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Instructions for Use – US
vHIT

EyeSeeCam



Interacoustics

Table of Contents

1	Introduction	1
1.1	About this manual	1
1.2	Intended use	1
1.3	Included parts	0
1.4	Notes on safety	0
2	Unpacking and installation	1
2.1	Unpacking and inspection	1
2.2	Markings	2
2.3	General warnings and precautions	2
3	Getting started and system setup	5
3.1	Hardware requirements	5
3.2	Power	5
3.2.1	Maximizing the power supply	5
3.2.2	Entering BIOS	5
3.2.3	Changing BIOS setting	5
3.2.4	Windows Power Setting Setup	6
3.2.5	USB mode	7
3.3	Hardware setup	7
3.3.1	Goggle setup	7
3.3.2	IR illumination	8
3.3.3	Focus adjustment	9
3.3.4	Calibration laser Adjustment	9
3.4	Servicing and maintenance	10
3.5	Software setup	10
3.5.1	Installing EyeSeeCam software	10
3.5.2	Uninstalling the EyeSeeCam vHIT software -	10
3.5.3	Starting EyeSeeCam from OtoAccess® 1.5	10
3.5.4	Starting EyeSeeCam from OtoAccess® 2.0	11
3.5.5	Backing up files in OtoAccess®	11
4	Test procedures	13
4.1	Opening Screen	13
4.2	Eye calibrations	13
4.2.1	Prepare the patient	13
4.2.2	Adjust the eye/camera	14
4.2.3	Calibrate the patient	15
4.3	Head calibrations	17
4.3.1	Prepare Patient	17
4.3.2	Start Head calibration	17
4.3.3	Calibration report – Head	18

4.3.4	Edit and Default Calibrations	19
4.4	Lateral impulses	20
4.4.1	Training guide	20
4.4.2	3D Head Modeling	21
4.4.3	Display laser during HIT.....	22
4.4.4	Reject Noisy Eye Velocity.....	23
4.4.5	Auto-Stop	23
4.4.6	Peak Head Velocity Limits	23
4.4.7	Set Normative Threshold Ranges.....	24
4.4.8	Default Settings.....	26
4.4.9	Prepare to test	27
4.4.10	Start test.....	28
4.4.11	Impulse counter	28
4.5	Vertical impulses- RALP/LARP	30
4.5.1	Background	30
4.5.2	Eye Orientation	31
4.5.3	Head Orientation.....	32
4.5.4	Prepare	33
4.5.5	Direction/plane guide	33
4.5.6	Start test.....	34
4.5.7	Stop.....	34
4.6	Suppression Head Impulse Test (SHIMP)	35
4.7	Nystagmus test.....	36
5	Reports.....	37
5.1	Report Menu Options	37
5.1.1	Select and Edit Traces.....	37
5.1.2	Saccade Numerical Data Tables	39
5.1.3	Edit Saccades	40
5.1.4	3D wave	43
5.1.5	Display	44
5.1.6	Maximum time.....	45
5.1.7	Mirrored.....	46
5.1.8	Denoise	47
5.2	Generate reports	48
5.2.1	Individual Test Reports	48
5.2.2	EyeSeeSix report.....	48
5.3	Printing Reports.....	51
5.3.1	De-identify Patient Information	51
5.3.2	Print to external printer or PDF	51
5.4	Export completed session data	52
5.5	Video Recording	53

6	Licensing	55
6.1	New Systems.....	55
6.2	Upgrade existing systems	55
7	Maintenance	57
7.1	General maintenance procedures	57
7.2	How to clean Interacoustics Products	57
7.3	Concerning repair	57
7.4	Warranty	58
8	Technical information.....	59
8.1	Appendix A: Electromagnetic compatibility (EMC).....	60



1 Introduction

1.1 About this manual

This manual is valid for the EyeSeeCam system (revision 1.3). The product is manufactured by:

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It is the purpose of this manual to provide users of the Interacoustics EyeSeeCam module with all the information required to carry out safe and reliable measurements.

Dizziness is a frequent symptom in ENT, Neurology, and General Medicine. Part of the clinical examination of dizzy patients is based on the head impulse test (HIT) of the vestibulo-ocular reflex (VOR). Head impulses are movements with small positional amplitude (10-20 degrees) but high acceleration (3.000-6.000 degrees/s²) and high velocity (150-300 degrees/s). When performed clinically with no quantitative analysis, the test only detects the presence of a corrective saccade as an indirect sign of a VOR deficit.

The HIT can easily be conducted at the bedside, but it has only a moderate sensitivity (63% in experts and 72% in non-experts). Its specificity is 78% in experts and 64% in non-experts. Sensitivity, however, can be improved to up to 100% when quantitative data of the VOR are obtained during the head impulse. In patients with an acute unilateral vestibular deficit the quantitative HIT is as reliable as the caloric irrigation test. Chronic patients, however, show a pathological caloric result in only 64% of the cases but they were reliably identified by quantitative HIT. Hence, in the acute phase of a vestibular deficit either of these tests is sufficient, but in the chronic phase, which is typical for a vertigo and dizziness outpatient unit, the quantitative HIT is better.

EyeSeeCam with its lightweight goggles and the integrated inertial measurement unit (IMU) provides a measurement device for an objective and quantifiable HIT. The mobile setup with a battery-driven laptop ensures that the HIT can be applied at the patient's bedside and in the emergency room. With it, a doctor can objectively and reliably assess peripheral vestibular function in a few minutes and differentiate peripheral from central vertigo. This video-based HIT is a novel, time-saving and low-cost tool that can be readily applied in all clinical setups, such as in vertigo outpatient units or in emergency rooms.

1.2 Intended use

The EyeSeeCam vHIT is used to present information on the performance of the balance system by providing objective measures of eye-velocity response to head-velocity stimulus, showing the VOR gain in the plane of rotation of the head

The system is to be used by trained personnel only such as audiologists, ENT surgeons, neurologists, hearing healthcare professionals or personnel with a similar level of education.



The EyeSeeCam is intended for patient from 5 years and up. The patient must be physically sound as the procedures include some physical stimulation/movement. Patient must be able the see the target without the use of spectacles.

Contra indications

- Blindness
- Broken nose or other face/head trauma
- Problems with the cervical spine, e.g., neck trauma, acute cervical disc herniation
- Recent eye surgery
- Ptosis
- Excessive eye blinks
- Excessive eye make up

1.3 Included parts

EyeSeeCam – vHIT camera and goggle ¹
USB cable
EyeSeeCam vHIT Software and manuals CD
OtoAccess® Database software CD
Tape measure

1.4 Notes on safety

Our instruction manuals contain safety notes which follow the ANSI recommendations (American National Standards Institute) for safety notes.



WARNING indicates a hazardous situation which, if not avoided, could result in death or serious injury.



CAUTION, used with the safety alert symbol, indicates a hazardous situation which, if not avoided, could result in minor or moderate injury.

NOTICE

NOTICE is used to address practices not related to personal injury.

¹ Applied part including the USB cable as according ti IEC 60601-1:2005



2 Unpacking and installation

2.1 Unpacking and inspection

Check box and contents for damage

When the instrument is received please check the shipping box for rough handling and damage. If the box is damaged it should be kept until the contents of the shipment have been checked mechanically and electrically. If the instrument is faulty please contact your local distributor. Keep the shipping material for the carrier's inspection and insurance claim.

Keep carton for future shipment

The EyeSeeCam comes in its own shipping carton, which is specially designed for the EyeSeeCam. Please keep this carton. It will be needed if the instrument has to be returned for service. If service is required, please contact your local distributor.

Inspect before connection

Prior to connecting the product it should once more be inspected for damage. All the cabinet and the accessories should be checked visually for scratches and missing parts.

Report immediately any faults

Any missing part or malfunction should be reported immediately to the supplier of the instrument together with the invoice, serial number, and a detailed report of the problem. In the back of this manual you will find a "Return Report" where you can describe the problem.







Please use "Return Report"

Please realize that if the service engineer does not know what problem to look for he may not find it, so using the Return Report will be of great help to us and is your best guarantee that the correction of the problem will be to your satisfaction.



2.2 Markings

The following markings can be found on the instrument:

Symbol	Explanation
	Type B applied parts. Patient applied parts that are not conductive and can be immediately released from the patient.
	Follow instructions for use
	WEEE (EU-directive). This symbol indicates that when the end-user wishes to discard this product, it must be sent to separate collection facilities for recovery and recycling. Failing to do so may endanger the environment.
	The CE-mark indicates that Interacoustics A/S meets the requirements of Annex II of the Medical Device Directive 93/42/EEC. TÜV Product Service, Identification No. 0123, has approved the quality system.
	Year of manufacture.
	This product is laser class 1. This means the maximum permissible exposure (MPE) cannot be exceeded when viewing a laser with the naked eye.

