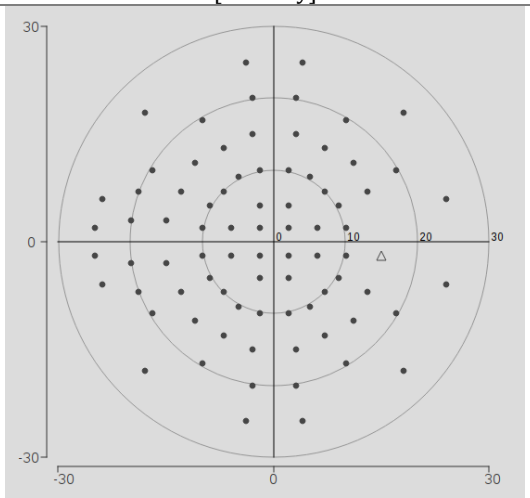




S-64 / Central 64 Points
[IFA Only]

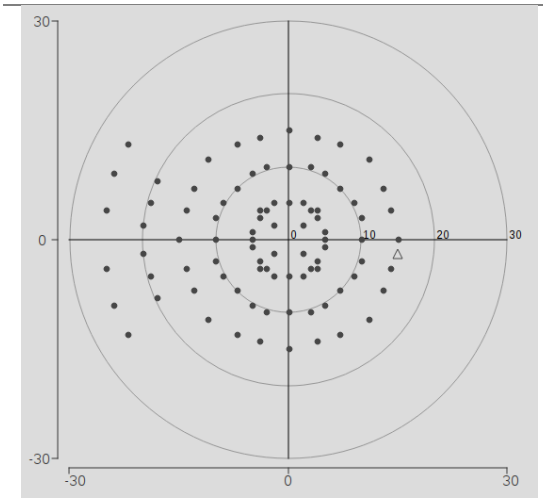


S-64 / Central 64 Points
[IVS Only]

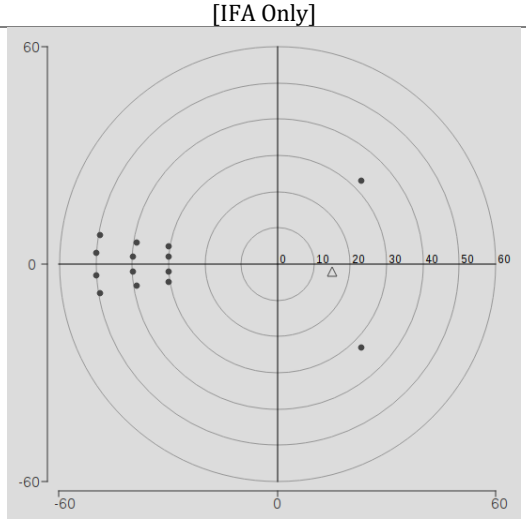


S-76 / Central 76 Points

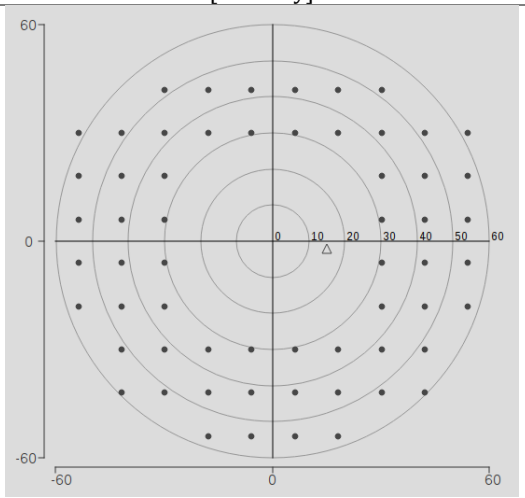
S-80 / Central 80 Points
[IFA Only]



