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Additional Information

VisualEyes™ 515/525

Micromedical
by Interacoustics

Interacoustics

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Table of Contents

1 Basics to Perform Tests

1.1 Moving through VisualEyes™

VisualEyes™ 515/525 software suite is compatible with both touch capable (Figure 1.1-1) and standard (non-touch) computer systems. Maneuvering through the software can be done by touch, mouse, keyboard, foot pedal and remote control.

Selecting a patient profile:

The user can create or select a patient profile through OtoAccess® to enter VE system. The user can also switch to OtoAccess® screen to choose different patient profile while using OtoAccess® ver 2. The user has to exit the VE system in order to access the different patient profile while using earlier versions of OtoAccess®.

Figure 1.1-1 Touch user interface

1.2 Begin testing

To begin the testing process, from the main screen select **Begin Testing** button (Figure 1.2-1). The software will enter the first test of the selected protocol. If any specific protocol is not selected then, preconfigured default protocol will be started. The user can change the protocol using the drop-down box below the Begin Testing button.

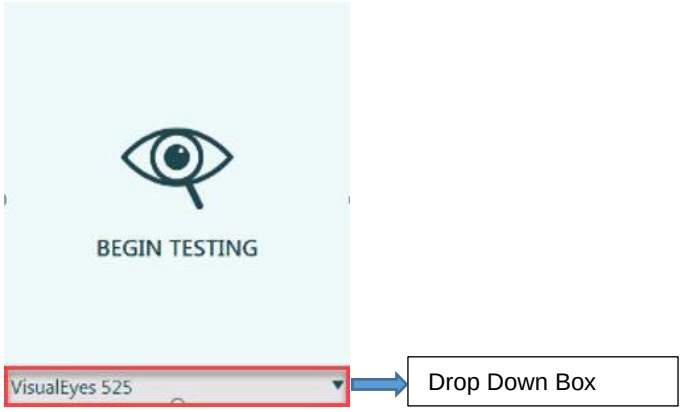


Figure 1.2-1 Begin Testing Button with protocol selected

The VisualEyes™ system has a default protocol defined by the product installed. VisualEyes™ 515 (VNG or ENG without oculomotor tests) and VisualEyes™ 525 (VNG or ENG with oculomotor tests) protocols with default settings are created that allows the user to begin testing immediately. The following tests and their order make up the default VNG test battery:

VisualEyes 515 Protocol:

- Calibration
- Spontaneous Nystagmus
- Dix-Hallpike
- Positional
- Calorics

VisualEyes 525 Protocol (includes the VisualEyes 515 protocol):

- Video Frenzel
- Gaze
- Smooth Pursuit
- Random Saccade
- saccadometry
- Optokinetic
- Ocular Counter Roll

If rotational chair hardware is available and licensed these additional tests will appear with the VisualEyes 515 or VisualEyes 525 protocol (The VisualEyes™ system supports seven types of chairs including Nydiag 200, System 2000 Reclining, System 2000 AutoTraverse, System 2000 Comprehensive, Orion Reclining, Orion AutoTraverse and Orion Comprehensive chairs) :

- Step Velocity
- Sinusoidal Harmonic Acceleration
- VOR Suppression
- Visual VOR
- Subjective Visual Vertical (SVV)-Static (Only with Orion Autotraverse, Orion Comprehensive, System 2000 AutoTraverse and System 2000 Comprehensive chairs)
- Subjective Visual Vertical (SVV)-Dynamic (Only with Orion AutoTraverse and System 2000 AutoTraverse chairs)

The test battery can be customized with additional tests being compatible with other additional components such as VORTEQ™ IMU / VORTEQ™ rate sensor with VLink or EyeSeeCam.

- VORTEQ™ AHR (525)
- vHIT for VORTEQ™ (525)
- Dynamic Visual Acuity (DVA) (505, 515 and 525)
- Dix Hallpike Advanced (505, 515, 525)
- Lateral Head Roll (505, 515, 525)
- ESC vHIT (505, 515 and 525)

The process of creating custom protocols is explained in detail in section 8 of this manual.

Using the touch screen or mouse to select the **Begin Test** and the first test in the list of your test battery will be shown on screen (Figure 1.2-2).

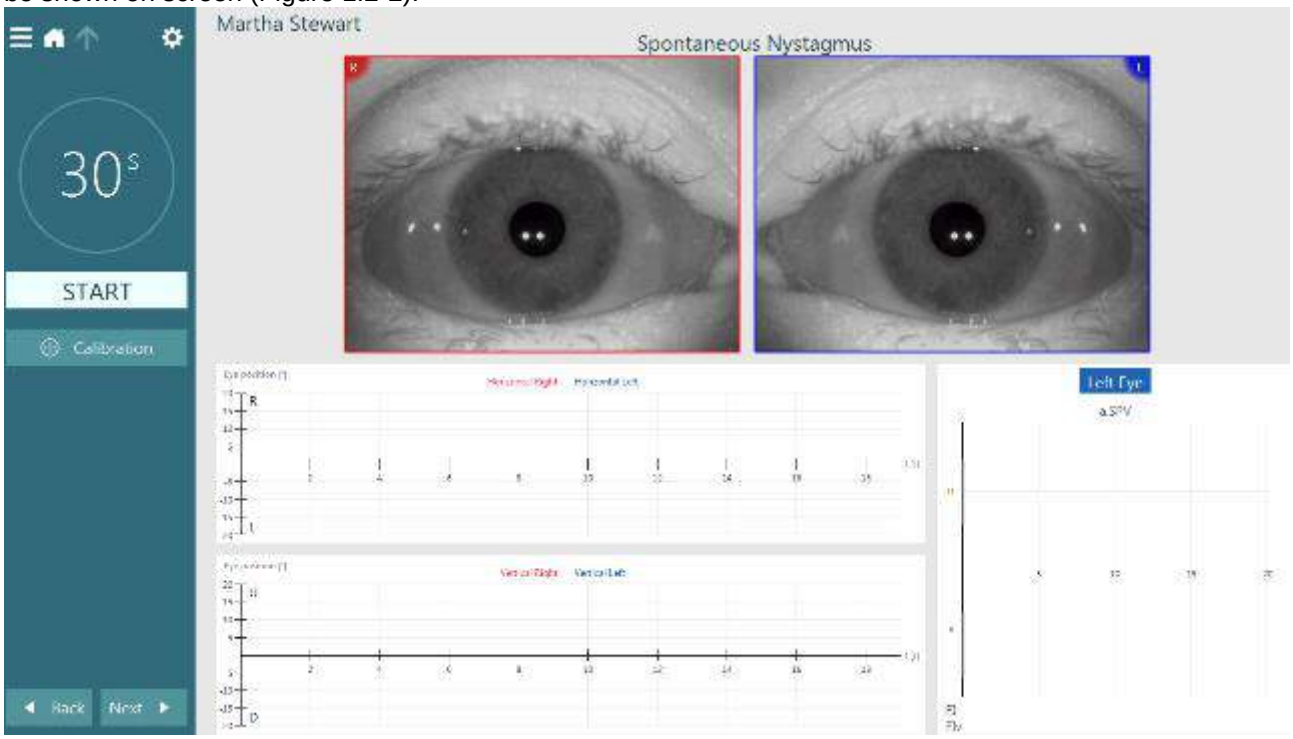


Figure 1.2-2 First test displayed

1.3 Starting a test

Tests can be started in multiple ways:

- Click the **Start** button on the Test Screen. This option is available for all tests.
- Press the **Enter** button on the RF Remote (if available). Ideal for starting the test when not at the computer. This option is available for all VNG tests. Rotational chair tests do not respond to the RF Remote's **Enter** button as a patient safety measure.
- On the Top mount goggle, press the **Goggles Switch** on the side of the goggles. The Top mount camera goggles switch is ideal for starting the test when at the patient's side such as in Dix-Hallpike and Positional tests.
- Press the **irrigator handle button** on the Air Fx or Aqua Stim to start the irrigation and Caloric test. This is only available in caloric tests.
- Press the **foot pedal** (if available). Ideal for starting the test when not at the computer. This option is available for all tests. Care should be taken if using the foot pedal with the reclining chair that the foot pedal is far enough away from the reclining chair for the operator to not be injured from the chair in rotation.

Moving through the screens

- Test menu which is in the upper right corner of the test navigation bar allows a user to view current test session.
- Home button will return to the main screen
- The up-arrow button will exit current subtest and go to the individual subtest summary screen (Figure 1.3-1)
- The settings icon which is present next to up-arrow allows a user to adjust the parameter for the test temporarily (refer Figure 1.3-1).
- Remote control will navigate the buttons in pop up message windows, allowing the user to respond to pop up messages with the remote control

Restarting the test:
Tests can be restarted using the Esc key on the keyboard or the RF Remote. While the test is running, the Esc key or ESC key on the RF Remote will abort the data collection and clear the data already collected. In caloric tests, the software will require confirmation of this request.

Rotational chair tests can be restarted using the Esc key on the keyboard, though the use of the RF Remote is ignored during rotational chair tests as a patient safety measure. The software will require confirmation of this request.

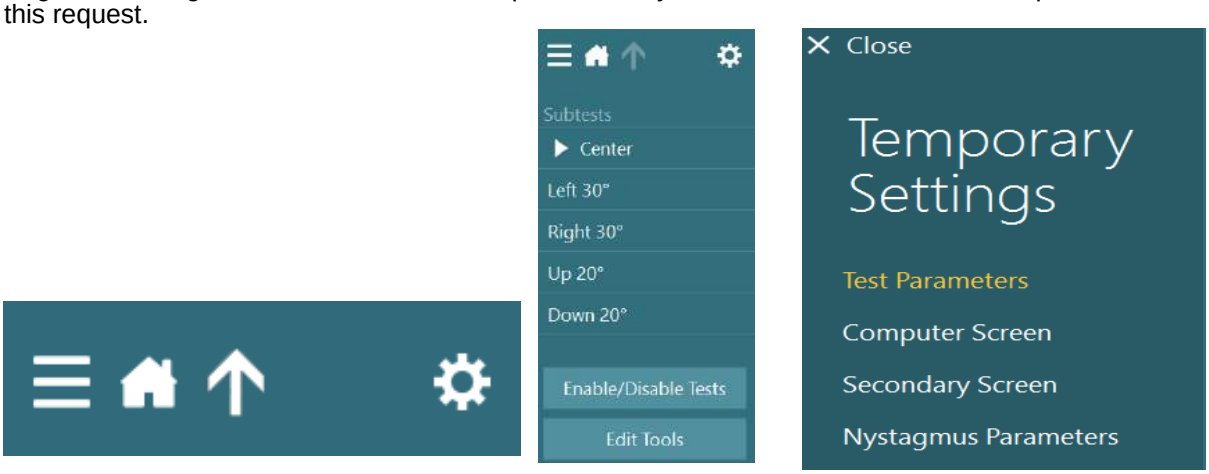


Figure 1.3-1 Test Navigation Bar, Test summary with all subtests, Temporary setting option (left to right)

Caution
No other PC programs should be running or minimized while testing the patient with the software. This can interfere with the running of the VisualEyes™ Software.

1.4 Session tree

Clicking icon will display the list of tests in the current session. The test listed in yellow is the active test. Tests that have been completed are given either a green checkmark or a red diamond depending on the test results. This also means those are the tests with data. In case the operator decides to change the test result, she/he can manually change the green checkmark into a red diamond with green pencil and vice versa by clicking or touching that icon in the menu (Figure 1.4-1). Clicking or touching the test title will navigate to the desired test.

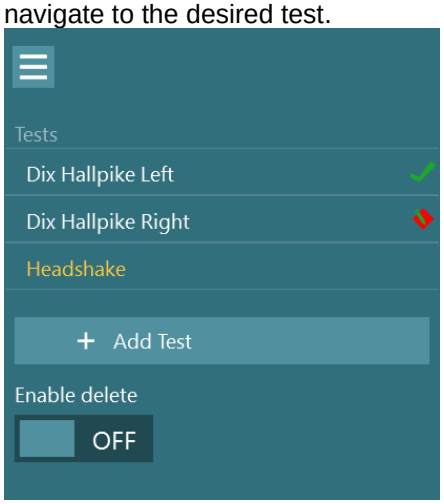


Figure 1.4-1 Session tree displaying tests completed

1.5 Eye image adjustment

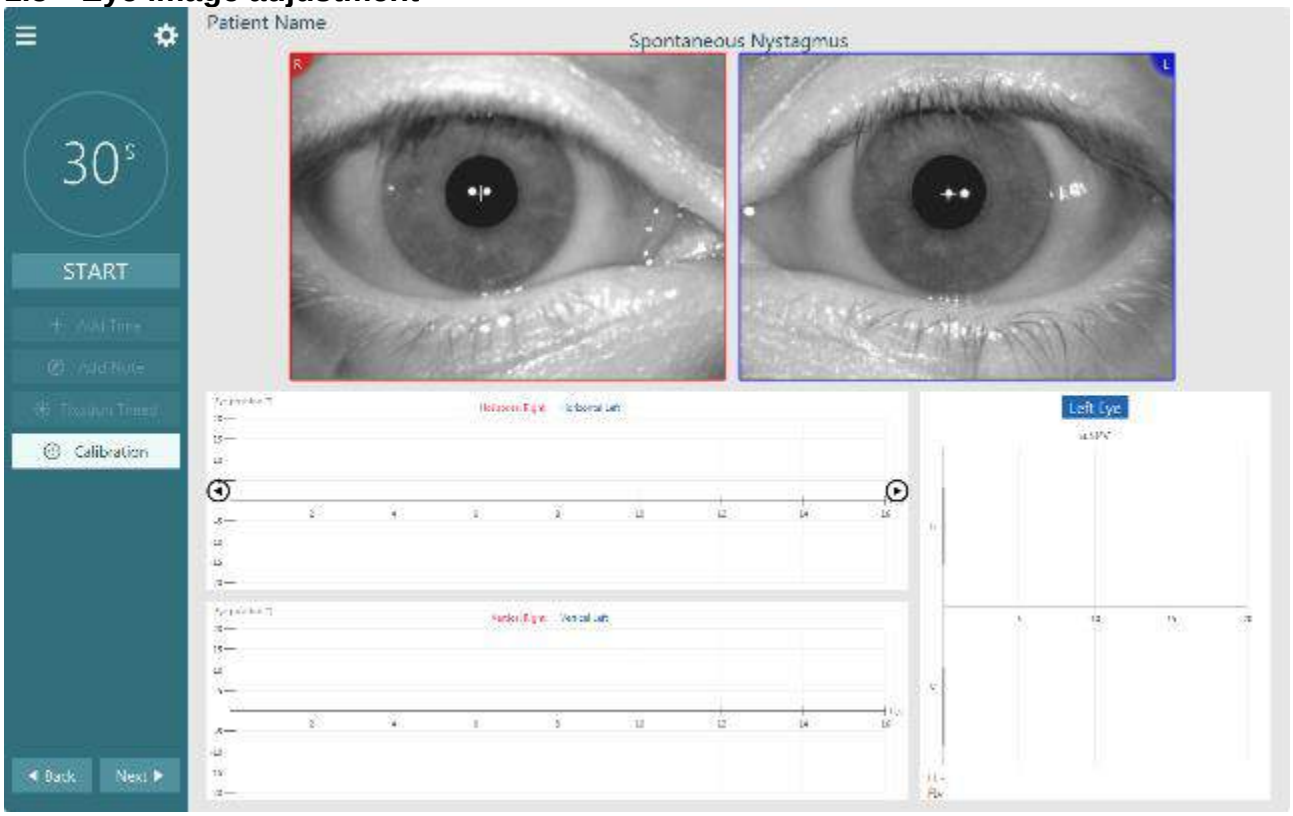


Figure 1.5-1 Test Screen Display (Spontaneous Nystagmus)

The user can see the patient's eye image as soon as **Begin Testing** option is selected from the main menu display. This will open the first test and the image of the patient's eyes (Figure 1.5-1) will appear in the upper portion of the user display. Prior to starting the testing procedure, it is required that the eye images are aligned (horizontally/vertically) so that the pupil is centered in the observed eye image.

The inner canthus of the right eye should be seen on the right side of the red outlined eye image. The inner canthus of the left eye should be seen on the left side of the blue outlined eye image. The eye images have L and R captions in the corners, which refer both to the eye selected and the direction the eye is looking.

NOTICE Prior to launching VisualEyes™ make sure that the cameras are connected. If the user couldn't view the eye image it indicates that cameras are disconnected, and an informational status will be displayed as shown in the Figure 1.5-2.

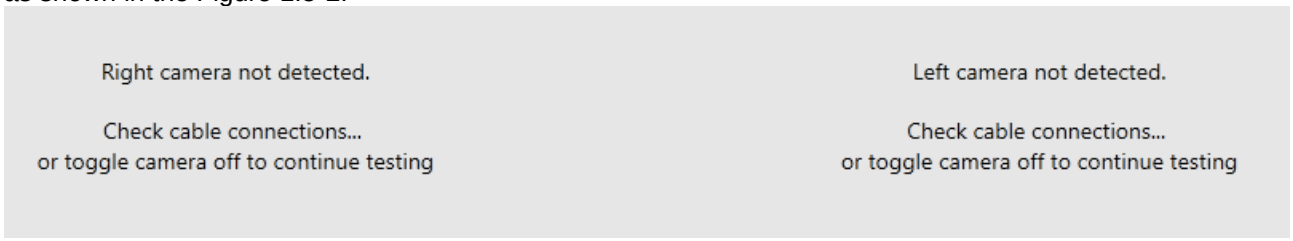


Figure 1.5-2 Cameras Disconnected Status

This can happen with one or both of the cameras, in that case check the camera cables to make a solid connection between the camera and the computer.

How to adjust eye image using Side-Mounted Camera Goggles
Use the knobs on the camera cabinet to move the camera horizontally and vertically to center the eye image on the screen. (Figure 1.5-3).

Figure 1.5-3 Side mount cameras adjustment knobs for regulating image and focus

1. The upper knob moves the camera vertically.
2. The left knob moves the camera horizontally.
3. The center knob adjusts image focus.

The mirrors can also be rotated inward by holding the mirror edges. A gentle inward rotation of mirrors can help to adjust for smaller faces and narrow inner-canthal spaces (e. g. with children). When the mirrors are rotated, the image will need to be re-centered and may need focus adjustment. (Figure 1.5-4)

Figure 1.5-4 Mirror adjustment for smaller faces or narrow inner-canthal spaces

How to adjust eye image using Top-Mounted Camera Goggles

When the top-mount camera goggles are used, the user can see a ‘Center eyes’ icon in the screen where the eye images are displayed. By clicking or touching the center eyes icon (Figure 1.5-5), the eye images will be centered.

The same function can be performed by clicking the CENTER button on the IR handheld remote control.

Figure 1.5-5 Center eyes icon

Front mounted cameras

Position the front mounted camera unit on the viewport with the fixation light at the top center. Use the ball and socket mechanism on the camera unit to aim the camera and center the eye image approximately in the software. Next, with one hand on the back of the patient’s head, push in gently on the camera to lock it in place. Lock the cable in the clip on top of the goggles.

Figure 1.5-6 Placement of Front Mount Camera in Goggles

How to adjust eye image using EyeSeeCam camera Goggles
When the ESC camera goggles are used, move the whole camera unit to adjust the camera images in the screen (Figure 1.5-7).

Figure 1.5-7 ESC cameras adjustment knobs for regulating image

1.6 Focus adjustment

The VisualEyes™ system requires a focused eye image for the pupil tracker to locate the pupil center to optimally record the eye movements. The pupil center is marked with a crosshair (Figure 1.6-1).

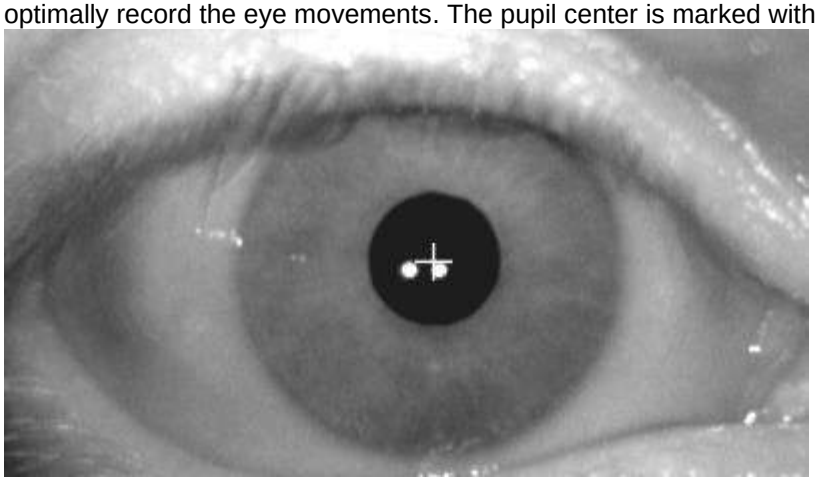


Figure 1.6-1 Pupil tracker (crosshair)

The camera image can be focused by adjusting the focus knob on each camera (Figure 1.6-2). Each image must be adjusted separately. Turn the knob clockwise or counterclockwise while watching the image on the screen. Stop turning the knob when the pupil outline and iris pattern is clear even if the eye surroundings may be blurry at this point.

If the image is not optimally focused, the eye tracker may fail to adequately record the eye movements which may lead to poor results.

NOTICE *This crosshair will also be present in the review videos for easier discrimination between abnormalities and technical difficulties.*

Figure 1.6-2 Adjustment control for focusing eye image on each camera

1.7 Eye image contrast adjustment

The VisualEyes™ system automatically adjusts the threshold (contrast), in order to display an optimized eye image. Nevertheless, in some cases it might be necessary to adjust the threshold. In these cases, the automatic threshold adjustment can be turned off before or during recording by clicking the threshold adjustment button (Figure 1.7-1). The button will be shown when the user touches the eye image or places the mouse over the eye images.

Figure 1.7-1 Threshold adjustment button

When the threshold adjustment button is selected, a scrollbar will appear for each eye's contrast level. By default, the A button will be highlighted indicating the system is automatically adjusting the contrast threshold level. Slide the scrollbar value with the mouse or finger to the position where the crosshair is viewable. Have the look left, right, up, and down to verify the threshold level and adjust as necessary so the crosshair will track the pupil while looking in each direction. (Figure 1.7-2). To reset it back to automatic threshold, click the A icon below each slider.

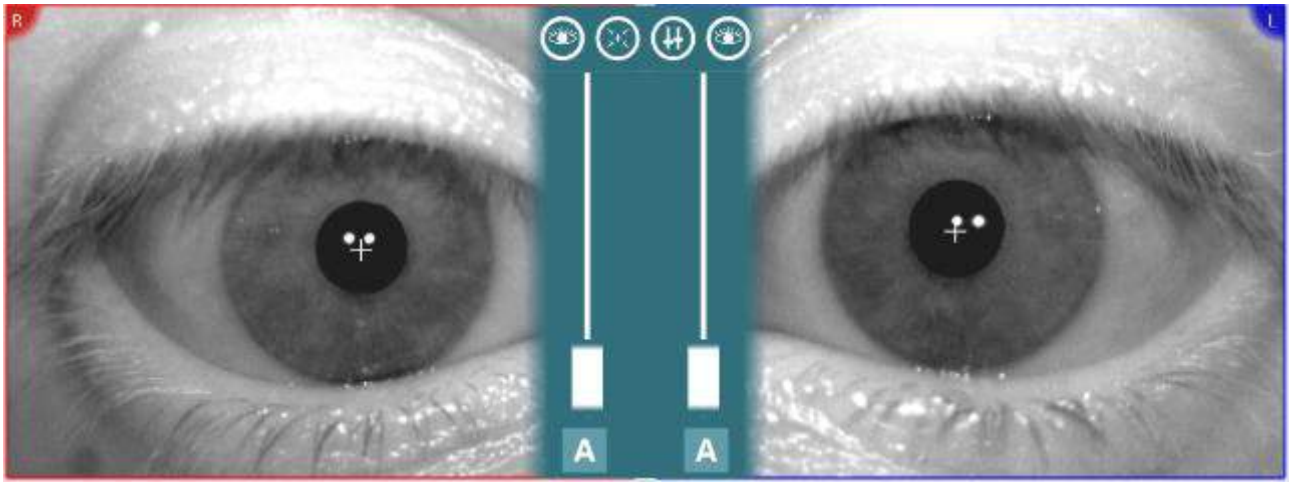


Figure 1.7-2 Threshold adjustment scrollbars

1.8 Enlarging eye images

Enlarging the eye images can help the clinician clearly visualize the eye image during eye image adjustments and within different tests. Alternatively, if a stimulus display is connected the eyes are displayed on that screen when no target is used, providing an even larger image of the eyes for viewing. Double clicking on one of the displayed eyes will enlarge the eye windows on the screen. (Figure 1.8-1 and Figure 1.8-2). The eye position traces screen are hidden while the eye images are enlarged. To exit this viewing mode, double click on the eyes again.

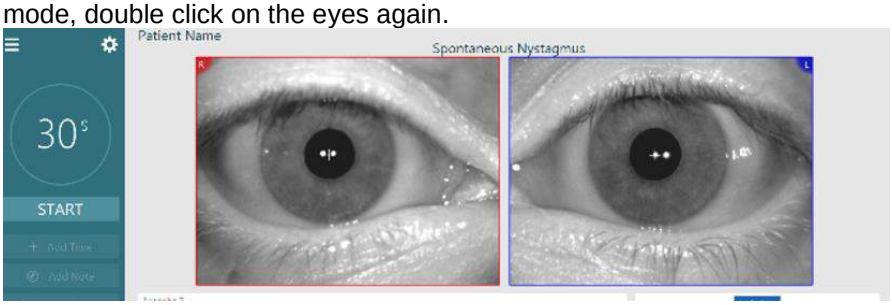


Figure 1.8-1 Before enlarging eye images

Figure 1.8-2 Enlarged eye images

1.9 Monocular vs binocular eye recordings

VisualEyes™ system can record in either monocular (one camera) or binocular (two cameras) mode. Monocular mode may be beneficial for those occasions needing to run a single eye test because one eye may be unable to be tested. (i. e. the eye is artificial or severe ptosis). To deselect an eye during testing, touch the eye images or hovering over with the mouse to display the eye tools menu (Figure 1.9-1). Click or touch the eye button for the eye to be ignored (Figure 1.9-2) during testing and the software will ignore the selected camera for the duration of testing. To track the pupil again, display the eye tools menu again and select the ignored camera.

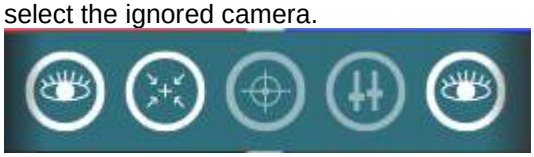


Figure 1.9-1 Eye tools menu

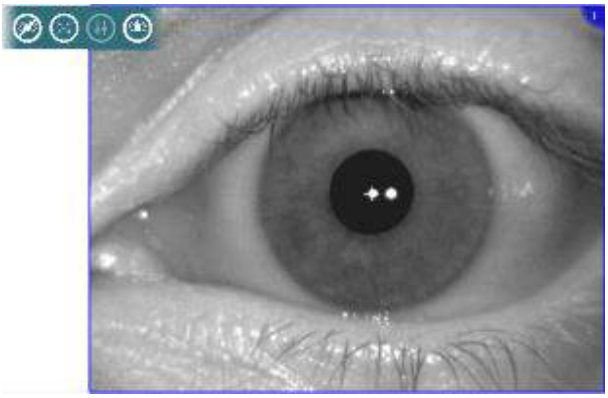


Figure 1.9-2 Left eye selected and right eye ignored

1.10 Eye Tracker selection

VisualEyes™ can utilize different tracking methods depending on the test performed and the patient's eyes. The crosshair button in the eye tools menu allows the user to change the eye tracker when needed.

- Curve Tracker – Standard eye tracker using a curve recognition algorithm for isolating the pupil outline
- IPM Tracker – Blob analysis eye tracker for locating the pupil center for high speed VHIT tracking
- Convex Hull Tracker – Eye tracker with geometric compensation for torsion tracking. Also recommended for large pupil tracking e. g. with pediatric testing.
- EyeSeeCam Tracker – Eye tracker used with EyeSeeCam camera for high speed VHIT tracking (exclusive for ESC and it preslected, so no need to select anything in the software)

When the test is complete, the eye tracker will be listed in the Temporary Settings for reference.

1.11 Common test functions

The following basic test functions apply to all tests within VisualEyes™ VNG.

Start – Begins the testing procedure (video and eye trace recordings).

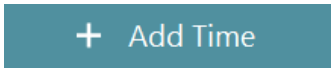
Stop – Stops the testing procedure (video and eye trace recordings).

Next – Moves onto next test/subtest in the protocol.

Back – Moves back one test/subtest in the protocol.

Timer
During testing (all tests) the timer will display how much time has elapsed or remains in the current test based on Count Style. Based on the default system settings, the timer will provide audible beeps and voice prompts at indicated intervals to prompt the examiner and provide audible feedback for the elapsed or remaining time in the test. To change these settings, see the section 13.4 Test Type settings.

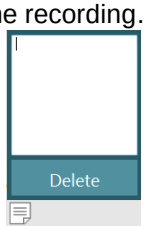
Add Time - Further time may be added to the test during the procedure by pressing the **Add Time** button. This will add a further 30 seconds (default) to the time remaining on the counter.



1.12 Add Note

One can insert a note at a specific point in the raw trace, during or after testing by selecting **Add Note** (Figure 1.12-1). This can also be used as an event marker to identify a unique event within the recording.

The time at which the note is inserted is shown with the symbol " " (figure XXXX): The text for note taking is limited to 33 characters. It will be hidden in the traces but will be uncovered when hovering over or clicking on the note symbol. When printing the test in the report, the note added will be displayed after the graphical printouts. The user can also delete the note using delete option which is seen under the note.



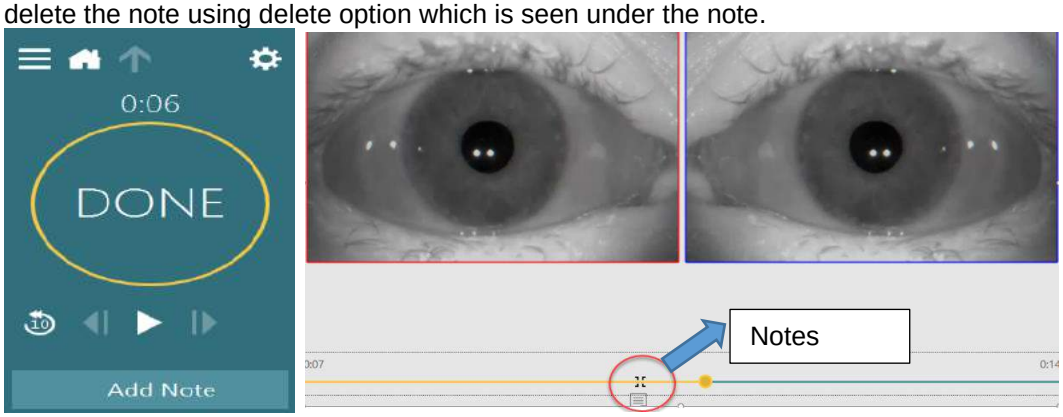


Figure 1.12-1 Add Note button and The location of note during the test.

1.13 Fixation suppression

There may be times in certain tests where a fixation light is presented to the patient to differentiate peripheral from central abnormalities.

The fixation light can be turned on manually (Figure 1.13-1) by the examiner by pressing the 'Fixation' button or by using the remote control.

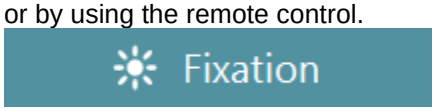


Figure 1.13-1 Fixation light button

The fixation light can also be set to be displayed in either left or right eye (default is left eye). This allows the examiner to select the better eye for fixation, particularly in those patients with visual impairments. This setting can be changed from the Input tab in the System Default Settings screen.

A yellow bar appears in the timeline when reviewing the test to mark the duration of the fixation light (Figure 1.13-2). The length of the bar determines the length of time the fixation light was active.

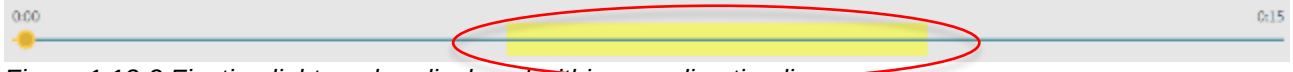


Figure 1.13-2 Fixation light marker displayed within recording timeline

1.14 Add Tests or Delete Tests

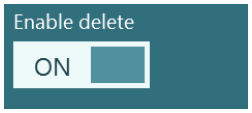
Each test has ‘Test menu’ in left up corner of test panel. If you click ‘Test menu’ the user can view the current test session with a test list.

To Add Tests

At the end of the test list, the user can find **Add Test** button, and this allows a user to find the list of tests to make his choice. Once the test is selected, it is added to the bottom of the patient’s test session.

Delete Tests

The user can also delete and/or replace any test (with or without data) the session to make new customized test list. To delete any test, the user should activate the ‘**Enable delete’** option which is at the end of the test list.




symbol appears besides each test in the test lists. This allows the user to delete any test of his/her choice. Clicking or touching this symbol will remove the test from the session. Refer Figure 1.14-1 for sample pictures.

NOTICE: Current test will be highlighted with yellow color and cannot be deleted. Once deleted, the test data cannot be recovered.

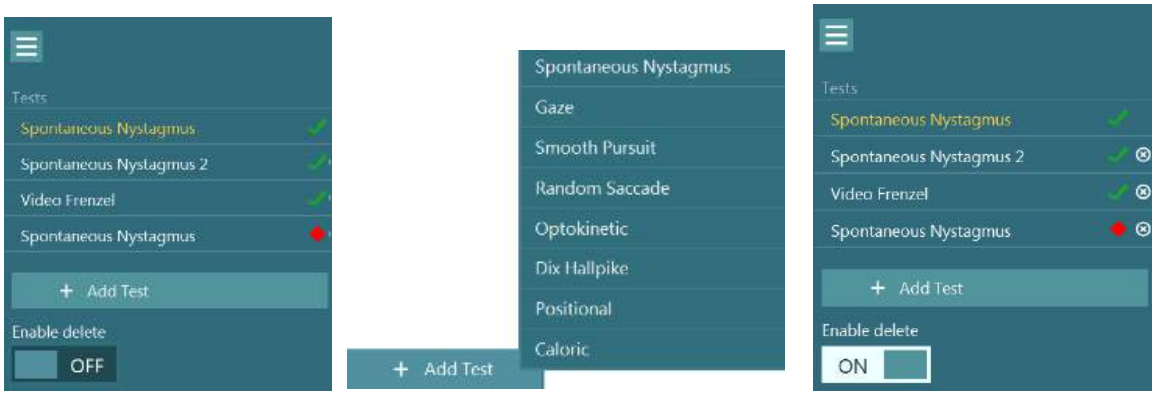


Figure 1.14-1 Test menu, Addition of a test and Deletion of a test

1.15 Repeating tests

A test can be repeated or replaced. After the test is completed, the user can click on the Repeat Test button (Figure 1.15-1). The software will ask if the test should be overwritten or a new test instance should be created to repeat the test (Figure 1.15-2). If the test is overwritten, the name will remain the same. If the test is repeated, then the name will have a number at the end of the test signifying the repeated status (e. g. Dix-Hallpike 2).

Figure 1.15-1 Repeat Test button

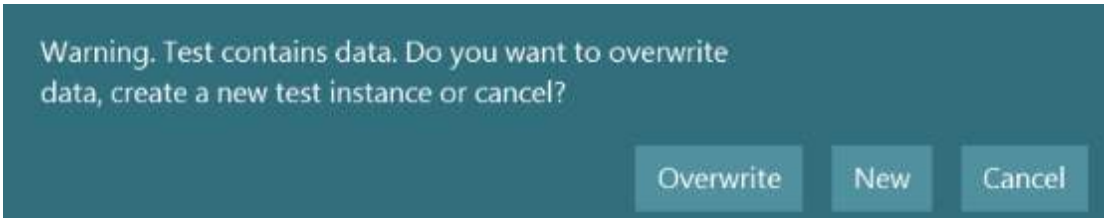


Figure 1.15-2 Overwrite or Repeat Confirmation Prompt.

1.16 Test review

Once the operator has ended the test, the software will allow the operator to review the patient's response during the test. The test review screen (Figure 1.16-1) contains the playback menu, timeline, eye and room video recordings. The eye videos and room camera video are played synchronously from the Test Review screen. The playback will begin by clicking on the play button in the playback menu. As the test plays back, a yellow circle will show the current position of the video on both the timeline and the playback timer. This circle can be grabbed or dragged with the mouse to jump to a new location in the video playback. The size slider is available during the test review, allowing the user to make the eyes or the room camera video larger dynamically to focus on the selected video during playback.

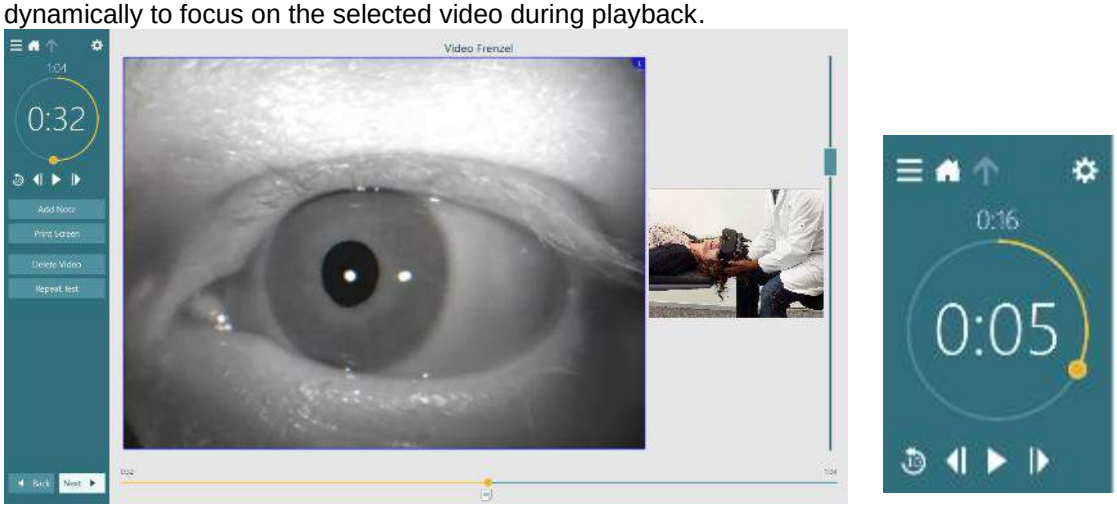


Figure 1.16-1 Test Review screen

Go to previous frame (hold to play backwards in slow motion).

Play/pause.

Go to next frame (hold to play forwards in slow motion).

Go back 10 secs in video playback.

2 Calibration

Calibrations are particularly important in tests where eye movements are compared with a given stimulus of a known position and/or velocity (e. g. Saccade test). Calibration can be performed on both eyes (binocular) or individually (monocular) by turning off the non-essential eye or using a monocular goggle. Calibration is strongly recommended for all tests to accurately measure the velocity of the nystagmus.

2.1 Source selection

Before selecting 'calibration option', user has to select the hardware source (Top mounted goggles / Side mounted goggles / Front mounted goggles / ESC / Pediatric observation camera / ENG in chair / Datalink) using 'select source' option (Figure 2.1-1). The options are based on their user license.

After selecting the data source, select the stimuli (TV / DLB / Laser and drum).

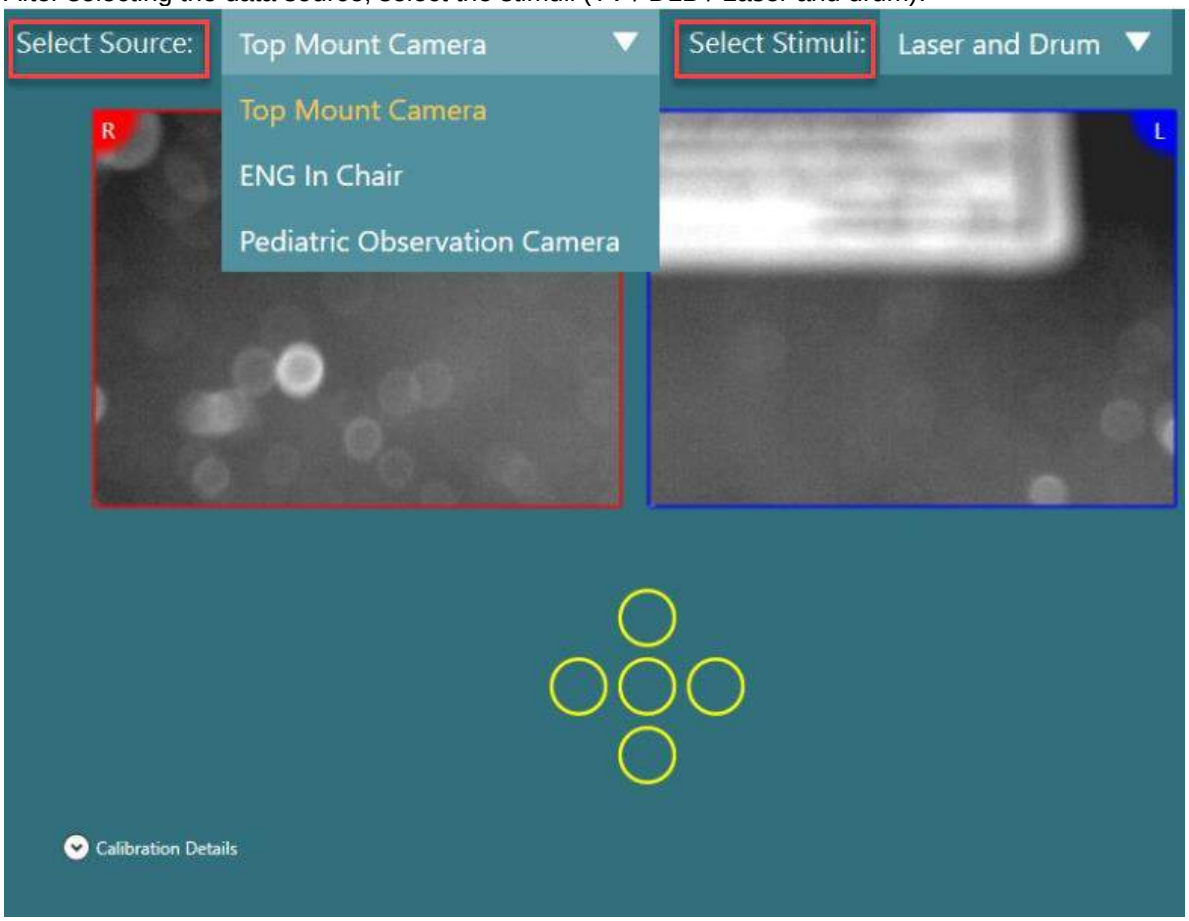


Figure 2.1-1 Hardware source selection

2.2 Checking Electrode Impedance (only with ENG option)

As a first step for impedance test, ensure that the hardware source for the input is set as 'DataLink' or 'ENG in Chair' depends on the license. This can be set using *system default setting>Input>DataLink or ENG in chair*. After setting the input source, the operator can view the ENG option as part of system default setting. The operator can now select the type of electrode montage under ENG option based on their choice and this can be set as default option for ENG evaluations

To start an impedance test for a patient, the operator clicks on 'Begin Testing' button on home page and now he can see the 'Calibration' option. The operator can also track the hardware (Datalink / Orion AT/C with ENG option) connection status below the '**Calibration'** button / **Impedance test** button. Clicking the 'Calibration' button shows options including 'Impedance Test' Clicking 'Impedance Test' button takes to the Impedance test screen (Refer Figure 2.2-1).

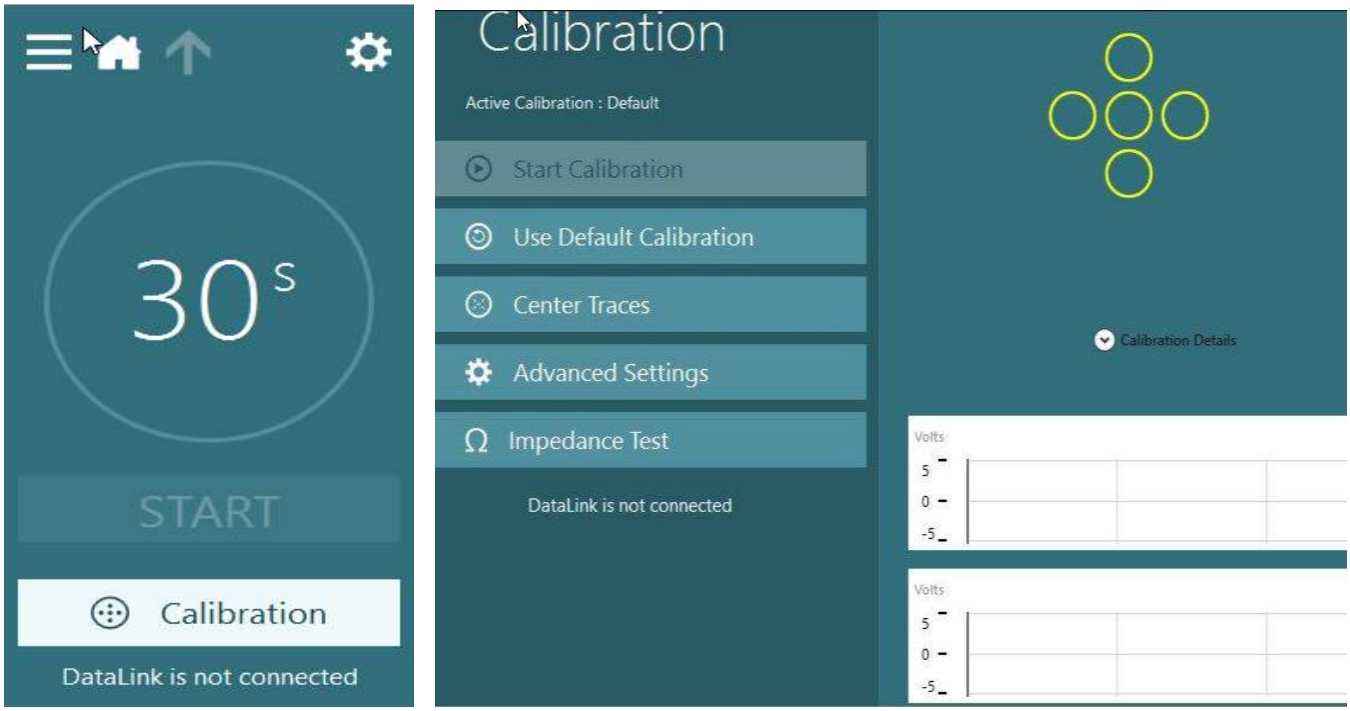
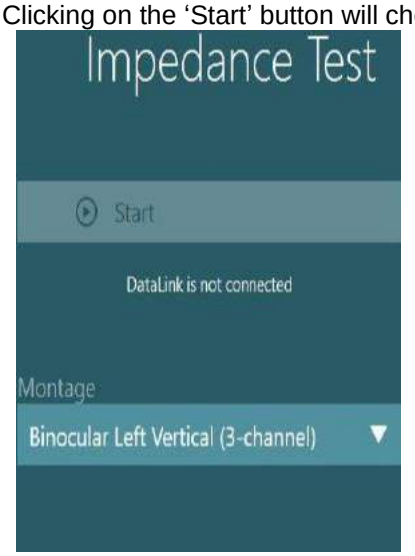


Figure 2.2-1 Sample screen for calibration and Impedance test options

The Impedance Test screen will show the default montage configuration which is set by the operator. The operator can change the montage type using the drop-down options (refer

Figure 2.2-2 **Error! Reference source not found.**). The operator can also refer section 4. 5. 4 of the IFU to know more about montages and electrode placement. Initially the electrode impedance values will be blank. ***Note:*** It is recommended to wait for approximately 5 minutes after placing electrodes to allow the electrodes to stabilize the signals before testing the impedance.

Clicking on the 'Start' button will check each electrode and report the impedance.



If the impedance is measured as value of 10 or less (good indicated by green color), between 11 and 15 (medium indicated by yellow color and between 16 and 20 (poor indicated by red color) and sometimes there may not be clean ENG signals are produced (indicated by black color).

If the electrodes are showing good (green) or medium (yellow) impedance, then click on the 'Accept and Close' button to exit the Impedance Test screen to proceed further. If the impedance is poor, the operator can repeat the test by clicking 'Redo all' button after a minute and if it continued to be poor, then it is recommended to remove the electrode sensor, abrade the skin again, then re-fix the electrodes. The operator can also click on the specific sensor to retest the impedance of that sensor only. Please refer Figure 2.2-3 for the impedance test screen with possible options.

Figure 2.2-2 Impedance Test button with hardware connection status

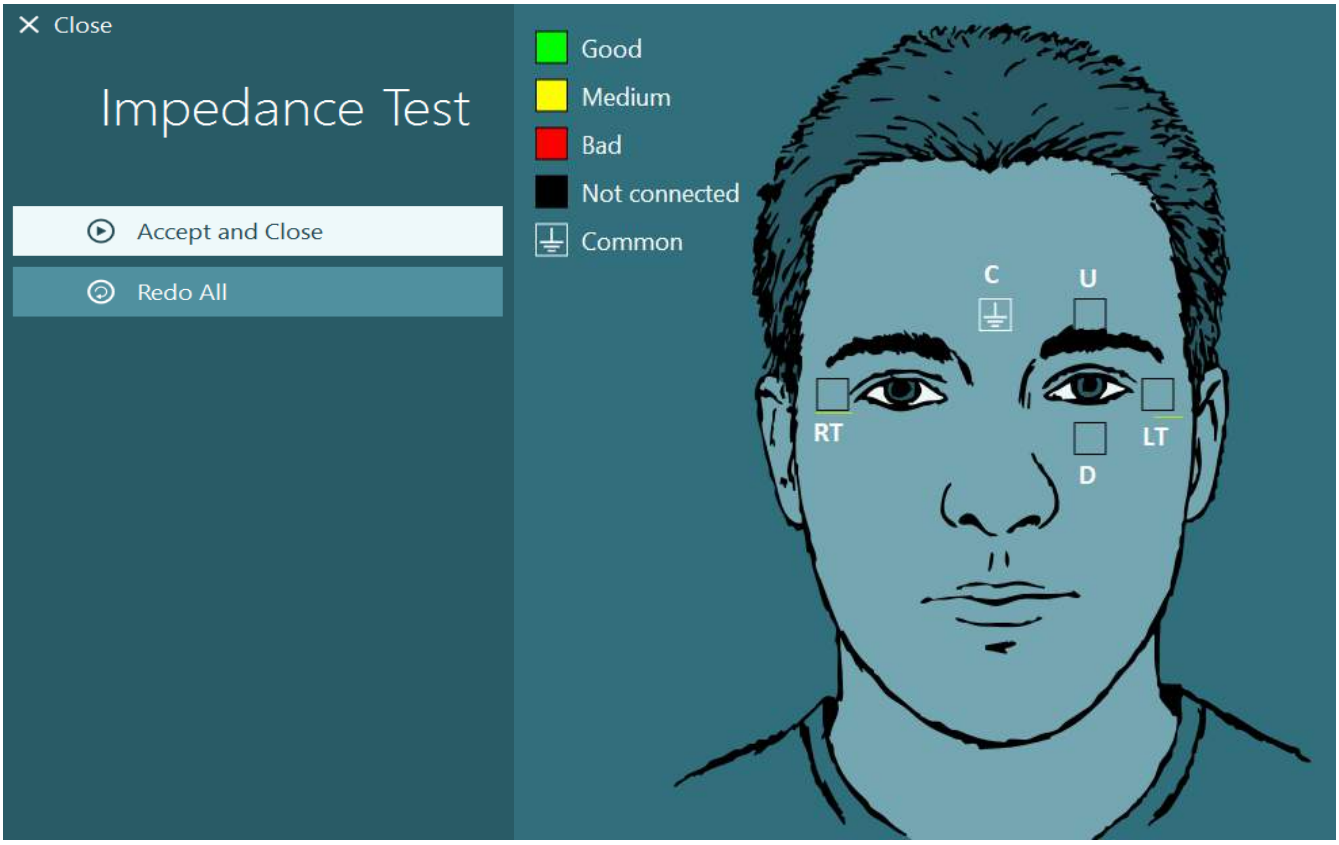


Figure 2.2-3 Impedance Test Screen

2.3 Performing calibration

In the test screen side panel, click the **Calibration** button (Figure 2.3-1)

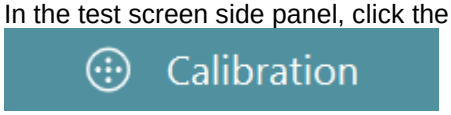


Figure 2.3-1 Calibration button

The Calibration dialog box will open (Figure 2.3-2)

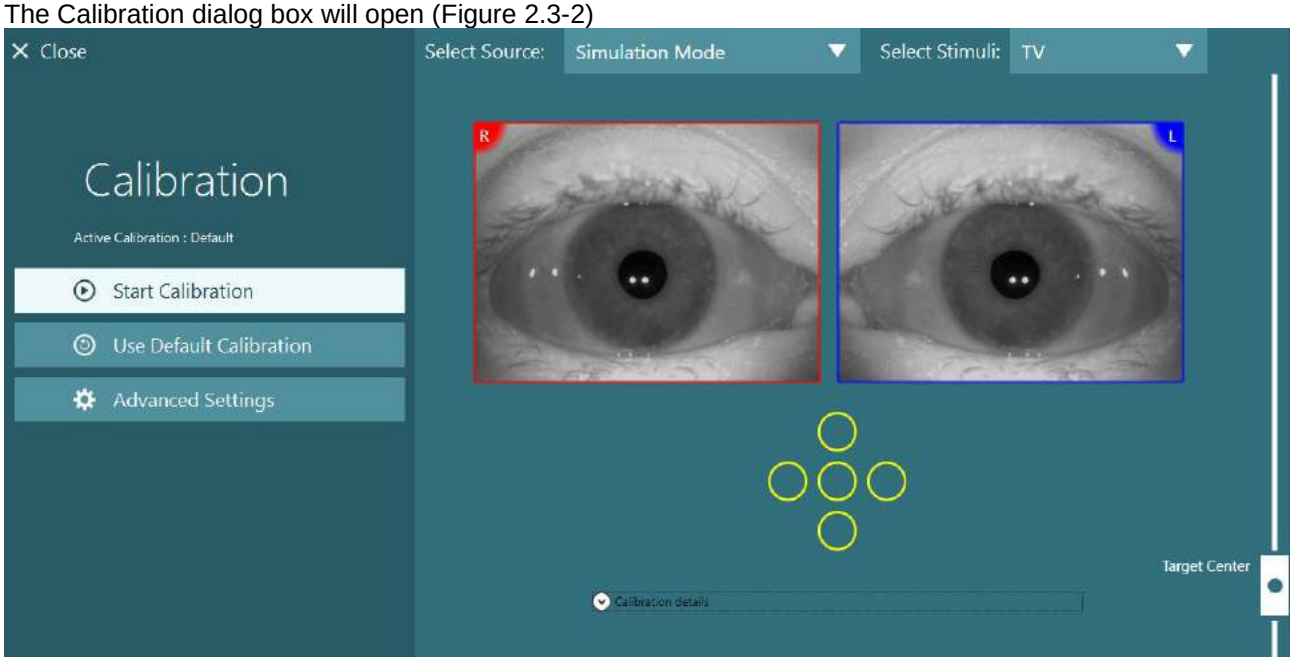


Figure 2.3-2 Calibration screen with Cameras

Before beginning calibration, ensure that the correct hardware source will be used for calibration and subsequent testing. Then center the calibration stimulus for the patient using the target center slider. Vertical tests will still display the target from the center of the screen, but horizontal tests will display the target centered at the target center position specified by the target center slider. (Figure 2.3-3)

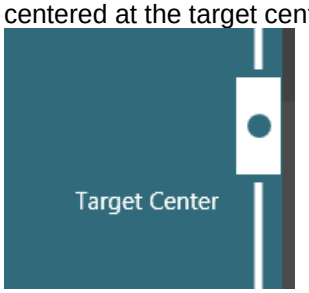


Figure 2.3-3 Target Center slider

When testing with an ENG source (e. g. DataLink, ENG in Chair), the electrode traces for horizontal and vertical traces are displayed. If the electrode signal shows drift, then traces can be manually centered using the **Center Traces** button. If the patient's eye movements are not shown in the electrode traces, then the Amplifier Gain can be adjusted below the traces to magnify the patient's electrode signals (refer Figure 2.3-4).

When testing with a VNG source, the upper area of the dialog shows the video images of the eyes that are being calibrated. If necessary, adjust the pupil threshold to achieve optimal eye detection.

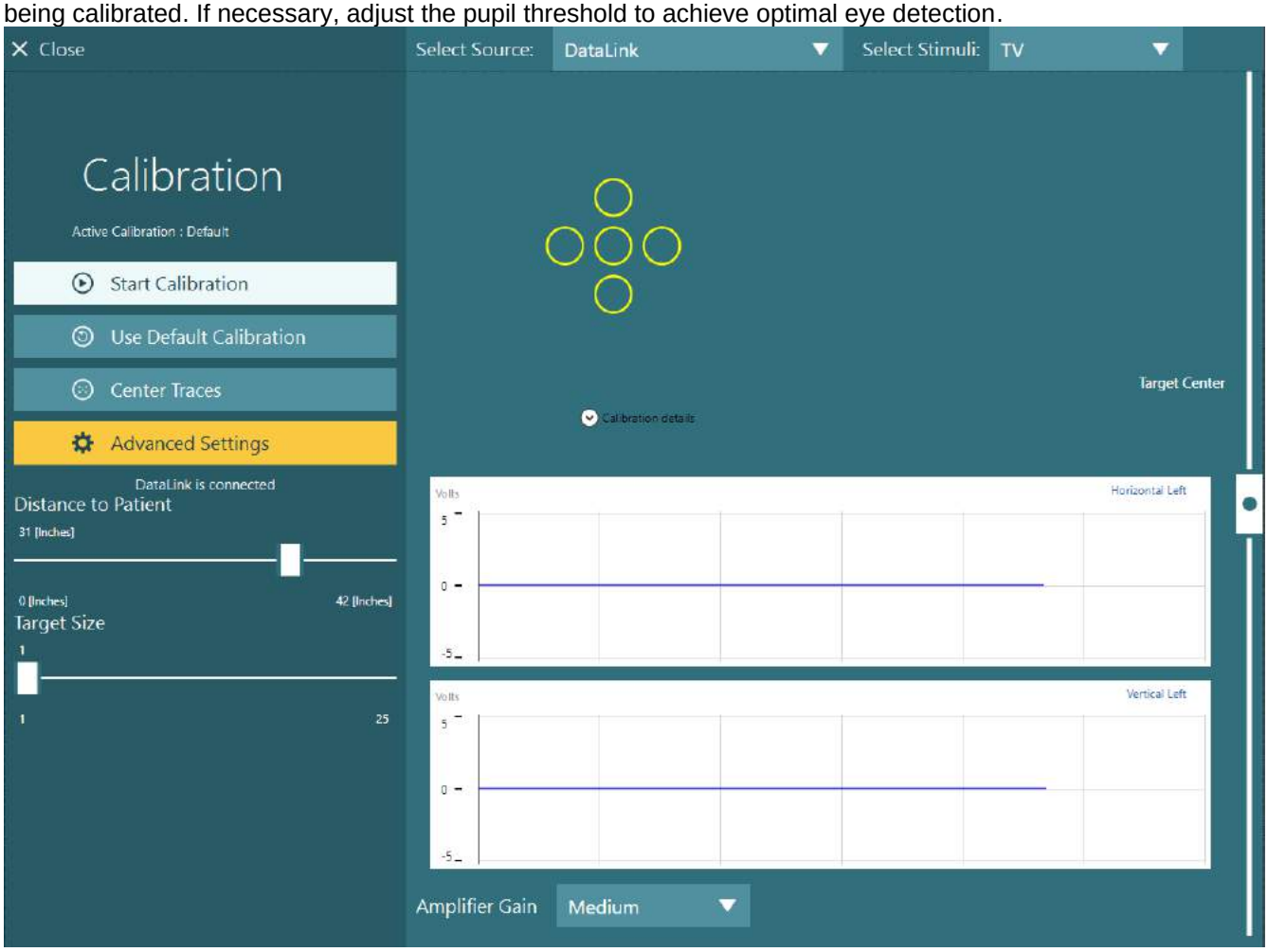


Figure 2.3-4 Calibration Screen with ENG

Click the **Start Calibration** button to begin the calibration routine. (Figure 2.3-5)

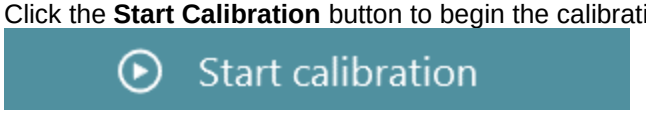


Figure 2.3-5 Start calibration button

Ask the patient to look at the first calibration point. After a few seconds of fixation a target confirmed mark (Figure 2.3-6) will appear to confirm calibration of the center point. If the patient fails to fixate on the center point, the software will present a warning message. (Figure 2.3-7)

Figure 2.3-6 Target confirmed mark

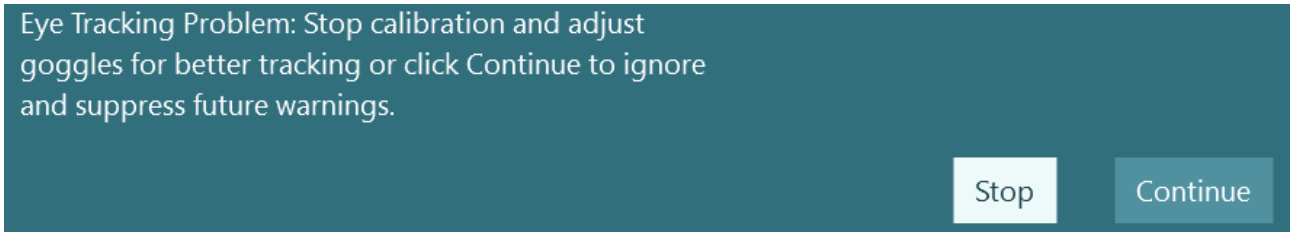


Figure 2.3-7 Eye tracking problem warning

Automatic fixation detection may not be achieved successfully in some patients. In such cases, by observing the video image of the calibrated eye on the screen, if the calibration point has been fixated upon, clicking the **Accept point** button will manually accept the value and move to the next target position. (Figure 2.3-8).

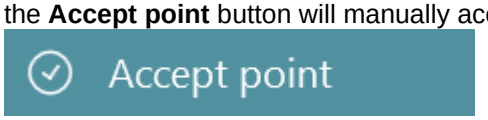


Figure 2.3-8 Accept point button

Ask the patient to fixate on the target to the left without moving his / her head. After a few seconds of fixation, a yellow target confirmed mark will appear to confirm calibration. The target will then move to the right, center, up, and then down. Below the checkmarks the patient's eye positions will be displayed graphically (Figure 2.3-9).

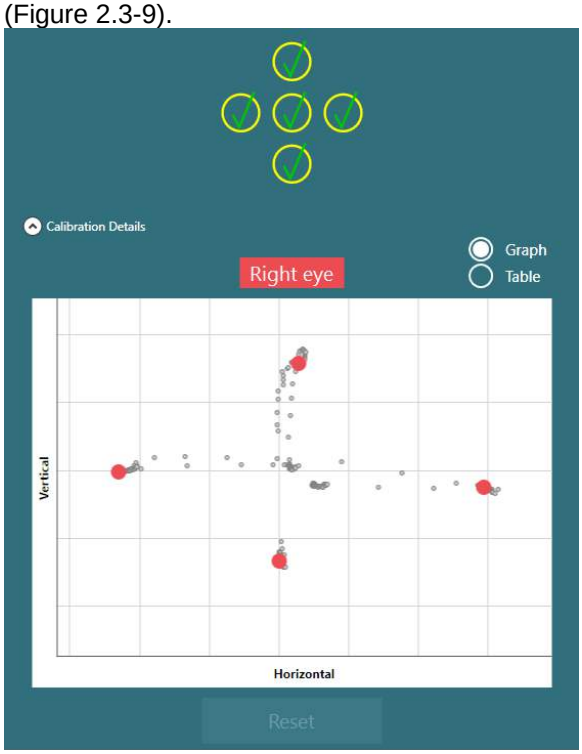


Figure 2.3-9 Calibration completed with all positions accepted

Once calibration is complete, the yellow tick marks will change to green, indicating the patient has achieved appropriate calibration that is within tolerance at each of the calibration points. (Figure 2.3-9). The user can choose either graphical or / tabular explanation for the calibration (Figure 2.3-10).

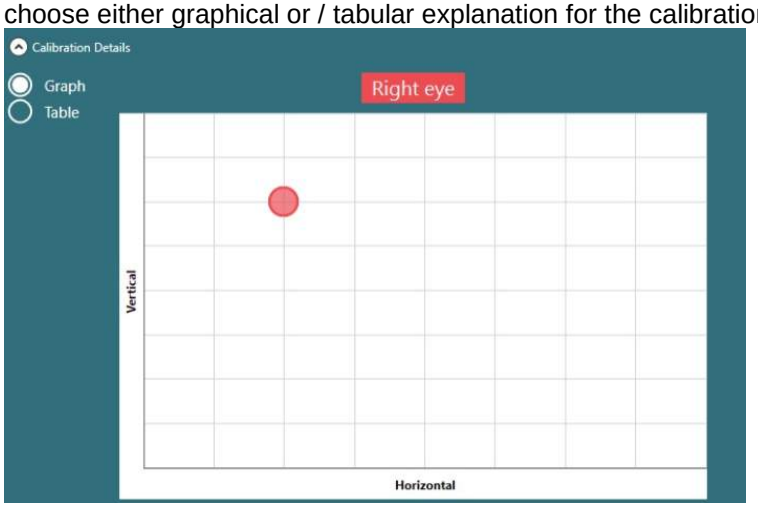


Figure 2.3-10 Calibration failure with values and failure reason

If the patient could not fixate on one or target positions, a red cross mark (Figure 2.3-11) shall appear to indicate failure. The software will provide a **Redo Horizontal**, **Redo Vertical**, or **Redo All** button to clear the failure points and allow the calibration of the direction(s) again.

Figure 2.3-11 Unsuccessful target mark

If the calibration is completed successfully, the **Accept and Close** action becomes available (Figure 2.3-12). Selecting this action will use the patient derived calibration values and close the calibration screen.

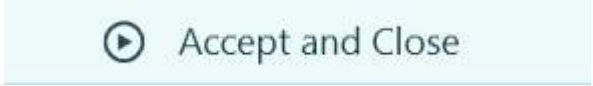


Figure 2.3-12 Accept calibration and close calibration screen button

Figure 2.3-13 Target Size option

Target Size: This option adjusts size of target in degree increments. Note if the target size is increased, the maximum angle will decrease (Figure 2.3-13).

2.4 Torsion calibration

Tests that use the torsion tracker will need to be calibrated before use, Click on the “Torsion” button in the side panel to start the calibration process (Figure 2.4-1).

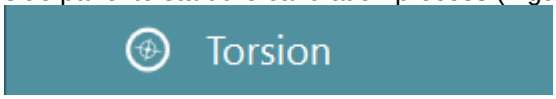


Figure 2.4-1 Torsion Calibration button

Have the patient look straight ahead, then click on the Auto Detect button. The software will select an iral segment with good contrast to track rotation. The tracking area can be adjusted using the sliders below the eyes.

If the torsion tracker is to be utilized in the dark with dilated pupils, it is very important to perform the torsion calibration in the dark with dilated pupils. If possible, ask the patient to look slightly up – this will make the iris more visible.

The white circle indicating the tracking area must never be filled out by the pupil, this will lead to unstable torsion tracking (Figure 2.4-2).

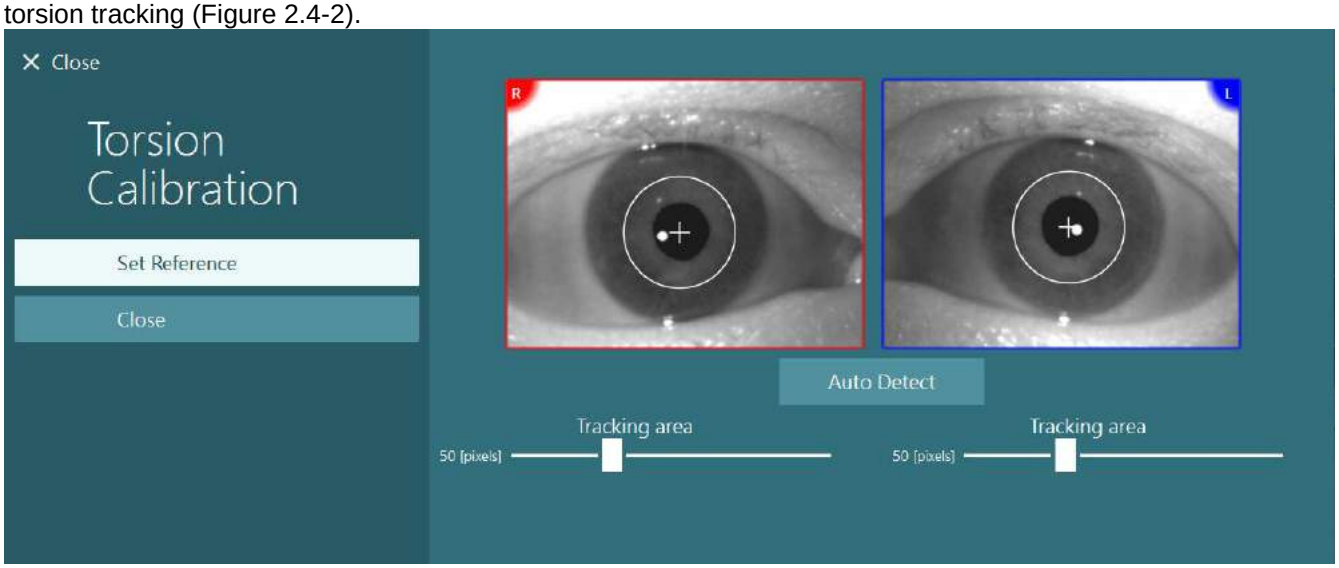


Figure 2.4-2 Adjusting the Tracking area

Once the adjustments have been made, click on the Set Reference button. The crosshair will now show a circle with crosshair. Confirm that the torsion angle is responding with the patient's eye movements, otherwise adjust the tracking area and click on Set Reference to update. To return to the calibration settings, click on the Close button (Figure 2.4-3).

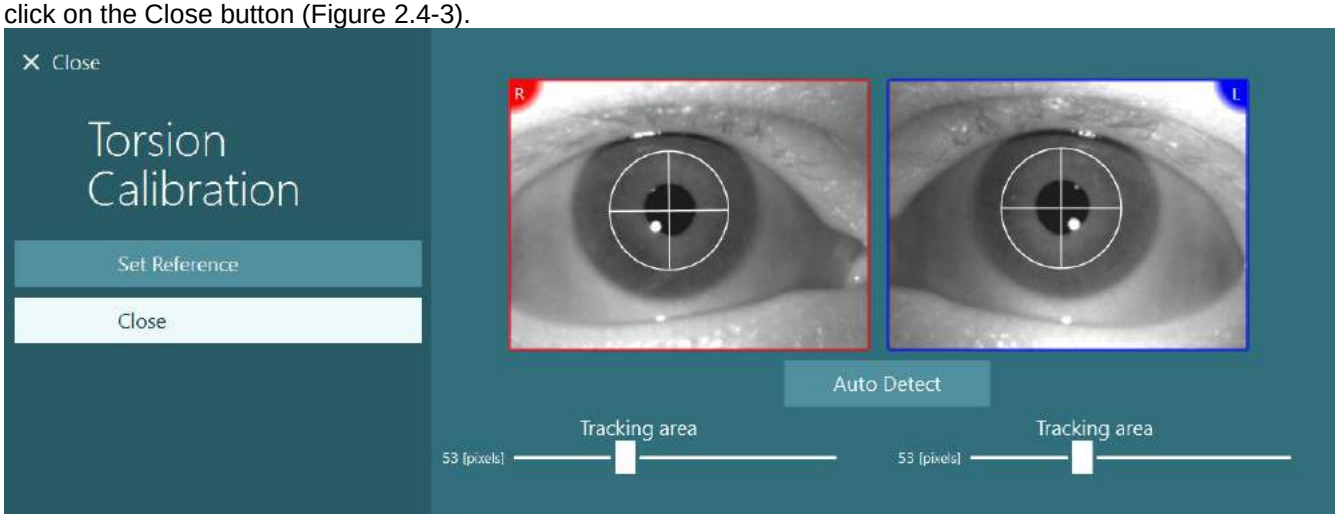


Figure 2.4-3 Torsion Crosshairs with reference area selected

2.5 Default calibration

If a calibration is unable to be completed, use the default calibration option (Figure 2.5-1). This sets the VisualEyes™ system to use software default calibration settings which provide only an approximate calibration value. Be aware that results for oculomotor tests and nystagmus velocities need to be interpreted with caution.

Figure 2.5-1 Use default calibration button

2.6 Review calibrations

The patient's calibration traces (Figure 2.6-1) and videos are saved for later review. These results can be used to determine if the patient's eyes were properly calibrated before the VNG / ENG test was performed. During review it can be determined which subtests are related to which calibrations, if calibration was performed more than once. The traces and videos can be accessed from the **Session Review** screen and **Patient Sessions** screen.

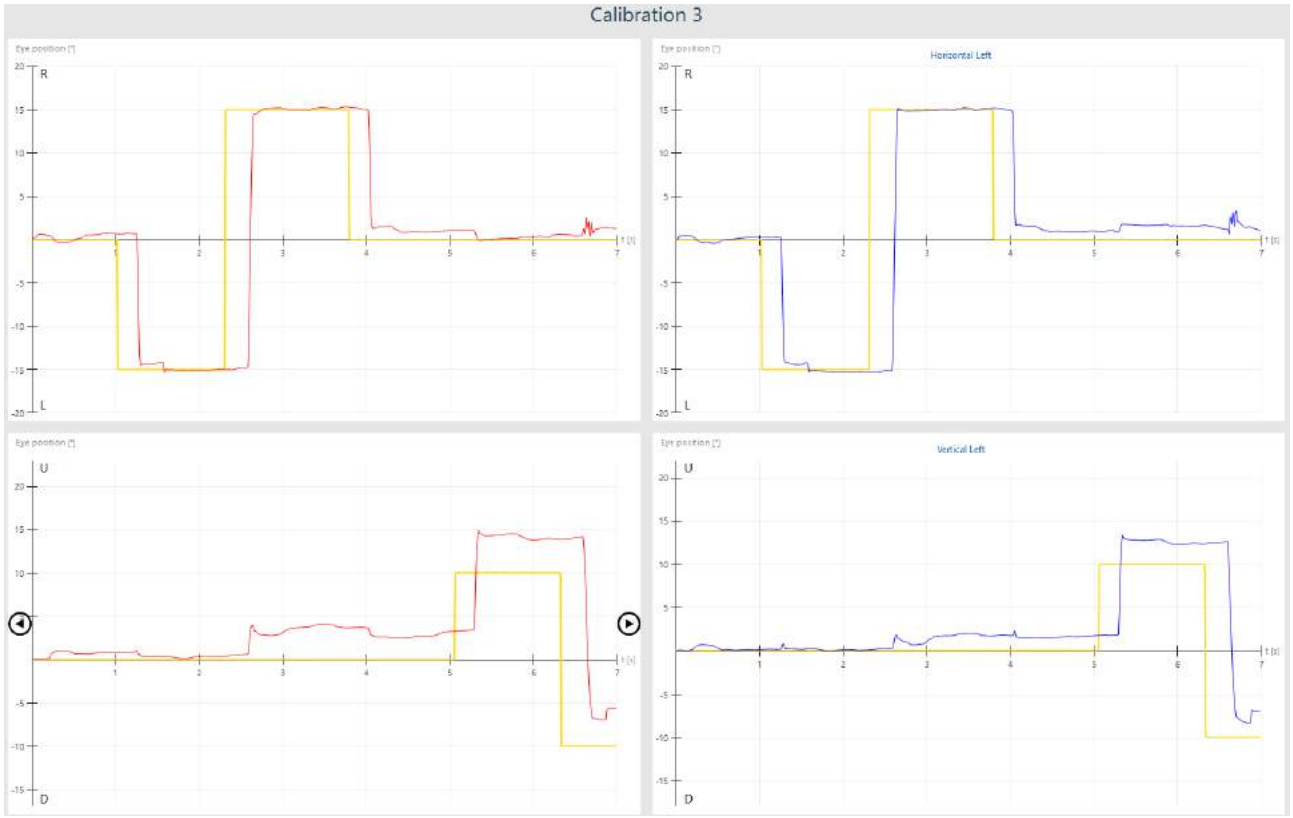


Figure 2.6-1 Calibration traces

The results are printed by default in the patient report (Figure 2.6-2).

Figure 2.6-2 Print Calibration from Session Review screen

3 Testing

3.1 Overview

To start testing click on **Begin Testing** from the main menu. The first test in the chosen protocol is displayed. To begin testing with a different test in the protocol, select the desired test using the test menu button.

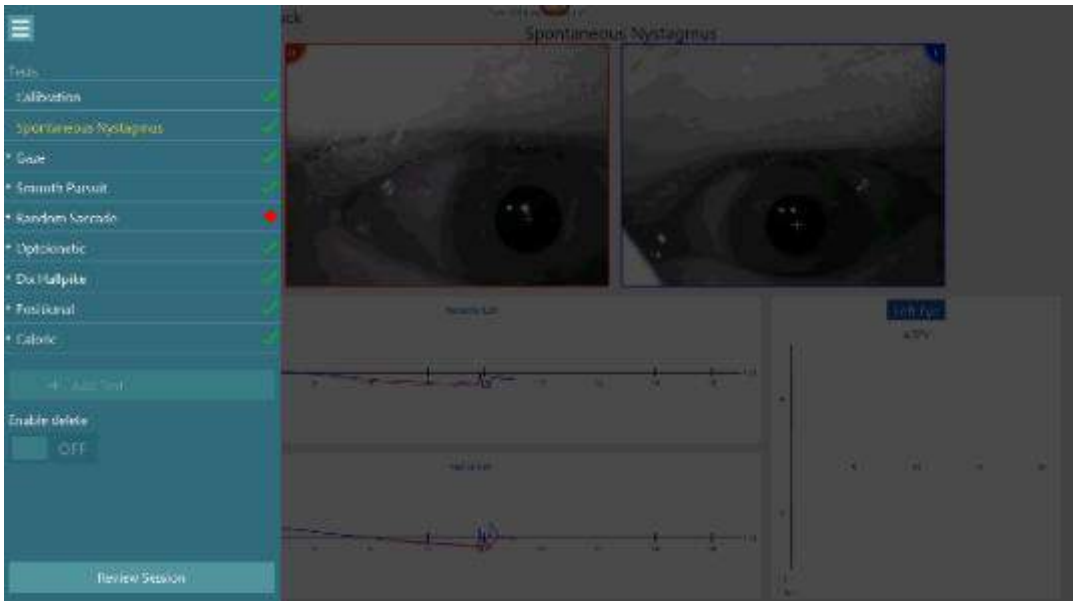


Figure 3.1-1 Session tree displayed

The left side panel displays a session tree, which shows all tests included in the current protocol (Figure 3.1-1).

- The current test is displayed in yellow text.
- Completed tests that fall within test thresholds are marked with a green checkmark.
- Completed tests that fall outside test thresholds are marked with a red diamond.
- Completed tests that have been marked as within limits when the software marked the test originally as falling outside test thresholds are marked with a green checkmark with pencil.
- Completed tests where no test thresholds have been defined use a hollow green checkmark

Navigate to a test by clicking or touching the test title to perform (if incomplete) or review (if complete). By clicking or touching the plus button to the left of the test title, the test menu will expand to show the subtests available (Figure 3.1-2).

Figure 3.1-2 Expanded test, displaying subtests

VisualEyes™ VNG offers an easy way to visualize video eye and trace recordings during data collection and review. The general display shows the eye images in the top portion of the screen and directly below it the raw tracings for horizontal and vertical channels (Figure 3.1-3). The eye images are presented in real time in synchrony with raw eye movement traces.

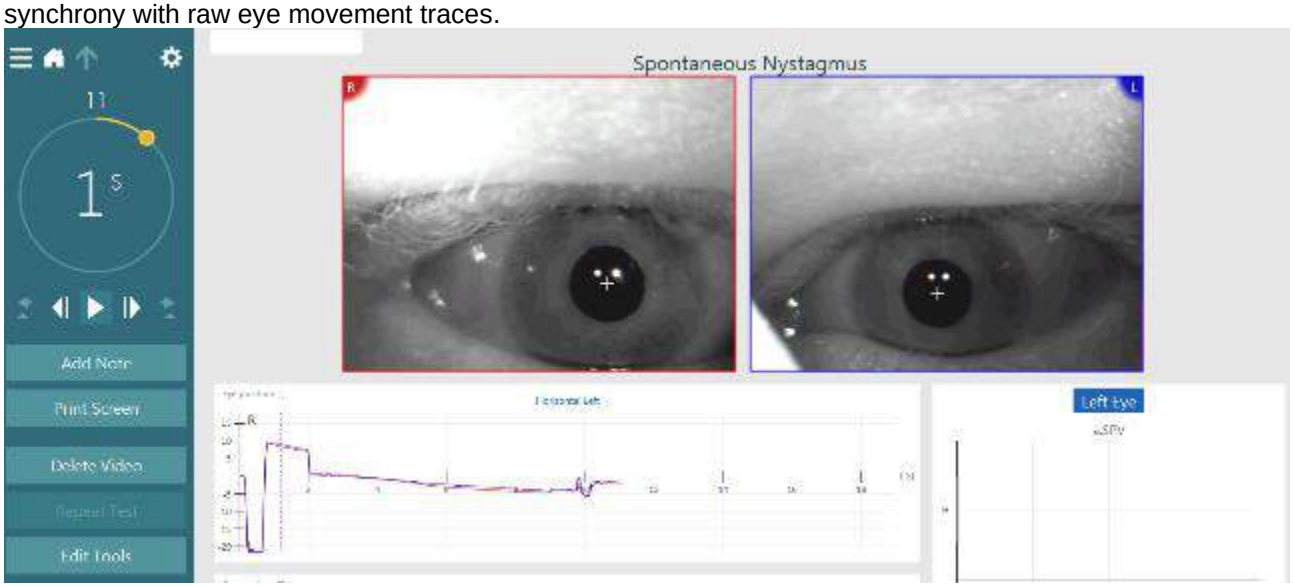


Figure 3.1-3 Test screen

Results are recorded and displayed in a large graphical display that shows the raw data tracing of the eye movements (Figure 3.1-4). The right eye movements are recorded in red and the left eye movements are recorded in blue. The stimulus position is shown in a yellow color.

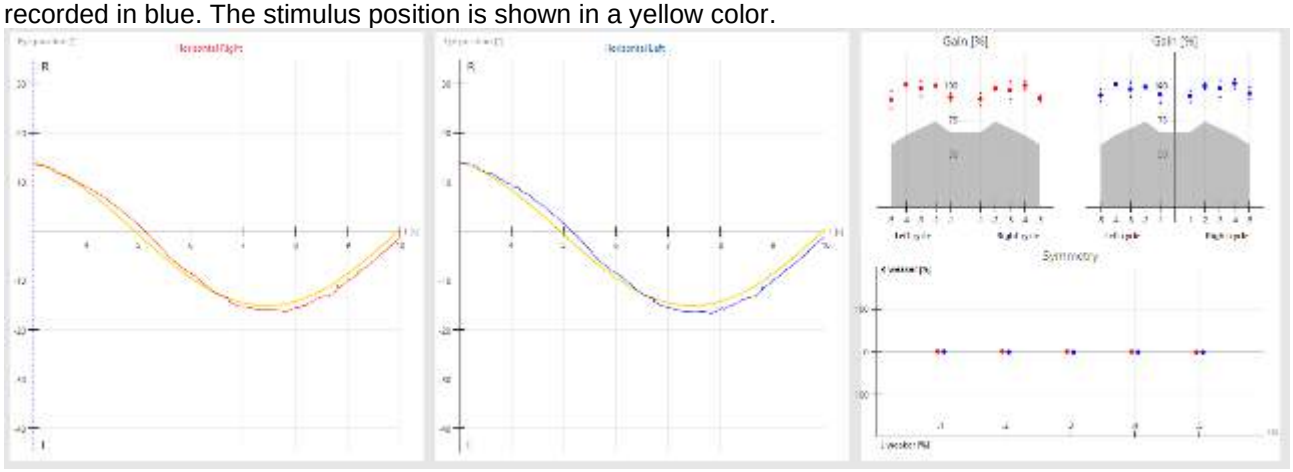


Figure 3.1-4 Waveform and results display

Both eye/s and raw tracings can be enlarged for easier viewing by double-clicking or double-touching the item of interest. The graphical area shows time (in seconds) on the horizontal axis and eye and or stimulus movement (in degrees) on the vertical axis. Direction labels on the graph show the direction of the waveform.

3.2 Nystagmus Marking and Peak Response

Nystagmus beats are marked by small triangles in the eye trace graphs. During data collection, the nystagmus beats are marked by triangles showing the inflection point between the slow and fast phases of the nystagmus beat. Triangles that point **upwards (below the tracing)** indicate right-beating nystagmus. Triangles that point **downwards (above the tracing)** indicate left-beating nystagmus (Figure 3.2-1).

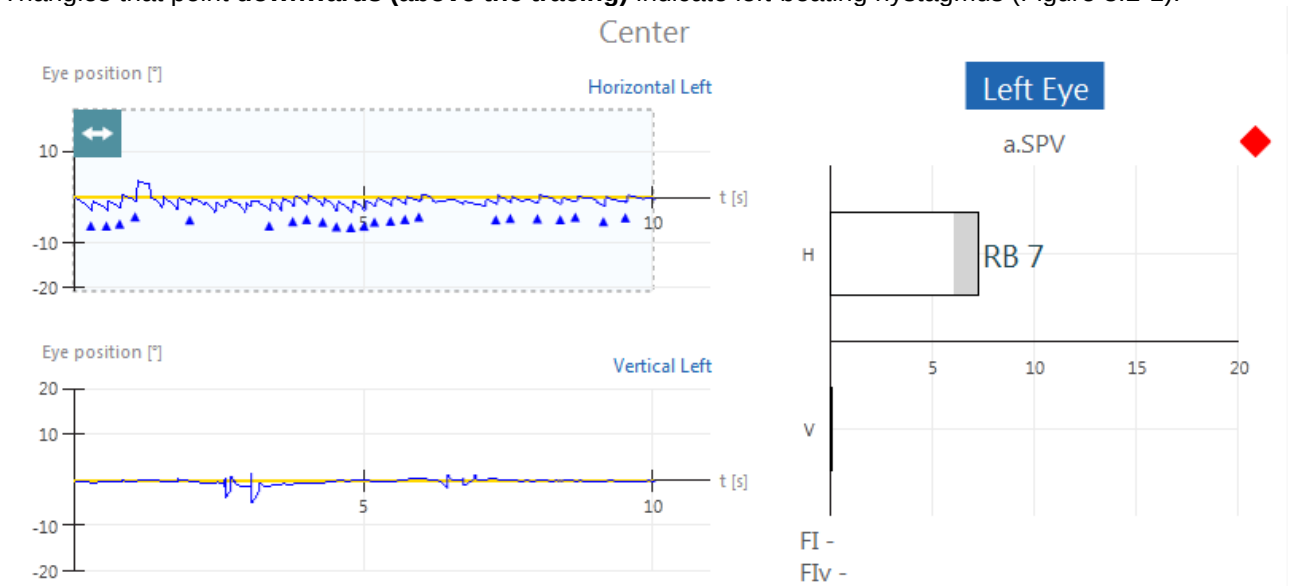


Figure 3.2-1 Nystagmus beats with triangles

After the test is complete, the software will show nystagmus beats and triangle nystagmus markers. The user can select 'highlight nystagmus slow phase' option to have colored in green (Figure Figure 3.2-2). The user can also enable or disable triangle markers. This option can be set in System Default Settings under General settings.