2.3 General warnings and precautions



This equipment is intended to be connected to other equipment thus forming a Medical Electrical System. External equipment intended for connection to signal input, signal output or other connectors shall comply with the relevant product standard e.g. IEC 60950-1 for IT equipment and the IEC 60601-series for medical electrical equipment. In addition, all such combinations – Medical Electrical Systems – shall comply with the safety requirements stated the general standard IEC 60601-1, edition 3, clause 16. Any equipment not complying with the leakage current requirements in IEC 60601-1 shall be kept outside the patient environment i.e. at least 1.5 m from the patient support or shall be supplied via a separation transformer to reduce the leakage currents. Any person who connects external equipment to signal input, signal output or other connectors has formed a Medical Electrical System and is therefore responsible for the system to comply with the requirements. If in doubt, contact qualified medical technician or your local representative.

A Separation Device (isolation device) is needed to isolate the equipment located outside the patient environment from the equipment located inside the patient environment. In particular such a Separation Device is required when a network connection is made. The requirement for the Separation Device is defined in IEC 60601-1, edition 3, clause 16.



- The EyeSeeCam is not intended for operation in oxygen rich environment, flammable anesthetics, flammable agents or similar
- The goggle should not be worn by patients with strong defective vision and abnormal rare blink. Please consult a specialist in such circumstances before using the mask on these types of patients.
- The system must be switched off before cleaning
- When used for longer time in environments temperatures above 30 °C the surface temperature of the camera unit can exceed 43 °C (max 44 °C). If this feels uncomfortable for the patient turn off the equipment for a while.



- The EyeSeeCam system must be serviced at least once a year. The service must include a safety test. No parts can be serviced while in use with the patient.
- Do not use the equipment if the enclosure is not intact, but have the equipment serviced.
- Only personnel with proper training (skilled personnel) should operate the system.
- Proper use of this device depends on careful reading of this manual and all additional instructions and labels
- Let the system obtain room temperature before turning it on. Extra time for obtaining room temperature may be needed to avoid condensation if the system has been moved from a very cold location to a warmer one.
- The patients or test persons should not wear any optical utilities such as glasses or contact lenses.
- The patients or test persons should not wear makeup around the eyes





3 Getting started and system setup

3.1 Hardware requirements

System requirements USB EyeSeeCam systems:

Laptop PC: One USB 2 port available

Desktop PC: One USB 2 port available

Furthermore, Microsoft .Net 2.0 Framework and Windows Installer 3.x should be available. If these programs are not installed on your computer, you will be prompted to install them when running the EyeSeeCam installation. Just click yes when the installer asks you, and they will be installed automatically.

Operating System Requirements:

Windows®7 (32 & 64 bit).

Windows® 8 (32 & 64 bit).

Windows® 10 (32 & 64 bit).

3.2 Power

3.2.1 Maximizing the power supply

Eye images in the vHIT user interface can become flickering and unstable if the power supplied to the camera is not maximized.

These problems mainly occur in PC systems using chipset technology from INTEL.

To maximize the power supply, CPU power saving features must be disabled either in the bios setup or via the software as described below. It is recommended to control the CPU power saving features in the computer's BIOS rather than via software.

3.2.2 Entering BIOS

BIOS setup can be entered by following the instruction on the screen shortly after the system is switched on.

3.2.3 Changing BIOS setting

CPU power saving features need to be changed to have maximum power / performance by disabling Speed Step and other power controlling features.

See example below - changes into 'Disabled' must be applied to the functions inside the red boxes.

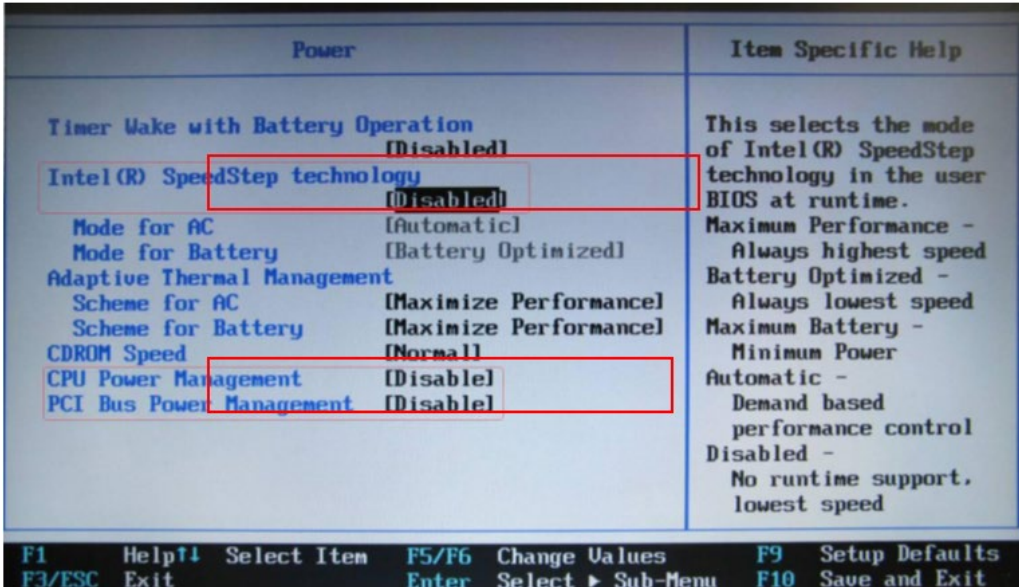


Figure 3.2.3-1 Bios settings

3.2.4 Windows Power Setting Setup

It is also necessary to disable Windows' own power saving features:

In control panel -> Power options properties, power manager, set power schemes to maximum performance as shown below:

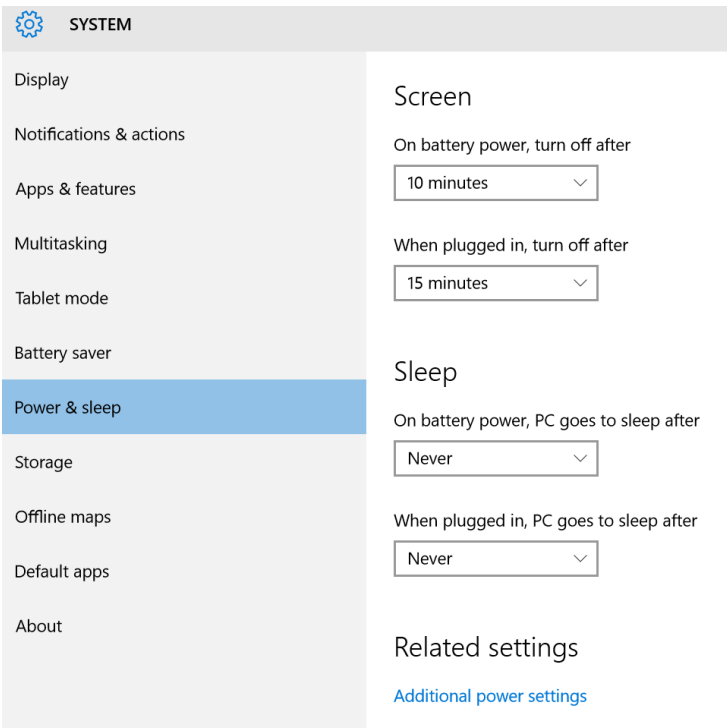


Figure 3.2.4-1 Power Option properties



3.2.5 USB mode

The EyeSeeCam vHIT camera must only be connected to a USB 2.0 port. If the computer only has USB 3.0 ports the USB 3.0 controller must be disabled so that the ports will work in USB 2.0 mode.

To downgrade from USB 3.0 to USB 2.0 please go to the BIOS/Config menu and select "USB". Set the USB 3.0 controller mode to "Disabled" and press F10 to Save and Exit the BIOS Config menu.

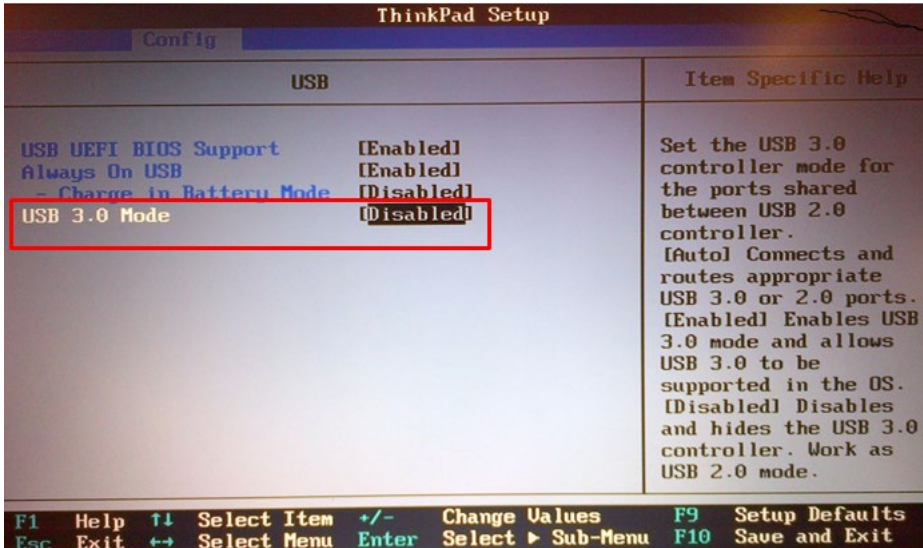


Figure 3.2.5-1 Bios Menu

3.3 Hardware setup

- Connect the USB cable to the computer
- Connect the other end of the USB cable to the EyeSeeCam camera
- Mount the camera on the goggle using the spherical ball-and-socket joint
- Mount the calibration laser on the bridge of the goggle
- Connect the computer power supply to a wall outlet, then connect to computer

3.3.1 Goggle setup

The vHIT goggle generally has one camera (monocular) fixed at the top side(s) of the mask. The camera is held in place mechanically with a spherical ball-and-socket joint. The vHIT goggle has two spherical sockets: one for the left and one for the right eye. The spherical joint allows the camera to be moved from the mask and plugged into the spherical socket of the other side. This allows for examining either the left or the right eye, depending on which eye is better suited for examination. This feature is particularly useful in patients with either a glass eye or with a ptosis.