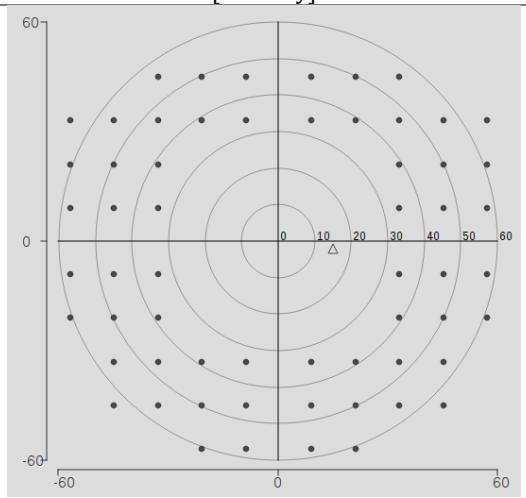
S-Armaly / Armaly Central
[IFA Only]



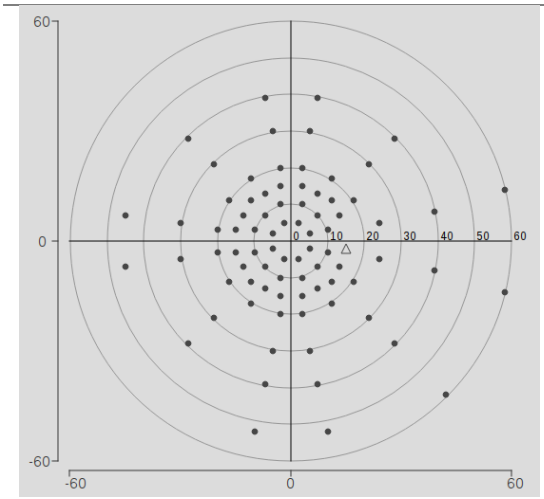
S-NS / Nasal Step
[IFA Only]



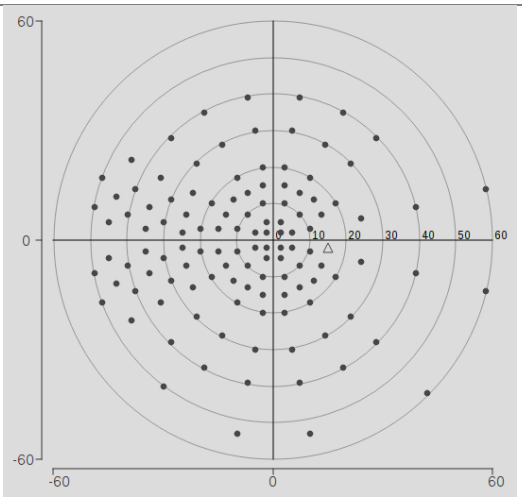
S-60 / Peripheral 60 Points
[IFA Only]



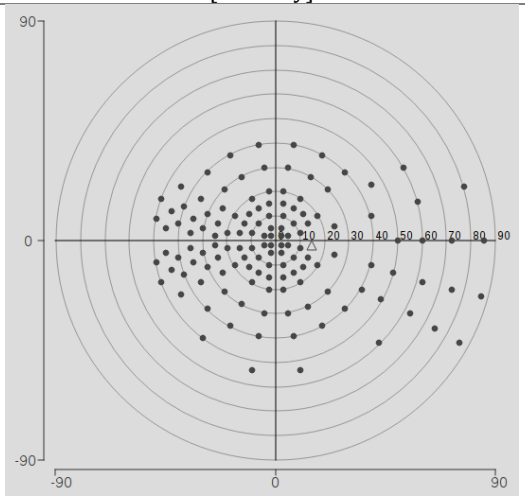
S-60 / Peripheral 60 Points
[IVS Only]