Figure 3.2-2 Nystagmus slopes marked green

The a. SPV (average slow phase velocity) is determined by averaging the slow phase values of each nystagmus beat in the selected peak response time. Three beats in the selected peak response time are required to calculate a. SPV. The peak response time is specified in the test's settings. The a. SPV is measured in degrees/second and displayed in the result graph beside the waveform. In nystagmus tests the a. SPV graph only displays the results of one eye at a time. Clicking or touching the label for the eye selected will switch the a. SPV values for the other eye tested.

The peak response window is updated as the test progresses and is marked by a dashed window that is shaded in a light blue color (Figure 3.2-3) for the area with the largest a. SPV. This window can be moved to the desired area by using the scroll button in the upper left corner of the peak response window or reset to the software selected location using the reset button in the upper right corner of the peak response window.

NOTE: The waveform window can be scrolled quickly using the mouse scroll wheel.

Figure 3.2-3 Peak Response window

The time for determining peak response can be set in the test settings under Nystagmus parameters. The peak response cannot be longer than the allotted test time (Figure 3.2-4).

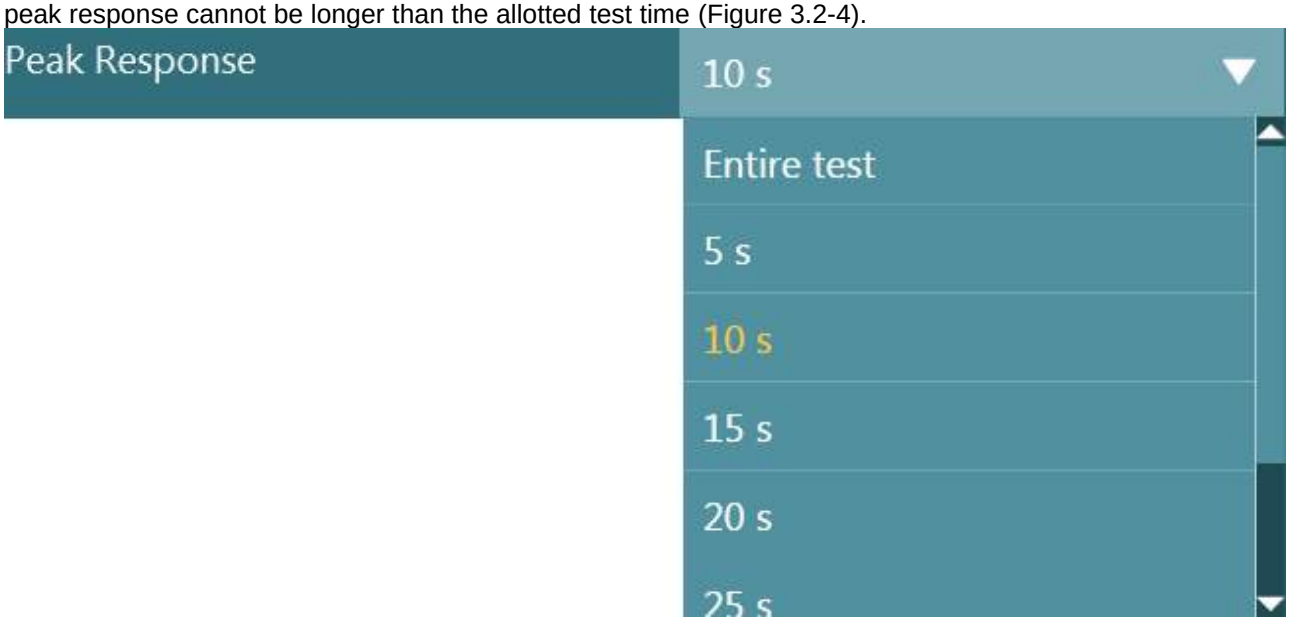


Figure 3.2-4 Peak Response times

3.3 Nystagmus Testing

Nystagmus tests (spontaneous, Dix Hallpike, Positional) measure the patient's nystagmus response when placed in different head and body positions. VisualEyes will measure the eye movements to detect the magnitude of nystagmus if present. In tests where the patient's nystagmus direction changes, the average slow phase velocity (a. SPV) will be measured separately in each direction and the results will be displayed in the a. SPV graph. Nystagmus tests are available in VisualEyes 515 and VisualEyes 525 configurations.

3.3.1 Spontaneous nystagmus test

The spontaneous nystagmus test is used to record non-evoked eye movements. This test is conducted with the vision denied cover attached to the front of the mask. This allows for recordings with the eyes open in complete darkness thus eliminating any possibility of fixation. If nystagmus is detected, the Add Time button can be used to extend the testing time. The fixation light will come on automatically at 15 seconds and last for 10 seconds. This can be changed in the test settings to come on manually if desired.

Note: This test can be performed using electrodes for ENG evaluations. To perform this test in an Orion rotational chair, the user needs to have either external Datalink connection with Orion reclining chair or a built-in EOG option for the Orion AT/C chair.

The average slow phase velocity (a. SPV) graph to the right side of the data graph shows the a. SPV for horizontal and vertical channels. The result value is displayed as a bar with the white portion representing values within test thresholds and grey portions exceeding the test threshold (refer Figure 3.3-1).

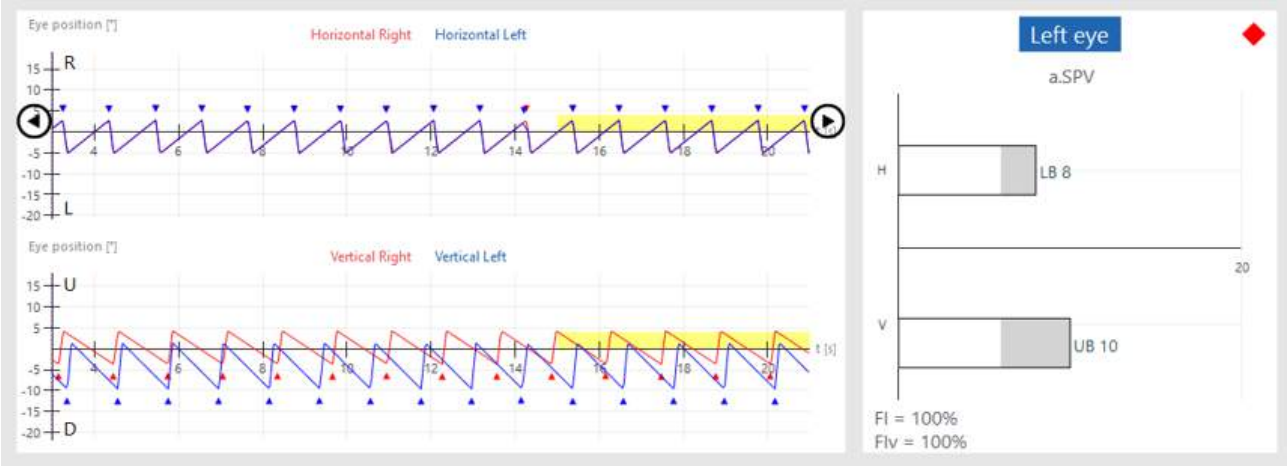


Figure 3.3-1 Spontaneous Nystagmus Waveform and a. SPV graph

3.3.2 Dix-Hallpike test

The Dix-Hallpike test is a specific test to diagnose BPPV (benign paroxysmal positional vertigo).

The Dix-Hallpike test is contraindicated in patients who exhibit the following: current or past injuries of the neck or spine, brainstem malformations, such as Arnold-Chiari, pre-existing neurological symptoms including but not to limited to: blurred vision, numbness, weakness of the arms or legs and confusion.

The test is performed by starting the subtest and reclining the patient into the supine position with the head turned to the direction tested. After 60 seconds, the software will provide an audible “ding” sound and mark the waveform to indicate the time to bring the patient to a sitting position. The test will then continue for another 60 seconds. Each portion of the test may be shortened by pressing the foot pedal, RF Remote’s Enter button, side switch on the top mount goggles, or Enter key on the keyboard.

The Dix Hallpike test has two subtests, Left and Right. In the Dix Hallpike summary, the left test will be displayed on top and the right test will be displayed on bottom. Horizontal and vertical eye positions are separated. The eye selected can be switched for each test by clicking or touching on the eye title of the a. SPV bar graph. (Figure 3.3-2).

Note: This test can be performed using electrodes for ENG evaluations. To perform this test in an Orion rotational chair, the user needs to have either external Datalink connection with Orion reclining chair.

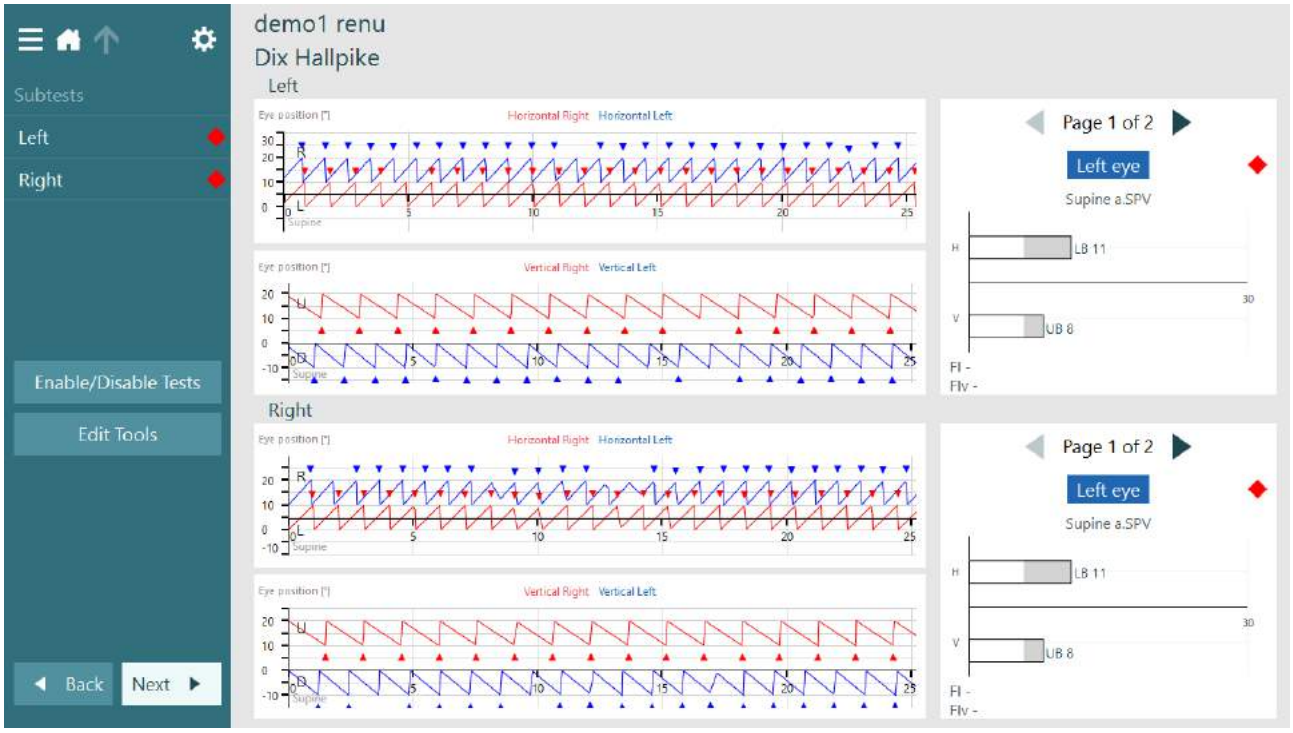


Figure 3.3-2 Horizontal and vertical eye positions in the Dix Hallpike summary

3.3.3 Dix-Hallpike Advanced test

The Dix-Hallpike Advanced test is a specific test to diagnose BPPV (benign paroxysmal positional vertigo) with using the VORTEQ IMU to aid the examiner in placing the patient in the correct positions.

The Dix-Hallpike test is contraindicated in patients who exhibit the following: current or past injuries of the neck or spine, brainstem malformations, such as Arnold-Chiari, pre-existing neurological symptoms including but not to limited to: blurred vision, numbness, weakness of the arms or legs and confusion.

Before starting the test, verify the VORTEQ IMU sensor is connected to the computer (either by Bluetooth wireless or by a micro-USB cable). Switch on the VORTEQ IMU and verify the VORTEQ IMU is connected. Have the patient wear the goggles with the VORTEQ IMU and have the patient face forward while sitting upright. When the test begins, the software will center the VORTEQ IMU in preparation for the test (Figure 3.3-3).

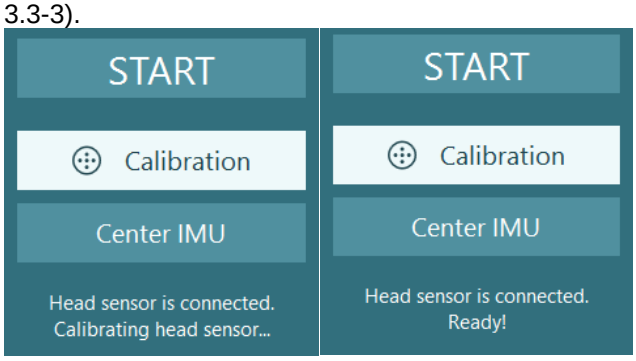


Figure 3.3-3 Head Sensor Connected, Calibrating, and Ready statuses

Once the subtest is started, recline the patient into the supine position with the head turned to the direction tested. The VORTEQ IMU spatial location will be shown with a black bar on the position sliders. As the head is moved into position, the position marker will be updated on the slider with the head representation. When the head is pointing at the desired angle, the spatial target location will be shown green instead of orange (Figure 3.3-4). Note that, the user can also start collecting data, even if he/she couldn't reach a head position that turns the bar green. Once the test is started, after 60 seconds, the software will provide an audible "ding" sound and mark the waveform to indicate the time to bring the patient to a sitting position (Figure 3.3-4). The test will then continue for another 60 seconds. Each portion of the test may be shortened by pressing the foot pedal, RF Remote's Enter button, side switch on the top mount goggles, or Enter key on the keyboard.

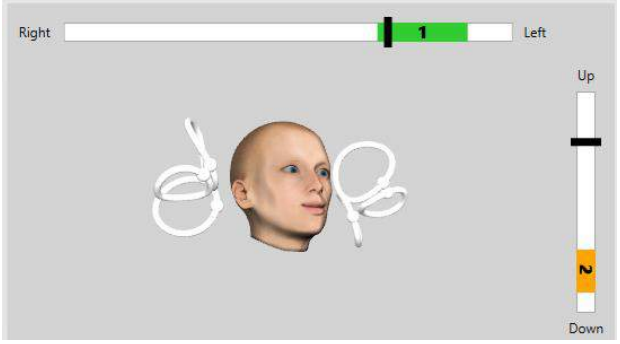


Figure 3.3-4 Head Orientation

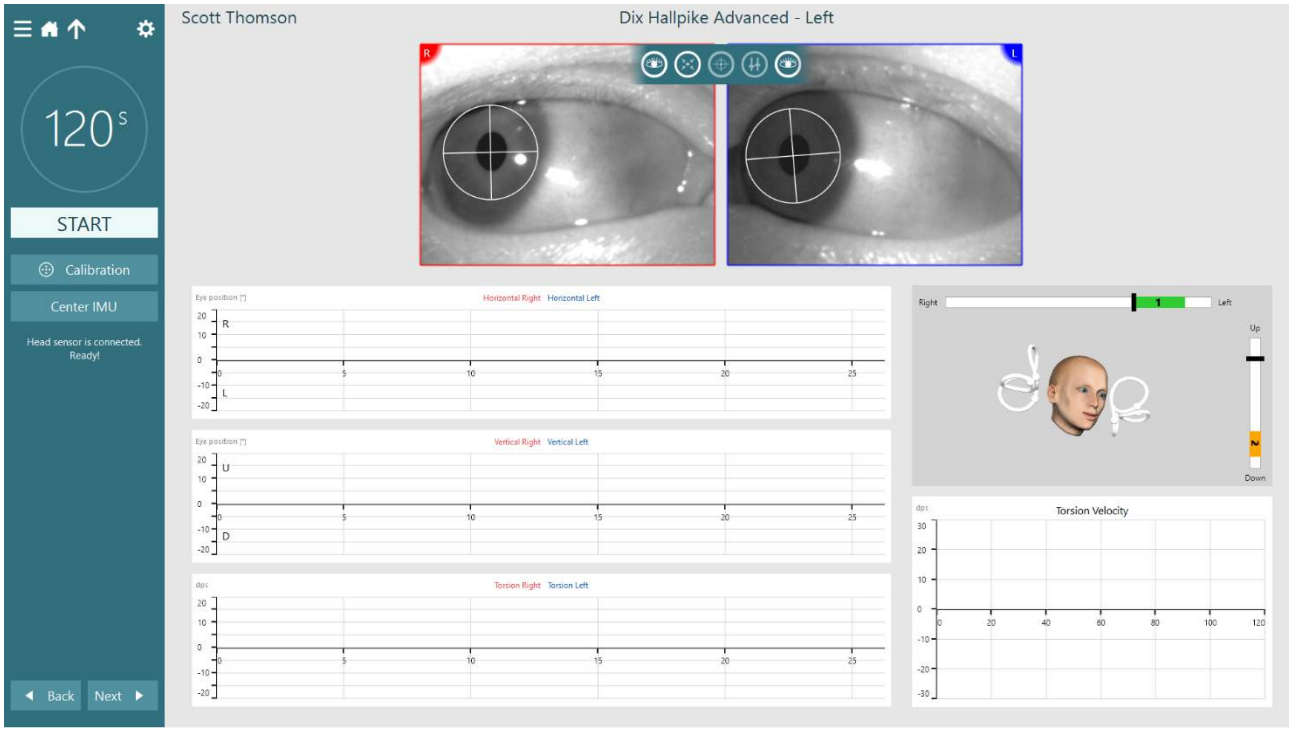


Figure 3.3-5 Dix-Hallpike Advanced subtest

The Dix Hallpike Advanced test has two subtests, Left and Right. In the Dix Hallpike Advanced summary, the left test will be displayed on the first page and the right test will be displayed on the second page. Additional pages are created for subtests that are repeated. The graphs will club the eyes together and separate the horizontal, vertical, and torsion traces. The eye selected can be switched for each test by clicking or touching on the eye title of the a. SPV bar graph. (Figure 3.3-6). The Torsion Velocity graph will display both left and right eye's torsional velocity values.

Note: This test does not support the use of electrodes for ENG evaluations.

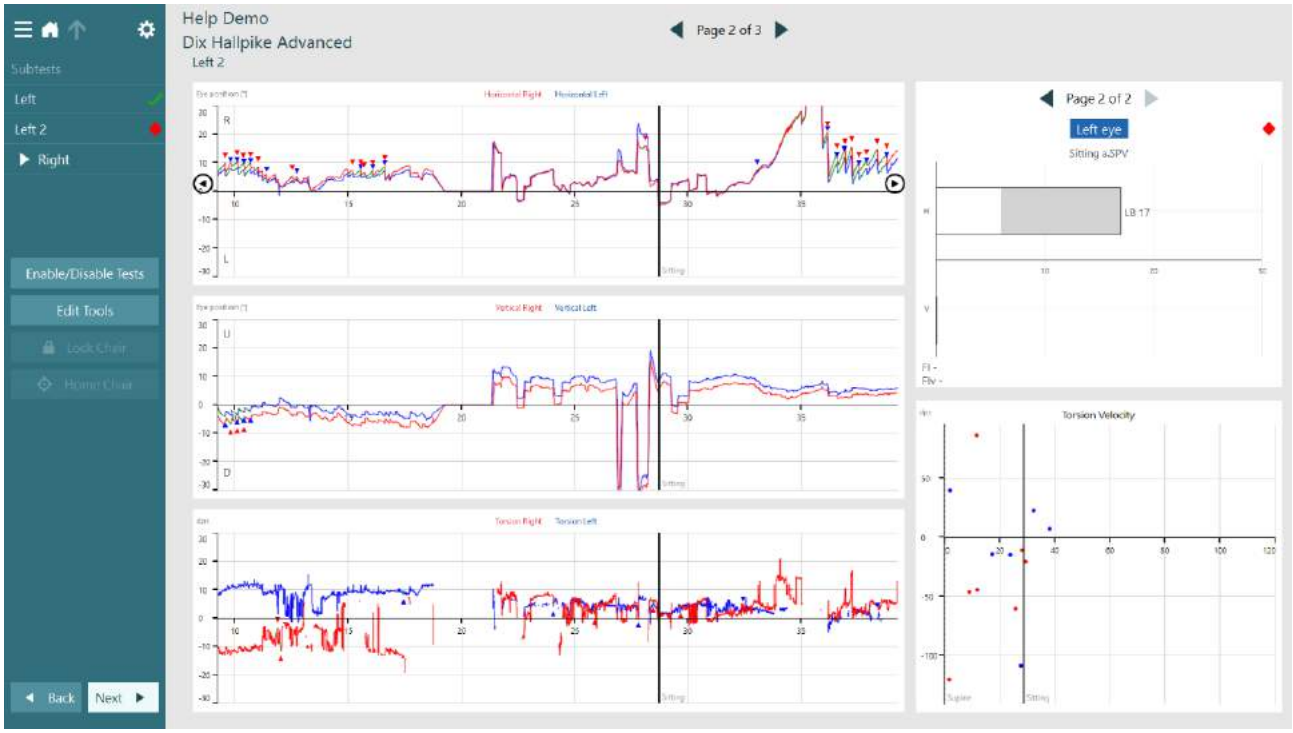


Figure 3.3-6 Horizontal, vertical, and torsional eye movements in the Dix Hallpike Advanced summary

3.3.4 Positional test

The Positional tests allow the examiner to compare several measurements collected with the patient in a variety of head and body positions. Each subtest is set to record for 30 seconds. The Positional test can record Supine, Head Right, Head Left, Body Right, Body Left and additional subtests of Bow and Lean positions.

Note: This test can be performed using electrodes for ENG evaluations with an Orion rotational chair. To perform this test, in addition to appropriate license, the user needs to have external Datalink connection with Orion reclining chair.

Please note that Positional testing is contraindicated in patients who exhibit the following: Current or past injuries of the neck or spine. Brainstem malformations, such as Arnold-Chiari. Pre-existing neurological symptoms including but not to limited to: blurred vision, numbness, weakness of arms or legs, confusion.

The Positional summary screen will display the subtests performed in a grid pattern. For each subtest one eye's results are displayed with the corresponding eye movements. Horizontal and vertical eye movements are separated. The Positional summary can contain a mix of left eye and right eye results, based on the selected eye from each subtest. To change the selected eye in a subtest, click or touch on the eye title in the a. SPV bar graph (refer Figure 3.3-7).

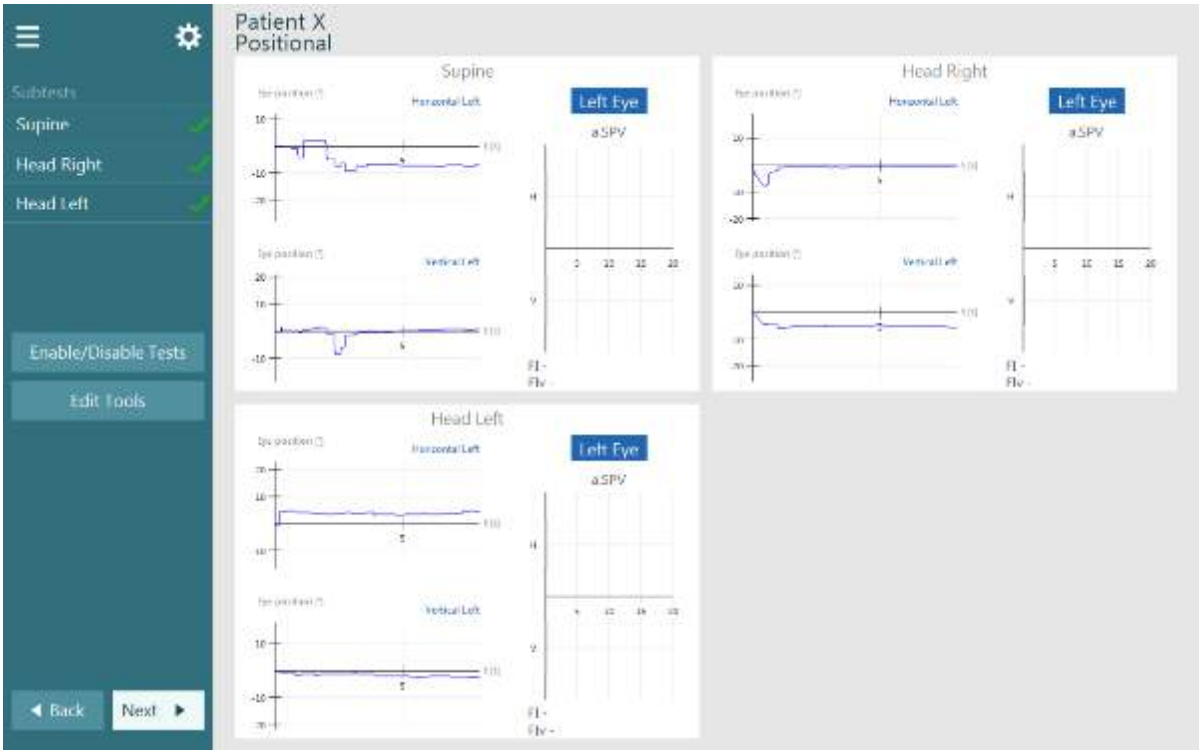


Figure 3.3-7 Positional summary screen

Note: This test can be performed using electrodes for ENG evaluations. To perform this test in an Orion rotational chair, the user needs to have external Datalink connection with Orion reclining chair.

3.3.5 Lateral Head Roll Test

The Lateral Head Roll test is part of the VORTEQ Assessment bundle. The Lateral Head Roll test is performed to identify horizontal canal BPPV. The Lateral Head Roll test has 2 additional features that provide significant improvements over the standard positional tests 3D Head Model Guide and Guide to assist in proper head placement.

Select the Lateral Head Roll test from your test menu. Once the system is calibrated you are ready to begin testing. You will use the 3D Head Model to guide you through the appropriate head/body positions for the Lateral Head Roll test. Make sure the VORTEQ IMU is attached to the goggle and turned on. The test is performed with the patient Supine (laying down).

1. Step 1 is to turn the patient's head 45 degrees towards the Right.
2. Step 2 is to turn the patient's head 45 towards the Left.

The black bar represents the head movement and when the head is in the correct position the shaded area will turn green. Once you have reached the first position you can record for a minimum of 20 seconds, then press enter and proceed to the second step. Record another 20 seconds at minimum and then stop the test (Figure 3.3-8).

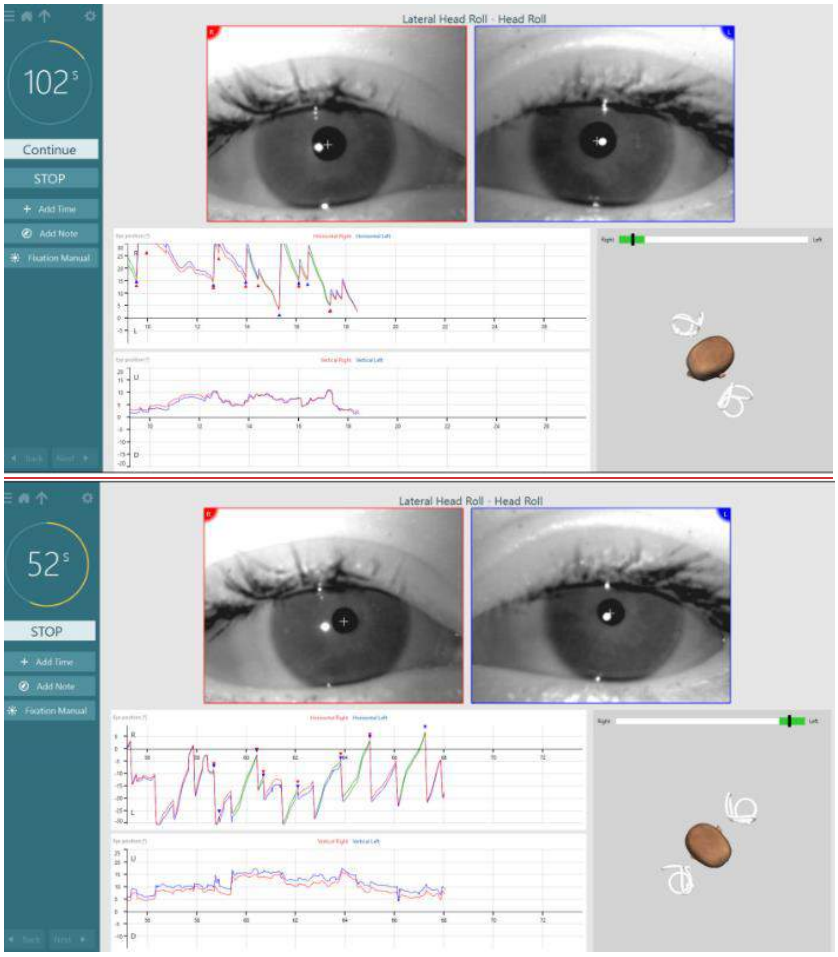


Figure 3.3-8 Performing Lateral Head Roll Test

When you have completed the test (Figure 3.3-9) you will see a summary screen with bar graphs representing any nystagmus that was generated during the maneuver. Any nystagmus greater than 6 deg/sec is shown highlighted in grey and represents an abnormal finding.

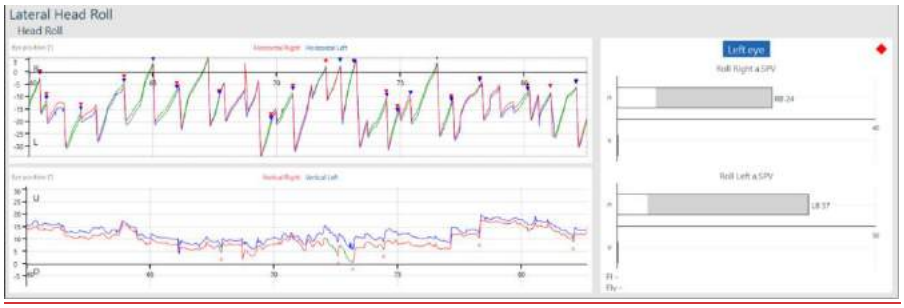


Figure 3.3-9 Lateral Head Roll result screen

3.4 Oculomotor Testing

Oculomotor tests require the patient to follow a target stimulus or pattern. These tests require an external stimulus, such as a TV or projector or DLB, and are found in the VisualEyes 525 software configuration.

3.4.1 Gaze test

During a gaze test, eye movements are measured while the patient is fixating on a stationary target. Each subtest has the patient look at a different target for a default time of 10 seconds. At the start of the test, the target is displayed in the center position of the screen (adjusted by the Target Center slider from Calibration if already set) for two seconds, then the target will be displayed in the location specified by the subtest properties. The default Gaze test will test the following positions: Center, Left, Right, Up, and Down. Each cardinal gaze direction is set close to the maximum angle provided in each direction. With a widescreen television as the stimulus, the gaze angles tested horizontally will be approximately 1. 8 times larger than the vertical angles. An optional Center2 subtest is provided for testing center gaze again after testing the cardinal gaze directions. By default, the Gaze subtests are run automatically, therefore after testing the Center position, the software will proceed to the Left position, again to the Calibration test. If additional time is required, the user can add time with the **Add Time** button.
The Gaze summary screen will display all the subtests performed in a grid pattern. For each subtest one eye's results are displayed with the corresponding eye movements. Horizontal and vertical eye movements are separated. The Gaze summary can contain a mix of left eye and right eye results, based on the selected eye from each subtest. To change the selected eye in a subtest, click or touch on the eye title in the a. SPV bar graph (refer Figure 3.4-1).

Note: This test can be performed using electrodes for ENG evaluations. To perform this test in an Orion rotational chair, the user needs to have either external Datalink connection with Orion reclining chair or a built-in EOG option for the Orion AT/C chair.

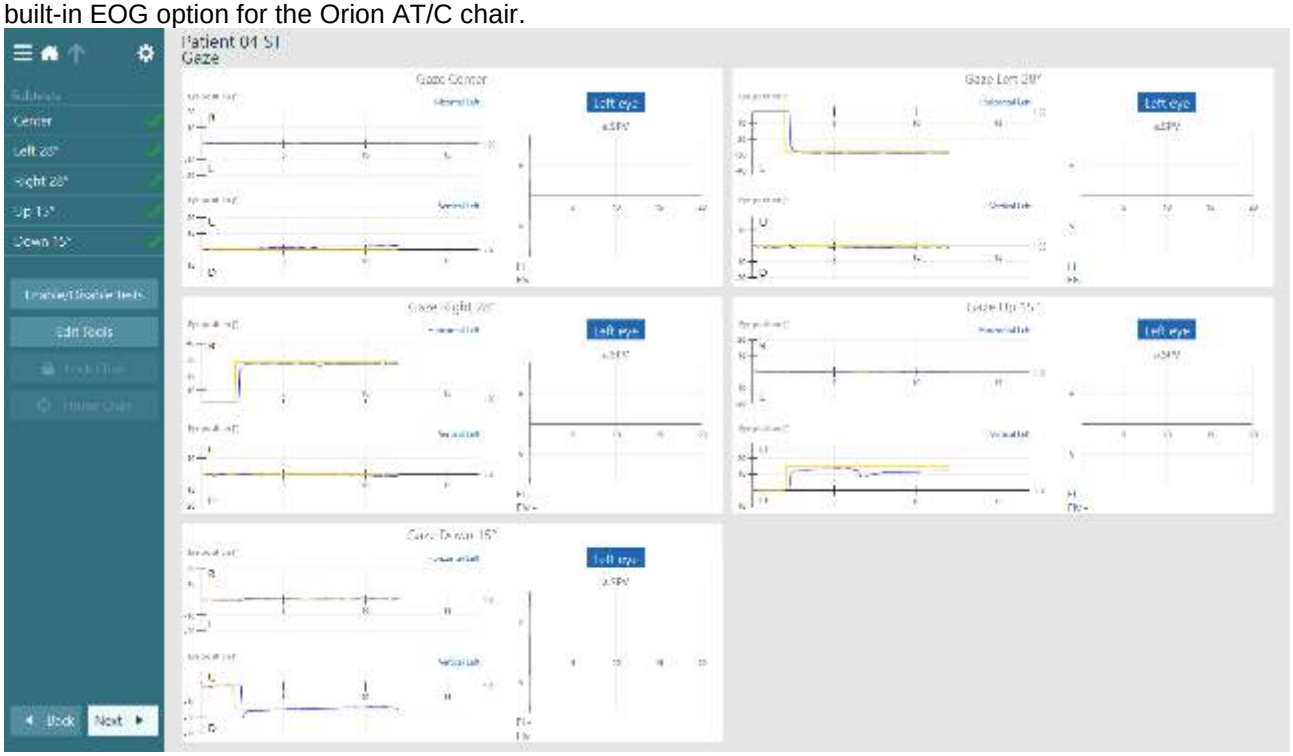


Figure 3.4-1 Gaze summary

3.4.2 Smooth Pursuit test

In the smooth pursuit test, the patient's eyes follow a target that is moving back and forth across the stimulus screen. The velocity of the target stimulus will increase with every two cycles. By default, both left and right eyes will be displayed together in the waveform traces and the Gain and Symmetry graphs to allow the operator to see if the patient experiences disconjugate eye movement. The test settings have the option to split the eyes into separate graphs if needed to better ascertain an eye's specific response. The default smooth pursuit test only tests horizontally. If desired the operator can elect to enable the vertical subtest as well (Figure 3.4-2).

Note: This test can be performed using electrodes for ENG evaluations. To perform this test in an Orion rotational chair, the user needs to have either external Datalink connection with Orion reclining chair or a built-in EOG option for the Orion AT/C chair.

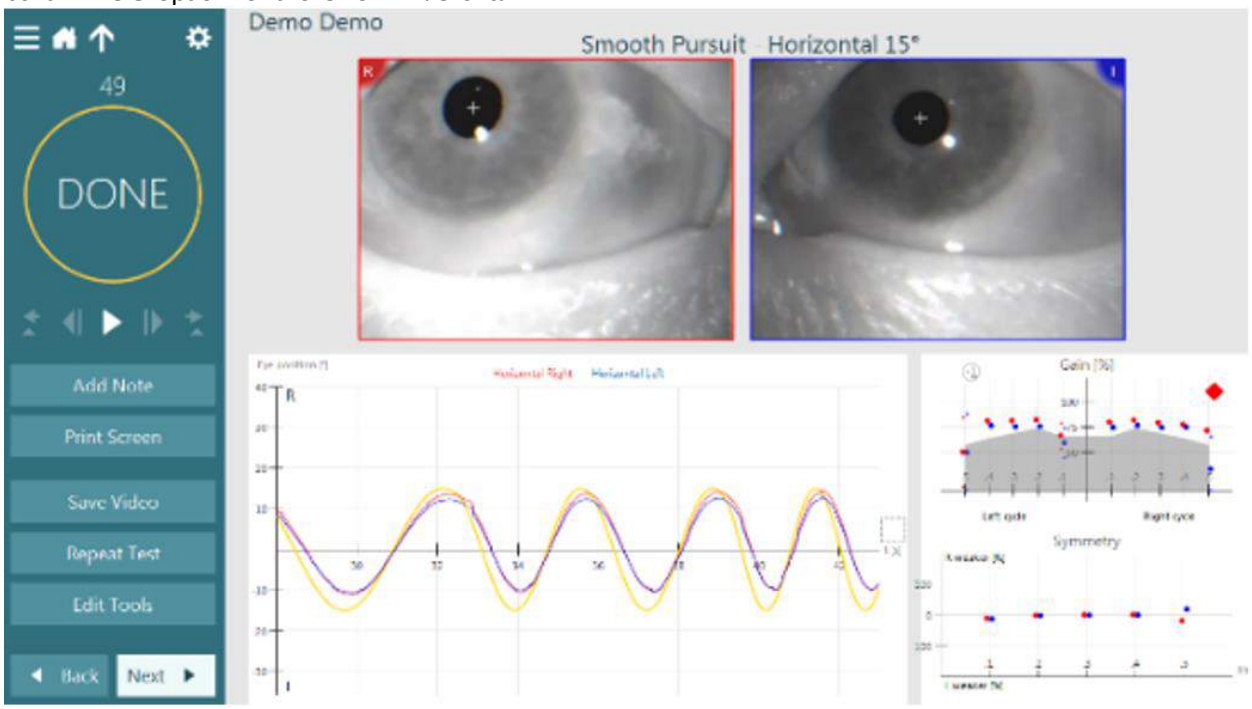


Figure 3.4-2 Smooth Pursuit subtest

The Gain value is given as a percentage value representing the ability of the patient to track the sinusoidal target without saccadic intrusions (short jumps in the eye position to catch up to the target). Each eye's gain is measured for each cycle and displayed on the gain graph as a small dot in either blue (for left eye) or red (for right eye). A larger dot is displayed on the gain graph representing the average of the eye's gain at the selected frequency (e. g. 0. 1 Hz). Test thresholds based on age matched patient data studies are displayed as gray shaded areas and will vary based on the selected frequency. If the average gain value (large dot) from either eye falls into the shaded area of the gain graph, the software will mark the test as outside thresholds and use a red diamond (refer Figure 3.4-3).

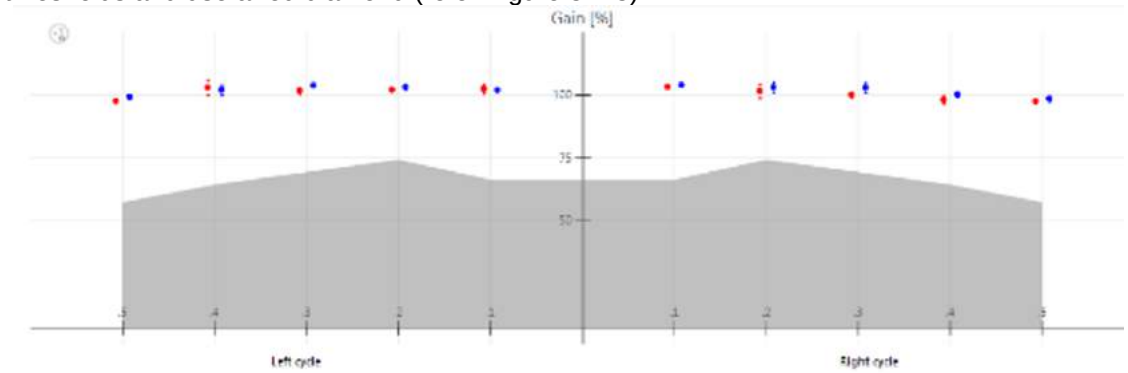


Figure 3.4-3 Gain graph with individual and average gain values

Optionally the Symmetry graph will compare the average left moving gain to the average right moving gain (up versus down in vertical subtests) and display this result for each eye and each frequency (Figure 3.4-4). By clicking the symbol, the user can view the numerical value of gain and symmetry in the graphical representation (refer section 7.5 for details).

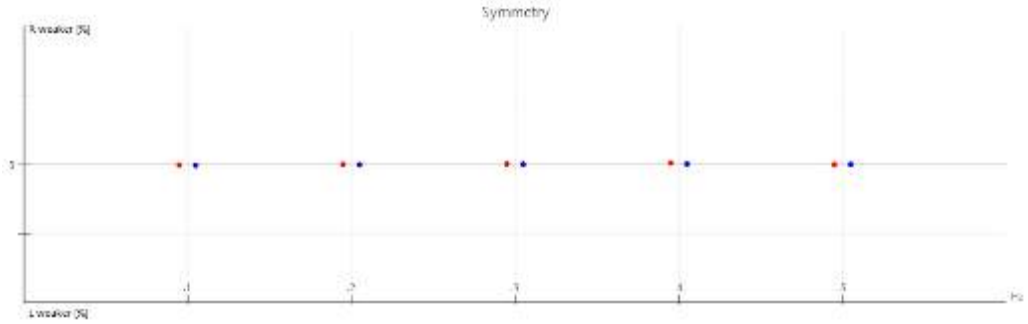


Figure 3.4-4 Symmetry graph

3.4.3 Saccade test

During the saccade test the patient's eyes must follow a randomly moving target jumping from side to side. The default Saccade test will have the target jump horizontally, but the test has optional vertical and combined (a mix of horizontal and vertical positions) subtests available. The patient must fixate on the target and then move to the next target with fast eye movements (saccades). Ideally, the saccades should consist of one single fast movement that leads to re-fixation on the next target. By default both eyes are displayed on the same waveform graph and analysis graphs to show if the patient exhibits any disconjugate eye movements. The test settings have the option to split the eyes into separate graphs if needed to better ascertain each eye's specific response.

Note: This test can be performed using electrodes for ENG evaluations. To perform this test in an Orion rotational chair, the user needs to have either external Datalink connection with Orion reclining chair or a built-in EOG option for the Orion AT/C chair.

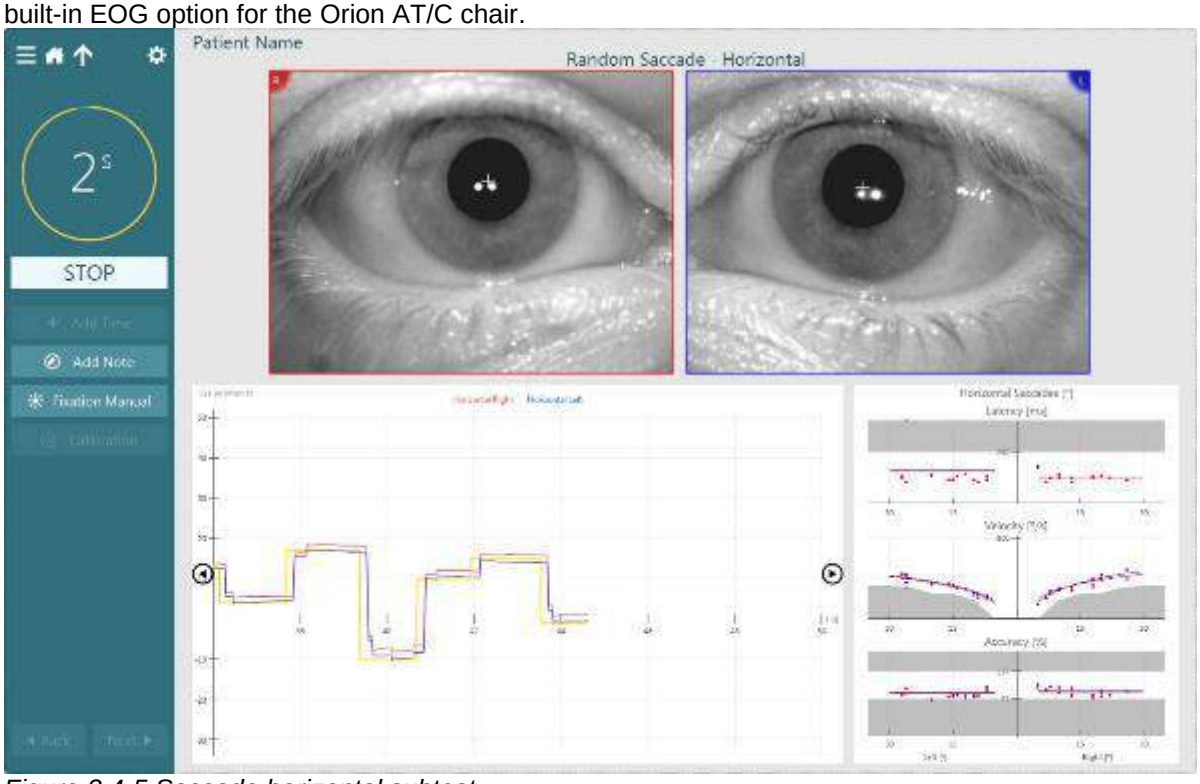


Figure 3.4-5 Saccade horizontal subtest

The saccades are automatically analyzed as the test is performed, and the results are displayed for latency, velocity and accuracy for each saccade. Each eye will be analyzed separately with results plotted for each eye (default) or for a selected eye (right or left).

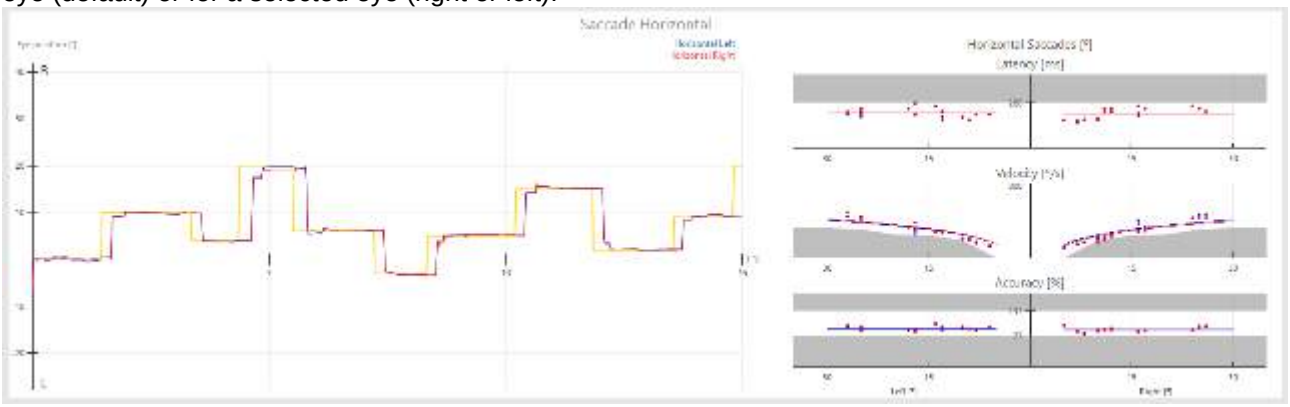


Figure 3.4-6 Saccade results horizontal subtest

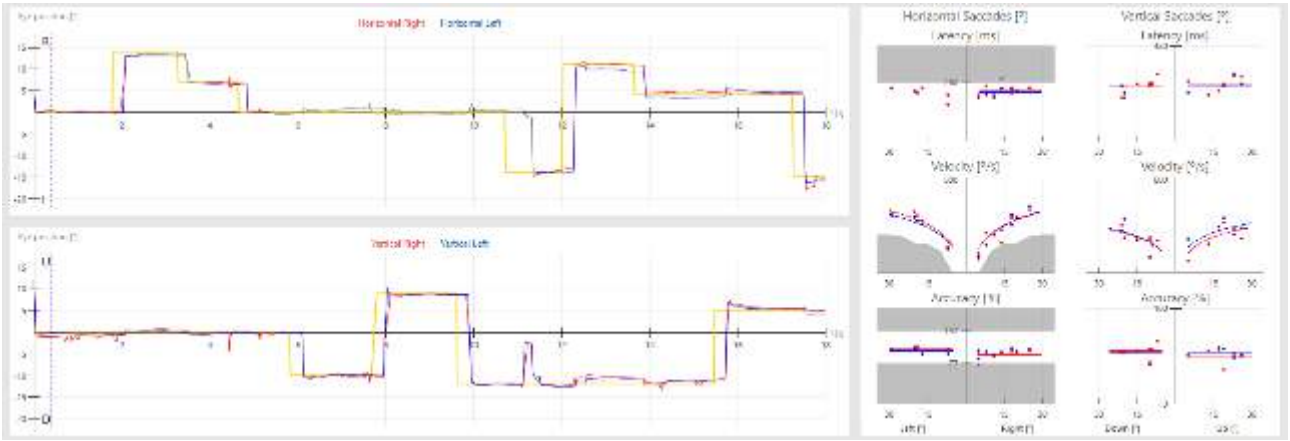


Figure 3.4-7 Saccade results combined subtest

The three essential parameters (latency, velocity and accuracy) are analyzed and displayed for both eyes for horizontal and vertical saccades (Figure 3.4-6). If the Combined subtest is performed, the software will analyze the horizontal saccades separately from the vertical saccades (Figure 3.4-7). The results will display each saccade jump as a dot colored for the respective eye. Average lines for the Latency and Accuracy graphs are calculated for each direction (e. g. left versus right movements) of saccade jumps and regression curve fits are calculated for each eye and direction for the saccade Velocities. Test thresholds are available for horizontal saccades and will be marked in the graphs with gray shading. If one of the average lines or part of the regression curve fit falls into the shaded areas, the software will mark the analysis with a red diamond.

3.4.4 Saccadometry test

The Saccadometry test analyzes the patient's response to fixed saccades where the patient follows the target presented (prosaccades) and looks in the opposite location to where the target is presented (anti saccades). The saccadometry test can be configured with up to five subtests (Figure 3.4-8). The default test has a subtest with 100 prosaccade jumps between 10° followed by a subtest with 100 anti-saccade jumps at 10°. Each subtest has three positions where the target can be found. The saccadometry test is a long and repetitive test. Patients may become inattentive or fatigued during the test.

Note: This test can be performed using electrodes for ENG evaluations. To perform this test in an Orion rotational chair, the user needs to have external Datalink connection with Orion reclining chair.

Practice Mode

The test can optionally begin with a practice segment. This option is enabled from the temporary settings screen (or Protocol Management) to begin the test with ten jumps that the software will not count as part of the test. Using this practice mode can improve the patient's understanding of how to perform the test. If activated, when the test is started, the waveform will be dimmed and a practice mode counter will be displayed. Once the practice mode is completed, the test will begin recording data.

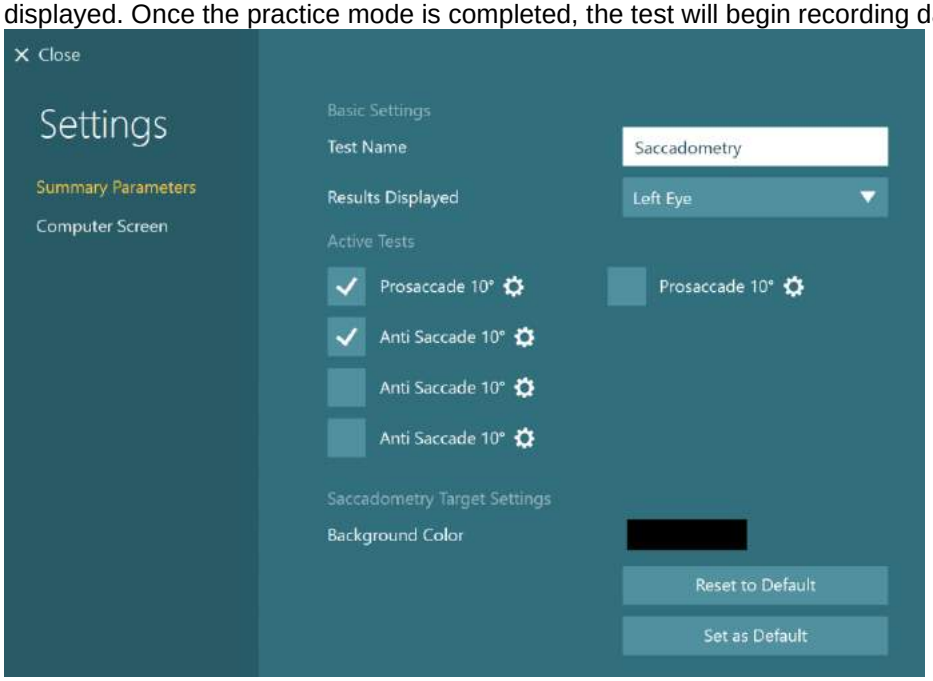


Figure 3.4-8 Configuration screen for saccadometry test

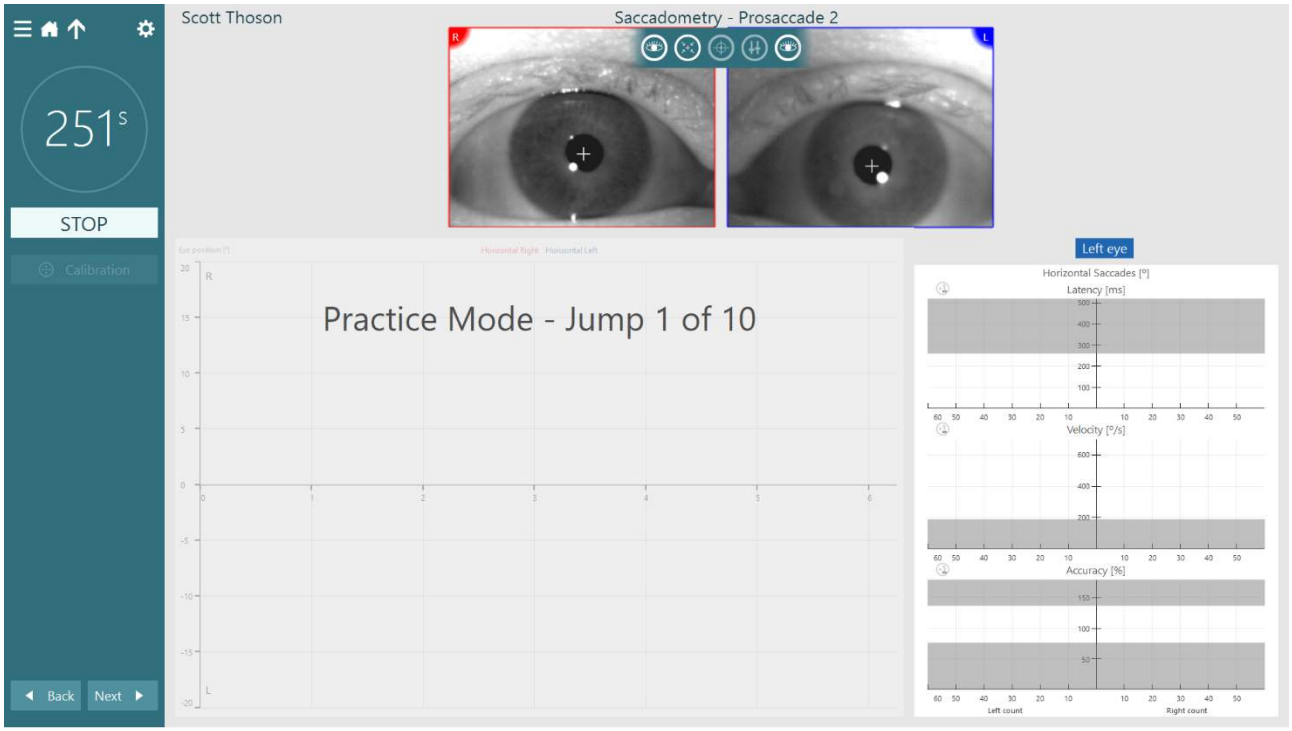


Figure 3.4-9 Prosaccade test screen

Prosaccade
The target will be displayed in the center of the stimulus screen (Figure 3.4-9). The target will jump back and forth between the two locations. The patient should follow the pattern of the moving target.

Using one target position
If the number of dots is set to one, then the target will alternate between the left and right position as defined in the Jump Size field. If the field is set to 10°, then the target will alternate between left 10° and right 10°.

Using two target positions
If the number of dots is set to two, then the center target will be displayed. The patient will look at the center dot, then look at the location of the target stimulus which will be displayed either left or right of the center dot, then return to the center position.

Anti Saccade
The target will be displayed in the center of the stimulus screen. The target will jump back and forth between the two locations. The patient should look in the opposite location of the moving target.

Using one target position
If the number of dots is set to one, then the target will jump from the center position to the left or right position briefly then return to center.

Using two target positions
If the number of dots is set to two, then the center target will be displayed and the target position will briefly appear. The patient will need to look at the center target, then look at the opposite target than the one thatt flashed, then return to the center position.

Using three target positions
If the number of dots is set to three, then the center and both left and right dots will be displayed. The target will flash briefly. The patient will need to look at the center target, then look at the opposite target than the one that flashed, then return to the center position (Figure 3.4-10).

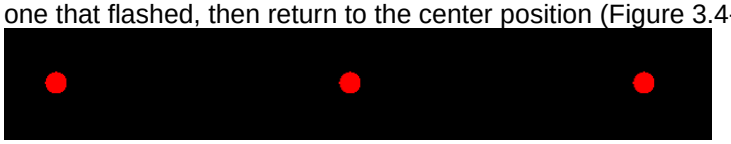


Figure 3.4-10 Anti Saccade stimulus with three dots

Results Displayed
The Saccadometry results are displayed on the summary screen (Figure 3.4-11). The individual prosaccade subtest and anti saccade subtest are analyzed in the same manner as the standard saccade subtest. The summary screen shows each prosaccade or anti saccade jump overlapped. Solid traces are saccades made in the correct direction, and dashed lines are saccades made in the incorrect direction. The plot for the Directional Error Rate gives a quick glance at how effective the patient was able to perform the subtest.

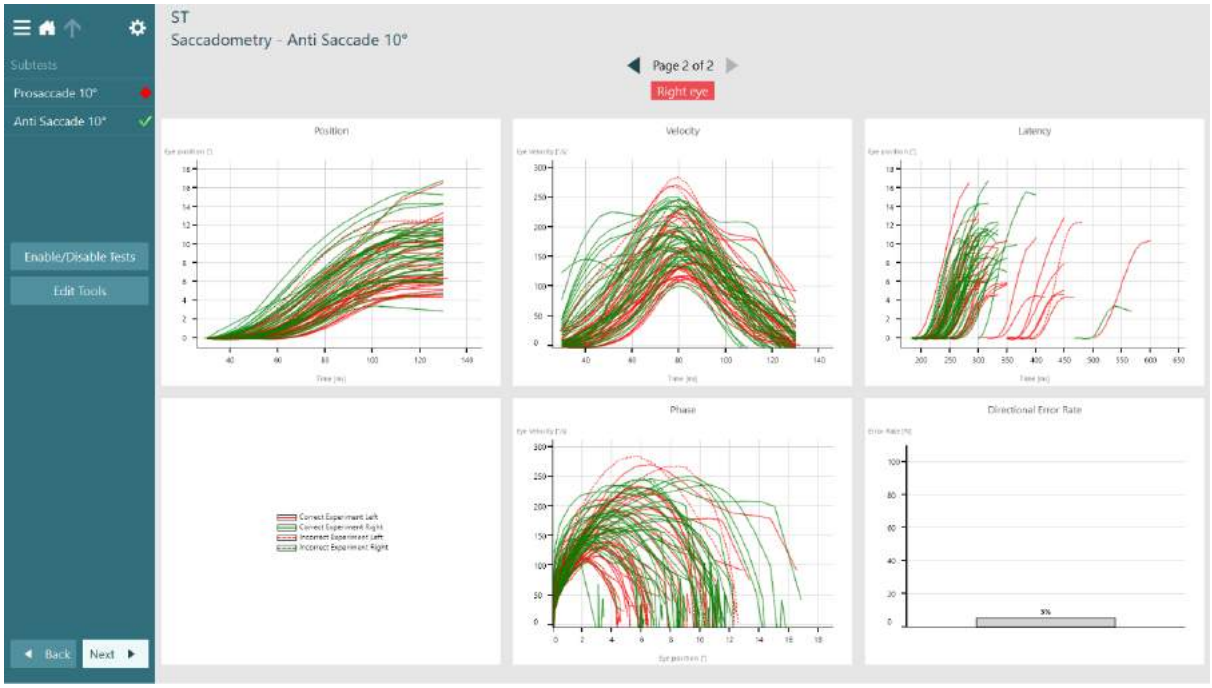
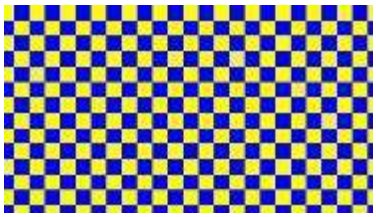


Figure 3.4-11 Anti Saccade Summary

3.4.5 Optokinetic test

The Optokinetic test is used to examine eye movement during stimulation from a large, moving pattern. The VisualEyes™ 525 software can generate various stimuli patterns that can move across the TV or projection screen in horizontal or vertical directions.



Checker Board

Trains with Tracks

Spheres

During the slow phase of the nystagmus the eyes move with the velocity of the projection pattern.
The eyes then make a fast corrective eye movement (saccade) back to center. This nystagmus continues to occur throughout the duration of the test. In the default Optokinetic test, the patient's ability is assessed in four tests following moving stimulus patterns at 20 degrees per second (left moving and right moving) and 40 degrees per second (left moving and right moving). An optional pair of tests at 30 degrees per second is also available. These velocities can be changed if desired, though it is recommended to test each direction at default velocities which will then be shown in the Symmetry graph on the Optokinetic summary.

Note: This test can be performed using electrodes for ENG evaluations. To perform this test in an Orion rotational chair, the user needs to have either external Datalink connection with Orion reclining chair or a built-in EOG option for the Orion AT/C chair. Orion AT/C chair has only line pattern as stimuli.

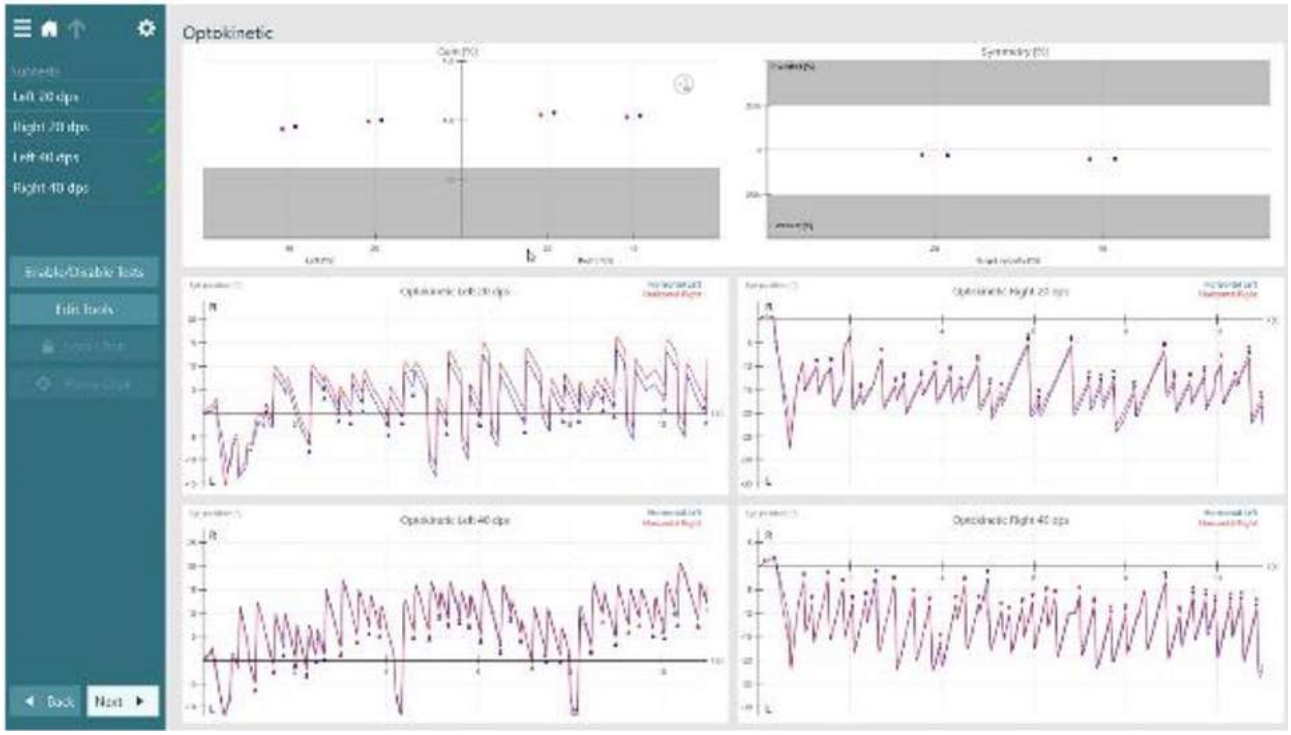


Figure 3.4-12 Optokinetic summary

The optokinetic subtest will display the stimulus pattern on the TV or projection screen. The test will last 15 seconds (though more time can be added with the **Add Time** button) and display the stimulus moving in the selected direction. Have the patient follow the targets as they go across the screen. Typically the patient should focus on the center ±5° of the stimulus, picking up the target as it comes from one side, then as the target leaves the patient's field of focus, the patient will go back and pick up the next target. The optokinetic test is considered fairly intensive and may not be performed correctly by the patient on the first attempt. If the patient does not appear to be following the target and producing a noticeable nystagmus pattern, you may need to instruct the patient again and redo the test (Figure 3.4-13).

During data collection, the Gain graph will update with the patient's response with an average gain for each eye. The average gain is defined as the patient's average slow phase velocity divided by the stimulus velocity as a percentage. In the Optokinetic summary (Figure 3.4-12), the average gain from each subtest will be compared with the other subtests and the results will be displayed in the Symmetry graph. If the average gain falls outside the test thresholds or the symmetry value at one of the velocity pairs falls outside the test thresholds, the test will be marked as outside thresholds and have a red diamond displayed.

By clicking the symbol , the user can view the numerical value of gain and symmetry in the graphical representation (refer section 7.5 for details).

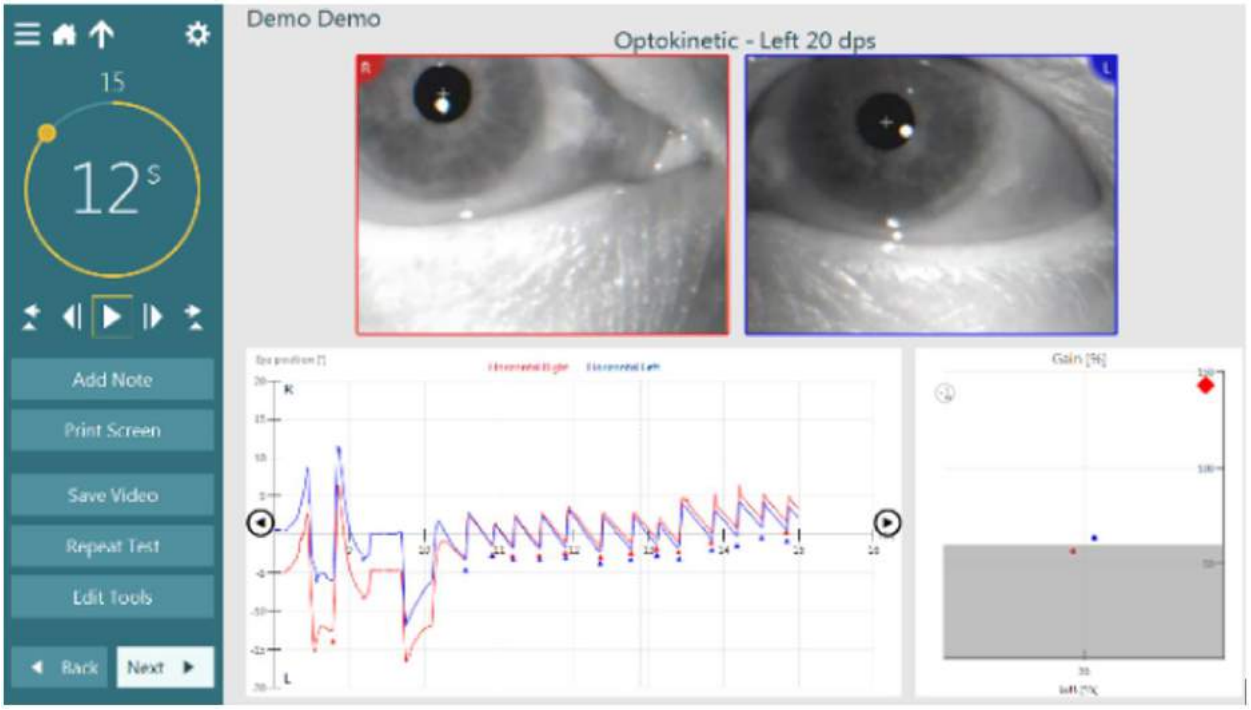


Figure 3.4-13 Optokinetic test display (during data collection)

3.5 Head Rotation Testing

Head rotation testing encompasses active head rotation, dynamic visual acuity, and head impulse testing. The tests utilize the VORTEQ 2nd gen. IMU or VORTEQ rate sensor to measure head velocity along with eye position. In dynamic visual acuity testing, the patient is required to distinguish an optotype character while moving his / her head in the specified direction at the required velocity.

Active head rotation testing has the patient shake his / her head to the required velocity and frequency. When the patient is not able to achieve this action, the examiner may perform passive head rotation tests (horizontal/vertical) with the examiner moving the patient's head in time with the software metronome at low frequencies.

3.5.1 Active Head Rotation test (VORTEQ AHR)

Active Head Rotation testing involves the patient shaking his head from side to side (horizontal active) or up and down (vertical active) in rhythm to a pre-determined metronome pattern of beeps emitted by the computer. During the test, the software monitors the velocity of the turning head and matches this velocity data against the velocity of the patient's eyes. The resulting analysis of the data provides information about the efficiency of the vestibulo-ocular reflex system (VOR). The tests are performed either actively by the patient or passively by the operator moving the patient's head.

The Active Head Rotation test can be performed using the VORTEQ rate sensor or the VORTEQ 2nd gen IMU. The VORTEQ rate sensor provides angular velocity data for one direction tested, and the VORTEQ 2nd gen IMU will provide angular velocity data in three directions. When using the VORTEQ rate sensor, make sure the orientation of the sensor is correct for the type of subtest performed.

The target size using a TV or projector will be defined by the size of the calibration target. If the patient is unable to see the target clearly, enter the calibration section and adjust the calibration target size accordingly. The target will remain at the larger size until it is reset from the Calibration screen.

The test will begin with a practice segment. At the start of the test the metronome will beep at the initial frequency for 5 seconds with "Practice Mode (5s)" displayed overlayed on the waveform (Figure 3.5-1). After the practice mode, if the software does not detect the movement of the VORTEQ rate sensor, the software will warn the user to check the rate sensor orientation.

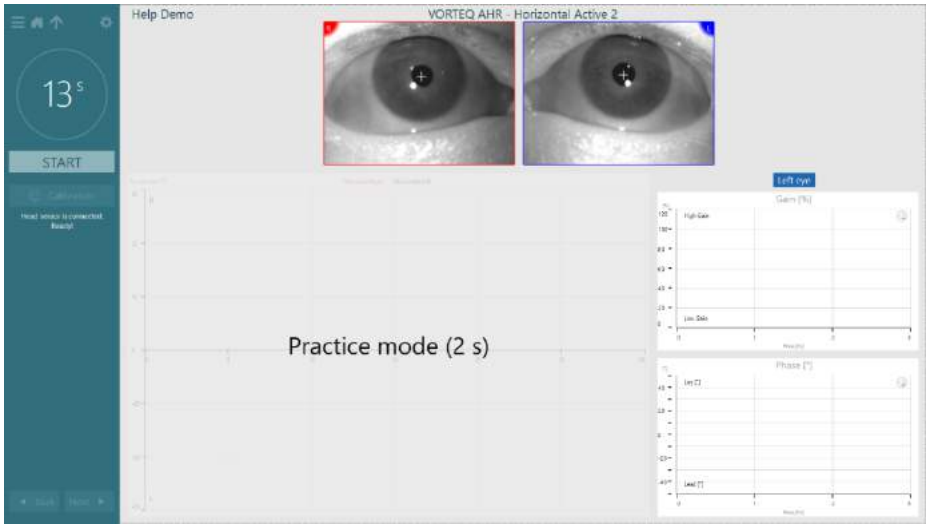


Figure 3.5-1 Active Head Rotation Practice Mode

The patient will continue head shaking to the sound of the metronome beep. After the minimum cycle count is reached the metronome frequency will increase by 1 Hz. The test will end once the minimum cycle count is reached for the end frequency (default is 2 Hz). The program will then analyze the cycles and average the gain, phase, and symmetry values at each frequency.

By clicking the symbol , the user can view the numerical value of gain and symmetry in the graphical representation (refer section Figure 3.5-2 and 7.5 for details). If the user chooses to show the numerical values at each frequency, the value will be displayed on the graph along with the number of cycles used to calculate the average in parentheses.

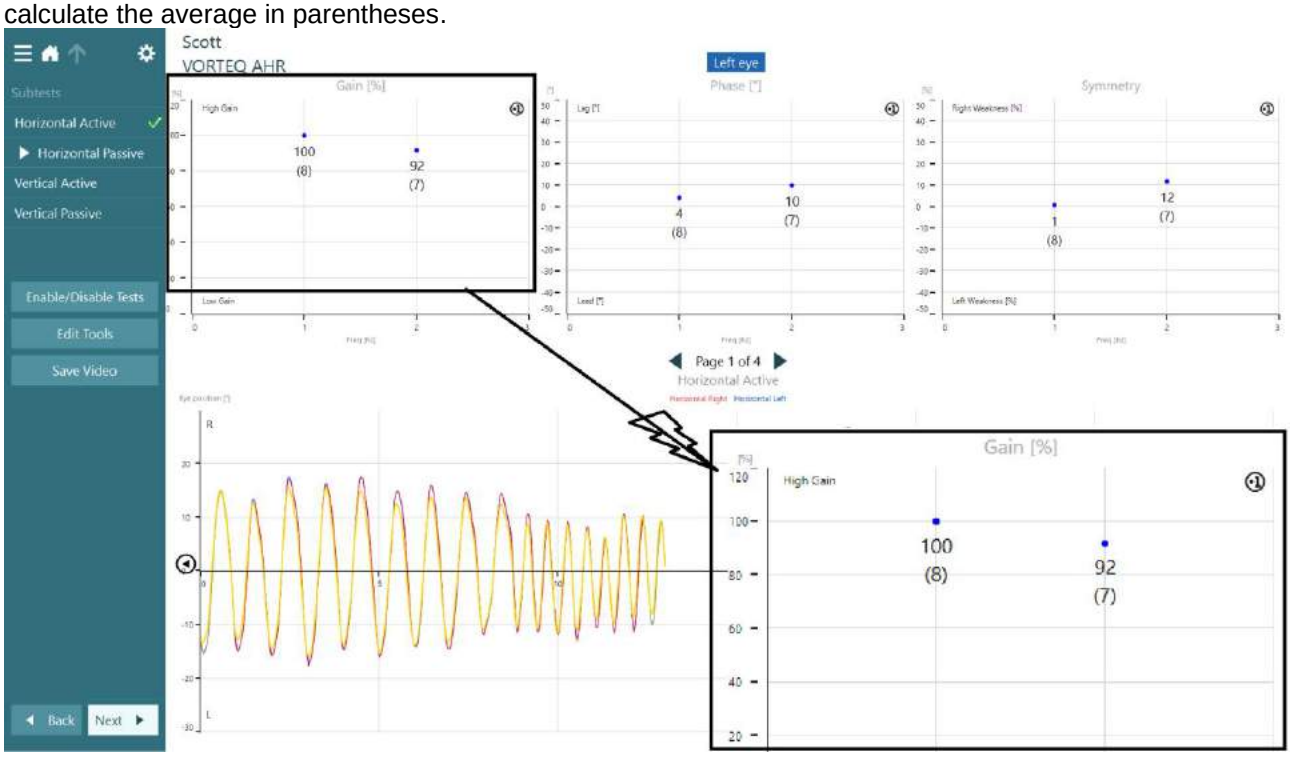


Figure 3.5-2 Active Head Rotation Test with Gain Graph Emphasized

3.5.2 Dynamic Visual Acuity test

Dynamic Visual Acuity (DVA) testing has the patient distinguish the orientation of the optotype character as the patient moves his / her head at a specified velocity and direction. The DVA test is performed with the patient wearing the DVA headband instead of the binocular goggles. If the patient normally wears eyeglasses or contact lenses these should also be used during the DVA test, and the DVA headband will allow this.

The default patient distance to the stimulus is eight feet (2. 4 meters) in a standard laptop setup. This distance and stimulus size can be configured from Configuration > System Default Settings > DVA Stimulus. The DVA stimulus can be displayed on the TV or on the primary computer screen if the office dimensions do not allow for the required patient distance. If the stimulus is set to the TV, the computer screen will show a large optotype for the operator instead of the required size for the DVA logMAR assessment.

Static Acuity

The first subtest of the DVA test is the static acuity assessment. Once the test begins (either by the operator or the patient) the optotype will appear in a random orientation. After setting the patient's static acuity the software will display the static acuity in the DVA results graph as a solid black circle (Figure 3.5-3).

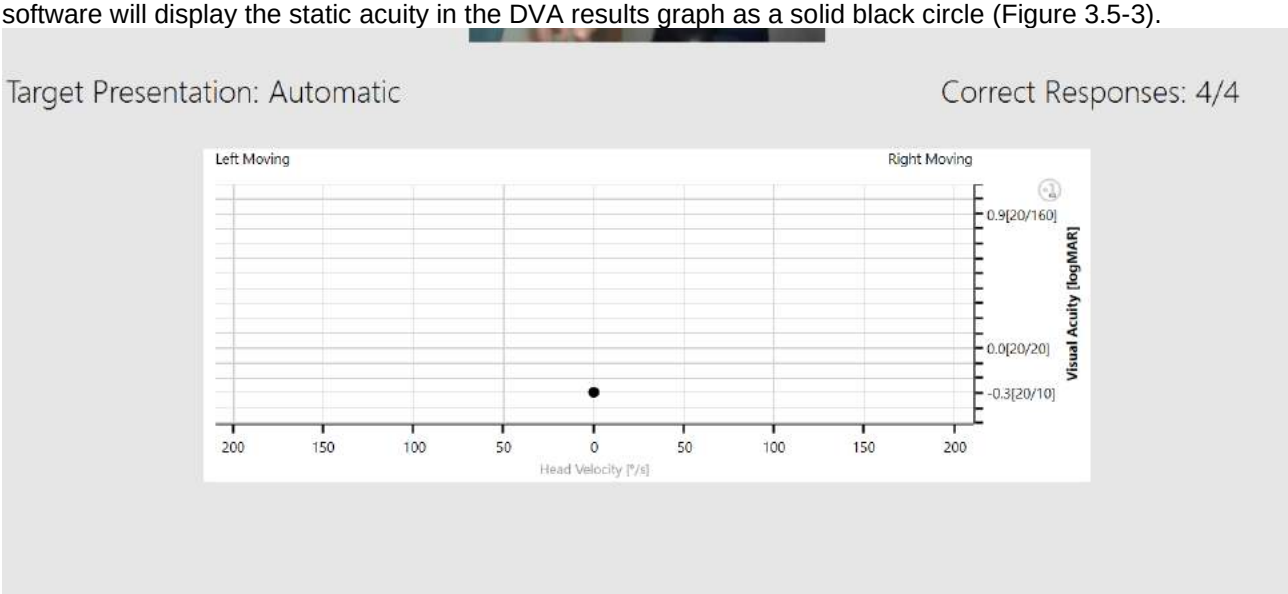


Figure 3.5-3 Static Acuity

Automatic Presentation

In the automatic presentation style, the patient can confirm the orientation of the optotype using the matching direction button on the RF Remote control. Alternatively the patient can say the orientation out loud and the operator can then use the keyboard arrow keys or the direction buttons in the side panel to enter the patient's response. When the patient correctly distinguishes the optotype, the size will decrease. Conversely if the patient incorrectly distinguishes the optotype, the size will increase. The static acuity is defined when the patient can distinguish the optotype orientation three times at a particular LogMAR level.

Manual Presentation

In the manual presentation style, the operator sets the initial optotype size to LogMAR 0, then uses the Increase Size and Decrease Size buttons to adjust the optotype size to the size where the patient can clearly identify the orientation. The operator will then use the Rotate Optotype button to randomly change the orientation of the optotype. If the patient can correctly distinguish the optotype orientation at a specific LogMAR level three times, then the operator will use the Set Acuity button to lock in the value of the patient's DVA static acuity (refer Figure 3.5-4).

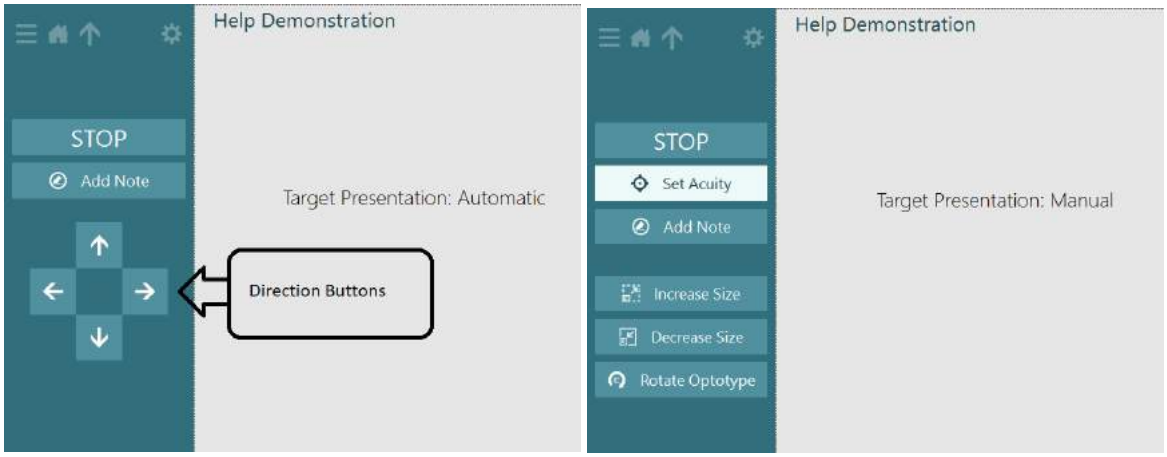


Figure 3.5-4 Dynamic Visual Acuity Direction Buttons (Automatic) vs. Size and Rotation Buttons (Manual)

Dynamic Acuity

The remaining subtests of the DVA test are dynamic acuity assessment in different directions. Once the subtest begins (either by the operator or the patient) the optotype will appear in a random orientation. The patient will move his / her head in tune with the metronome.

Automatic Presentation

In the automatic presentation style, the patient shakes his / her head and chooses the orientation of the optotype using the matching direction button on the RF Remote control. Alternatively the patient can say the orientation out loud and the operator can then use the keyboard arrow keys or the direction buttons in the side panel to enter the patient's response. When the patient correctly distinguishes the optotype, the size will decrease. If the patient incorrectly distinguishes the optotype, the size will increase. The dynamic acuity is defined when the patient can distinguish the optotype orientation three times at a particular LogMAR level. The optotype will only be displayed when the patient moves his / her head to the noted direction at the desired velocity. Horizontal subtests are set to 100 degrees per second, and vertical subtests are set to 75 degrees per second.

Manual Presentation

In the manual presentation style, the operator sets the initial optotype size to LogMAR 0, then uses the Increase Size and Decrease Size buttons to adjust the optotype size to the size where the patient can clearly identify the orientation (also activated by the up and down arrow keys respectively). The operator will then use the Rotate Optotype button to randomly change the orientation of the optotype (also activated by the left and right arrow keys). If the patient can correctly distinguish the optotype orientation at a specific LogMAR level three times, then the operator will use the Set Acuity button to lock in the value of the patient's DVA dynamic acuity.

The results will be displayed after each subtest is completed (refer Figure 3.5-5).

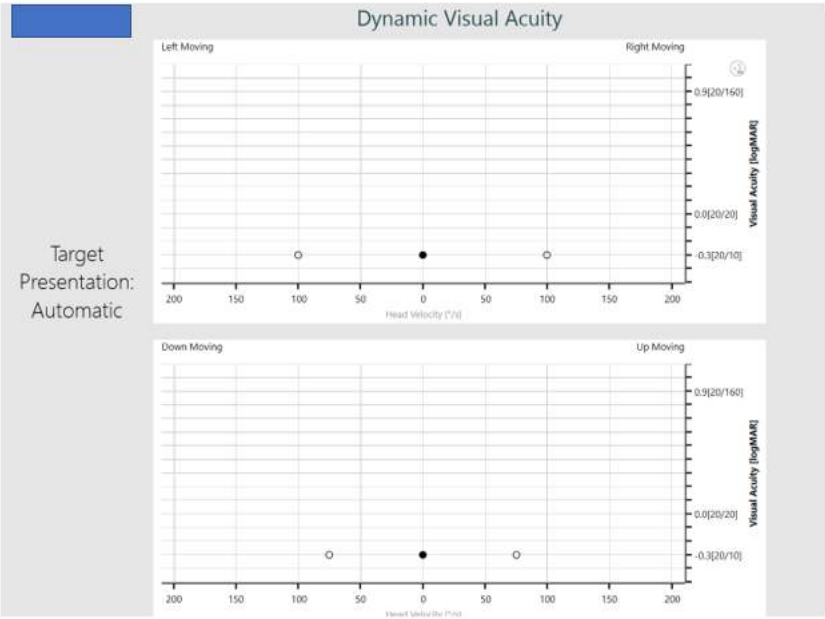


Figure 3.5-5 Dynamic Visual Acuity Results

3.6 Video Head Impulse Testing

3.6.1 vHIT VORTEQ

Using the top mount or side mount binocular goggles, the user can perform the head impulse test using the VORTEQ head sensor or VORTEQ second generation IMU sensor. If using the VORTEQ head sensor on the VLink interface box, the head sensor will have to be rotated to the correct orientation for the subtest.

Instruct the patient to gaze at the target and keep the neck muscles relaxed. Let the patient know the head impulses will be of small amplitude so the patient can relax the neck muscles.

The VHIT VORTEQ tests use higher sampling rates than standard VNG tests. To accomplish this with the same cameras, the height of the eye windows is reduced to increase the temporal resolution. The eye windows are then scaled on the screen for optimal fit to maintain the video ratio.

Test Type	**Frame Rate (Hz)**	**Width (pixels)**	**Height (pixels)**	**Ratio**
Standard VNG Test	100	320	240	4:3
LARP / RALP VHIT	150	320	160	4:2
Lateral VHIT	250	320	80	4:1

Lateral VHIT
Perform the test by holding the patient's jaw while standing behind the patient (Figure 3.6-1). During the test, the patient's teeth should be clenched so the hand thrust will be transferred to the patient's head. Practice a few impulses before beginning the recording. This will also familiarize the patient with the stimulus. Do **not** allow the hands to touch or move the goggles during head impulses as that movement will affect the gain measurement.