Figure 3.3.1-1vHIT goggle and ball and socket joint for camera. Calibration laser is placed on the bridge of the goggle.

The vHIT goggle supports the USB camera that is used to record the eye images. This constitutes the major component of your USB vHIT system.

The USB camera uses infrared light (IR), which is not visible to the naked eye. The IR illumination enables sessions to be performed in complete darkness. Although it seems to be dark, the eye images will be displayed as clear and visible images due to the IR-illumination.

The USB vHIT goggle functions as free field of view only.



Before using the USB vHIT goggle please consider the following:

- The goggle and camera contain sensitive electronic and optical devices. Do not expose the goggle or cameras to mechanical shock
- Do not expose the goggle to moisture (IPX 0 according to IEC 529)
- USB vHIT goggle is not to be used around explosive gas.

In addition to the camera, there is a calibration laser in the center providing the visual fixation targets for calibration. The laser projects a luminous dot pattern in front of the head, for example, onto the wall, if the tested subject is sitting in front of the wall, or onto the ceiling, if the tested subject is lying. Just like the camera, this calibration laser can also be removed together with the camera. The calibration laser is connected to the camera by means of a flexible wire.

3.3.2 IR illumination

Light Emitting Diodes (LEDs) are positioned at the side of the camera objective lens. The lateral LEDs emit infrared light (IR).



3.3.3 Focus adjustment

The lens of the camera module allows you to focus the image. As eye sockets vary in physical dimension from patient to patient, absolute focus requires adjustment to provide focused images – and focused images are a precondition for stable eye tracking and noise-free data. The eye is in focus if details of the individual patterns in the iris (iral signature) are well visible.



Figure 3.3.3-1 Focus adjustment for camera

3.3.4 Calibration laser Adjustment

The calibration laser, in the center of the goggle, has a knob that allows you to align the dots on the wall by slightly rotating the knob until the 5 laser dots are aligned horizontally and vertically. Do not adjust the calibration laser unduly. Adjust only if the dots have gone out of horizontal/vertical alignment.

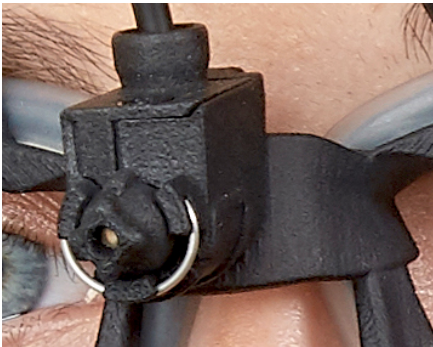


Figure 3.3.4-1 Calibration laser adjustment



3.4 Servicing and maintenance

The vHIT system must be serviced at least once a year. The service must include a safety test.

3.5 Software setup

Installation of OtoAccess® – Please refer to the OtoAccess® manual and documentation.

Installation of EyeSeeCam vHIT software - Please refer to the EyeSeeCam installation CD and instruction.

3.5.1 Installing EyeSeeCam software

Follow the prompts on the screen to step through the software installation.

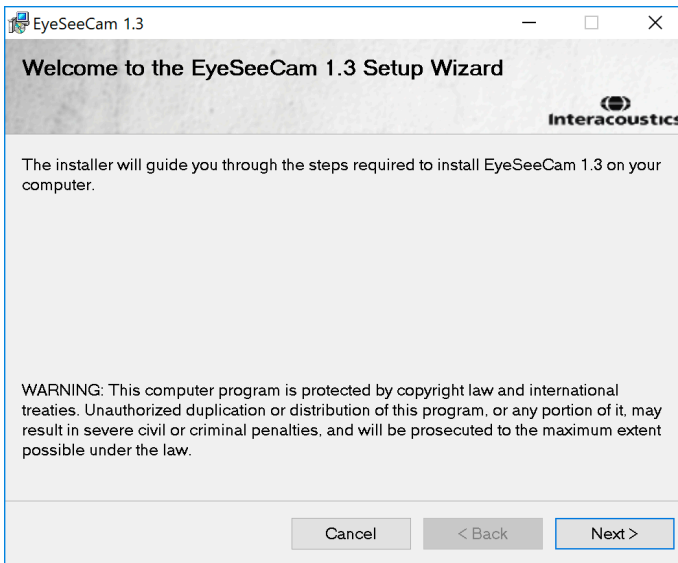


Figure 3.5.1-1 Set up Wizard for EyeSeeCam

3.5.2 Uninstalling the EyeSeeCam vHIT software -

Please refer to the EyeSeeCam installation CD and instruction.

3.5.3 Starting EyeSeeCam from OtoAccess® 1.5

To start EyeSeeCam:

1. Double Click the OtoAccess® icon on the desktop which will open the OtoAccess® program
2. Select the instrument (in this example, EyeSeeCam) by double-clicking EyeSeeCam in the Select Instrument box. EyeSeeCam will open in a new window.

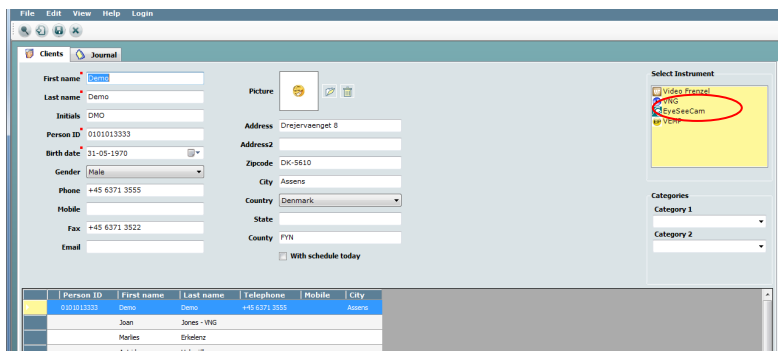


Figure 3.5.3-1 OtoAccess® 1.5 Opening Screen



Note

See the OtoAccess® Online Manual for more information about the user interface.

3.5.4 Starting EyeSeeCam from OtoAccess® 2.0

Open OtoAccess® and select the tab for EyeSeeCam.

Select the instrument module (in this example, EyeSeeCam) by clicking the EyeSeeCam icon in the upper left-hand corner. EyeSeeCam will open in a new window.

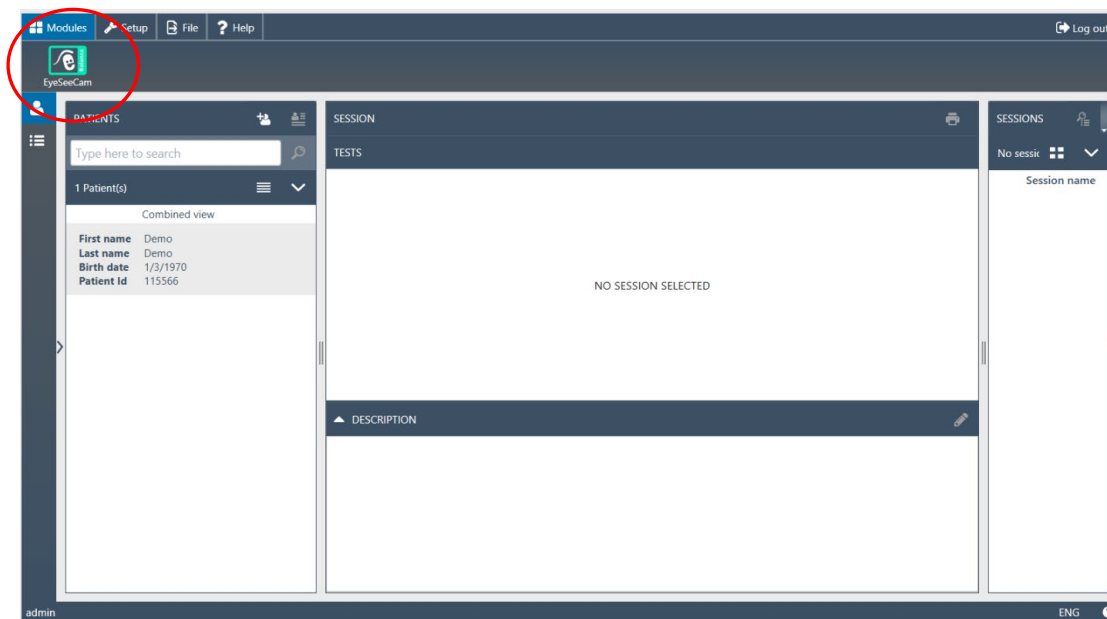


Figure 3.5.4-1 OtoAccess® 2.0 Opening Screen

3.5.5 Backing up files in OtoAccess®

Please refer to your OtoAccess® manual for the procedures on how to back up your patient files.