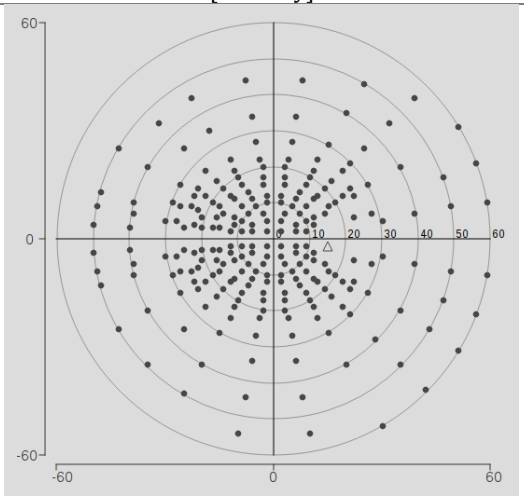
SF-81 / Full Field 81 Points
[IFA Only]



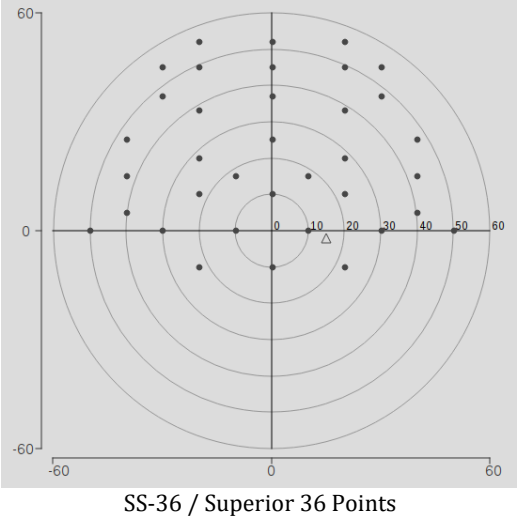
SF-120 / Full Field 120 Points
[IFA Only]



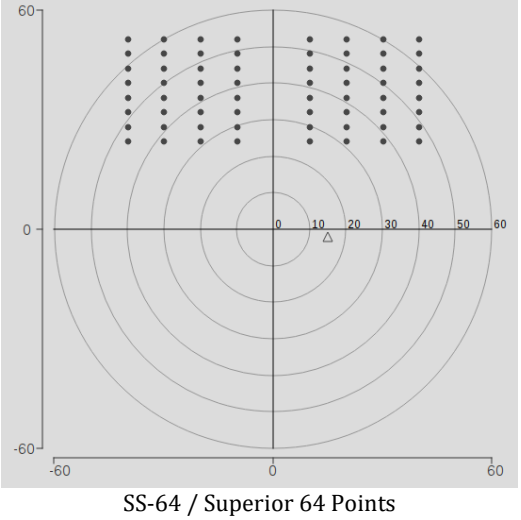
SF-135 / Full Field 135 Points
[IFA Only]



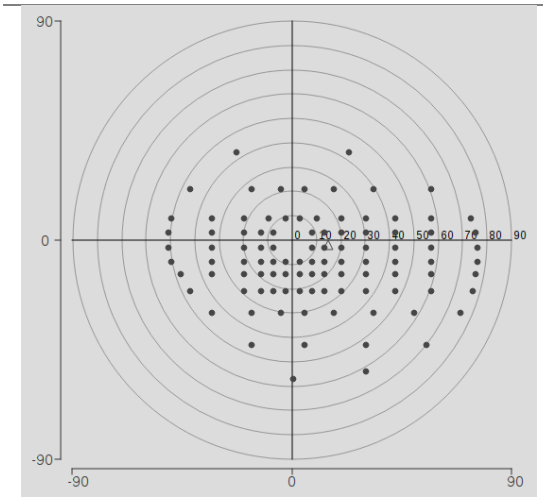
SF-246 / Full Field 246 Points
[IFA Only]