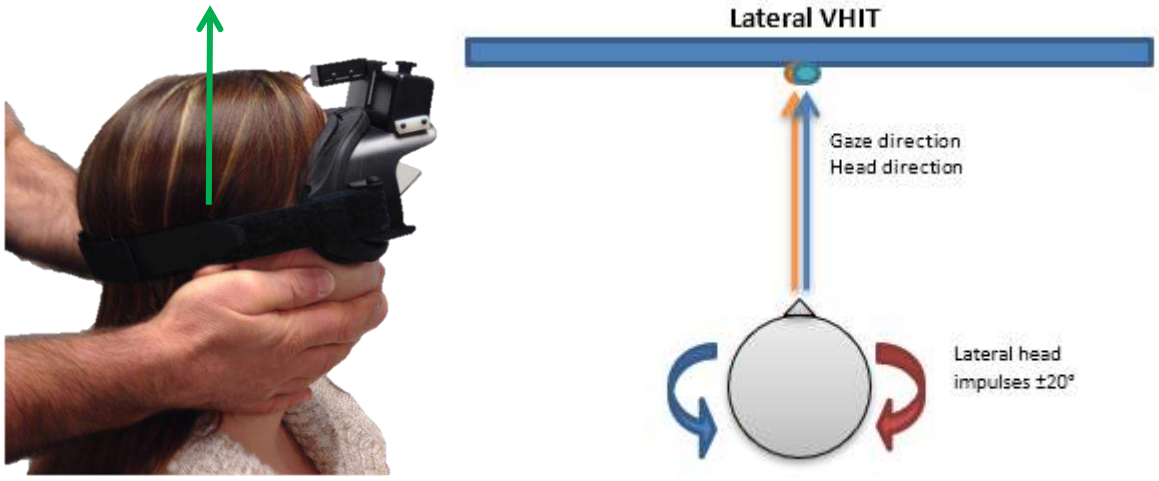


Figure 3.6-1 Lateral VHIT

Left Anterior Right Posterior (LARP) / Right Anterior Left Posterior (RALP) VHIT
The modified vertical head impulse test method allows LARP and RALP VHIT to be performed using purely vertical eye tracking. The test is performed by placing both hands on top of the head or alternatively by holding the head with one hand on top and the other holding the chin, administering vertical impulses with the head turned to the side by about 30-35 deg (Figure 3.6-2). This orientation places the vertical canals in the direction of head travel producing a vertical eye movement response.

The patient's head is turned 35deg to the right for LARP test and 35deg to the left for RALP test (Figure 3.6-3). Patient's gaze is directed at the center target. Pitch head down about 10deg (chin drops 1 inch), pitch head up about 10deg.

To achieve 35 degrees, place a mark on the wall 25" / 64cm from a center target with patient seated 36" / 91 cm away from the center target.

Figure 3.6-2 LARP VHIT

Figure 3.6-3 RALP VHIT

Performing the test

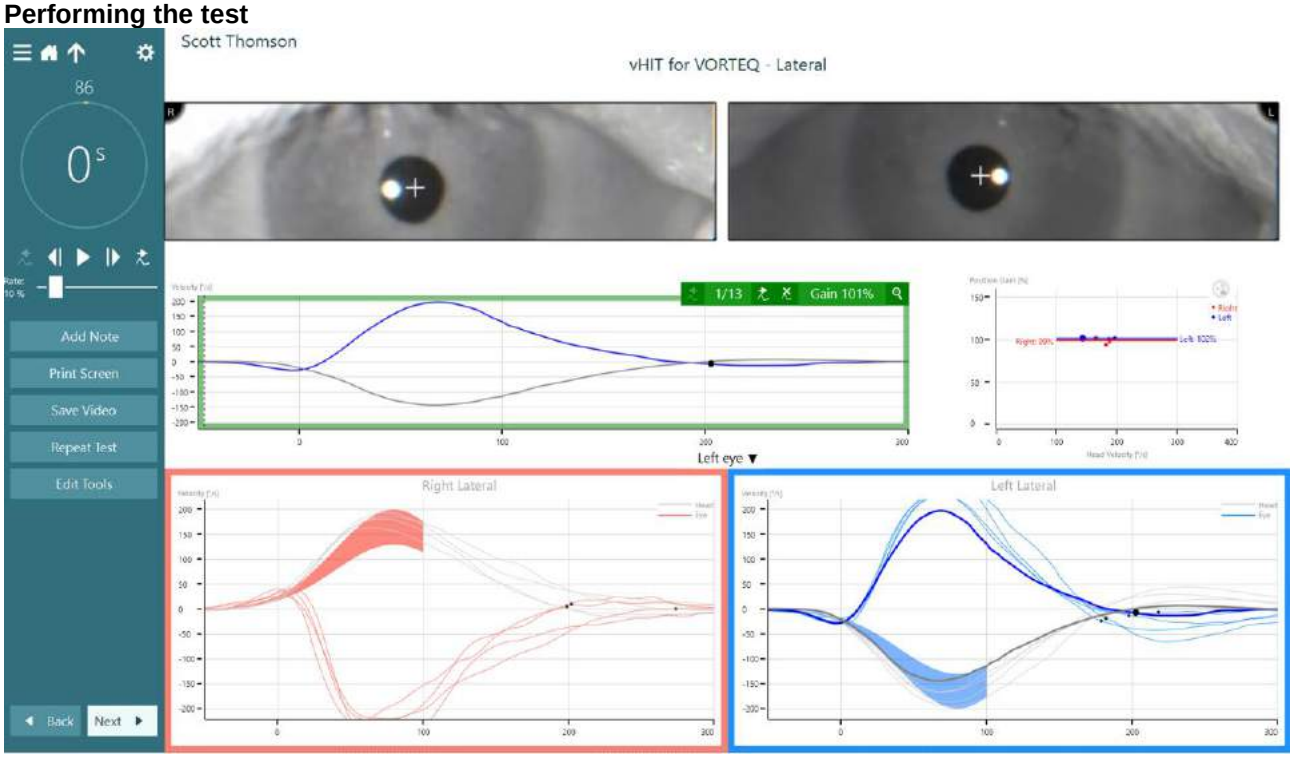


Figure 3.6-4 Reviewing the Lateral vHIT for VORTEQ Test

During the test, the head impulses will be shown in the center of the screen as well as in the head impulse window at the bottom. Left head impulses are shown in the blue window on the right side, and right head impulses are shown in red on the left side. If the head impulse fits the swoosh pattern the head impulse box in the center will be outlined in green. If the head impulse is too slow the box will be outlined in yellow, and if the head impulse is performed to fast the box is outlined in red.

Due to the speed in which the head impulse is performed, the video playback speed can be adjusted slower to better detect if saccades are present in the eye position data. The video playback speed is adjusted using the slider below the playback timer (Figure 3.6-4).

3.6.2 vHIT EyeSeeCam

Using the EyeSeeCam camera goggle, the user can perform the head impulse test with one camera recording either eye with minimal goggle slippage. As the clinician performs small head thrusts on the patient's head, the waveform will show the head impulse in the waveform trace window and a close-up of that head impulse below. If the head impulse and eye movement are in opposite directions and the head impulse was performed so that the impulse fell within the swoosh profile, then the software will accept the head impulse and show a green checkmark in the upper right corner of the respective head impulse window. If the head impulse failed the criteria, a red '**X'** will be displayed in the upper right corner. Accepted head impulses will increment the appropriate head impulse count in the timer on the side panel. When the accepted head impulse count reaches the defined amount (default is 7 head impulses in each direction), the test will end automatically. The clinician can also end the test manually by clicking on the STOP button.

The operator can perform 4 different sub tests using VisualEyes™ system including Lateral vHIT, LARP vHIT, RALP vHIT and SHIMP test. These tests are explained below in detail. Before starting any vHIT test using the EyeSeeCam goggle, the user has to ensure that standard calibration and head calibration is done with EyeSeeCam goggle. If the camera position is adjusted during testing the head calibration must be repeated.

Standard calibration for ESC vHIT
When the user enters the test the calibration options ‘Start Calibration’ and ‘Head Calibration’ will appear. The user can also choose ‘Use Default Calibration’.

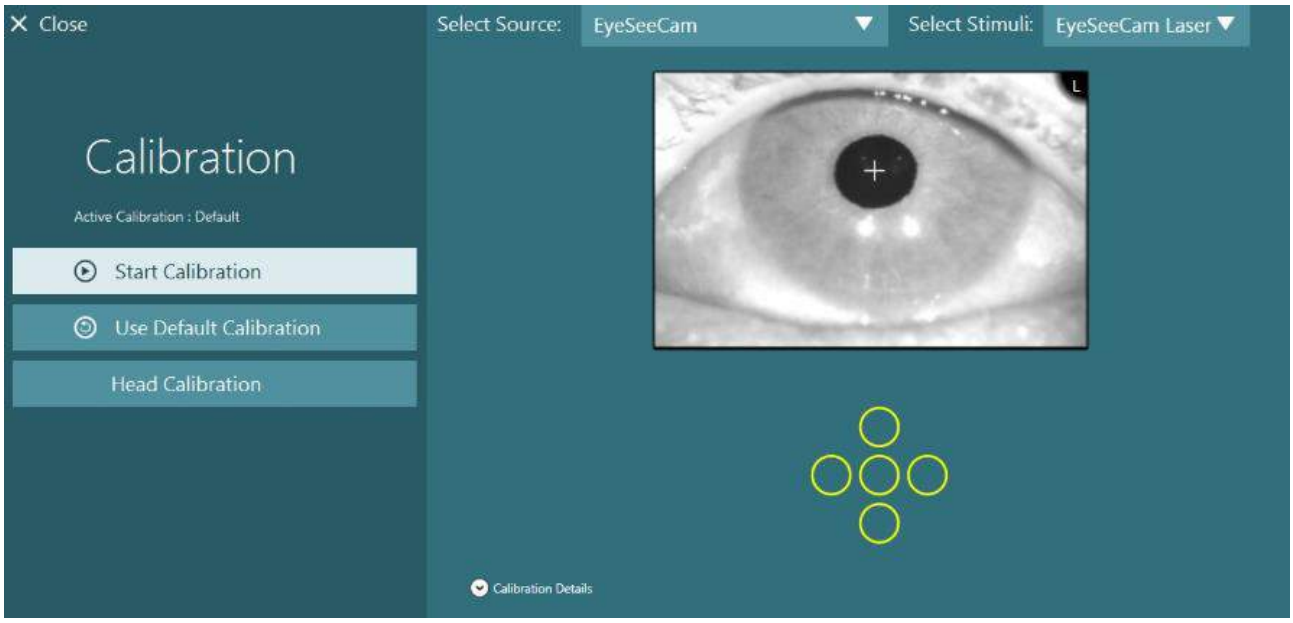


Figure 3.6-5 Standard calibration screen for ESC vHIT

By clicking ‘Start Calibration’, the standard 5 point calibration can be done. Refer to section 2 for detailed method to do the standard calibration (Figure 3.6-5).

Once the standard calibration is done, the user can proceed to ‘Head Calibration’. Ask the patient to fixate at a point as a first step, click ‘Head Calibation’ and ‘Start’ to start head calibration. Ask the patient to shake the head slowly in a horizontal direction. When the system can track the head movement horizontally you get a green bar in the screen. After a few seconds, the system moves to vertical calibration, and you must ask the patient to move his/her head slowly in a vertical direction. When the system can track the head movement vertically you get a green bar in the screen. Once the calibration is done, the user can get a report of head calibration. The user can now proceed with subtest of their choice (Figure 3.6-6).

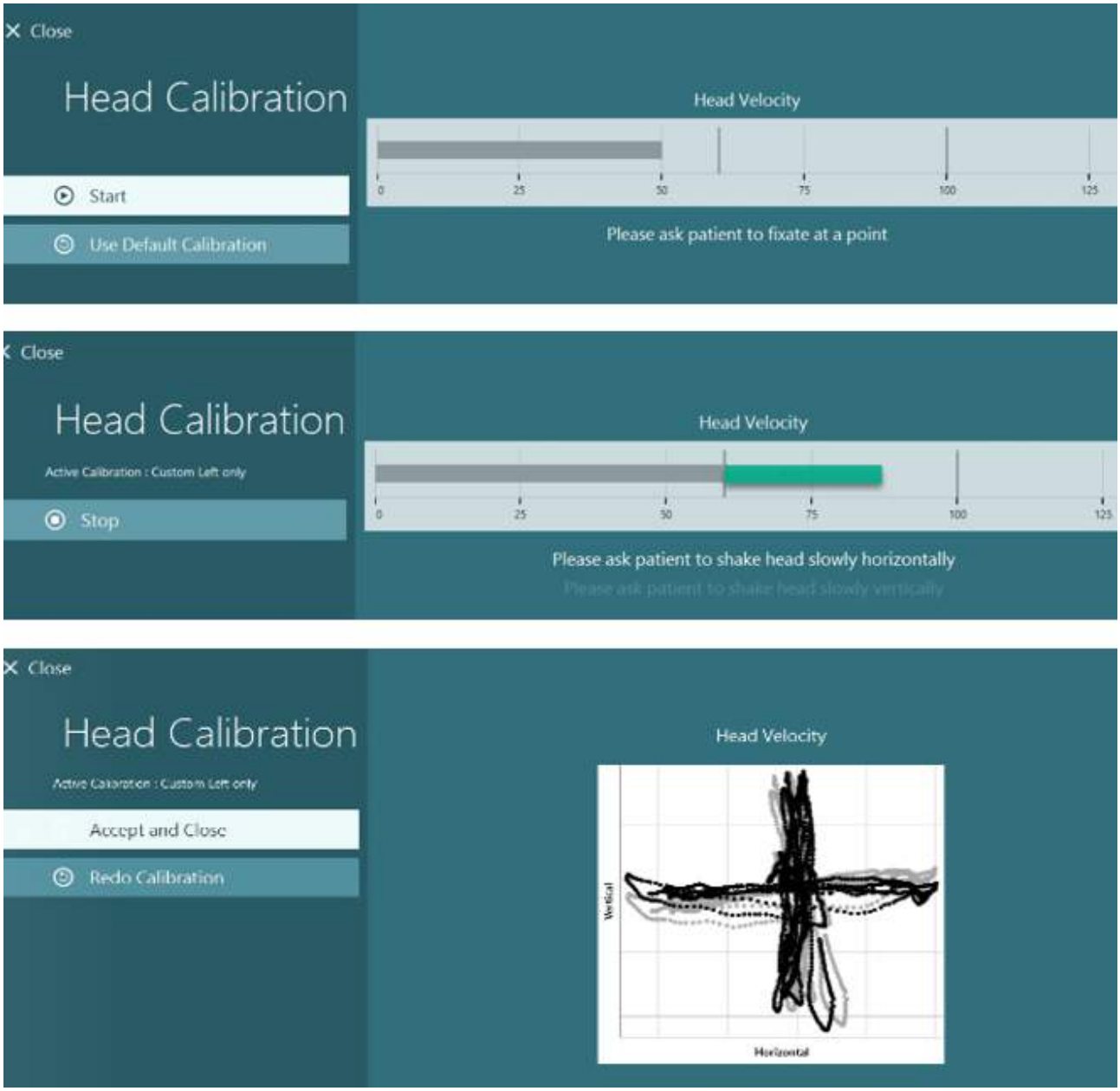


Figure 3.6-6 Head calibration procedure and result screen for ESC vHIT

Lateral VHIT

The Lateral vHIT test assesses the function of the lateral semicircular canals. For this test, hold the patient's jaw while standing behind the patient (Figure 3.6-7). During the test, the patient's teeth should be clenched so the hand thrust will be transferred to the patient's head. Practice a few impulses before beginning the recording. This will also familiarize the patient with the stimulus. Do **not** allow the hands to touch or move the goggles during head impulses as that movement will affect the gain measurement.

Figure 3.6-7 Lateral vHIT hand placement

Left Anterior Right Posterior (LARP) / Right Anterior Left Posterior (RALP) VHIT
The LARP and RALP tests assess the function of the vertical semicircular canals. For assessing the function of the vertical semicircular canals, the head is rotated right-downward to left-upward in the plane of the right anterior and left posterior canals (RALP) or left-downward to right-upward in the plane of the left anterior and right posterior canals (LARP). Alternatively, the head can be rotated 45 degrees to the right for LARP testing and 45 degrees (Figure 3.6-8) to the left for RALP testing. Regardless of setup the patient must always gaze straight ahead.

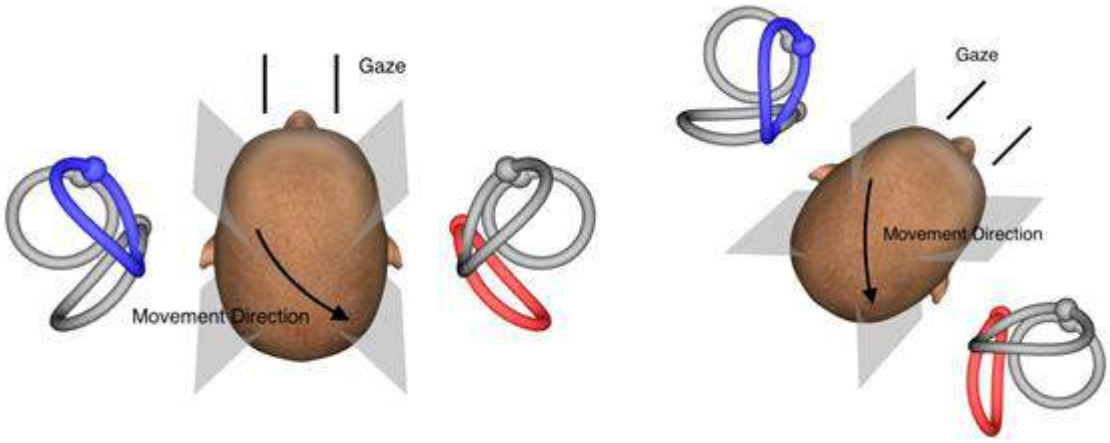


Figure 3.6-8 vHIT testing with head-on gaze and corrected straight gaze in LARP testing

Performing the Test
A three-dimensional head model with the semicircular canals (Figure 3.6-9) is displayed in the upper right corner of the screen. The EyeSeeCam head sensor will automatically tare (i. e. reset) if the sensor is left still. At the start of the test, have the patient look straight ahead and keep the head still. The EyeSeeCam head sensor will then tare and the head model should appear looking forward. As the head impulses are performed, the activated semicircular canal pair are highlighted in blue and red depending on the direction of the impulse.

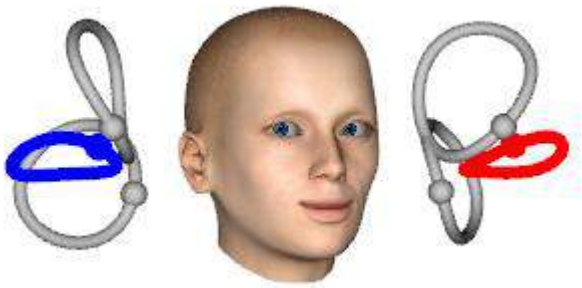


Figure 3.6-9 Head model with highlighted semicircular canals

When the operator performs the head impulse, the software will display the head movement and eye movement in the appropriate impulse graph depending on the impulse direction. If the head movement fits the swoosh velocity profile, the head impulse will be accepted and show a green check mark in the upper right corner of the impulse graph (Figure 3.6-10). Rejected head impulses will display a red x in the upper right corner.

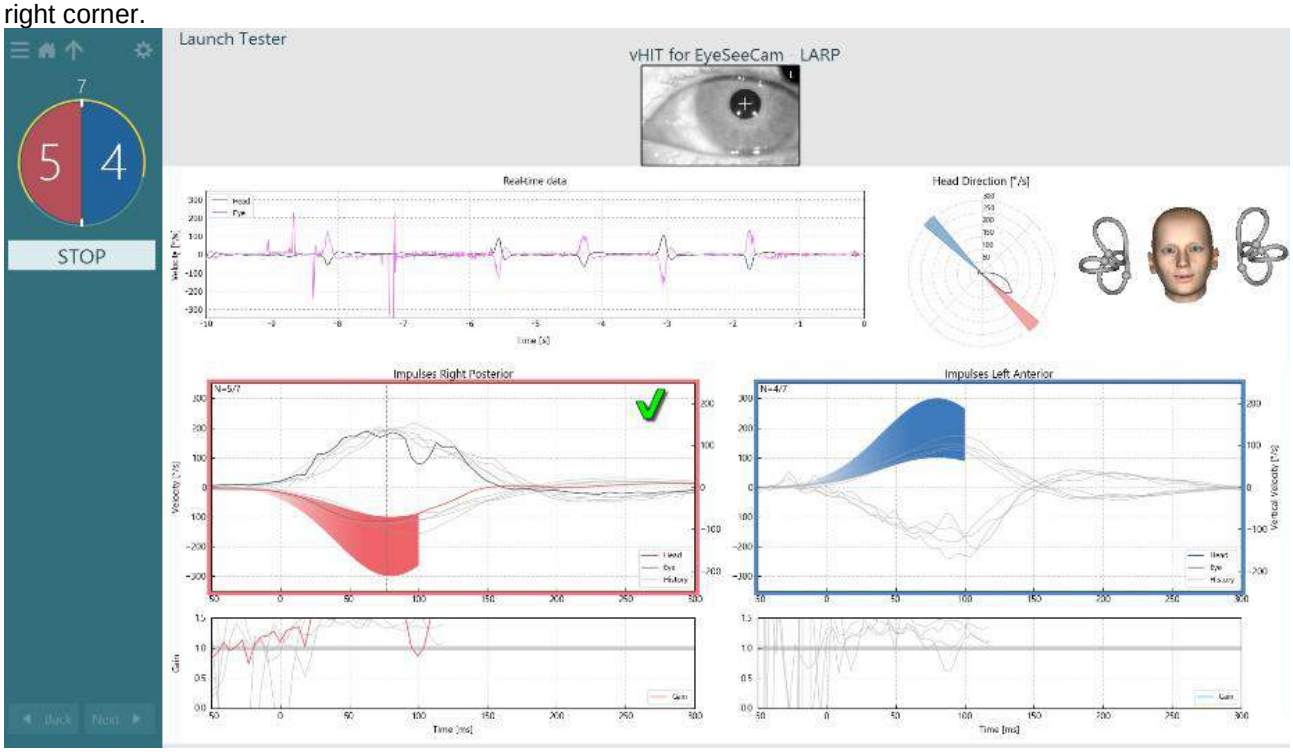


Figure 3.6-10 Example of EyeSeeCam test showing a green checkmark (LARP)

The test will end automatically once the required number of successful head impulses are performed in both directions. The timer is replaced with the head impulse counter with the head impulses separated and the required number of successful head impulses at the top. The clinician can stop the test at any time using either the Enter key on the RF Remote, the STOP button on the screen, or using the foot pedal.

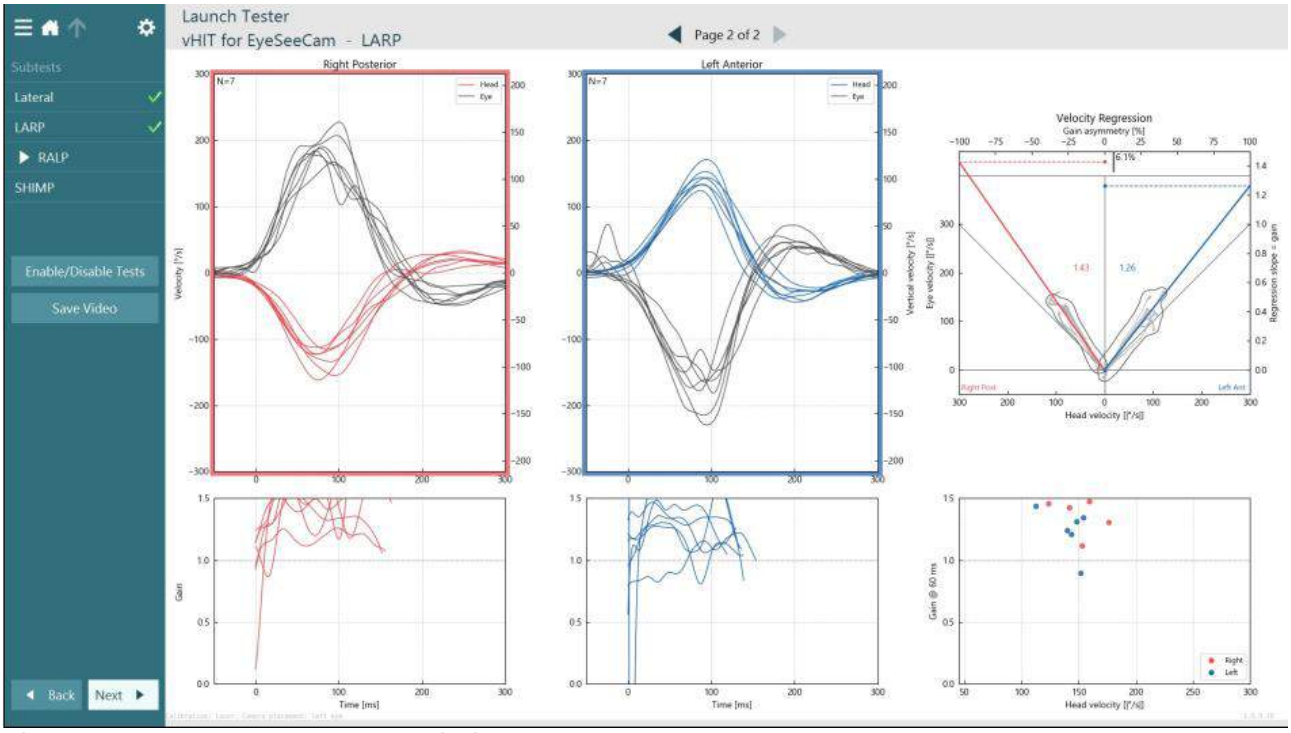


Figure 3.6-11 VHIT EyeSeeCam analysis

As each subtest is performed, the software displays each subtest's analysis on a page (Figure 3.6-11). The analysis displayed is defined by the page navigation at the top of the screen. Once the Lateral, LARP, and RALP tests have been performed, the EyeSeeSix report can be created from the VHIT for EyeSeeCam summary's side panel. If a subtest is repeated, the desired subtest can be selected from the combo boxes at the top of the EyeSeeSix report (Figure 3.6-12).

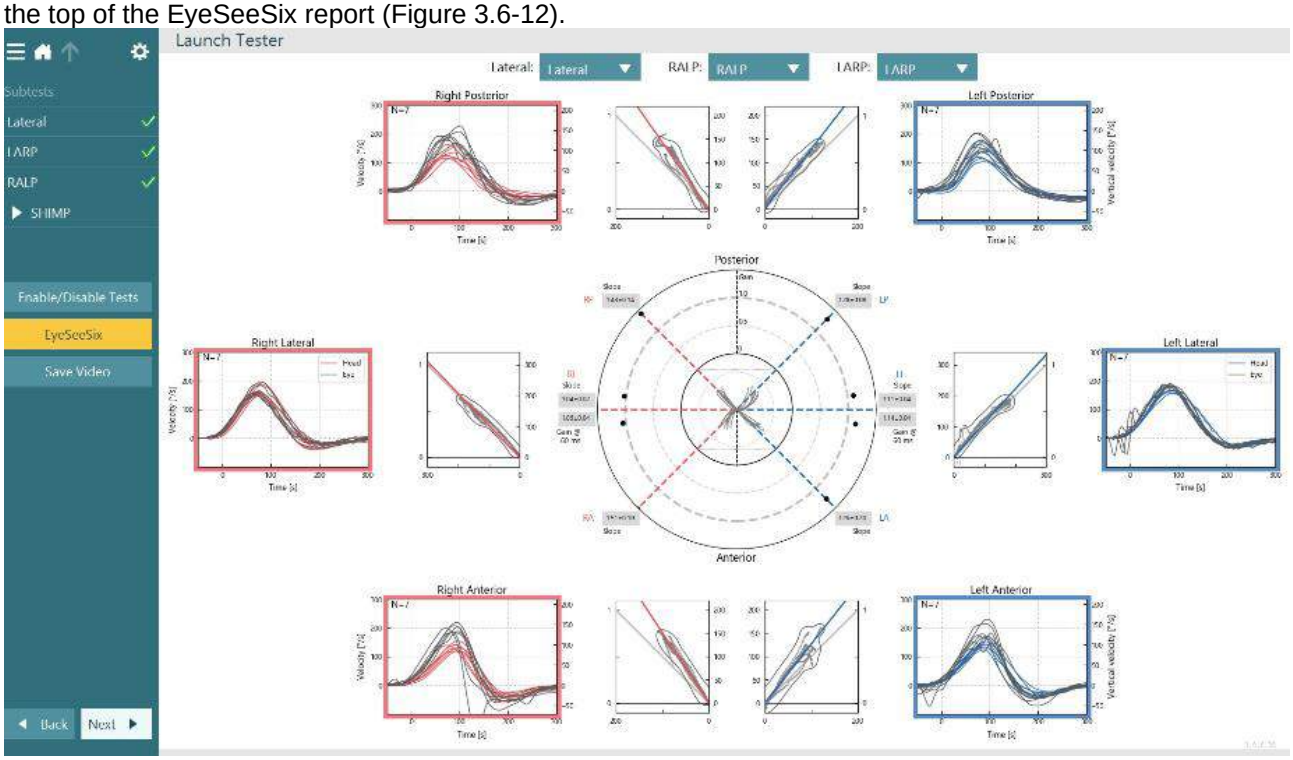


Figure 3.6-12 VHIT EyeSeeSix report

To view the information in a tabular form, click on the Numerical Results button (Figure 3.6-13). The text can be copied (click and drag or by using Ctrl + A on the keyboard) and pasted into Excel or other spreadsheet software.

Summary

Velocity Gain

	Right				Left			
	mean	std	median	iqr	mean	std	median	iqr
Gain @ 40 ms	0.75	0.05	0.75	0.06	0.96	0.08	0.96	0.12
Gain @ 60 ms	0.83	0.04	0.83	0.06	1.01	0.05	1.01	0.07
Gain @ 80 ms	0.90	0.05	0.90	0.07	1.02	0.02	1.02	0.02
Median 0-100 ms	0.80	0.05	0.80	0.07	1.02	0.07	1.02	0.10
Regression	0.86	0.03	0.86	0.05	1.03	0.04	1.03	0.06

Saccades

	Right			Left		
	1st Saccade	2nd Saccade	3rd Saccade	1st Saccade	2nd Saccade	3rd Saccade
Amplitude [°]	14.99 ± 000.92	-	-	13.58 ± 000.52	7.24 ± 002.52	-
Peak Velocity [°/s]	142.23 ± 004.12	-	-	136.61 ± 016.03	243.53 ± 050.31	-
Duration [ms]	185.50 ± 010.50	-	-	168.00 ± 011.00	83.00 ± 008.00	-
Latency [ms]	8.50 ± 010.50	-	-	22.00 ± 003.00	579.00 ± 024.00	-
Total	2	0	0	2	2	0

Data

Saccade Parameters

	Head Impulse			1st Saccade				2nd Saccade				3rd Saccade			
	Direction	Peak Time [ms]	Peak Velocity [°/s]	Amplitude [°]	Peak Velocity [°/s]	Duration [ms]	Latency [ms]	Amplitude [°]	Peak Velocity [°/s]	Duration [ms]	Latency [ms]	Amplitude [°]	Peak Velocity [°/s]	Duration [ms]	Latency [ms]
1	right	74.00	189.40	14.07	146.35	175.00	-2.00	-	-	-	-	-	-	-	-
2	left	95.00	190.06	14.10	152.64	157.00	25.00	9.76	293.84	91.00	603.00	-	-	-	-
3	right	92.00	197.11	15.90	138.10	196.00	19.00	-	-	-	-	-	-	-	-
4	left	79.00	160.99	13.07	120.58	179.00	19.00	4.72	193.23	75.00	555.00	-	-	-	-

Figure 3.6-13 Numerical Results

Clicking on the 3D Waves button will toggle the display of the waveforms in 3D space (Figure 3.6-14).

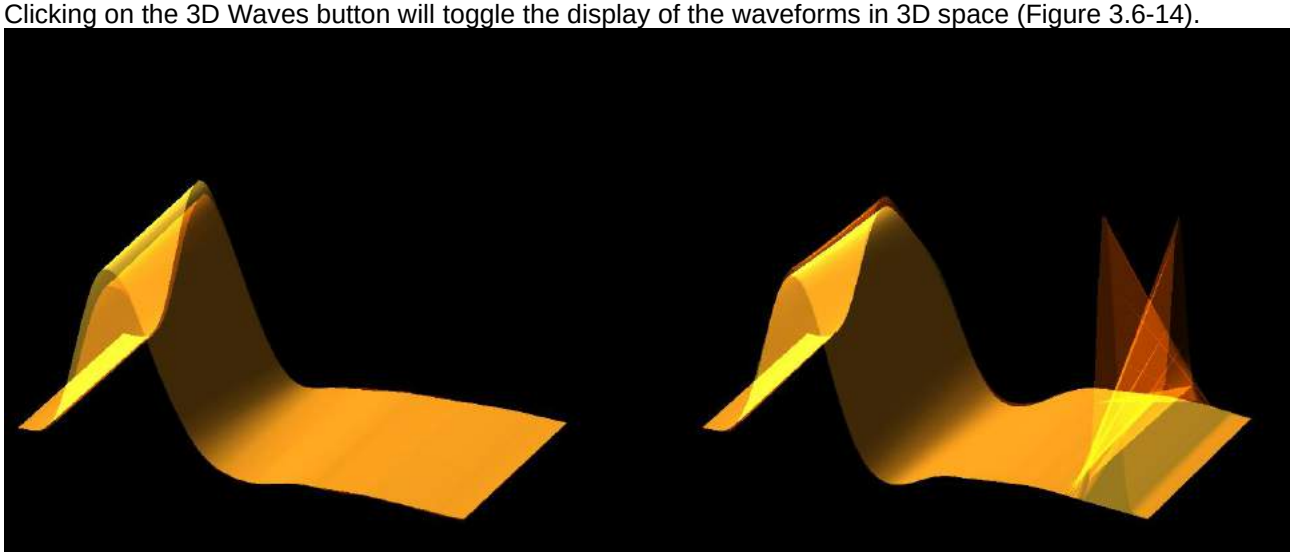


Figure 3.6-14 Eye Movements rendered in 3D space

Suppression Head IMpulse Paradigm (SHIMP) test

Along with the video Head Impulse Test or Head Impulse Test, the SHIMP test helps the operator to determine the residual vestibular function. This test resembles the lateral vHIT test and assesses the lateral semicircular canals. In addition to that a laser target is used as suppression medium for the SHIMP test.

The vHIT goggle is placed on the patient head as in other vHIT tests. The eye is centered in the viewing area taking care that the reflections are beneath the pupil. After adjusting the patient, calibrating and centering the laser fixed dots on the wall, you are ready to begin the SHIMP test.

Test preparation:

The head fixed laser projects a 5 dot pattern on the wall as used for calibration. The patient is instructed to focus on the center dot for fixation and align the center dot of laser to the wall fixed dot (for traditional vHIT testing). SHIMPs are performed on the lateral canal by turning the head 7 – 25 (depends on preset numbers) times at high velocities to the left and right side.

Performing test:

1. The first step is to have the patient relax his neck, open his eyes wide and fixate on the center dot in the 5 dot pattern.
2. The second step is to turn the patient's head either to the right or the left. The 5 dot laser pattern will move with the head so they are now located in a new position.
3. The patient is instructed to keep his eye on the center dot, so when the head moves the eyes should be focused on the newly positioned center laser dot.

The VOR gains should be similar in vHIT and SHIMP tests. However, the pattern of saccades generated is different. vHIT rarely generates compensatory saccades in normal patients, while in SHIMP testing, healthy subjects will make a large anti-compensatory saccade at the end of the head turn (Figure). This is referred to as a "SHIMP saccade". This pattern of result is exactly opposite for impaired patients. An impaired VOR system will lead to a catch-up saccade on the vHIT but no (or very few) compensatory SHIMP saccades. Sample test and result screens are provided below (Figure 3.6-15 and Figure 3.6-16).

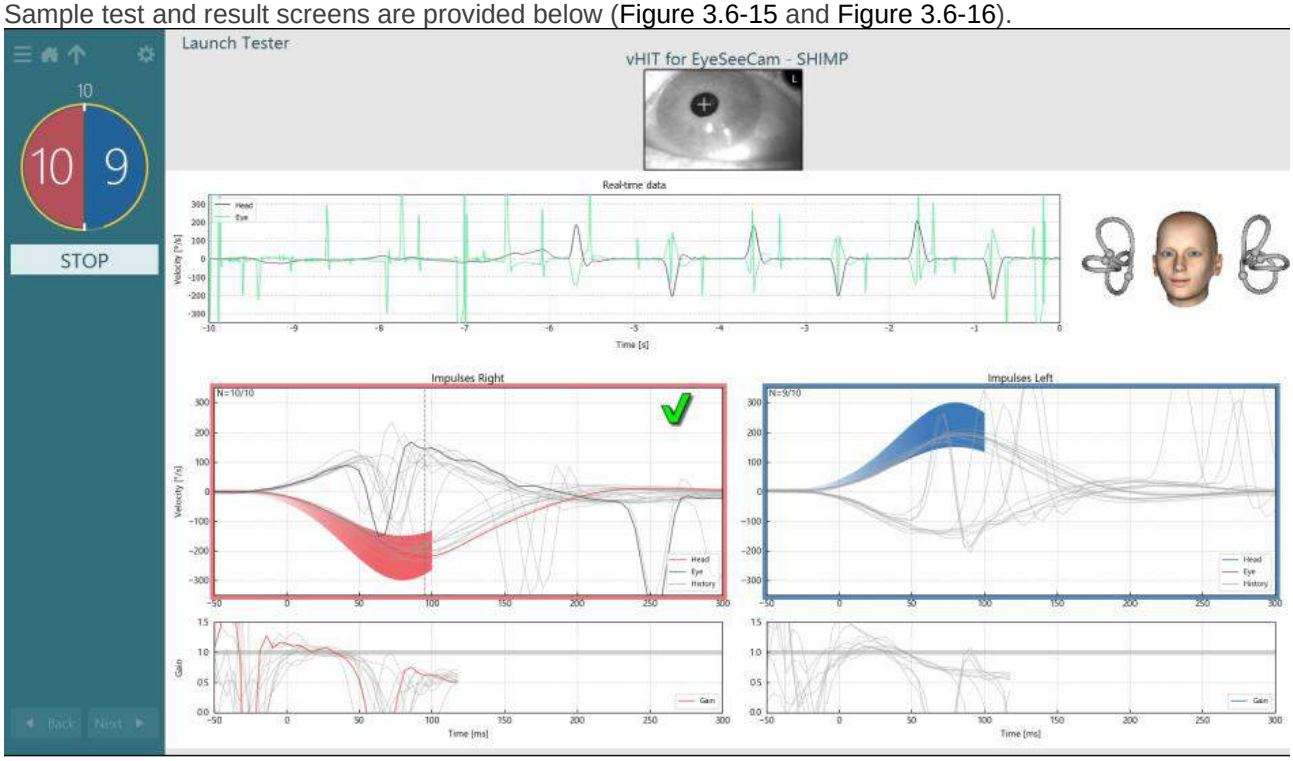


Figure 3.6-15 Test screen for SHIMP test

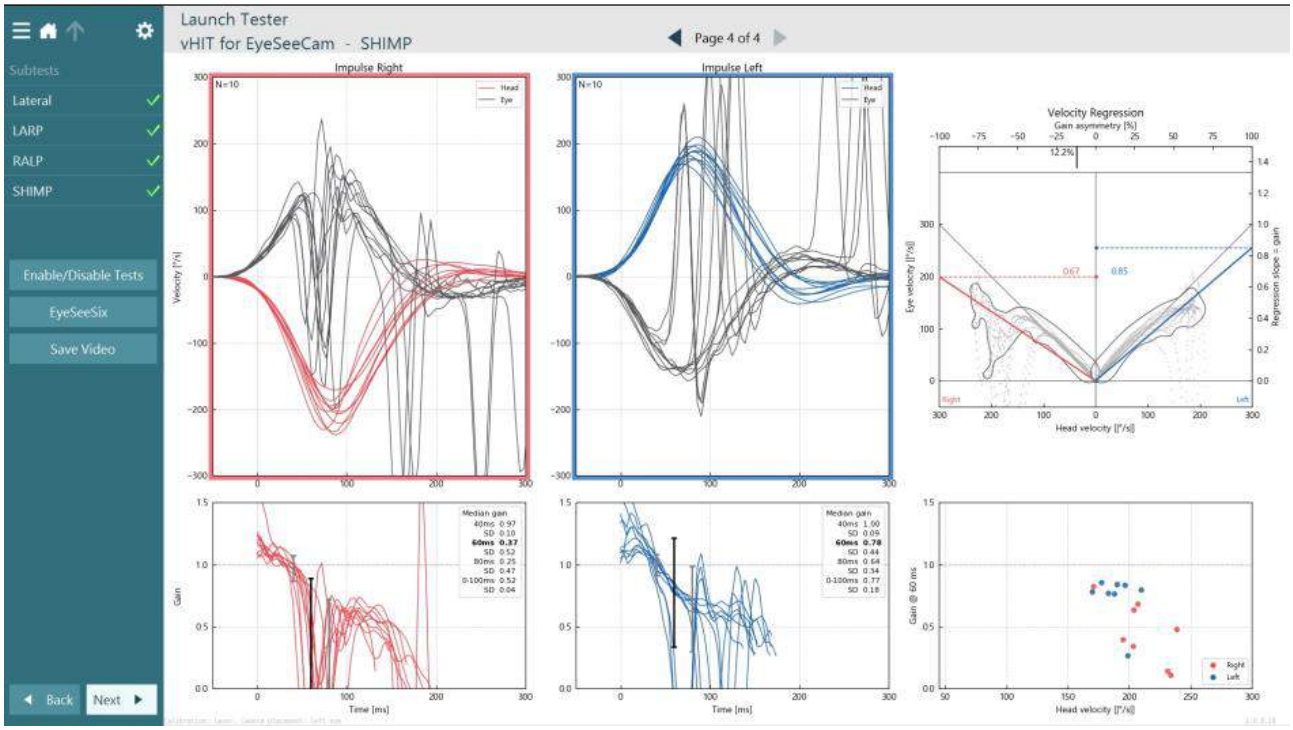


Figure 3.6-16 Result screen for SHIMP test

3.7 Ocular Counter Roll

The ocular counter roll test acquires torsional eye movement data while rolling the patient's head into specific positions. Note that the ocular counter roll test is contraindicated in persons exhibiting head or neck trauma.

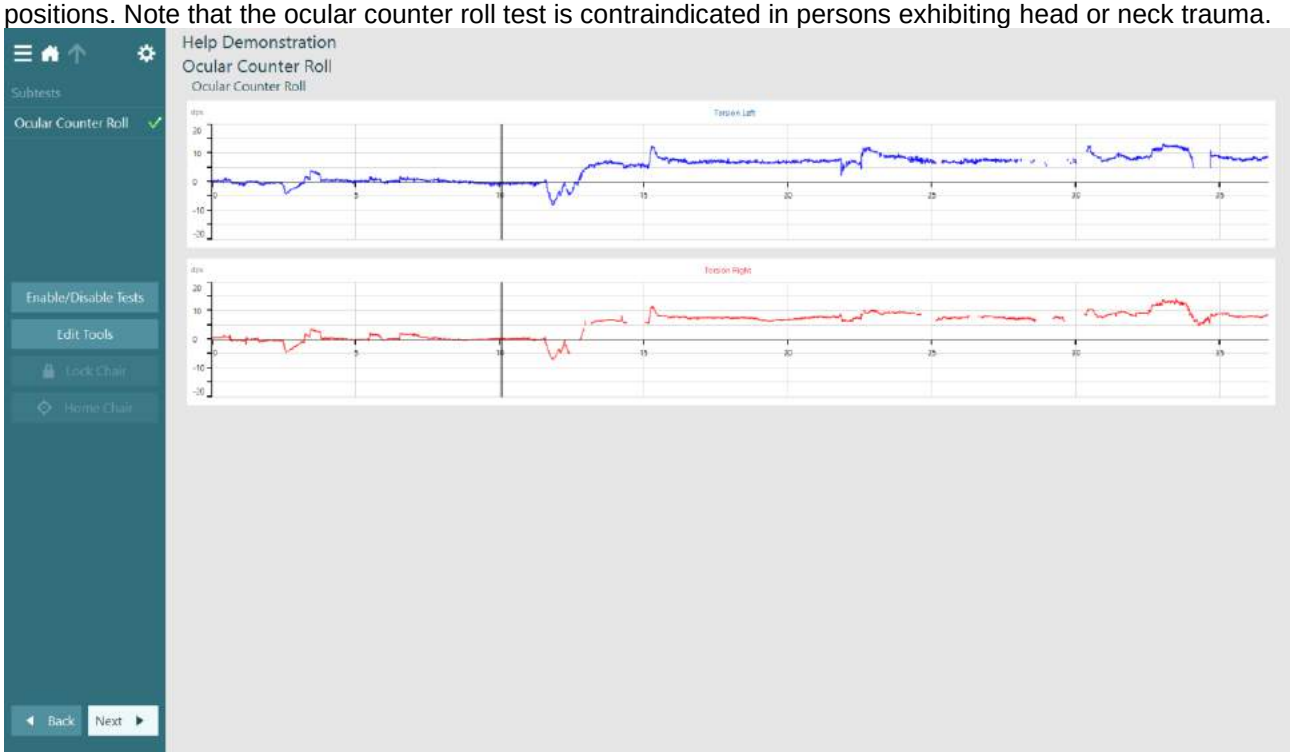


Figure 3.7-1 Ocular Counter Roll summary screen

If the test is repeated, the retests will be displayed sequentially in the summary screen (Figure 3.7-1). This test is configured to have three sections to test the patient with the head in the center, left, and right positions. These settings can be modified from the Temporary Settings screen.

The start button will be disabled if the patient's iris diameter and eye diameter have not been defined from the Calibration screen. Once the test starts, the software will record the torsion angle displayed in separate trace windows. The patient will roll the head into the different positions when directed by the examiner. The testing section is completed when the time has elapsed, or the operator has ended the section early by pressing the Enter key on the RF Remote or clicking on the Continue button on the test screen. The end of the section will be shown with a black vertical line and the name of the section will be displayed beside it.

During the ocular counter roll test (Figure 3.7-2), the software may not accurately be able to determine the torsion angle of the eye. In this case the software will leave a blank space in the data trace indicating the gap in data. The video of the eye will show the larger torsion crosshair and outline of the iris when the torsion angle was calculated.

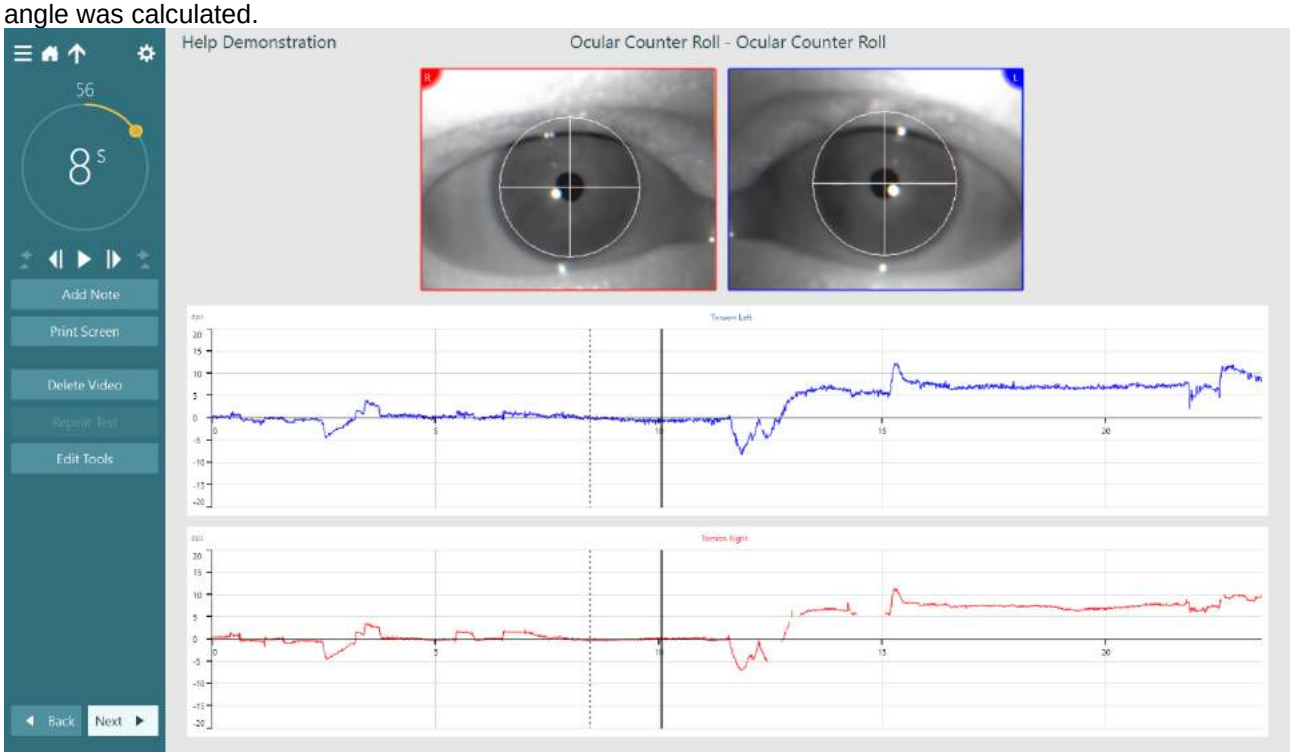


Figure 3.7-2 Ocular Counter Roll subtest

When reviewing the ocular counter roll test, click on Edit Tools to access the Add Marker and Remove Marker tools. Use the Add Marker tool and click on the waveform at the point of interest to display the current torsion angle. For more information on marking see section 7.11 Editing ocular counter roll tests.

When the test is printed, the waveform and any markers will be printed (Figure 3.7-3). The section name will be shown above the selected trace.

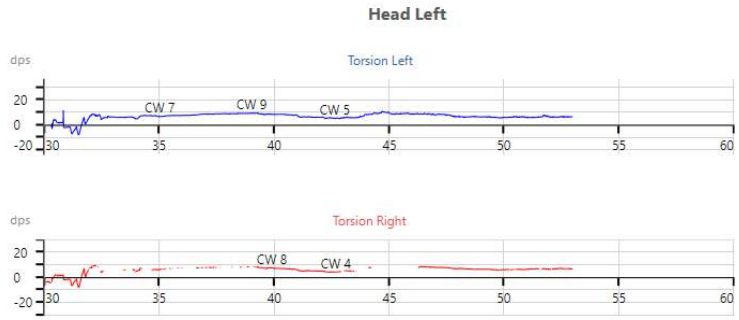


Figure 3.7-3 Ocular Counter Roll print layout

3.8 Caloric testing

The caloric irrigation test acquires eye movement data during direct stimulation of the vestibular end organ using an air or water irrigator to provide a temperature controlled stimulus. Recorded data is analyzed for slow phase velocity and frequency of nystagmus beating and is displayed in various standard diagrams. Caloric testing is available in both VisualEyes 515 and VisualEyes 525 software.

Note: This test can be performed using electrodes for ENG evaluations. To perform this test in an Orion rotational chair, the user needs to have external Datalink connection with Orion reclining chair.

Please note that Caloric testing is contraindicated in persons exhibiting the following:

- History of hypertension (uncontrolled, acute or de-compensated phase)
- History of cardiac problems (arrhythmias especially bradycardia or Stokes-Adams attack; acute or de-compensated phase) e. g. if someone has unstable angina, a recent myocardial infarction (within last 3-6 months) or is undergoing cardiac investigations
- Psychotic/neurotic disorders (acute or de-compensated phase)
- Epilepsy (acute or de-compensated phase)
- Eye surgery (within the previous 3 months)
- Ear surgery (within the previous 6 months)
- Perforated eardrum (water stimulation is not allowed; air stimulation may be tolerated)

The caloric test will connect with the Air Fx air caloric irrigator or Aqua Stim water caloric irrigator based on the test configuration. If the clinic uses a third party caloric irrigator, the test will have to be configured for a manual irrigator setup where the operator runs the irrigator outside of software control. In either case the caloric irrigator should be turned on prior to starting the test.

The default caloric test will start with the right warm subtest. The connected irrigator should begin to warm up to the specific temperature as defined in the test settings. If using a third party irrigator, turn on the irrigator and have it reach the warm temperature setting. When the irrigator is ready to dispense the warm water or air, the Start button will become available.

When the test is ready to begin, use the button on the Air Fx or Aqua Stim handle to begin the irrigation and start recording in the software. If using a third party irrigator, start the test using the RF Remote or foot pedal then begin irrigation. As the irrigation proceeds, the software will record the patient's eye movements. As the nystagmus beats are detected, the software will calculate the slow phase velocity for the beats and display the velocity in the Pod View graph on the right side of the screen. The average slow phase velocity (a. SPV) will be calculated based on the peak response window settings (by default 10 seconds). As with nystagmus tests, the software will display triangles on the waveform indicating left beating or right beating nystagmus.

If the irrigation needs to be suddenly aborted, remove the speculum or silicone tube from the ear and direct stimulus flow elsewhere. The irrigator stimulus flow will continue until the pre-selected irrigation time has elapsed, at which time an indicator tone will sound and the irrigation will stop. Alternatively, press and hold the irrigator button for three seconds to abort the irrigation. A message will be displayed on the computer test screen asking "Are you sure you want to stop?". Click or touch yes to stop the recording. Click or touch no to continue recording.

After the irrigation has completed, remove the irrigator handle from the patient's side and have the patient begin alerting tasks to stay focused during the test and provide a stronger nystagmus response. As the patient continues alerting tasks, the patient's a. SPV will rise. Once the a. SPV begins to drop by 10% of the maximum value, the fixation light will come on inside the goggle. If the patient's maximum a. SPV value is too low (such as with cool air calorics), the software may not detect the drop in the response, so the operator must watch the Pod View and intercede with activating the fixation light (using the Fixation button on the RF Remote or the Fixation button on the screen). The fixation light will turn off after 10 seconds if activated automatically, otherwise the operator must turn off the fixation light manually after 10 seconds. This will allow the software to calculate the fixation index value. After the fixation light is turned off, the remaining nystagmus will still be tracked and recorded for post-fixation information.

When the test is completed (Figure 3.8-1), the software will either color the nystagmus slow phase portions of the waveform in green or leave the triangles depending on the System Default Settings. The peak response window will be displayed in the Pod View with a small dashed box in light blue color.

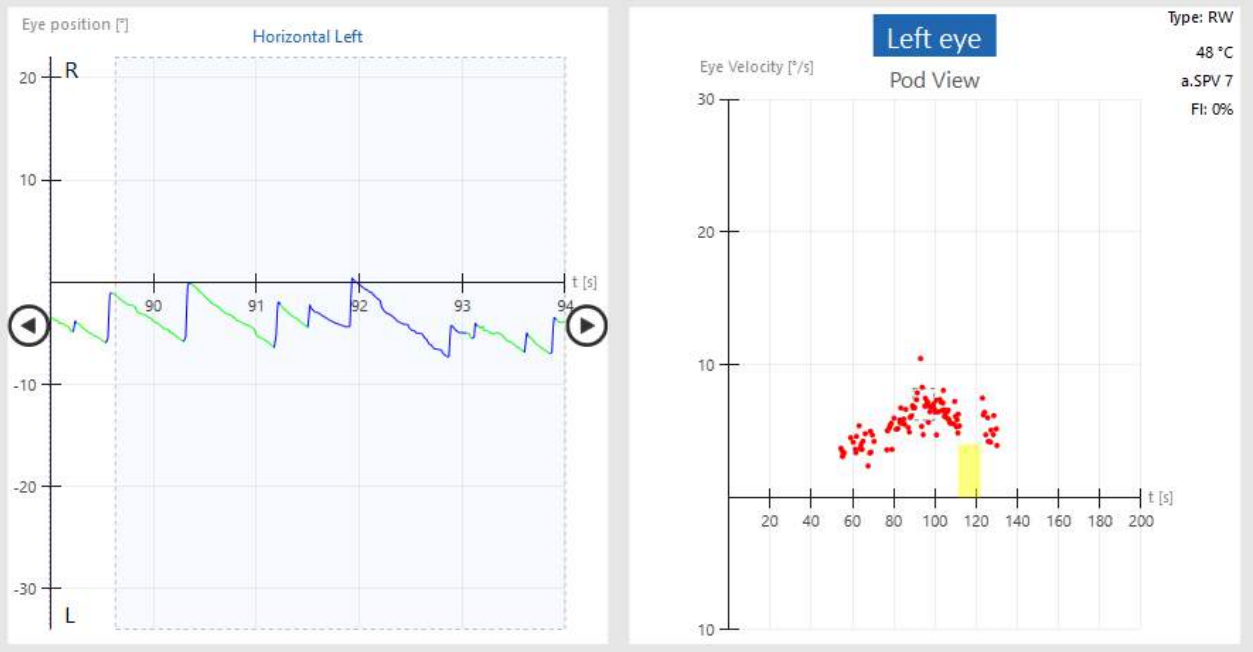


Figure 3.8-1 Caloric test results

Figure 3.8-2 Caloric summary

As each caloric test is performed, the caloric summary will display the results of the caloric subtests together. The caloric summary can be a mix of left eye and right eye results as desired. These results are displayed in the right upper corner of the caloric results display (Figure 3.8-2).

Unilateral Weakness (UW)
Unilateral Weakness is a calculated value that compares the nystagmus strength induced by irrigation of the left ear with that of the right ear. It is calculated automatically by the software.
The unilateral weakness is given in percent [%]. The default threshold level is 25%.

Directional Preponderance (DP)
Directional Preponderance is a calculated value that compares the nystagmus strengths in the right beating direction with the nystagmus strengths in the left beating direction.
The directional preponderance is given in percent [%]. The default threshold level is 30%.

Fixation Suppression Index (FI)
The fixation suppression index (FI) quantifies the ability of a patient to deliberately suppress nystagmus by fixating on a given target. It is determined just after the peak response by switching on the fixation light within the mask (the default protocol automatically turns on the fixation lights at the appropriate time). This time interval is shaded in yellow on the graph.

The value for FI is represented as a percentage with the test threshold of 50% used as a cut-off value. 0% indicates perfect nystagmus suppression during fixation, 50% indicates complete failure of fixation suppression.

Spontaneous Nystagmus Correction (SPN)
If the Spontaneous Nystagmus subtest is performed inside the Caloric test, the software can correct the nystagmus values using the nystagmus value when the patient is laying in the supine position. If the patient experienced nystagmus in the supine test of the Positional test or during the Spontaneous Nystagmus test, then change the test settings to include the Spontaneous Nystagmus subtest. After the Spontaneous Nystagmus subtest is performed, the Spontaneous Nystagmus switch will become available. The graphs will then display the corrected x-axis for adjusting the caloric response due to the patient's latent nystagmus (Figure 3.8-3).

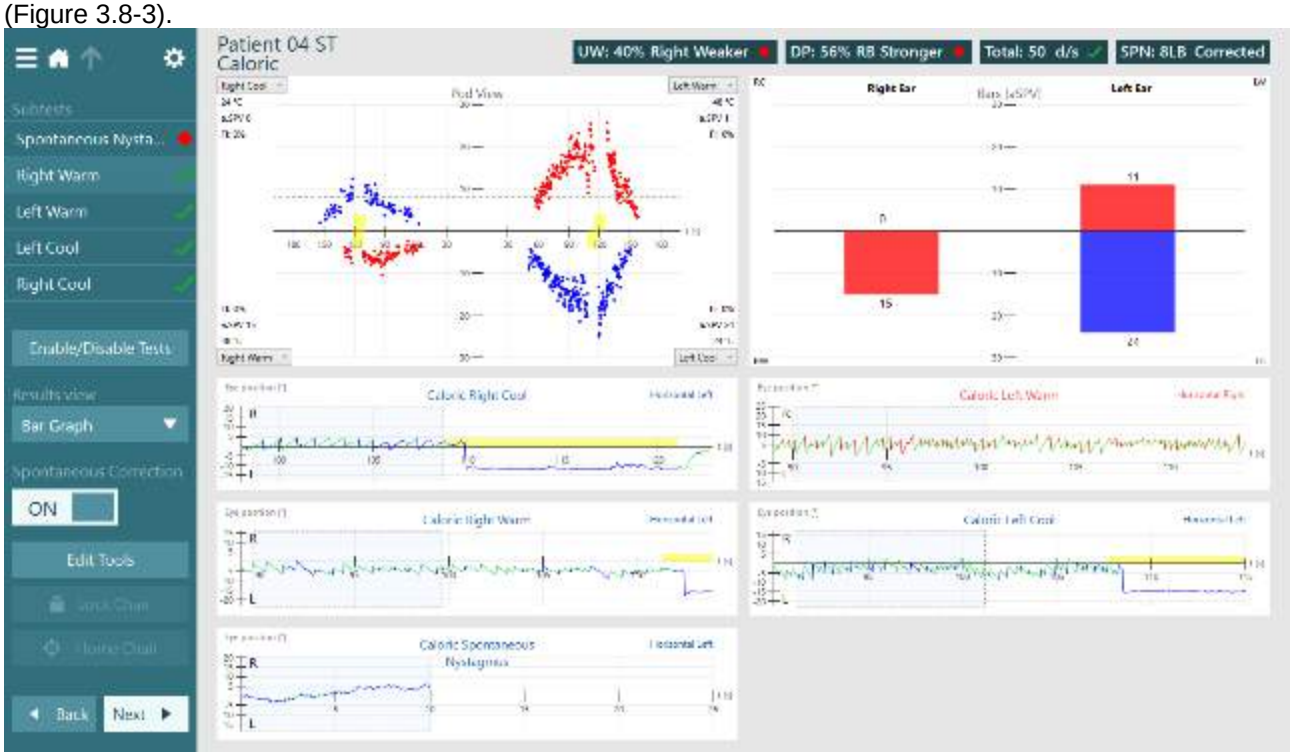


Figure 3.8-3 Caloric summary with Spontaneous Nystagmus correction enabled

Monothermal Warm Screening Test (MWST)
If only two warm irrigation subtests are performed, the system will calculate a MWST value based on these subtests. It is not a separate test to the caloric but will be calculated automatically in the default protocol set up or anytime the 2 warm caloric tests are performed as the first 2 tests.
When both warms are complete, the software will automatically generate an MWST score (Figure 3.8-4).
If the clinician moves on to perform cools, then the MWST score is replaced with a UW score.
The default suggested value is 30%. If the maximum result exceeds 30% then an out of threshold symbol (red diamond) will be present for this test.

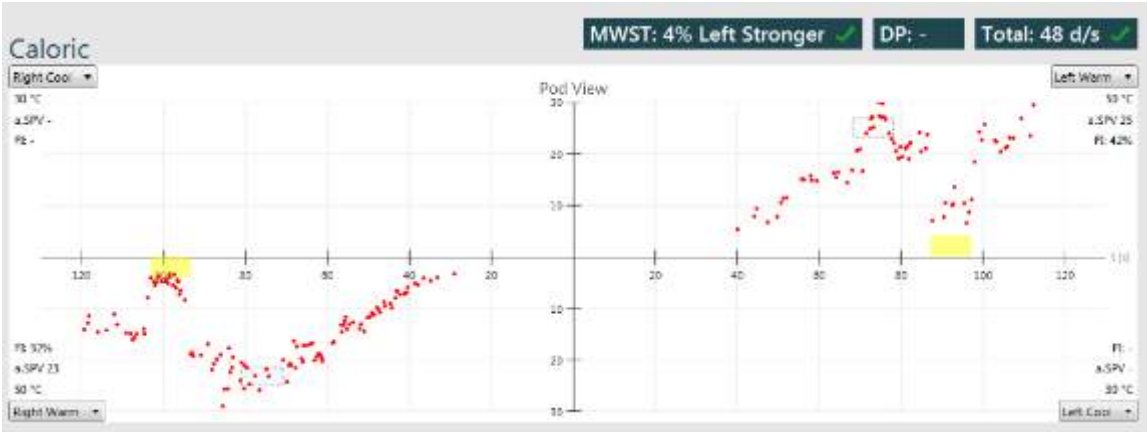


Figure 3.8-4 Caloric summary results for MWST

Caloric Results Views

The caloric results may be displayed in a number of different standard diagrams (Figure 3.8-5). In addition to the Pod View, the caloric results can be displayed in the Bar graph and Freyss Diagram. In certain regions the additional options of Scherer, Claussen, and Haid-Stoll graphs are available. To select an additional view, use the Results View selection box and choose the desired view.

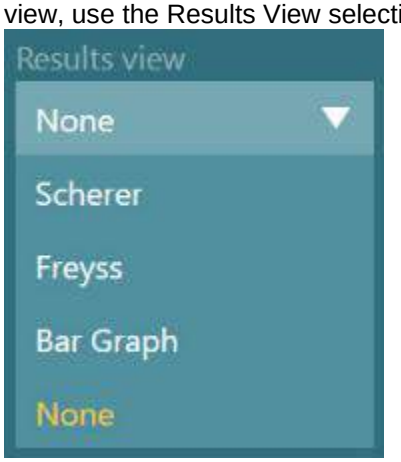


Figure 3.8-5 Caloric Results View selection box

All diagrams are positioned in the upper portion of the review screen next to the pods diagram.

Pods

In the pod diagram (Figure 3.8-6), the slow phase velocity (SPV) of horizontal nystagmus beats are plotted over time.

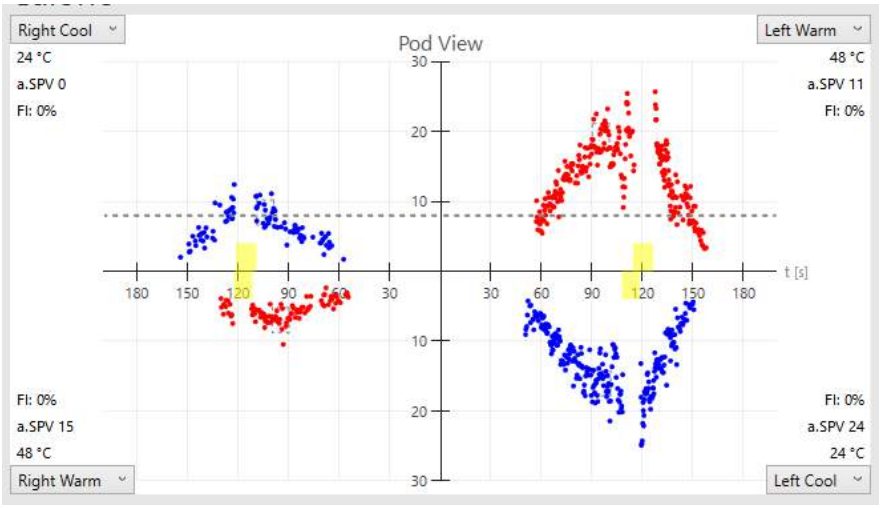


Figure 3.8-6 Pod View

The horizontal axis represents time (seconds) and the vertical axis is the SPV (degrees). In the corner of each quadrant is an area that displays temperature of irrigation, a. SPV and FI.
In subjects with normal vestibular function this specific arrangement of data plots results in a shape similar to the outlines of a pea pod. Click on a beat in the pod diagram, to open the edit mode.

Normally nystagmus beats are illustrated by triangles in the same color as the waveform. However, if data collected is contradictory to what would be expected, i. e. warm irrigation of the right ear resulting in all left-beating nystagmus, triangles will appear in a green color to alert the examiner of the unexpected outcome: An alert message will also appear indicating an unexpected result.

Bar graph

The bar graph (Figure 3.8-7) represents the average slow phase velocity during the peak response of each irrigation. Warm irrigations are indicated in red color and cool irrigations in blue. The graph is divided in two, with one side displaying the right eye and the opposite the left eye. The vertical axis displays the average slow phase velocities, which correspond to the height of each individual bar. The numerical value defines the maximum average slow phase eye velocity.

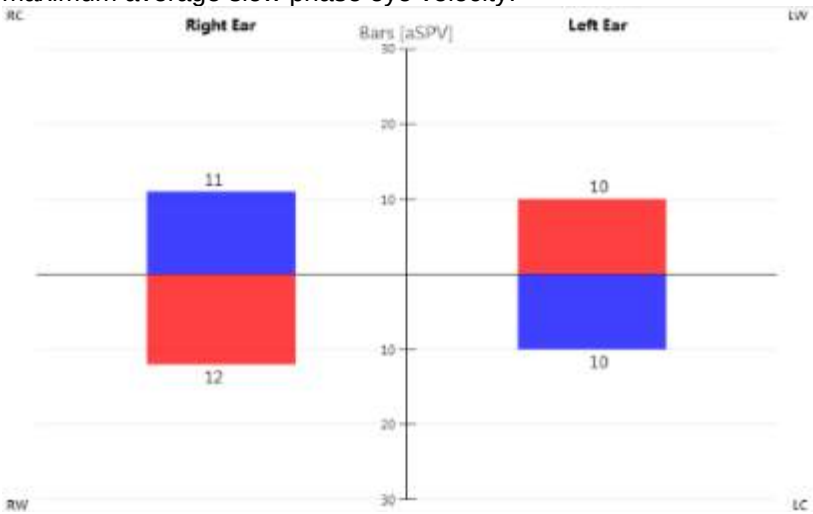


Figure 3.8-7 Bar graph

Freyss diagram
The Freyss Diagram (Figure 3.8-8) graphically represents the average slow phase velocities (a. SPV) during the peak response of each irrigation.

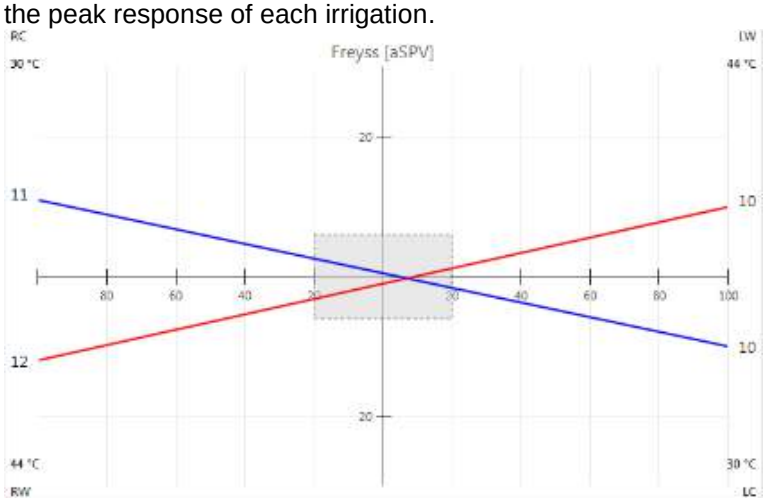


Figure 3.8-8 Freyss diagram

On the left vertical axis, the a. SPV calculated for the irrigations of the right ear are plotted; data points on the right vertical axis show the a. SPV values for left ear irrigations.
The rectangular box in the center of the Freyss diagram outlines the Unilateral Weakness cut-off value.
The diagram is completed by two lines: one connecting the data points obtained for the two warm irrigations, the other one connecting the data points representing the two cool irrigations. The two lines described above will intersect either to the left or to the right of the rectangle in patients with UW larger than the threshold value.

3.9 Rotational Chair Testing
Rotational chair testing is available in licensed VisualEyes 515 and VisualEyes 525 systems that utilize a reclining chair. The Nydiag 200 and System 2000 Reclining chairs utilize FireWire cameras, and the Orion Reclining, Orion AutoTraverse and Orion Comprehensive chairs utilize USB cameras.

3.9.1 Safety checks prior to beginning rotary chair tests
Prior to beginning the first rotary chair test in a rotational chair, a safety checklist will be presented to ensure the safety of the patient before the chair is set into motion. Please use the checklist as a guide to ensure patient safety during the test. Check each box after performing the task. The chair will not be able to move until all boxes are checked and the OK button is pressed (see Figures below, Figure 3.9-1, Figure 3.9-2, Figure 3.9-3 and Figure 3.9-4).

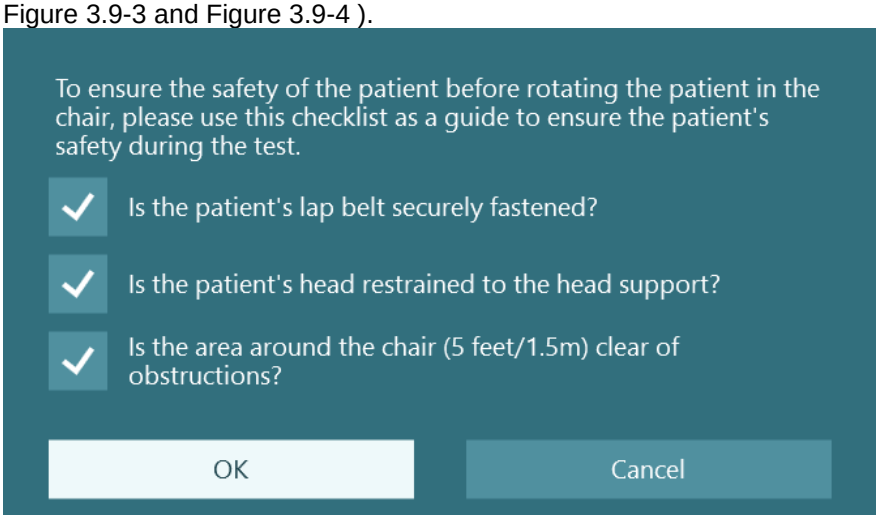


Figure 3.9-1 Safety checklist for reclining chair (Orion and System 2000)

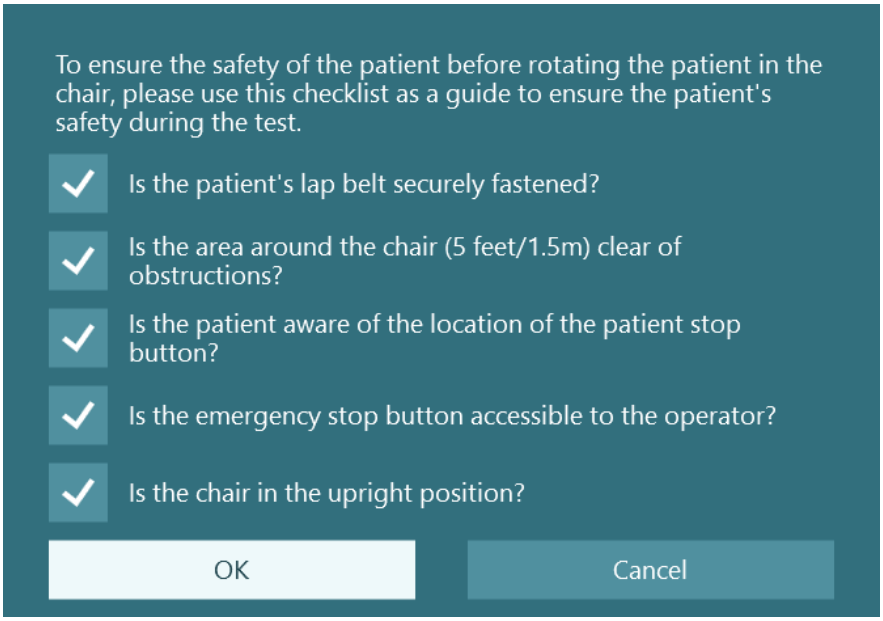


Figure 3.9-2 Safety checklist for Nydiag 200 reclining chair

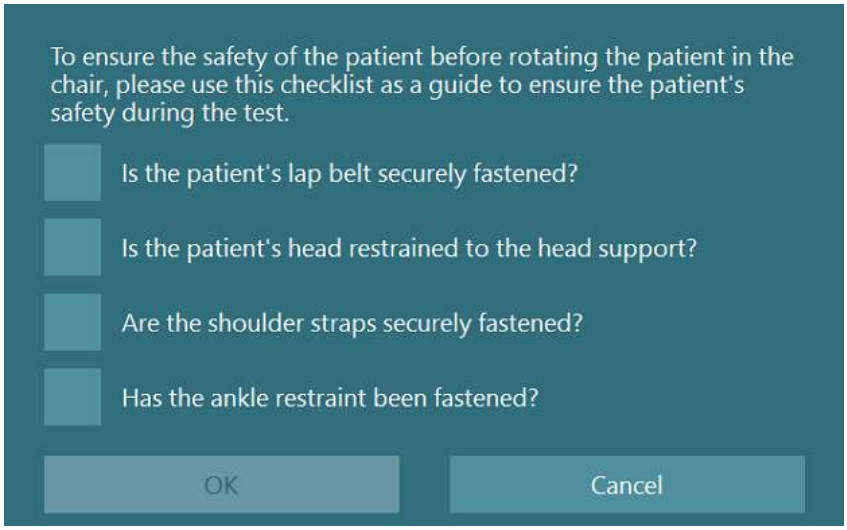


Figure 3.9-3 Safety checklist for System 2000 AT/C chair

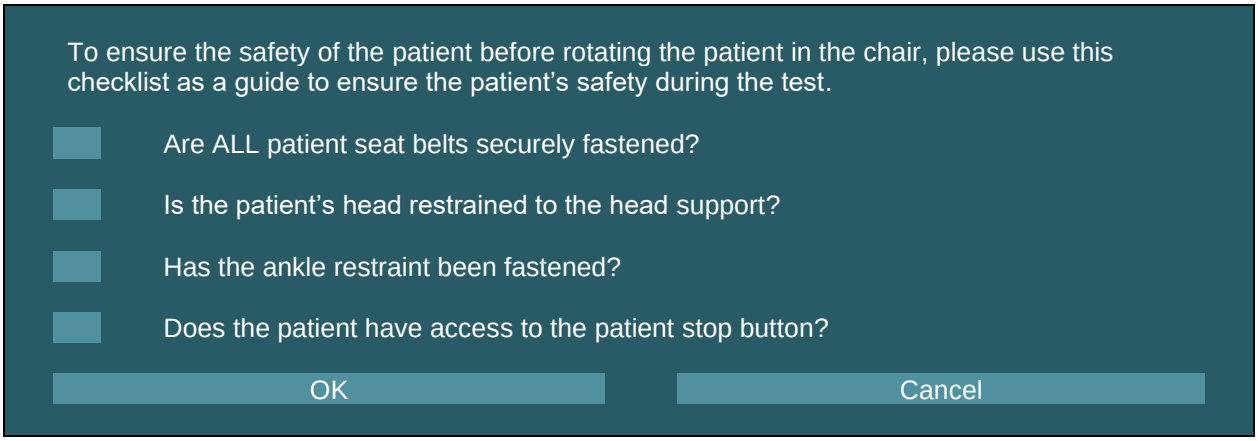


Figure 3.9-4 Safety checklist for Orion AT/C chair

3.9.2 Sinusoidal harmonic acceleration (SHA) test

During the Sinusoidal Harmonic Acceleration (SHA) test the patient is positioned in the rotational chair and is rotated in a sinusoidal pattern alternating from side to side. Analysis of the vestibular response is performed by recording the eye movements with VisualEyes™ VNG goggles in a fixation-denied condition or with electrodes (ENG assessment) depending on rotational chair type. The patient is rotated in alternating directions at multiple individual frequencies. The frequencies most often tested during SHA test are the octave frequencies 0. 01 Hz, 0. 02 Hz, 0. 04 Hz, 0. 08 Hz, 0. 16 Hz and 0. 32 Hz. The frequency of 0. 64 Hz is also available. It is also recommended to start the test with mid frequency before going to very low frequency to avoid making patient nauseous.

Note: This test can be performed using electrodes for ENG evaluations. To perform this test, in addition to appropriate license, the user needs to have the built-in EOG option with Orion AT/C chair.

The responses are displayed in real-time (in relation to the stimulus). The eye position and eye velocity results are plotted within the test window along with two summary graphs showing gain and phase results for the frequency being tested. (See Figure 3.9-5).

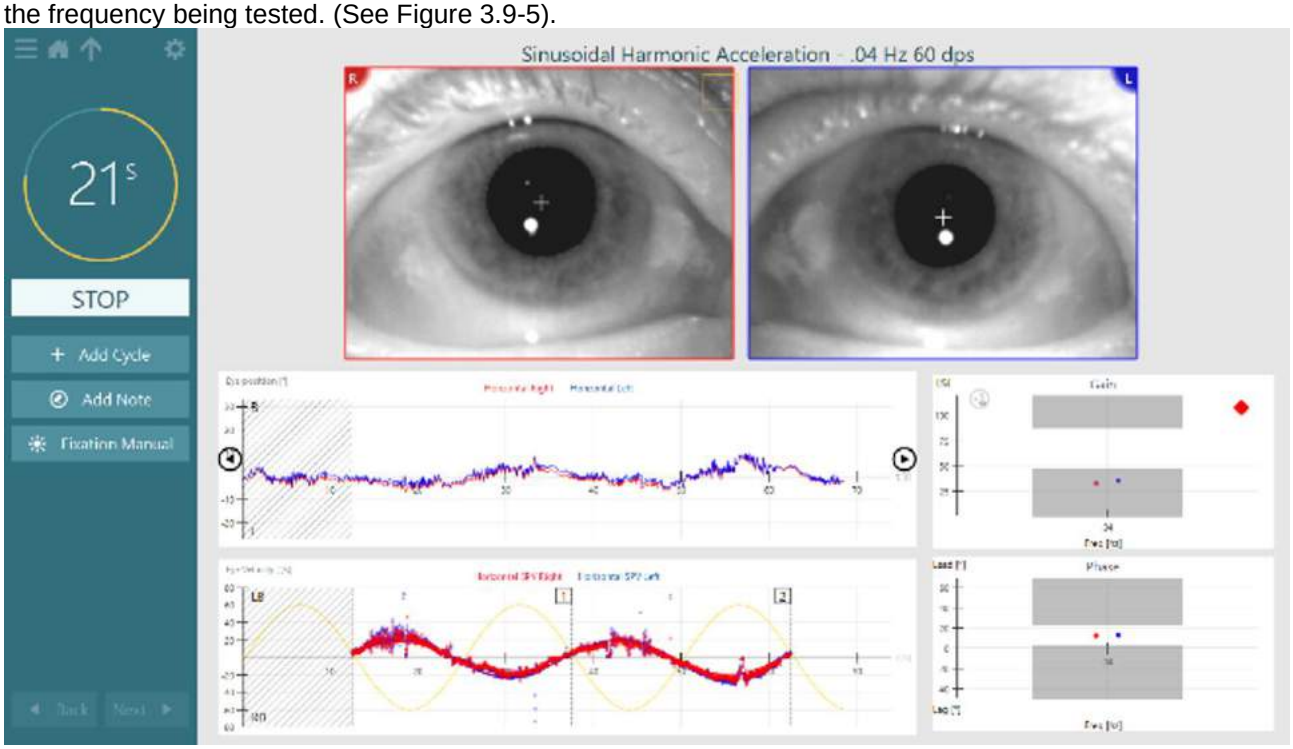


Figure 3.9-5 Sinusoidal Harmonic Acceleration testing

To begin the testing procedure, select ‘Begin Testing’ from the main VisualEyes™ menu.

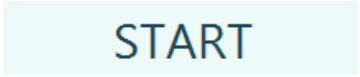
The SHA test will be available within the protocol or may be selected directly from the side menu panel by tapping the ‘hamburger’ icon in the upper left corner of the test screen to view the test battery list. Select SHA to begin testing. This will open the first frequency within the Sinusoidal Harmonic Acceleration test sequence. Alternatively, if the examiner chooses to perform the SHA test frequencies out of sequence, tap the plus sign to the left of SHA which will expand to show all subtests and select the desired frequency (Figure 3.9-6).

Figure 3.9-6 Expanded test battery view

Example Instruction for the Patient:
”You will feel yourself rotating back and forth slowly in the chair. While you are rotating, I will be asking you several questions to keep you alert. We will test different frequencies and the entire test will take a few minutes. Please keep your eyes open the entire time. ”

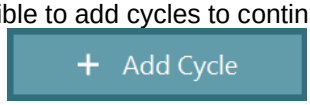
To begin the test (for operator):

1. Select ‘Start’ from the left menu panel.



2. The timer will begin counting down. The length of test time is pre-defined by the number of cycles selected for the test frequency.

The chair will activate and begin moving in a sinusoidal pattern.
Camera recordings will begin at the onset of chair movement.
The stimulus and eye movements will be displayed in real-time (see Figure 1. 86).

While the test is active, it is possible to add cycles to continue testing beyond the protocol-specified number of SHA cycles. Click or touch the 

button to add a cycle, which will increase the test time by the number of seconds associated with one full cycle of SHA rotation for that given frequency.

To abort the chair rotation prior to test completion, click or touch the Stop button. A message will be displayed on the computer test screen asking “Are you sure you want to stop?”. Click or touch yes to have the recording end. Click or touch no to continue recording the tracing.

Once the test is complete a summary test results page will appear (Figure 3.9-7).

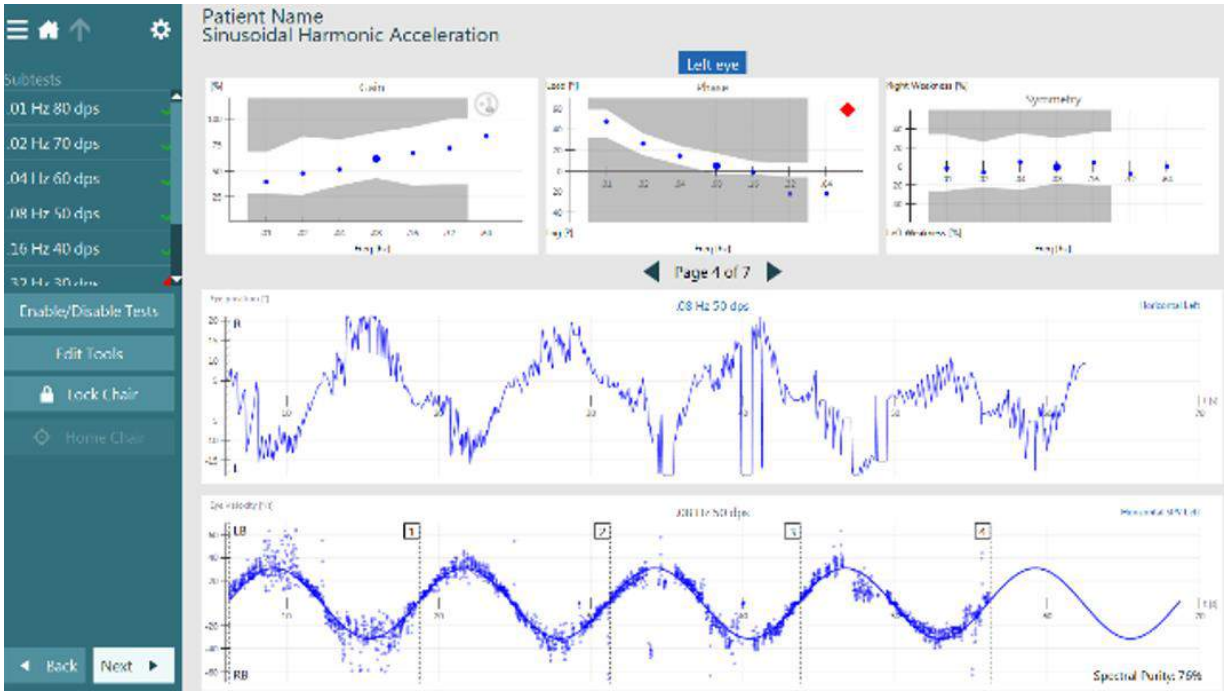


Figure 3.9-7 Sinusoidal Harmonic Acceleration summary

Sinusoidal Harmonic acceleration analysis is performed on cycles of pendular movement for specific frequencies. One complete cycle represents the pendular movement period consisting of acceleration/deceleration in one direction, and acceleration/deceleration in the opposite direction. **Please note: The first half cycle (hatched region) is excluded from the analysis for improved test reliability.**

Analysis of eye movements is performed separately for the right and left eyes and the results are displayed separately. Left eye results are displayed by default. The displayed results can be changed to the right eye by selecting the eye title in the top center of the summary test results screen (Figure 3.9-8).