4 Test procedures

4.1 Opening Screen

The opening screen displays the image of the eye in the upper left hand corner and a Recording menu that allows you to select which test you want to perform.

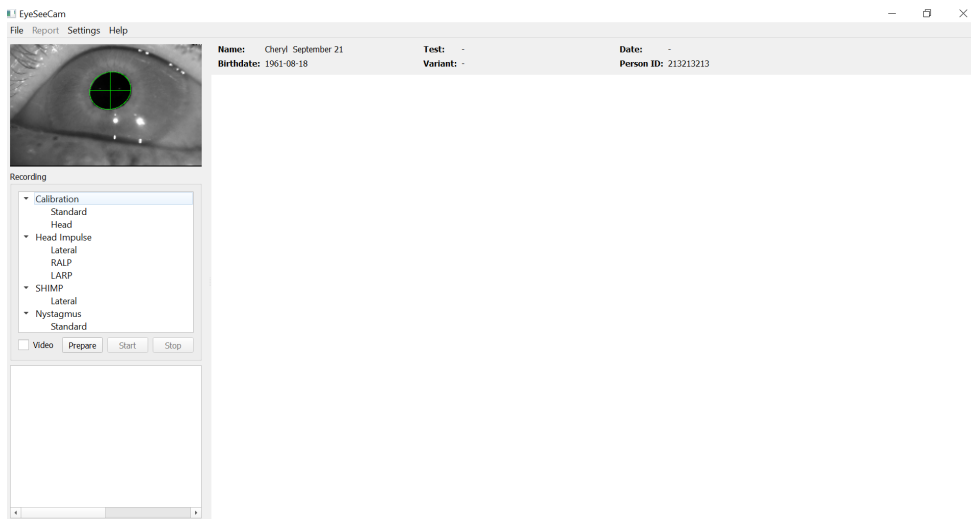


Figure 3.5.5-1 vHIT User Interface

4.2 Eye calibrations

Place the goggle on the patient and select Calibration - Standard. Fasten the goggle strap. This is essential to avoid the artifact “slippage”, e.g. a delayed recording of the eye movement in relation to the head movement. Position the camera cable centered in the back of the head. This is important to avoid touching it during head impulses.

4.2.1 Prepare the patient

A click on the **Prepare** button will display the calibration screen and turn on the red calibration laser dots. In prepare mode you can instruct the patient and use the real-time tracings to monitor eye and head movements and check for noise or artifact before beginning the calibration.

Ask the participant if all five appearing laser points are clearly visible. If not, special lenses can be applied to the goggles for short sight correction.

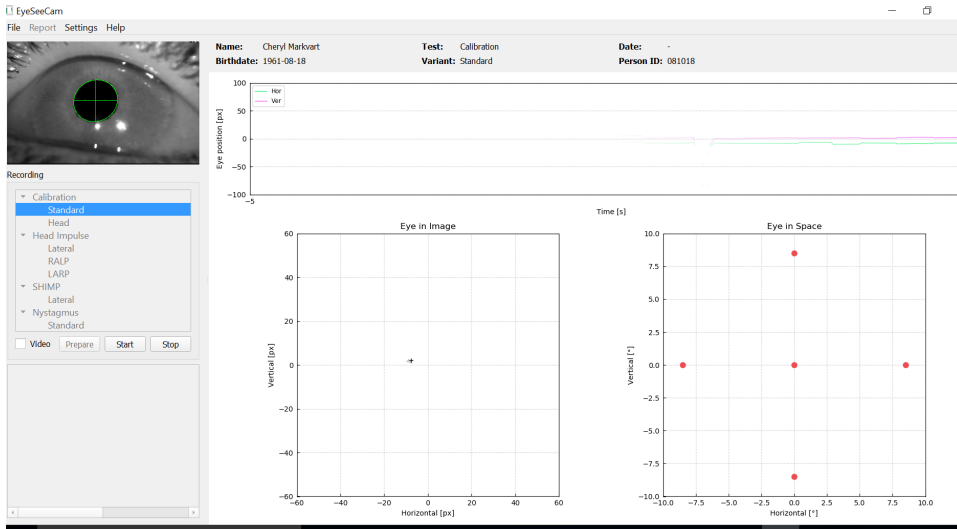


Figure 4.2.1-1 Calibration Preparation Screen

4.2.2 Adjust the eye/camera

Instruct the patient to fixate on the center luminous dot.

Optimize pupil detection by focusing and adjusting the camera. The pupil should be centered. To avoid partial occlusion by receding eyelids, participants can be told to open their eyes wide, the eyelids can be torn gently under the rim of the goggles.

Align the camera by rotating it in its ball-and-socket joint such that the eye is finally centered in the image. The camera can be rotated in three directions: yaw, pitch, and roll. At one time, however, rotate the camera only in one of these three possible directions. After the eye is centered in one direction, e.g., in the horizontal direction, choose the next rotation direction, e.g., the vertical direction. A possible alignment sequence to center the eye is shown below.

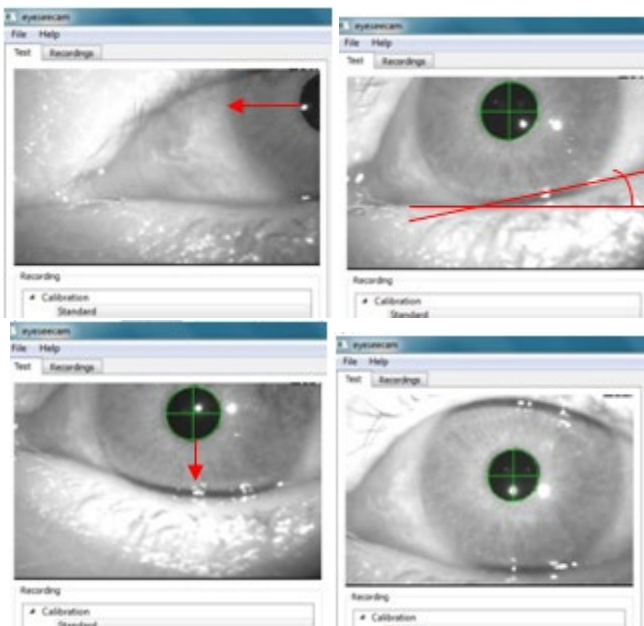


Figure 4.2.2-1 Centering the pupil in the image with a sequence of three camera rotations. Immediately after the goggles are placed on the patient, the eye can assume a position as in the upper left image. From this starting position, the camera first needs to be rotated such that the pupil is centered horizontally.



The red arrow in the top left image indicates how the pupil will move during such a camera rotation in roll. After this rotation the pupil is centered horizontally (top right image). Then a yaw rotation of the camera aligns the lower eye lid to an approximately horizontal orientation, as indicated by the red rotated line in the top right image. Finally, a camera rotation in pitch will move the pupil vertically (red arrow in bottom left image) until the pupil is completely centered (bottom right image).

4.2.3 Calibrate the patient

Start and stop standard calibration

You can begin testing without calibrating by just selecting a test and starting the impulses. In this case a default calibration will be taken. This is a good solution for difficult situation or challenging patients, but we still recommend that the user perform a calibration whenever possible.

To begin calibration, the patient is seated 1.5 meters from the wall where the red laser dots are projected and is asked to hold their head still. Instruct the patient to alternate fixating on the 5 brightest projected dots as announced by the examiner.

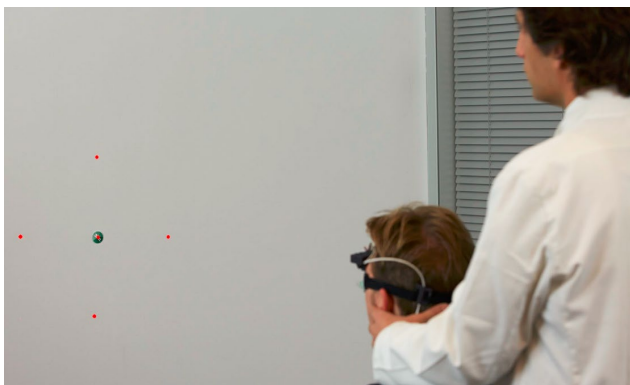


Figure 4.2.3-1 Calibration target with laser images.

Press **Start** when you are ready to begin recording. You will be able to see the eye looking at each target as a cross appears in the Eye in Image area.