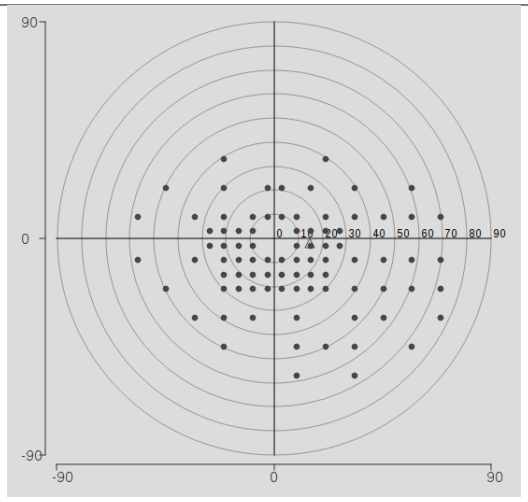
SS-36 / Superior 36 Points
[IFA Only]



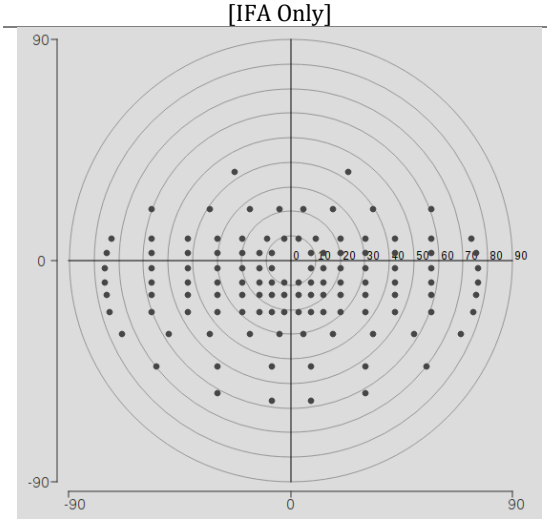
SS-64 / Superior 64 Points
[IFA Only]



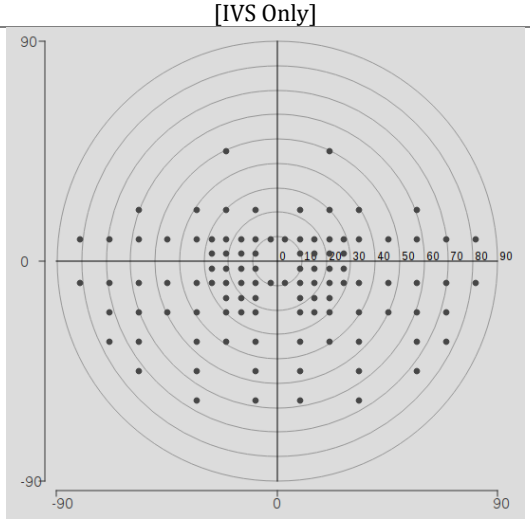
EM-M / Esterman Monocular
[IFA Only]



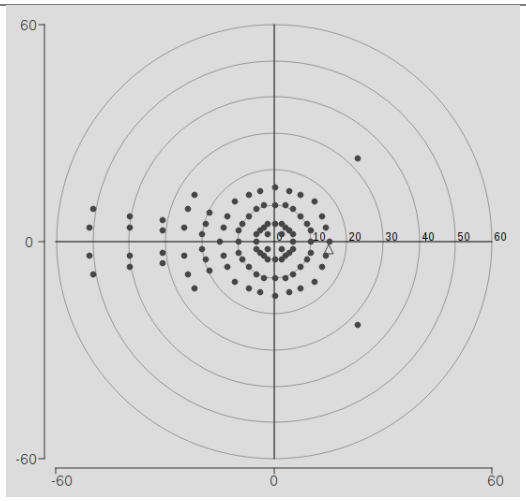
EM-M / Esterman Monocular
[IVS Only]



EM-B / Esterman Binocular
[IFA Only]



EM-B / Esterman Binocular
[IVS Only]



SF-Armaly / Armaly Full Field
[IFA Only]

D. EMC

EN 60601-1-2

	Note: The perimeter needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided herein.

	Note: Portable and mobile RF communications equipment can affect medical electrical equipment.