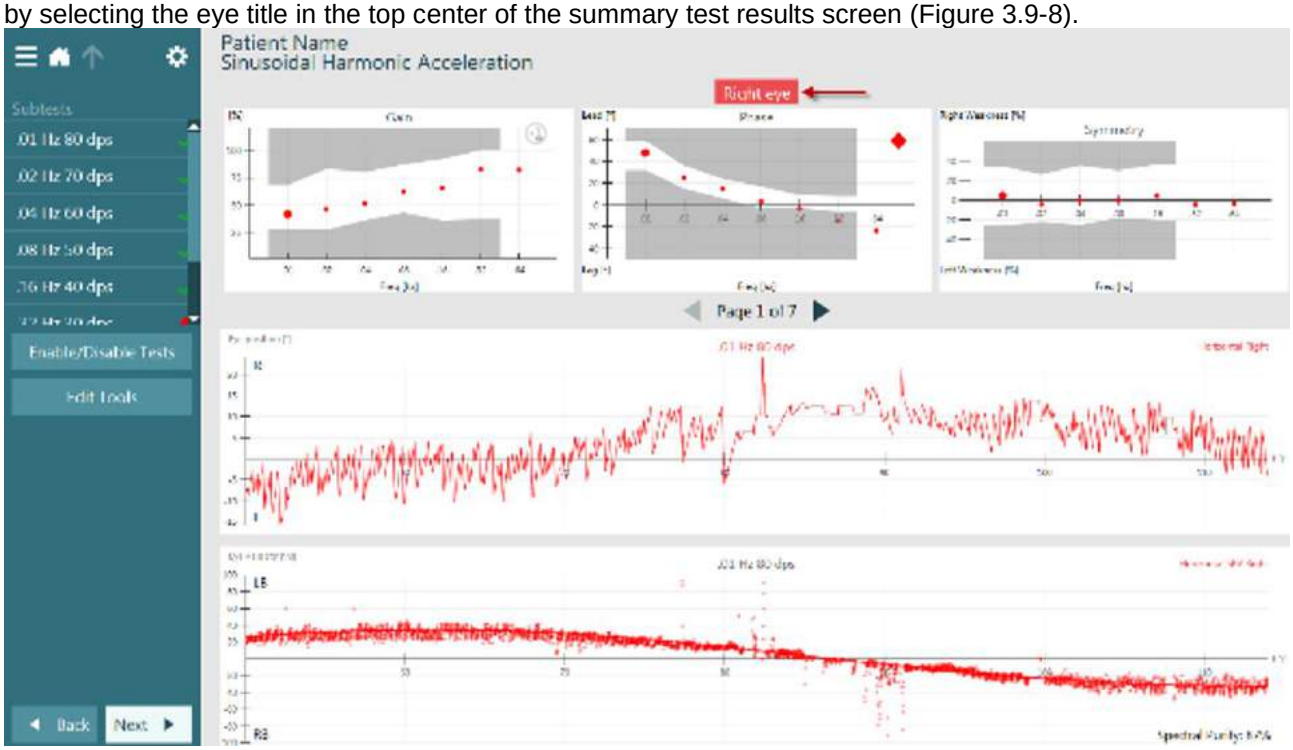


Figure 3.9-8 Right eye results for Sinusoidal Harmonic Acceleration test

The summary test results screen displays various analyses. The top portion of the summary results screen displays plots for Gain, Phase and Symmetry. These parameters are explained in detail in the following section.

Phase

Phase is the value, in degrees, to which compensatory eye movements lead or lag movement of the head. As such, phase measurements characterize the timing relationship between motion of the head and the resulting Vestibular Ocular Reflex (VOR) response, allowing for the quantification of the phase lead or lag. Mathematical functions are used to calculate the phase shift between the reclining chair stimulation (head movement) and the eye response. The resulting values are plotted within the phase graph (Figure 3.9-9).

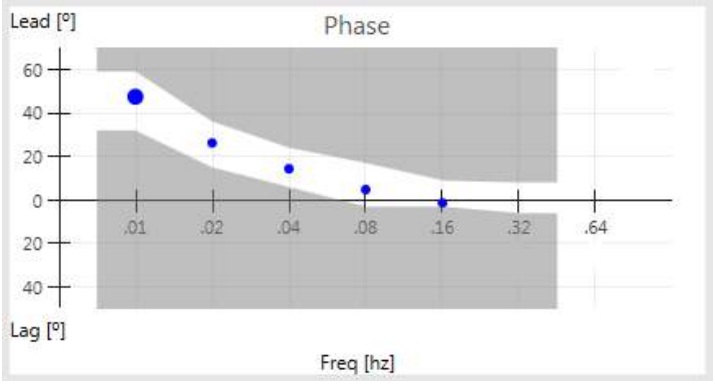


Figure 3.9-9 Phase graph

Phase values are expressed in degrees (°). A positive value indicates a phase lead. Values within the white region of the graph are considered to be within suggested threshold levels and those in the grey shaded regions are considered to be outside of the suggested threshold levels or criteria. When data points fall in the grey shaded regions, the graph will be marked with a red diamond to indicate that the patient's data was outside of the suggested threshold level.

Phase < 0°
Eye movement lags the head movement.

Phase > 0°
Eye movement leads the head movement

Gain

Gain measurement provides an indication of the responsiveness of the peripheral vestibular system. If the function of the (VOR) is to produce an eye movement that compensates for head movement, then under perfect conditions the slow phase eye velocity of the response to rotation should be a mirror image of head velocity producing a gain of 60 %.

The gain is the relation between amplitude of the sine wave function (generated from the eye-movement data) and the amplitude of the sine wave function fitted to the reclining chair data.

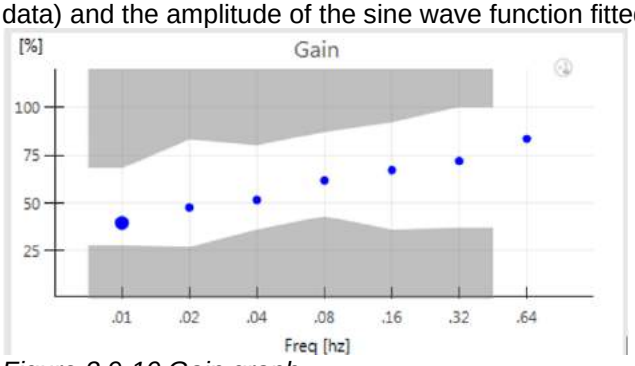


Figure 3.9-10 Gain graph

Gain values are expressed as a percentage (%). Values within the white region of the graph are considered to be within suggested threshold levels and those in the grey shaded regions are considered to be outside of the suggested threshold levels or criteria (Figure 3.9-10). When data points fall in the grey shaded regions, the graph will be marked with a red diamond to indicate that the patient's data was outside of the suggested threshold level.

Symmetry

The Symmetry is measured as the difference between maximum left-beating and right-beating eye velocities divided by the total of the left- and right-beating maximum slow phase eye velocities.

Values describing asymmetry of response are calculated by comparing slow-phase eye velocities with right-moving rotation and left-moving rotation. Calculation is based on the average maximum slow phase velocity for left and right cycles.

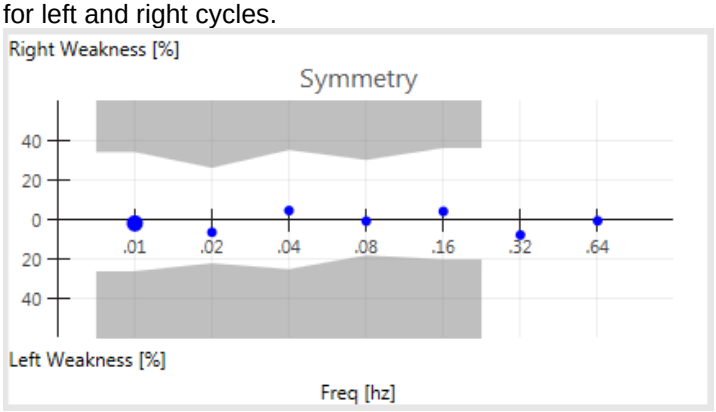


Figure 3.9-11 Symmetry graph

Values displayed in the Symmetry Graph are provided as a percentage (%). Values within the white region of the graph are considered to be within suggested threshold levels and those in the grey shaded regions are considered to be outside of the suggested threshold levels or criteria (Figure 3.9-11). When data points fall in the grey shaded regions, the graph will be marked with a red diamond to indicate that the patient's data was outside of the suggested threshold level.

Graph numerical values

The user can choose to view the numerical values of graph. By clicking the symbol , the numerical values will be shown for all the relevant graphs in the selected test. The symbol can be seen in the right/left corner of gain graph (refer section 7.5 for details).

Eye position display

In the middle portion of the summary results screen, the eye position (°) tracing is displayed. The eye position tracing (Figure 3.9-12) represents eye movement during chair rotation and is displayed as a function of eye position in degrees (y-axis) over time in seconds (x-axis).

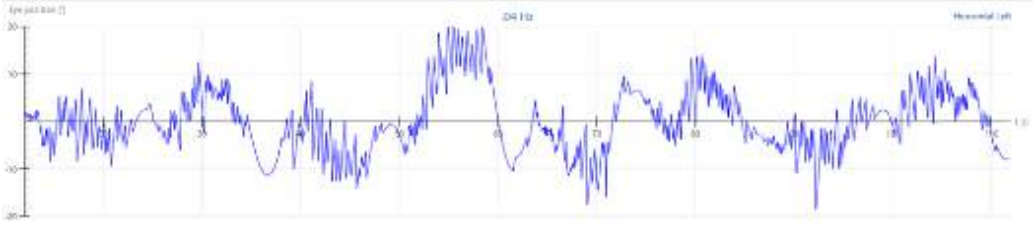


Figure 3.9-12 Eye position trace

Eye velocity display

The eye velocity in °/s (blue) relative to stimulus chair velocity (yellow) is displayed beneath the eye position tracing (Figure 3.9-13).

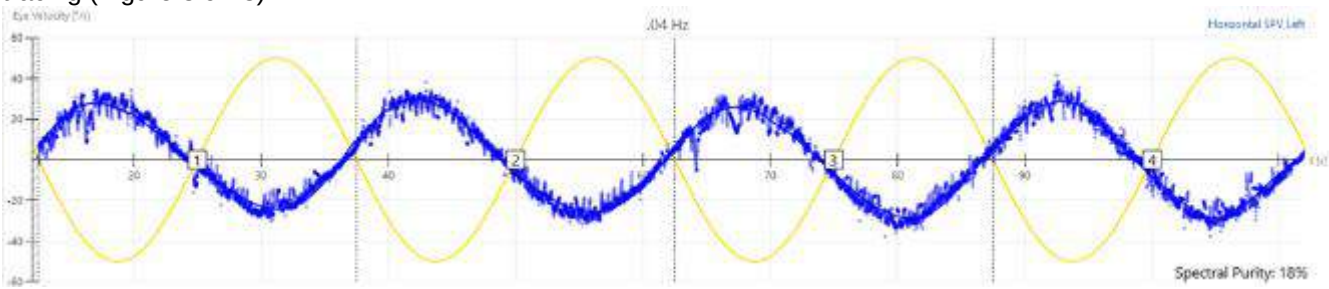


Figure 3.9-13 Display showing detailed individual cycles for eye velocity vs. stimulus velocity

This graphical display provides a detailed individual cycle view for the examiner to see the patient's results in relation to the stimulus. The user can also view the cycle numbers in this display. VisualEyes™ software may display the stimulus and eye movement data opposite one another (as shown above) or overlapping each other, depending on user preference. This preference can be selected within the Sinusoidal Harmonic Acceleration protocol setup. Both viewing methods are designed to provide the user with an easy way to analyze results and cross check gain, phase and symmetry.

Alternatively, a concise combined cycles view can also be selected (Figure 3.9-14). When this view is selected, the eye position tracing is not available. This view can be selected within protocol setup.

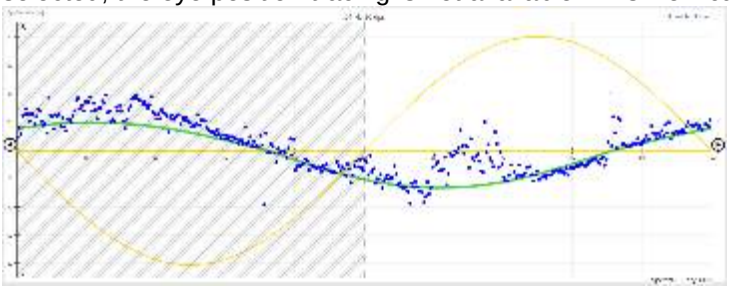


Figure 3.9-14 Concise Combined Cycles view

When further details for review are needed, the examiner can select an individual frequency from the left side menu to see both eyes displayed together for the selected frequency. This view allows the examiner to add notes, review or delete eye video recordings, print the screen, and edit the results for a specific frequency (Figure 3.9-15).

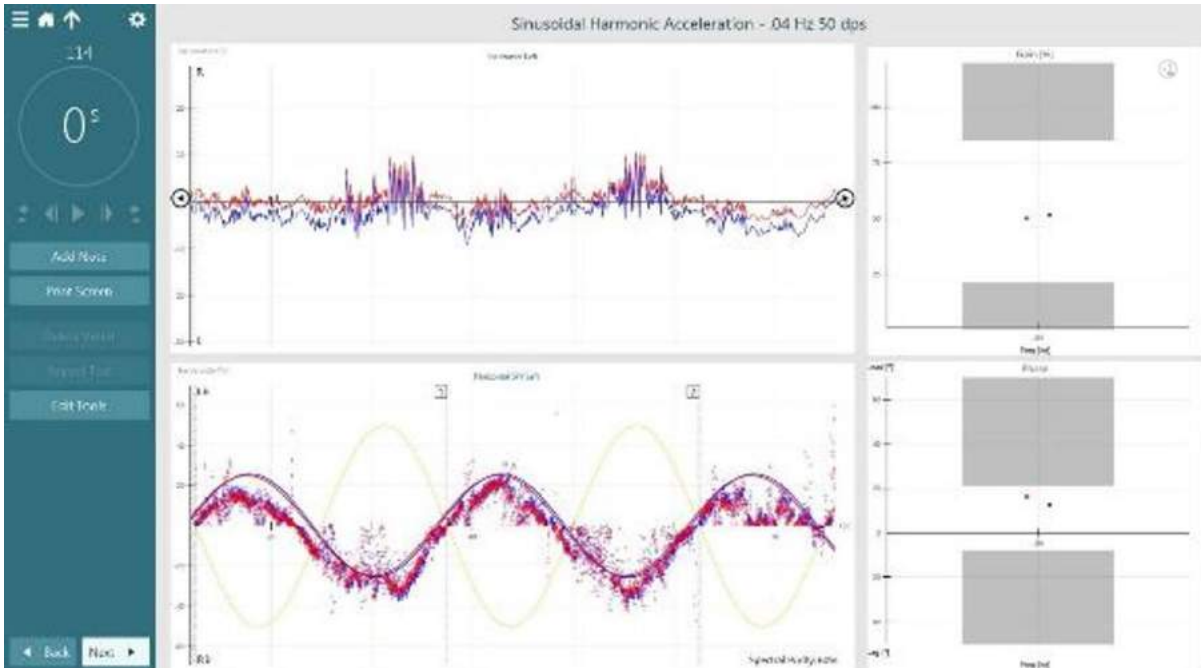


Figure 3.9-15 Review individual SHA frequency

Spectral purity

A spectral purity value for each given frequency tested can be viewed in the lower right corner of the eye velocity display (Figure 3.9-16). The spectral purity of the evoked nystagmus may be useful to indicate whether the test values have been influenced by artifact, for instance from failure to adequately alert the patient or from calibration errors affecting the peak eye velocity measurements. The higher the spectral purity value, the more reliable the sinusoidal harmonic acceleration result. Values are displayed as a percentage (%).

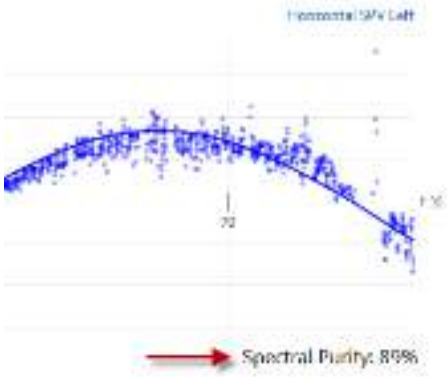


Figure 3.9-16 Spectral purity value

3.9.3 Step rotation test

During the Step Rotation test, the patient is positioned on a motor driven rotational chair and the test has two parts. As a first part of the test, the chair rotation is initiated through the software and accelerate up to defined speed (initial speed would be 50°/s^2). After the defined speed is attained, the chair rotates at a constant speed for 60 seconds and automatically stops by decelerating to 0°/s^2. Now the test moves to second part of the test, that the software continues to record the patient's eye movements for 60 sec when the chair is not moving. The patient is examined in the same way in opposite direction to complete the test in defined speed.

The speeds of rotation most often tested Step Velocity test are 50°/second and 100°/second. The speed of 180°/second is also available. Eye movements are recorded with VisualEyes™ VNG cameras or with electrodes (for ENG) and results are displayed in real-time on screen. The patient's eyes, along with both eye position tracings (°) and eye velocity tracings (°/s) are visible during the testing procedure. The chair velocity information can be viewed in the left menu panel, as well as above the patient's eyes (Figure 3.9-17).

Note: This test can be performed using electrodes for ENG evaluations. To perform this test, in addition to appropriate license, the user needs to have in-built EOG option with Orion AT/C chair.

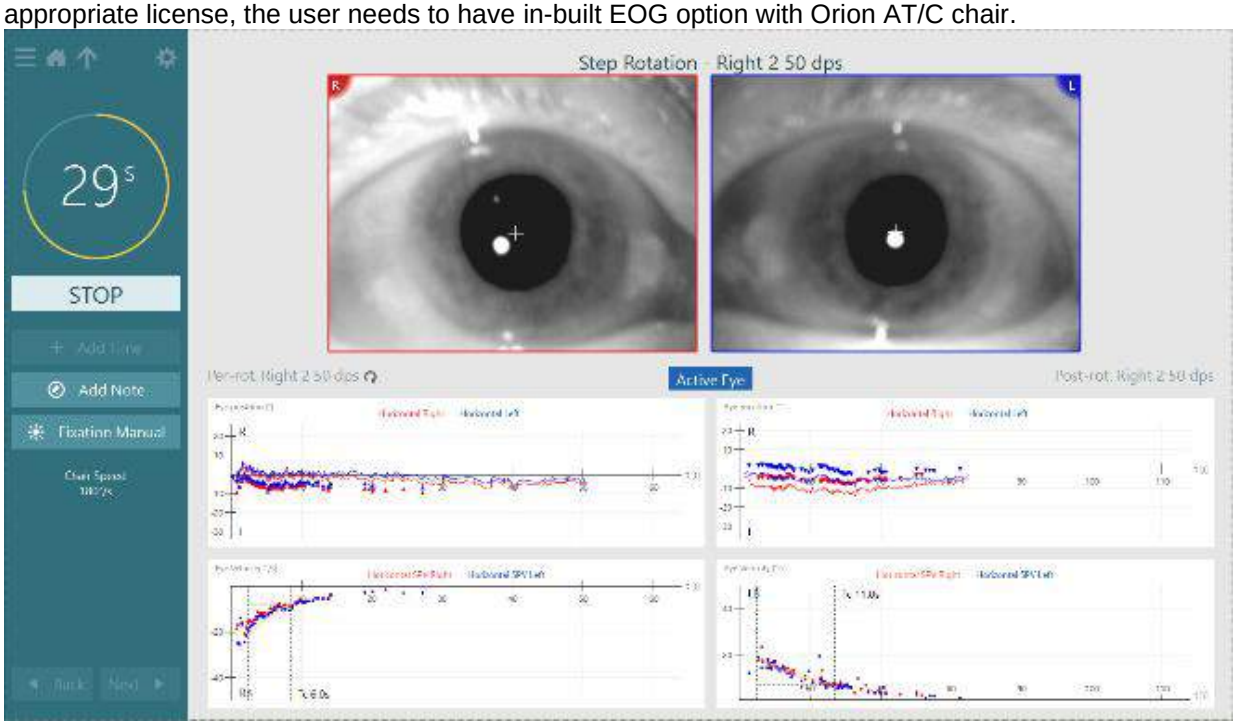


Figure 3.9-17 Step rotation testing

To begin the testing procedure, select 'Begin Testing' from the main VisualEyes™ menu.

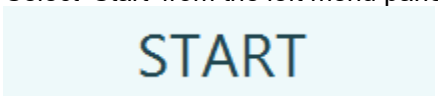
The Step Rotation test will be available within the protocol or may be selected directly from the side menu panel by tapping the 'hamburger' icon in the upper left corner of the test screen to view the test battery list. Select Step Rotation to begin testing. Alternatively, if the examiner chooses to perform the Step Rotation test velocities/directions out of sequence, tap the plus sign to the left of Step Rotation which will expand to show all subtests and select the desired velocity and direction (Figure 3.9-18).

Figure 3.9-18 Expanded test battery view

Example Instructions for the Patient:
"You will feel yourself rotating in one direction for several seconds. During the rotation, I will be asking you several questions to keep you alert. As you are rotating, you may feel as though you are slowing down. When the chair stops, you will feel as though you are rotating in the opposite direction. There will be four segments and each segment will take approximately 1 minute. Please keep your eyes open during the entire test."

To begin the test (for operator):

1. Select 'Start' from the left menu panel.



2. The timer will begin counting down. The amount of time is pre-defined by the test parameters.

The chair will activate and begin accelerating to a constant velocity in the selected direction.
Camera recordings will begin at the onset of chair movement.
The stimulus and eye movements will be displayed in real-time.

Once the per-rotary selected speed and direction has been completed the chair will automatically stop after a pre-determined time. The recording will continue into the post-rotary segment. If the per-rotary segment in the opposite direction has not yet been completed the software will automatically start the last per-rotary segment in the opposite direction immediately following the pre-defined stop time for the post-rotary segment. Again, after the final per-rotary condition has been completed the chair will automatically stop and the final post-rotary segment will begin recording. Each segment is pre-defined to last 60 seconds. If the examiner chooses to stop prior to 60 seconds, tap the "Stop" tab from the left menu panel to move into the next test segment. Once the test is complete a summary test results page will appear (Figure 3.9-19).

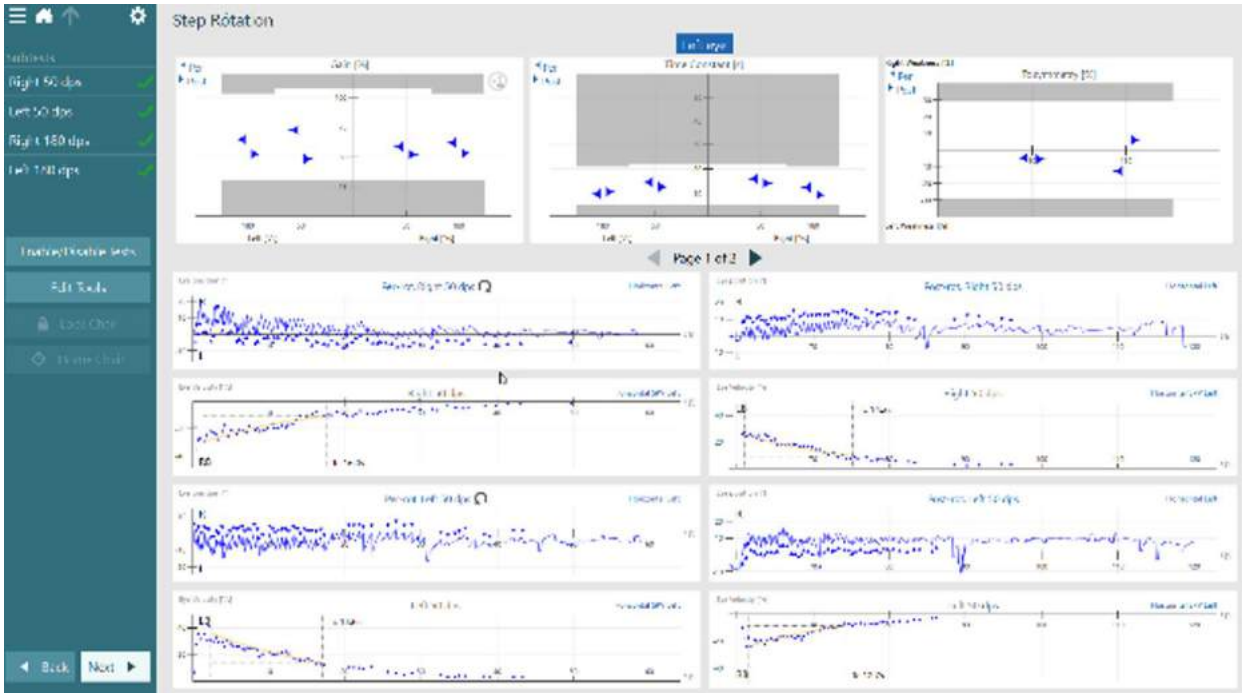


Figure 3.9-19 Step rotation summary

If the examiner has selected to move the chair to zero position after testing, then the chair will move to zero position after all four segments for an individual Step Velocity test have been completed.

It is optional to perform a spontaneous test as part of the Step Test battery. This can be selected in Step Test setup. If the spontaneous test is performed within the Step Test battery, then the option to toggle for spontaneous nystagmus correction becomes available in the left panel menu (Figure 3.9-20). When spontaneous correction is toggled on, it will adjust the responses based on the nystagmus a. SPV collected during the spontaneous subtest. The degree and direction of correction will be displayed in the upper right corner of the summary results screen.

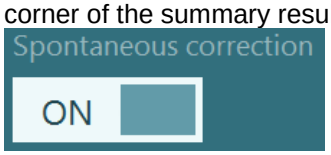


Figure 3.9-20 Step test Spontaneous correction

Analysis of per-rotatory segments (acceleration + constant chair speed period) are separated from the post-rotatory segments (deceleration + chair stopped). One complete analysis consists of per and post-rotary segments for rotations in both directions at a single speed.

Analysis of eye movements is performed separately for the right and left eyes and the resulting waveforms are displayed separately. Left eye results are displayed by default. The displayed results can be changed to the right eye by selecting the eye title in the top center of the summary test results screen (Figure 3.9-21).

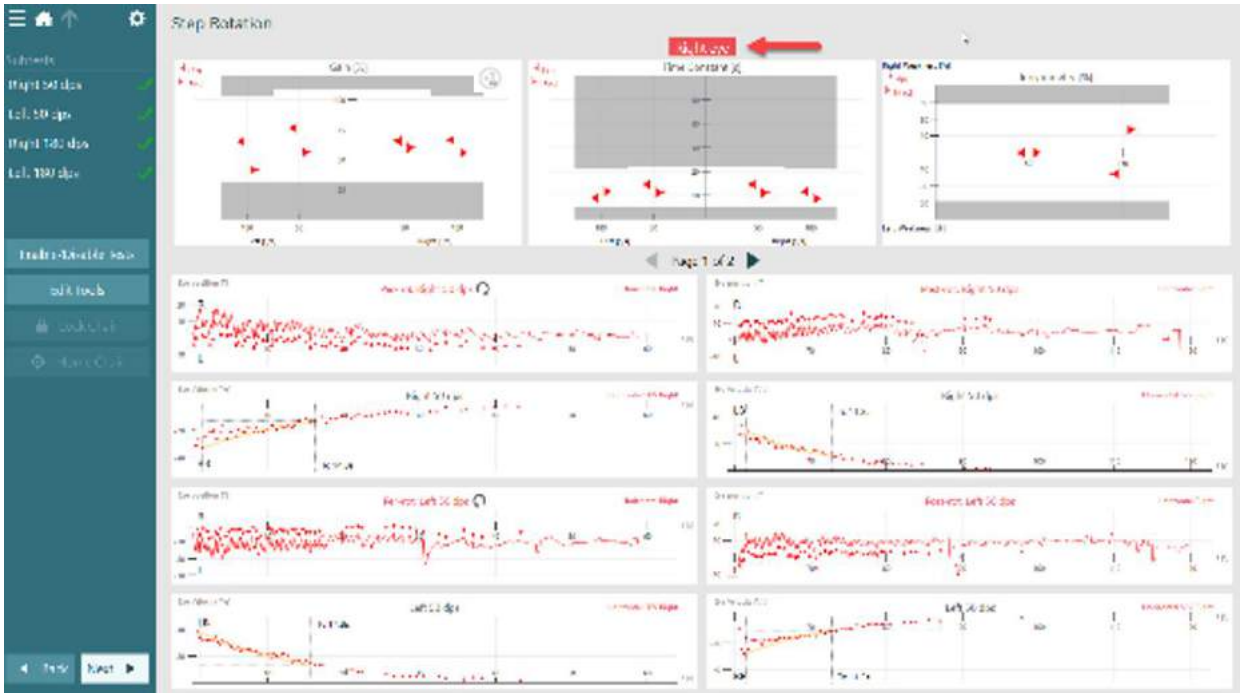


Figure 3.9-21 Right eye results for Step Rotation test

The summary test results screen displays various analyses. The top portion of the summary results screen displays plots for Gain, Time Constant, and Time Constant Symmetry. These parameters are explained in detail in the following section.

Gain

Gain is the relation between the patient's maximum slow phase velocity (SPV) of nystagmus and the maximum velocity of the rotary chair (stimulus). A total of four gain values will be present for each Step Rotation speed tested (per-rotary left, post-rotary left, per-rotary right, post-rotary right).

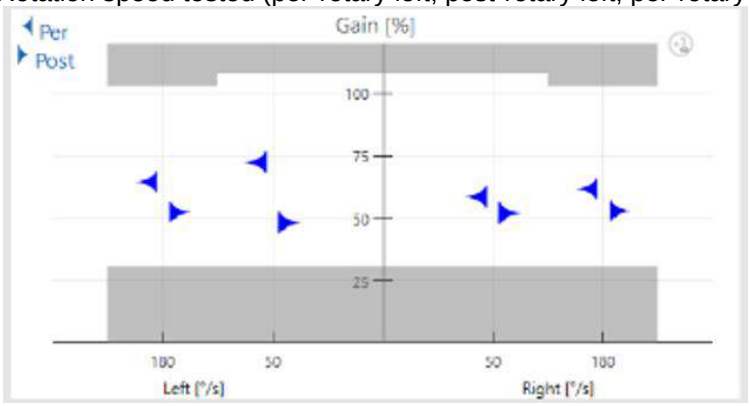


Figure 3.9-22 Gain graph

The gain values are expressed as a percentage (%). Values within the white region of the graph are considered to be within suggested threshold levels and those in the grey shaded regions are considered to be outside of the suggested threshold levels or criteria (Figure 3.9-22). When data points fall in the grey shaded regions, the graph will be marked with a red diamond to indicate that the patient's data was outside of the suggested threshold level.

Time constant (Tc)

Time constant is the value, in seconds, that represents the amount of time it took for the response to reach 33% of its maximum SPV value.

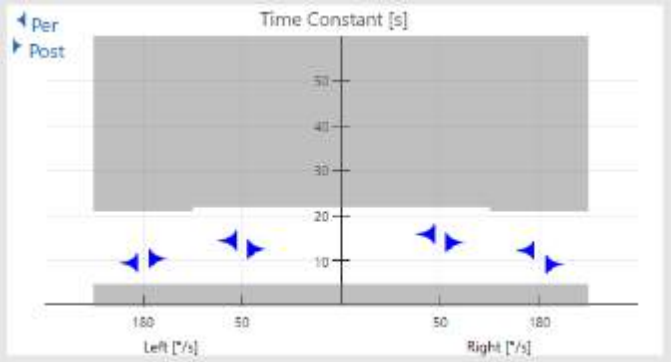


Figure 3.9-23 Time constant graph

Time constant values are expressed in seconds (s). Values within the white region of the graph are considered to be within suggested threshold levels and those in the grey shaded regions are considered to be outside of the suggested threshold levels or criteria (Figure 3.9-23). When data points fall in the grey shaded regions, the graph will be marked with a red diamond to indicate that the patient's data was outside of the suggested threshold level.

Tc symmetry

Tc symmetry provides a way to compare the time constants during chair rotations to the left with time constants during chair rotations to the right. Tc Symmetry is calculated for per- and post-rotatory comparisons.

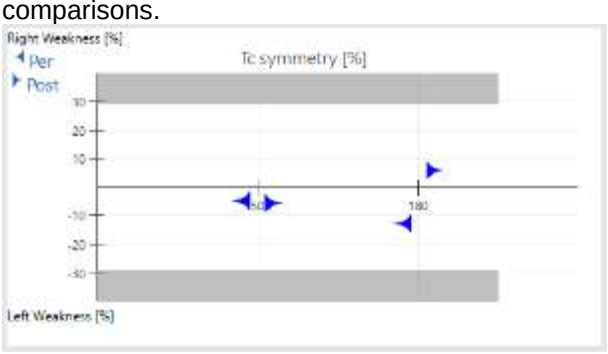


Figure 3.9-24 Symmetry summary plot

Tc symmetry values are expressed as a percentage (%). Values within the white region of the graph are considered to be within suggested threshold levels and those in the grey shaded regions are considered to be outside of the suggested threshold levels or criteria for Tc symmetry (Figure 3.9-24). Data points that fall in the upper grey shaded region are suggestive of a right weakness and data points that fall in the lower grey shaded region are suggestive of a left weakness. When data points fall in the grey shaded regions, the graph will be marked with a red diamond to indicate that the patient's data was outside of the suggested threshold level.

Graph numerical values

The user can choose to view the numerical values of graph. By clicking the symbol , the numerical values will be shown for all the relevant graphs in the selected test. The symbol can be seen in the right/left corner of gain graph (refer section 7.5 for details).

Eye position and eye velocity display

The raw eye position tracings and corresponding slow phase velocity (SPV) results (Figure 3.9-25) are displayed underneath the Gain, Time Constant, and Tc Symmetry graphs on the summary test results screen. These are placed one above the other for simplified viewing of all segments within a single Step Rotation speed tested.

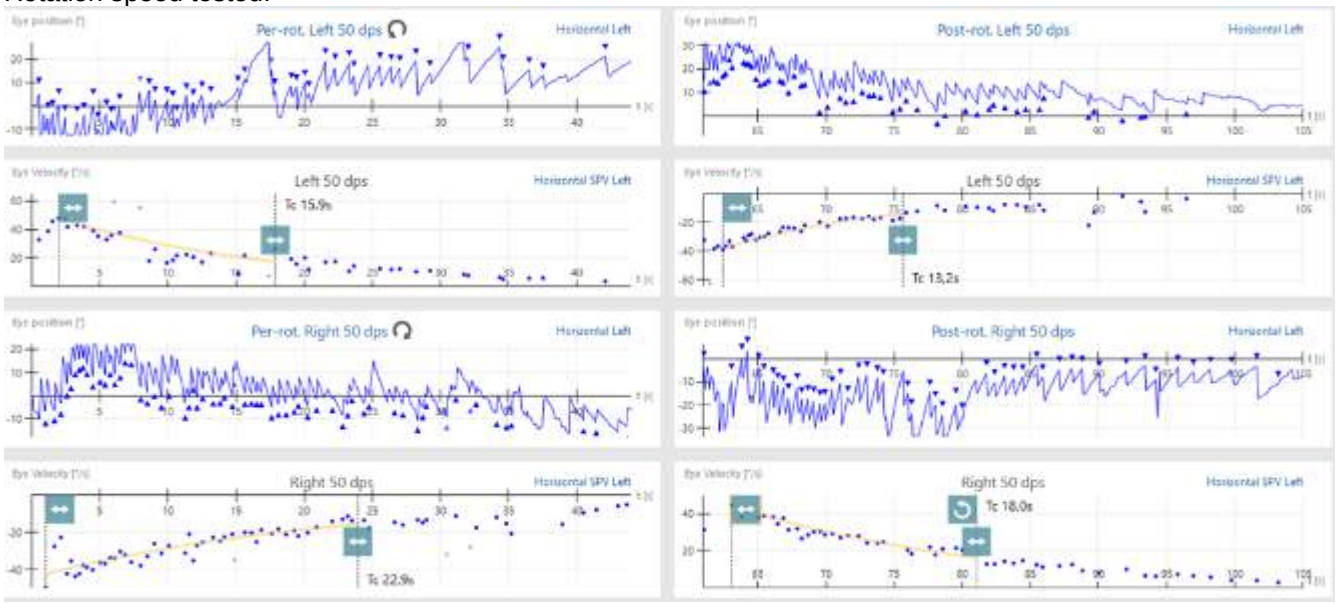


Figure 3.9-25 Raw eye movement data and time constant data for per and post rotary stimuli

The upper portion displays the raw eye position tracing for the specific condition (per/ post-rotary and its relative velocity). Nystagmus beats are marked with triangles to identify left/right beating nystagmus (Figure 3.9-26).

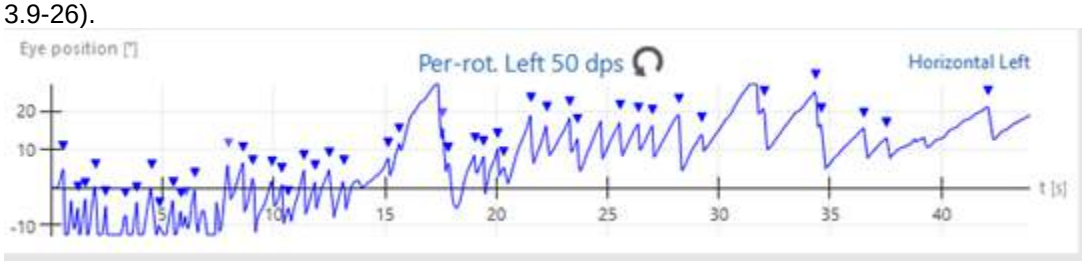


Figure 3.9-26 Raw eye movement data trace with identified nystagmus

The lower portion displays data points for the corresponding SPV values for the detected beats of nystagmus as they reduce from a peak value to their relative time constant (Tc), or 37% of the maximum generated response. The initial vertical dashed line represents the point at which the peak maximum response was detected. The second vertical dashed line represents the point at which the response declined by 37% of the maximum peak response. The horizontal dashed line represents the amount of time between the two vertical dashed lines and indicates the time constant for that segment of the Step Rotation test. The yellow line represents the curve fit from the peak maximum evoked response to the Tc in seconds. The Tc numerical value is displayed next to the dashed line (Figure 3.9-27).

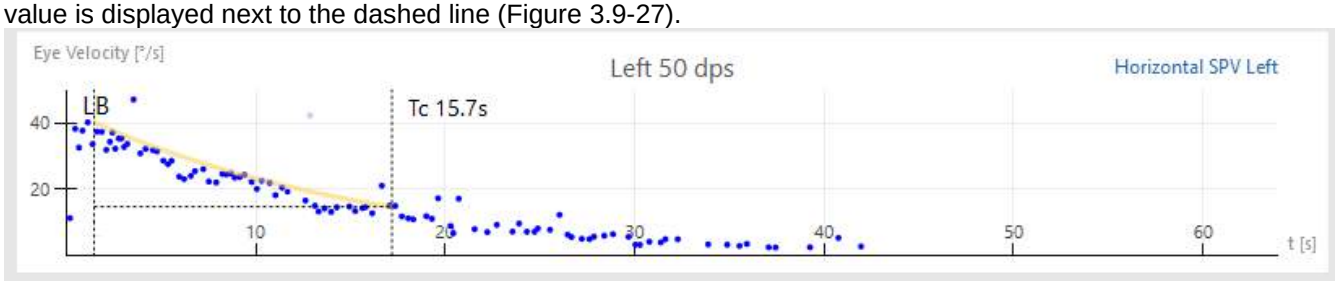


Figure 3.9-27 Eye velocity graph displaying peak response declining to 37% of its maximum (Tc)

SCEP calculations

Slow cumulative eye position (SCEP) information can be optionally displayed. SCEP is calculated by numerically integrating the area under the actual slow-phase velocity of the patient's RVS response. This integration starts from the point of initial SPV until end SCEP. Enabling this feature allows SCEP information for each step to be available within the eye velocity graph, along with the Tc information (Figure 3.9-28). SCEP calculation is not enabled by default but can be enabled within Step Test setup.

Figure 3.9-28 SCEP calculation

When further details for review are needed, the examiner can select an individual velocity and direction from the left side menu panel to see both eyes displayed together for the selected segment (Figure 3.9-29). This view allows the examiner to review both the per- and post-rotary segments for the selected Step Rotation test, add notes, review or delete eye video recordings, print the screen, and edit the results for a specific segment.

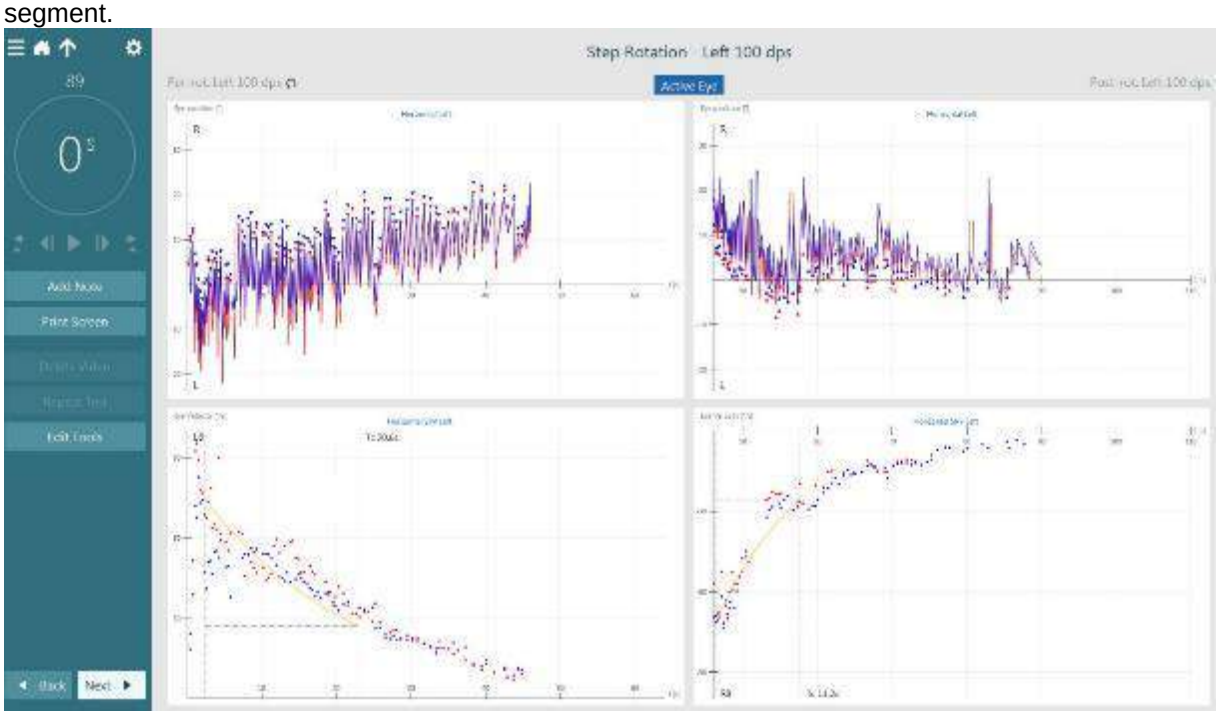


Figure 3.9-29 Review individual Step Rotation segment

3.9.4 VOR suprresion test

During VOR Suppression, the patient is rotated in the same sinusoidal alternating pattern as in the SHA test, but this time with a fixation light illuminated within the VisualEyes™ VNG goggles or – in the Orion AT/C chairs – projected onto the wall of the enclosure so as to assess the patient's ability to suppress the Vestibulo-Ocular Reflex (VOR) while rotating.

The available test frequencies are octave frequencies from. 01 Hz up to. 64 Hz. By comparing the patient's vision-denied SHA results to the VOR suppression results at the same frequency of rotation, a percentage of gain reduction can be calculated. A failure to sufficiently suppress the VOR can be an indicator of possible central pathology.

Eye movements are recorded with the VisualEyes™ VNG cameras and the responses are displayed in real-time. The patient's eyes, along with eye position tracings (°), eye velocity tracings, and two graphs for gain (%) and reduction (%) are visible during the testing procedure (Figure 3.9-30).

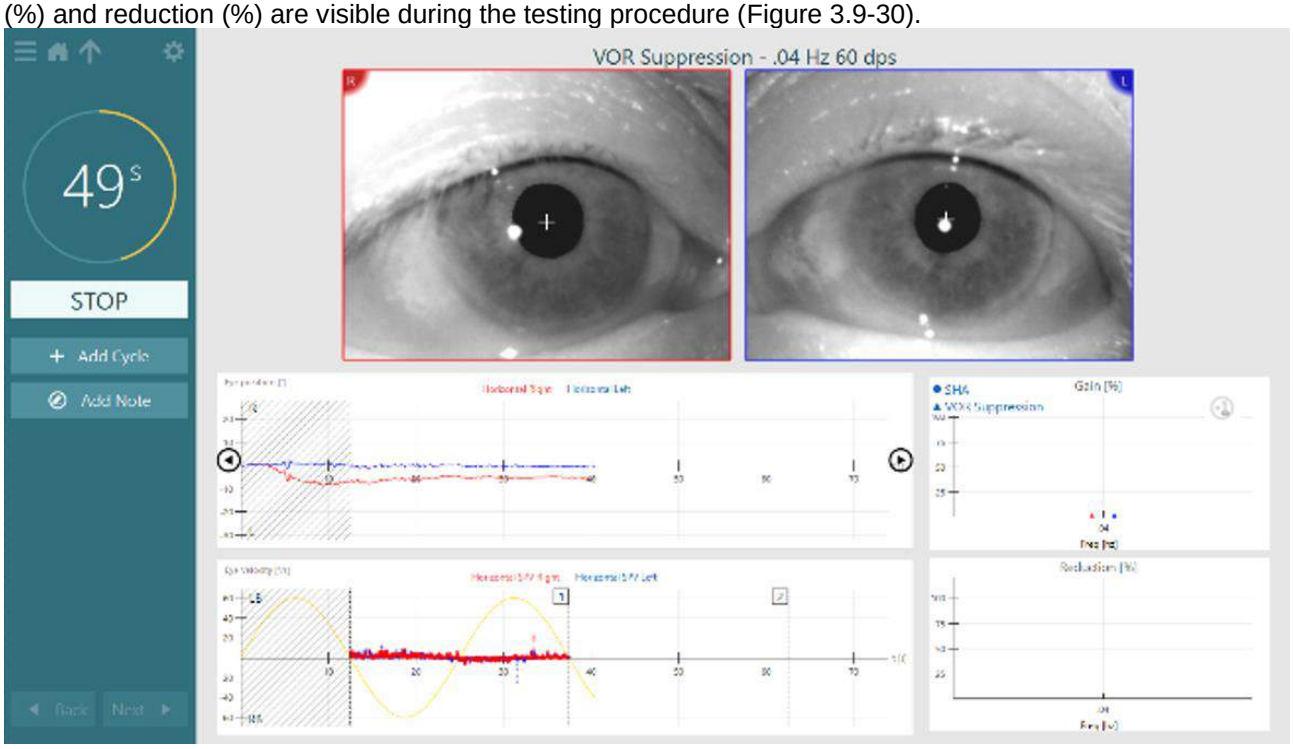


Figure 3.9-30 VOR Suppression testing

The VOR suppression test will be available within the protocol or may be selected directly from the side menu panel by tapping the 'hamburger' icon in the upper left corner of the test screen to view the test battery list.

Example instructions for the patient:
"You will feel yourself rotating back and forth slowly in the chair. During the rotation, you will see a small light appear within the mask. Please keep your eyes open and focused on the light during the entire test. Try to prevent the light from 'bouncing' around in your view."

To begin the test (for operator):

1. Select 'Start' from the left menu panel.
2. The timer will begin counting down. The test time is pre-defined by the number of cycles selected for the test frequency.

The chair will activate and begin moving in a sinusoidal pattern.
Camera recordings will begin at the onset of chair movement.
The fixation light will also appear within the goggles.
The stimulus and eye movements will be displayed in real time (Figure 3.9-31).
Once the test is complete a summary test results screen will appear.

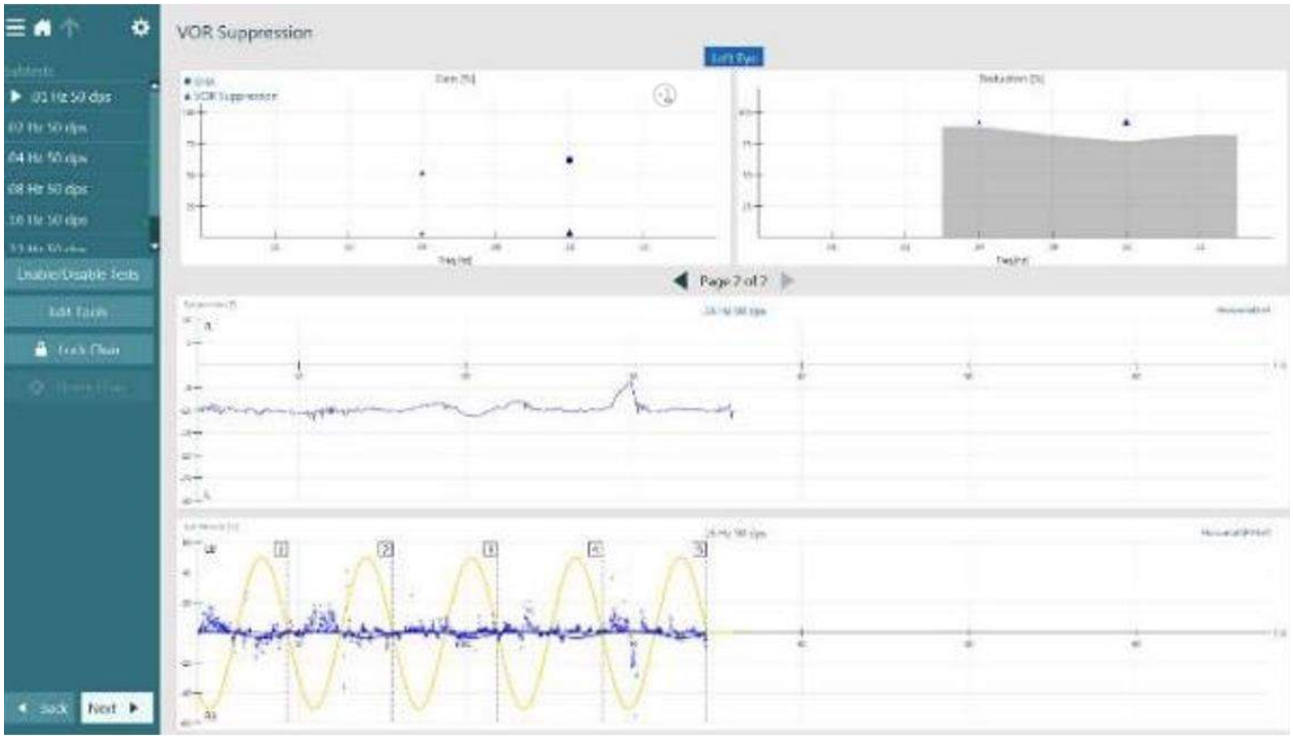


Figure 3.9-31 VOR suppression summary

A patient with normal VOR suppression results will produce a tracing that shows significantly reduced nystagmus as the patient is rotated from left to right in the chair. The data points for each frequency tested will appear as triangles in the Gain (%) and Reduction (%) graphs. The circular data points represent the previously recorded SHA results.

Please note: The first half cycle (hatched region) of each frequency tested is excluded from analysis for improved test reliability.

Analysis of eye movements is performed separately for the right and left eyes and the results are displayed separately. Left eye results are displayed by default. The displayed results can be changed to the right eye by selecting the eye title in the top center of the summary test results screen.

The summary test results screen displays various analyses. The top portion of the summary results screen displays plots for Gain, Reduction. These parameters are explained in detail in the following section.

Gain

The software will automatically compare the patient's gain during a VOR suppression test to the gain during a Sinusoidal Harmonic Acceleration at the same frequency so that both can be plotted on the VOR Suppression gain graph. Sinusoidal Harmonic acceleration results are plotted with circles and VOR suppression results are plotted with triangles (Figure 3.9-32).

VOR Suppression gain is simply the raw value for the ratio of maximum slow phase nystagmus velocity to head (chair) velocity. The lower the gain value, the better the patient was able to suppress his/her nystagmus by fixating on a target during SHA rotation. An inability to sufficiently suppress the VOR is indicative of possible central vestibular pathology.

Values are expressed as a percentage (%).

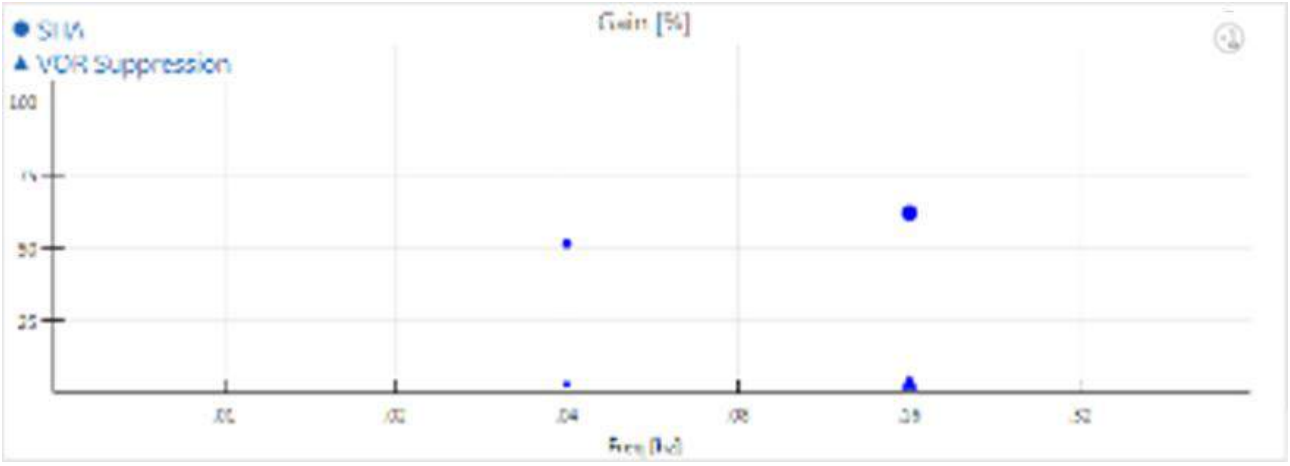


Figure 3.9-32 Gain graph with VOR and VOR Suppression tests

Gain reduction

The percent gain reduction result is obtained by comparing any given frequency of rotation with no visual fixation to the gain result at the same frequency of rotation with visual fixation. Percent gain reduction is a percentage by which the nystagmus has reduced as a result of fixating on a target. Among the normal population, it is not uncommon to see % Gain Reduction of 50% (Figure 3.9-33).

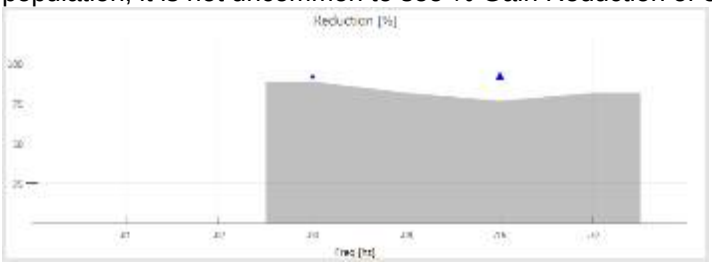


Figure 3.9-33 Gain reduction graph

The percent reduction results are plotted with triangles. Values are expressed as a percentage (%).

Graph numerical values

The user can choose to view the numerical values of graph. By clicking the symbol , the numerical values will be shown for all the relevant graphs in the selected test. The symbol can be seen in the right/left corner of gain graph (refer section 7.5 for details).

Eye position display

In the middle portion of the VOR Suppression summary results screen, the eye position (°) tracing is displayed. The eye position tracing (Figure 3.9-34) represents eye movement during chair rotation and is displayed as a function of eye position in degrees (y-axis) over time in seconds (x-axis). The tracing should appear relatively flat if the patient is able to suppress the nystagmus while fixating.

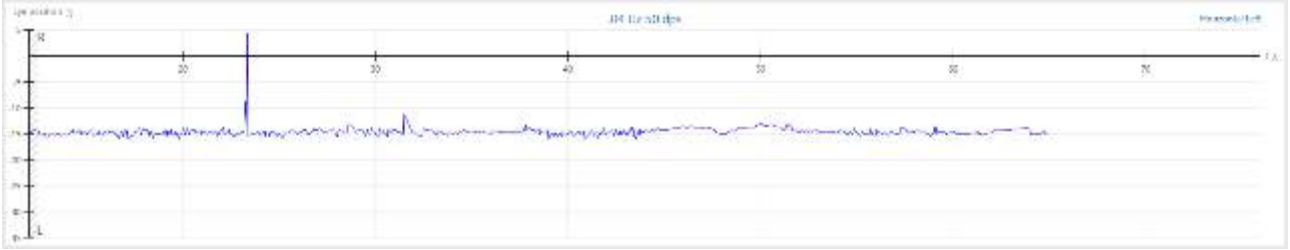


Figure 3.9-34 Eye position trace

Eye velocity display

The eye velocity in °/s (blue) relative to stimulus chair velocity (yellow) is displayed beneath the eye position tracing (Figure 3.9-35).

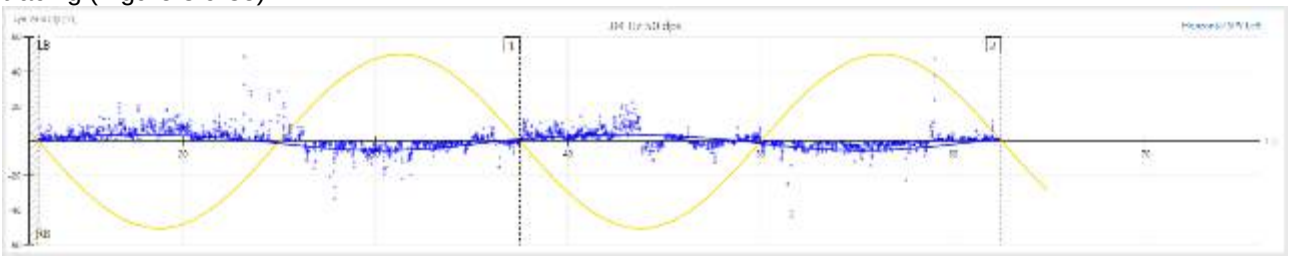


Figure 3.9-35 Display showing detailed individual cycles for eye velocity vs. stimulus velocity

This graphical display provides a detailed individual cycle view for the examiner to see the patient's results in relation to the stimulus. The user can also view the cycle numbers in this display. The eye velocity should be relatively flat compared to the stimulus chair velocity if the patient is able to suppress the nystagmus while fixating.

3.9.5 Visual VOR test

Visual VOR test requires the patient to be moved in a pendular motion, as in sinusoidal harmonic acceleration with the addition of a visual stimulus on screen. The fixation cover is removed from the goggles for this test and the patient is required to focus on a stationary target on the oculomotor screen during chair rotation from right to left and vice versa. This test provides the user with more information about the calibration, system function, as well as the patient's central vs. peripheral vestibular function.

The test can be performed at any SHA frequency, but is most commonly performed at 0. 32 Hz, which is the frequency defined in the VisualEyes™ 515/525 default protocol.

The Visual VOR test will be available within the protocol or may be selected directly from the side menu panel by tapping the 'hamburger' icon in the upper left corner of the test screen to view the test battery list.

Note: This test can be performed using either goggles or electrodes with AT/C Chair in the enclosure. The target stimulus will be displayed on the enclosure wall.

Example Instructions for the Patient:
"You will feel yourself moving back and forth slowly in the chair. During the rotation, you will see a target appear on the screen in front of you. Please keep your eyes focused on the target during the entire test.

To begin the test (for operator):

1. Select 'Start' from the left menu panel.
2. The timer will begin counting down. The test time is pre-defined by the number of cycles selected for the test frequency.

The chair will activate and begin moving in a sinusoidal pattern.
Camera recordings will begin at the onset of chair movement.
The target will be displayed on the secondary monitor.
The stimulus and eye movements will be displayed in real time.

Once the test is complete a summary test results screen will appear (Figure 3.9-36).

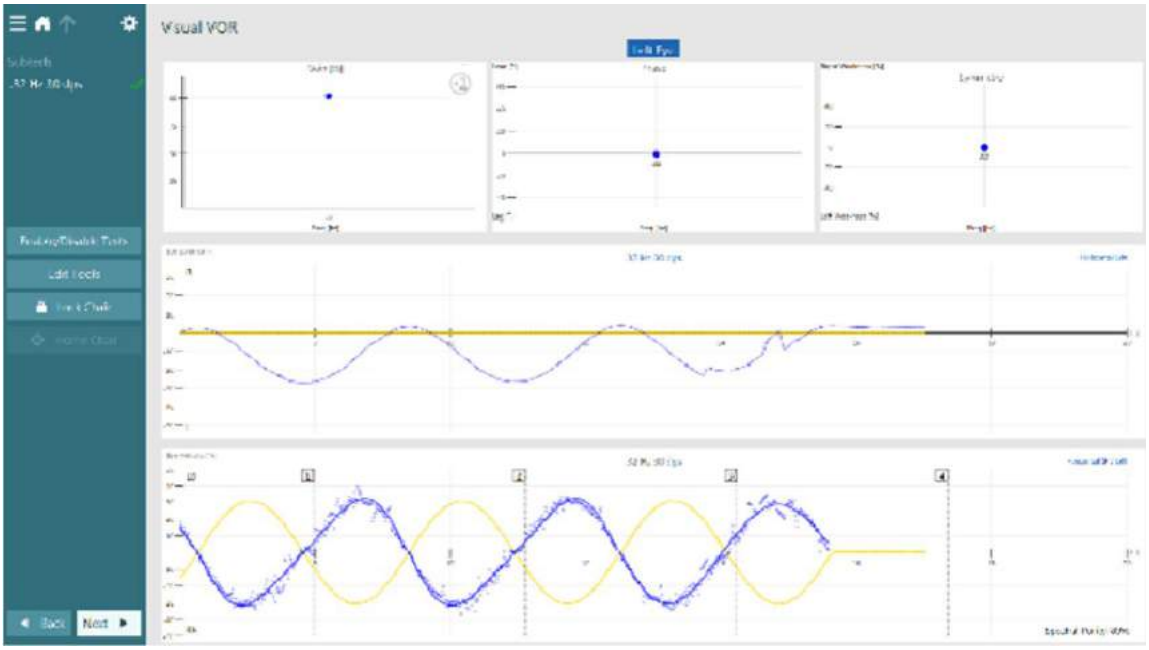


Figure 3.9-36 Visual VOR summary

A patient with normal Visual VOR results will produce a tracing that resembles a sinusoid that mirrors the sinusoid of chair movement. When the VOR is functionally as expected, the patient's eyes will move equal and opposite to the chair while he/she is focused on a stationary target. Visual VOR analysis is performed in a similar manner to SHA in that gain, phase and symmetry are calculated. The data points for each frequency tested will appear as circles in the graphs.

Please note: The first half cycle (hatched region) of each frequency tested is excluded from analysis for improved test reliability.

Analysis of eye movements is performed separately for the right and left eyes and the results are displayed separately. Left eye results are displayed by default. The displayed results can be changed to the right eye by selecting the eye title in the top center of the summary test results screen.

The summary test results screen displays various analyses. The top portion of the summary results screen displays plots for Gain, Phase and Symmetry. These parameters are explained in detail in the following section.

Gain

Gain (%) is the ratio of maximum slow phase eye velocity to maximum head (chair) velocity. The function of the Vestibular Ocular Reflex (VOR) is to produce an eye movement that compensates for head movement, so under perfect conditions the eye velocity of the response to rotation should be a mirror image of head velocity producing a gain of 60 % (Figure 3.9-37).

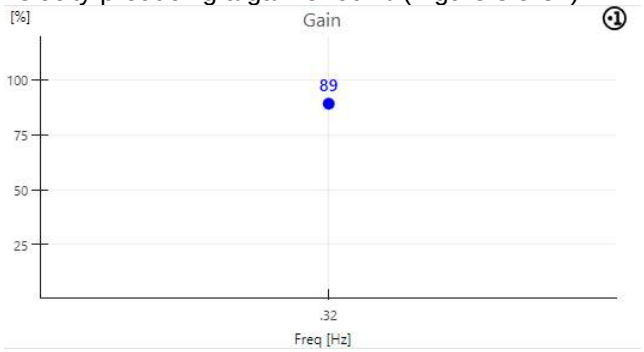


Figure 3.9-37 Visual VOR Gain graph

Phase

Phase (°) displays the timing relationship between the motion stimulus and the ocular response to that stimulus (Figure 3.9-38). Abnormal phase is associated with physiological damage to the VOR. The magnitude of the deviation from normal correlates with the severity of damage.

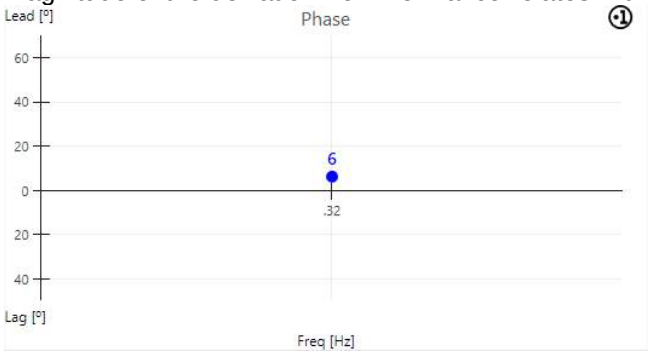


Figure 3.9-38 Visual VOR Phase graph

Symmetry

Symmetry (%) indicates the presence of an imbalance in the system and helps to identify which side is weaker (Figure 3.9-39). A normal finding would present with the data point positioned on the zero line.

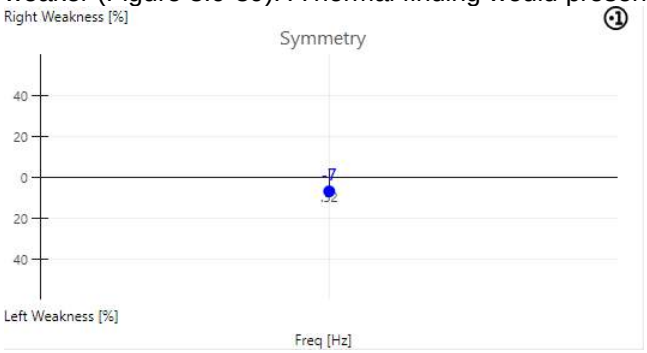


Figure 3.9-39 Visual VOR Symmetry graph

Numerical values for graph

The user can choose to view the numerical values of graph. By clicking the symbol , the numerical values will be shown for all the relevant graphs in the selected test. The symbol can be seen in the right/left corner of gain graph (refer section 7.5 for details).

Eye position and eye velocity displays

Below the Gain, Phase, and Symmetry graphs are the eye position and eye velocity displays, just as in SHA and VOR Suppression (Figure 3.9-40). The eye position tracing should resemble a sinusoid. The eye velocity should appear as a mirror image to chair velocity.

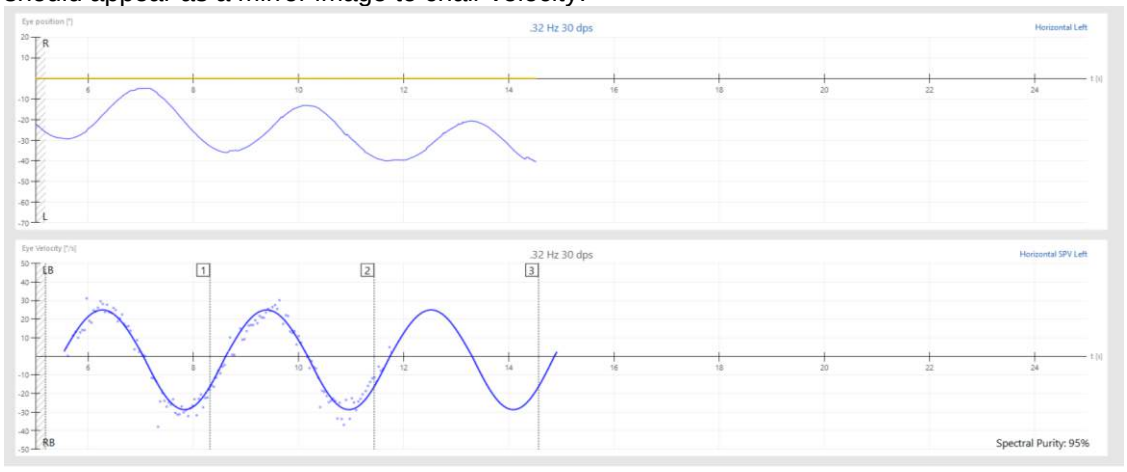


Figure 3.9-40 Visual VOR eye position and eye velocity displays

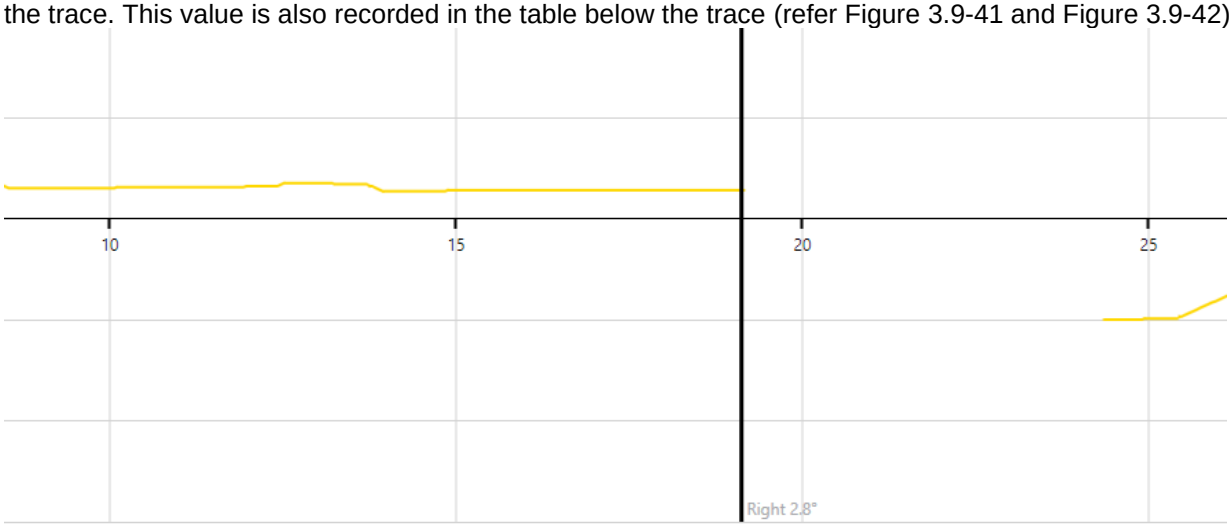
Spectral purity

A spectral purity value for each frequency tested can be viewed in the lower right corner of the eye velocity display. The spectral purity of the evoked nystagmus may be useful to indicate whether the test values have been influenced by artifact. The higher the spectral purity value, the more reliable the Visual VOR result. Values are displayed as a percentage (%).

3.9.6 Subjective Visual Vertical (SVV) test

The subjective visual vertical test checks the patient's otolith function by spinning the patient in the Auto-Traverse chair at a high velocity. A baseline vertical measurement is acquired in the static subtest where the laser line is displayed with the chair stopped. By shifting the patient from the chair's central axis to align the one ear over the chair's central axis, the patient has one otolith charged by the rotation and the other negated of rotation, causing an imbalance and resulting in a perceived variation of vertical. The laser line traced on the booth wall during the test can be adjusted by the patient with the left and right buttons of the chair SVV remote control. Unlike the operator's RF remote control, the patient's SVV remote control buttons can be held down to continually activate and adjust the laser line's angle of rotation.

When the test begins, the chair will begin spinning quickly to the desired velocity (typically 300 degrees / second). Once the velocity is reached, the chair will continue to rotate at the velocity until meeting the time delay setting to provide patient habituation to the chair velocity. The laser is then displayed at the start angle and chair offset settings. The patient must use the SVV remote control acknowledged the line is rotated to perceived vertical, the operator will press the Continue button to move to the next angle and chair offset combination. A vertical line is drawn on the graph with the final vertical orientation recorded at the bottom of the trace. This value is also recorded in the table below the trace (refer Figure 3.9-41 and Figure 3.9-42).



Chair Velocity Chair Offset

0 dps 0 cm

Target	Chair Offset	Patient Response
Right 10°	Left 4 cm	Right 2.8°
Left 10°	Left 4 cm	Right 2.3°
Right 5°	Left 4 cm	Right 2.4°
Left 5°	Left 4 cm	Right 2.4°

Figure 3.9-41 SVV subtest waveform aligned

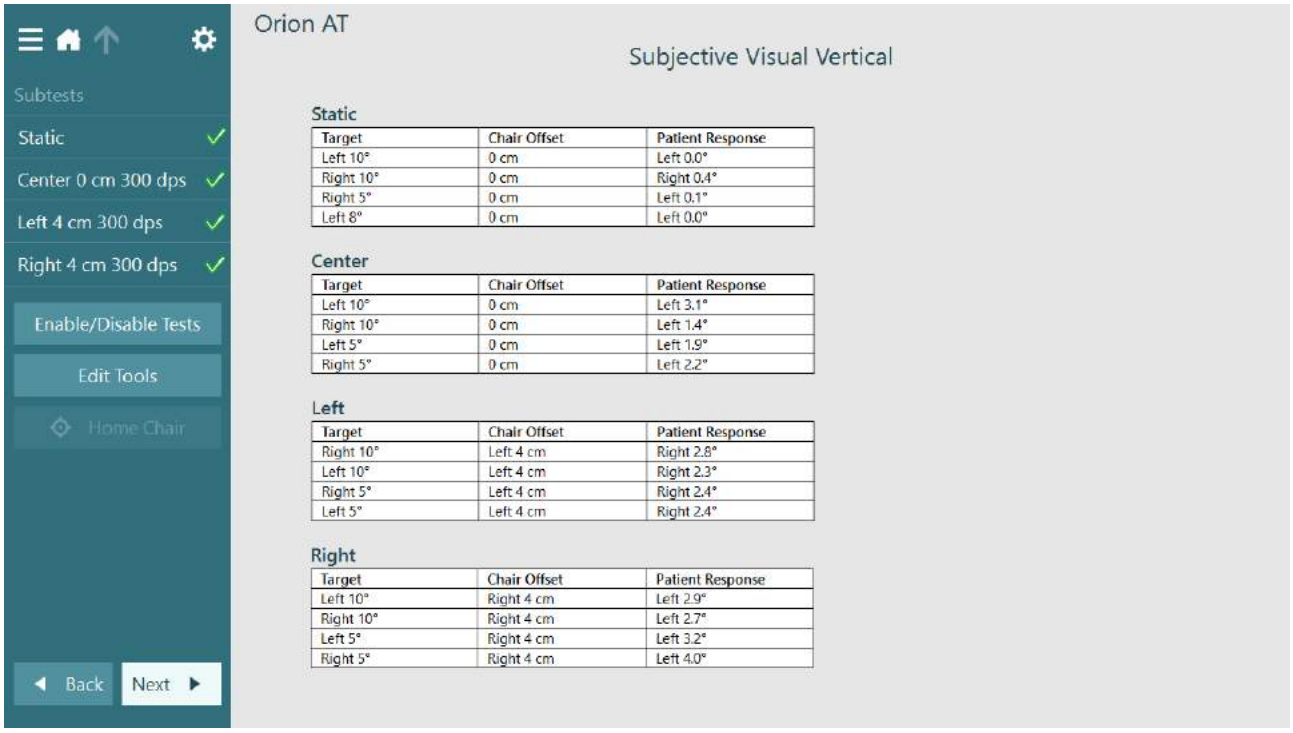


Figure 3.9-42 SVV summary

4 Research module

The research module is an advanced add-on feature for researchers and scientists who would like to quickly export large amounts of data so that they can perform customized analysis of the recorded eye movements.

4.1 Nystagmus parameters

This feature will work with any completed test with recorded eye movements (Figure 4.1-1).

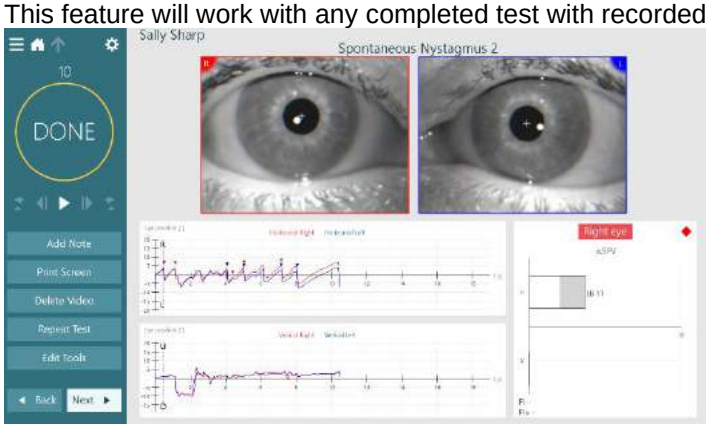


Figure 4.1-1 Nystagmus test screen

For example, for the above test, you can enter the temporary setting menu and adjust the parameters to accommodate your research protocol (Figure 4.1-2).

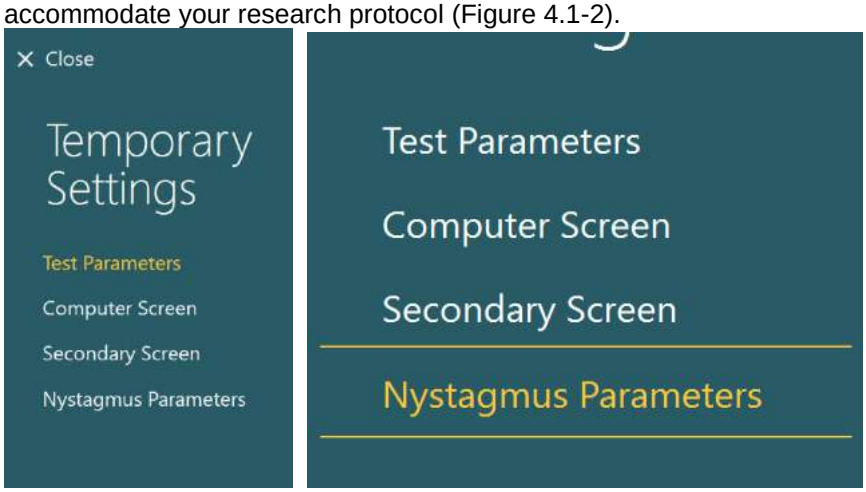


Figure 4.1-2 Nystagmus parameter settings

Once in the settings menu, you can adjust the parameters that are used in the nystagmus detection algorithm (Figure 4.1-3).

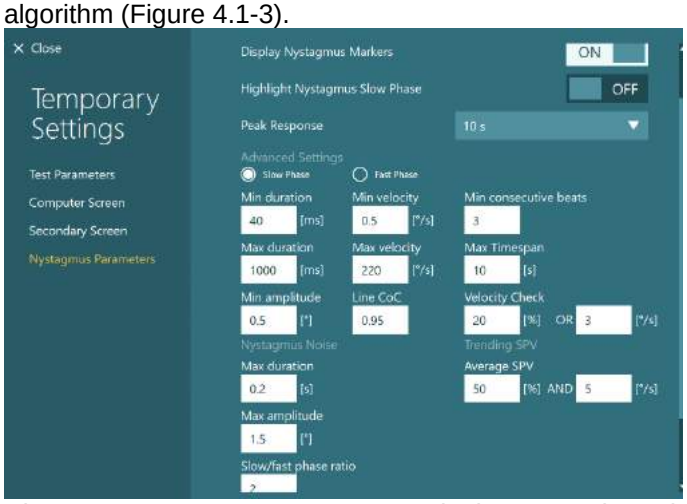


Figure 4.1-3 Nystagmus parameters in the research module

4.2 Data export

When you have completed your testing, in the Summary Review you can choose to export the raw eye movements data to a csv file that is readable by the Excel spreadsheet program for further analysis (Figure 4.2-1).

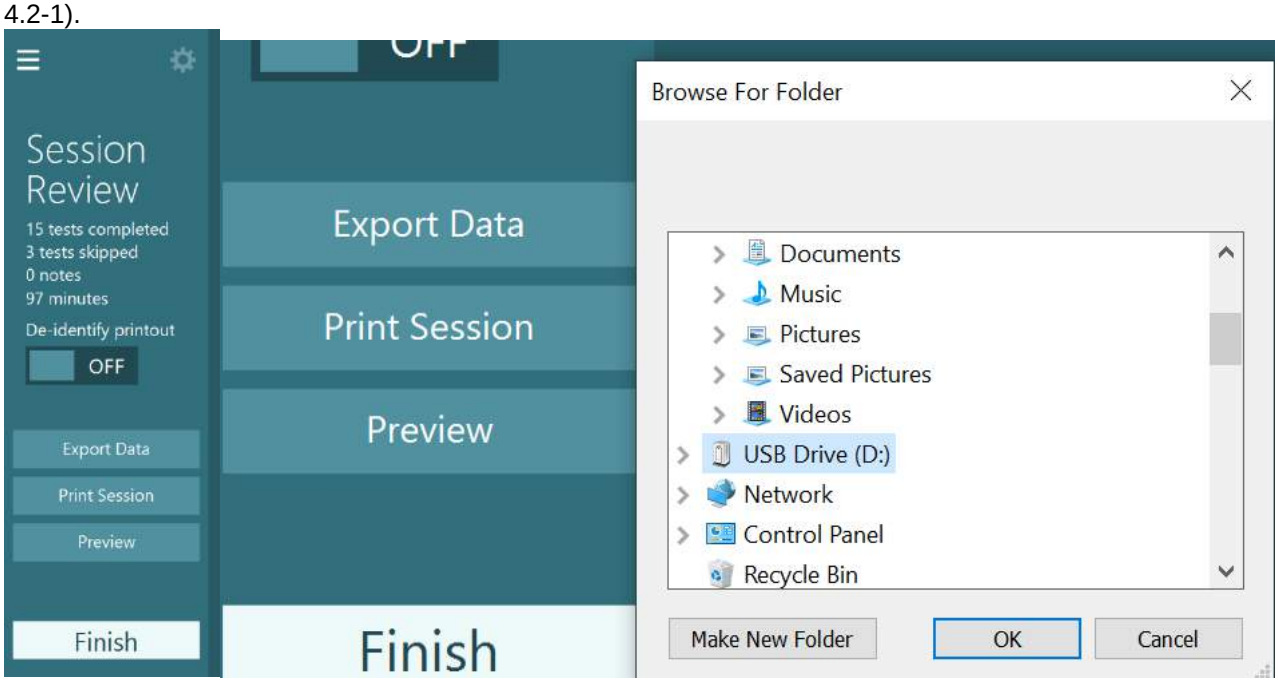


Figure 4.2-1 Export data option in research module

5 Patient session

5.1 Selecting a session

The VisualEyes™ system easily allows review of current and or previous sessions for the selected patient. After selecting the desired patient profile, the operator can select the **Patient Sessions** button from the VisualEyes main screen. This helps to review a previous test sessions of the selected patient (Figure 5.1-1).

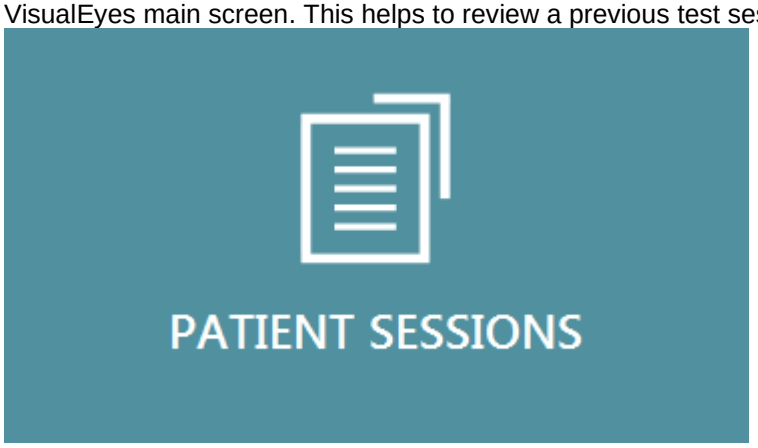


Figure 5.1-1 Patient Sessions button

The Patient Sessions screen (Figure 5.1-2) displays a list of all previous test sessions in the side panel menu. Selection of a specific session date will display all the tests performed on that date and an indication of whether the test results were completed (green checkmark). When completed and test is outside of threshold it will be marked with a red diamond.

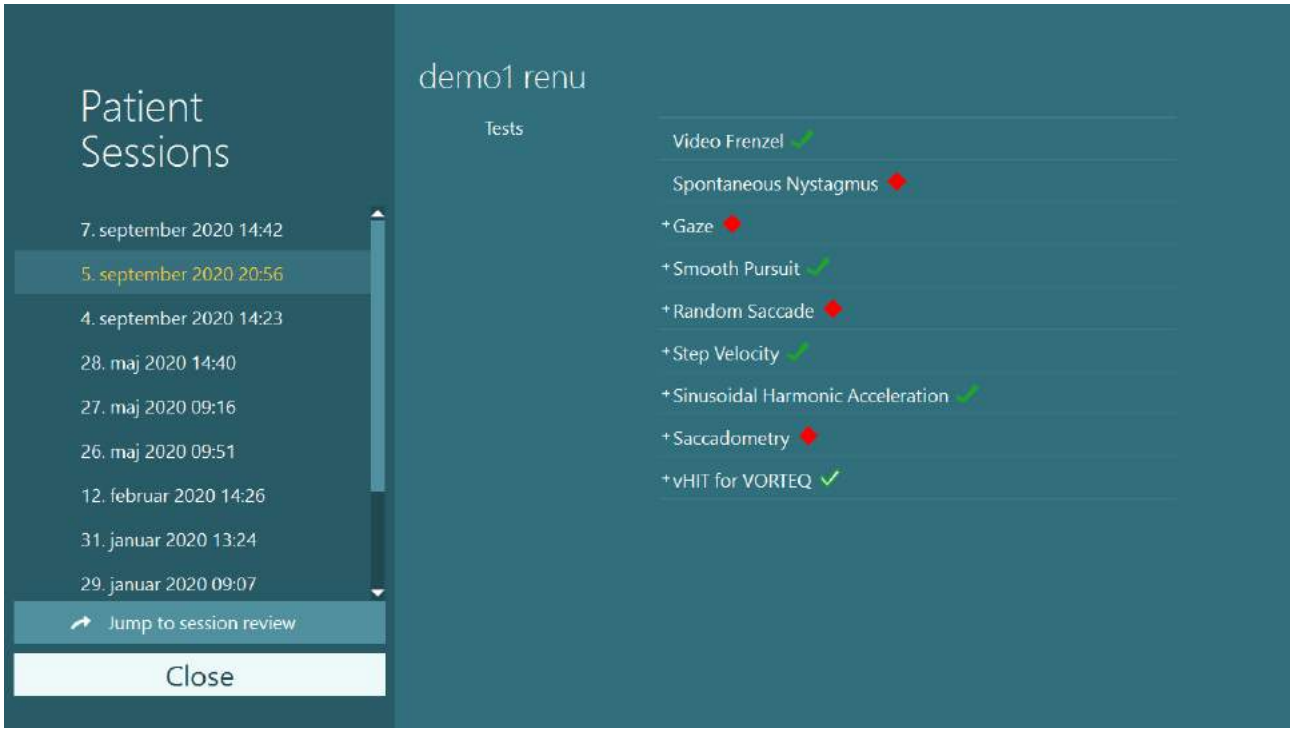


Figure 5.1-2 Patient Sessions screen

After selecting the patient session from the listing, click on the Jump to session review button to go to the Session Review screen (Figure 5.1-3). This will provide further options like export data, print session, preview, print to database and etc…

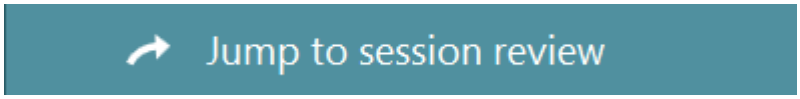


Figure 5.1-3 Jump to session review button

5.2 Session Review

From the test screen the results can be reviewed by selecting the test menu button in the top left corner of the test screen.

A drop down menu will appear with the 'Review Session' button displayed at the bottom (Figure 5.2-1).

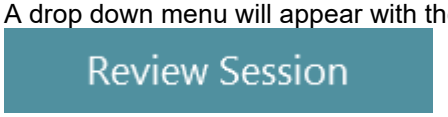


Figure 5.2-1 Review Session button

Review Session will list the tests within the protocol that have been or are yet to be completed (Figure 5.2-2). A symbol will be present next to completed test names indicating whether the test resulted in a within threshold (green tick) outcome or an outside of threshold (red diamond) outcome. Tests can be reviewed, clinical report can be written, and the tests can be printed from the Session Review screen.

Figure 5.2-2 Session Review screen

Click or touch the **Finish** button in lower left corner of the Session Review screen to return to the main screen.

6 Video recordings

6.1 Recording patient videos

Video recording is set to record some tests in the protocol by default. Which tests to record the video is set in the individual test settings in Protocol Management.