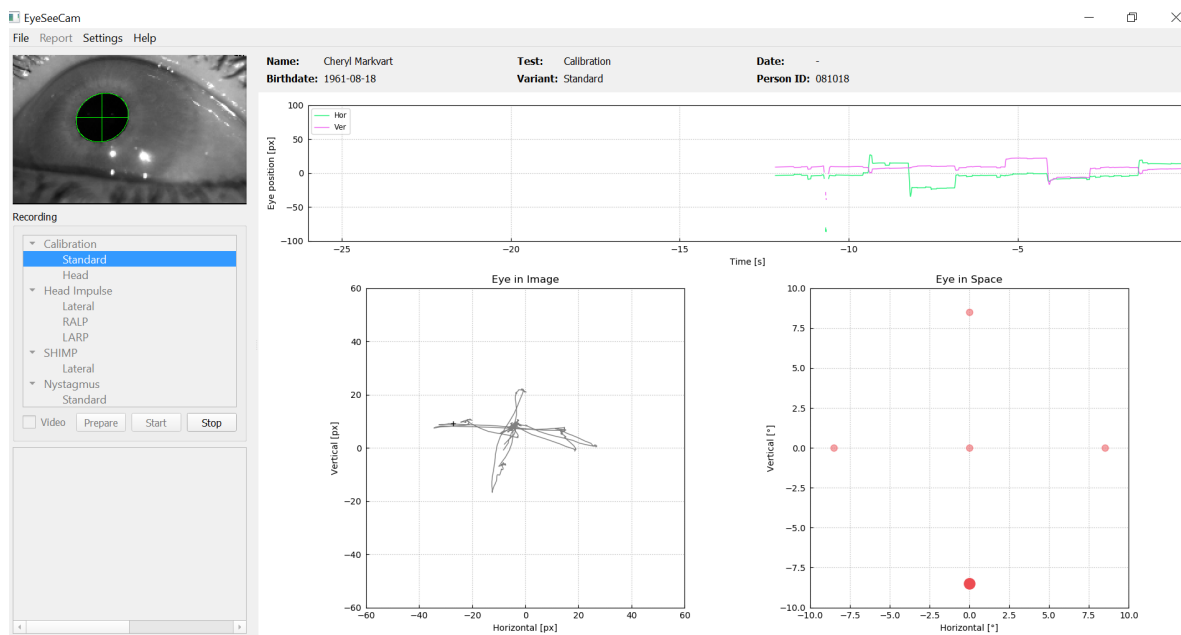


Figure 4.2.3-2 Calibration in progress screen. The big red dot in the Eye in Space plot (bottom right) indicates that the patient should fixate on the right calibration dot.



During the calibration, a suggested target will be displayed with a large red dot which will move in a sequence of jumps from fixation point to fixation point, indicating the next desired fixation. With the help of this display, the examiner can announce to which target the patient should be looking at.

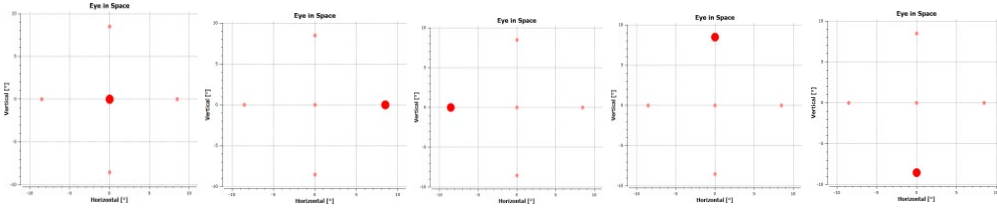


Figure 4.2.3-3 Sequence of calibration fixations displayed in the Eye in Space plot at the bottom right of the calibration screen. The sequence is: center, right, left, upper, lower. This sequence is repeated twice within a duration of 24 seconds.

The calibration procedure will automatically stop after about 24 seconds. If you wish to end the calibration before, then select **Stop**.

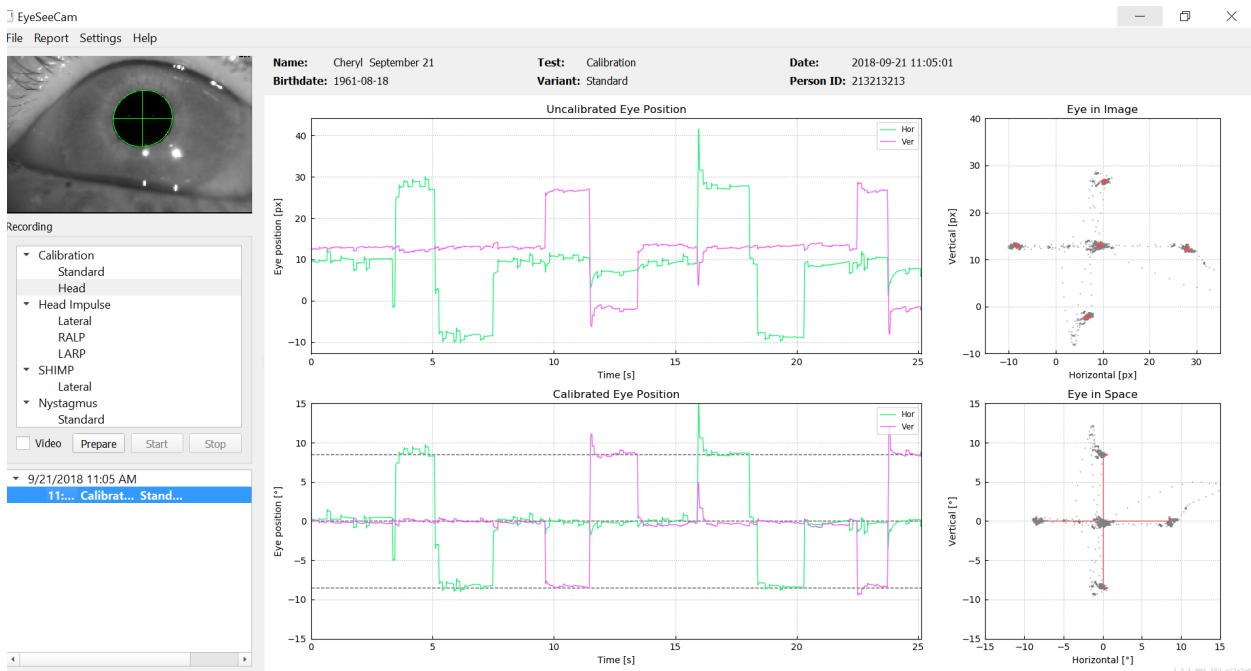


Figure 4.2.3-4 Completed Standard Eye Calibration screen.

Evaluate the calibration: a successful calibration should form a cross with accumulations of gaze points around the instructed laser points. A false calibration shows scattered gaze points and has to be repeated.



4.3 Head calibrations

After completing the standard (eye) calibration, then you should calibrate the head position of the patient before beginning impulses. You can click on the Head calibration heading in the recordings menu to begin.

4.3.1 Prepare Patient

Begin by selecting **Prepare** and instructing the patient.

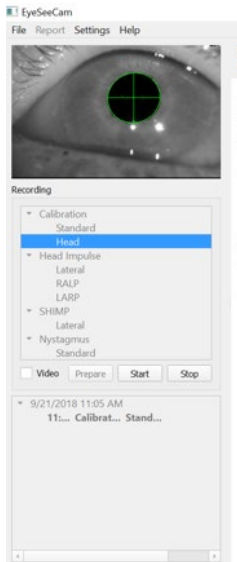


Figure 4.3.1-1 Lateral Impulse Prepare

The head movements can be passive, where the clinician moves the patient's head, or active where the patient moves their own head.

The patient is instructed to keep his eyes on the target on the wall and oscillating the head gently, first around the yaw axis (like shaking your head “no”) and, after a few oscillations, around the pitch axis (like nodding your head “yes”). The examiner can perform the head calibration by standing behind the patient and grabbing the head the same way as during head impulse testing of the lateral canals. About five sinusoidal oscillations in both yaw and pitch directions need to be performed at moderate peak head velocities not exceeding 100 deg/sec. The total duration of the head calibration is on the order of 15 sec.

4.3.2 Start Head calibration

Select Start to begin the test and select stop when finished.

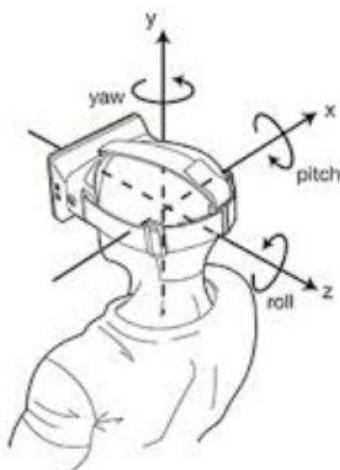


Figure 4.3.2-1 Diagram showing the different planes of head rotations.