	WARNING: The use of accessories, transducers and cables other than those specified may result in increased emissions or decreased immunity of the equipment.

	WARNING: The perimeter should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the equipment or system should be observed to verify normal operation in the configuration in which it will be used.

	**Accessory Equipment** WARNING: Accessory equipment connected to the analog and digital interfaces must be certified according to the respective IEC standards (e.g., IEC 60950 for data processing equipment and IEC 60601-1 for medical equipment). Furthermore, all configurations shall comply with the system standard IEC 60601-1-1. Any person who connects additional equipment to the signal input part or signal output part configures a medical system, and is therefore responsible for ensuring that the system complies with the requirements of the system standard IEC 60601-1-1. If in doubt, consult the technical service department or your local representative.

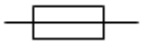
E. Troubleshooting

Please follow below troubleshooting instruction to solve the failures of perimeter. If the problem remains, please contact Shanghai VisuScience Meditech Co., Ltd. or its authorized distributor for further assistance. The model name and serial number are required when reporting troubleshooting.

The serial number is printed on label on the back side of perimeter or could be found on the login window of the software.

Perimeter can't turn on
Check power cord connections to perimeter, power table and wall outlet. Check power switch on power table.
Touch screen malfunctioned when pressed
Make sure finger is perpendicular to the touch screen. Try using pencil eraser to make selection. Perform touch screen calibration.
Patient responder does not beep when pressed
Check the connection of patient response button to the perimeter. Confirm if patient properly press and release responder's button.
Date on screen is incorrect
Update it by pressing DATE AND TIME on System Setup window.
Does not print
No power to printer – check if the power cord is connected and check if power switch is on – Check if there is power to power table No paper in printer

F. Labels & Symbols

	Caution, consult accompanying documents
	Type B applied parts
	Fuse
	Alternating current(AC)
	Protective earth(ground)
	Power On
	Power Off
	USB Connector
	Keep Dry
	This end up
	Fragile
	Avoid squeezing

G. Product Specifications

Δ Optional

Dimension and Weight

Dimension	56 L x 49 W x 60 H (cm)
Weight	24 Kg

Product Safety & Classification

Standard	IEC 60601-1
Class I Equipment	Protection against electrical shock
Type B	Degree of protection against electric shock of applied part (chin and forehead supporters)
Ordinary Equipment (IPX0)	Degree of protection against ingress of liquids (none)
Continuous Operation	Mode of operation

Operation Conditions

Temperature	+5 to +40 deg. C
Relative Humidity	≤85%, excluding condensation
Atmospheric Pressure	760 to 1060hPa

Expected Lifespan

Storage	20 years
Usage	15 years

Contraindications

Mentally retarded or uncooperative subject

Electrical Requirements

Input	AC 100-240V，50～60Hz
Power consumption	100 VA

General

Max temporal range	90°
Testing distance	30cm
Threshold strategy	Full Threshold，Fast Ladder，HISA，Standard Threshold
Screening strategy	Two Zone，Three Zone，Quantify Defects
Responder	Hand held，Foot pedal$^{\Delta}$（for upper limb disabled）
OS	Dedicated OS，immune for general computer viruses
Operator interface	15" LCD touch screen，Keyboard & Mouse$^{\Delta}$
Data Storage	≥32GB，More than 1,000,000 test results
Data Backup	Flash Disk，Portable Hard Disk$^{\Delta}$，Networking
Networking	Ethernet & WIFI

IVS-201B Specification

Stimulus generation	IVS - Hidden LED Array	
Background illumination	31.5 asb (10cd/m^2)	
Stimulus size	Goldmann III	
Threshold test library	T30-2, T24-2, T10-2, T-Macula, T60-4, T60-2	
Screening test library	S-40, S-64, S-76, S-60	
Specialty test patterns	D-30, D-60, EM-M, EM-B, Horizontal (Driver test in China)	
Software features	Visual Field Index	Glaucoma Hemifield Test
	Single field analysis	Serial field overview
	HISA Analysis	Glaucoma Progression Analysis
	Networking	PosEYE
	Pupil Measurement	Horizontal Analysis