- Select **Configuration**
- Select **Protocol Management**
- Highlight the protocol from the list for editing
- Select a test from the protocol
- Select **Edit Test** the gear icon next to the subtest
- Select **Test Parameters** option

- A Video Auto- Save Settings dialogue box will appear (Figure 6.1-1)

Figure 6.1-1 Activate/ Deactivate Eye/s and or Room Recordings

VisualEyes™ provides a manual video save option for those times where one may encounter interesting results in a test without video auto-save settings. Following the completed test, a **Save Video** button will appear in the left side panel. By pressing this button, video recordings of the eyes will be automatically saved to the patient session for current or later review.

6.2 Video playback

The videos recorded during the patient session may be reviewed during and/or after testing.
If the operator is within a current test session and has not yet completed the entire protocol, it is possible to view the videos after each subtest.

This can be done by clicking on the play button within the review screen (Figure 6.2-1). A number above the timer will specify how much recording time in seconds is available for review. The video playback will play full recording from beginning to end.

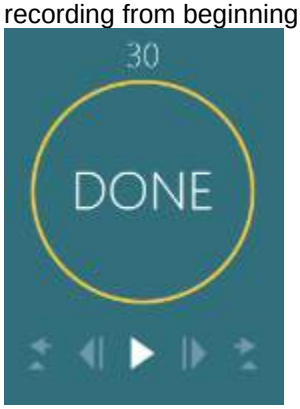


Figure 6.2-1 Video playback display

The video playback can be controlled by buttons (Figure 6.2-2) displayed in a playback menu bar underneath the timer:

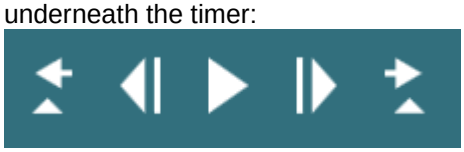


Figure 6.2-2 Playback menu

Go to previous frame (hold to play backwards in slow motion).

Play/pause.

Go to next frame (hold to play forwards in slow motion).

Go to previous visible nystagmus point.

Go to next visible nystagmus point.

The video playback presents both eyes and raw trace data in parallel.
The eye movements can be reviewed on both primary and secondary screens. The eye recordings will show the crosshair for easier identification of abnormal eye movements.
A moving dashed line (Figure 6.2-3) within the raw trace indicates the current point of video playback.

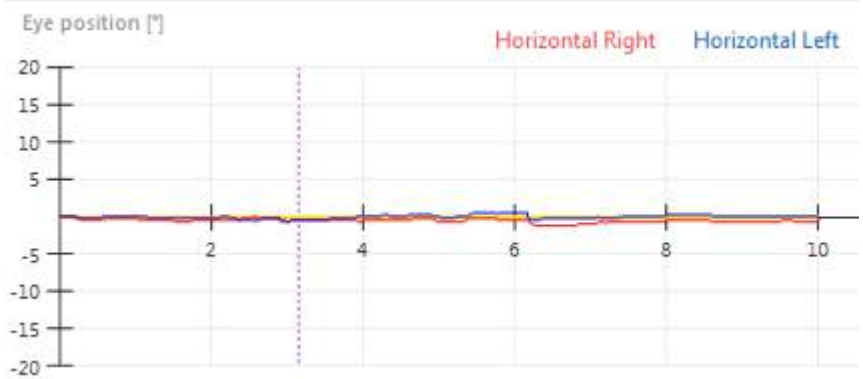


Figure 6.2-3 Dashed line indicating point of video playback

Following a completed session, the recorded videos are archived in the Patient Videos menu.
The video for each individual test can be reviewed by selecting the **Patient Videos** menu from the main screen (Figure 6.2-4).

Figure 6.2-4 Patient Videos button

The tests are categorized by date and test type (Figure 6.2-5).

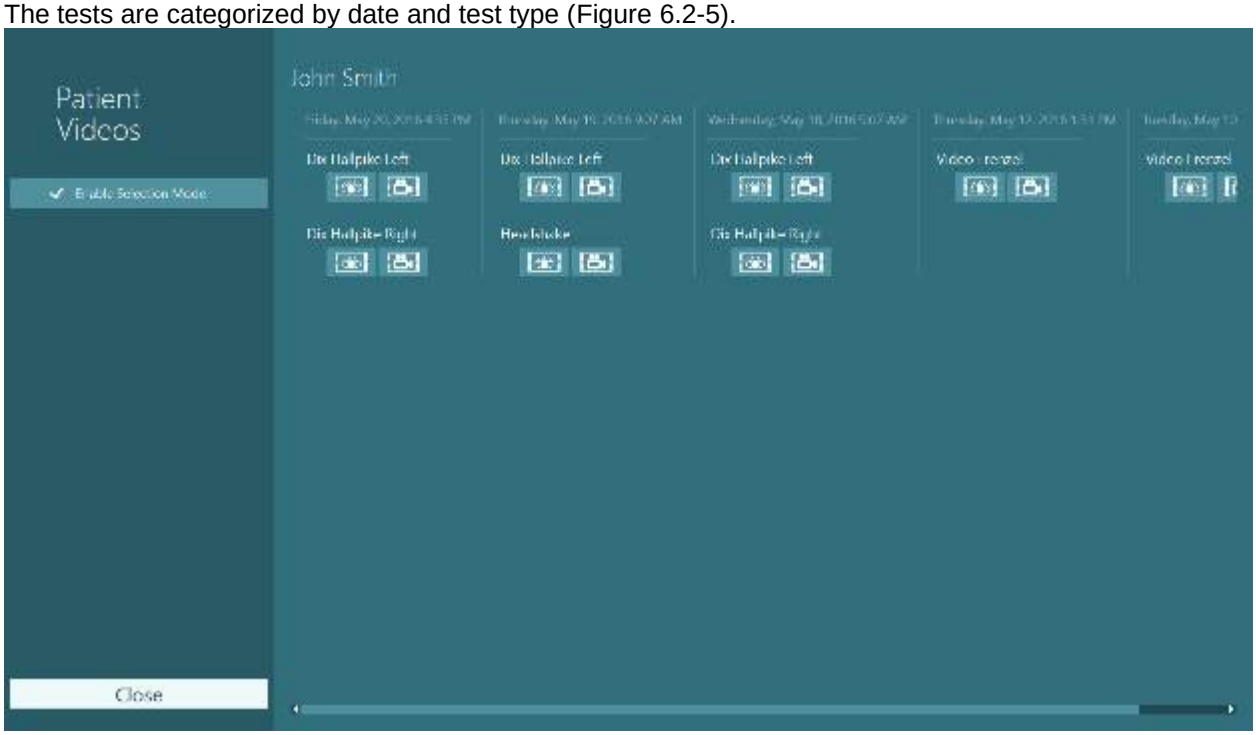


Figure 6.2-5 Patient videos display categorized by date and type of test

To playback the video click on the video file of interest. It will be launched in a compatible video player (Figure 6.2-6).

Video of eye recordings (no raw data).

Videos of room recording

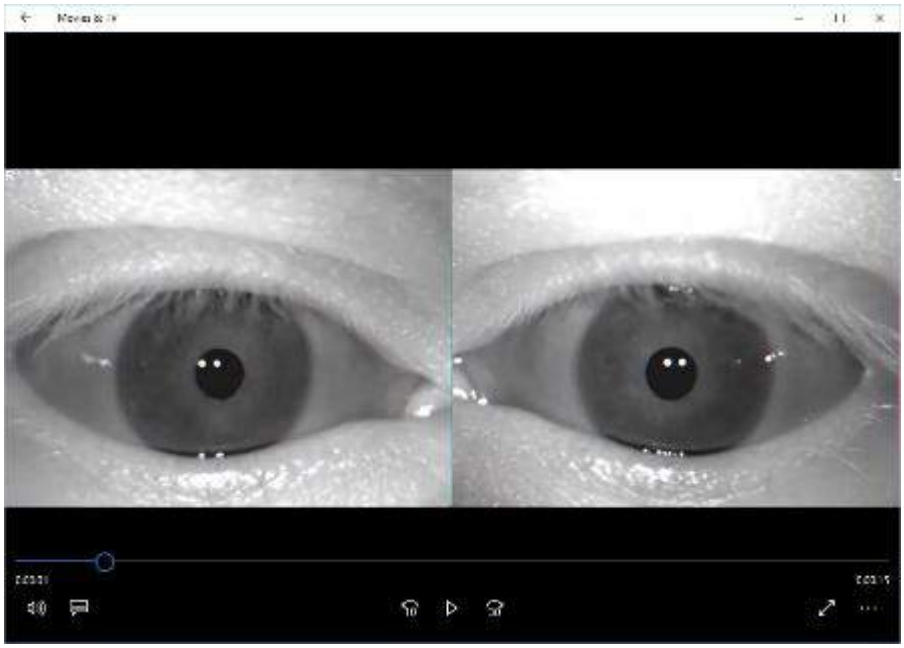


Figure 6.2-6 Video playback within a compatible video player

6.3 Delete selected patient videos

Should it be decided that the video recording for a specific test is of low importance (i. e. normal) it can be deleted after the test is complete.

Select the 

from the side bar menu.

A prompt to confirm removal will appear (Figure 6.3-1):

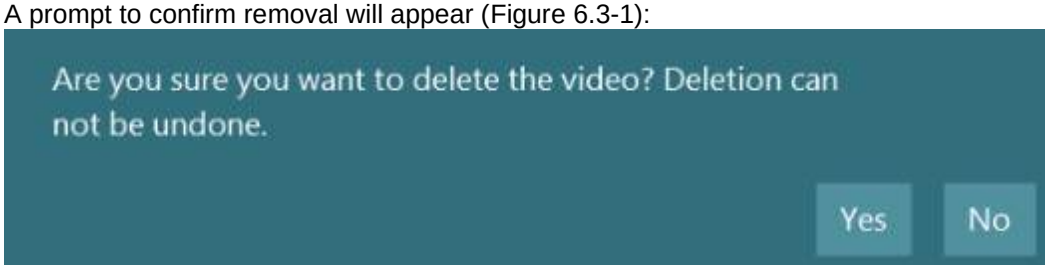


Figure 6.3-1 Warning to delete video

Select **Yes** to continue or N**o** to cancel.

The user can delete the videos from the Patient Videos menu:

- Open **Patient Videos**
- Select **Enable Selection mode (**Figure 6.3-2**)** will highlight the option in yellow color to indicate the option is turned on.

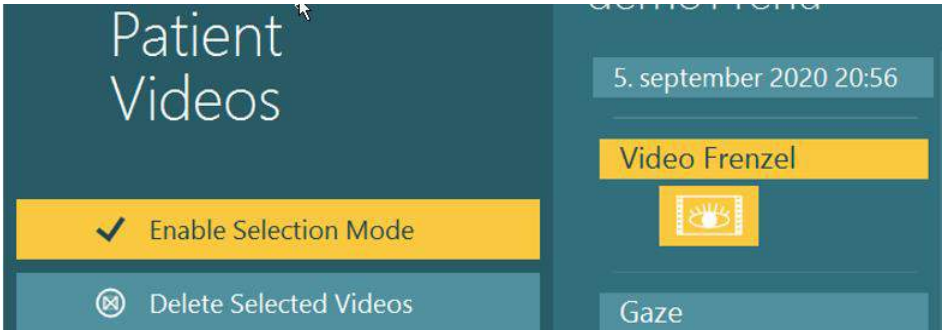


Figure 6.3-2 Selection mode for patient videos

This will allow choosing the videos that are to be deleted from VisualEyes™.

- Touch or click the videos for removal. Both room and eye recordings can be deleted.
- The files will highlight yellow to indicate that these are the chosen files for removal (Figure 6.3-3)


Figure 6.3-3 Highlighted selected videos

- Select the **Delete Selected Videos** option

- Prior to removal a prompt will appear, confirming removal of selected videos (Figure 6.3-4)

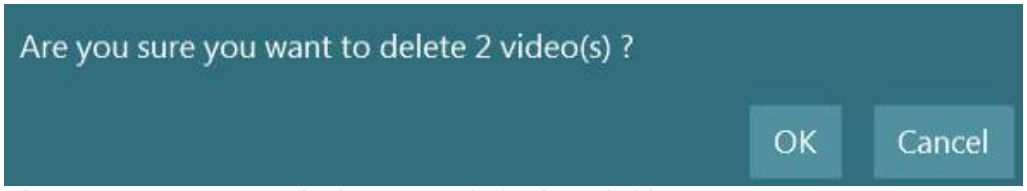


Figure 6.3-4 Prompt confirming removal of selected videos

- Touching or clicking OK will delete the videos permanently from the VisualEyes™ system

6.4 Exporting patient videos

VisualEyes™ can export videos to another directory or onto an external device. This option is useful when the clinician like to use the recorded video material for teaching purposes or for confirmation of results.

Touch or click on the Enable Selection Mode button to activate video selection mode. When the video selection mode is active, multiple videos can be selected. When the selection mode is inactive, clicking or touching the video will play the video.

To export selected videos:

- Open **Patient Videos**
- Select **Enable Selection Mode**

This will allow the user to choose the videos that are to be exported from VisualEyes™ onto another storage device.

- Touch or click the videos of interest for export, which can be room and eye recordings
- The files will highlight yellow to indicate that these are the chosen files for export (Figure 6.4-1)

Figure 6.4-1 Highlighted selected videos

Select the **Export Selected Videos** button.

Figure 6.4-2 Export Selected Videos button

The Export Video Files dialog will be displayed. Select the destination directory for exporting the files of interest (Figure 6.4-2). By default, the eye and room recordings will be merged together (if both the eye and room recordings are selected) to make it easier to use in presentations. Uncheck the option Combine eye and room videos to export the videos without merging.

Figure 6.4-3 Destination selection for export video files

When Export is complete a dialogue message will appear confirming successful transfer of video files: ‘Export succeeded’ (Figure 6.4-3Figure 6.4-3 Destination selection for export video files).

7 General and editing tools

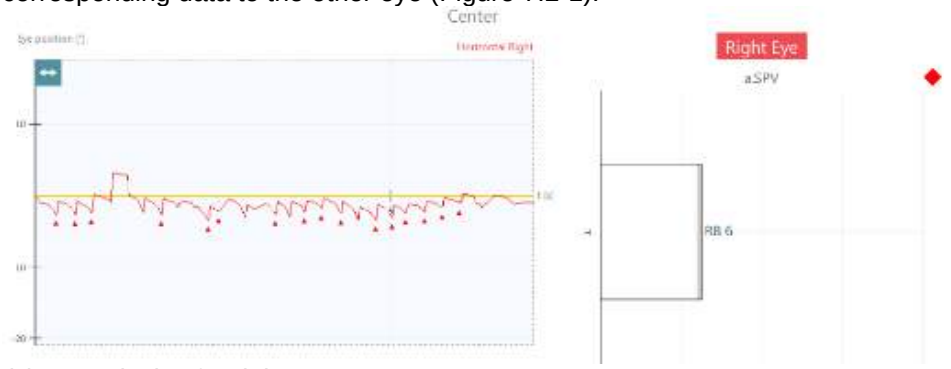
7.1 Quick access test properties

There may be times where it is necessary to make a quick change to a specific test in the protocol. VisualEyes™ VNG software suite provides a way to quickly access test properties that allow temporary changes to be made to a test. This can be accessed by selecting the configuration icon in the side panel.

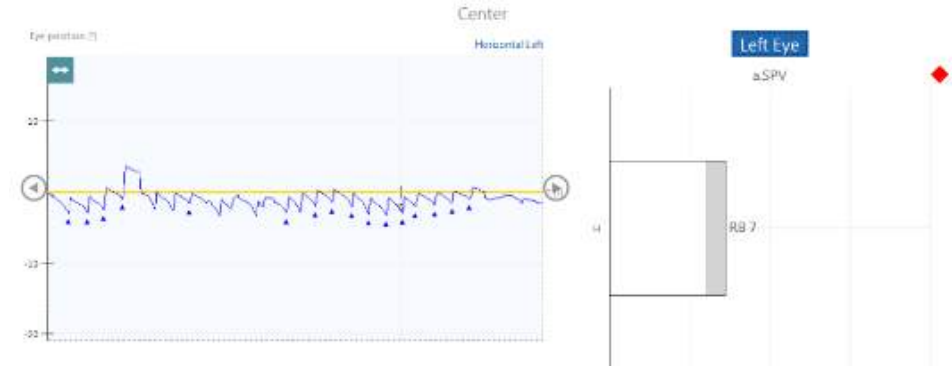
The temporary settings that can be changed will depend on the type of test (nystagmus, oculomotor etc. …) (for more information see configuration section). Any changes made will be to the patient's current session and will not be saved in the selected protocol.

7.2 Selecting eyes

The VisualEyes™ system is set by default to show results for the best eye recording in the case of nystagmus tests. However, there may be times where the best eye varies from one subtest to another. In such cases the VisualEyes™ system allows the user to change the eye being displayed by simply clicking or touching the Eye display title (i. e. left/right eye). This will change the Eye display title and all the corresponding data to the other eye (Figure 7.2-1).



(a) Display for right eye



(b) Display for left eye

Figure 7.2-1 Results display for right (a) and left (b) eyes

VisualEyes™ VNG suite provides the option of displaying individual eye traces (i. e. right or left only) for all nystagmus tests. The default SPV indicator (a. SPV bar graph) is set to display the eye with the larger response.

7.3 Pupil diameters

This graph shows how the pupil diameter changes over time. It is used for pupillometry assessment. The value is given in pixels and refers to the pupil size shown on the camera. Only relative size is indicated, and it is not possible to indicate the absolute size (e. g. millimeter).

To activate this trace, select ‘pupil diameter’ (Figure 7.3-1) in the test settings (Go to Temporary settings/Computer Screen to see this option):

Figure 7.3-1 Pupil Diameter option

7.4 Editing nystagmus

There is an **Edit Tools** item (Figure 7.4-1) for editing the nystagmus in the recordings. This menu will be available in spontaneous, gaze, optokinetic, positional, Dix Hallpike, caloric, and step rotation tests.

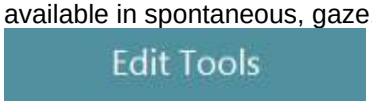


Figure 7.4-1 Edit Tools button

The editing options in this menu include (Figure 7.4-2):

Figure 7.4-2 Edit Tools menu for nystagmus configuration

7.4.1 Add Beats

	Selecting this function allows insertion of nystagmus beats that were not originally detected by the nystagmus algorithm (Figure 7.4-3).

- Use the selection box to define the start and end points of a nystagmus beat’s slow phase velocity to add to the analysis
- The software will measure the slope identified in the tracing and place a SPV marker in this position or highlight the slope green depending on the system setting

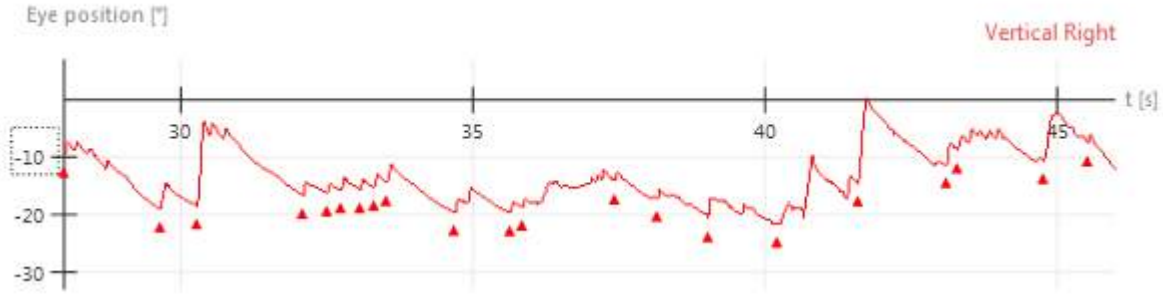


Figure 7.4-3 Added beats to nystagmus trace

7.4.2 Remove Beats

	This function will remove multiple nystagmus beats at the operator's discretion (Figure 7.4-4)

- Use the selection box to define the start and end points of the time to remove all nystagmus beats in the selected time frame
- Once removed, the beats become translucent and are removed from the analysis

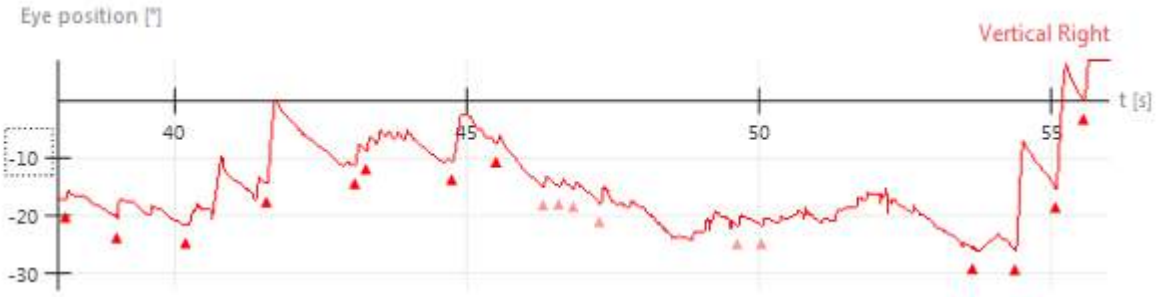


Figure 7.4-4 Removed beats with translucent triangles

7.4.3 Edit Slopes

	This function enables overriding the current slope measurement and toggle inclusion of the nystagmus beat in analysis.

- Selecting the tool, the slope of the nystagmus beat will be highlighted in bright green (Figure 7.4-5)

Figure 7.4-5 Selected nystagmus slope

- The operator can tab through individual beats using the left and right arrow keys on the keyboard or by using touch screen
- For each beat the current SPV value will be displayed on the graph
- Use the up and down arrow or buttons in the tool bar to increase or decrease the slope respectively, 1 degree at a time
- During slope editing (
  Figure 7.4-6), the slope line color changes from green to red. Accepting the new value will change the slope line color to green

Figure 7.4-6 Editing selected nystagmus slope

- One cannot reverse the phase of the slope, i. e. change a right beating slope into a left beating slope
- The slope value cannot be zero, instead reject the slope from the analysis using the exclude button
- The toolbar displays the current beat's slow phase velocity in the center of the toolbar. To examine the slope values for each nystagmus beat, use the right and left arrow keys to move through the nystagmus beats and note the slow phase velocity value for each beat

Alternative display for viewing nystagmus

- VisualEyes can either display triangles to show the location and direction of nystagmus beats or highlight the nystagmus slow phase in green. In addition to a system wide setting in System Default Settings (see Section 13.5 General), the current test settings (*Figure 7.4-7*) can be changed if desired
- Access the test settings from the gear button on the side panel. Select Nystagmus Parameters
- **Display nystagmus markers** will control whether the nystagmus triangle markers are displayed
- **Highlight nystagmus slow phase** will control whether the nystagmus slow phase is drawn in green color. This setting is applied after the test collection is complete

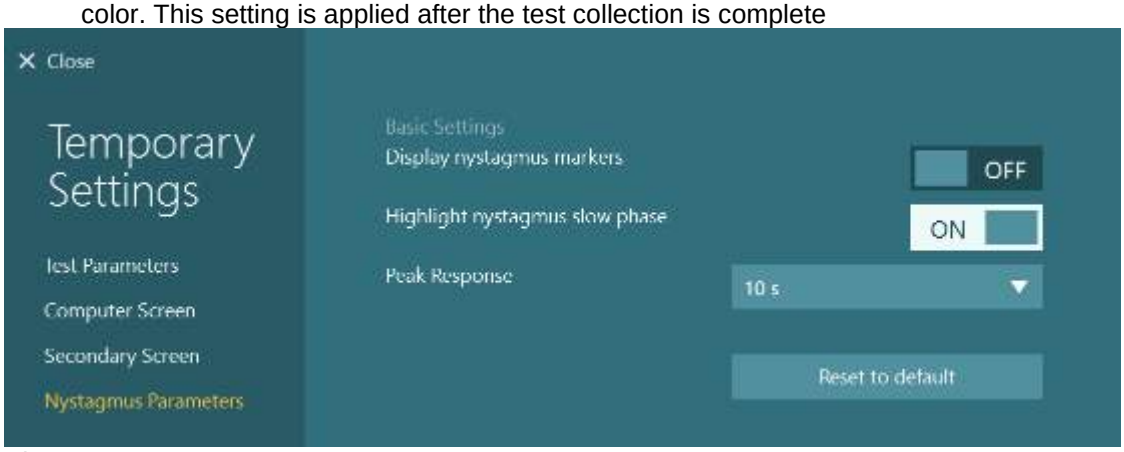


Figure 7.4-7 Nystagmus Parameters

- This will give a quick view of the actual slow phase velocity of the nystagmus (*Figure 7.4-8*)

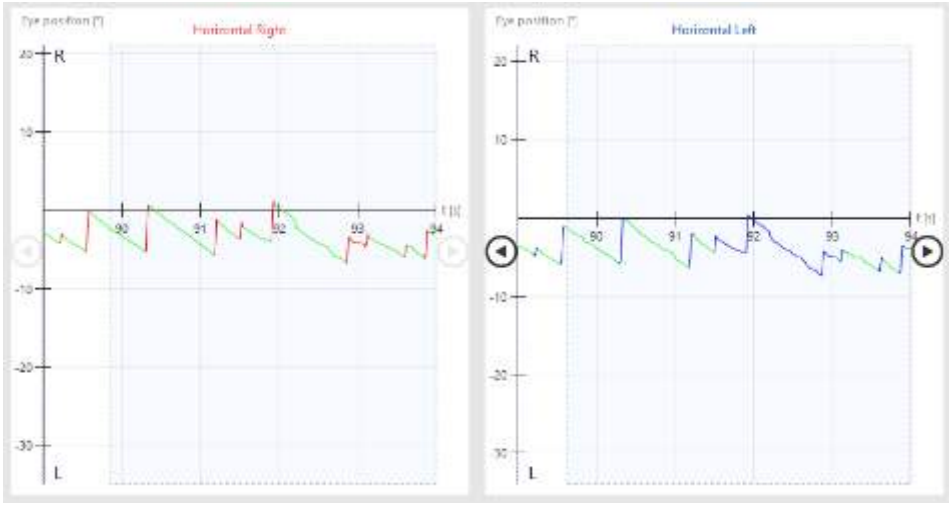


Figure 7.4-8 Slow phase velocities highlighted and eyes split into separate graphs

7.4.4 Smooth data

	Data smoothing uses an algorithm to remove noise from a dataset, allowing important patterns to standout

7.4.5 Zoom Trace

	Zoom Trace function provides the ability to zoom in and enlarge segments of the completed test graph for a closer look of the raw data (Figure 7.4-9 and Figure 7.4-10). The magnification allows the operator to look at the fine details of the waveform to help determine if a beat is actually noise or a real response.

- Select the tool and click on the area of interest
- The area selected will be magnified 2X
- To exit magnification, click anywhere on the graph and it shall return to original view

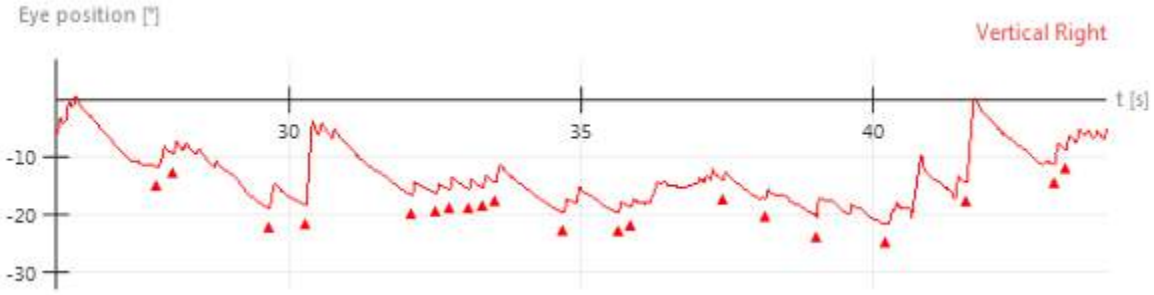


Figure 7.4-9 Gaze test Right 30 degrees raw results (no zoom)

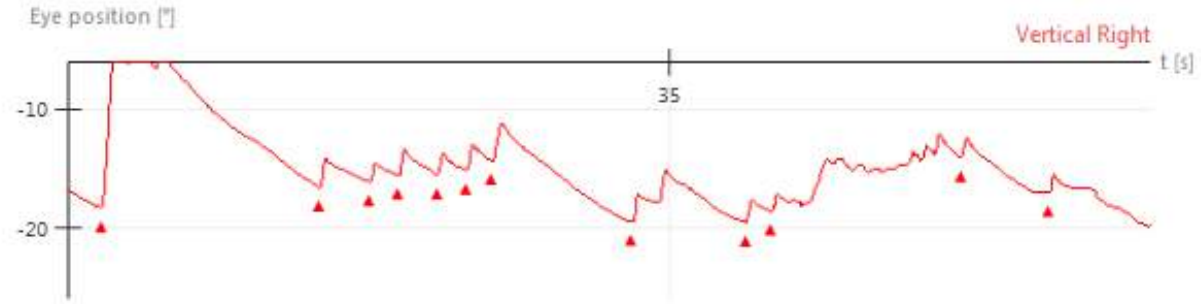


Figure 7.4-10 Gaze test Right 30 degrees 2X magnification (time and amplitude)

7.4.6 Enable beats

	This option provides an ability to enable the previously deleted beats in the selected trace area.

7.4.7 Undo last Action

	This option allows user to go one step back in their action.

7.4.8 Reset Beats

	This feature resets the waveform back to the original software analysis. (Figure 7.4-11 and Figure 7.4-12).

- By selecting this tool all data altered will return to its original software analysis

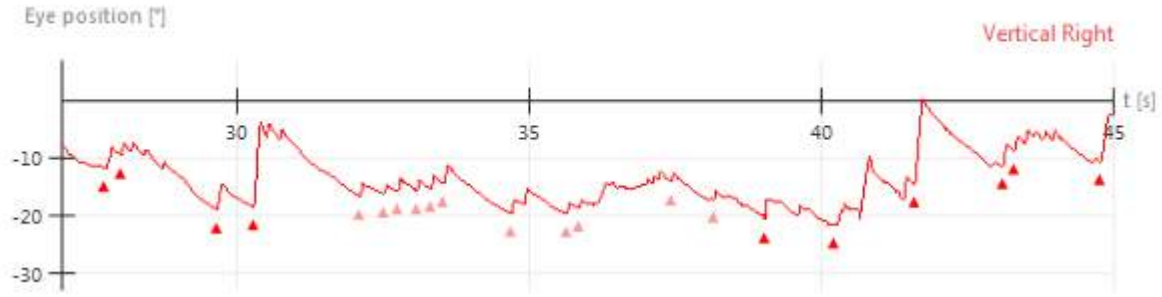


Figure 7.4-11 Nystagmus waveform with removed beats

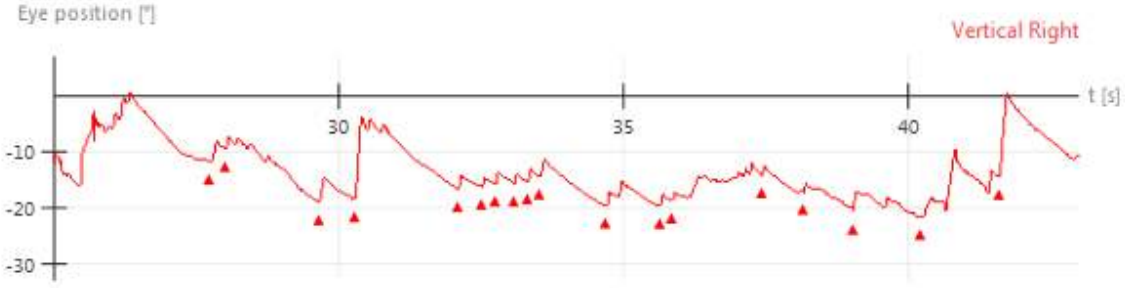


Figure 7.4-12 Nystagmus reset to original software analysis

7.4.9 Done Editing

Figure 7.4-13 Done Editing button

This function saves the edits made to the data and hides the editing tools (Figure 7.4-13).

7.5 Numerical value for graphical display

For some of the tests, the results are measured using parameters like gain, gain reduction, symmetry, eye velocity and etc. When these parameters are displayed graphically, the user can turn on the numerical value option by clicking symbol which presents on the top (either right or left) of the gain graph. When the symbol is clicked it shows all the numberical values of relevant graphs for the selected test. The example view is given below (refer Figure 7.5-1, *Figure 7.5-2*, Figure 7.5-3 and Figure 7.5-4).

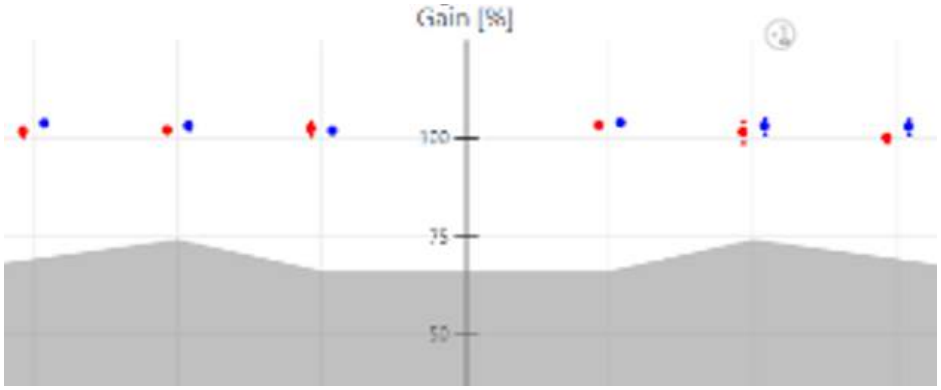


Figure 7.5-1 Graphical display of gain data without numerical value to display

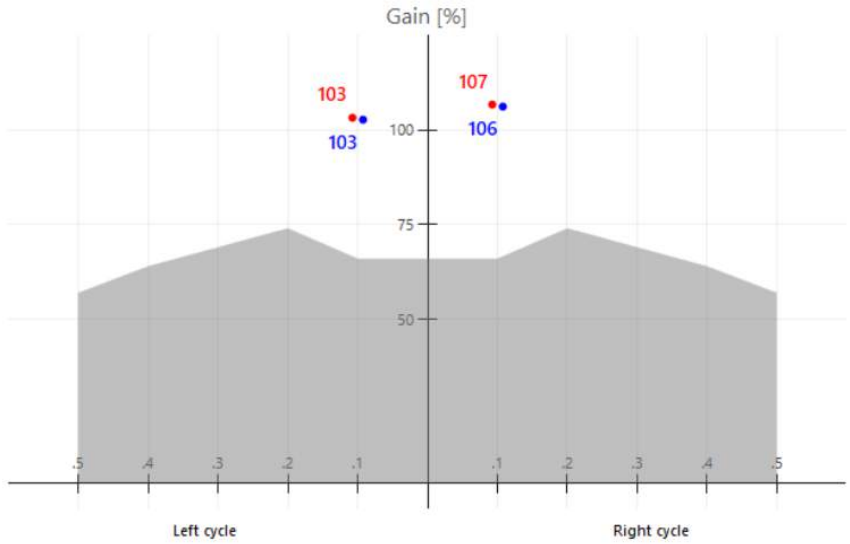


Figure 7.5-2 Graphical display of gain data with numerical values turned on

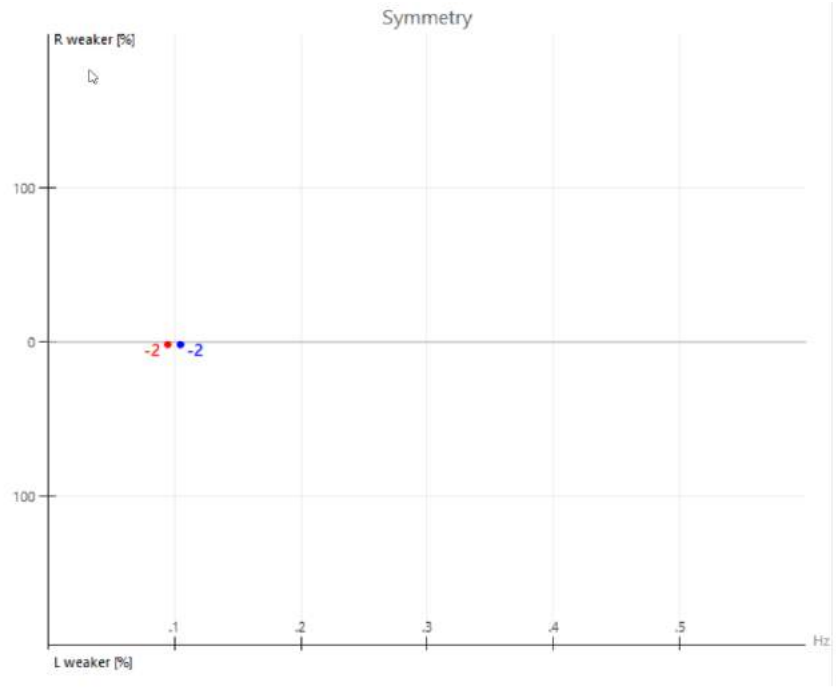


Figure 7.5-3 Graphical display of Symmetry data with numerical display turned on

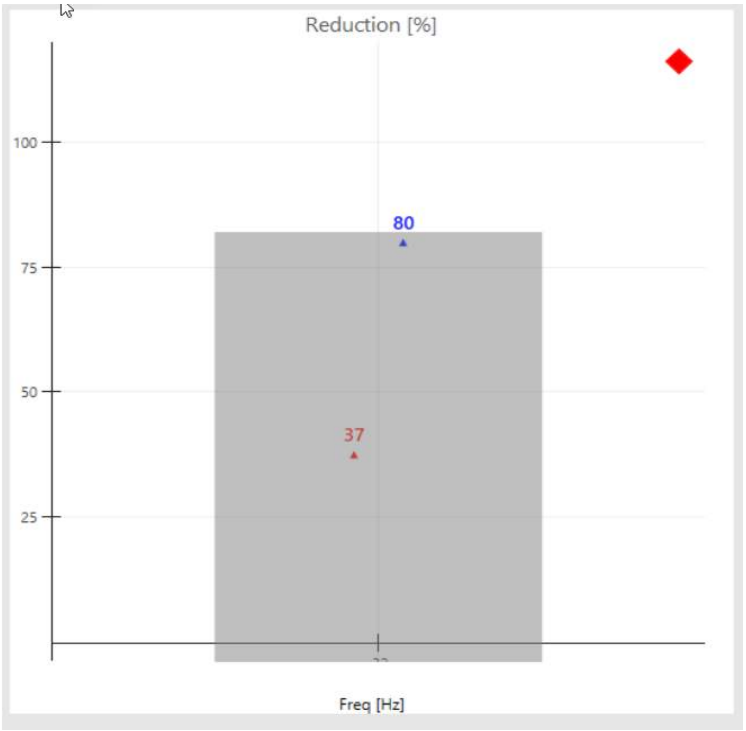


Figure 7.5-4 Graphical display of Reduction data with numerical display turned on

7.6 Editing saccade test results

Editing tools are available for viewing and editing the saccades. These tools are accessed after the data collection is complete by selecting the **Edit Tools** button (Figure 7.6-1). These tools are also available from the Saccade summary view. If accessed from the Saccade summary, select the tool then select the test to edit (Figure 7.6-2). Saccadometry subtests can be edited but the summary page cannot.

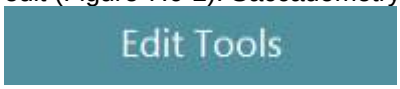


Figure 7.6-1 Edit Tools button for Saccade tests

Figure 7.6-2 Saccade editing tools

	Click or touch the **Enable Saccades** button. The selection box that the user creates on the waveform will enable any saccades that were disabled the analysis.
	Click or touch the **Disable Saccades** button. The selection box that the user creates on the waveform will disable any saccades and remove them from the saccade analysis.
	The **Edit Saccades** button highlights the first visible saccade in the waveform and displays the individual saccade results in the editing toolbar (latency, velocity, and accuracy). Use the previous saccade and next saccade buttons or the left and right arrows on the keyboard to move through the saccades. Use the disable / enable saccade button to toggle the saccade from the analysis. To switch between the left and right eye saccades (if the saccades are not split in separate graphs), select one of the three analysis results in the editing toolbar. Select the **Edit Saccades** button again to exit editing.
	The **Smooth Data** button reduces noise in the data tracing.
	The **Zoom Trace** button provides the ability to enlarge segments of the completed test graph for a closer look of the raw data.
	The **Reset** button will restore the waveform to the original program analysis.

Select the **Done Editing** button to exit the editing tools and keep the edits to the saccade analysis.

7.7 Editing smooth pursuit test results

Editing tools are available for viewing and editing the smooth pursuit tests. These tools are accessed after the data collection is complete by selecting the **Edit Tools** button. These tools are also available from the Smooth Pursuit summary view (Figure 7.7-1 and Figure 7.7-2). If accessed from the Smooth Pursuit summary, select the tool then select the test to edit.

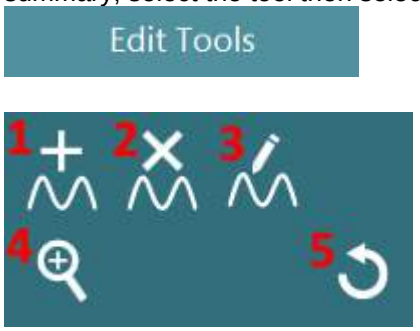


Figure 7.7-1 Smooth Pursuit editing tools

1. Click or touch the **Enable Half-cycles** button. The selection box that the user creates on the waveform will enable each half cycle that was disabled in the analysis.
2. Click or touch the **Disable Half-cycles** button. The selection box that the user creates on the waveform will disable each half cycle and remove it from the analysis.
3. The **Edit Half-cycles** button highlights the first visible half cycle in the waveform and displays the individual half cycle gain results in the editing toolbar. Use the previous half cycle and next half cycle buttons or the left and right arrows on the keyboard to move through the pursuit cycles. Use the disable / enable half cycle button to toggle the half cycle from the analysis. To switch between the left and right eye waveforms (if the pursuit waveforms are not split in separate graphs), select the gain value in the editing toolbar. Select the **Edit Half-cycles** button again to exit editing.
4. Click or touch the **Zoom Trace** button. Click or touch on a spot on the waveform to magnify that area by 2X (in time and amplitude). Select another spot or select the **Zoom Trace** button again to exit magnification.
5. The **Reset Half-cycles** button discards the user's edits and returns the waveform to the original software analysis.

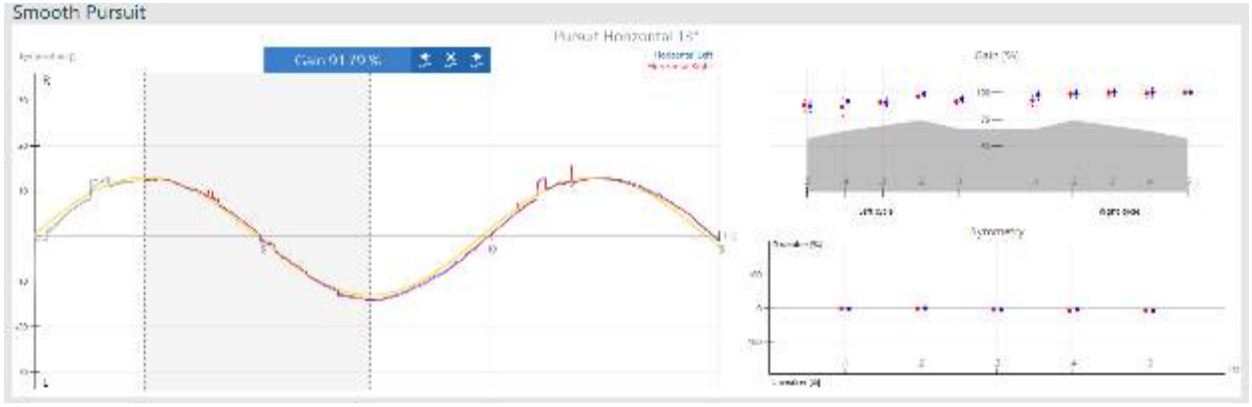


Figure 7.7-2 Smooth Pursuit editing

6. Select the **Done Editing** button to exit the editing tools and keep the edits to the pursuit analysis.

7.8 Editing rotary chair test results

7.8.1 Editing SHA Tests

This section pertains to all tests in which the rotary chair rotates in a sinusoidal harmonic acceleration pattern (SHA, VOR Suppression, and Visual VOR). The following edit tools can be accessed by tapping the Edit Tools button in the left side menu available within a specific test review screen, or from the summary test results screen.

	The **Enable Section** tool allows the user to include a section of the response in the analysis. Once the **Enable Section** button has been activated, click and drag over the section of the eye velocity trace that should be included in the analysis of the response.
	The **Disable Section** tool allows the user to exclude a section of the response from the analysis. With the **Disable Section** activated, click and drag over the section of the eye velocity trace that should be excluded from the analysis (i. e. artifact). A dashed line box will appear around the section being disabled. The disabled section will turn grey to indicate that it is no longer included in the analysis (Figure 7.8-1). The section can again be re-enabled by using the enable section tool.
	The **Reset Graph** button discards all user edits and returns the waveform to the original software analysis.
	Select the **Done Editing** button to exit the editing tools and keep the edits to the analysis.

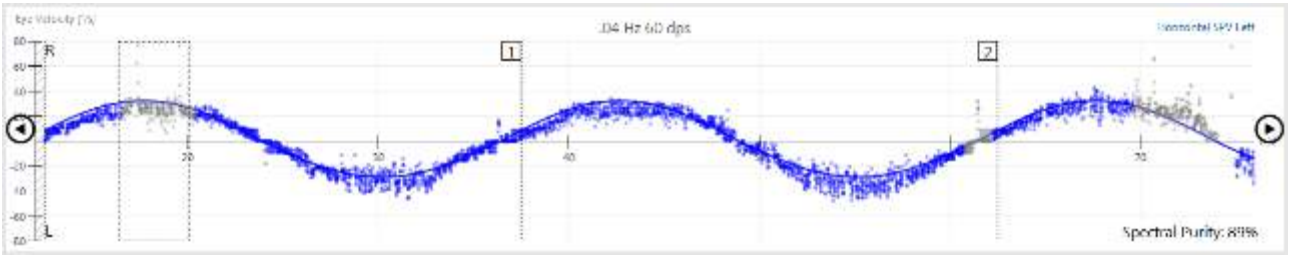


Figure 7.8-1 Disable section edit tool in SHA tests

7.8.2 Editing Step rotation tests

The edit tools available for Step Rotation tests are the same tools available for all nystagmus tests. Please refer to the section pertaining to edit tools for nystagmus tests (Refer section 6.4). The Step Rotation edit tools can be accessed by tapping the Edit Tools button in the left side menu available within a specific test review screen, or from the summary test results screen.

7.9 Editing video head impulse tests (vHIT for VORTEQ)

The video head impulse test compares the patient's eye movement to the head impulse from the operator quickly moving the head from side to side. The clinician can override accepted head impulses either from the center graph showing the currently selected head impulse and eye movement, or the clinician can select multiple head impulses at once and remove them from the analysis. To access the tools, the user must click on the Edit Tools button, and the user will need to click on the Done Editing button to exit the tools.

7.9.1 Select Multiple

Selecting this tool will highlight the tool in yellow and set the program to highlight each trace the user selects, whether that trace is selected by the head velocity line or the eye velocity line. Selected traces will be plotted with thicker lines, though the current trace is not included unless the user clicks on the trace (Figure 7.9-1).

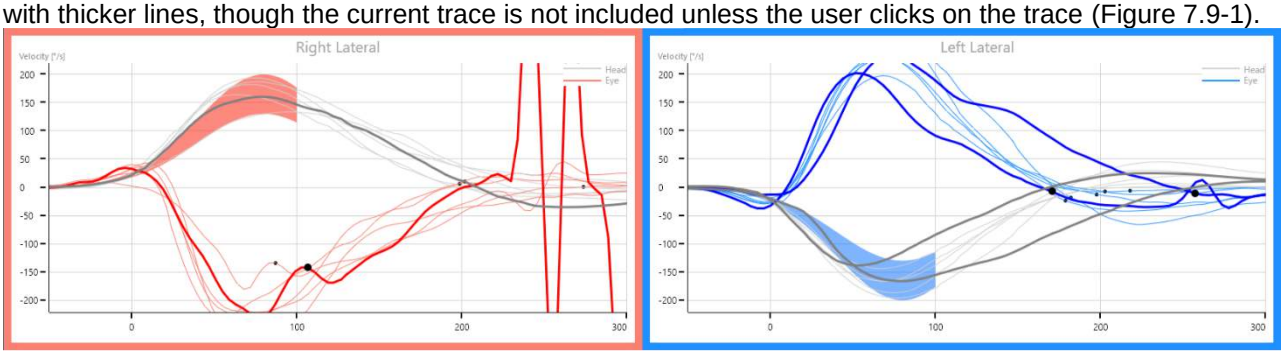


Figure 7.9-1 Multiple impulses selected

7.9.2 Delete Selected

Selecting this tool will reject the selected impulses and remove them from the analysis (Figure 7.9-2).

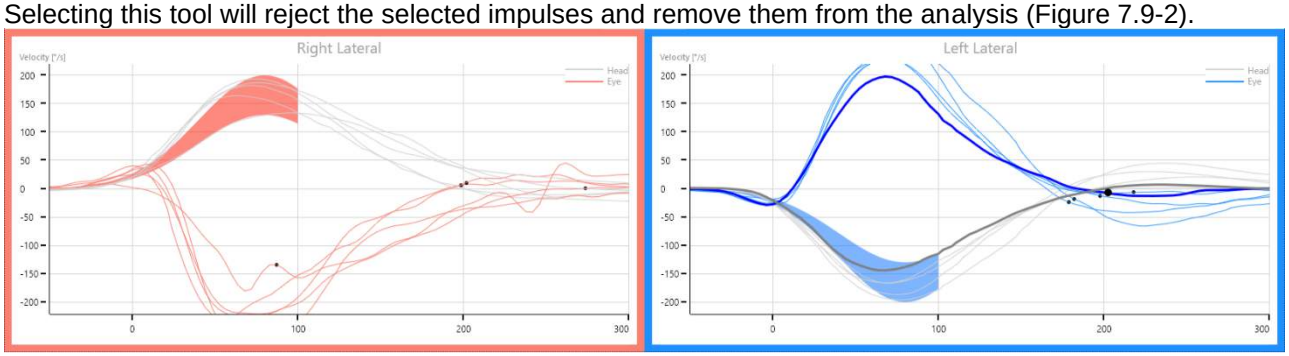


Figure 7.9-2 Selected impulses removed

7.9.3 Reset

Selecting this tool will restore the default analysis with only traces that meet the swoosh velocity criteria selected (Figure 7.9-3).

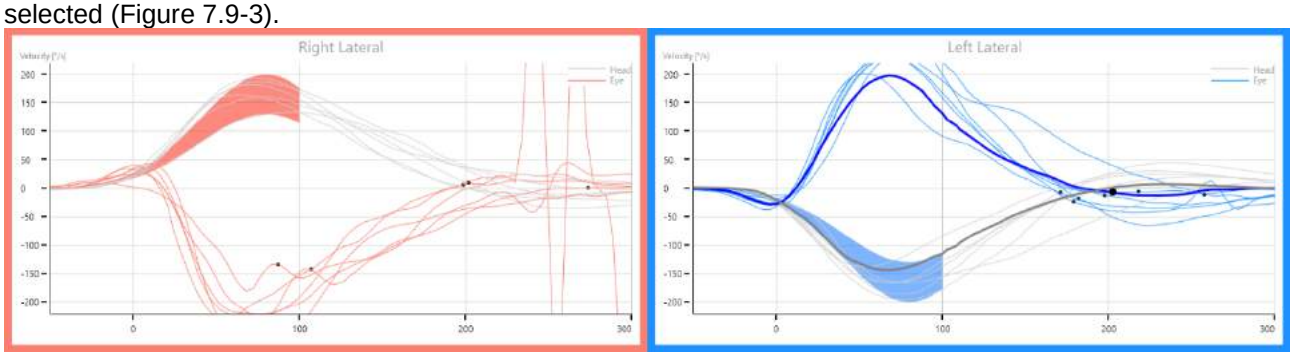


Figure 7.9-3 Impulses reset to analysis defaults

7.9.4 Show All Impulses

Selecting this tool will accept all head impulses that were performed, even if they failed to fall within the swoosh velocity criteria. The clinician should then review each of the head impulses to see which ones were performed correctly (Figure 7.9-4).

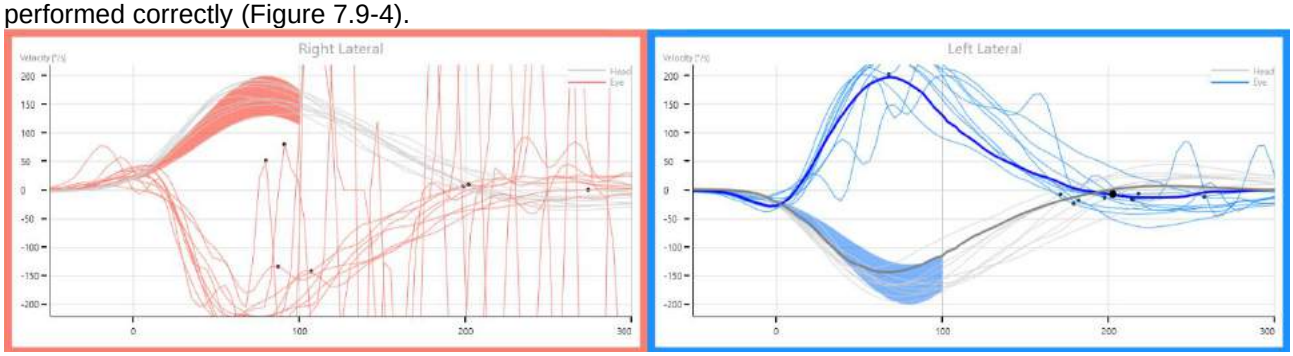


Figure 7.9-4 Show all impulses performed which includes impulses that did not conform to standards

7.10 Editing video head impulse tests (vHIT for EyeSeeCam)

The video head impulse test compares the patient's eye movement to the head impulse from the operator quickly moving the head from side to side. The clinician can override accepted head impulses either from the center graph showing the currently selected head impulse and eye movement, or the clinician can select multiple head impulses at once (Figure 7.10-1) and remove them from the analysis. To access the tools, the user must click on the Select Traces button, and the user will need to click on the Accept button to exit the tools.

7.10.1 Delete

The trace that should be removed can be selected with the left mouse click. To remove multiple traces at a time, hold the Ctrl key on the keyboard and select the additional traces. Click on the Delete button to remove the selected traces (Figure 7.10-2). Deleted traces will be shown in this edit view with light gray lines. Click on the Accept button to keep those changes and return to the analysis.

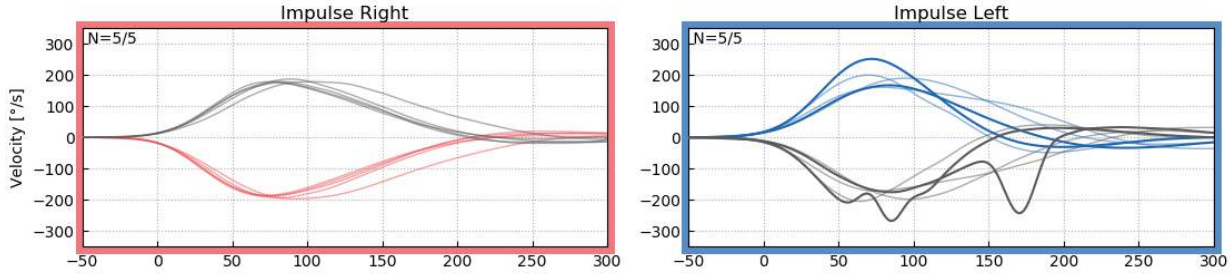


Figure 7.10-1 Multiple Impulses Selected

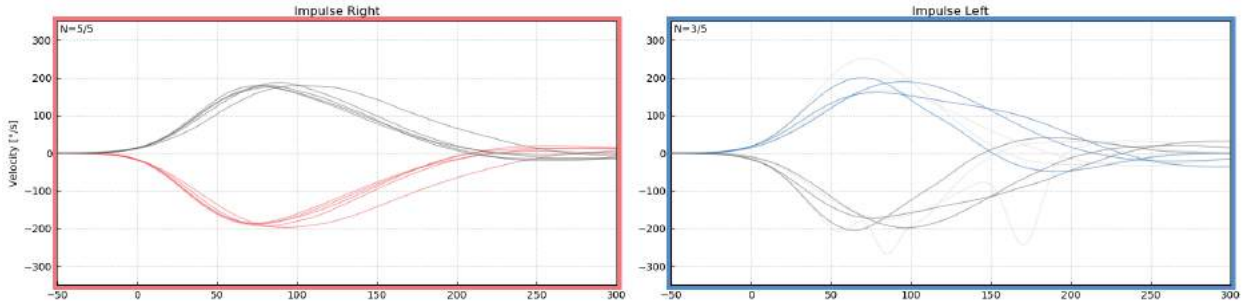


Figure 7.10-2 Outlier traces deleted

7.10.2 Reset / Cancel

Selecting the reset tool will restore the default analysis with only traces that meet the swoosh velocity criteria selected (Figure 7.10-3). The cancel tool will exit the select traces screen abandoning traces that were removed.

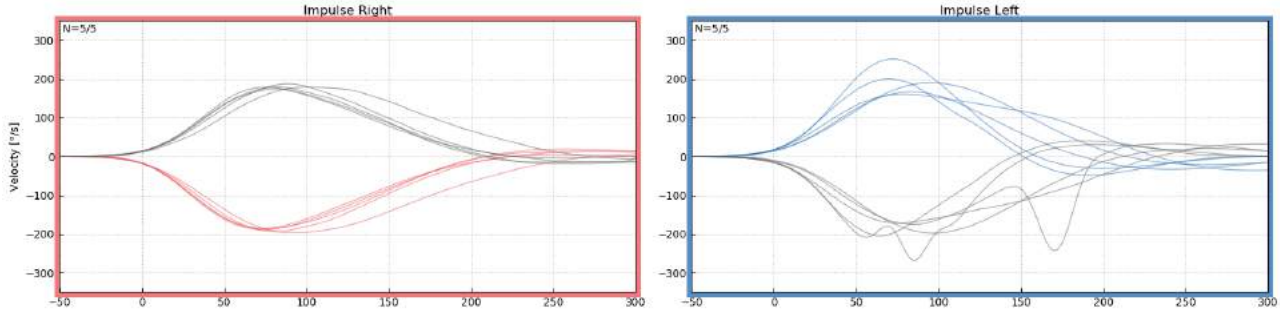


Figure 7.10-3 Impulses reset to analysis defaults

7.10.3 Edit Saccades

Selecting the Edit Saccades tool will allow the user to fine-tune the length of time of the head impulse as well as the length of time of any saccades detected for the impulse. The length of time can be adjusted by dragging the edge of the highlighted area. A small window will overlay the trace displaying reflecting the change in the shape of the waveform selected and a dashed line between the endpoints of the selection window. Click on the Accept button to keep the changes and Cancel to discard the changes. To move to another accepted head impulse, click on the head impulse in the timeline window at the bottom of the screen (Figure 7.10-4 and Figure 7.10-5).

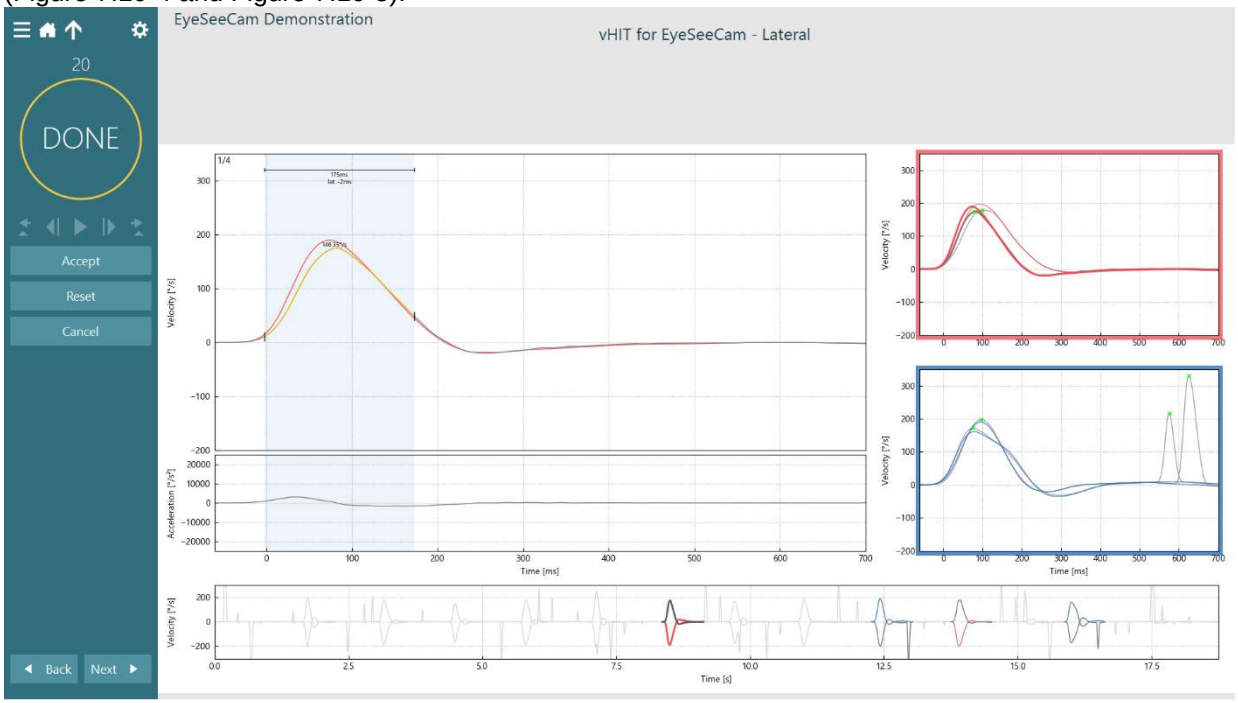


Figure 7.10-4 Edit Saccades

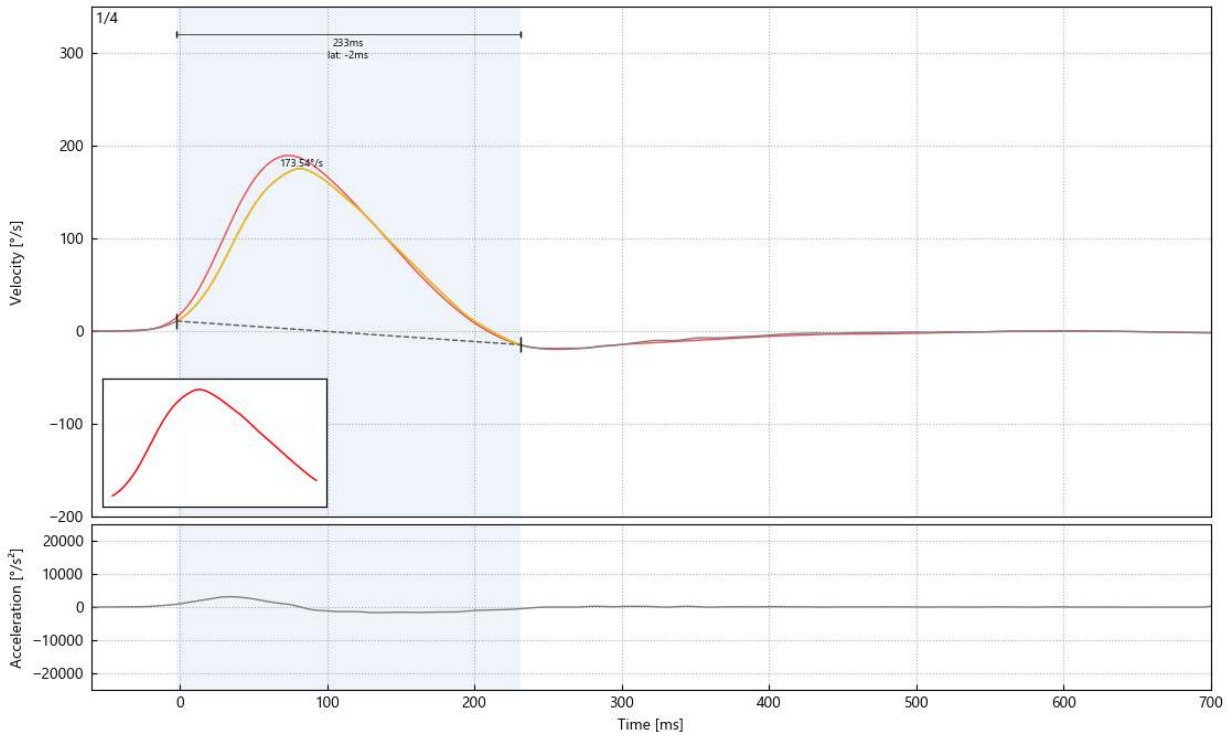


Figure 7.10-5 Adjusting the time

7.11 Editing ocular counter roll tests

The ocular counter roll test has the user mark positions on the waveform graph that are of interest. These markers will display the current torsion angle and can be used to detect torsional nystagmus qualitatively.

7.11.1 Add Marker

	Selecting this function will display a mark at the current location. The direction of rotation and magnitude will be displayed where the user clicked (Figure 7.11-1).

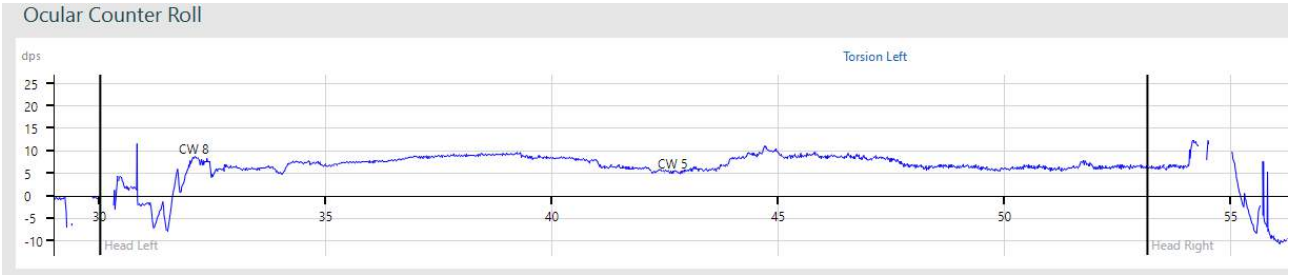


Figure 7.11-1 Torsion trace with markers added

7.11.2 Zoom Trace

	Zoom Trace function provides the ability to zoom in and enlarge segments of the completed test graph for a closer look of the raw data. The magnification allows the operator to look at the fine details of the waveform to help determine if a beat is actually noise or a real response.

7.11.3 Remove Marker

	This function will remove the torsion marking at the current location.

7.11.4 Reset Markers

	This feature will clear all markers added by the user.

7.12 Other functions available inside menu

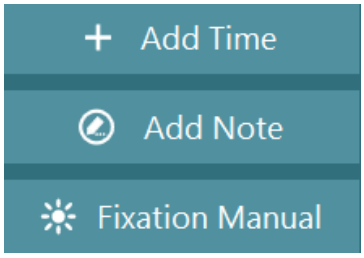


Figure 7.12-1 Additional functions available during testing

Add Time: Adds 30 seconds to the test recording (Figure 7.12-1).
Add Note: Insert a note at the current time during recording.
Fixation Manual: Turns on the selected fixation light defined in the System Default Settings (see Chapter 13.2 Input) (controlled by user, not automatic). Also activated using the RF Remote.

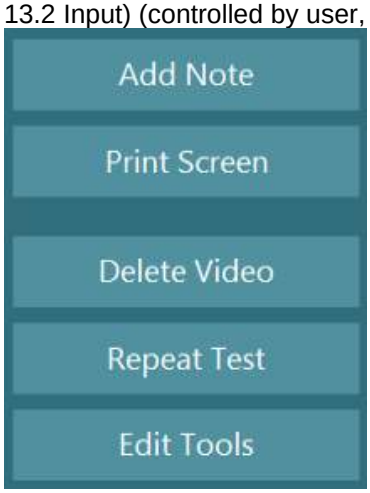


Figure 7.12-2 Additional functions available after testing is complete

After the test has finished the following options will be available (Figure 7.12-2).
Add Note: Adds a note to the end of the test.
Print Screen: Will print whatever is present on screen at the current time.
Delete Video: Deletes the video of the eye recording and room camera (if recorded) from the computer for this test.
Edit Tools: Provides access to tools used to override the analysis results.
Repeat Test: Repeat / replace the current test. A dialog box will be presented asking if the user would like to overwrite the current test (replace) or create a new instance (repeat) (Figure 7.12-3).

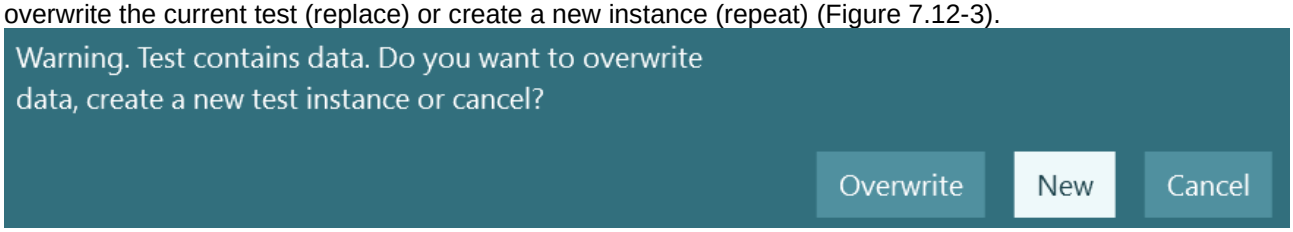


Figure 7.12-3 Repeat Test dialog

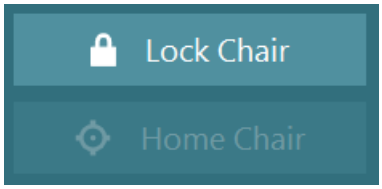


Figure 7.12-4 Rotational Chair functions

When a reclining rotary chair is configured with VisualEyes™ 515/525 there may be additional side menu functi
ons available to the user (Figure 7.12-4).

Lock Chair:
Orion Reclining Chair
This function is designed to place the chair into an immobile state in order to ensure patient safety when seating and/or disembarking the patient from the reclining chair. It is also used to keep the chair immobile during the VNG test battery. The lock chair function is only made available prior to the test and cannot be activated during the testing procedure. This will automatically be switched off when performing a rotational chair test. To lock or unlock the chair at any other time, tap the **Lock Chair** button. The chair is locked when the button is yellow and unlocked when the button is light green. The chair can be unlocked as well using the electronic locking mechanism (ELM) switch found (Figure 7.12-5) on the top left of the chair. While depressing the ELM switch, the chair can be rotated freely. Releasing the ELM switch will lock the chair approximately in that position (may require minor rotation to allow the gear lock to engage properly).

Figure 7.12-5 Electronic Locking Mechanism (ELM) switch on Orion Reclining chair

Nydiag 200 Chair
This function is designed to place the chair into an immobile state in order to ensure patient safety when seating and/or disembarking the patient from the reclining chair. It is also used to keep the chair immobile during the VNG test battery. The lock chair function is only made available prior to the test and cannot be activated during the testing procedure. This will automatically be switched off when performing a rotational chair test. To lock or unlock the chair at any other time, tap the **Lock Chair** button. The chair is locked when the button is yellow and unlocked when the button is light green.

System 2000 Reclining Chair
The System 2000 Reclining chair does not have an electronic braking system. A manual foot brake is found on the side of the chair drum. The operator should apply the brake to keep the chair in place for patient entry and VNG testing. When reclining the chair for Dix Hallpike, Positional, and Caloric tests, the foot brake should be released (Figure 7.12-6) in order to rotate the chair if needed due to space constraints. The foot brake should then be reapplied (Figure 7.12-7) when the chair is reclined to the appropriate position to keep the chair from rotating during the test. When the rotational chair tests are performed, verify the foot brake is released.

Figure 7.12-6 Foot brake released

Figure 7.12-7 Foot brake applied

Home Chair: Orion Reclining Chair and Nydiag 200 Chair
The chair will have a default position to which it will move prior to testing. This position is called the home position. Ideally the chair should be set in front of the television or projection screen so the home position is lined up with the center of the screen. If the chair is installed with the home position not centered with the screen, the Zero Position can be adjusted to the new location. This value is found in System Default Settings (see Chapter 13.8 Print.) The **Home Chair** button will move to this override location.

7.13 Fixation suppression

There may be times in certain nystagmus tests (i. e. spontaneous and positional) where a fixation light is presented to the patient to differentiate peripheral from central abnormalities.
The fixation suppression index (FI) quantifies the ability of a patient to deliberately suppress nystagmus by fixating on a given target. It is determined by switching on the fixation light within the goggles. The value quantified will be displayed as a percentage in the bar graph in both horizontal and vertical channels.
A yellow bar appears in the trace to acknowledge the presence of the fixation light (Figure 7.13-1). The length of the bar determines the length of time the fixation light was active.

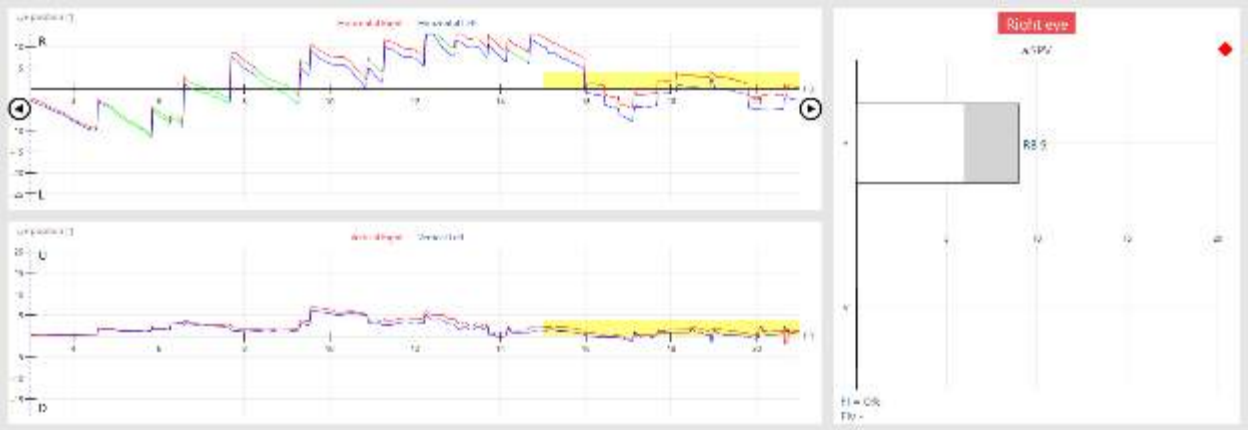


Figure 7.13-1 Yellow bar shows presence of fixation light in eye recording trace

The fixation light can be turned on in one of three different ways:

- Manually: Controlled by examiner using the RF Remote or **Fixation Manual** button
- Timed: Time predefined in the test settings. If the examiner turns on the fixation light manually before the time set in the test settings, the software will change to manual mode
- Automatic: In the caloric test, the fixation light is turned on automatically post detection of peak response

The fixation light can also be set to be displayed in either left or right eye (see 13.2 Input).

7.14 Override test results

Results will automatically be classified whether inside or outside threshold levels based on the criteria set in the suggested threshold tables in the system settings. The red diamond will indicate results outside of threshold and the green tick will indicate results within threshold. Should the user decide to overrule an outside of threshold test result, clicking on the red diamond (next to title of test/ sub test) will convert it to a green checkmark and pencil symbol, indicating the user changed the results to within threshold levels.

Symbol	Explanation
	Within Suggested Thresholds
	Altered Result
	Outside of Suggested Thresholds

Should any subtests outside the threshold ranges be altered, the overall test will convert to a within threshold result.

8 Protocol Management

8.1 Protocols

Protocols are able to be customized to the desired settings of the end user. They are composed of a list of tests and designated to be performed in a specific order at the preference of clinician or clinic. Protocols can be created for a specific clinician's testing style, screening versus clinical test lists, or to create a default protocol template for a clinic. There is no practical limit to the number of protocols that can be created.

The protocols are accessed from the Protocol Management button under the Configuration menu on the main screen (Figure 8.1-1 and Figure 8.1-2).

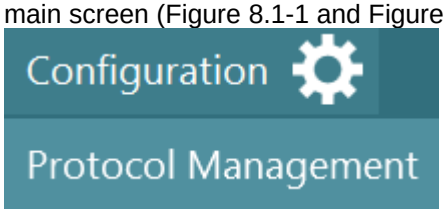


Figure 8.1-1 Configuration drop down menu with Protocol Management displayed

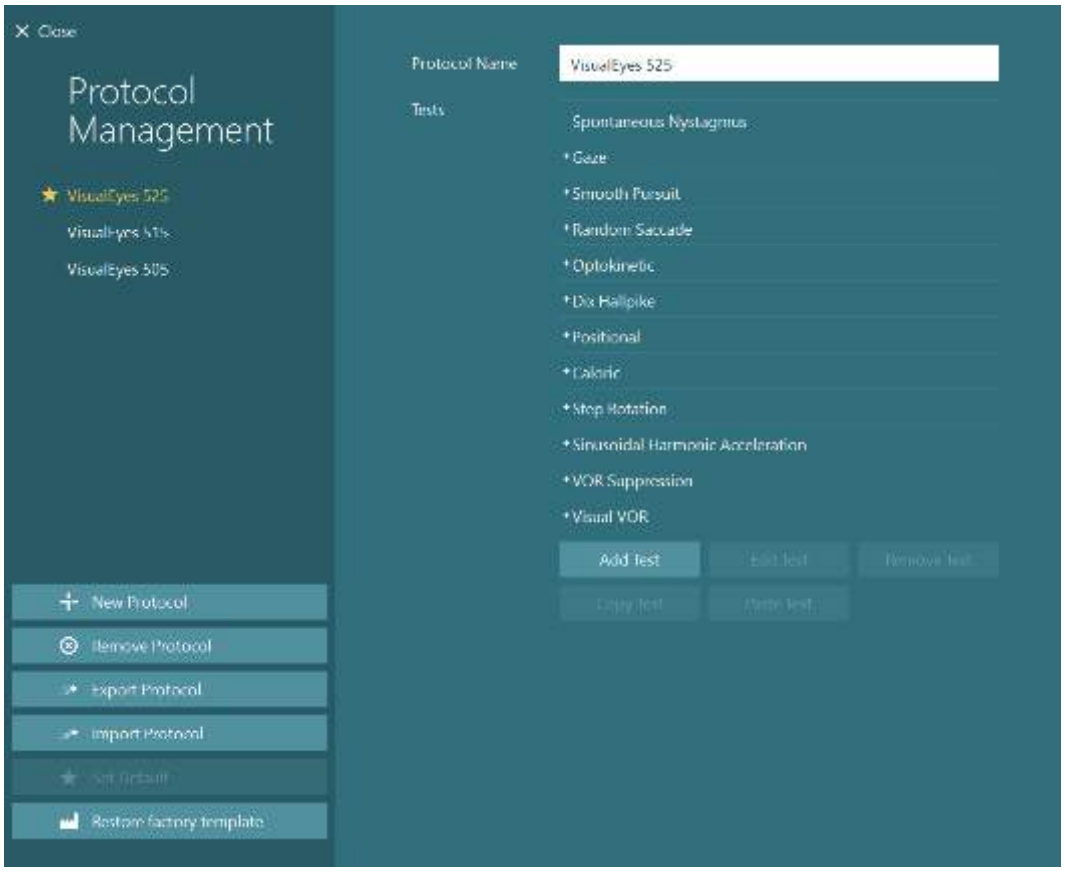
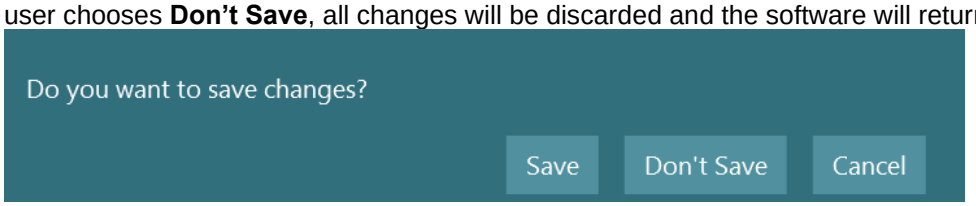


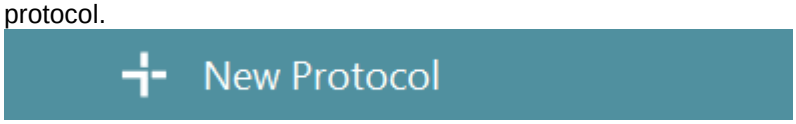
Figure 8.1-2 Protocol Management screen

Upon exiting Protocol Management, the user will be asked to confirm to save changes to the protocols. If the user chooses **Don't Save**, all changes will be discarded and the software will return to the main screen.



8.2 Creating a new protocol

The left side panel displays the existing protocols. The **New Protocol** button is used to create a new blank protocol.



Enter a name for the new protocol (Figure 8.2-1). By default this will be called New Protocol 1.

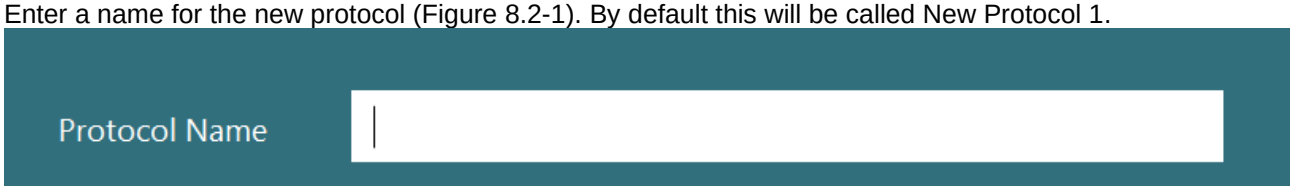


Figure 8.2-1 Enter Protocol Name

To add tests to the protocol, press the **Add Test** button (Figure 8.2-2) and select one of the tests. Tests that don't match one of the default test types (e. g. Fistula test, Head shake test, etc.) can usually be entered as a basic Spontaneous Nystagmus test.

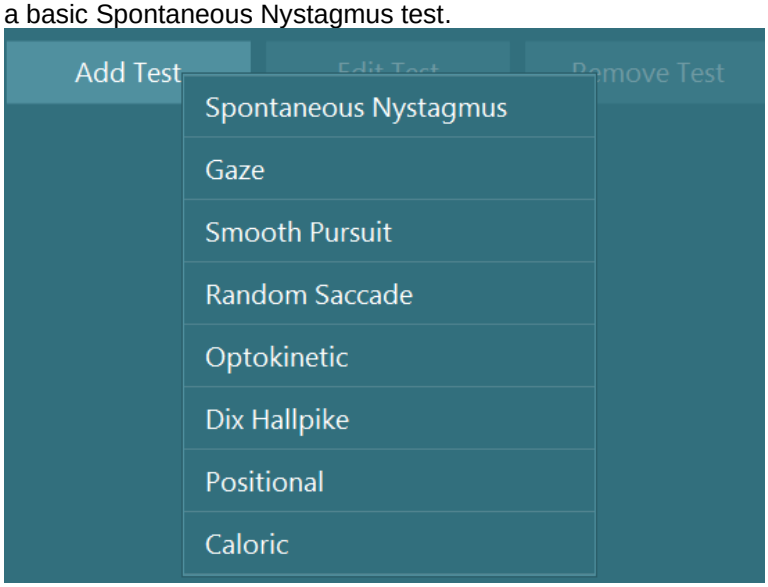


Figure 8.2-2 Add Test button

If two or more of the same test type are desired, click on the test of interest. The test title will appear with an additional numeric ending to indicate its position (i. e. Spontaneous Nystamus2, Spontaneous Nystagmus3 etc.). These test titles can be renamed for easier identification or customization.

When added to the protocol, these tests will appear in the bottom of the protocol test sequence. The tests within the protocol can be reordered by clicking the specific test and dragging it up or down the list to the desired position using the mouse.

8.3 Setting default protocol

The Default protocol will be marked in the side menu with a star (Figure 8.3-1). When a new patient is entered into OtoAccess® and the VisualEyes software is started, this default protocol will be selected automatically.

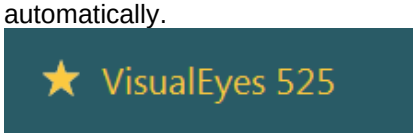


Figure 8.3-1 Default Protocol

Select the protocol of interest, then select the **Set Default** button (Figure 8.3-2) to confirm its designation as the Default protocol. A star shall appear next to the Protocol name to symbolize the change.

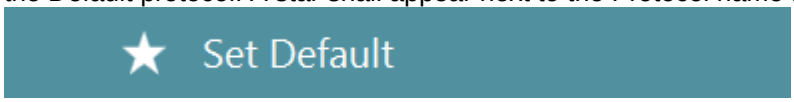


Figure 8.3-2 Set Default Protocol button

8.4 Remove protocol

To permanently remove a protocol and all tests in the selected protocol, select the Remove Protocol button. The software will ask to confirm the protocol removal (Figure 8.4-1).

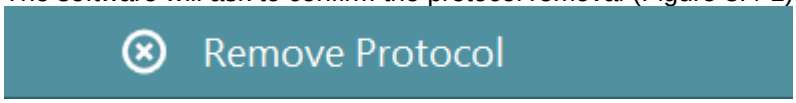


Figure 8.4-1 Remove Protocol button

8.5 Exporting protocols

Protocols can be exported for later use. Highlight the chosen protocol and select the **Export Protocol** button from the left menu panel (Figure 8.5-1).

Figure 8.5-1 Export protocol button

An export dialog with a destination folder location will appear (Figure 8.5-2). Select the desired destination folder for the exported protocol and select the **Export** button. This will save the protocol to the selected location for later use (e. g. to import into another VisualEyes™ 515/525 system). Select **Close** to return to the Protocol Management screen.

Figure 8.5-2 Export Protocol dialog

8.6 Importing protocols

Previously exported protocols can be imported into Protocol Management using the **Import Protocol** button (Figure 8.6-1).

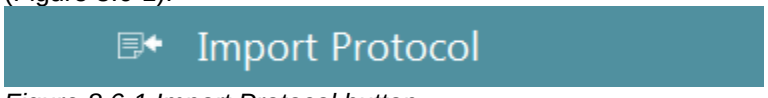


Figure 8.6-1 Import Protocol button

An import dialog with a source folder location will appear (Figure 8.5-2). Select the folder with the protocol file and select the **Import** button. This will save the protocol to the selected location for later use (e. g. to import into another VisualEyes™ 515/525 system). Once imported, the protocol can be edited or set as default like other protocols. Select **Close** to return to the Protocol Management screen.

Figure 8.6-2 Import Protocol dialog

8.7 Restore factory template

The VisualEyes software has a default test template for each test type licensed in the system. The settings for the default test template can be overridden using the **Set as default** button in each page of the test and subtest settings pages (e. g. override the default setting and set all tests based on Spontaneous Nystagmus should have the Split Eyes option set ON). To restore the default test template back to the system default settings, select the Restore factory template button (Figure 8.7-1). Any protocols currently created will not be affected, but any new protocols and tests will be created using the default test template settings.

Figure 8.7-1 Restore factory template button

8.8 Selection of protocol

Select the protocol for testing by accessing the drop down menu below the **BEGIN TESTING** button. The default protocol will be selected initially. The drop down menu will list the available protocols. After selecting the desired protocol, click or touch the BEGIN TESTING button to begin testing with the first test of the selected protocol (Figure 8.8-1).