During the head calibration procedure, you will see a graphical representation of the data. The areas of interest to you are (a) Head velocity in degrees per second, (b) eye position in degrees, (c) a circular plot of roll/pitch and (d) yaw/pitch

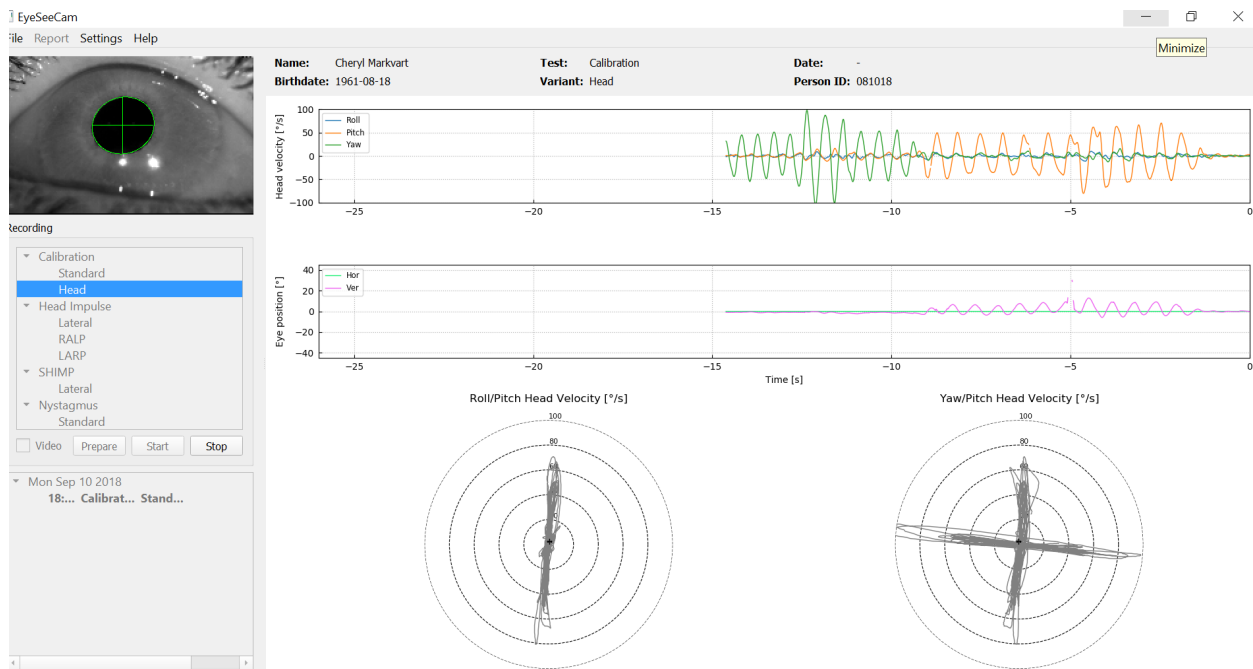


Figure 4.3.2-2 Graphical representation of the data

The head calibration aligns the possibly oblique inertial sensor axes with the true earth-horizontal and earth-vertical directions. During head calibration the Real-Time Preview shows in the upper two diagrams the head velocity and eye position over time. Please try to keep peak head velocity around 50 deg/sec, although the exact value is not important. However, it is important to not exceed 100 deg/sec such that the patient can keep the eyes on the fixation target on the wall. At head velocities exceeding 100 deg/sec patients with a vestibular loss will not be able to keep their eyes on the target due to the limitations of the human smooth pursuit system.

The lower two polar diagrams show the head movement directions in the coordinate system of the camera-attached inertial sensors. From this information the calibration analysis will automatically remap the alignment of the sensors.

4.3.3 Calibration report – Head

After the calibration is completed the Full report for the head calibration will be generated automatically. This report presents the information in a similar way as the polar diagrams of the Real-Time Preview. However, the eye and head motions over time are not shown. Instead, a three-dimensional representation of head movements with respect to the earth horizontal and vertical directions is shown together with the head movements with respect to the possibly oblique axes of the inertial sensor. The three polar diagrams at the right of the report show the head movements from three different perspectives.

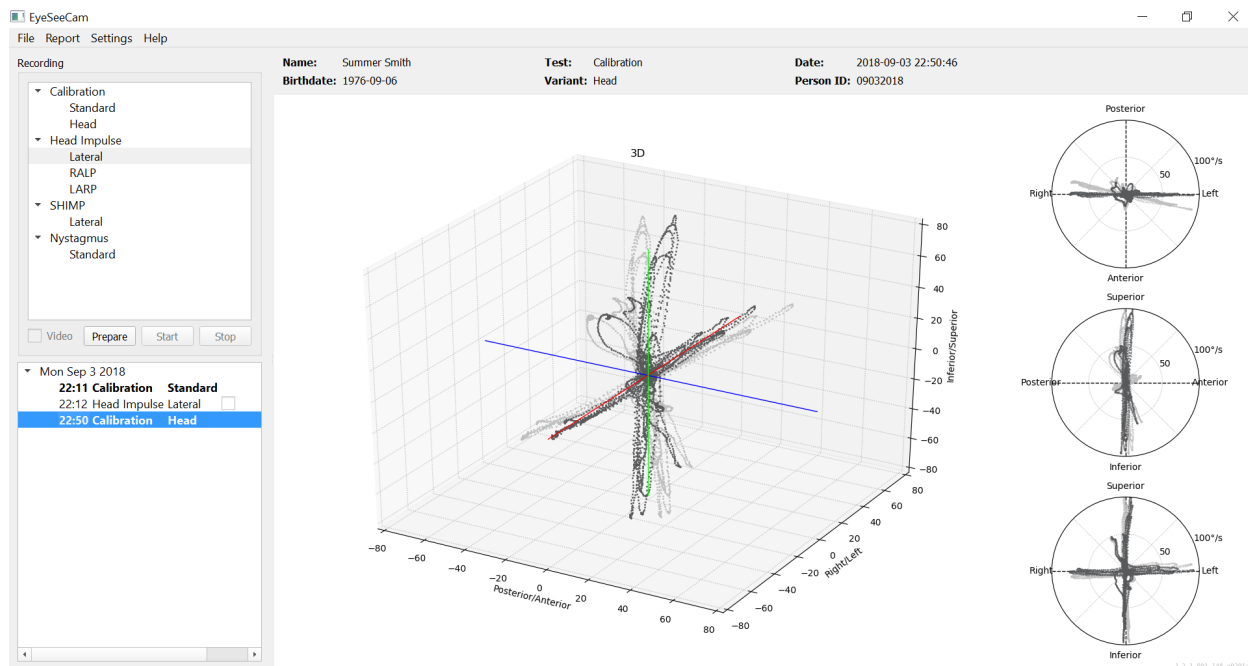


Figure 4.3.3-1 Full calibration report

4.3.4 Edit and Default Calibrations

You can select the default calibration for the eye calibrations or the head calibration value but there is no option to edit the head calibration.

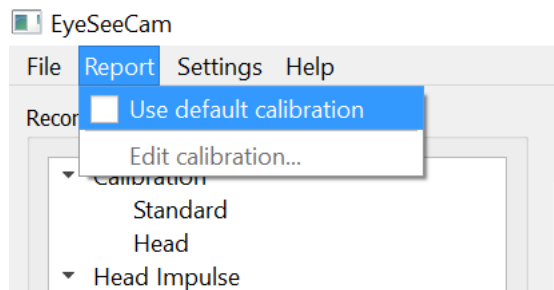


Figure 4.3.4-1 Report function for calibration to allow default values or edit existing eye calibrations.

You can edit the eye calibrations by clicking on one of the red dots and moving the dot to a new location.

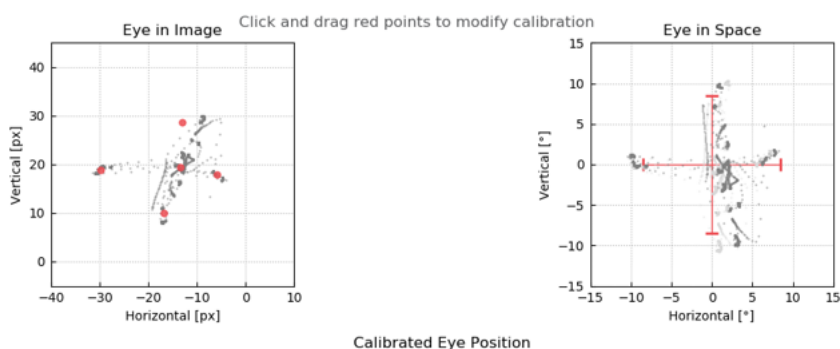


Figure 4.3.4-2 Edit eye calibrations



4.4 Lateral impulses

4.4.1 Training guide

Before starting the test you can decide if you need to use a training guide. You can choose this option under the Setting drop down menu by making sure there is a check mark in the box in front of the **Training Guide**.

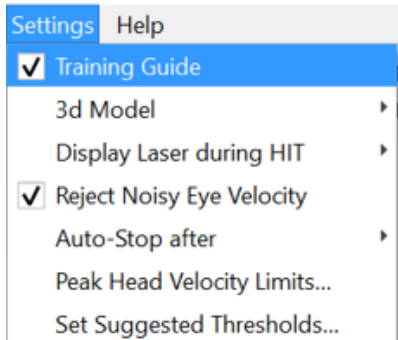


Figure 4.4.1-1 Setting Menu Training Guide Option

Peak Head Velocities are set in the velocity limits table (section 4.4.7).

The values entered into peak velocity table will determine the limits of the colored impulse guides (red shading for right impulses and blue shading for the left impulses) The peak Head impulses that are in the accepted range will peak in shaded areas with a default setting of a lower cut-off of 150 degree/sec and must peak by 80 ms into the thrust. When the requirements are met, the waveforms for head and eye movements will be shown together with a green check mark. If the head impulse does not meet these requirements a red cross will be shown. The head movements are seen as red for right impulses and blue for left impulse and the black lines represent the eye movements. In the raw data real time tracings the head is black and the eye is in green. The lighter gray lines show the historical impulses that were previously collected. The most recent impulse is in a bolder black color.