IVS-201A Specification

Stimulus generation	IVS - Hidden LED Array
Background illumination	31.5 asb (10cd/m^2), 100 cd/m^2
Stimulus size	Goldmann III

Threshold test library	T30-2, T24-2, T10-2, T-Macula, T60-4, T60-2
Blue/Yellow perimetry	T24-SWAP，T30-SWAP
Screening test library	S-40, S-64, S-76, S-60
Specialty test patterns	D-30, D-60, EM-M, EM-B
Software features	Visual Field Index　Glaucoma Hemifield Test Single field analysis　Serial field overview HISA Analysis　Glaucoma Progression Analysis Networking　PosEYE Pupil Measurement　SWAP Analysis DICOM　Custom Program

IFA-900 Specification

Stimulus generation	Front Projection
Background illumination	31.5 asb (10cd/m^2)
Stimulus size	Goldmann III
Threshold test library	T30-2, T24-2, T10-2, T-Macula, T-NS, T60-4, T60-2
Screening test library	S-40, S-64, S-76, S-80, S-Armaly, S-NS, S-60, SF-81, SF-120, SF-135, SF-246, SS-36, SS-64, SF-Armaly
Specialty test patterns	EM-M, EM-B
Software features	Visual Field Index　Glaucoma Hemifield Test Single field analysis　Serial field overview HISA Analysis　Glaucoma Progression Analysis Networking　PosEYE Pupil Measurement

IFA-950 Specification

Stimulus generation	Front Projection
Background illumination	31.5 asb (10cd/m^2) , 100 cd/m^2
Stimulus size	Goldmann I - V
Threshold test library	T30-2, T24-2, T10-2, T-Macula, T-NS, T60-4, T30V-2, T60-2
Blue/Yellow perimetry	T24-SWAP，T30-SWAP
Regional Condensed Test (Micro Perimetry)	RCS-30, RCS-24

Colored perimetry	Blue stimuli	
Screening test library	S-40, S-64, S-76, S-80, S-Armaly, S-NS, S-60, SF-81, SF-120, SF-135, SF-246, SS-36, SS-64, SF-Armaly	
Specialty test patterns	EM-M, EM-B	
Software features	Visual Field Index	Glaucoma Hemifield Test
	Single field analysis	Serial field overview
	HISA Analysis	Glaucoma Progression Analysis
	Networking	PosEYE
	Pupil Measurement	SWAP Analysis
	DICOM	Custom Program

IFA-960 Specification

Stimulus generation	Front Projection	
Background illumination	31.5 asb (10cd/m^2) , 100 cd/m^2	
Stimulus size	Goldmann I - V	
Threshold test library	T30-2, T24-2, T10-2, T-Macula, T-NS, RT30-2, GT30-2, T60-4, T30V-2, T60-2	
Blue/Yellow perimetry	T24-SWAP，T30-SWAP	
Regional Condensed Test (Micro Perimetry)	RCS-30, RCS-24	
Colored perimetry	Blue stimuli, Red stimuli, Green stimuli	
Screening test library	S-40, S-64, S-76, S-80, S-Armaly, S-NS, S-60, SF-81, SF-120, SF-135, SF-246, SS-36, SS-64, SF-Armaly	
Specialty test patterns	EM-M, EM-B	
Kinetic perimetry	Standard, Scotoma Map, Blind Spot Map, Static Points, Custom Scan	
Software features	Visual Field Index	Glaucoma Hemifield Test
	Single field analysis	Serial field overview
	HISA Analysis	Glaucoma Progression Analysis
	Networking	PosEYE
	Pupil Measurement	SWAP Analysis
	DICOM	Custom Program

Service Contract

A Warranty Extension Agreement (Service Contract) is available after one-year. Please contact local distributor for perimeter for more information.