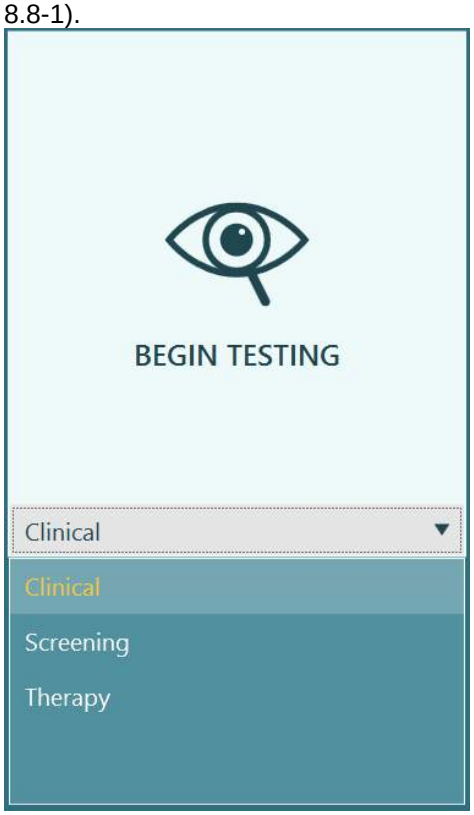


Figure 8.8-1 Begin Testing button with protocol selection

9 Test Properties

9.1 Configuring the tests

All tests within the VisualEyes™ VNG software suite can be configured to the user' preference. The changes need to be performed prior to conducting the test (cannot be changed post-test).

The specific test can be adjusted in 2 ways:

1. From the main screen select **Protocol Management** section (under configuration).

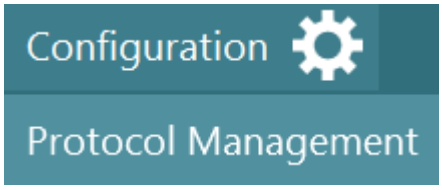


Figure 9.1-1 Configuration drop down menu with Protocol Management displayed

Select the test in Protocol Management and choose **Edit Test**.
Settings changed under the protocol management will be made permanent.

2. In the Test screen, by clicking the configuration button:

Figure 9.1-2 Configuration button from testing

Settings changed under the configuration button are temporary and only apply to the current patient.

Temporary test settings will also have fewer options to alter compared to those under the Protocol management menu.

Each test will have some unique features to it that other tests may not. However, there are many features that will be similar and may be adjusted based on user preference.

Once the user is satisfied with the changes made to the test parameters, the settings may be incorporated into the protocol by selecting **Set as default**. These parameters will now be applied to that test within the specific protocol. A prompt will ask for confirmation to inherit the settings (Figure 9.1-3):

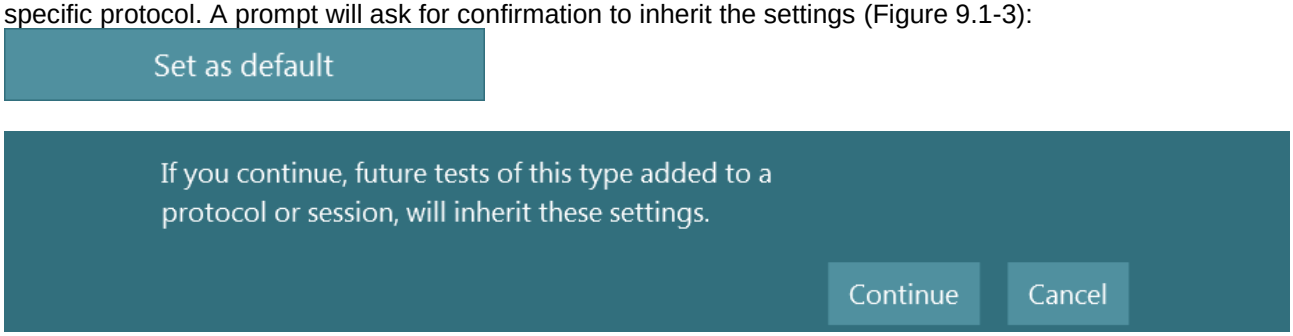


Figure 9.1-3 Saving test parameters to the protocol's default settings

By selecting **Reset to default** all settings for the page of settings with that test will return to the factory default settings (Figure 9.1-4).

Figure 9.1-4 Reset to default button

9.2 Configuring oculomotor tests

9.2.1 Configuring the gaze test

Configuration options through protocol management (Permanent settings, refer Figure 9.2-1):

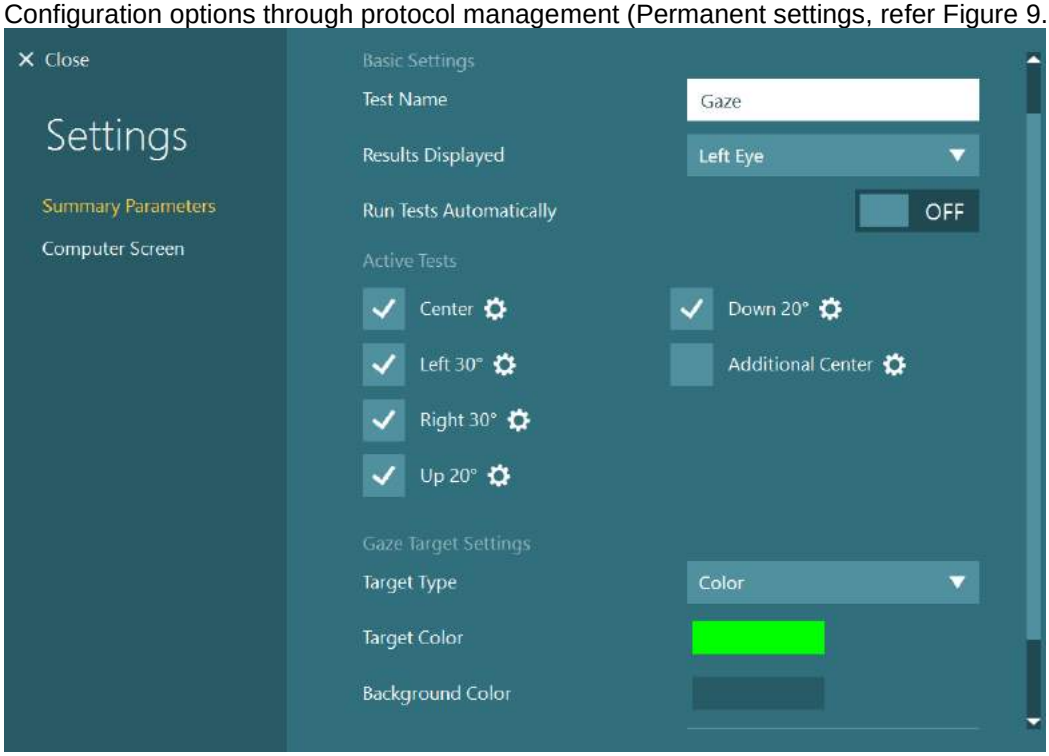


Figure 9.2-1 Gaze summary settings

Test Name: Name of the test
Results Displayed: Selects which eye is shown by default. Mixed Eyes will allow the user to choose the best eye for each subtest. Left Eye will set each subtest to display the left eye. Right Eye will set each subtest to display the right eye.
Run Tests Automatically: If enabled, when the subtest completes, the next subtest will be loaded and started automatically. This makes the Gaze test function similarly to the Calibration procedure.
Active Tests: The subtests selected will appear in the testing screen. The configuration gear button beside each test will open the subtest settings. By default, the active tests would be Center, Left, Right, Up, and Down. Center 2 is optional for a follow-up center gaze.
Gaze Target Settings:
Target Type: Selects the stimulus for all Gaze subtests (circle of solid color, flower, potato head, or smiley face).
Target Color: If the target type is set to color, this option will change the target color.
Background color: Select different colors for the background.

Configuration options through temporary settings for individual test session (refer Figure 9.2-2):

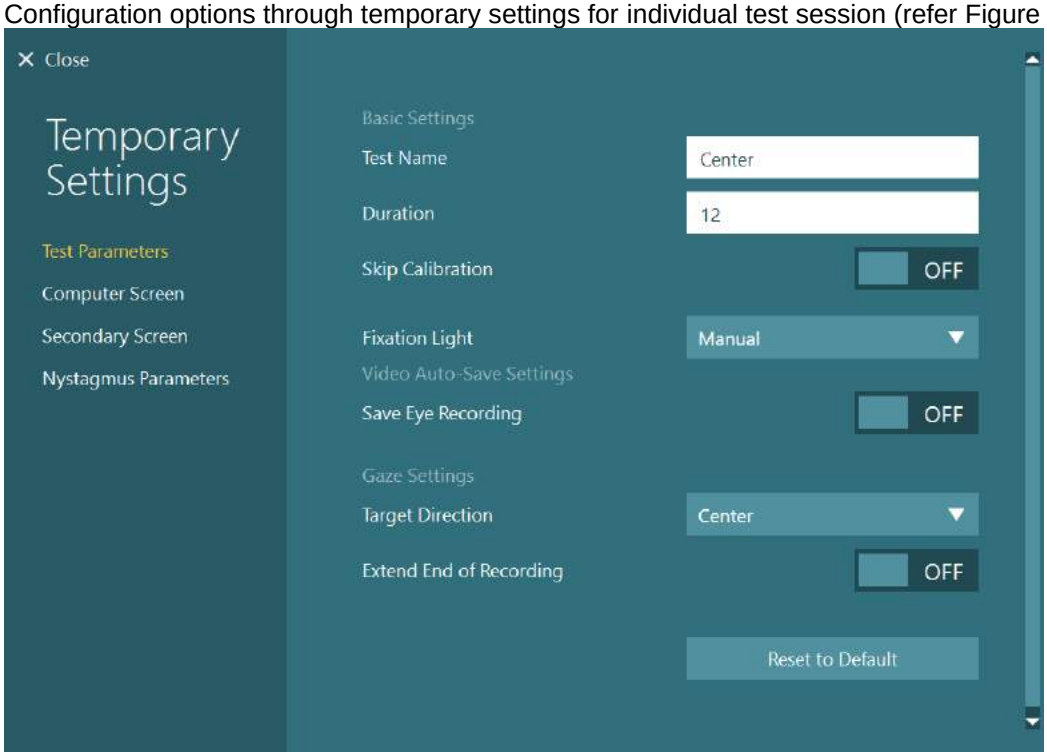


Figure 9.2-2 Gaze subtest settings

Test Name: Name of subtest
Duration: Define how long the eye movement is to be recorded and analyzed (in seconds).
Skip Calibration: The user can skip calibration to proceed with the test
Fixation light: Determines when the fixation light in the goggles is displayed. Manual (default) will leave the operator to determine when the fixation light should be displayed. Timed will have the fixation light come on automatically at the designated time.
Save Eye Recording: Choice to save eye video recordings.
Target Direction: Defines direction of target movement.
Extend end of Recording: If enabled the test will return the target back to center for two seconds. Not recommended if the tests are run automatically.

9.2.2 Configuration of saccade Test

Configuration options of summary parameters through protocol management (Permanent settings) or through temporary Settings (Figure 9.2-3):

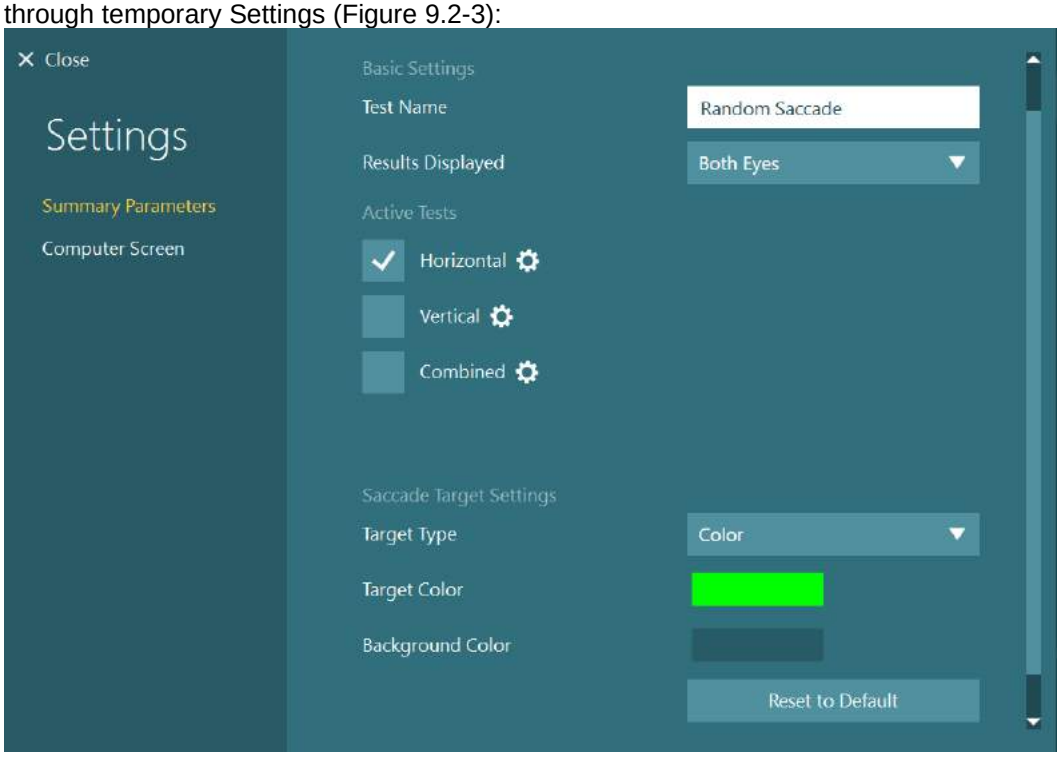


Figure 9.2-3 Saccade summary settings

Test Name: Name of the test
Results Displayed: Selects which eye is shown by default. Both Eyes will show both eyes overlapping to allow easy viewing of disconjugate eye movements. Left Eye will set each subtest to display the left eye. Right Eye will set each subtest to display the right eye.
Active Tests: The subtests selected will appear in the testing screen. The configuration gear button beside each test will open the subtest settings. Horizontal is selected by default. Vertical and Combined tests are optional tests. In the Combined subtest the target will jump horizontally or vertically randomly for each jump.
Saccade Target Settings:
Target Type: Selects the stimulus for all Gaze subtests (circle of solid color, flower, potato head, or smiley face).
Target Color: If the target type is set to color, this option will change the target color.
Background color: Select different colors for the background.

Subtest settings through Temporary Settings (Figure 9.2-4):

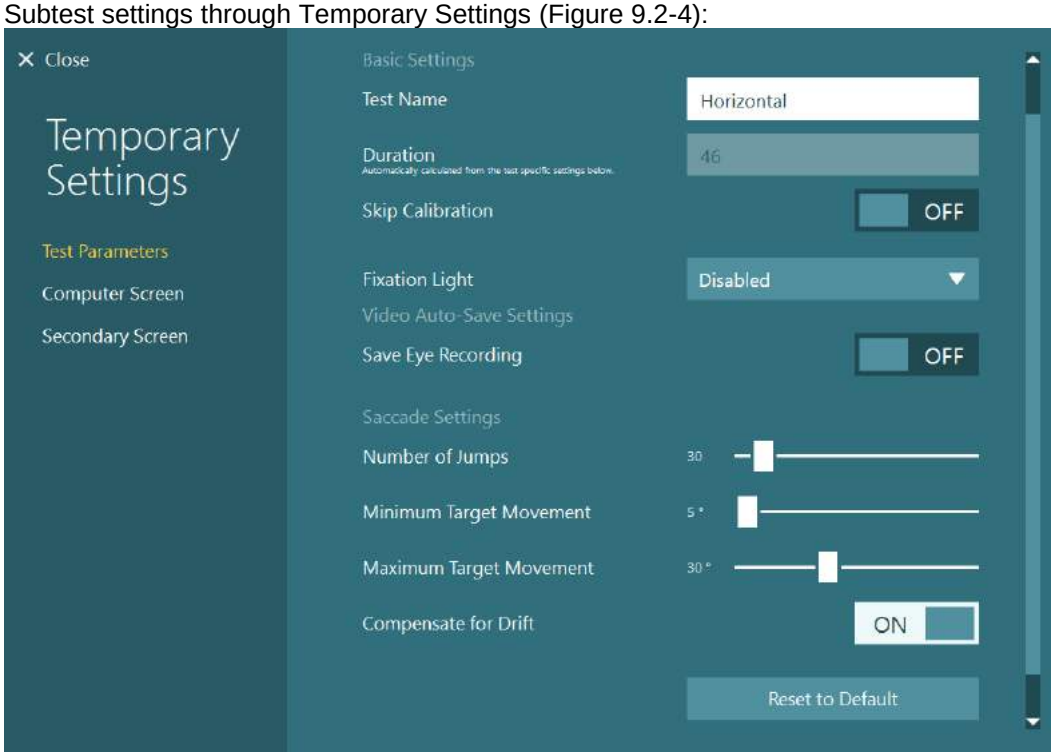


Figure 9.2-4 Saccade subtest settings

Test Name: Name of subtest
Duration: Length of time to perform the test based on the number of saccades
Skip Calibration: The user can skip calibration to proceed with the test
Fixation light: Determines when the fixation light in the goggles is displayed. Manual will leave the operator to determine when the fixation light should be displayed. Timed will have the fixation light come on automatically at the designated time. Disabled (default) will block the fixation light from turning on in the test.
Save Eye Recording: Choice to save eye video recordings.
Number of Jumps: Defines how many saccade jumps the patient will follow.
Maximum target movement: Define maximum degrees target can move relative to previous target position.
Minimum target movement: Define minimum degrees target can move relative to previous target position.
Compensate for drift: If enabled, the software will adjust the patient's response to better align with the target.
Extend end of Recording: If enabled the test will return the target back to center for two seconds. Not recommended if the tests are run automatically.

9.2.3 Configuration of Saccadometry Test

Configuration options of Summary Parameters through protocol management (Permanent settings) or Temporary Settings (Figure 9.2-5):

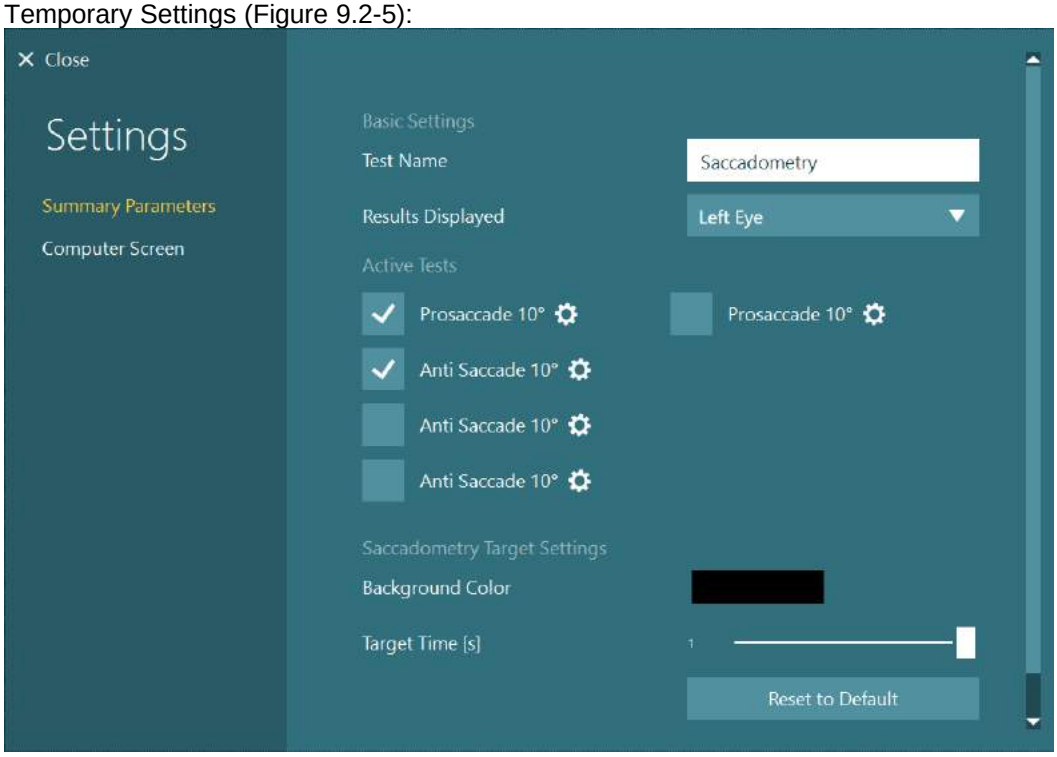


Figure 9.2-5 Saccadometry summary settings

Test Name: Name of the test
Results Displayed: Selects which eye is shown by default. Left Eye will set each subtest to display the left eye. Right Eye will set each subtest to display the right eye.
Active Tests: The subtests selected will appear in the testing screen. The configuration gear button beside each test will open the subtest settings.
Saccadometry Target Settings:
Background Color: Selects the background color for the target stimulus. Select different colors for the background.
Target Time: The display time of the target visbility can be adjusted using this option.

Subtest settings through Temporary Settings (Figure 9.2-6):

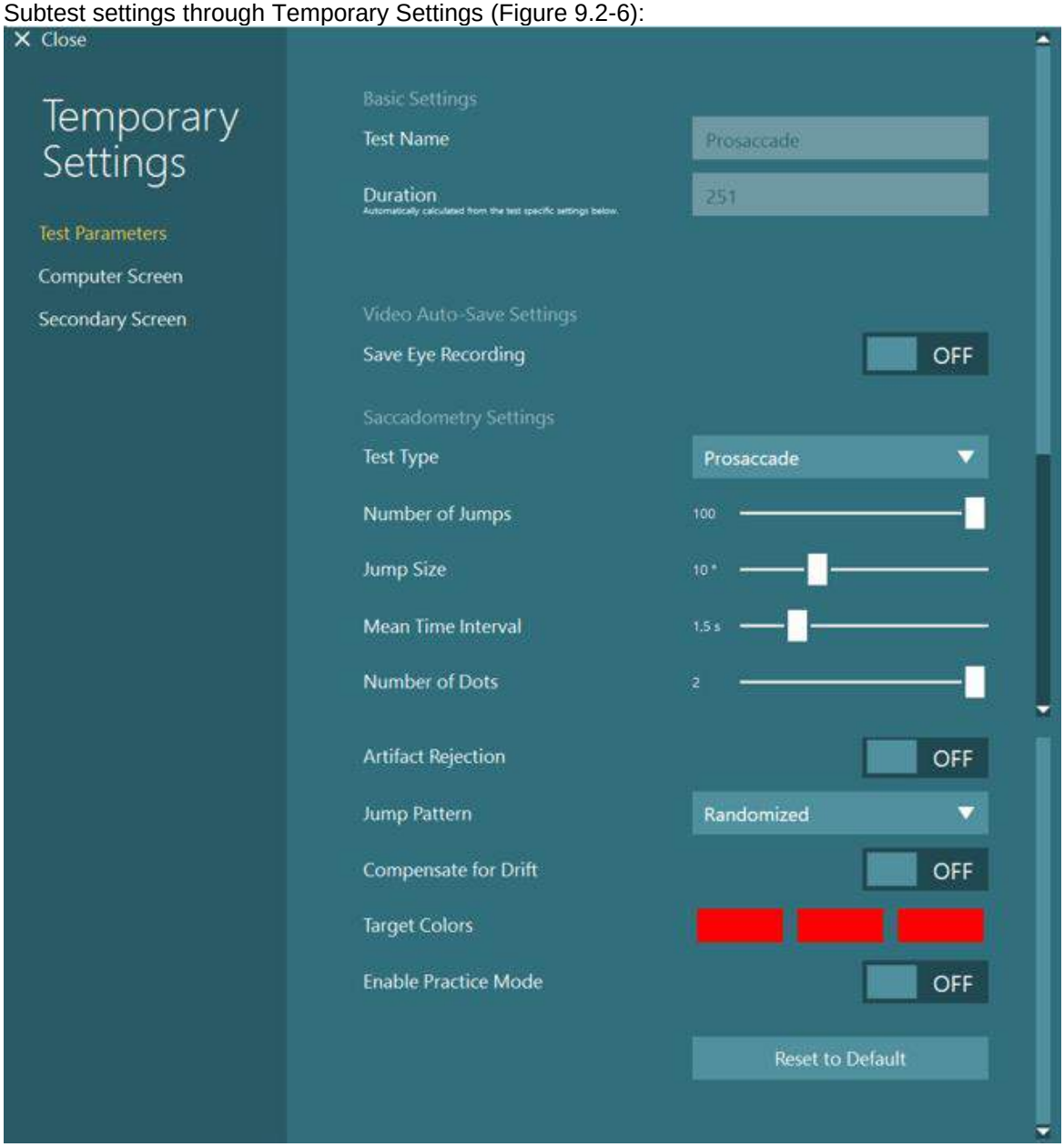


Figure 9.2-6 Saccade subtest settings

Test Name: Name of subtest, defined by the Test Type and Jump Size
Duration: Length of time to perform the test based on the number of saccade jumps
Save Eye Recording: Choice to save eye video recordings.
Test Type: Specifies whether the subtest is a Prosaccade or Anti Saccade subtest
Number of Jumps: Defines how many jumps the patient will follow (maximum of 100).
Jump Size: Defines the degrees the target will be displayed left or right from the center of the stimulus.
Mean Time Interval: Defines the average amount of time between saccade jumps.
Number of Dots: Changes the style for displaying the dots on the screen. In Prosaccade subtests, the maximum number of dots is 2, Anti Saccade tests may use 3 dots.
If the number of dots is set to one, then the target will alternate between the left and right position as defined in the Jump Size field. If the number of dots is 2, then the center target is displayed, and the left or right position is briefly shown. If the number of dots is 3, then the center target, left target, and right target are displayed, with the left or right target flashing briefly to indicate the direction not to look at in anti-saccades.
Jump Pattern: If performing the anti-saccade subtest, this setting will determine if the target randomly flashes between sides or performs a standard jump pattern where the target will flash between the left and right positions evenly.
Compensate for drift: If enabled, the software adjusts the patient's response to better align with the target.

Target Colors: Displays the selected colors for the left, center, and right targets.
Enable Practice Mode: If enabled the test will run ten saccade jumps as a trial for the patient to perform and get used to the test style.

9.2.4 Configuration of smooth pursuit tests

Configuration options of Summary Parameters through protocol management (Permanent settings) or Temporary Settings (Figure 9.2-7):

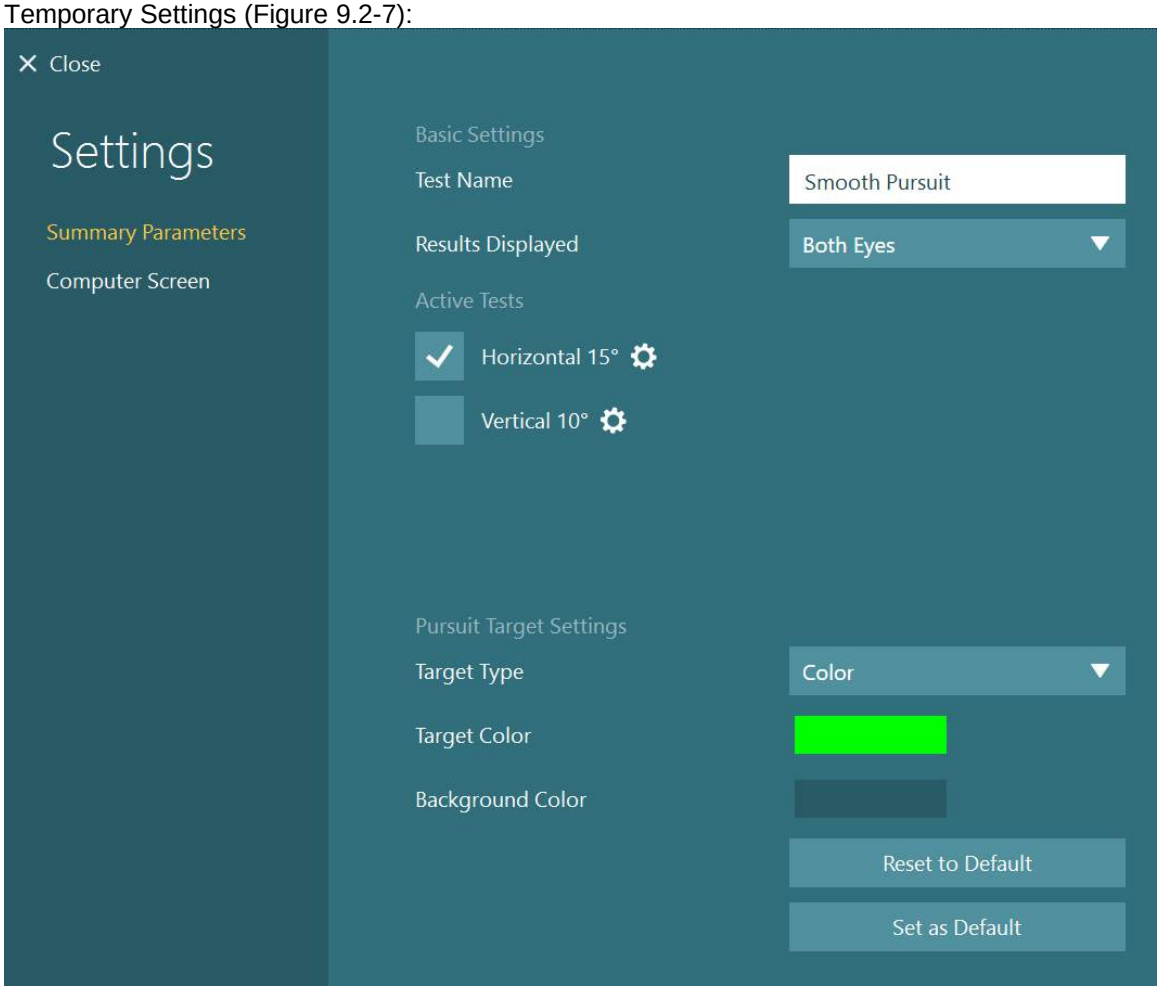


Figure 9.2-7 Smooth Pursuit summary settings

Test Name: Name of the test
Results Displayed: Selects which eye is shown by default. Both Eyes will show both eyes overlapping to allow easy viewing of disconjugate eye movements. Left Eye will set each subtest to display the left eye. Right Eye will set each subtest to display the right eye.
Active Tests: The subtests selected will appear in the testing screen. The configuration gear button beside each test will open the subtest settings. Horizontal 15° is selected by default, and the clinician can choose to perform the Vertical 10° if desired.
Pursuit Target Settings:
Target Type: Selects the stimulus for all Gaze subtests (circle of solid color, flower, potato head, or smiley face).
Target Color: If the target type is set to color, this option will change the target color.
Background color: Select different colors for the background.

Subtest settings through Temporary Settings (Figure 9.2-8):

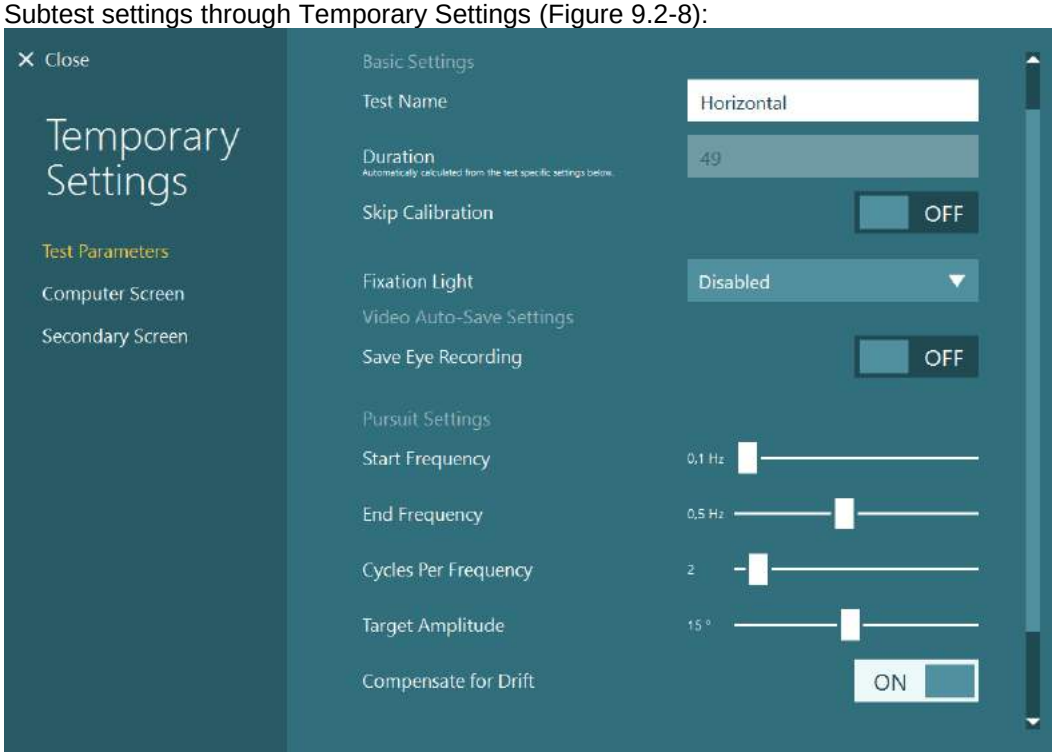


Figure 9.2-8 Smooth Pursuit subtest settings

Test Name: Name of subtest
Duration: Length of time to perform the test based on the number of pursuit cycles and frequencies tested
Fixation light: Determines when the fixation light in the goggles is displayed. Manual will leave the operator to determine when the fixation light should be displayed. Timed will have the fixation light come on automatically at the designated time. Disabled (default) will block the fixation light from turning on in the test.
Save Eye Recording: Choice to save eye video recordings.
Start Frequency [Hz]: Initial frequency of the smooth pursuit test
End Frequency [Hz]: End frequency of the smooth pursuit test
Cycles Per Frequency: Determines how many cycles will be required for each frequency step to be performed
Target Amplitude: Sets the distance the target can move (in degrees)
Compensate for drift: If enabled, the software will adjust the patient's response to better align with the target.

9.2.5 Configuring the OPK tests

Configuration options of Summary Parameters through protocol management (Permanent settings) or Temporary Settings (Figure 9.2-9):

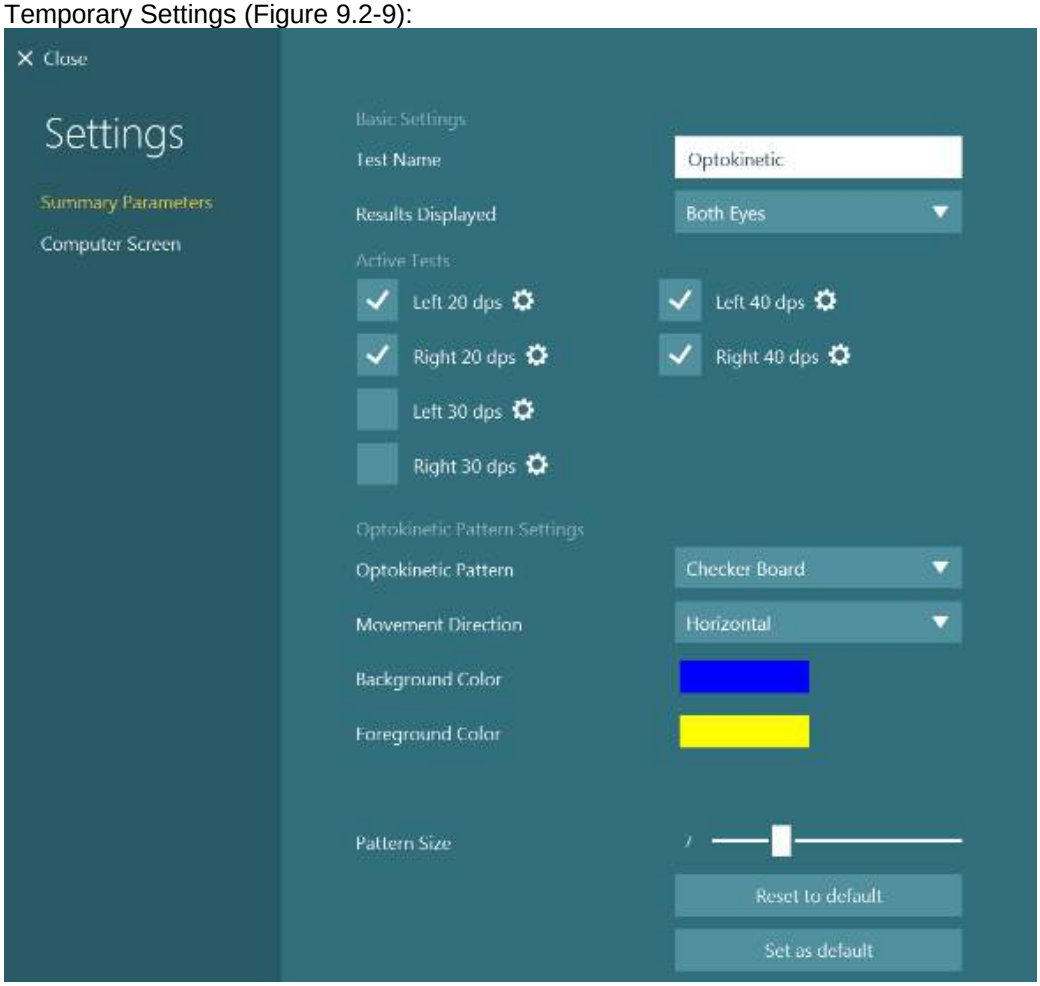


Figure 9.2-9 Optokinetic summary settings

Test Name: Name of the test
Results Displayed: Selects which eye is shown by default. Both Eyes will show both eyes overlapping to allow easy viewing of disconjugate eye movements. Left Eye will set each subtest to display the left eye. Right Eye will set each subtest to display the right eye.
Active Tests: The subtests selected will appear in the testing screen. The configuration gear button beside each test will open the subtest settings. By default the active tests would be Left 20 dps, Right 20 dps, Left 40 dps, and Right 40 dps. Left 30 dps and Right 30 dps are optional.
Optokinetic Pattern Settings:
Optokinetic Pattern: Creates a tessellation pattern or stretches a background image across the stimulus screen. Tessellation patterns include checkerboard, stripes, and spheres. Stretched image patterns include firetruck, pilot and airplane, landscape, toy train, yellow airplane, and trains and tracks.
Foreground Color: If the Optokinetic pattern is a tessellation pattern, this selection will change the color of the primary shape.
Alternate Color: If the Optokinetic pattern is set to Spheres, this selection will change the color of the even rows of spheres.
Background color: If the Optokinetic pattern is a tessellation pattern, this selection controls the background color or fill color depending on the tessellation pattern.
Pattern Size: Adjusts size of shape used in the pattern tessellation. As the target size is increased, the number of shapes used in the pattern will decrease. Only available with Optokinetic Patterns of Checkerboard, Stripes, and Spheres.

Configuration options through Temporary Settings (Figure 9.2-10):

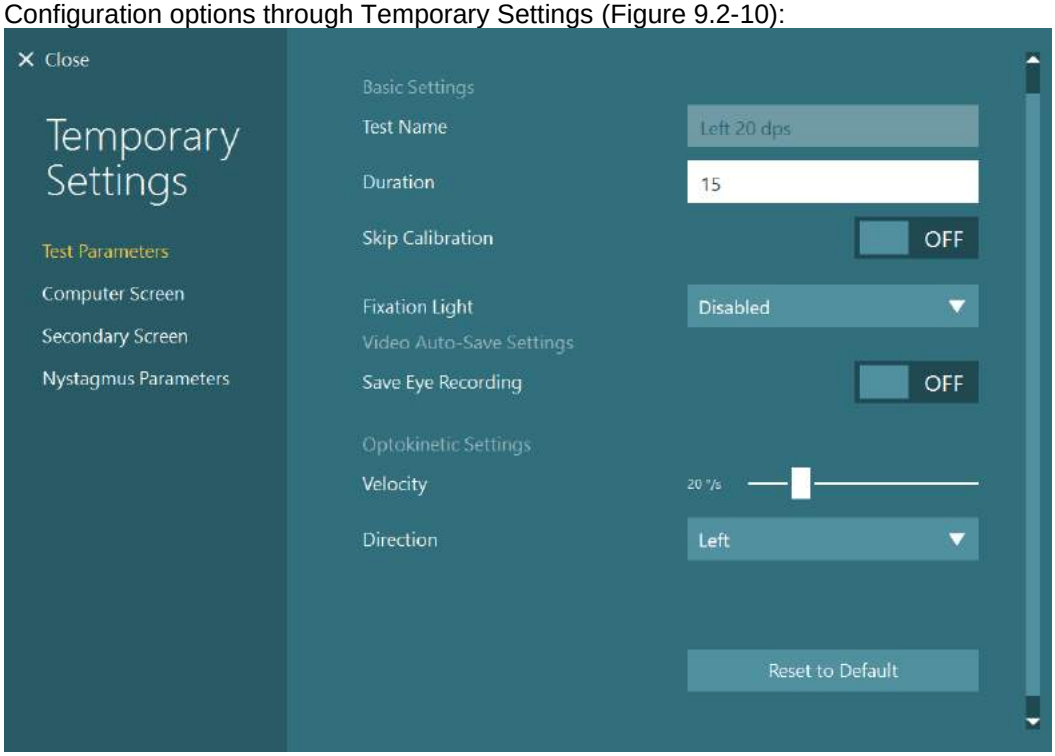


Figure 9.2-10 Optokinetic subtest settings

Test Name: Name of subtest
Duration: Define how long the eye movement is to be recorded and analyzed (in seconds).
Skip Calibration: The user can skip calibration to proceed with the test
Fixation light: Determines when the fixation light in the goggles is displayed. Manual will leave the operator to determine when the fixation light should be displayed. Timed will have the fixation light come on automatically at the designated time. Disabled (default) will block the fixation light from turning on in the test.
Save Eye Recording: Choice to save eye video recordings.
Velocity: Defines the speed the target pattern is displayed on the screen. Confirm that the Velocity value is used by another Optokinetic subtest with the Direction set to the opposite direction to ensure the Optokinetic Symmetry graph can be populated.
Direction: Defines direction of target movement.

9.3 Configuring the nystagmus tests

9.3.1 Configuring the spontaneous nystagmus test

Configuration options through protocol management (Permanent settings) or Temporary Settings (Figure 9.3-1):

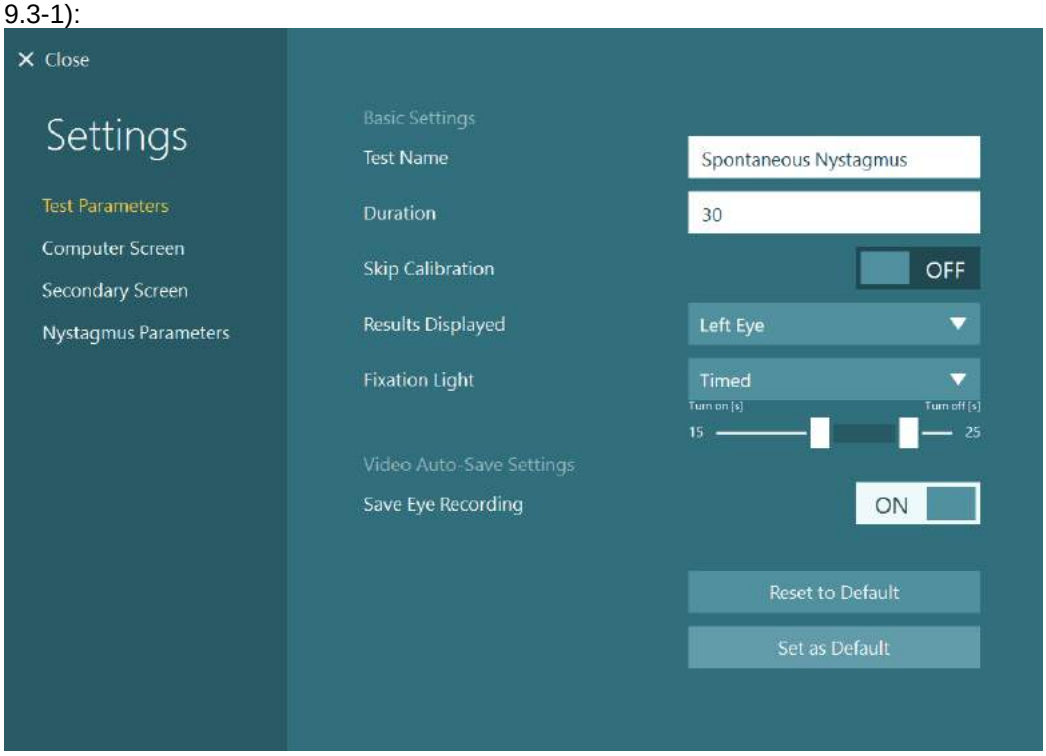


Figure 9.3-1 Spontaneous Nystagmus test settings

Test Name: Name of test
Duration: Define how long the eye movement is to be recorded and analyzed (in seconds).
Skip Calibration: The user can skip calibration to proceed with the test
Results Displayed: Selects which eye is shown by default. Left Eye will set each subtest to display the left eye. Right Eye will set each subtest to display the right eye.
Fixation light: Determines when the fixation light in the goggles is displayed. Manual (default) will leave the operator to determine when the fixation light should be displayed. Timed will have the fixation light come on automatically at the designated time.
Save Eye Recording: Choice to save eye video recordings.

9.3.2 Configuring the Dix-Hallpike tests

Configuration options of Summary Parameters through protocol management (Permanent settings, Figure 9.3-2):

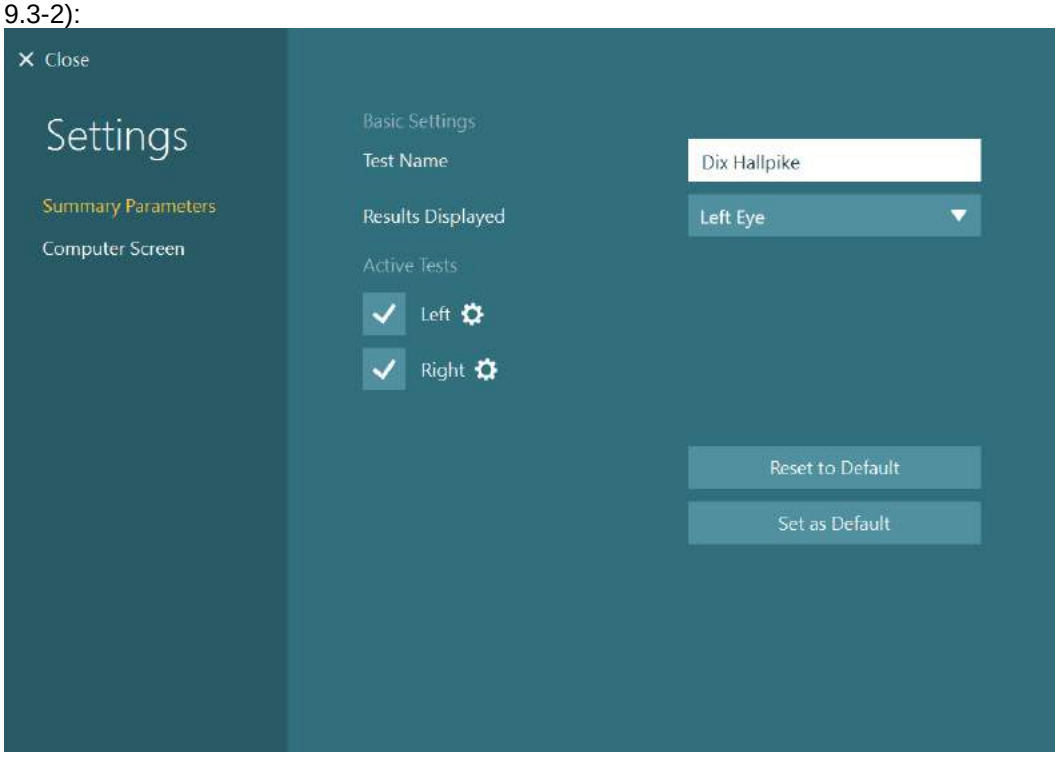


Figure 9.3-2 Dix Hallpike summary settings

Test Name: Name of the test
Results Displayed: Selects which eye is shown by default. Mixed Eyes will allow the user to choose the best eye for each subtest. Left Eye will set each subtest to display the left eye. Right Eye will set each subtest to display the right eye.
Active Tests: The subtests selected will appear in the testing screen. The configuration gear button beside each test will open the subtest settings. The active tests are Left and Right.

Configuration options through protocol management (Permanent settings) or Temporary Settings (Figure 9.3-3):

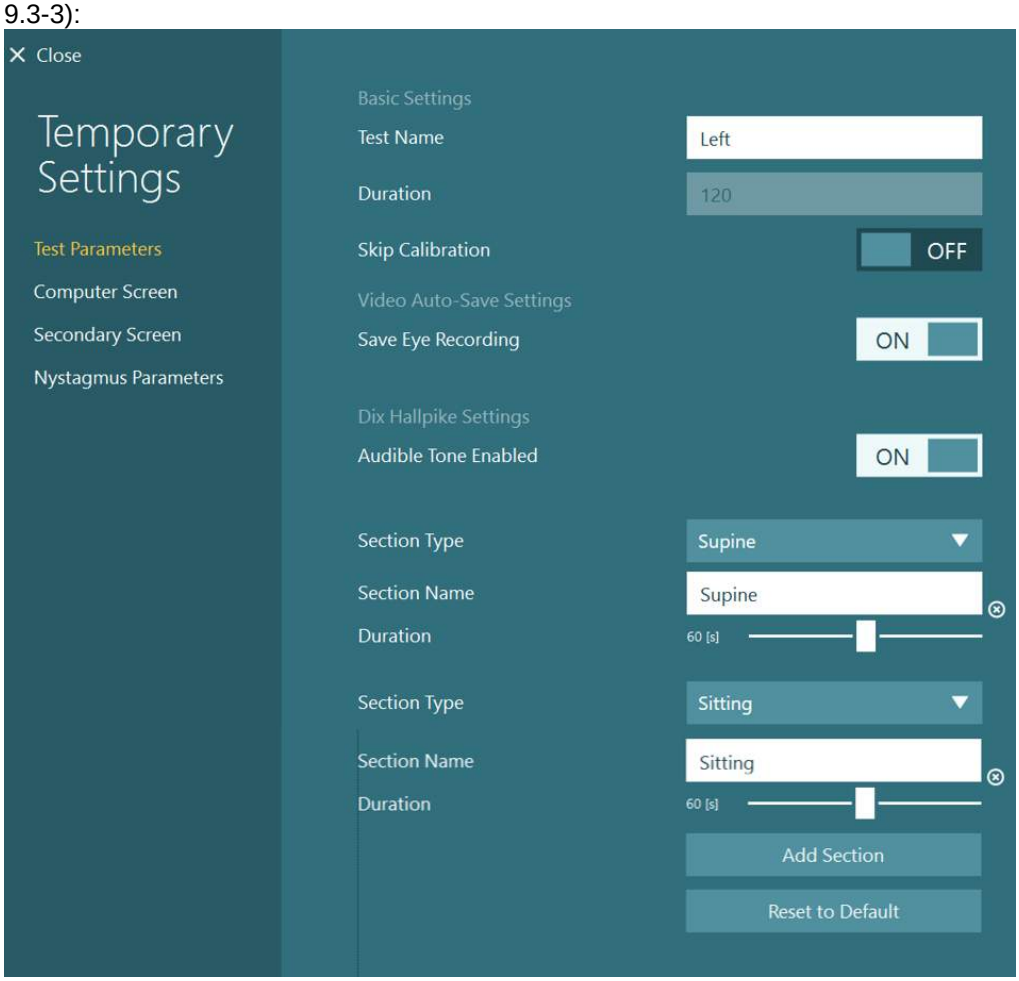


Figure 9.3-3 Dix Hallpike subtest settings

Test Name: Name of test
Duration: Define how long the eye movement is to be recorded and analyzed (in seconds).
Skip Calibration: The user can skip calibration to proceed with the test

Video Auto-save settings

Save Eye Recording: Choice to save eye video recordings.

Dix Hallpike Settings

Audible Tone Enabled: If enabled, the software will provide an audible beep after the Audible Tone Time has elapsed to signify to the operator to raise the patient to a sitting position.
Section type: The user can select patient position type using this option.
Section Name: The user can create a new name (e. g: in order to identify the individual test done in the same patient position).
Duration: The user can adjust the test duration for each position using this option.

9.3.3 Configuring the Dix-Hallpike Advanced test

The Dix-Hallpike Advanced test is an optional test that uses the VORTEQ IMU to ensure accurate head position during the test, and also uses torsion tracking to detect potential torsional nystagmus from the position.

Configuration options of summary parameters through protocol management (Permanent settings, Figure 9.3-4):

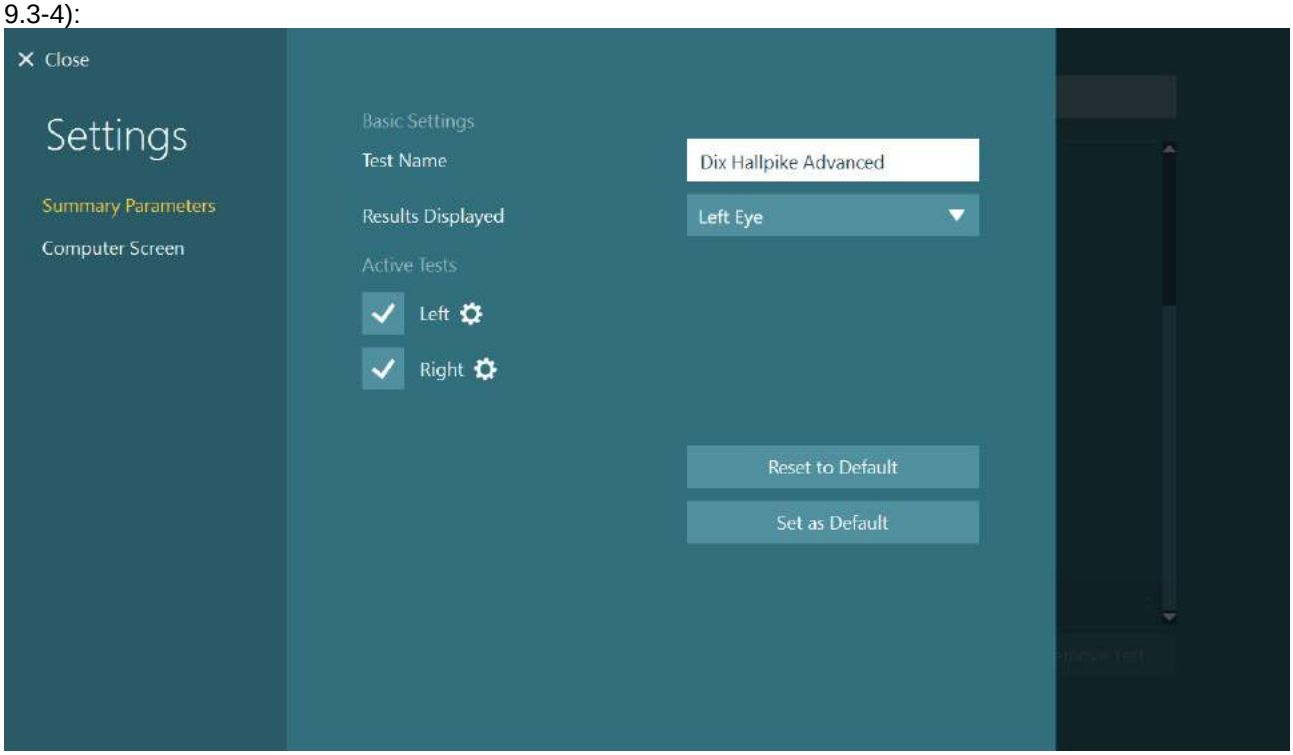


Figure 9.3-4 Dix Hall-pike advance test summary parameters

Test Name: Name of test
Results Displayed: Selects which eye is shown by default. Mixed Eyes will allow the user to choose the best eye for each subtest. Left Eye will set each subtest to display the left eye. Right Eye will set each subtest to display the right eye.
Active Tests: The subtests selected will appear in the testing screen. The configuration gear button beside each test will open the subtest settings. The active tests are Left and Right.

Configuration options of summary parameters through Temporary settings, Figure 9.3-5:

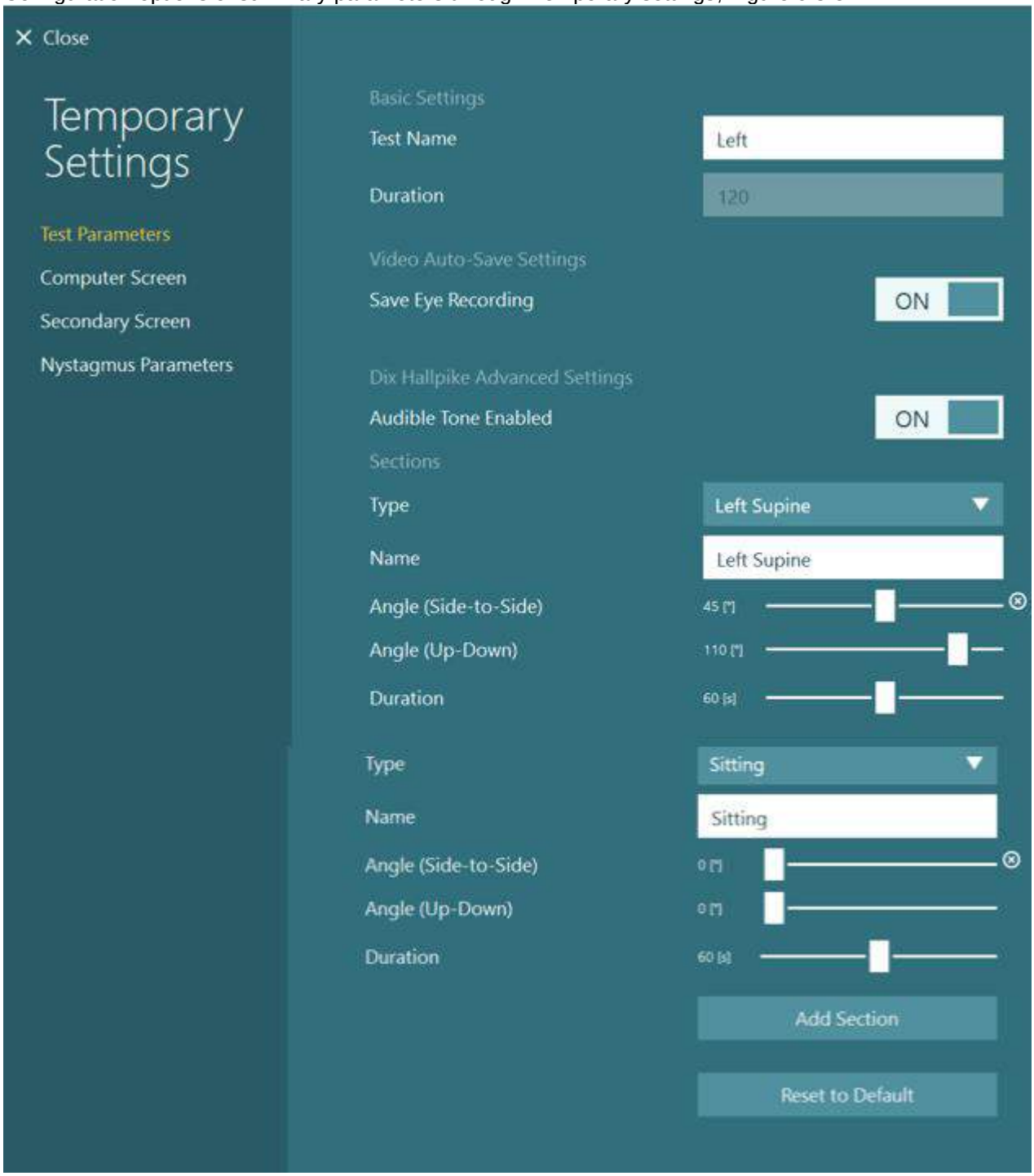


Figure 9.3-5 Dix-Hallpike Advanced subtest settings

Test Name: Name of subtest
Duration: Defines how long the eye movement is to be recorded and analyzed (in seconds) calculated from the duration of the sections
Save Eye Recording: Choice to save eye video recordings.

Dix Hallpike Settings
Audible Tone Enabled: If enabled, the software will provide an audible beep after the Audible Tone Time has elapsed to signify to the operator to raise the patient to a sitting position. If the test is ended early by the operator, this tone is not played.
Sections settings

Section Type: Method used to define the section style. This sets the plane to anticipate the target in a specific section of 3D space. The software can be set to Left Supine, Right Supine, Sitting, or Generic.
Section Name: Name displayed on the waveform for the current section
Angle (Side-to-Side): Angle the patient must have the head rolled when laying in the left supine or right supine position. This value ranges from 0 degrees (looking straight ahead) to 180 degrees (looking behind). Typical value is 45 degrees.
Angle (Up-Down): Angle the patient must have the head raised or lowered when laying in the left supine or right supine position. This value ranges from 0 degrees (head upright) to 180 degrees (head upside down). Typical value is 110 degrees.
Duration: Length of time in seconds of the current section.

9.3.4 Configuring the positional tests

Configuration options of Summary Parameters through protocol management (Permanent settings, Figure 9.3-6):

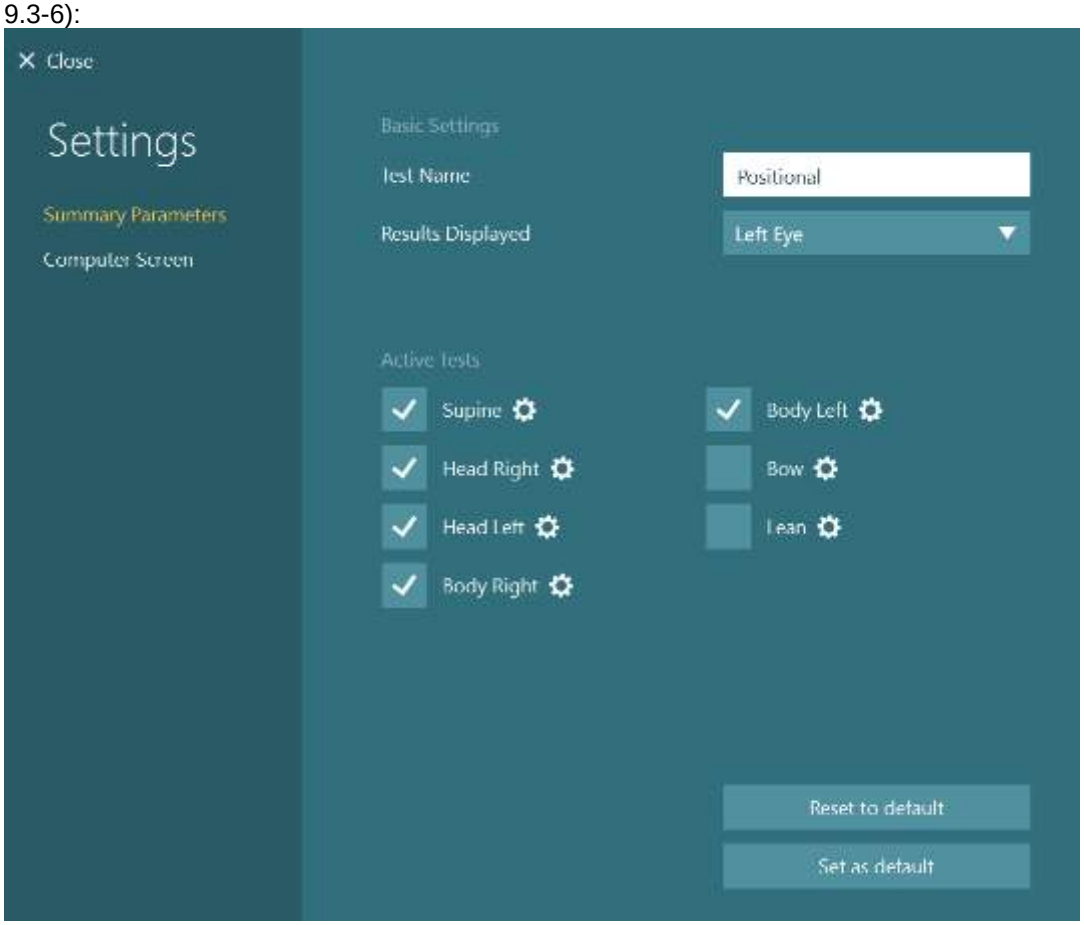


Figure 9.3-6 Positional Summary settings

Test Name: Name of the test
Results Displayed: Selects which eye is shown by default. Mixed Eyes will allow the user to choose the best eye for each subtest. Left Eye will set each subtest to display the left eye. Right Eye will set each subtest to display the right eye.
Active Tests: The subtests selected will appear in the testing screen. The configuration gear button beside each test will open the subtest settings. By default the active tests would be Supine, Head Right, Head Left, Body Right, and Body Left. Bow and Lean are optional body positions.

Configuration options through Temporary Settings, Figure 9.3-7:

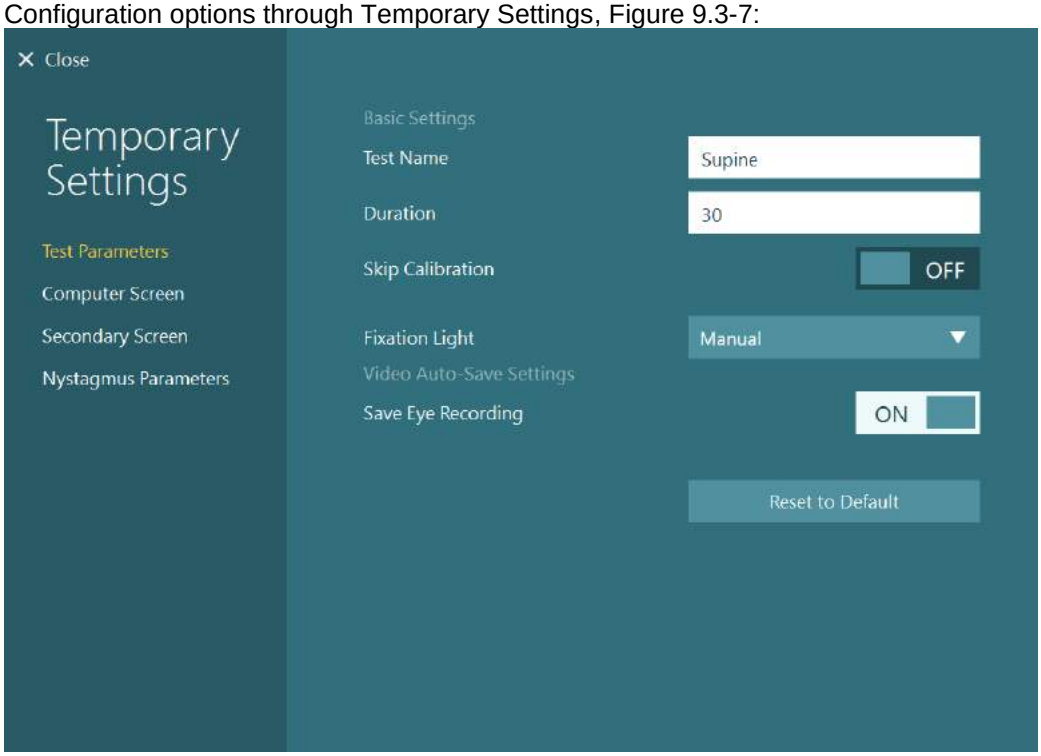


Figure 9.3-7 Positional subtest settings

Test Name: Name of test
Duration: Define how long the eye movement is to be recorded and analyzed (in seconds).
Skip Calibration: The user can skip calibration to proceed with the test
Fixation light: Determines when the fixation light in the goggles is displayed. Manual (default) will leave the operator to determine when the fixation light should be displayed. Timed will have the fixation light come on automatically at the designated time.
Save Eye Recording: Choice to save eye video recordings.

9.3.5 Configuring the caloric tests

Configuration options of Summary Parameters through protocol management (Permanent settings, Figure 9.3-8):

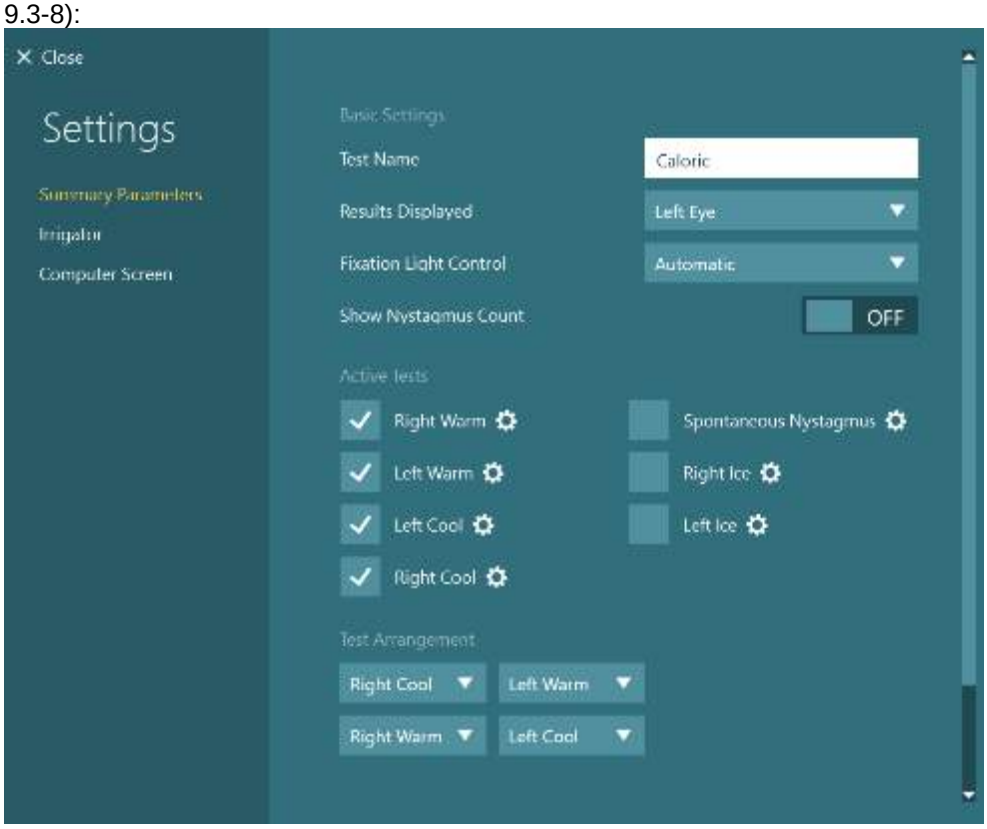


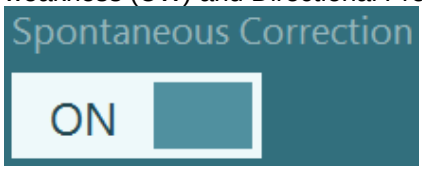
Figure 9.3-8 Caloric summary settings

Test Name: Name of test
Results Displayed: Selects which eye is shown by default. Left Eye will set each subtest to display the left eye. Right Eye will set each subtest to display the right eye.
Fixation Light Control: Determines when the fixation light in the goggles is displayed. Automatic (default) will have the fixation light turn on after the current average slow phase velocity has dropped 10% compared to the maximum average slow phase velocity. Manual will leave the operator to determine when the fixation light should be displayed. Timed will have the fixation light come on automatically at the designated time. The fixation index will not be calculated if the operator has turned the fixation light on early in the subtest.
Show Nystagmus Count: If enabled, the software will display the number of detected nystagmus beats in the peak response window and display the beat count in the pod view above the fixation index value. .
Save Eye Recording: Choice to save eye video recordings.

Before the caloric irrigation test is performed, a spontaneous nystagmus (SPN) test can be recorded. This is recommended for patients that have shown nystagmus in conditions without stimulation. The average slow phase velocity determined during the caloric SPN test is used in the calculation of directional preponderance.

Under the Summary parameters choose ‘Spontaneous Nystagmus’

Once a sub test is complete, the option to choose Spontaneous Correction’.
The calculations consider the presence of underlying spontaneous nystagmus in the analysis of unilateral weakness (UW) and Directional Preponderance (DP).



Test Arrangement: The order of the caloric subtests and how they are displayed on the screen can be changed by setting the test order. Analysis results will also display the test results in the test arrangement if possible.

Configuration options (under Irrigator option) in Protocol Management, Caloric test settings (Permanent settings, Figure 9.3-9):

Figure 9.3-9 Caloric Summary Irrigator settings

1. VisualEyes™ system is compatible with Interacoustics and Micromedical water (Aqua Stim) and air (AirFx) Caloric irrigators. These irrigators interact with the software allowing for automatic temperature adjustment and activation of the test via the irrigator handle push button. Selecting the Manual option allows using any third-party caloric irrigator, however the software will not directly communicate with the irrigator.
2. Enter the temperature of the cold and warm irrigations (**Error! Reference source not found.**). If set with the Air Fx or Aqua Stim, the irrigator will operate with these settings. If using a third-party irrigator, these values only provide a note to the desired temperature and shown in the caloric result graphs.
3. The duration to irrigate can be set to stop the flow of the air or water at the time desired for the irrigation. This is useful when there is a compatible irrigator. Selecting a time will allow the irrigator to perform the irrigation for the set time, automatically turn on and off.

Configurations options through Temporary Settings, Figure 9.3-10:

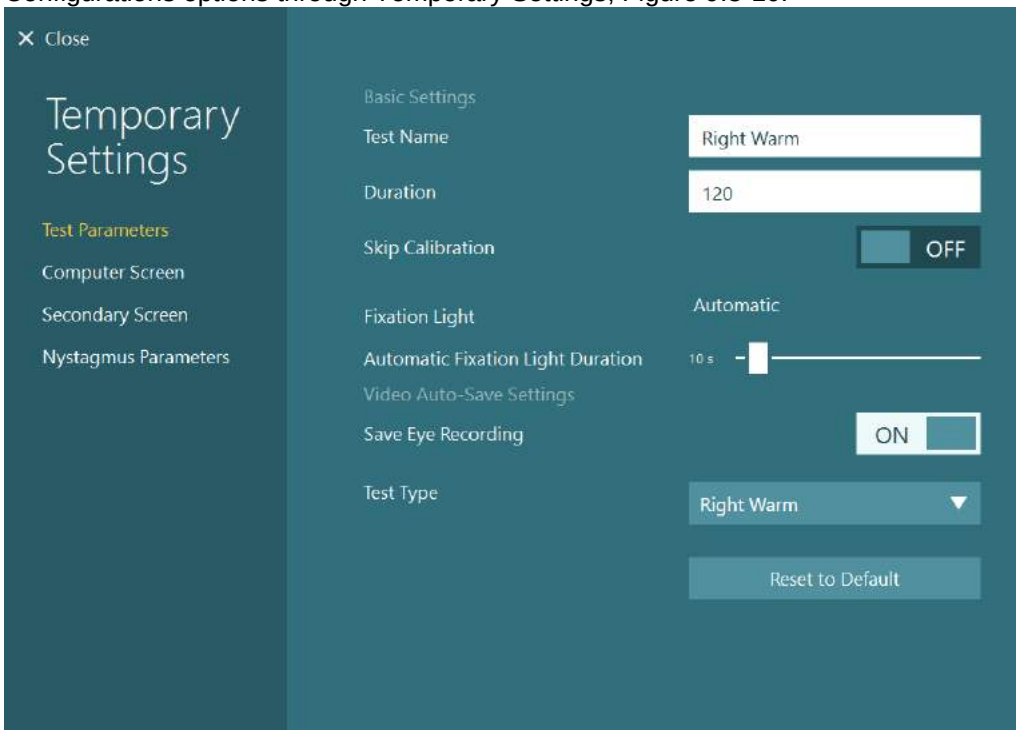


Figure 9.3-10 Caloric subtest settings

Test Name: Name of test
Duration: Define how long the eye movement is to be recorded and analyzed (in seconds).
Skip Calibration: The user can skip calibration to proceed with the test
Fixation light: Determines when the fixation light in the goggles is displayed. This value is set by the Caloric summary settings.
Automatic Fixation Light Duration: If the subtest is set to use Automatic Fixation Light, the length of time the light is displayed to the patient can be set using the slider.
Save Eye Recording: Choice to save eye video recordings.
Test Type: After the test has been performed, this setting is available to change the type of caloric test in the event the operator had irrigated the wrong ear during testing.

9.4 Configuring rotary chair tests

9.4.1 Configuring sinusoidal harmonic acceleration test

Configuration options of Summary Parameters through protocol management (Permanent settings) or Temporary Settings, Figure 9.4-1 and Figure 9.4-2:

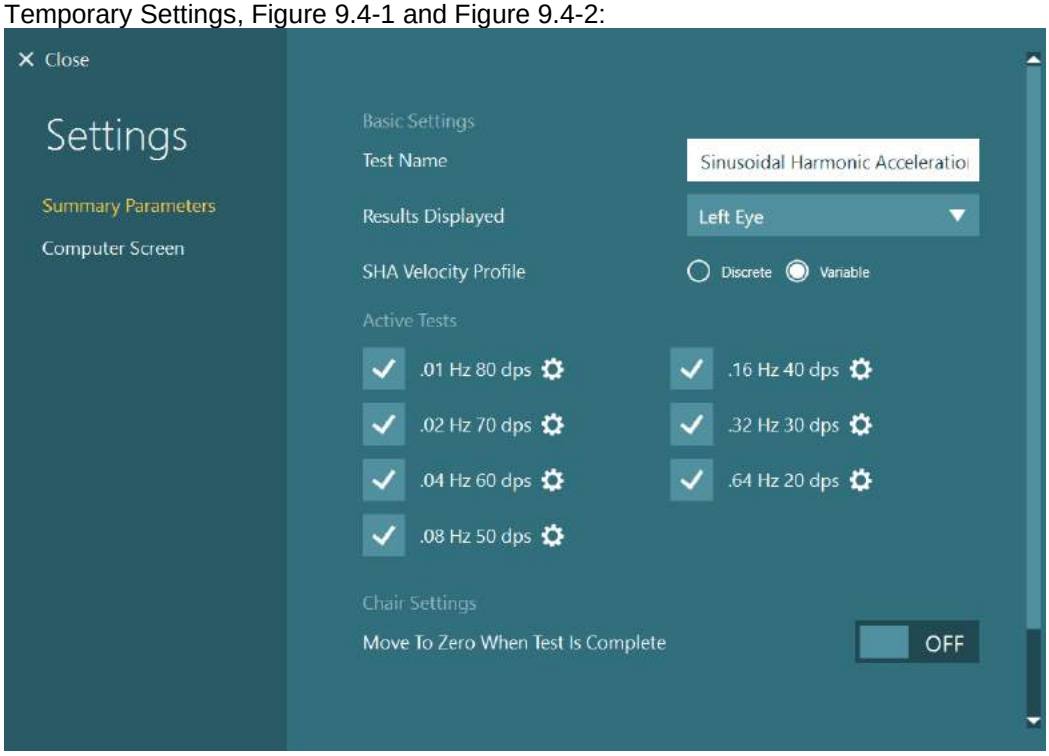


Figure 9.4-1 Sinusoidal Harmonic Acceleration summary settings

Test Name: Name of the test
Results Displayed: Selects which eye is shown by default. Left Eye will set each subtest to display the left eye. Right Eye will set each subtest to display the right eye.
SHA velocity profile: This option defines whether the SHA subtests use a discrete standard velocity of 60 dps or use a variable velocity which is higher at lower frequencies (80 dps at 0. 01 Hz and drops 10 dps for each increase in frequency to 20 dps at 0. 64 Hz.) The default setting is Variable.
Active Tests: The subtests selected will appear in the testing screen. The configuration gear button beside each test will open the subtest settings. The Nydiag 200 chair can test up to 0. 32 Hz, and the Orion Reclining chair and System 2000 Reclining chair can test up to 0. 64 Hz.
Move To Zero When Test Is Complete: If enabled, the chair (Nydiag 200 and Orion Reclining chair models only) will return to the zero position as set in System Default Settings.

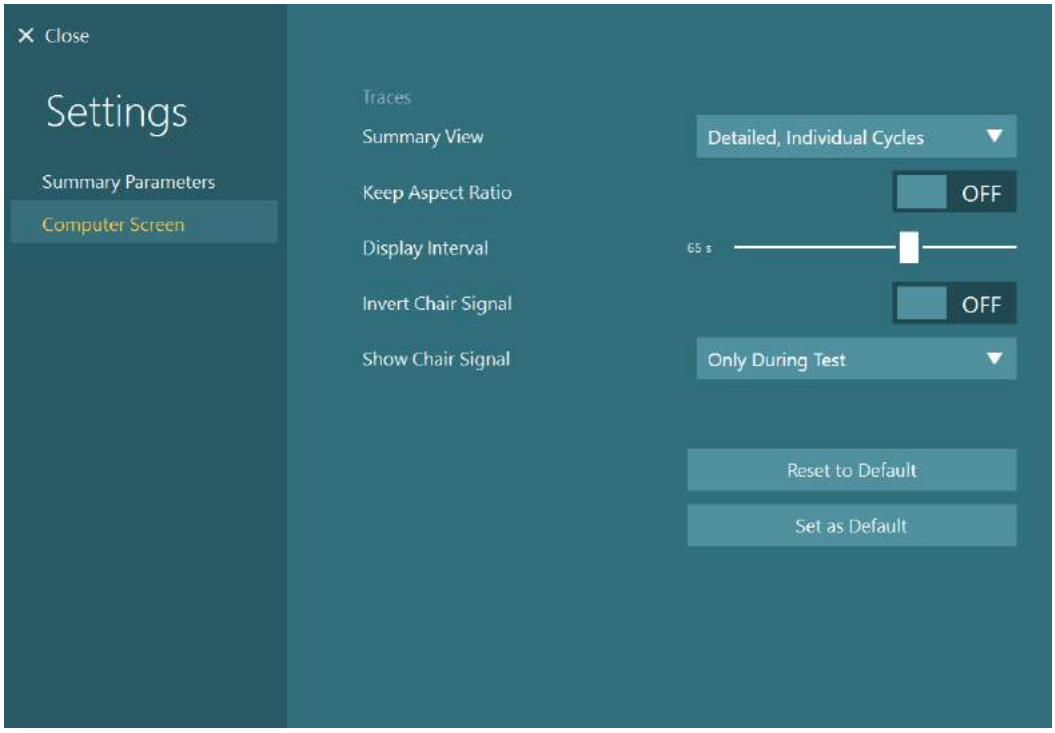


Figure 9.4-2 SHA Summary Computer Screen settings

Summary View, Figure 9.4-3**:**

Detailed, individual cycles: Detailed view will draw each cycle individually and fit a line to each cycle.

Concise combined cycles: Concise will show every cycle overlapped and a single fitted line is drawn through the concise view.

The choice is also used in the report. Below the gain, phase, and symmetry graphs the cycles will be printed in either Detailed or Concise view.

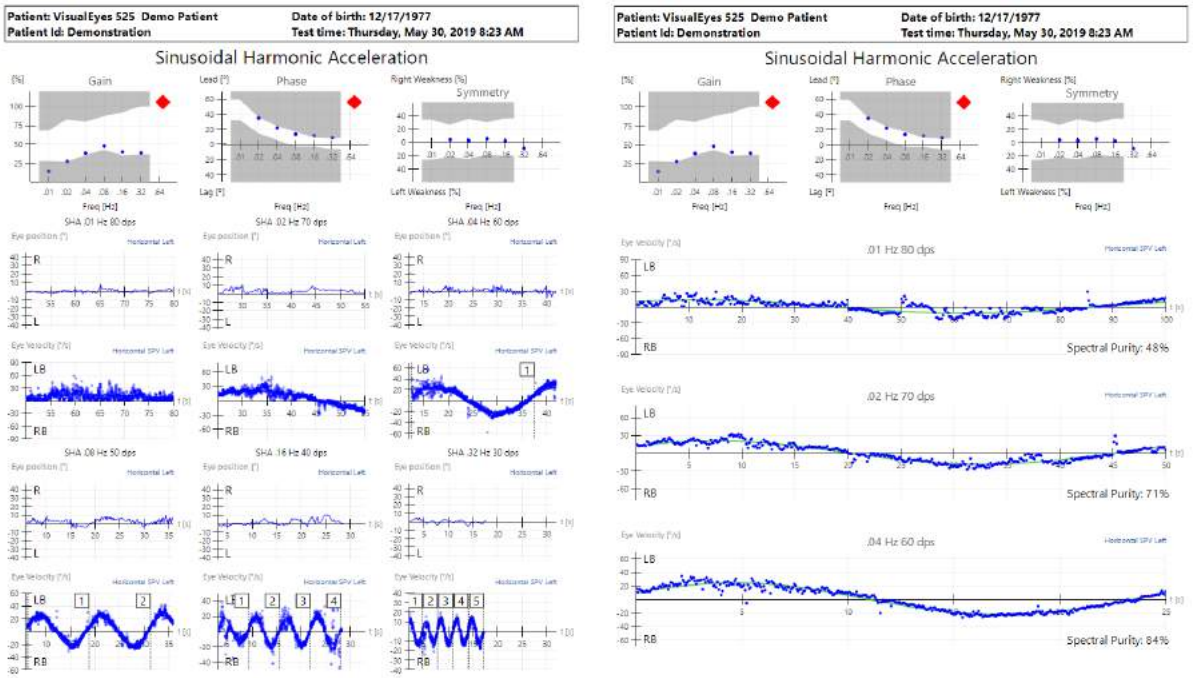


Figure 9.4-3 Print SHA tests with Detailed, individual cycles (left) and Concise combined cycles (right)

Keep aspect ratio: This allows the nystagmus to be displayed in a non-compressed form, allowing for easy recognition of the slow phase velocities of nystagmus. Disabling this feature will cause the nystagmus to appear more compressed.
Display Interval: Set the desired length of time (in seconds) to display data in the test window. This feature only becomes available when “Keep aspect ratio” is disabled.
Invert chair signal: Enabling this feature sets the eye trace to overlap the stimulus trace, providing a different view for comparing results. By default the setting is disabled.
Show chair signal: Enabling this feature shows the chair velocity trace. The user can either choose to view the trace all the time or only during the test.

Subtest settings through Temporary Settings, Figure 9.4-4 and Figure 9.4-5:

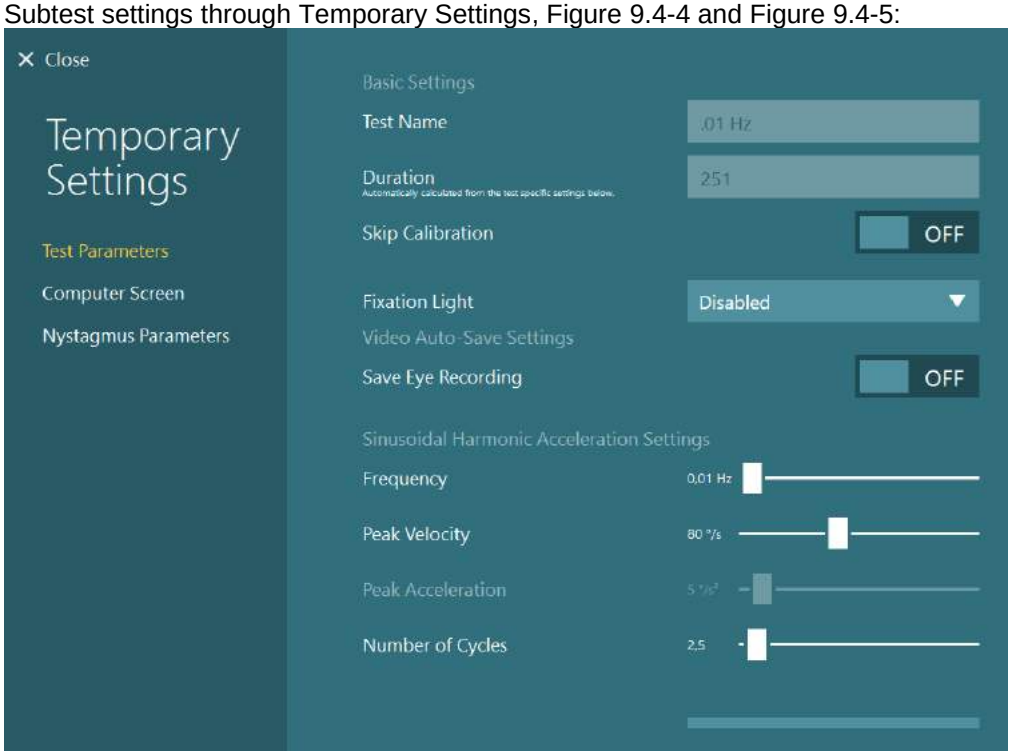


Figure 9.4-4 SHA subtest settings

Test Name: Name of subtest
Duration: Define how long the eye movement is to be recorded and analyzed (in seconds). This value is calculated based on the Frequency, Peak Velocity, and Number of Cycles.
Skip Calibration: The user can skip calibration to proceed with the test
Fixation light: Determines when the fixation light in the goggles is displayed. Manual (default) will leave the operator to determine when the fixation light should be displayed. Timed will have the fixation light come on automatically at the designated time.
Save Eye Recording: Choice to save eye video recordings.
Target Direction: Defines direction of target movement.
Extend end of Recording: If enabled the test will return the target back to center for two seconds. Not recommended if the tests are run automatically.
Sinusoidal Harmonic Acceleration Settings:
Frequency: Define the frequency (Hz) of Stimulus (Chair motion side to side). The frequencies available include 0. 01 Hz to 0. 32 Hz with increments of 0. 01 Hz.
Peak Velocity: Define the peak velocity (in dps) the chair will rotate. Range of velocities is 1 to 200 degrees per second.
Peak Acceleration: The maximum rate at which the chair can accelerate (in m/s^2). This is automatically calculated based on the sinusoidal harmonic acceleration settings.
Number of Cycles: The total number of cycles to be performed for this frequency of chair movement. The initial half cycle is rejected automatically.