Figure 4.4.1-2 Legend for Head, Eye and History colors for impulses

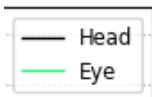


Figure 4.4.1-3 Legend for Head and Eye colors for real time data.

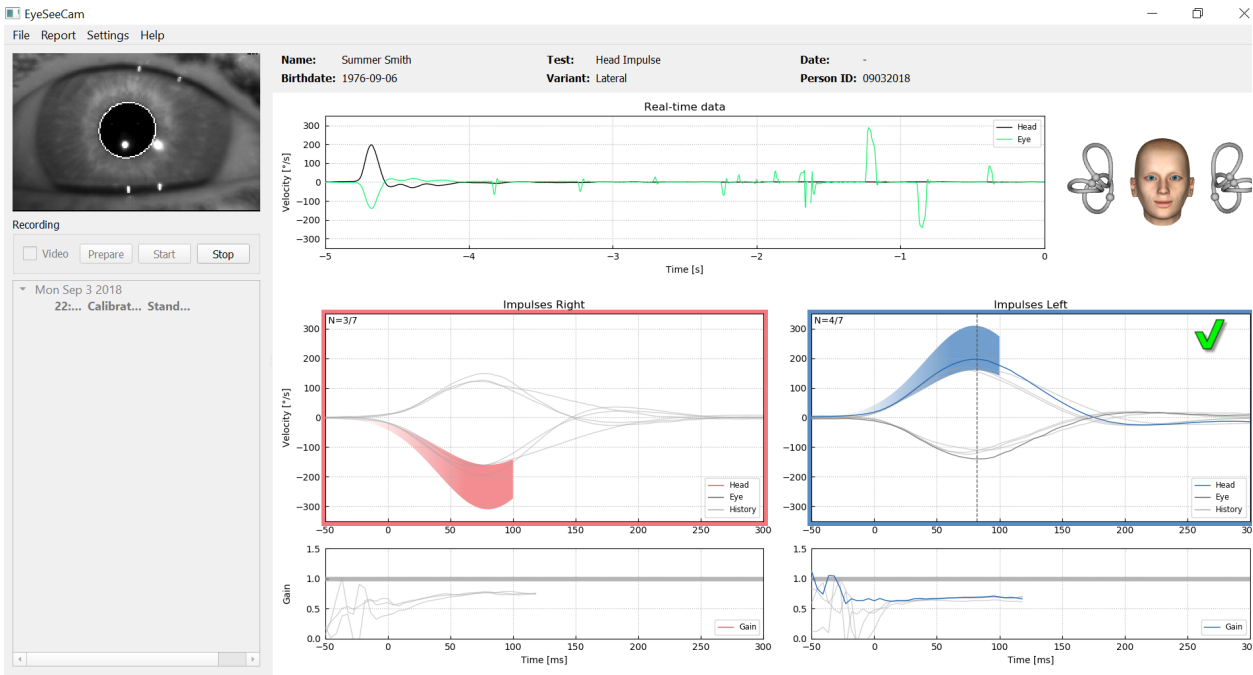


Figure 4.4.1-4 Lateral Test Screen showing shaded threshold areas and real time data.

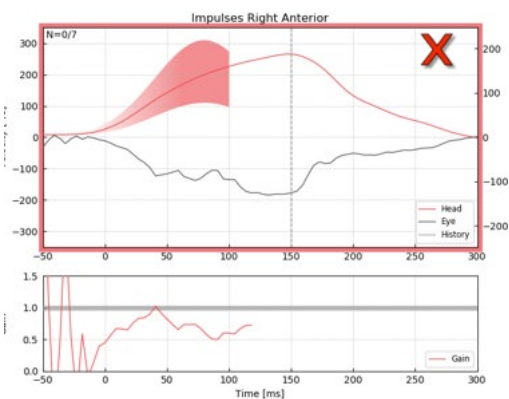


Figure 4.4.1-5 A right head impulse that did not meet the acceptable velocity requirements.

4.4.2 3D Head Modeling

A 3D head model with anatomically correct positioning and movement of the semicircular canals is presented. It can be used as a further guide to help you determine if the head is in the correct position and confirms which canals are being stimulated.



Figure 4.4.2-1 Head and semicircular canal model



The canal orientation can be selected from the Settings menu by selecting **3D Model**. If the model is enabled you can view it from any direction. You can also choose to have the model moving or static.

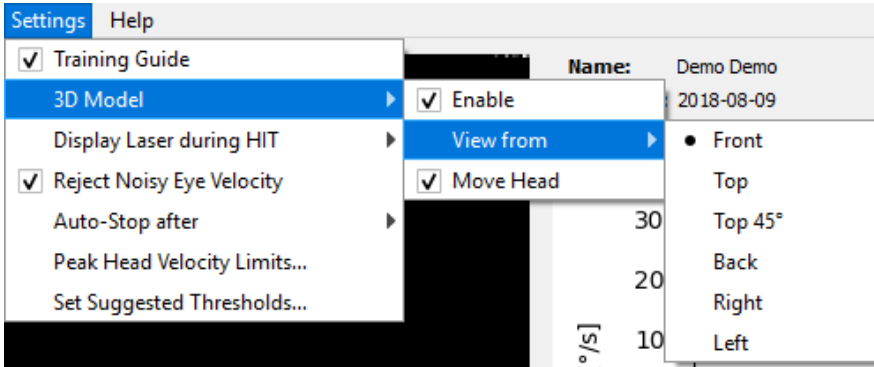


Figure 4.4.2-2 Setting Menu 3D Model options

The canals are shaded with red to indicate activation and blue to indicate inhibition of the involved canals.

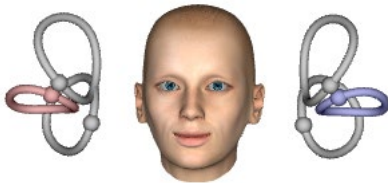


Figure 4.4.2-3 for a right lateral impulse, the right canal is activated and thereby shaded red and the left canal is inhibited and thereby shaded blue.

4.4.3 Display laser during HIT

Before starting a test you can decide if you want to use an external target you place on the wall or if you want to use the lights from the laser to project fixation targets for the patient to look at before and between the impulses.

In the Settings tab there is a menu item to **Display Laser during HIT**. Here you can opt to have the laser lights off or on during head movement. Some people will opt to use the center laser light as the target for the patient to focus on at the onset of the impulse. If you choose to use a method for generating impulses where the patient is rotated 45 degrees and gazing straight ahead, the availability of these laser dots will eliminate the need for you to move the target on the wall. For Suppression Head Impulses (SHIMP) the light will always be on.

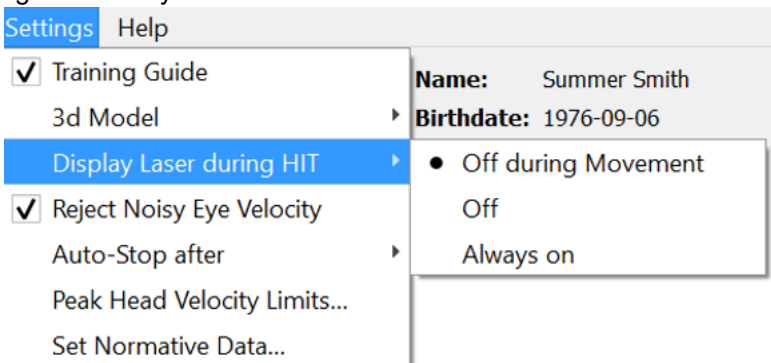


Figure 4.4.3-1 Display Laser during HIT menu



4.4.4 Reject Noisy Eye Velocity

If you would like to have the software automatically reject artifact and noisy eye movements you can tick the box on for *Reject Noisy Eye Velocity*.

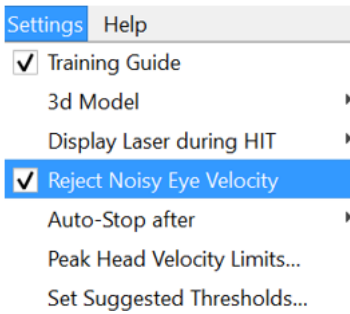


Figure 4.4.4-1 Settings Menu for Reject Noisy Eye Velocity

4.4.5 Auto-Stop

The software can be set to auto-stop (end data collection) after a pre-defined number (7 or 15) of valid impulses to each side, or it can be set to stop only after the Stop button is hit by the operator (Never).

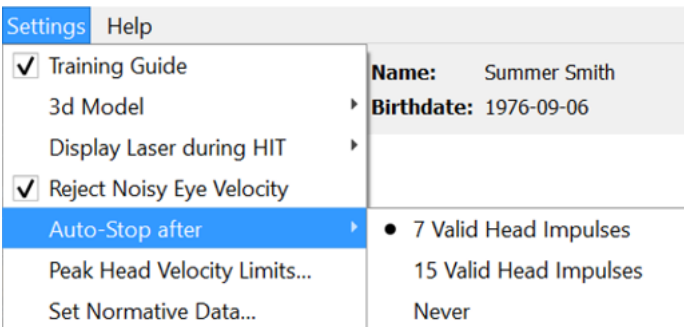


Figure 4.4.5-1: Auto-Stop enabled

4.4.6 Peak Head Velocity Limits

The peak velocity limits are the parameters that specify the minimum and maximum acceptable head velocities in the training guide (section 4.4.2). For the lateral head impulses, only one set of values are needed because the head moves only in the horizontal/lateral (yaw) plane. For LARP and RALP, the head moves in a combination of vertical (pitch) and roll planes. Only the vertical component is used for calculating the VOR gain. The minimum and maximum acceptable head velocities for RALP and LARP can be set either for the total head movements in both planes or just for the vertical plane. Changing the value in one column changes the value in the other column accordingly.