Limited Warranty

This Warranty gives you specific legal rights, and you may have other rights which vary from state to state. For one year from the date of delivery (the "Warranty Period") to the original purchaser ("You", "Your", "Purchaser"), IRC Medical Equipment Co., Ltd. ("IRC", "seller", "we", "are", "us") warrants its perimeter, excluding components and software as stated below (the "perimeter") to be free from defects in material or workmanship. In the event of failure, Seller's obligation is limited to repair or replace on an exchange basis the parts which have been promptly reported as defective by Purchaser during the Warranty Period and is confirmed as defect by Seller upon inspection. This Warranty only applies to the original Purchaser and shall not, in any way, be transferable or assignable.

Warranty claims procedure:

(1). Report the failure of perimeter in details with serial number to the authorized distributor.

(2). Authorized distributor will response to the failure within 48hours.

(3). Authorized distributor will remote guide troubleshooting

(4). Authorized distributor will send the engineer to check the failure on-site if it is needed.

The warranty does NOT cover: consumable items such as eye pouch, paper or storage media, or the service of any external printer will be covered by their manufacturer's warranty. This Warranty will NOT be applied if repair or parts replacement is required because of accident, neglect, misuse, acts of god, transportation or causes other than ordinary use, or supplies or accessories that do not meet the proper operating specifications of IRC. This Warranty does NOT apply to any part that have been repaired or altered by unauthorized distributor by IRC.

All data stored on the microSD card, USB storage devices are the Purchaser's records, and it is your responsibility to preserve the integrity of these files. IRC, VisuScience and his authorized distributor is not responsible for the loss of patient files stored on the microSD card, USB storage devices, or other storage medium.

User(s) bear the entire risk as to the quality and performance of the software. IRC does not guarantee that the software will meet user's requirements, that the operation of the software will be uninterrupted or error-free, or that all software errors will be corrected. User(s) assume the responsibility for the installation, use and results obtained from the perimeter and programs.

The Warranty does NOT extend to any diskette which has been damaged as a result of accident, misuse, abuse, or as a result of service, or

modification by anyone other than IRC. IRC has no liability or responsibility to any person or entity with respect to any claim, loss, liability, or damage caused or alleged to be caused directly or indirectly by any software supplied with the perimeter or by IRC.
Every reasonable effort has been made to ensure the specifications and functions described on the user manuals and marketing materials correct at the time of publication. However, because of on-going improvements and product updates, we cannot guarantee the accuracy of printed materials after the date of publication, and disclaims liability for changes, errors or omissions. All instrument specifications are subject to change without notice.

Software Copyright

The software program ("Software") included in perimeter is a proprietary of IRC and in certain instances contains material proprietary to Microsoft Corporation, Apple Computer. These proprietary products are protected by copyright laws and international treaty. You must treat the software like any other copyrighted material.

Copyright © 2019 IRC Medical Equipment Co., Ltd. All rights reserved.

Acknowledgment

You acknowledge that you have read all the provisions in this Appendix, including this License and Limited Warranty, understand and agree to be bound by the aforesaid terms and conditions.

Subject to change in design or specifications without advance notice

Version: 1.12 20191104

International Business Unit:

Shanghai VisuScience Meditech Co., Ltd.

Add: No. 344 Sanlin Road, Pudong New Area, Shanghai 200124, China

Tel/Fax: +86 21 349 736 59 | Website: www.visuscience.com | Email: info@visuscience.com

Manufacturer:

Chongqing IRC Medical Equipment Co., Ltd

Add: 402, Unit 3, Term 1, Standard Workshop, No. 98, Xiyuan 2 Road, Shapingba District, Chongqing, China

EC REP

Shanghai International Holding Corp. GmbH (Europe)

Address: Eiffestrasse 80, 20537 Hamburg, Germany

Tel.: +49 40 2513175

CE