Figure 9.4-5 SHA subtest Nystagmus Parameters

Display nystagmus markers: Enabling this feature will display a marker i. e. triangle above the nystagmus fast phase slope to assist identification of a nystagmus beat. The triangle may face upwards (referring to right/up beating nystagmus) and downwards referring to left/ down beat nystagmus.
Highlight nystagmus slow phase: By default, the slow phases are the same color as the rest of the trace. However should the user want to differentiate the slow phases amongst the trace data, enabling this feature will mark the slow phases in green.
Peak Response: Selecting the drop down menu presents several options to define the length of time for the analysis of the peak response. By default, the entire test will be included in the peak response for accuracy purposes.

9.4.2 Configuring step rotation test

Configuration options of Summary Parameters through protocol management (Permanent settings) or Temporary Settings Figure 9.4-6:

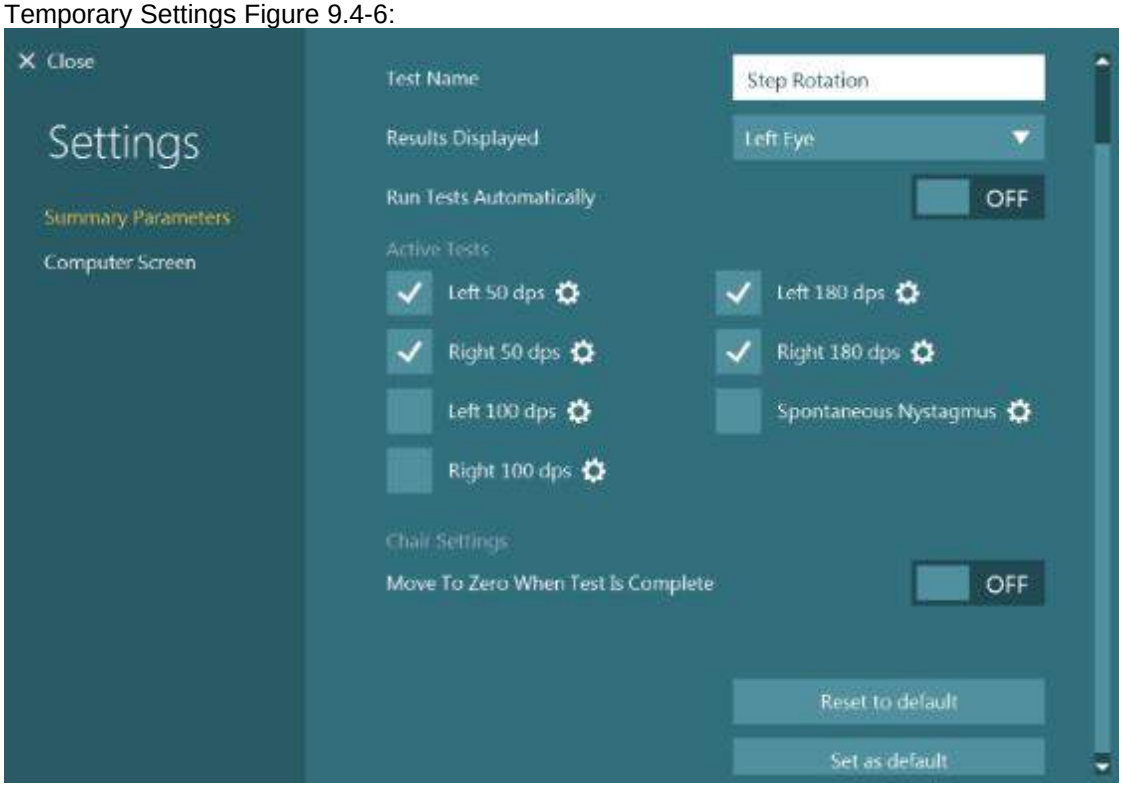


Figure 9.4-6 Step Rotation summary settings

Test Name: Name of the test
Results Displayed: Selects which eye is shown by default. Left Eye will set each subtest to display the left eye. Right Eye will set each subtest to display the right eye.
Run Tests Automatically: If enabled, when the subtest completes, the next subtest will be loaded and started automatically.
Active Tests: The subtests selected will appear in the testing screen. The configuration gear button beside each test will open the subtest settings. By default the Step Rotation test will test the patient in both directions at 50 and 180 dps. Optionally the test can also spin the patient at 100 dps.
Move To Zero When Test Is Complete: If enabled, the chair (Nydiag 200 and Orion Reclining chair models only) will return to the zero position as set in System Default Settings.

Subtest settings through Temporary Settings, Figure 9.4-7 and Figure 9.4-8:

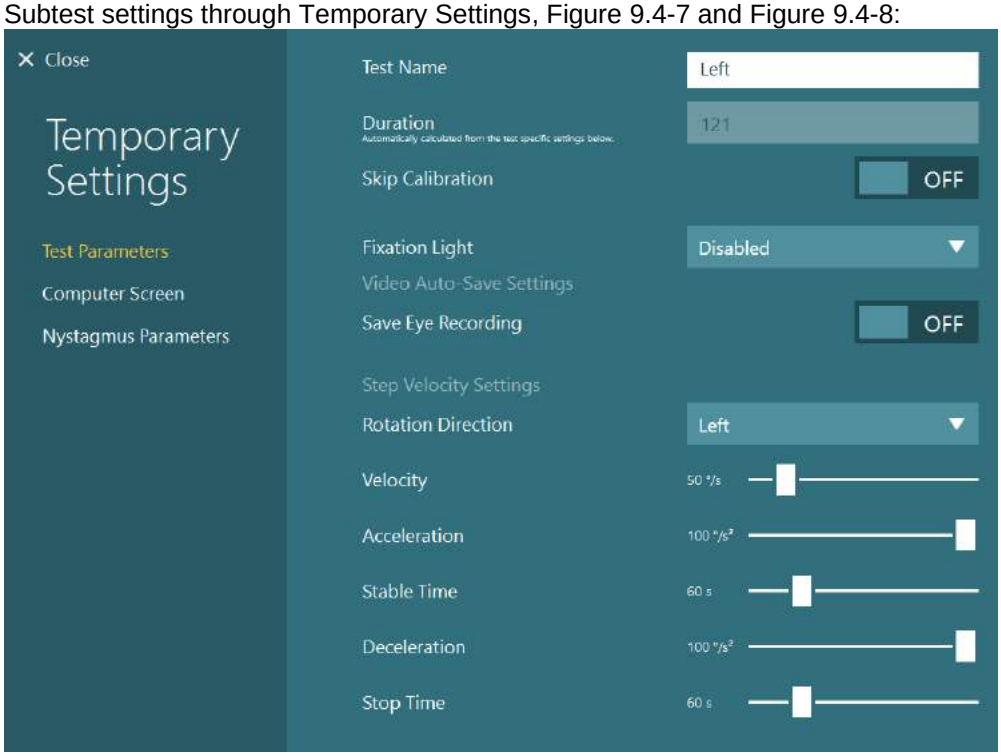


Figure 9.4-7 Step Rotation subtest settings

Test Name: Name of subtest
Duration: Length of time (in seconds) the test shall run. This is automatically calculated from the test specific settings. The length of time is dependent on the step rotation setting, i. e. velocity, acceleration, deceleration time.
Skip Calibration: The user can skip calibration to proceed with the test
Fixation light: Determines when the fixation light in the goggles is displayed. Manual (default) will leave the operator to determine when the fixation light should be displayed. Timed will have the fixation light come on automatically at the designated time.
Save Eye Recording: Choice to save eye video recordings.
Step Rotation Settings
Rotation direction: Defines the direction the chair will be rotating, Left (counterclockwise) or Right (clockwise).
Velocity: The peak velocity of chair movement
Acceleration: The rate at which the chair accelerates to reach the Velocity value.
Stable Time: Length of time the chair will be rotating at the Velocity value past the time required to reach the Velocity value using the Acceleration rate.
Deceleration: Defines the rate the chair decelerates (in deg/sec^2).
Stop Time: Length of time (in seconds) the test will continue recording after the chair has stopped.

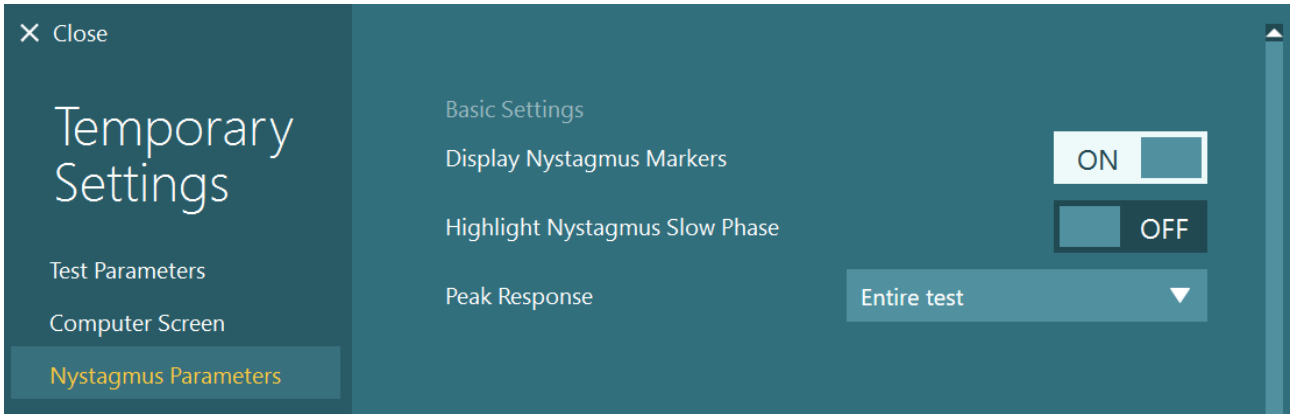


Figure 9.4-8 Step Rotation subtest Nystagmus Parameters

Display nystagmus markers: Enabling this feature will display a marker i. e. triangle above the nystagmus fast phase slope to assist identification of a nystagmus beat. The triangle may face upwards (referring to right/up beating nystagmus) and downwards referring to left/ down beat nystagmus. Nystagmus markers will be enabled by default.
Highlight nystagmus slow phase: By default, the slow phases are the same color as the rest of the trace. However should the user want to differentiate the slow phases amongst the trace data, enabling this feature will mark the slow phases in green.
Peak response: Selecting the drop down menu presents several options to define the length of time for the analysis of the peak response. By default, the entire test will be included in the peak response for accuracy purposes.

9.4.3 Configuring VOR suppression test

Configuration options through protocol management (Permanent settings, Figure 9.4-9 and Figure 9.4-10):

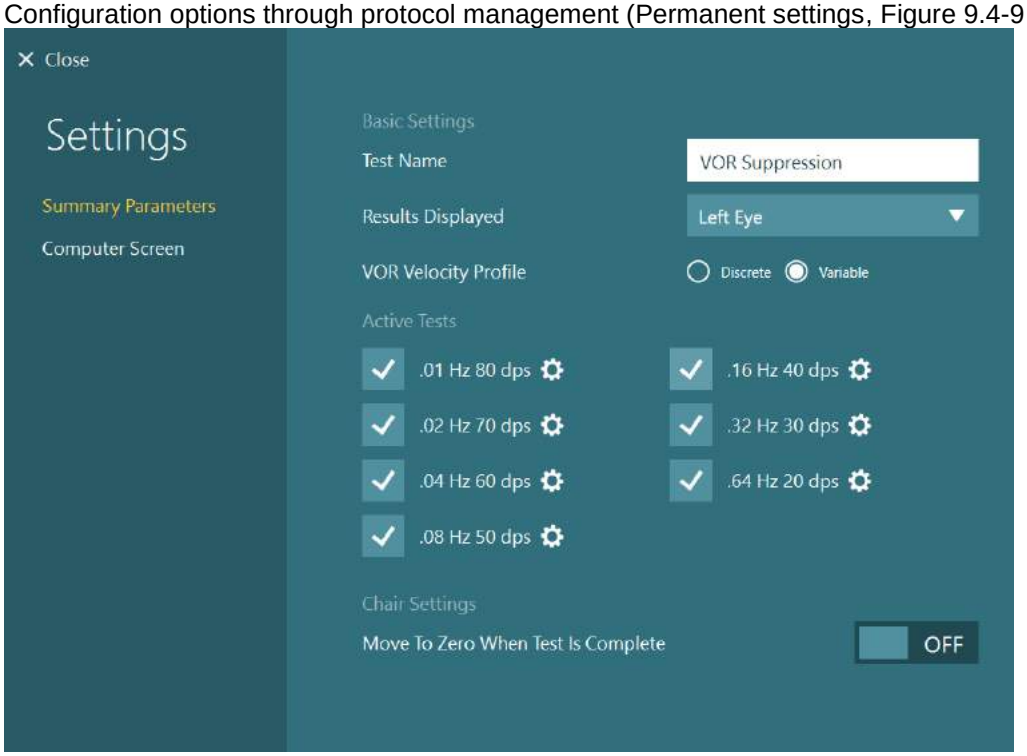


Figure 9.4-9 VOR Suppression summary settings

Test Name: Name of the test
Results Displayed: Selects which eye is shown by default. Left Eye will set each subtest to display the left eye. Right Eye will set each subtest to display the right eye.
SHA velocity profile: This option defines whether the VOR Suppression subtests use a discrete standard velocity of 60 dps or use a variable velocity which is higher at lower frequencies (80 dps at 0. 01 Hz and drops 10 dps for each increase in frequency to 20 dps at 0. 64 Hz.) The default setting is Variable. This value should be the same as the VOR tests that the VOR Suppression test will compare against.
Active Tests: The subtests selected will appear in the testing screen. The configuration gear button beside each test will open the subtest settings. The Nydiag 200 chair can test up to 0. 32 Hz, and the Orion Reclining chair and System 2000 Reclining chair can test up to 0. 64 Hz.
Move To Zero When Test Is Complete: If enabled, the chair (Nydiag 200 and Orion Reclining chair models only) will return to the zero position as set in System Default Settings.

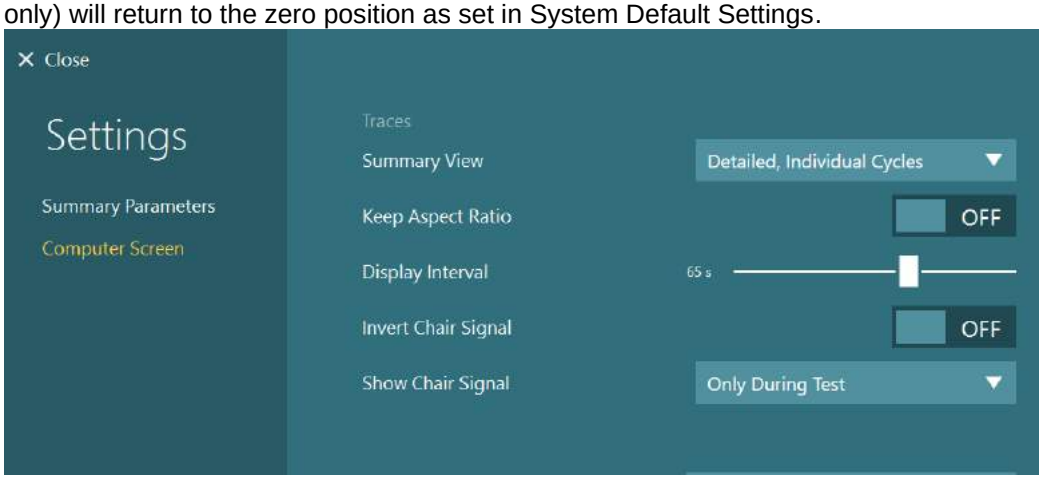


Figure 9.4-10 VOR Suppression summary Computer Screen settings

Summary View:
Detailed, individual cycles: Detailed view will draw each cycle individually and fit a line to each cycle
Concise combined cycles: Concise will show every cycle overlapped and a single fitted line is drawn through the concise view.
Keep aspect ratio: This allows the nystagmus to be displayed in a non-compressed form, allowing for easy recognition of the slow phase velocities of nystagmus. Disabling this feature will cause the nystagmus to appear more compressed.
Display Interval: Set the desired length of time (in seconds) to display data in the test window. This feature only becomes available when “Keep aspect ratio” is disabled.
Invert chair signal: Enabling this feature sets the eye trace to overlap the stimulus trace, providing a different view for comparing results. By default, the setting is disabled.
Show chair signal: Enabling this feature shows the chair velocity trace. The user can either choose to view the trace all the time or only during the test.

Subtest settings through Temporary Settings, Figure 9.4-11 and Figure 9.4-12:

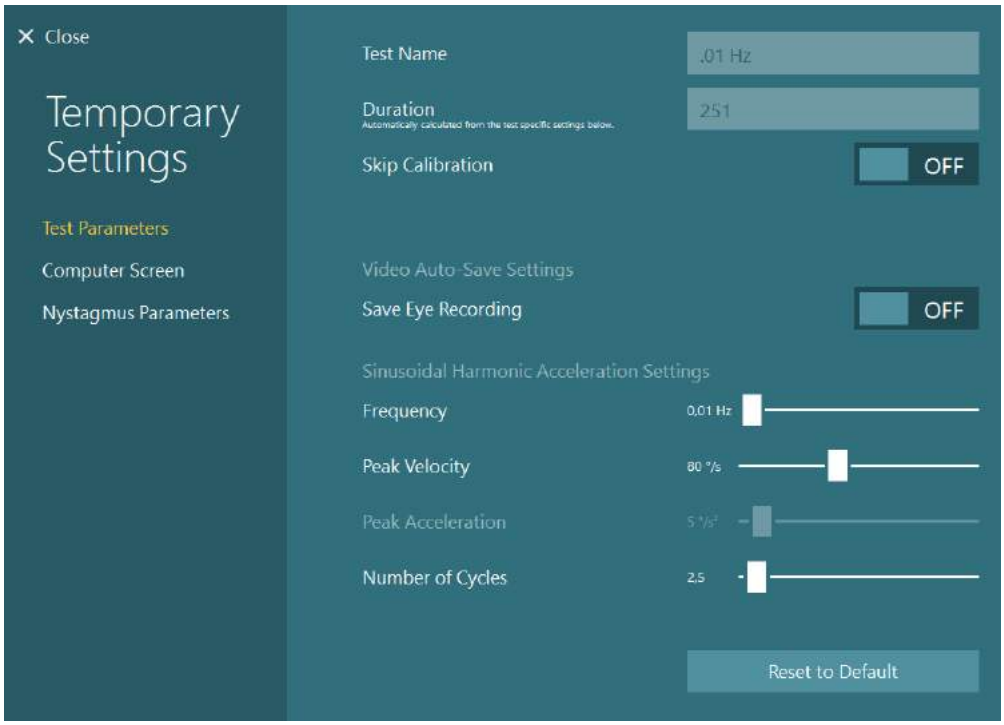


Figure 9.4-11 VOR Suppression subtest settings

Test Name: Name of subtest
Duration: Define how long the eye movement is to be recorded and analyzed (in seconds). This value is calculated based on the Frequency, Peak Velocity, and Number of Cycles.
Skip Calibration: The user can skip calibration to proceed with the test
Save Eye Recording: Choice to save eye video recordings.
Sinusoidal Harmonic Acceleration Settings:
Frequency: Define the frequency (Hz) of Stimulus (Chair motion side to side). The frequencies available include 0. 01 Hz to 0. 32 Hz with increments of 0. 01 Hz.
Peak Velocity: Define the peak velocity (in dps) the chair will rotate. Range of velocities is 1 to 200 degrees per second.
Peak Acceleration: The maximum rate at which the chair can accelerate (in m/s^2). This is automatically calculated based on the sinusoidal harmonic acceleration settings.
Number of Cycles: The total number of cycles to be performed for this frequency of chair movement. The initial half cycle is rejected automatically.

Figure 9.4-12 VOR Suppression subtest Nystagmus Parameters

Display nystagmus markers: Enabling this feature will display a marker i. e. triangle above the nystagmus fast phase slope to assist identification of a nystagmus beat. The triangle may face upwards (referring to right/up beating nystagmus) and downwards referring to left/ down beat nystagmus.

Highlight nystagmus slow phase: By default, the slow phases are the same color as the rest of the trace. However should the user want to differentiate the slow phases amongst the trace data, enabling this feature will mark the slow phases in green.

Peak Response: Selecting the drop down menu presents several options to define the length of time for the analysis of the peak response. By default, the entire test will be included in the peak response for accuracy purposes.

9.4.4 Configuring visual VOR test

Configuration options through protocol management (Permanent settings, Figure 9.4-13 and Figure 9.4-14):

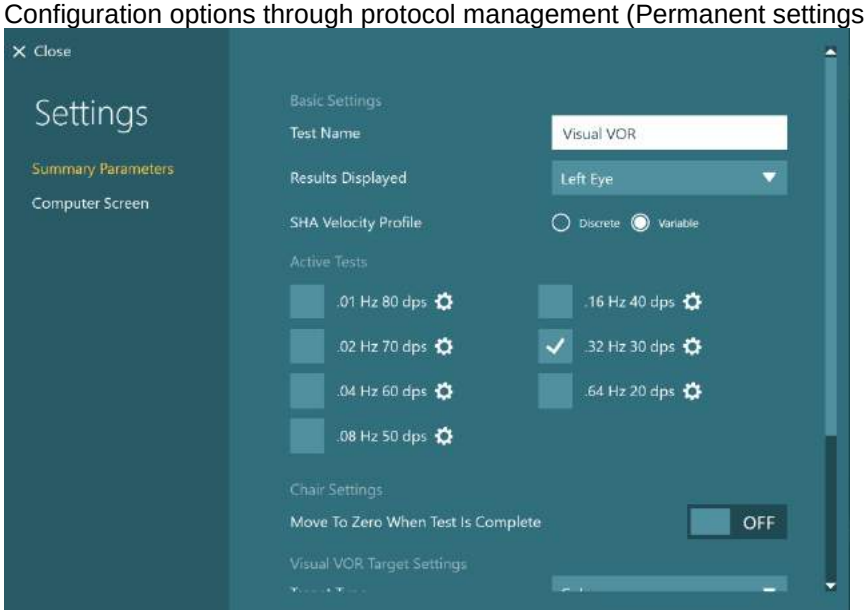


Figure 9.4-13 Visual VOR summary settings

Test Name: Name of the test
Results Displayed: Selects which eye is shown by default. Left Eye will set each subtest to display the left eye. Right Eye will set each subtest to display the right eye.
SHA velocity profile: This option defines whether the SHA subtests use a discrete standard velocity of 60 dps or use a variable velocity which is higher at lower frequencies (80 dps at 0. 01 Hz and drops 10 dps for each increase in frequency to 20 dps at 0. 64 Hz.) The default setting is Variable. This value should be the same as the VOR tests and VOR Suppression tests.
Active Tests: The subtests selected will appear in the testing screen. The configuration gear button beside each test will open the subtest settings. The Nydiag 200 chair can test up to 0. 32 Hz, and the Orion Reclining chair and System 2000 Reclining chair can test up to 0. 64 Hz. By default only the 0. 32 Hz test is selected.
Move To Zero When Test Is Complete: If enabled, the chair (Nydiag 200 and Orion Reclining chair models only) will return to the zero position as set in System Default Settings.
Visual VOR Target Settings:
Target Type: Creates a tessellation pattern or stretches a background image across the stimulus screen. Tessellation patterns include checkerboard, stripes, and spheres. Stretched image patterns include firetruck, pilot and airplane, landscape, toy train, yellow airplane, and trains and tracks.
Foreground Color: If the Target Type is a tessellation pattern, this selection will change the color of the primary shape.
Alternate Color: If the Target Type is set to Spheres, this selection will change the color of the even rows of spheres.
Background color: If the Target Type is a tessellation pattern, this selection controls the background color or fill color depending on the tessellation pattern.

Pattern Size: Adjusts size of shape used in the pattern tessellation. As the target size is increased, the number of shapes used in the pattern will decrease. Only available with Target Type of Checkerboard, Stripes, and Spheres.

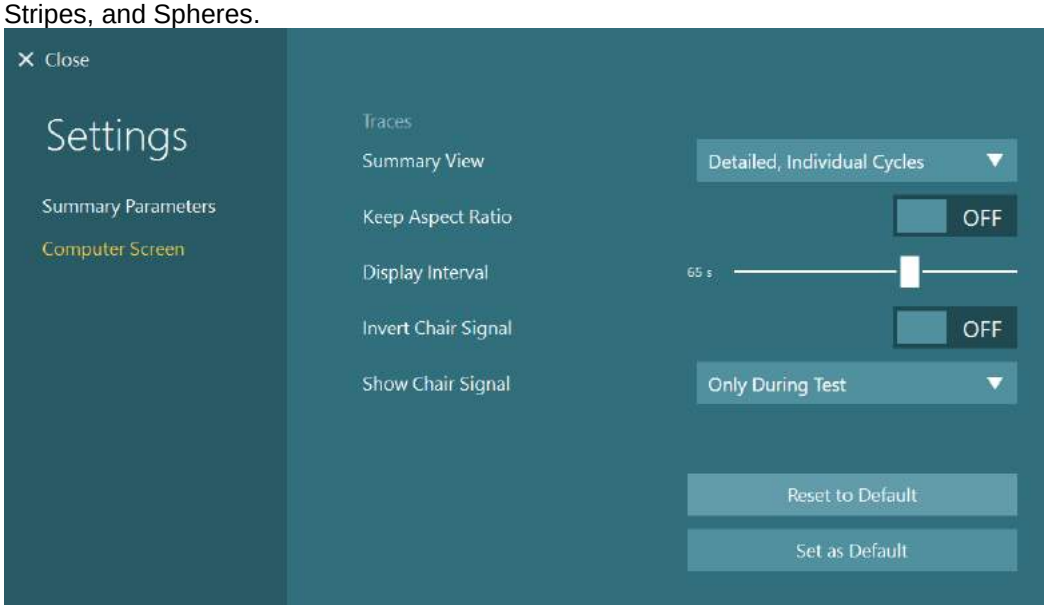


Figure 9.4-14 Visual VOR summary Computer Screen settings

Summary View:

Detailed, individual cycles: Detailed view will draw each cycle individually and fit a line to each cycle

Concise combined cycles: Concise will show every cycle overlapped and a single fitted line is drawn through the concise view.

Keep aspect ratio: This allows the nystagmus to be displayed in a non-compressed form, allowing for easy recognition of the slow phase velocities of nystagmus. Disabling this feature will cause the nystagmus to appear more compressed.

Display Interval: Set the desired length of time (in seconds) to display data in the test window. This feature only becomes available when “Keep aspect ratio” is disabled.

Invert chair signal: Enabling this feature sets the eye trace to overlap the stimulus trace, providing a different view for comparing results. By default the setting is disabled.

Show chair signal: Enabling this feature shows the chair velocity trace. The user can either choose to view the trace all the time or only during the test.

Configuration options through Temporary Settings, Figure 9.4-15 :

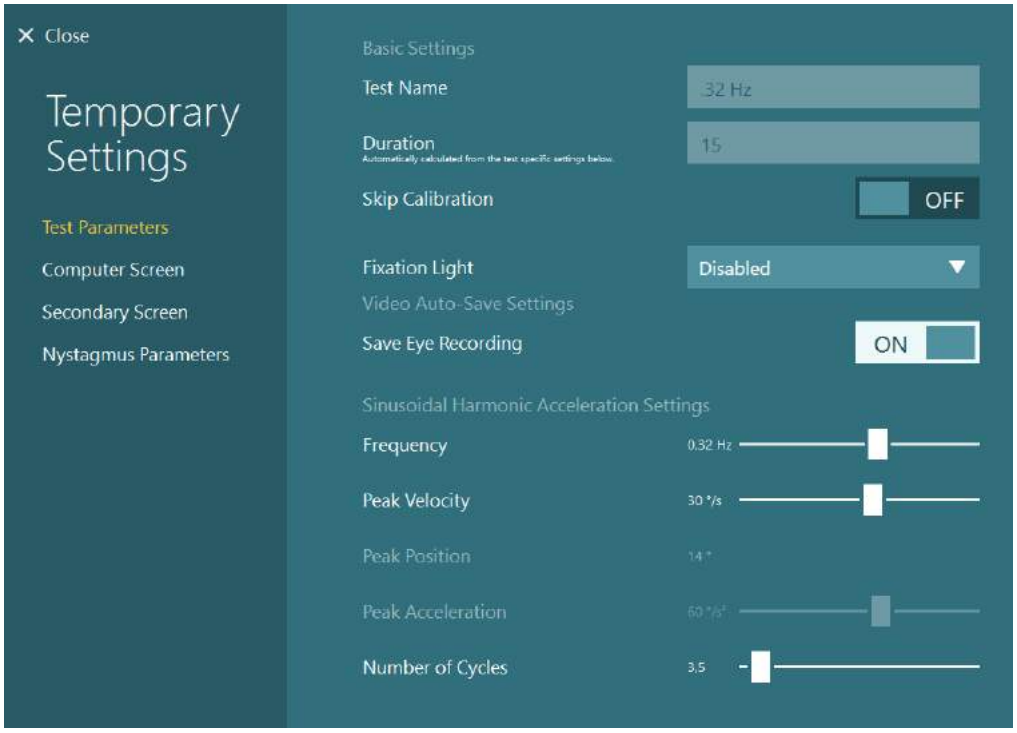


Figure 9.4-15 Visual VOR temporary test parameter settings

Test Name: Name of the test
Duration: Define how long the eye movement is to be recorded and analyzed (in seconds). This value is calculated based on the Frequency, Peak Velocity, and Number of Cycles.
Skip calibration: The user can skip calibration to proceed with the test
Fixation light: Determines when the fixation light in the goggles is displayed. Manual (default) will leave the operator to determine when the fixation light should be displayed. Timed will have the fixation light come on automatically at the designated time.
Save Eye recording: Choice to save eye video recordings.
Frequency: Define the frequency (Hz) of Stimulus (Chair motion side to side). The frequencies available include 0. 01 Hz to 0. 32 Hz with increments of 0. 01 Hz.
Peak Velocity: Define the peak velocity (in dps) the chair will rotate. Range of velocities is 1 to 200 degrees per second.
Peak Position: Define the maximum amplitude of the eye movement (right or left)
Peak acceleration: The maximum rate at which the chair can accelerate (in m/s2). This is automatically calculated based on the sinusoidal harmonic acceleration settings.
Number of cycles: The total number of cycles to be performed for this frequency of chair movement. The initial half cycle is rejected automatically.

9.4.5 Configuring Subjective Visual Vertical test

The summary settings for the subjective visual vertical test will list the name of the test and the names of the five subtests. The name for the subtest will combine the position of the chair and the speed of rotation, provided that these values are only set to one value. If multiple off-axis chair positions are available, then the name of the subtest will not list the position.

Configuration options through protocol management (Permanent settings, Figure 9.4-16):

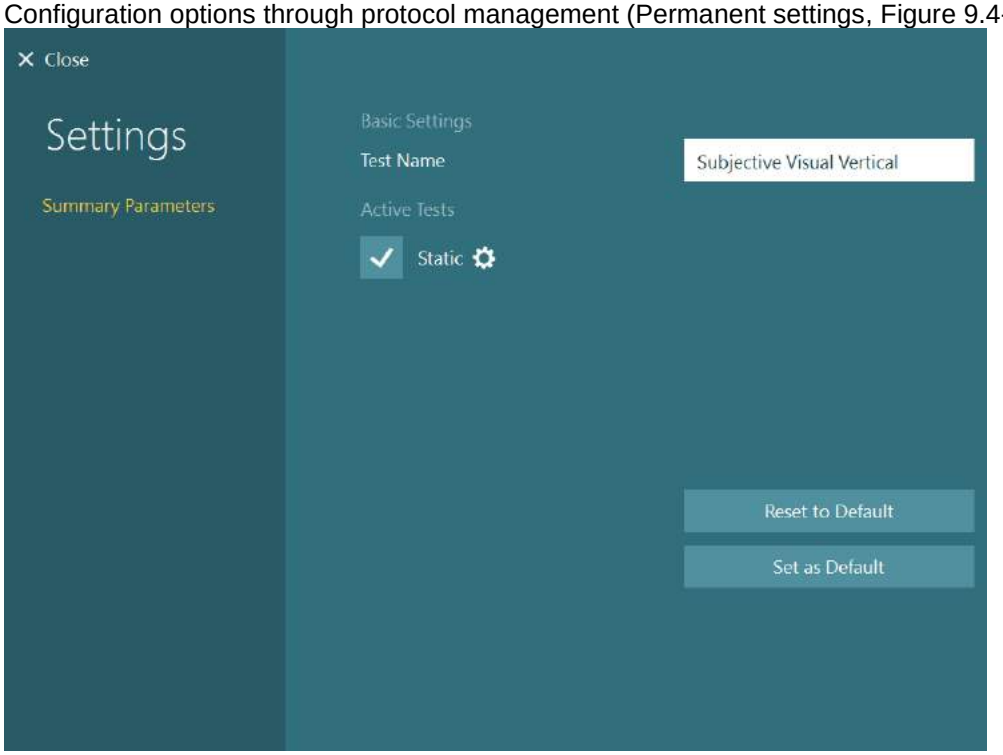


Figure 9.4-16 SVV Summary Settings

Subtest settings through Temporary Settings, Figure 9.4-17:

Figure 9.4-17 SVV Subtest Settings

Test Name: Name of test or subtest
Rotation Direction: Direction the chair is to rotate. Patients typically tolerate spinning forward better than backward, so if the patient is seated left of the center axis, the rotation direction should be set to right. Combination tests where the chair moves to different off-axis positions will only use one direction.
Line Length: Length of the laser line measured in degrees from the center. The default value is 9 degrees.
Maximum Test Time Per Trial: Sets the time limit for each trial of angle and chair offset.
Time Delay Prior to Laser: Time required before the laser will be turned on after moving to the chair offset position in the next trial.
Time Delay Prior to Offset: Time required for the patient to habituate to the chair velocity before moving the patient to the first chair offset value.
Test Velocity: Maximum velocity the patient will spin during the test.
Start Angle: Angle of rotation the laser line will be initially

9.5 Configuring active head rotation tests

9.5.1 Configuring VORTEQ AHR test

Configuration options through protocol management (Permanent settings, Figure 9.5-1):

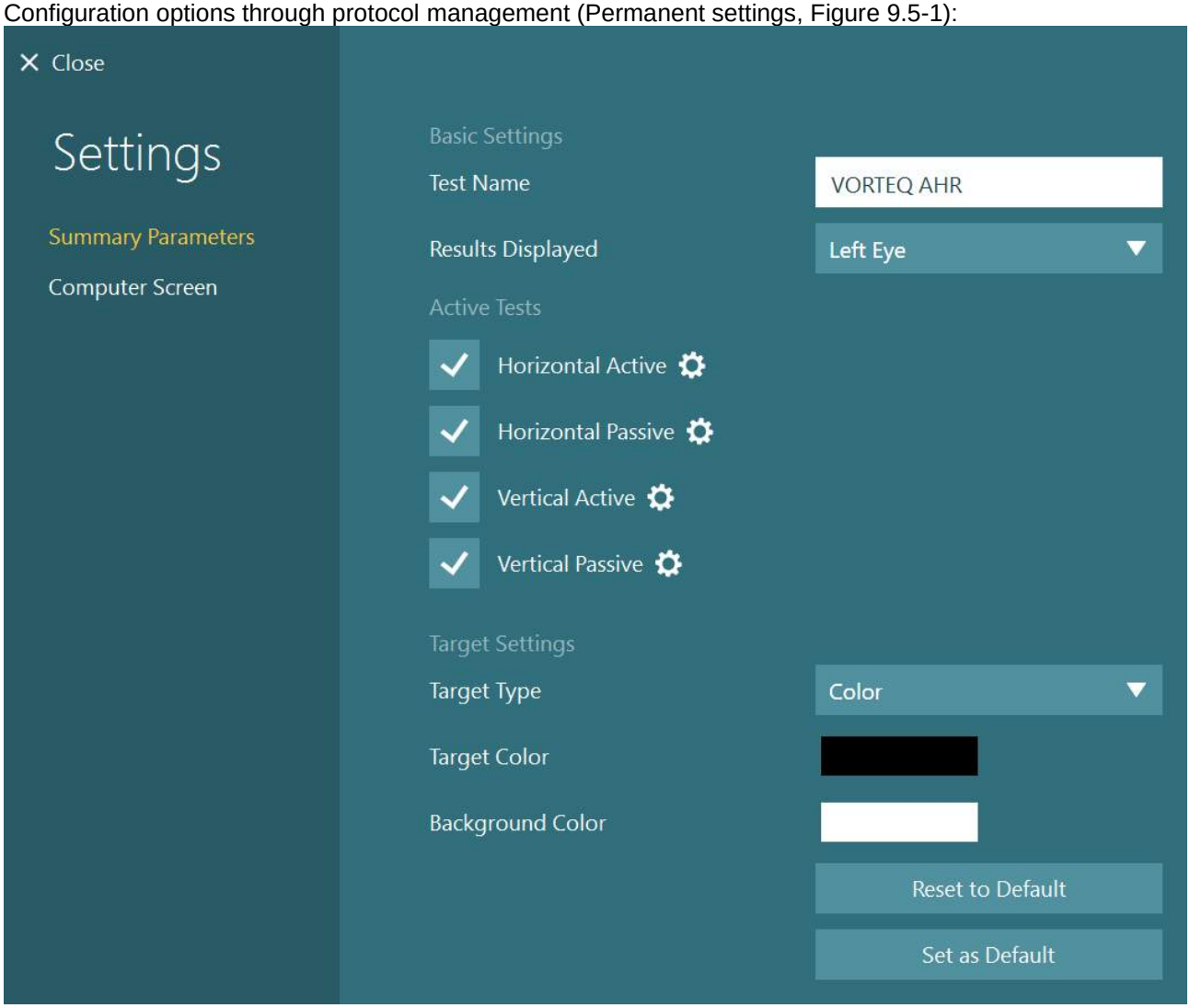


Figure 9.5-1 VORTEQ AHR Summary Properties

Test Name: Name of test or subtest
Results Displayed: Sets the default eye results to be displayed, which may be Left Eye or Right Eye.
Active Tests: This area lists the active and passive tests for the horizontal and vertical directions. The gear icon will access the subtest properties.
Target Type: Type of target displayed on the TV or projection screen, either a circle of a solid color or an image file. The size of the target is set by the calibration target size.
Target C / Target Image: Sets the Target color of the circle target or the desired target image to be used as the focus point for the VORTEQ AHR tests on the TV or projector stimulus. This field is not available with the Digital Light Bar or Laser and Drum stimulus.
Background Color: Selects the color used for the background of the TV or projector stimulus. This field is not available with the Digital Light Bar or Laser and Drum stimulus.

Configuration options through Temporary settings, Figure 9.5-2:

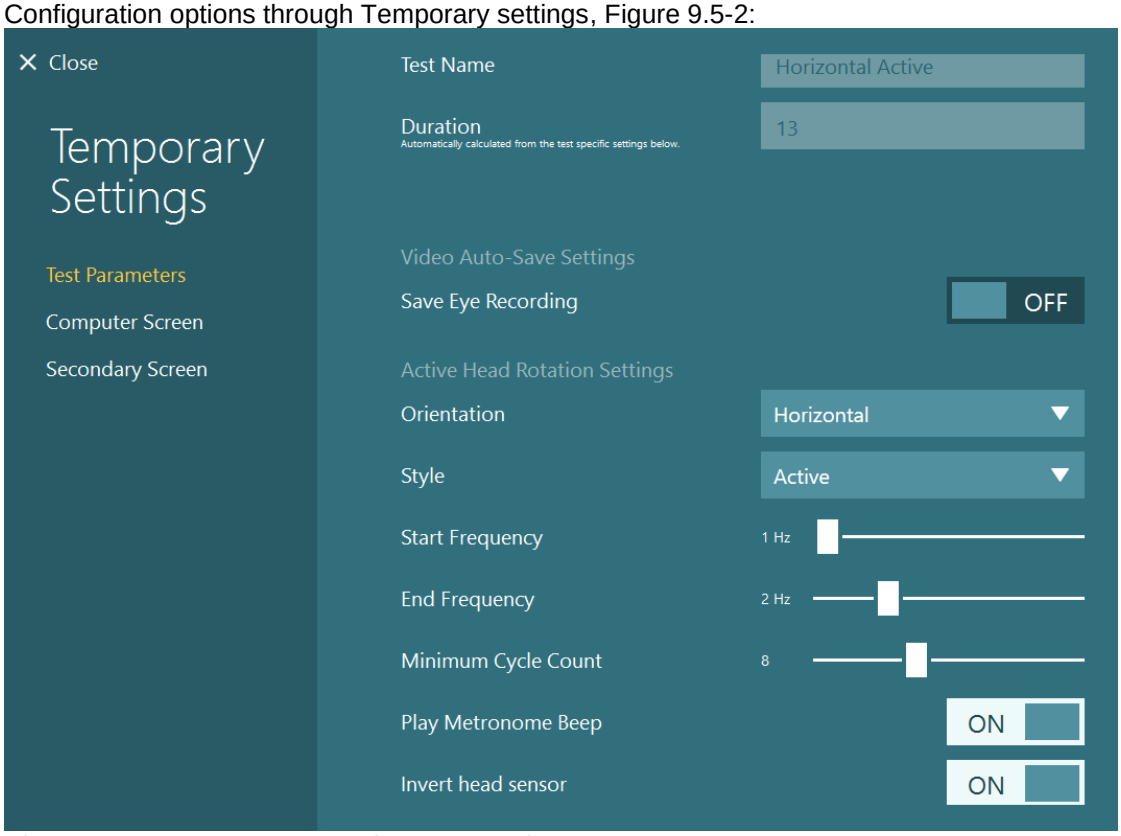


Figure 9.5-2 VORTEQ AHR Subtest Properties

Duration: Length of time the subtest will run calculated on the number of minimum cycles and frequencies tested rounded up to the nearest second. This time does not include the practice time of five seconds at the start of the test for the patient to practice the head shake.
Save Eye Recording: If set the software will automatically keep the eye and room camera videos after the test is reviewed. By default, this setting is off, therefore the software will delete the eye and room camera videos
Orientation: Sets the direction the test will be performed.
Style: Sets the method the test is intended to be performed. If the style is set to Active, the test is intended to be performed by the patient shaking his / her head to the metronome beep. If the style is set to Passive, the test is intended to be performed by the operator moving the patient's head back and forth.
Start Frequency: This is the initial frequency for the metronome beep.
End Frequency: This is the final frequency for the metronome beep. The software will start the test using the start frequency value for the number of cycles defined by the minimum cycle count value, and then increase the frequency by one hertz and for the minimum cycle count until the end frequency is reached.
Minimum Cycle Count: This is the number of cycles the patient will have to shake his / her head at each frequency.
Play Metronome Beep: By default, this value is set to ON to play an audible beep when the patient is to swing his / her head to the side.
Invert head sensor: During the VORTEQ AHR test, the head direction moves in the opposite direction to the eye position. By setting this value to ON (the default value) the head sensor trace is vertically flipped to align the trace to the eye position movement trace.

9.5.2 Configuring dynamic visual acuity test

Configuration options through protocol management (Permanent settings, Figure 9.5-3):

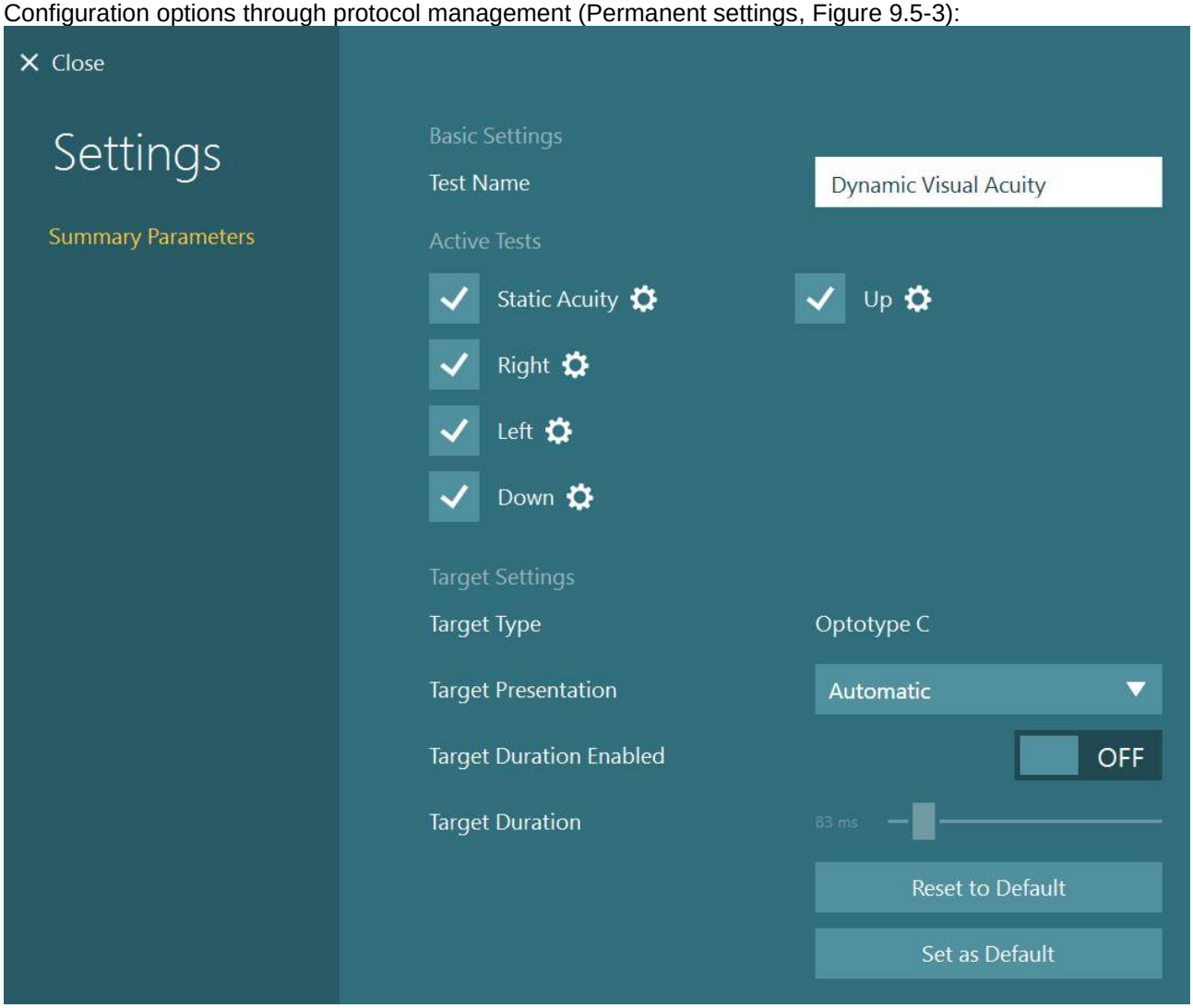


Figure 9.5-3 DVA Summary Properties

Test Name: Name of test or subtest
Active Tests: This area lists the Static Acuity test and four direction subtests. The gear icon will access the subtest properties.
Duration: Define how long the eye movement is to be recorded and analyzed (in seconds).
Target Type: Method of displaying the optotype used in testing, currently limited to Optotype C where a C character is displayed in one of four orientations during the test
Target Presentation: Determines the method of presenting the optotype – Automatic will increase or decrease the optotype during the test based on the patient's response, Manual will require the operator to adjust the size of the optotype based on the patient's response
Target Duration Enabled and Target Duration: If turned ON, the optotype will remain visible for the time set in the Target Duration field after the patient's head velocity decreases from the required velocity for the direction. If left OFF, the optotype will be visible only during the time the patient's head velocity exceeds the required velocity for the direction.

Configuration options through Temporary settings, Figure 9.5-4:

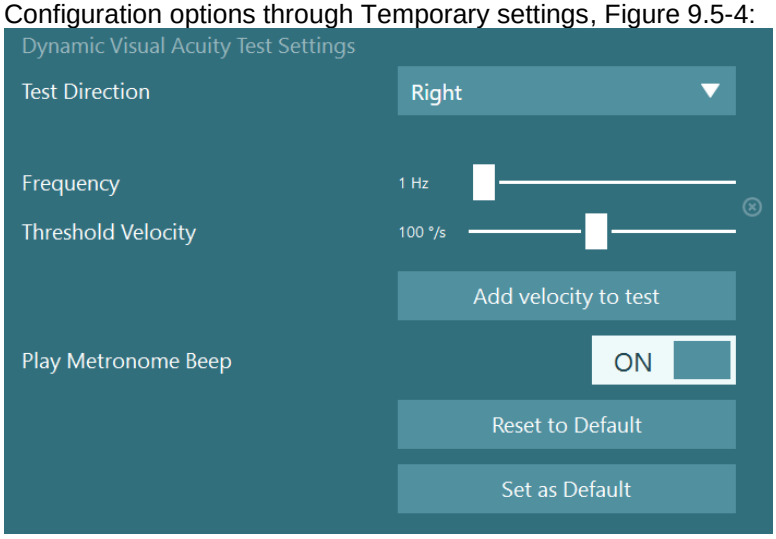


Figure 9.5-4 DVA Subtest Properties

Test Direction: Selects the direction the patient will have to achieve the required velocity. The name of the subtest will be the same as the test direction selected.
Frequency: Frequency the metronome will beep. By default, this is 1 Hz, though it can be set up to 5 Hz.
Threshold Velocity: Velocity needed for the patient to achieve in the test direction before the optotype is displayed.
Play Metronome Beep: By default, the metronome beep will be played at the desired frequency. If this is set to OFF, then the metronome beep will not be played during the test.

9.6 Configuring video head impulse tests

Configuration options through protocol management (Permanent settings, Figure 9.6-1):

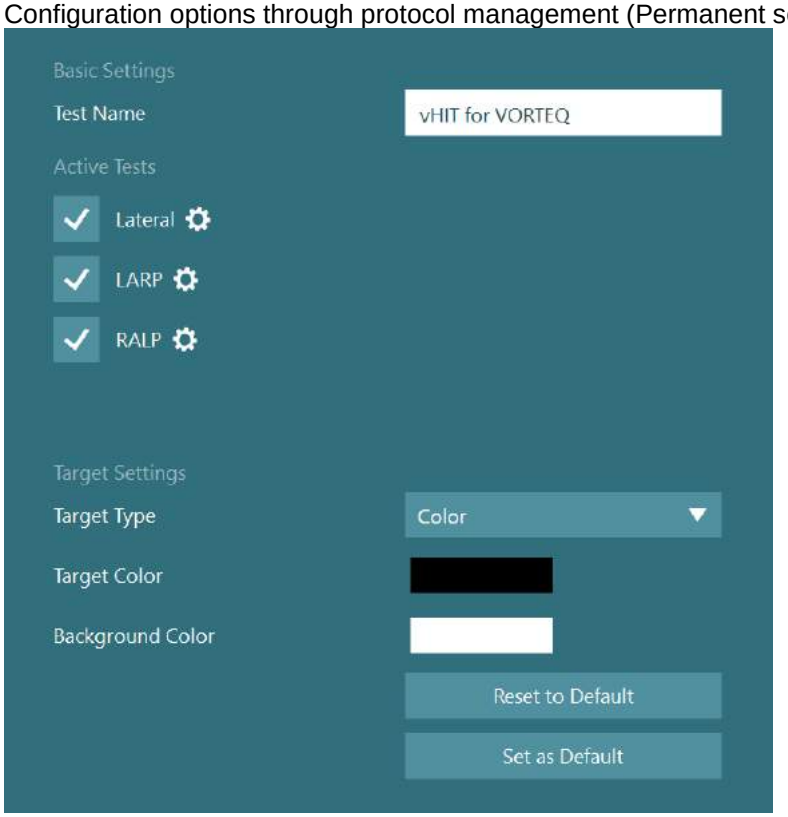


Figure 9.6-1 vHIT for VORTEQ Test Properties

Test Name: Name of test or subtest
Active Tests: This area lists the video head impulse tests for Lateral, LARP, and RALP planes.
Target Type: Method of displaying the stimulus on a TV or projector. This can be color for a solid background color with a dot in the center or image for a specific image.
Target Color: If the target type is set to color, then the target color refers to the color of the solid dot in the center of the screen for fixation. The default color is set to black.
Target Image: If the target type is set to image, then the target image is the selection of the stimulus image rendered instead of a solid colored circle. The target image is used often with pediatric patients.
Background Color: This is the color of the stimulus background. The default color is set to white. With a white background the pupils constrict more due to the extra ambient light. This results in a pupil that can be more easily tracked in smaller viewing windows required to achieve the higher temporal rates (up to 250Hz) in vHIT tests.

Configuration options through Temporary Settings, Figure 9.6-2:

Figure 9.6-2 Video Head Impulse subtest properties

Skip Calibration: If set, the software will not set the Calibration button as the default action if a valid calibration has not yet been performed. By default this setting is off.
Save Eye Recording: If set the software will automatically keep the eye and room camera videos after the test is reviewed. By default this setting is off, therefore the software will delete the eye and room camera videos
Head Impulse Count: This setting is the number of head impulses that must be performed successfully in each direction and is configurable if the Impulse Limit setting is set to on.
Impulse Limit: This setting will automatically end the test after the Head Impulse Count has been achieved in both directions.
Frame Rate: The test's sample rate is listed here. This is not configurable by the end user. This value is seen in vHIT for VORTEQ subtests.

In addition to these settings are the analysis properties (Figure 9.6-3) for the video head impulse subtests.

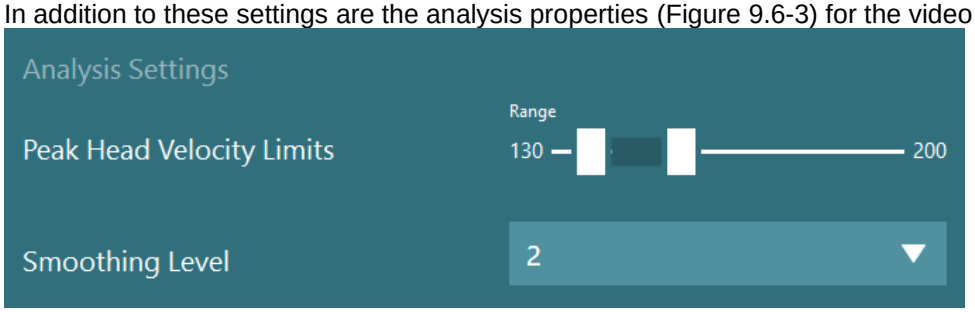


Figure 9.6-3 Video Head Impulse subtest analysis properties

Peak Head Velocity Limits: These settings define the size of the swoosh pattern expected for the head impulse. The lower limit is displayed to the left of the slider, and the upper limit is displayed to the right of the slider. Expanding this range will allow more head impulses to be treated as acceptable by the software.
Smoothing Level: This setting will reduce the noise seen in the data traces. The smoothing level indicates the size of the window used to smooth the data – larger window sizes will smooth the data greater. The default value is two. Setting the smoothing level to zero will bypass smoothing. This setting is available in vHIT for VORTEQ tests.
Reject Noisy Eye Velocity: By enabling this option, the software will throw out head impulses that meet the swoosh criteria but have excessive variation in the eye or head velocity trace. By default this values is set to ON. This setting is available in vHIT for EyeSeeCam tests.

9.7 Configuring torsion tests

9.7.1 Configuring ocular counter roll test

Configuration options through Temporary Settings, Figure 9.7-1:

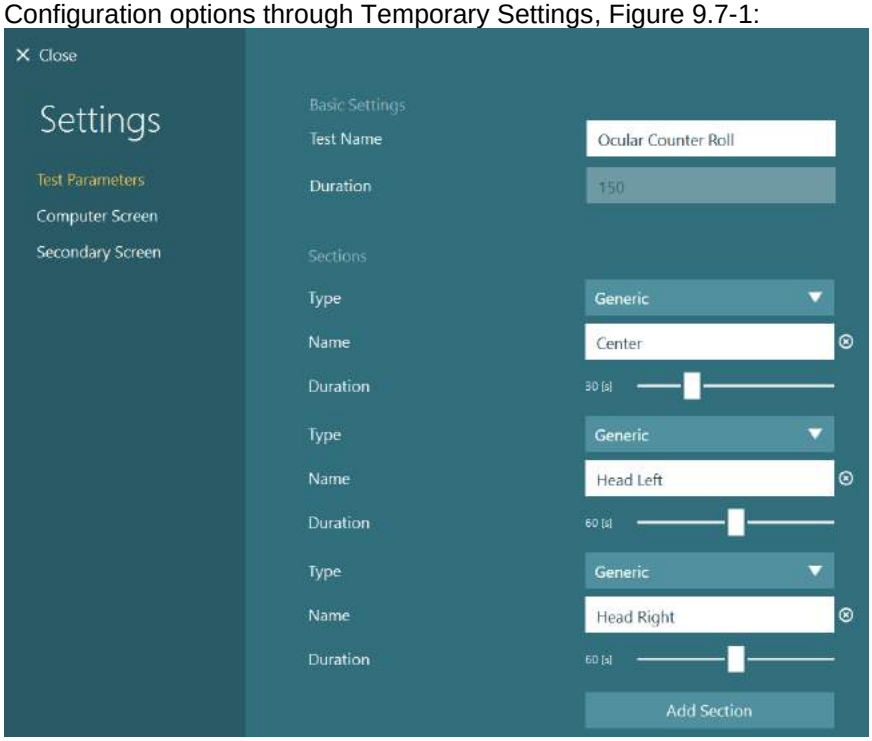


Figure 9.7-1 Ocular Counter Roll subtest properties

Test Name: Name of subtest
Duration: Define how long the eye movement is to be recorded and analyzed (in seconds).
Section Type: Method used to define the section style. This is set as Generic.
Section Name: Name given to the specific section. Clicking on the x button beside the name will delete this section's name
Section Duration: Amount of time set to perform the specific section (in seconds)

10 Suggested threshold values

The VisualEyes™ system software suite has suggested threshold tables. The values in these tables are suggested threshold values as published from the textbook of Gary Jacobson and Neil Shepard, Balance Function Assessment and Management 2nd edition unless otherwise referenced. Both VNG and ENG have the same suggested threshold values. ENG uses electrodes for recording instead of video.

NOTICE It is recommended that the clinician collects a sample of data from the clinic, using the customized protocols and settings and document any differences to the findings in these tables. If the clinic decides to use custom test thresholds, the test thresholds can be updated to reflect the clinic settings.

10.1 Updating test thresholds

- Tap the **Configuration** option from main screen
- Select **System Default Settings**
- Choose **Threshold Levels** from the list in the side panel menu
- A disclaimer will appear (Figure 10.1-1), prior to allowing access to the suggested threshold values. Click **Ok** to accept the disclaimer and move onto the threshold data tables.

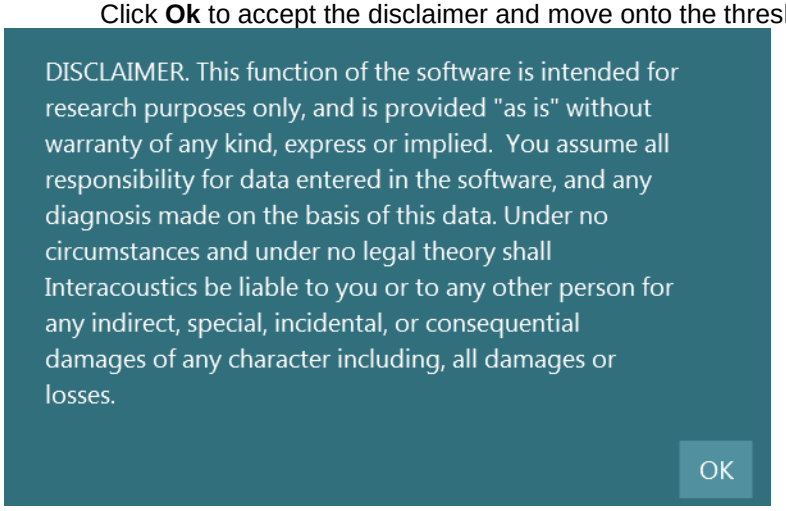


Figure 10.1-1 Disclaimer for suggested threshold values

	Changes can be made to the threshold data by entering the new value(s) into the appropriate fields. When entering the threshold values into the 5-6 age group, clicking on the copy values button to copy all of the values to the remaining age groups.

	Use the plus button to add a new threshold level. Use the cross button to delete a threshold level.

An **Undo** button is available to restore all values back to the values prior editing. To save the new laboratory specific threshold data for use with all patients (new or previously tested), click the **Save** button. To reload the default suggested threshold data, click the **Reset all Thresholds to Default** button. The user can also **Import** or **Export** threshold data based on the requirements.

10.2 Nystagmus tests

The average slow phase velocity (a. SPV) bar graph displays the a. SPV of 3 or more beats found within the peak response time period defined in the test properties. The Max Slowphase Velocity value of 6 degrees per second is treated as within threshold limits and will be displayed as a white bar. Values exceeding this threshold will have the threshold value portion in white and the remaining displayed in grey (refer Figure 10.2-1 and Figure 10.2-2).

NOTICE Advanced Dix Hallpike and Lateral Head Roll tests are standard nystagmus detection tests and use the same threshold value suggested in nystagmus test.

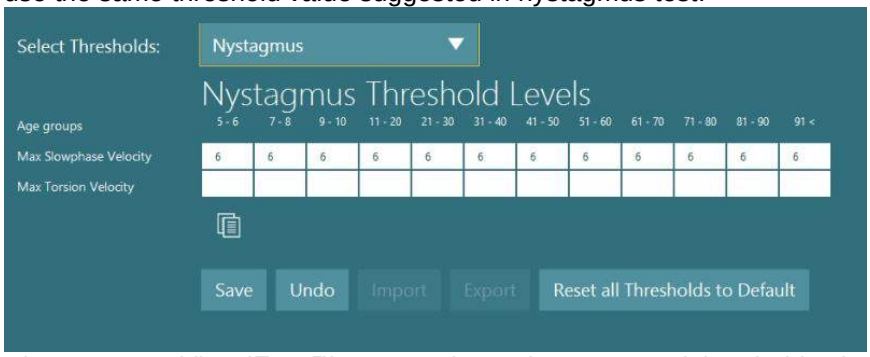


Figure 10.2-1: VisualEyes™ system shows the suggested threshold values for Nystagmus test

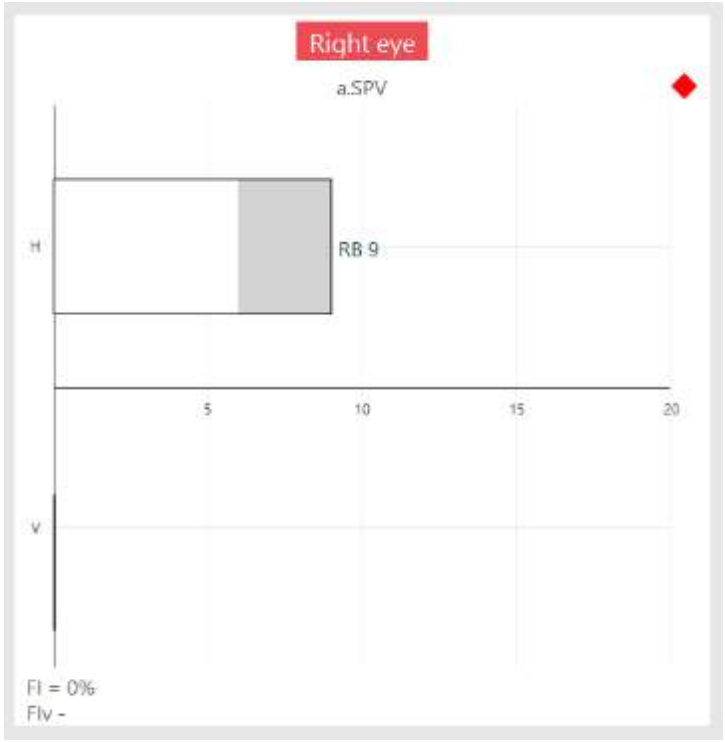


Figure 10.2-2 Average Slow Phase Velocity bar graph with 6 dps threshold

10.3 Caloric tests

Unilateral Weakness and Directional Preponderance are calculated using Jongkees formula. Values can be calculated using the direct values or compensated values that are adjusted with the nystagmus value from the caloric spontaneous nystagmus subtest.

$$Total\ Eye\ Speed = Left\ Cool + Left\ Warm + Right\ Cool + Right\ Warm$$

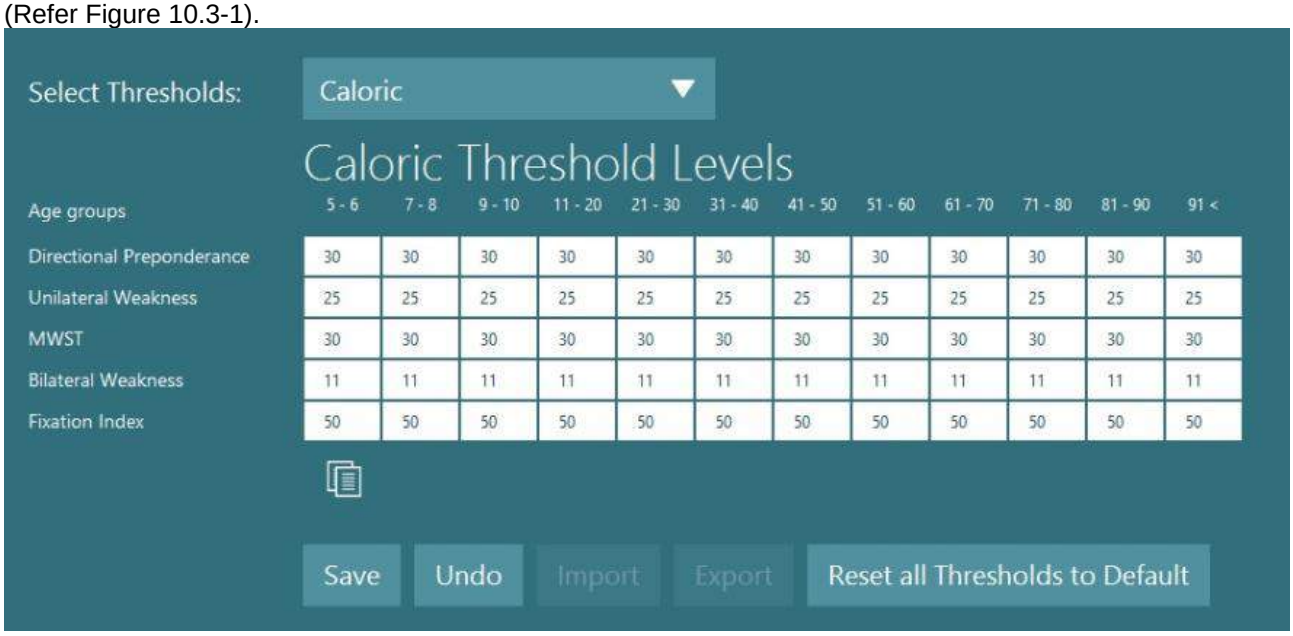
$$Unilateral\ Weakness\ (UW) = \frac{(Left\ Cool + Left\ Warm) - (Right\ Cool + Right\ Warm)}{Total\ Eye\ Speed} \times 100\%$$

$$Directional\ Preponderance\ (DP) = \frac{(Left\ Cool + Right\ Warm) - (Right\ Cool + Left\ Warm)}{Total\ Eye\ Speed} \times 100\%$$

$$Monothermal\ Warm\ Screening\ Test\ (MWST) = \frac{Right\ Warm - Left\ Warm}{Right\ Warm + Left\ Warm} \times 100\%$$

If the caloric test has been performed with only the warm caloric tests, then the software will use the Monothermal Warm Screening Test (MWST) threshold value to measure the patient's weakness. Directional Preponderance is not calculated in the MWST.

If the cool caloric tests are performed the software will use the Unilateral Weakness threshold value. Unilateral weakness is 25%. Directional Preponderance is 30%. Bilateral Weakness is defined if the total slow phase velocity is less than 11 degrees per second. The Fixation Index threshold is considered 50%. Patients with a Fixation Index higher than 50% is said to have a failure to suppress nystagmus with fixation (Refer Figure 10.3-1).



Age groups	5 - 6	7 - 8	9 - 10	11 - 20	21 - 30	31 - 40	41 - 50	51 - 60	61 - 70	71 - 80	81 - 90	91 <
Directional Preponderance	30	30	30	30	30	30	30	30	30	30	30	30
Unilateral Weakness	25	25	25	25	25	25	25	25	25	25	25	25
MWST	30	30	30	30	30	30	30	30	30	30	30	30
Bilateral Weakness	11	11	11	11	11	11	11	11	11	11	11	11
Fixation Index	50	50	50	50	50	50	50	50	50	50	50	50

Figure 10.3-1 VisualEyes™ system shows the suggested threshold values for caloric test

10.4 Oculomotor tests:

The suggested threshold levels for oculomotor test covers three subtests optokinetic test, smooth pursuit test and saccade test. The individual threshold values for each test is described below.

10.4.1 Optokinetic tests

The Optokinetic test measures nystagmus and displays gain and symmetry. The analysis of the optokinetic test calculates the average velocity of the movement during the peak response window (a. SPV) and compares this velocity with the stimulus velocity. The relation of velocity values is called gain.

$$Gain = \frac{a.SPV}{Stimulus\ Velocity}$$

$$Asymmetry = \frac{Left\ Moving\ Gain - Right\ Moving\ Gain}{Left\ Moving\ Gain + Right\ Moving\ Gain}$$

Data acquired in the first three seconds of a measurement is not included in the analysis. The difference between the 2 eyes is the symmetry value. When shown in the symmetry chart, the asymmetry will be displayed as a percentage, though the value in the Threshold values table will be a decimal value.
The default OPK Minimum Gain is 0. 60 and the OPK Maximum Asymmetry is 0. 25 (Refer Figure 10.4-1).

Age groups	5 - 6	7 - 8	9 - 10	11 - 20	21 - 30	31 - 40	41 - 50	51 - 60	61 - 70	71 - 80	81 - 90	91 <
OPK Minimum Gain	0,60	0,60	0,60	0,60	0,60	0,60	0,60	0,60	0,60	0,60	0,60	0,60
OPK Maximum Asymmetry	0,25	0,25	0,25	0,25	0,25	0,25	0,25	0,25	0,25	0,25	0,25	0,25

Figure 10.4-1 VisualEyes™ system shows the suggested threshold values for Optokinetic test

10.4.2 Smooth pursuit tests

Gain is measured for each frequency. For each frequency between 0. 1 Hz and 0. 5 Hz, the average gain value for all cycles for the selected frequency is compared to the minimum gain value in the table of thresholds. If the average gain value is less than the minimum gain value specified in the table then the test will be labeled as outside threshold. Smooth Pursuit threshold data varies on the patient's age (Refer Figure 10.4-2).

Age groups	5 - 6	7 - 8	9 - 10	11 - 20	21 - 30	31 - 40	41 - 50	51 - 60	61 - 70	71 - 80	81 - 90	91 <
Smooth Pursuit Min Gain 0.1 Hz	0.66	0.66	0.66	0.66	0.66	0.66	0.66	0.66	0.53	0.40	0.40	0.40
Smooth Pursuit Min Gain 0.2 Hz	0.74	0.74	0.74	0.74	0.74	0.74	0.74	0.74	0.70	0.68	0.68	0.68
Smooth Pursuit Min Gain 0.3 Hz	0.69	0.69	0.69	0.69	0.69	0.69	0.69	0.69	0.61	0.61	0.61	0.61
Smooth Pursuit Min Gain 0.4 Hz	0.64	0.64	0.64	0.64	0.64	0.64	0.64	0.64	0.49	0.51	0.51	0.51
Smooth Pursuit Min Gain 0.5 Hz	0.57	0.57	0.57	0.57	0.57	0.57	0.57	0.57	0.36	0.41	0.41	0.41

Figure 10.4-2 Pursuit threshold values

10.4.3 Saccade tests

Saccade tests measure three values: velocity, latency, and accuracy. Saccade thresholds do vary with patient age. To create the velocity graph, minimum velocities at velocities between 5 degrees and 30 degrees are used to create a velocity profile (Refer Figure 10.4-3).

Age groups	5 - 6	7 - 8	9 - 10	11 - 20	21 - 30	31 - 40	41 - 50	51 - 60	61 - 70	71 - 80	81 - 90	91 <
Saccade Max Accuracy	137	137	137	137	137	137	137	137	134	121	121	121
Saccade Max Latency	260	260	260	260	260	260	260	260	260	270	270	270
Saccade Min Accuracy	77	77	77	77	77	77	77	77	80	85	85	85
Saccade Min Velocity 5°	0	0	0	0	0	0	0	0	0	0	0	0
Saccade Min Velocity 10°	191	191	191	191	191	191	191	191	191	191	191	191
Saccade Min Velocity 15°	249	249	249	249	249	249	249	249	249	249	249	249
Saccade Min Velocity 20°	257	257	257	257	257	257	257	257	257	257	257	257
Saccade Min Velocity 25°	315	315	315	315	315	315	315	315	315	315	315	315
Saccade Min Velocity 30°	329	329	329	329	329	329	329	329	329	329	329	329

Figure 10.4-3 Saccade threshold values

10.5 Saccadometry tests

Saccadometry tests measure the three values in saccades of velocity, latency, and accuracy at each target deflection. The software has thresholds for every 5-degree deflection up to 30 degrees. Saccade thresholds do vary with patient age. To create the velocity graph, minimum velocities at velocities between 5 degrees and 30 degrees are used to create a velocity profile. Thresholds are separated for prosaccades (patient looking at the target, Refer figure XXXX). and antisaccades (patient looking at the opposite location of the target). For antisaccades, there are no published thresholds values available. Hence, no suggested threshold values are provided in the *VisualEyes™ system.* However, you can collect and enter your own normative thresholds to customize your reference values (Refer Figure 10.5-1 and Figure 10.5-2).

Prosaccade Threshold	**5°**	**10°**	**15°**	**20°**	**25°**	**30°**
Saccade Max Accuracy	137	137	137	137	137	137
Saccade Min Accuracy	85	85	85	85	85	85
Saccade Max Latency	270	270	270	270	270	270
Saccade Min Velocity	0	191	249	257	315	329

Figure 10.5-1 Summary of prosaccade threshold values from 5° to 30° deflection

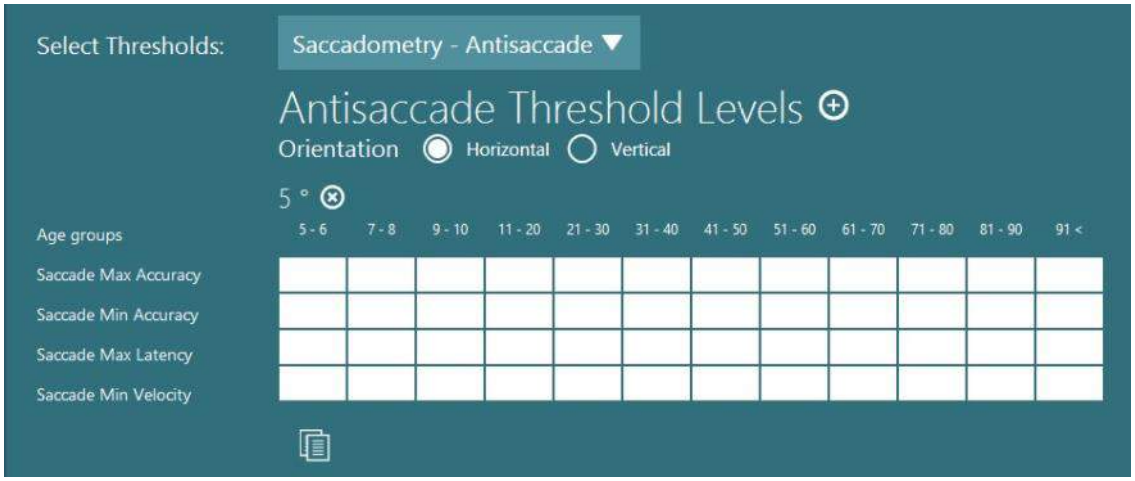


Figure 10.5-2 VisualEyes™ system shows no suggested threshold values for Antisaccade test for 10° deflection

10.6 Step Velocity tests

Step Velocity tests display threshold values for gain, time constants, and time constant asymmetry. The threshold values are applicable for all ages (Refer Figure 10.6-1).

Reference:
Step Velocity threshold values referenced from the Leen Maes et al. Publication: Normative Data and Test-Retest Reliability of the Sinusoidal Harmonic Acceleration test, Pseudorandom Rotation Test and Step Velocity Test. Journal of Vestibular Research 14 (2004) 153–204.

Threshold	**50°/s**	**100°/s**	**180°/s**
Minimum Gain	0. 31	0. 31	0. 31
Maximum Gain	1. 08	1. 06	1. 03
Minimum Time Constant	5	5	5
Maximum Time Constant	22	21	21
Maximum Asymmetry	0. 29	0. 29	0. 29

Figure 10.6-1 Summary of suggested threshold values for Step Velocity test for all age groups.

10.7 Sinusoidal harmonic acceleration and VOR suppression tests

For Sinusoidal harmonic acceleration (SHA) tests, threhold values for gain, phase, and symmetry are displayed. There are values for both discrete velocity tests (based on 60 deg/sec for all frequencies) and variable velocity (increased velocity with decreased frequency). See the following references below for threshold values (Refer Figure 10.7-1). The threshold values are the same for all ages. VOR suppression tests will compare the patient's gain with fixation to the corresponding VOR test without fixation to calculate the VOR Gain reduction value according to the following formula:

$$VOR\ Gain\ Reduction = \frac{VOR\ Gain_{without\ fixation} - VOR\ Gain_{with\ fixation}}{VOR\ Gain_{without\ fixation}}$$

All values are listed as decimals though the analysis graphs for gain and reduction will display these values as percentages.

Reference:
SHA Variable or Discrete Velocity threshold values referenced from Henry, D. F. publication: Closed-Loop, Sinusoidal Harmonic Acceleration, and Active Head Rotation Tests Norms and Reliability. Otolaryngol Head and Neck Surg. 1553; 65: 531-43.

Threshold	0. 01 Hz	0. 02 Hz	0. 04 Hz	0. 08 Hz	0. 16 Hz	0. 32 Hz	0. 64 Hz
Minimum Gain	0. 28	0. 27	0. 36	0. 43	0. 36	0. 37	
Maximum Gain	0. 68	0. 83	0. 80	0. 87	0. 92	1. 00	
Minimum Phase	32	15	6	-3	-3	-6	
Maximum Phase	59	36	24	17	9	8	
Minimum Symmetry	-0. 26	-0. 22	-0. 25	-0. 18	-0. 20		
Maximum Symmetry	0. 34	0. 26	0. 35	0. 30	0. 36		
Minimum VOR Gain Reduction			0. 89	0. 82	0. 77	0. 82	0. 74

Figure 10.7-1 Summary of suggested threshold values for SHA test for all age groups

10.8 Active Head Rotation (AHR) tests

Active Head Rotation supports threshold values for minimum and maximum gain, phase, and symmetry for frequencies between 1 and 5 Hz. For AHR tests, there are no published threshold values available. Hence, no suggested threshold values are provided in the VisualEyes™ system. However, you can collect and enter your own normative thresholds to customize your reference values (Refer Figure 10.8-1).

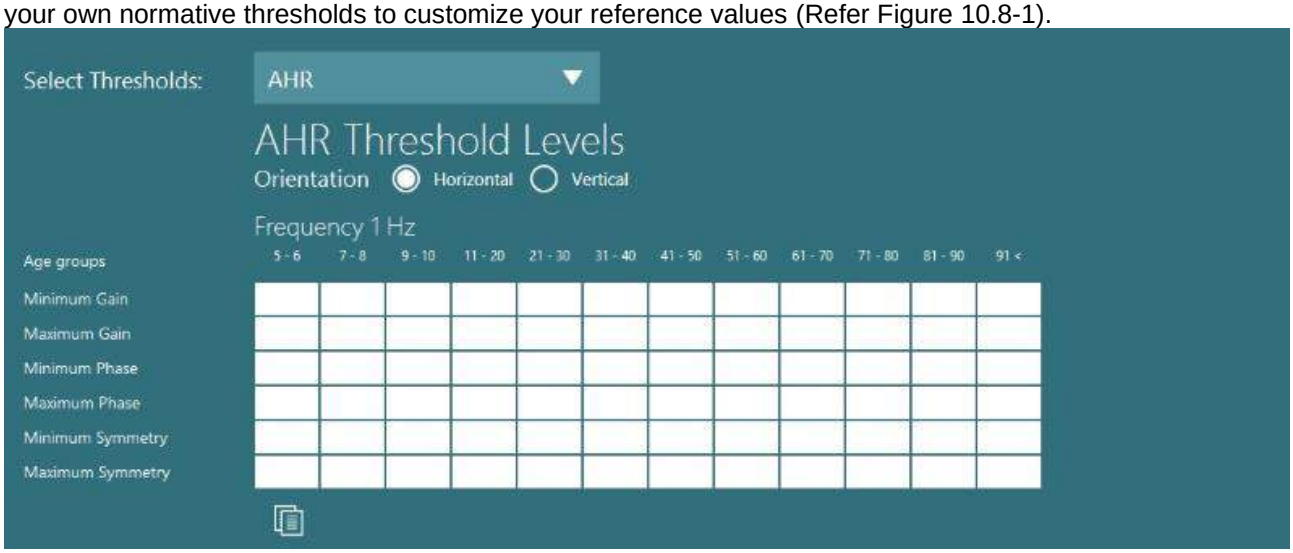


Figure 10.8-1 VisualEyes™ system shows no suggested threshold values for AHR test for the frequency of 1 Hz

10.9 Dynamic Visual Acuity (DVA) tests

Dynamic Visual Acuity thresholds are applied to the patient's static visual acuity (SVA). The relative threshold (RT) which is the same for all ages is applied to the patient's static acuity logMAR value to determine the dynamic visual acuity value at that velocity. If the velocity is not one of the listed values, the relative threshold at that velocity is averaged linearly between the neighboring relative thresholds. For DVA tests, there are no published thresholds available. Hence, no suggested threshold values are provided in the VisualEyes™ system. However, you can collect and enter your own normative thresholds to customize your reference values (Refer Figure 10.9-1).

Figure 10.9-1 VisualEyes™ system shows no suggested threshold values for DVA test

$$DVA_{velocity} = SVA + Velocity \times \frac{RT_{upper\ velocity} - RT_{lower\ velocity}}{Velocity_{upper} - Velocity_{lower}}$$

So the DVA at 150 degrees per second with a patient's static visual acuity of -0. 1 would be calculated as follows:

$$DVA_{150} = -0.1 + 150 \times \frac{0.40_{200} - 0.28_{140}}{200_{200} - 140_{140}} = 0.2_{150}$$

10.10 Video Head Impulse Tests (vHIT) for EyeSeeCam

Video Head Impulse Tests using the EyeSeeCam goggles measure the gain of the eye position with the head position and calculate the regression line for the head impulses. The threshold values are applicable for all ages. For vHIT tests, there are no published threshold values available. Hence, no suggested threshold values are provided in the VisualEyes™ system. However, you can collect and enter your own normative thresholds to customize your reference values (Refer Figure 10.10-1).

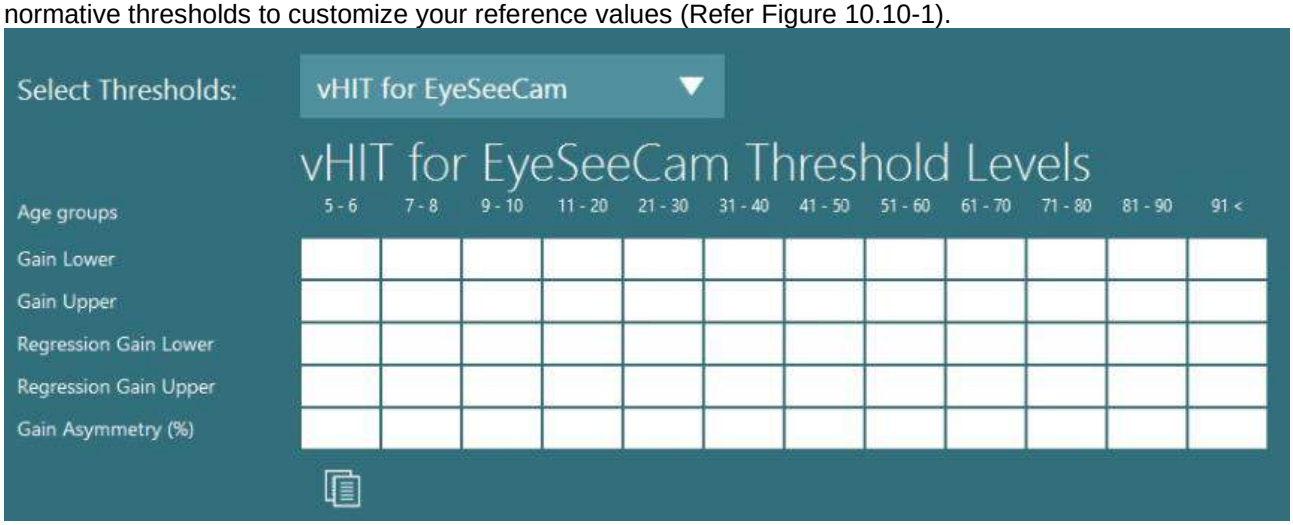


Figure 10.10-1 VisualEyes™ system shows no suggested threshold values for EyeSeeCam vHIT test

11 Patient report

11.1 Write report editor

A written report can be created within the VisualEyes™ 515/525 software. This is a word processor that saves the created document in the patient review sessions for later viewing or printing. The write report editor can be accessed from the session review screen by selecting ‘Write report’ from the Session Review screen (Figure 11.1-1).

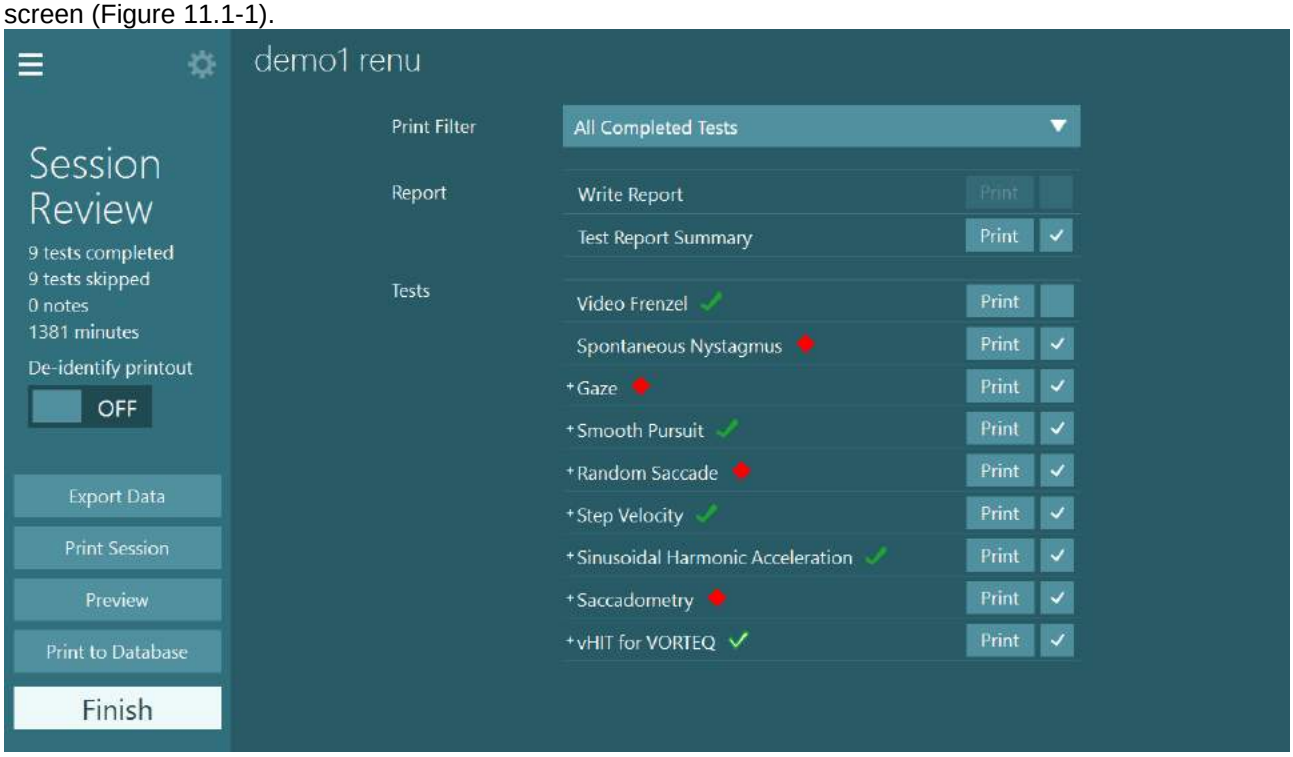


Figure 11.1-1 Write Report feature

11.2 Text styles

The report can be written as per a normal word processor. There are options within the left menu panel in the report editor (Figure 11.3-1) to change the font, size and alignment of the text, as well as the font weight of bold, italics, and underline.

11.3 Templates

The templates section (Figure 11.3-1) gives the operator an option to customize the patient report using patient information from the OtoAccess® database, keywords, and findings templates. Creating a template allows the user to then access the predefined template from the Templates button to use in the report. Using a predefined template will erase the currently written report and replace it with the template. Use the Manage Templates item from the Templates button to enter the Template Editor (Figure 11.3-2).

Figure 11.3-1 Manage templates from the templates menu

Figure 11.3-2 Template Editor screen

With a new installation of VisualEyes™ 515/525, there are four predefined templates included, Normal vHIT and VNG, Normal vHIT detailed, Normal VNG and Normal VNG Detailed. To view these templates, select one of the templates from the pull-down box. Otherwise click on the New template button (Figure 11.3-3) to create a report template.

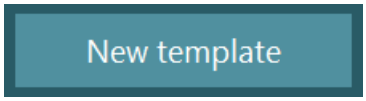


Figure 11.3-3 New template button

By default,t the name of the template will be New Template 1. This name can be changed at the top of the screen. The report template is then populated with text and can have both keywords and findings added to the template. Select the position in the template report to add the keyword, then select the keyword on the right side of the screen. Click on the add keyword button to add the keyword to the template text. The keyword will be shown with double arrows around the keyword text, e. g. <<Client_FirstName>>. To add a specific finding, click on the Show Findings option in the upper right, then select the appropriate finding from the list and add it with the add finding button (Figure 11.3-4).

Figure 11.3-4 Add keyword or finding button

Once the template text has been written, tap the Save template button (Figure 11.3-5).

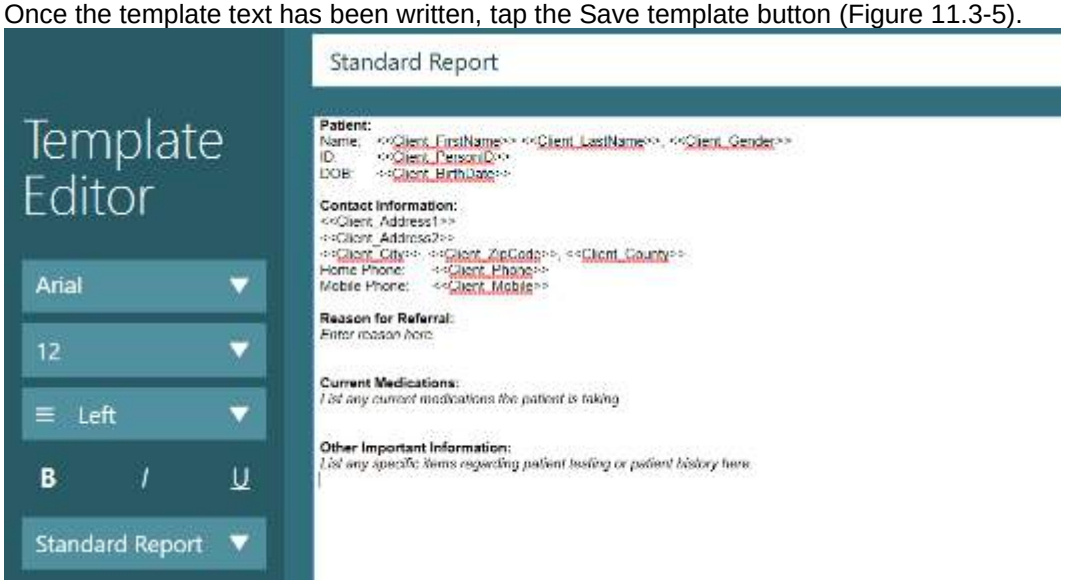


Figure 11.3-5 Template Editor displaying sample template

Report templates can be imported or exported to template files using the Import/Export button. A dialog will be shown for selecting a report template to import or choose a location to export the current report template (Figure 11.3-6).

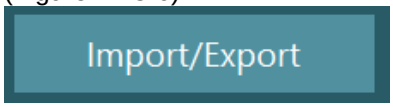


Figure 11.3-6 Import/Export templates button

Tap the Close editor button (Figure 11.3-7) exit the Template Editor screen and return to the Report Editor screen.

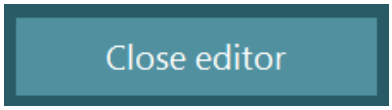


Figure 11.3-7 Close editor button

Within the Report Editor screen, use the Templates selection box and select the template that was created. VisualEyes™ 515/525 will ask to confirm (Figure 11.3-8) replacing the report with selected report template.

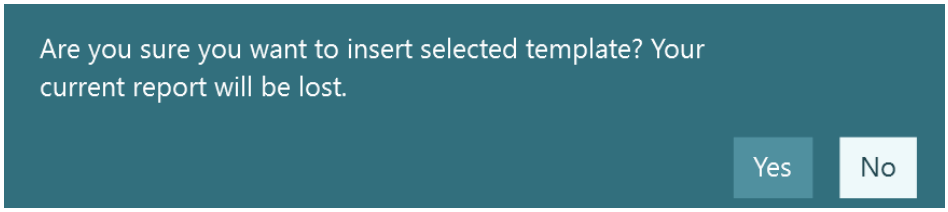


Figure 11.3-8 Confirm insert selected template message

When the report template is applied, the keywords will be filled with the information from the patient demographics entered into OtoAccess® ™. Fields that are not filled will be blank in the report (Figure 11.3-9).

Figure 11.3-9 Report Editor with example template

11.4 Findings

Findings are predefined templates that can be added into the written report within report editor. They are used to quickly add a comment regarding the patient's test result into the report. To use one of the findings in the report, move the cursor to the location in the report to insert the finding, then select the desired finding from the Findings selection menu (Figure 11.4-1).

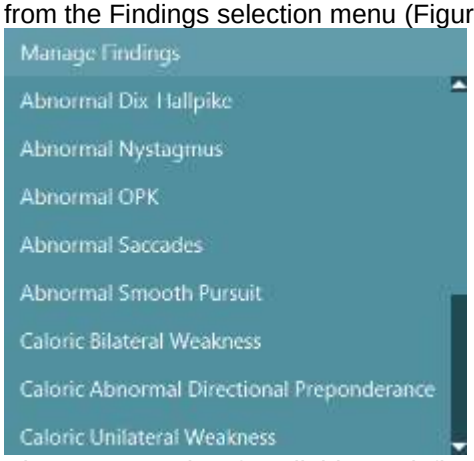


Figure 11.4-1 List of available predefined findings

To add a new finding to the list of findings, choose Manage Findings from the Findings menu. This will launch the Findings Editor screen (Figure 11.4-2).

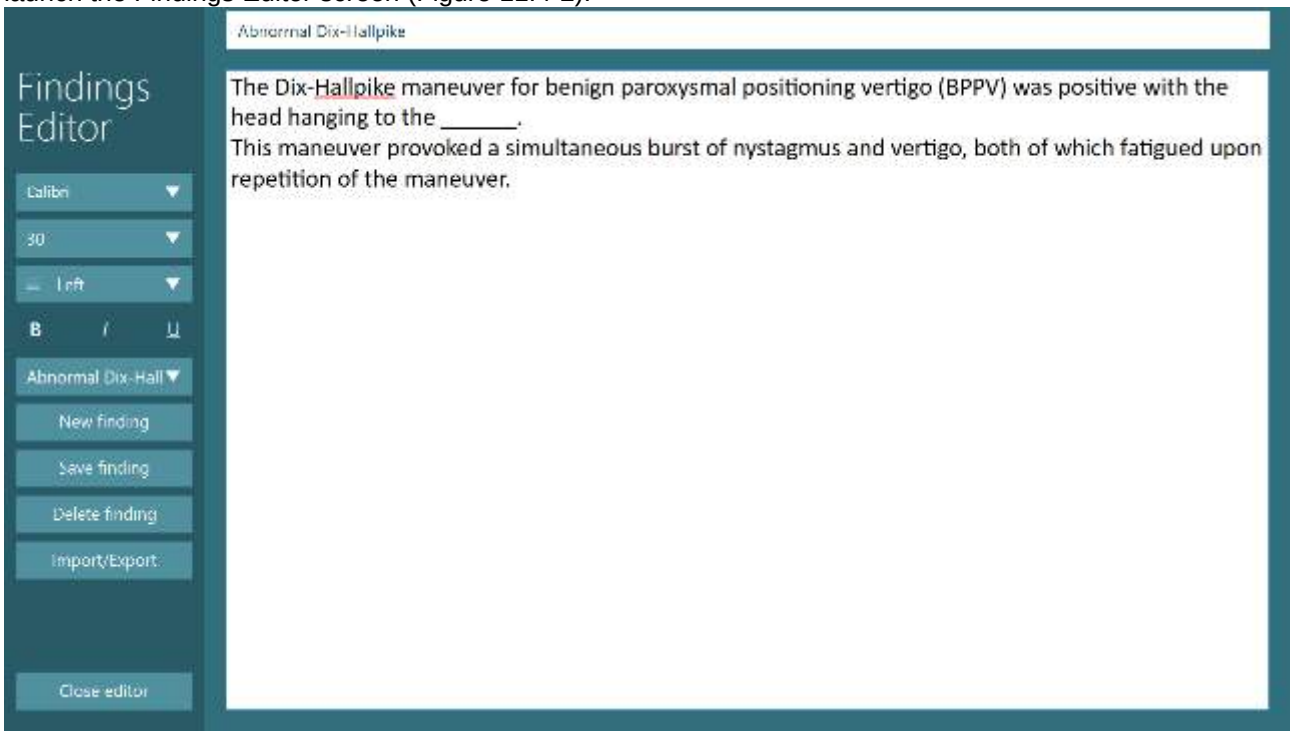


Figure 11.4-2 Findings Editor screen

To create a new finding, tap New finding. A new finding called New Finding 1 will be displayed. Overwrite New Finding 1 in the upper white text box with the desired keyword for the finding. Next enter the text for the finding in the lower white text box. The font name, size, and other style attributes will be kept with the text and will be displayed as such when added to the report. Click on the Save finding button when finished, then click on the Close editor button to return to the Report Editor screen. The new finding will now appear within the dropdown menu when selecting the Findings button.

11.5 Save report

Once a report is complete, select the Close editor button to save the report with the patient's current session (Figure 11.5-1).

Figure 11.5-1 Session saved confirmation

12 Printing

12.1 Printing results

TheVisualEyes™ system gives the options for printing either a single test or several tests from an individual patient session. A clinical report, test report summary or individual test results can be printed out from the session review screen (*Figure 12.1-1*).

Figure 12.1-1 Session review and printing options

The Print Filter by default will select all the completed tests for printing a report from the session. The user can set other options as default setting by clicking filter drop down. Tests can be selected individually with the check boxes. Clicking the **Print Session** (*Figure 12.1-2*) button will print the report with the selected tests and the clinical report (if a report summary has been written).

Figure 12.1-2 Print button for the whole session

Once printing commences a status bar (*Figure 12.1-3*) will appear to show the progress.

Figure 12.1-3 Icon to show printing progress

12.2 Printing patient demographics or De-identify printout

When a report is printed the demographics for the patient entered into OtoAccess® ™ database will automatically be displayed as identifiers on each page of the printout. Activating the De-identify printout feature (Figure 12.2-1) will create the results without displaying vital information about the patient (Figure 12.2-2). This allows for patient data to be printed without disclosing any patient health information (PHI) but information useful for patient research studies will be available.

Figure 12.2-1 De-identify printout option

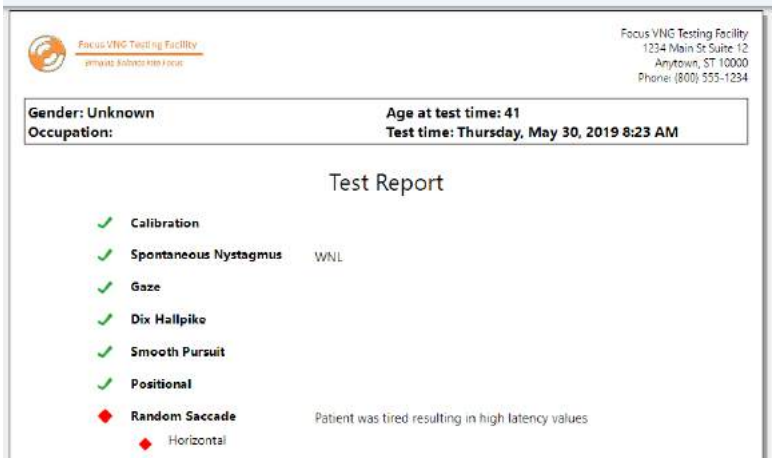


Figure 12.2-2 De-identified Patient Report

The examiner who administered the tests in OtoAccess® 2 will be listed in the footer of the report pages (Figure 12.2-3).

Figure 12.2-3 Examiner in Report Footer

12.3 Printing calibration

Calibration waveforms can be printed for monocular and or binocular recordings and for both horizontal and vertical eye movement calibrations. These waveforms can provide proof of acceptable calibrations vs technical errors.

12.4 Printing a single item

The clinical report can be printed individually using the Print button next to the Clinical Report. Similarly the test report summary can be printed using the Print button next to the Test Report Summary.

A single test report can be printed by clicking or touching the Print button beside the test name in the Session Review screen (Figure 12.4-1). The printed report will contain the notes for the test only.

Figure 12.4-1 Example of test printed from Session Review screen

12.5 Preview / Printing a session

Click on the Print Session to print the report directly to the selected printer. Click on the Preview button to review the report first. The report can be sent to the printer from the preview screen.

12.6 Printing traces (Print screen)

To print the entire trace for an individual test, open the desired test or subtest from the Session Review screen. A Print Screen button (Figure 12.6-1) will show up in the left menu panel. Click or touch this button to print the entire trace and graphs for the specific test or subtest.

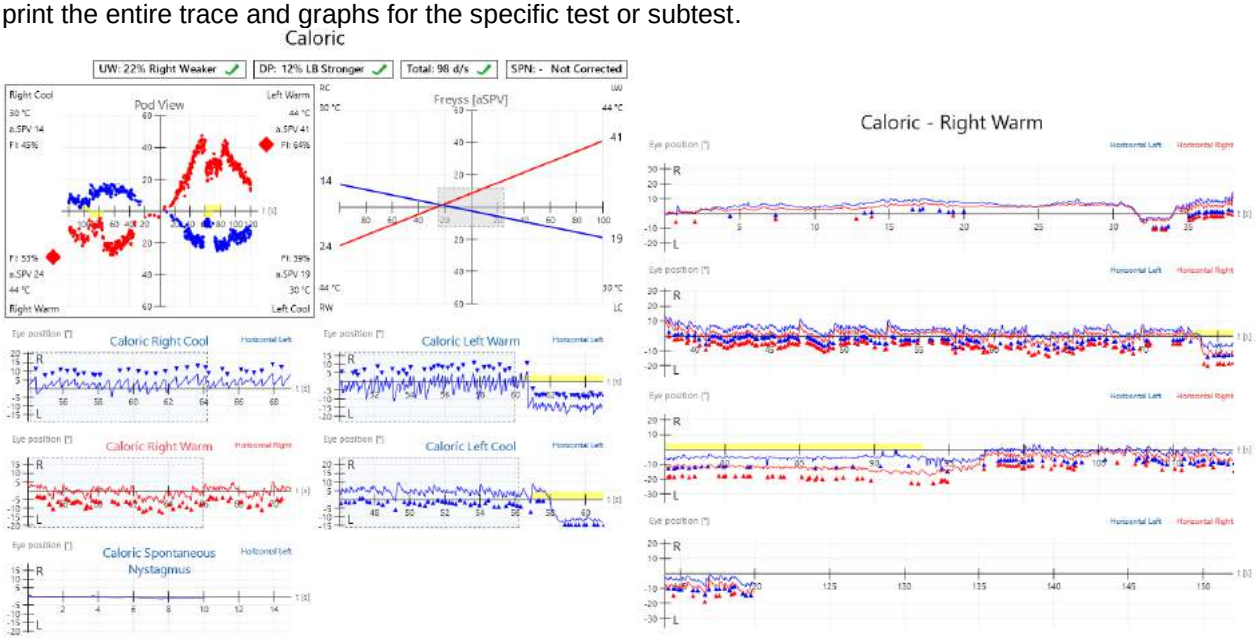


Figure 12.6-1 Printing Test (left) versus Printing Traces (right)

12.7 Create PDF

By selecting Create PDF the file is saved in the defined data location. For further information see Section 13.8 Print.

12.8 Print to Database

By selecting Print to Database, the report is saved in the open XML paper specification (XPS) format into the OtoAccess® 2 database. The report can then be reviewed from the OtoAccess® 2 database without having to access the VisualEyes software. For more information on how to view the XPS file in OtoAccess® 2, please consult the OtoAccess® 2 help documentation.

13 System default settings

13.1 System Default Settings

By selecting the Configuration button and choosing System Default Settings (Figure 13.1-1), the user will be able to access the various hardware and software settings.

Figure 13.1-1 System Default Settings from Configuration menu

13.2 Input

The Input settings screen provides access to the recording hardware (Figure 13.2-1).

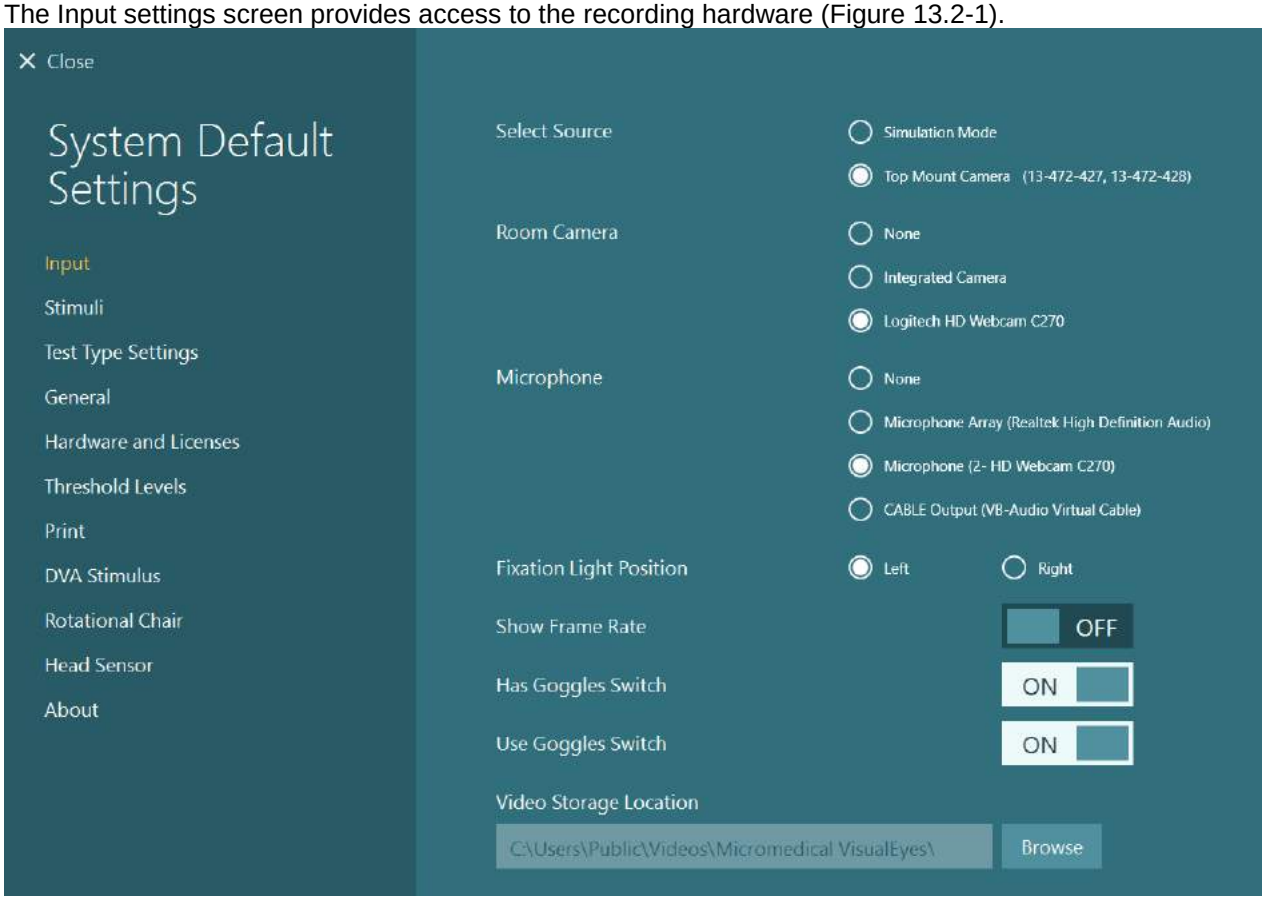


Figure 13.2-1 Input settings

Select Source determines which hardware will be used for data acquisition.

- Simulation Mode – demonstration option showing only an image of the eyes
- Top mount camera – binocular goggle mask with two cameras above the eyes
- Front mount camera – monocular camera pressed into the viewport in front of the eye
- Side mount camera – monocular or binocular camera configuration with cameras on the outside of the eyes
- DataLink – Electrode recording option using the DataLink box

- VLink – VORTEQ head sensor selected in DVA standalone systems
- ENG in Chair – Electrode recording option using the amplifier in the back of the Orion Comprehensive / Auto Traverse chair
- Pediatric Observation Camera – Single camera pointed at the pediatric patient from the front of the Orion Comprehensive / Auto Traverse chair

The Room Camera selection will choose the camera for room recording. Choosing None will not initialize any room camera and will prevent the recording of the patient interview.

The Microphone selection will choose the audio recording source combined with the room recording and patient interview. If the Room Camera selection is set to None, the Microphone selection is not used.

The Fixation Light Position selects which fixation light to use in the top mount camera goggles and the side mount camera goggles.

The Show Frame Rate option displays the frame rate of the cameras as they are capturing video. This is a diagnostic tool used to check if the cameras are working correctly with the computer and normally is off.

The Has Goggles Switch option is available only with the top mount camera goggles and defines the goggle type as having the side switch. If the camera model does not have a side switch, this option should be turned off. The default setting is on.

The Use Goggles Switch option is a user preference option available only with the top mount camera goggles. If the camera model has a side switch, but the user does not wish to use the side switch and wants to disable the side switch completely, then this option should be turned off. The default setting is on.

The Video Storage Location sets the location where the videos are stored for the eye recording and the room recording. By default this is set to a Micromedical VisualEyes™ subfolder under the public videos folder. This can be changed to use a network location if desired.

13.3 Stimuli

VisualEyes™ 525 systems utilize an external display for the stimulus or target pattern required for the test. This can be a TV or second computer monitor, digital light bar, video projector or the laser and drum combination for Comprehensive and Auto Traverse rotational chairs. The active stimulus is automatically selected depending on what is connected to the PC.

You can change active stimuli from the Calibration screen. The option for laser and drum will not be available unless the rotational chair is configured for an Orion or System 2000 Comprehensive or Auto Traverse chair.

13.3.1 TV Stimulus

TV stimulus allows you to configure the software to use a TV or second computer monitor as the target stimulus. Setting the Secondary Monitor to ON will indicate that you want to use the TV for stimuli. Setting the Secondary Monitor to OFF will disable TV for stimuli (Figure 13.3-1).

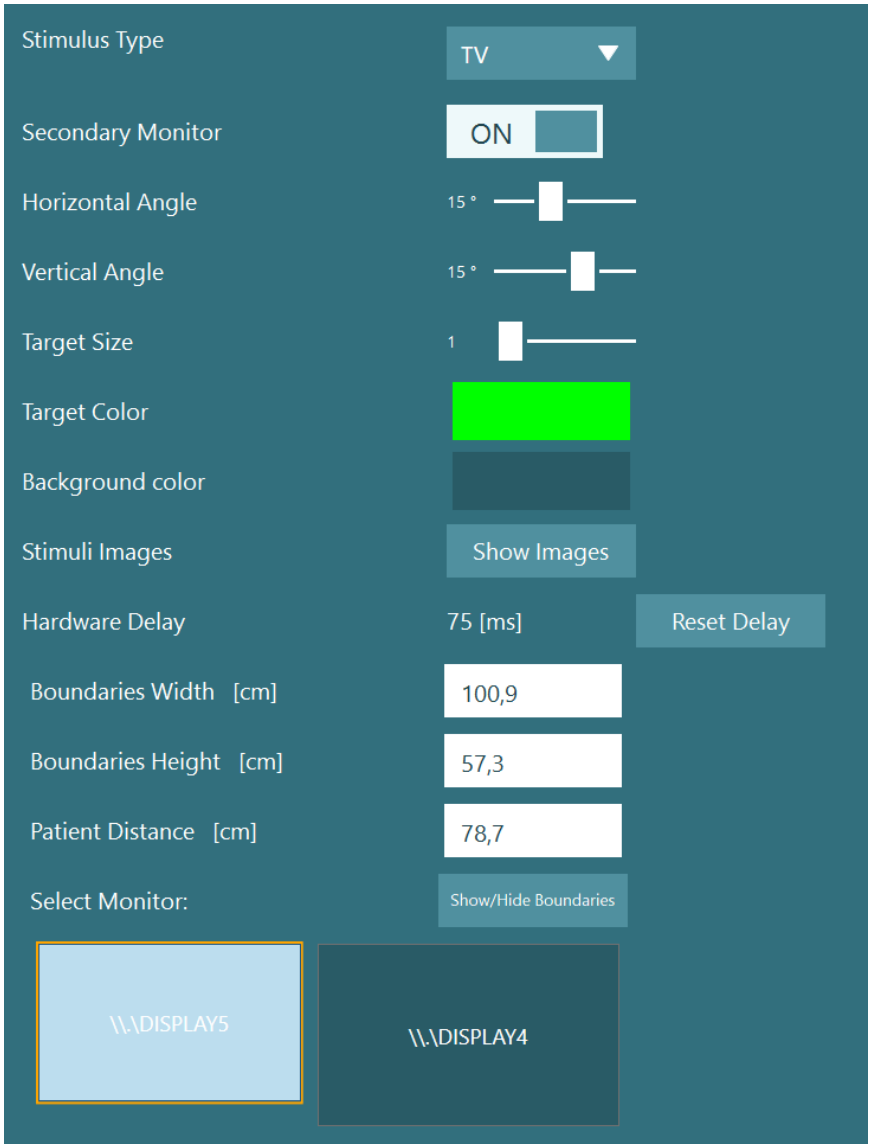


Figure 13.3-1 TV Stimulus Settings

The calibration angles are set by the Horizontal Angle and Vertical Angle sliders. The Target Size slider will adjust the maximum Horizontal Angle and Vertical Angle values and will be used by the software as the target size for tests that display the target (e. g. gaze, saccade, pursuit). The Target Color and Background color choices will apply to the calibration target and will be the default color choices for tests that display the target unless specified otherwise in the test properties.

Stimuli Images (Figure 13.3-2) allows the user to add or remove target and background images for use during testing. Background Images can be selected to be tiled if desired. To remove an image, click on the x button to the left of the image name.

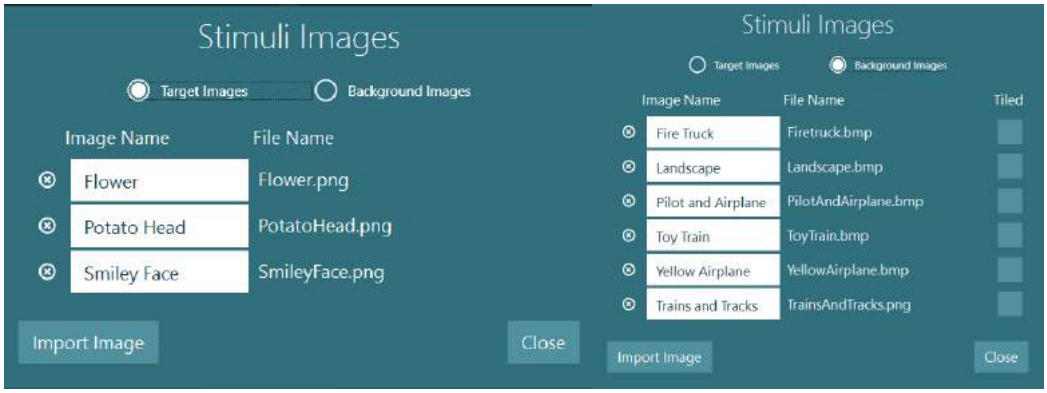


Figure 13.3-2 Stimuli Images

Hardware Delay is the amount of time to factor into the calculations for the TV or monitor to render the stimulus. By default, this value is set to 75 ms, but this value can be adjusted when performing the pursuit test. For more information see the section on configuring the smooth pursuit tests. The value can be reset by using the Reset Delay button.

Select which Monitor will show the TV stimulus. The monitors will be sized graphically by resolution. Click on the Show/Hide Boundaries button to display the grid boundaries where the target can be placed on the screen. Measure the width and height of the TV's screen boundaries and enter them into the Boundaries Width and Boundaries Height fields (measurements are defined by the computer's region settings). Enter the Patient Distance the patient will be seated from the TV screen during testing other than DVA testing.

13.3.2 Digital Light Bar Stimulus

Selecting Digital Light Bar (Figure 13.3-3) allows you to configure the Digtial Light Bar (DLB) as the target stimulus.
The DLB will automatically be used for stimuli if it is connected to the PC.
The DLB contains a number of LED lights inside a bar container that is mounted on a tripod and used primarily for portable systems.

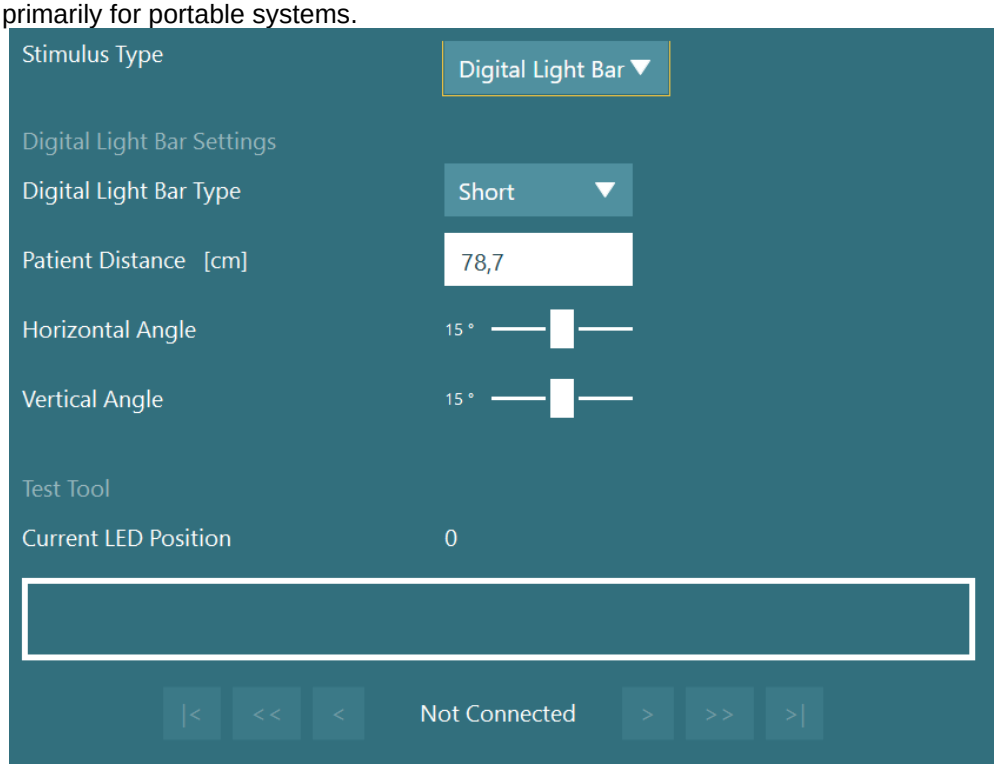


Figure 13.3-3 Digital Light Bar Settings

The Digital Light Bar Type should be set to Short. The Patient Distance should be set between 24 and 60 inches (61 and 152 cm) for optimal viewing and prevention of ocular convergence. Horizontal Angle and Vertical Angle are the angles used in calibration; the Vertical Angle used when the DLB is rotated vertically.

The Test Tool provides access to testing the lights of the DLB for troubleshooting purposes. The arrow and line buttons will light the end point LEDs. The single arrow buttons will light the next LED in sequence. The double arrow buttons will sweep the LEDs in the direction indicated and stop when reaching the end of the light bar.

13.3.3 Laser and Drum Stimulus

Selecting the Laser and Drum stimulus (Figure 13.3-4) allows you to configure the laser and drum stimulus inside the booth enclosure. Select the desired peripheral under the Settings and Calibration selector. Laser and drum will automatically be used for stimuli if correct chair is connected to PC.

The laser and drum will not be disabled while the booth door is open to enable the operator to adjust the settings. Make sure the laser beam is turned away from the door to prevent direct exposure to the eyes.

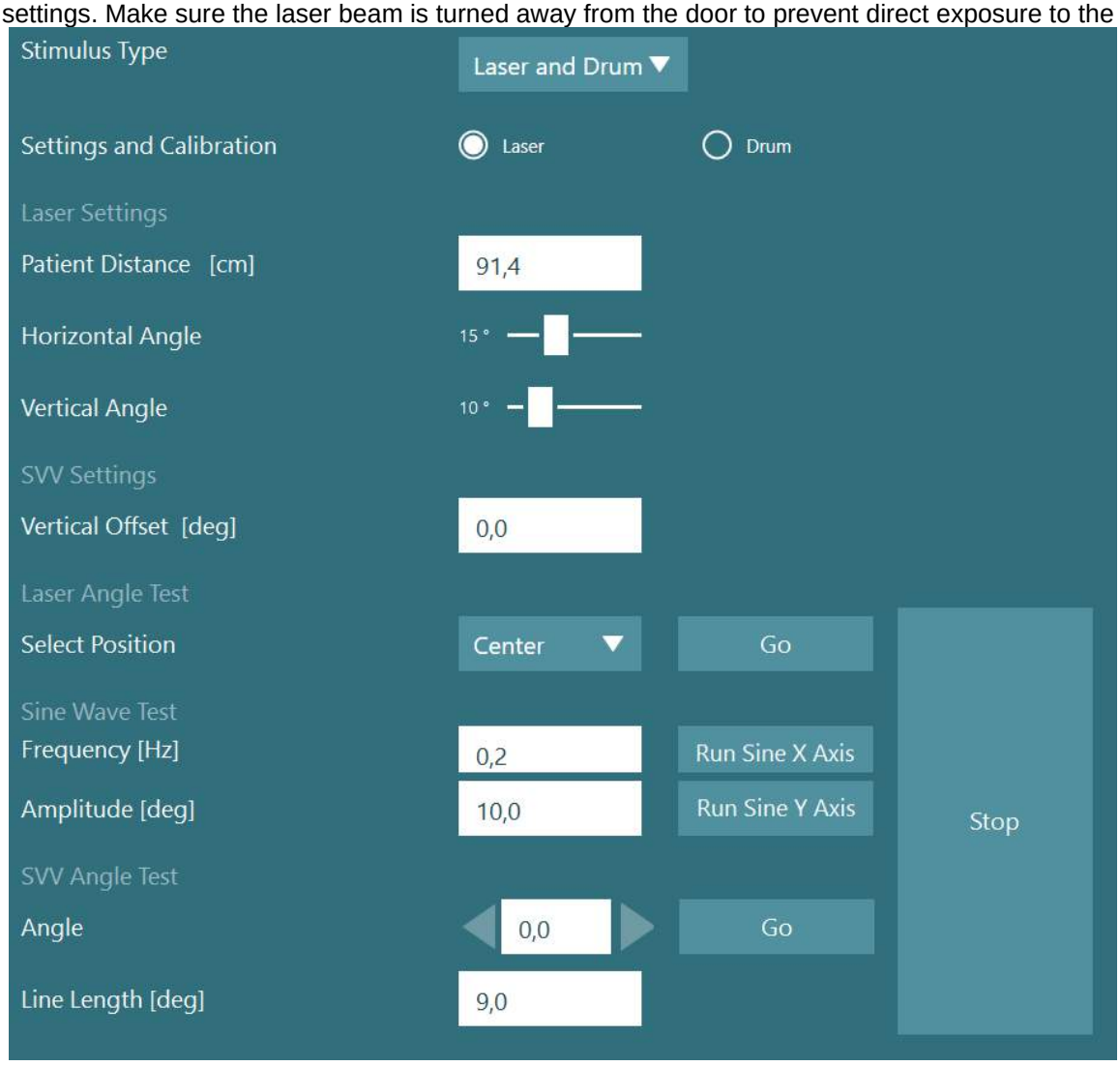


Figure 13.3-4 Laser and Drum Settings with Laser selected

The patient distance is the default patient distance between the patient's eyes and the booth wall. This value is set to 36 inches (91. 4 cm) by default. The Horizontal Angle and Vertical Angle are used in calibration.

The Vertical Offset value provides a numerical offset to adjust the initial rotation value of the SVV line. If a plumb line shows that the laser at 0. 0 degrees is not true vertical, then the offset can be set to compensate.

The Laser Angle test will display the laser dot in the center or each of the directions at the 15 and 25 degree positions based on the selection. Click on the Go button to display the laser position in the desired location. Click on the Stop button to turn off the laser.

The Sine Wave Test will run the laser in a sinusoidal pattern starting at the center at the Frequency value and Amplitude value specified. Click on the Run Sine X Axis or Run Sine Y Axis to run the sine wave test and click on Stop when finished.

The SVV Angle test will display the SVV line as defined on the booth wall enclosure. Select the angle to display and the length of the SVV line (default is 9 degrees or 4. 5 degrees on either side of center), then click on the Go button beside the Angle value. Negative values will be rotated counter-clockwise from vertical.

Figure 13.3-5 Laser and Drum settings with the Drum Calibration settings selected

Setting the Drum as the hardware to view will display the Maintenance Routines for Calibration and Validation of the drum stimulus. On the right side will be a graph that displays the voltage signal, tachometer voltage, and the pulse per revolution (PPR) trace which shows when the drum passes over the default Home position of the drum.

The Drift Calibration test will calibrate the drum to determine the voltage needed to hold the drum still. If the drum rotates, click on the Go button then use the left and right arrows to adjust the Drift Offset value. Click on Stop when the drum no longer drifts.

The Velocity Tach Calibration test will adjust the signal and tach voltage values to spin the drum correctly. Click on the Go button to run the calibration routine. The software will spin the drum and will calculate the signal and tach voltages needed (Figure 13.3-5).

Figure 13.3-6 Laser and Drum Settings with Drum Validation Selected

After the drum has been calibrated, set the maintenance routine to Validation (Figure 13.3-6). Clicking on the Go button will run the Sine Wave Validation test using the specified frequency, velocity, and cycle count values. The drum will be run according to the parameters and the results will be displayed in the graph. The signal and tach lines should coincide. If the waveform is shifted up and down, then the drift offset should be reset; if the tach magnitude differs from the signal trace, then the velocity tach calibration should be performed again.

13.4 Test Type settings

The test type settings menu (Figure 13.4-1) presents options to customize the numerical values for i. e. graphs, timer function and Intervals between irrigations depending on the selected test.

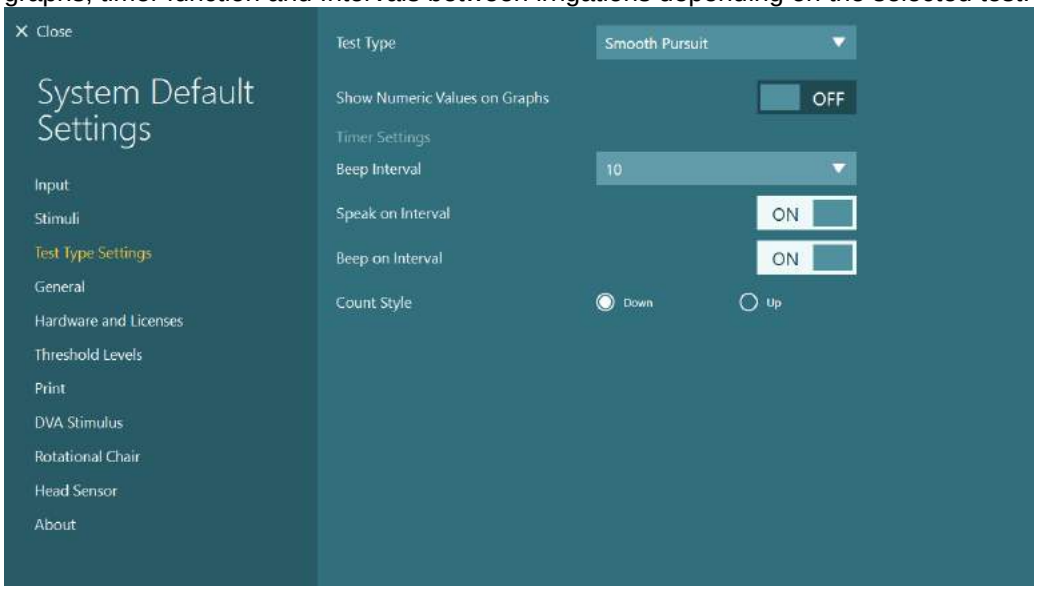


Figure 13.4-1 Test type settings

Beep interval: Assigns the length of time between presentations of the beep and/or speaker. Selecting the numerical field will provide a drop down menu with interval options of 5, 10, 20 and 30 seconds.
Speak on Interval: Activating this feature will enable a vocal alert in English for each interval. The voice pronounces the time at the interval.

Beep on Interval: Activating this feature will enable a tonal alert to be presented at each specified interval.
Shows Numeric Values on Graphs: Activating this feature will enable the option to view the numerical values in the graphical display.
Count Style: Choice to choose the ascending or descending order of counting style.

13.5 General

The General Settings (Figure 13.5-1) page contains additional program settings.

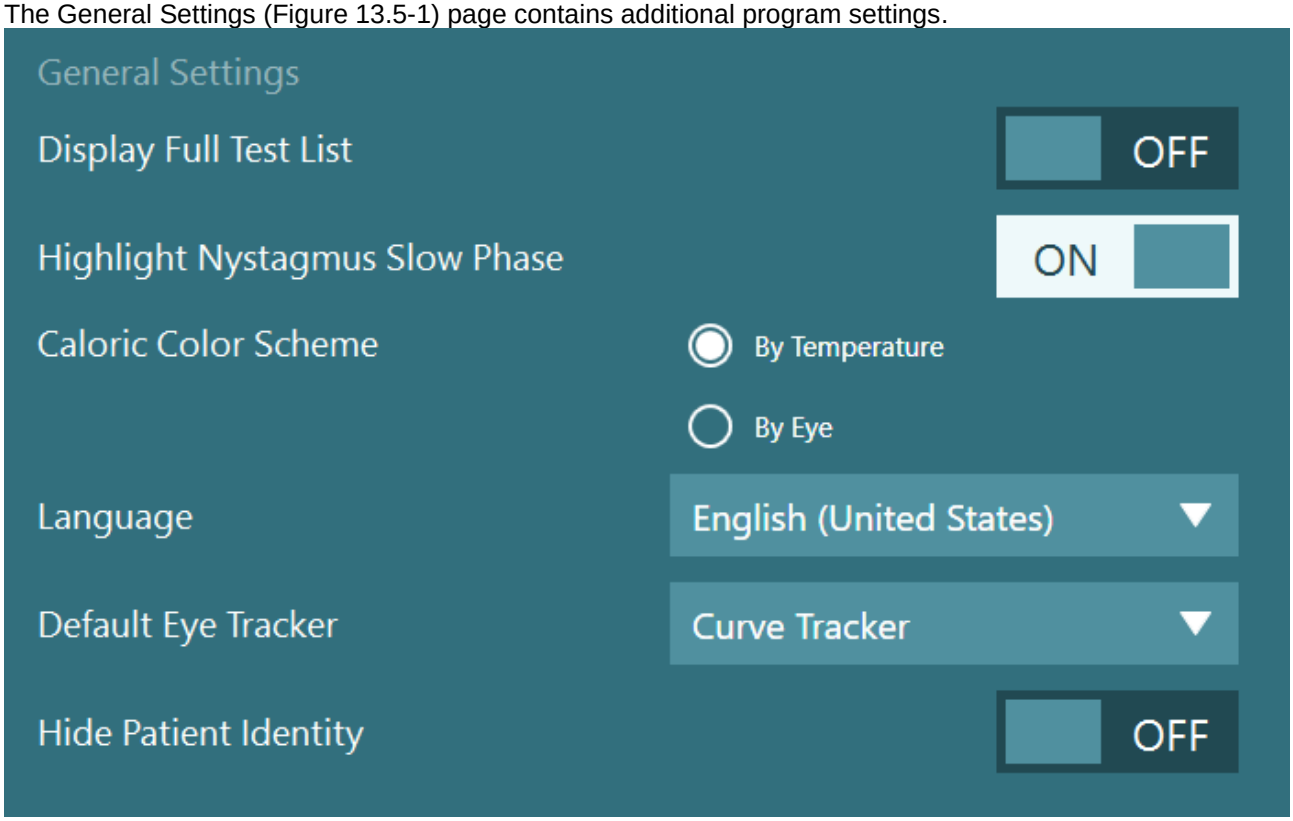


Figure 13.5-1 General settings

Dsiplay full test list allows the entire session tree with all tests and subtests to be displayed in expanded view. By default the test list is condensed to only show test headings. Clicking or touching the plus sign next to the test expands the heading to show subtests. Enable the Display Full Test List option to display heading expanded always (Figure 13.5-2).

Figure 13.5-2 Display Condensed Test List (left) vs. Display Full Test List (right)

If the Highlight nystagmus slow phase option (Figure 13.5-3) is enabled, then nystagmus-based tests will display the slow phase of the nystagmus beat with a green highlight after the test is completed. When the test is reviewed, the user can toggle the appearance of the highlight from the test's temporary settings.

Figure 13.5-3 Highlight Nystagmus Slow Phase

Caloric Color Scheme (Figure 13.5-4) can be set to temperature (cool irrigations in blue and warm irrigations in red) or set to eye (left eye recordings in light blue for cool irrigations and dark blue for warm irrigations, right eye recordings in light red for cool and dark red for warm).

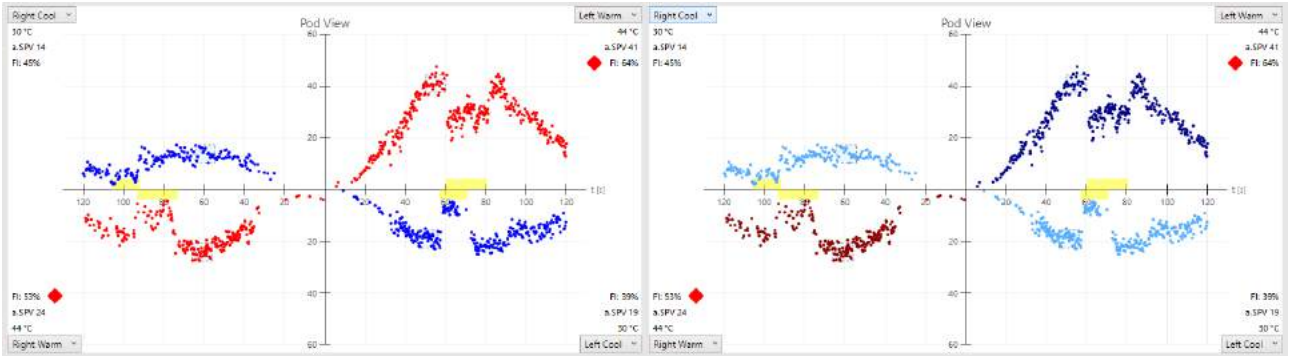


Figure 13.5-4 Caloric Color Scheme by Temperature (left) vs. by Eye (right)

The Default Eye Tracker is used as the eye tracking algorithm unless otherwise specified for a specific test.

- Curve Tracker – Standard eye tracker using a curve recognition algorithm for isolating the pupil outline
- IPM Tracker – Blob analysis eye tracker for locating the pupil center for high speed VHIT tracking
- Convex Hull Tracker – Eye tracker with geometric compensation for torsion tracking
- Eyeseecam Tracker – Eye tracker used with EyeSeeCam camera for high speed VHIT tracking

Hide Patient Identity will hide the patient name and ID from the software screens and report. The report will print blank values in the header and the clinical report. The patient name and ID will still be available in the OtoAccess® software.

Language can also be selected within General Settings. Changing the program language will display the text in the selected language. The software will ask if the user wishes to change the names of the tests in all of the protocols to the new language in the newly selected language. The software supports Chinese, English, French, German, Greek, Italian, Japanese, Korean, Polish, Portuguese, Russian, Slovenian, Spanish, Turkish, and Danish. The software will have to be restarted when the program language is changed.

13.6 Hardware and Licenses

The Hardware and Licenses screen allows the user to enter the license keys for the cameras. Multiple licenses for the same camera set can be added for dealer demonstrations. The tests available for the selected license will be listed at the bottom of the screen.

If new hardware is to be licensed, connect the hardware to the computer, then return to the Home Screen. Click on Configuration > System Default Settings and select Hardware and Licenses. The software will show the hardware that is not registered (Figure 13.6-1). From the hardware selection menu, choose the type of hardware to register. The following types of hardware are supported: Side Mount Binocular, Side Mount Monocular, Top Mount Camera, Front Mount Camera, Pediatric Observation Camera, EyeSeeCam, DataLink, Eng in Chair, Vlink, VORTEQ 2nd Gen, and Not in use (for ignored hardware).

Note: The VisualEyes™ system' recognizes 'ENG in chair' option as a default hardware input with identity of '88-888-888' for any System 2000 (AT/C/R) chair. During the system setup, the operator has to select the either 'ENG in Chair' or 'not in use' based on the configuration.

Figure 13.6-1 Unregistered hardware

If the camera type selected is a binocular camera, then select the paired serial number from the additional selection box. This will remove the second camera serial number from the list of unknown hardware.

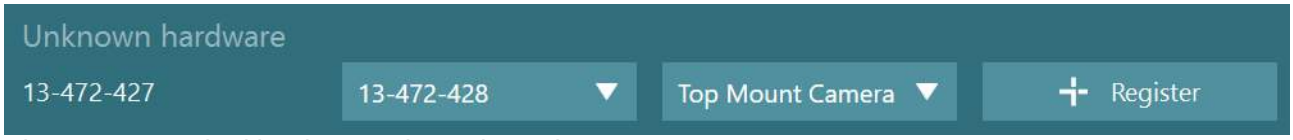


Figure 13.6-2 Paired hardware to be registered

Click on Register to add it to the registered hardware (Figure 13.6-2).

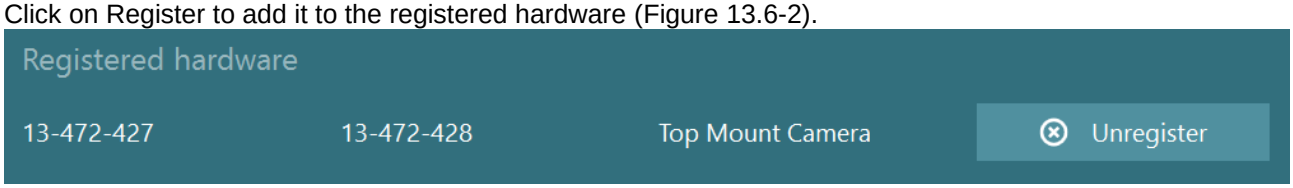


Figure 13.6-3 Cameras Registered

Once the hardware is registered, a license to use the hardware can be entered (Figure 13.6-3). Click on the Add new license button to enter the license code. If entering the license codes for a binocular camera set, when the license for one camera is entered, the software will show a green checkmark (Figure 13.6-4) if the license code is valid for that camera serial number.

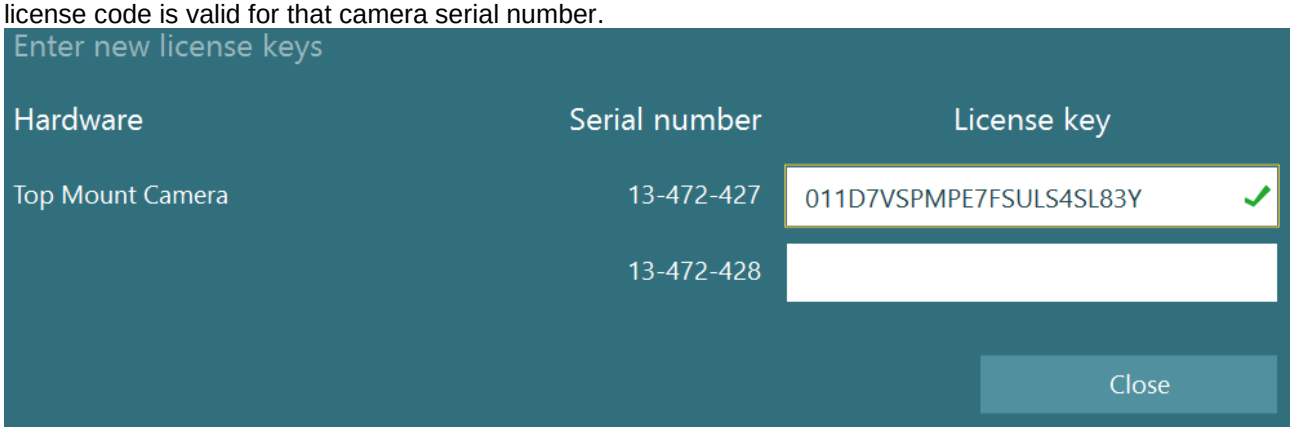


Figure 13.6-4 Entering license code for registered hardware

When the hardware license has been added, the new license will appear in the Registerd licenses section (Figure 13.6-5). The software will now use the registered license and change the input hardware to correspond with the license. For reference the hardware serial number and the license for the hardware serial number are displayed with the license type to help differentiate hardware or license types (for demonstration purposes).

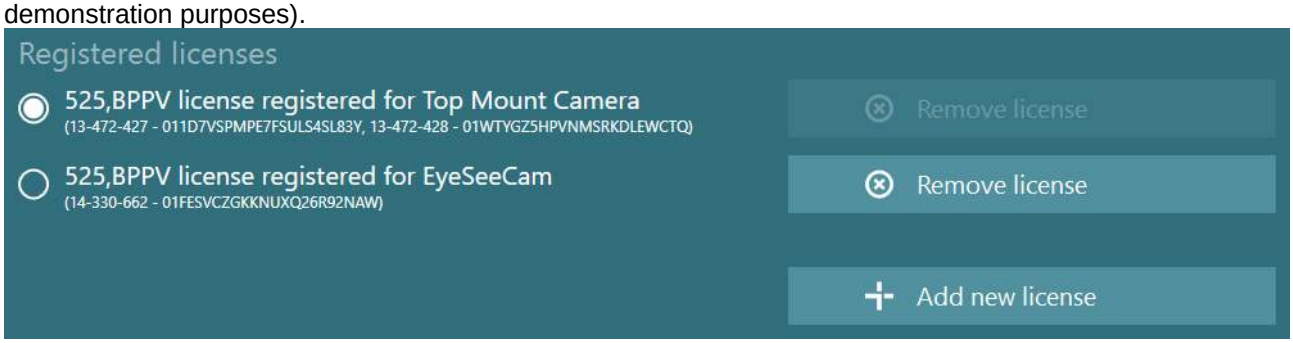


Figure 13.6-5 Registered licenses

When the InstaCal software is launched, the software will detect the rotary chair as the board type described in the following table (provided the isolation transformer is powered and the USB cable from the chair is connected to the computer). Click on the OK button to register the device in the program. In the case of the System 2000 Auto Traverse chair, click on the Configuration button for each board and change the Board Configuration settings for the Counter 1 Clock Source to be 10 MHz Clock.

Chair Model	Board Type	Number of Boards
Orion Reclining	USB-231	1
Orion Comprehensive	USB-231	2
Orion Auto Traverse	USB-231	2
System 2000 Reclining	PCI-DAS6025	1
System 2000 Comprehensive	PCI-DAS6025	1
System 2000 Auto Traverse	PCI-DAS6025	2

Connect the CAN motor control cable from the blue reclining chair to the computer's USB port.

13.7 Threshold levels

The Threshold Levels settings screen contains age-matched thresholds for various VNG, ENG and Rotary Chair tests. The theshold levels are explained in detail in Chapter 10 Suggested threshold values.

13.8 Print

The Print settings (Figure 13.8-1) screen provides access to PDF document settings and report printing settings.

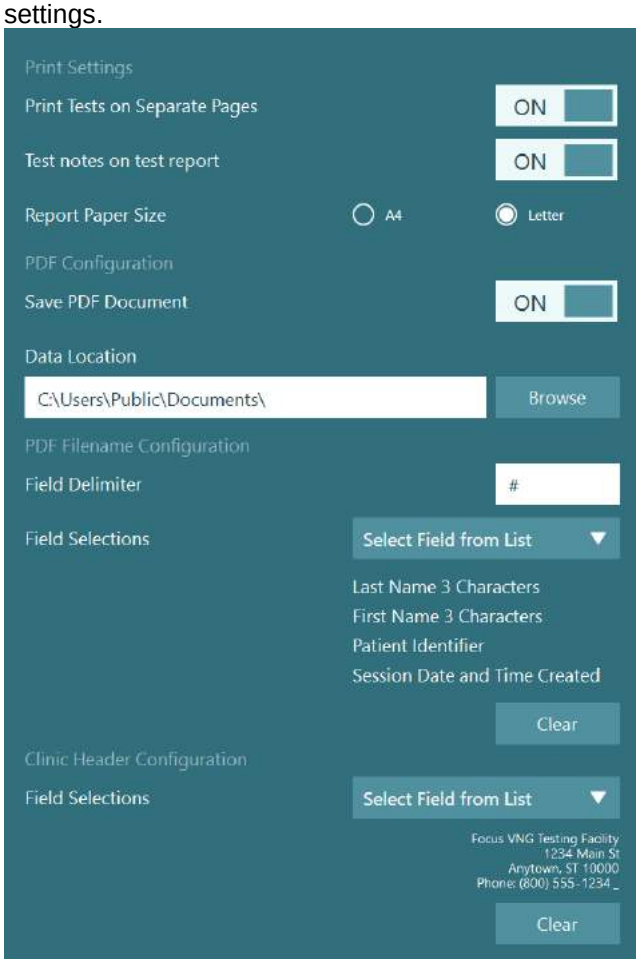


Figure 13.8-1 Print settings

Print Tests on Separate Pages: Selects whether page breaks should be added before each test is printed in the report. This option can be set off in VisualEyes™ 505 systems to reduce the extra space printed between tests, as only the notes are printed for video frenzel tests.
Test notes on test report: This option will print the test notes (Figure 13.8-2) in a second column on the test list. If this option is set off, then the test list will list the names of the tests in the center of the page.

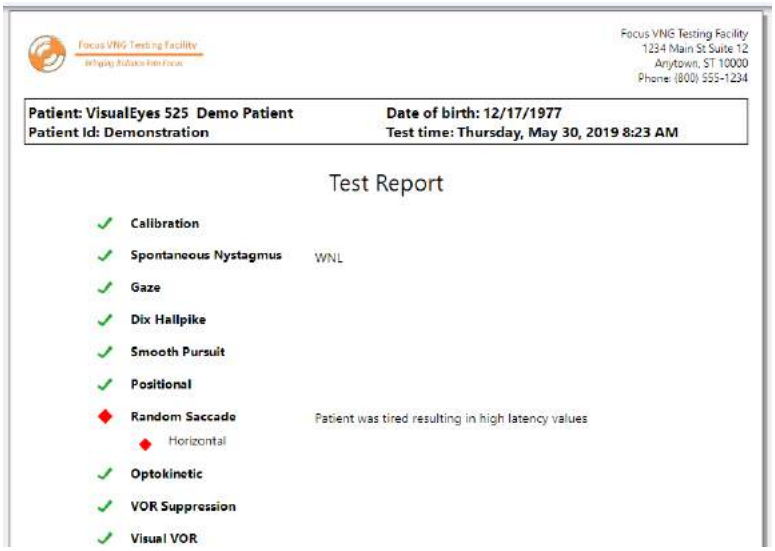


Figure 13.8-2 Test Report with Test Comments

Report Paper Size: Selects the paper format to print and or save the report to (choice of A4 or letter format)
Save PDF Document: If this option is selected, the Create PDF button is available from the Session Review screen to print the report to PDF to the specified location.
PDF Data Location: This is the folder where the PDF report is created. Use the Browse button to select the folder.
PDF Filename Configuration: These fields define the naming structure of the PDF report.

- Field Delimiter: Select a character to function as a field delimiter, typically a period, hashtag, or hyphen
- Field Selections: Select what is to be displayed on the report from following list:
    - First Name 3 Characters
    - Last Name 3 Characters
    - Module (Micromedical VisualEyes™)
    - Patient Identifier
    - Report Date and Time Created
    - Session Date and Time Created
    - Session Identifier

Clinic Header Configuration:
These fields define the naming structure of the clinic information printed in the top-right corner of each page of the report. If the VisualEyes software is launched from OtoAccess® 2. 0 or later, the company logo set in OtoAccess® will be displayed in the top-left corner of each page. Otherwise a default clinic icon will be displayed in the top-left corner. To create the clinic header, use the Field Selections combination box to insert the components of the clinic address, using the Line Break option to insert a line break in the address and the comma option to separate Clinic City and Clinic State. If a field is inserted after another field, the program will insert a space automatically to separate the fields (e. g. Clinic State and Clinic Zip code). Use the Clear button to clear the current address and restart if needed.

13.9 DVA Stimulus

The DVA Stimulus settings screen (Figure 13.9-1) provides the measurements for the stimulus used for the DVA tests. If the TV has too large of a screen to be used for DVA testing, then the computer monitor can be selected for the DVA test stimulus. Select the monitor to be used for DVA testing, then confirm the measurements for the display (as this can be the primary laptop / desktop screen, the boundaries must be entered for the display selected). If the Patient Distance value is not adequate for displaying on the display selected, the optotype will be drawn as much as possible, but may not be discernable at the lowest logMAR values.

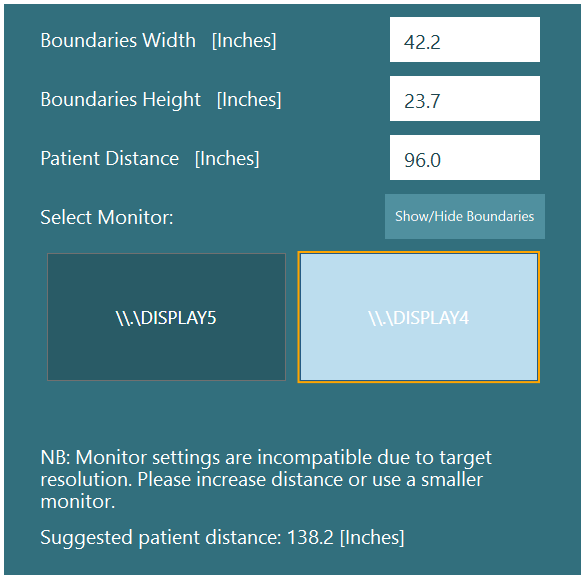


Figure 13.9-1 DVA Stimulus Settings with insufficient patient distance entered

13.10 ENG

The ENG settings screen (Figure 13.10-1) provides the default settings for recording electrode signals. These values can be changed per patient from the Calibration screen.

Amplifier Gain: Magnification level of the patient's electrode signals. Default value is Medium.

Electrode Montage: Method of the electrode placement. Bi-temporal recording will average the left and right horizontal potentials, providing a cleaner signal but preventing the ability to record disconjugate eye movement. Binocular recording records each eye's horizontal movements separately by adding an electrode to the side of the inner canthi. The default setting is Bi-temporal Left Vertical (2-channel).

Test Impedance: By clicking on the Start Test button, the software will check the impedance values for each connected electrode lead as defined by the Electrode Montage. The impedance values will be displayed and color-coded – good (green) for an impedance level of 10 or less, medium (yellow) for an impedance level of 11 to 15, and poor (red) for an impedance level of 16 to 20.

Enable Auto-Centering: By default the software will center the eye position traces if the traces drift during the test.

The software will record the electrode-based ENG test data at ideal frequency and filter settings. These options are designed based on the test that is performed. By default, tests are recorded using DC coupling and a filter frequency of 24Hz. Saccade tests will be recorded using a filter frequency of 40Hz and VORTEQ Active Head Rotation tests will use AC coupling.

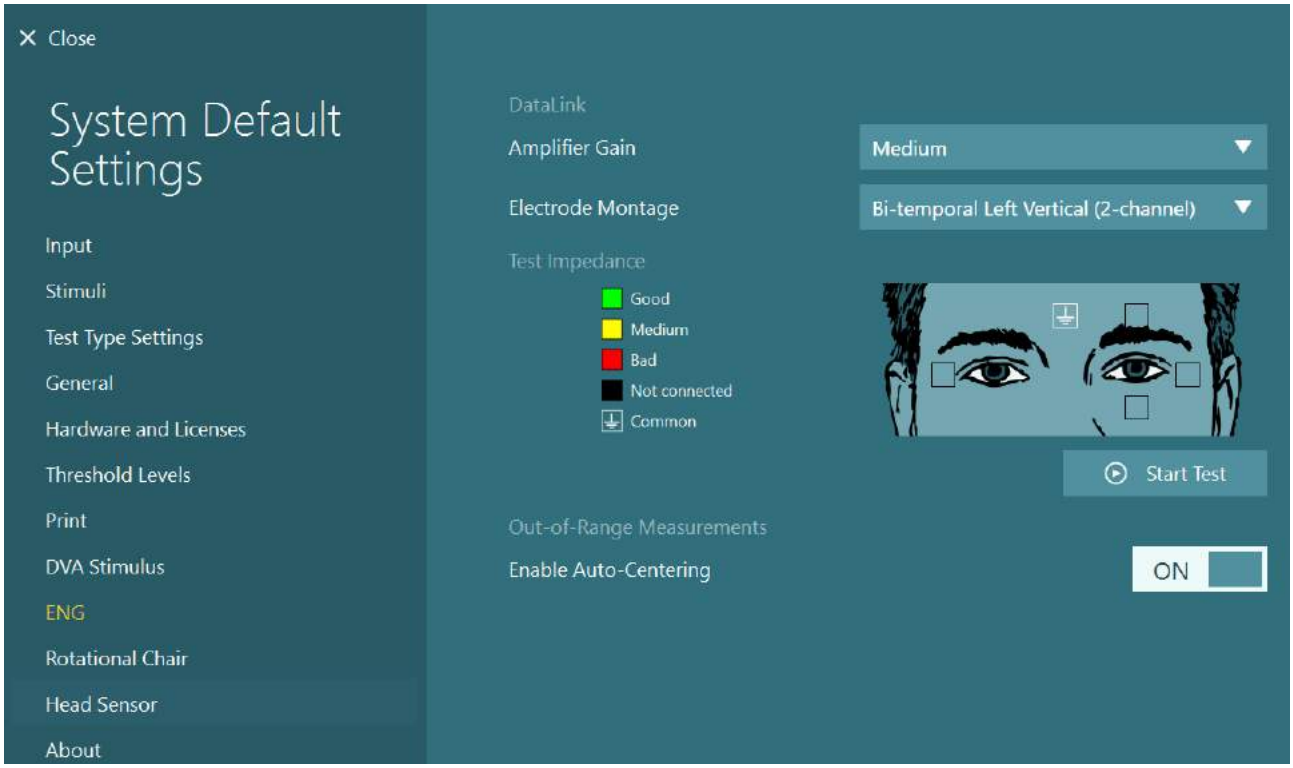


Figure 13.10-1 ENG System Settings

13.11 Rotational chair

The Rotational Chair settings (Figure 13.11-1, Figure 13.11-2 and Figure 13.11-4) screen provides access to selecting the rotational chair type connected, calibrating the rotational chair, and setting the safety limits for the tests that can be performed for patients of different age groups.

13.11.1 Chair Settings

The VisualEyes™ software supports multiple chair types. The Chair Type used is selected from the list, but if the system does not utilize a rotational chair type, the Chair Type selection should be set to None.

Chair Type	Controller Board	Camera Type	Reclines	Booth Enclosure	Off-Axis
Nydiag 200	Kvaser	FireWire side mount	Yes	No	No
System 2000 Reclining	PCI-DAS6025	FireWire top mount, FireWire front mount	Yes	No	No
System 2000 Comprehensive	PCI-DAS6025	FireWire top mount, FireWire front mount	No	Yes	No
System 2000 Auto Traverse	PCI-DAS6025	FireWire top mount, FireWire front mount	No	Yes	Yes
Orion Reclining	USB-231	USB side mount, USB top mount, USB front mount	Yes	No	No
Orion Comprehensive	USB-231	USB side mount, USB top mount, USB front mount	No	Yes	No
Orion Auto Traverse	USB-231	USB side mount, USB top mount, USB front mount	No	Yes	Yes

The Board Status will be green if the software can communicate with the System 2000 / Orion chair or red if there is an error. The Zero Position is used to align the chair with the center of the TV or projection screen for oculomotor testing or the booth door in booth enclosures. Select the position angle using the slider (fine tune the slider position using the left and right arrow keys) then click on the Home Chair button to rotate the chair to that position.

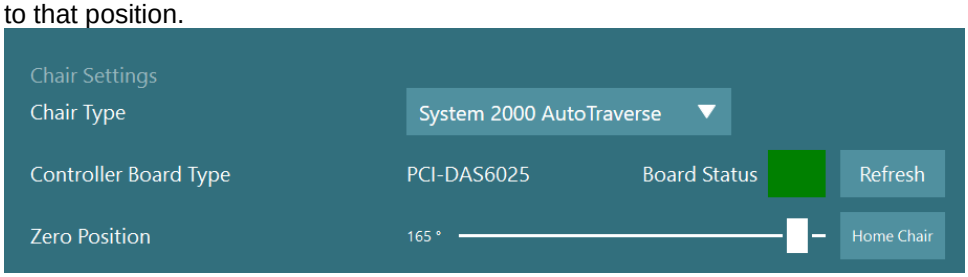


Figure 13.11-1 Chair settings

If the Nydiag 200 chair is selected, then the Gear Reduction value is displayed. This number acts as a gain value for the chair calculated from a separate calibration program.

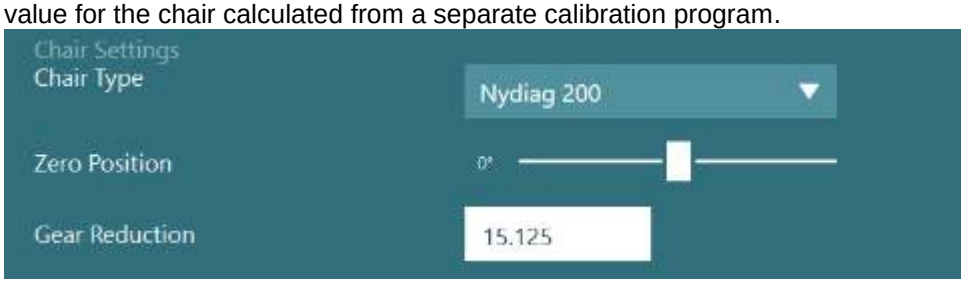


Figure 13.11-2 Chair settings for Nydiag 200 chair

13.11.2 Maintenance routines

The VisualEyes™ software calibrates the System 2000 and Orion rotational chairs to accurately spin the patient at the desired velocity and frequency. If the software has reported a calibration error during testing, or the reclining chair has not been calibrated yet, then select the Calibration option to view the calibration tests (Figure 13.11-3).

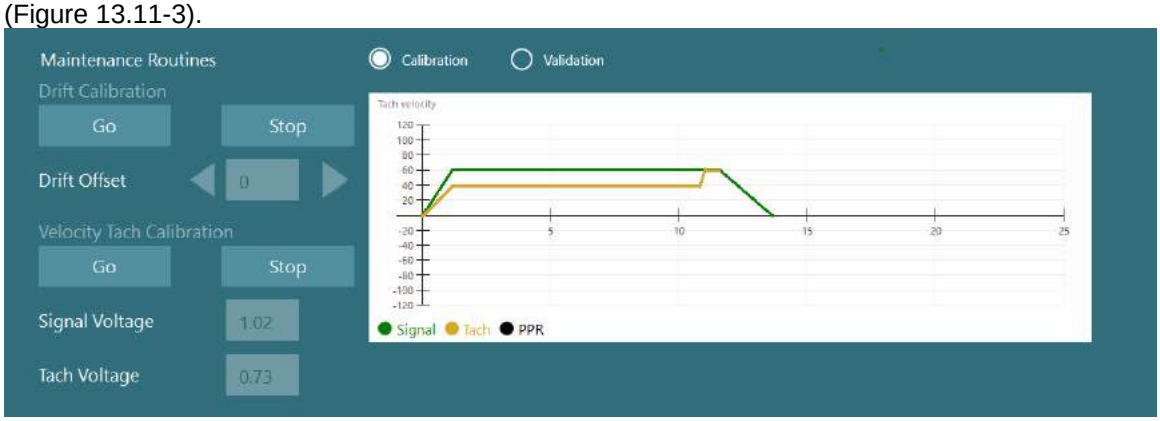


Figure 13.11-3 Reclining chair maintenance routines (Orion Reclining chair)

Drift calibration

Click or touch the Go button for the Drift Calibration to verify the chair does not drift (turn slowly) when enabled. The signal trace (green line) and the tachometer trace (yellow line) will be displayed in the graph. Adjust the Drift Offset value using the triangle buttons to adjust the chair offset to make the traces coincide. When they coincide, click or touch the Stop button to end the drift calibration test.

Velocity Tach calibration
Once the chair's drift has been corrected, click or touch the Go button for the Velocity Tach Calibration. The software will then spin the chair to optimize the Signal Voltage and Tach Voltage values to synchronize the traces. After two spins past the chair's zero position (seen by the deflections in the PPR trace), the software will stop the chair and update the signal and tach voltage values. Click or touch the Stop button to clear the traces from the graph or stop the test early.

Sine wave validation
Once both calibration tests have been performed, select the Validation option (Figure 13.11-4) for the maintenance routines to perform the Sine Wave Validation test. Click or touch the Go button to run a sinusoidal test for one cycle at 60 degrees per second at 0. 04 Hz. These settings can be adjusted if necessary. The chair will rotate using the calibrated settings and should have the signal and tach traces appear superimposed. If the traces are not adequately aligned, perform the calibration tests again.

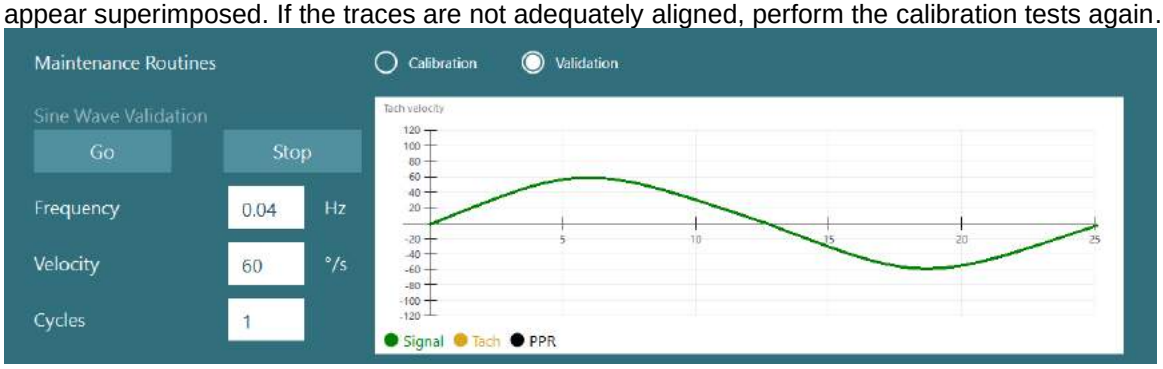


Figure 13.11-4 Sine Wave Validation (Orion Reclining chair)

13.11.3 Off-Axis Center Settings

System 2000 Auto Traverse/comprehensive and Orion Auto Traverse rotational chairs can be moved laterally off the central axis for subjective visual vertical testing (Figure 13.11-5). If the chair is off center, enter the current position on the scale and specify which direction from center the chair is located, then click on the Center Laterally button to move the chair back to the center location.

Figure 13.11-5 Off-Axis Center Settings

13.11.4 Rotational safety settings

Young patients may be tested in the reclining rotational chair. For the patient's safety, the reclining rotational chair will not allow faster tests to be performed for young patients. The software is configured to prevent the test from running if the patient's age falls within the values (Figure 13.11-6). In step tests the Max frequency is set to 1 as the setting is not used in step tests.

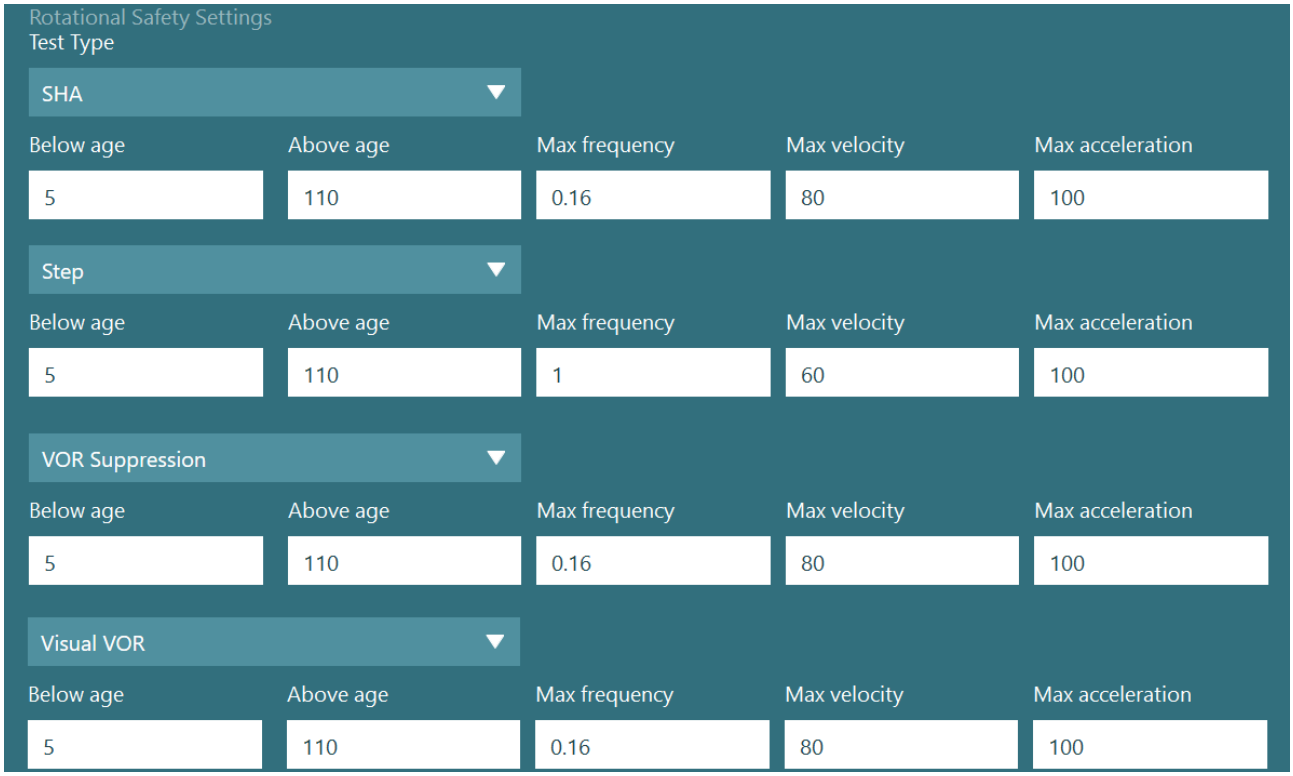


Figure 13.11-6 Rotational safety settings for each chair test

Using these default values, a patient below the age of 5 cannot be tested in Step tests with a max velocity greater than 60 degrees per second. If the patient would be prepared to perform a step test with a velocity of 60 degrees per second, when the test would be started, the software would block the clinician from testing and give an error message (Figure 13.11-7).

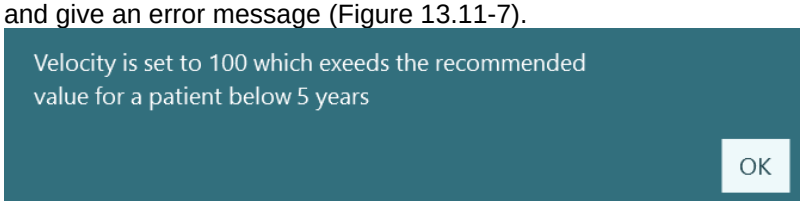


Figure 13.11-7 Warning message preventing the clinician from testing a young patient based on the test settings

13.12 Head sensor

The Head Sensor settings screen provides access to selecting the head sensor type connected and calibrating the head sensor (Figure 13.12-1).

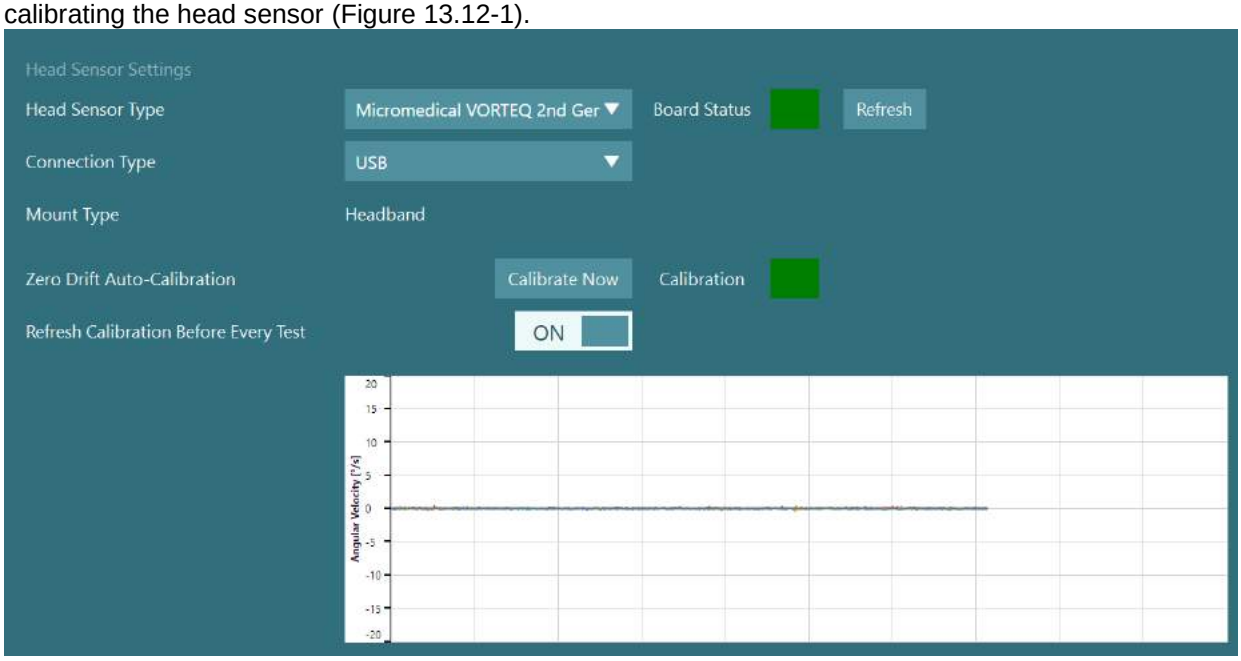


Figure 13.12-1 Head Sensor settings with VORTEQ IMU 2nd Generation

Head Sensor Type	**Rotation Axis**	**Connection**	**Goggle**
EyeSeeCam IMU	Multiple	USB	EyeSeeCam
Micromedical VORTEQ 2nd Generation IMU	Multiple	USB or Bluetooth	Side Mount, Top Mount, Headband
Micromedical VORTEQ	Single	USB	Side Mount, Top Mount, Headband

Based on the goggle used the appropriate IMU will be selected. Goggle type must be selected on the input settings screen and will be referenced in the Mount Type setting. Headband is also available if the camera configuration will not attach directly to the selected goggle type. The Micromedical VORTEQ 2nd Generation IMU has the additional Connection Type selection to choose if the head sensor will be connected by USB cable during testing or wirelessly using Bluetooth. The head sensor should be calibrated by placing the head sensor on a flat stable surface and clicking on the Calibate Now button. The trace line (Micromedical VORTEQ) or trace lines (EyeSeeCam IMU, Micromedical VORTEQ 2nd Generation IMU) should be centered on the angular velocity graph with minimal noise.

13.13 About this software

The About screen (Figure 13.13-1) lists the software version number and liceses used by the software.
The VisualEyes software will collect data about how the software is used to improve the software. This option will send back the system configuration information, test configuraton information for each test performed (no personal identifiable information is reported other than the patient's age), and any unhandled exceptions in the software from testing anomalies. This will require data transmitted along ports 80 and 443 on the testing computer.

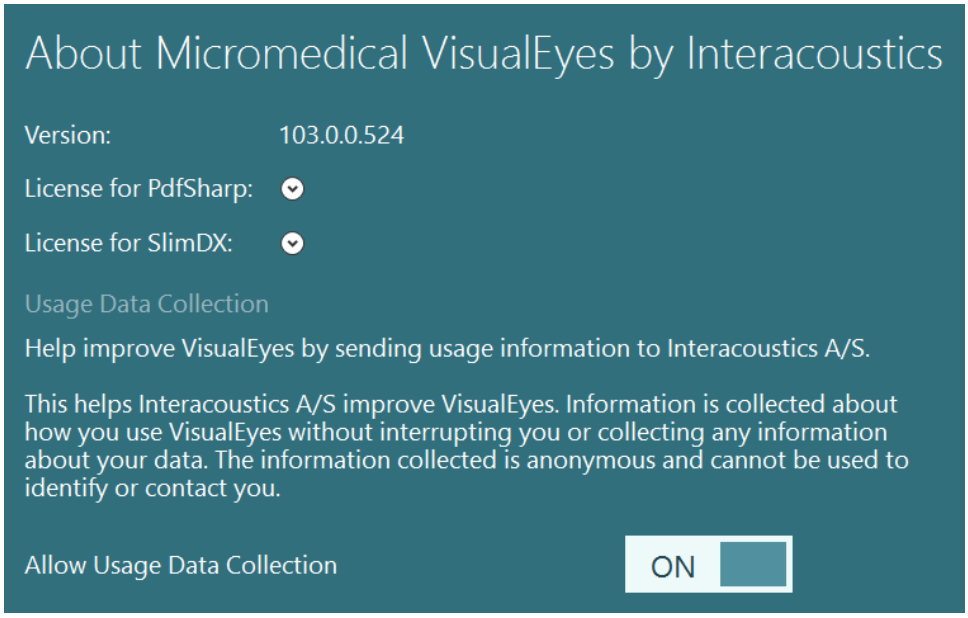


Figure 13.13-1 About Information with Usage Data Collection

14 Other functions

14.1 Help button

This manual and IFU for VisualEyes system are accessible by clicking or touching the Help button on the main screen or by pressing the F1 key within the software.

14.2 Exit button

Press the ‘Exit’ button from the main screen to leave the VisualEyes™ suite and return to OtoAccess® ™.