The values are set using a table for upper and lower limits. The values can be changed by using the up and down arrows to increase or decrease the values. For the vertical impulses you will see the total eye movements (including torsion) and then next to those values you will see the component specific to vertical eye movements only.

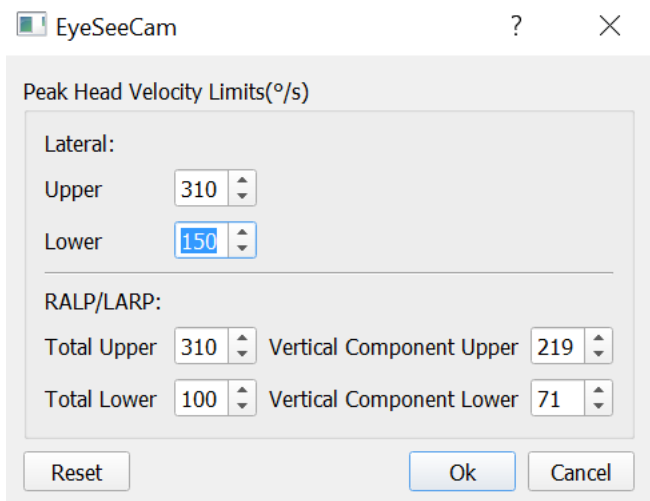


Figure 4.4.6-1 Peak Velocity Limits table

4.4.7 Set Normative Threshold Ranges

Suggested threshold values can be added in the table under *Settings Set Suggested Thresholds*.

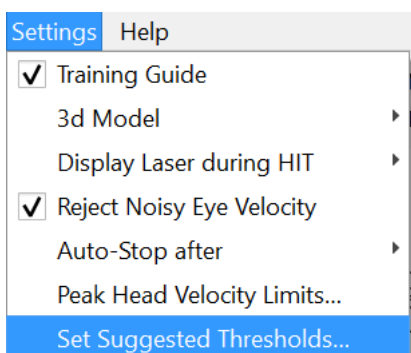


Figure 4.4.7-1 Setting Set Suggested Thresholds

In the table you can set the thresholds for Instantaneous Gain upper and lower limits, Regression Gain upper and lower limits and Gain Asymmetry in percentage. Each clinic should collect their own threshold levels and enter the values in the table. The values can be changed by clicking on the arrows keys after the numbers.

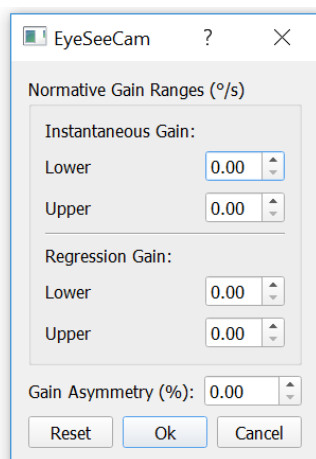


Figure 4.4.7-2 Suggested threshold table



When you enter numbers or change the numbers in the table you will get a pop-up message disclaimer. Please read through it and if you agree with press ok and then enter your new values.

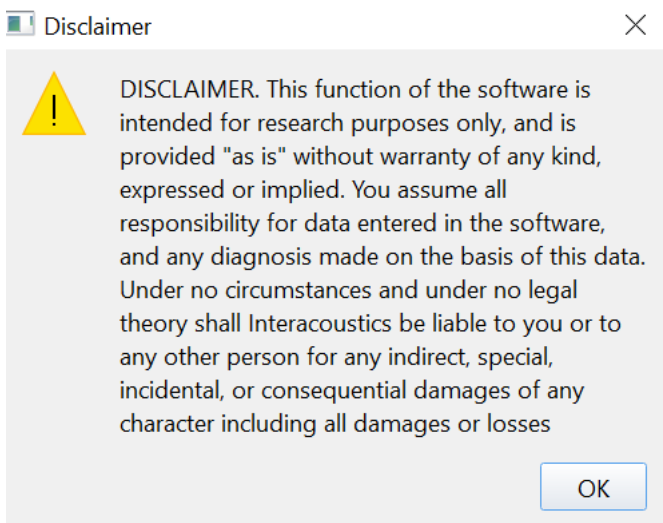


Figure 4.4.7-3 Disclaimer for suggested thresholds

After entering new values or changing existing values, you will need to restart the program before the values can be updated.

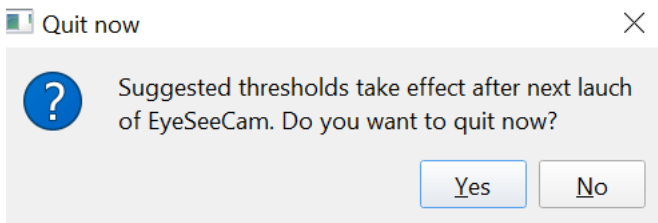


Figure 4.4.7-4 Restart EyeSeeCam to update threshold value changes

Once you have entered values into the table then you will see shaded areas on your graphical displays. Values plotted in the white area are within the suggested threshold levels.

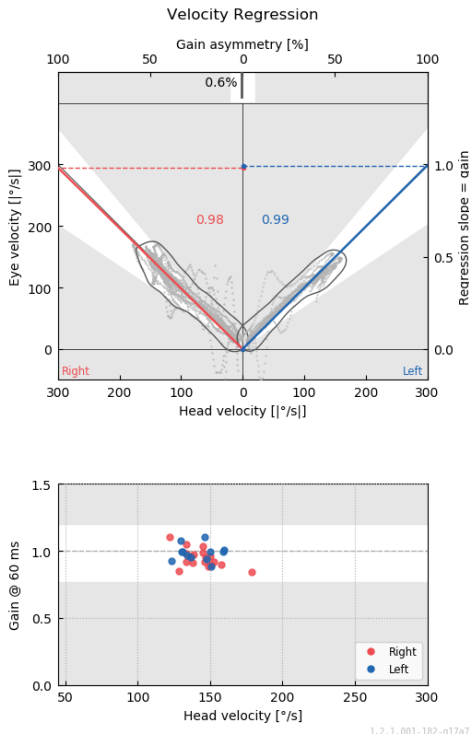


Figure 4.4.7-5 Shaded areas show suggested thresholds. Values plotted in the white area are within suggested threshold limits and values plotted in the gray area are outside the threshold areas. Head impulses to the right are shown in red and to the left in blue.

4.4.8 Default Settings

If you are unsure of any changes made to any of the settings in your protocols or suggested thresholds you can enter the Help menu and select Erase All Settings and Suggested Thresholds, which will reset all settings back to the default values.

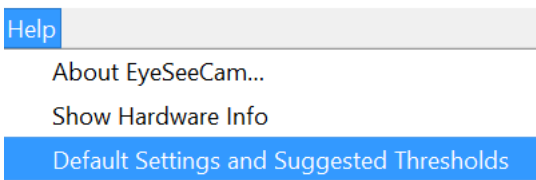


Figure 4.4.8-1 Help Menu for Default Settings

Before the default settings get reset you will get a pop-up message asking you to confirm the change. If you choose "Yes" to confirm the changes EyeSeeCam will quit and you will need to restart the program.

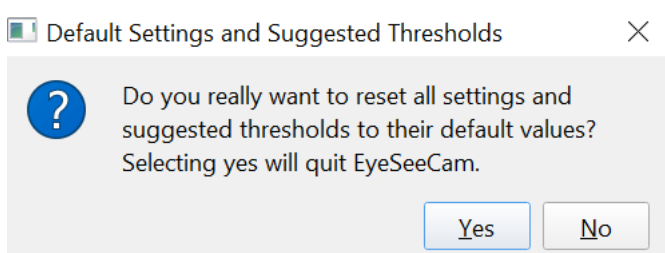


Figure 4.4.8-2 Pop-up message to confirm reset to default settings



4.4.9 Prepare to test

Click on Head Impulse – Lateral to get started. Next click on **Prepare** which will start the real time pretest eye movement raw data monitor and the practice mode which allows you to perform head impulses without collecting the data.

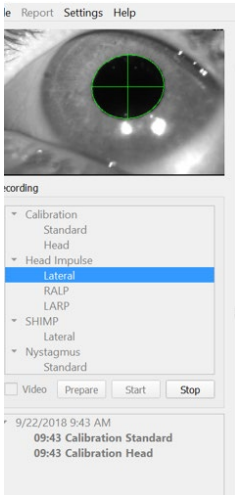


Figure 4.4.9-1 Prepare, Start and Stop functions for tests

After selecting Prepare the head impulse testing screen is displayed. The examiner needs to instruct the patient to focus on the target in front of them and to relax their neck muscles throughout the impulses. Instruct the patient to try not to blink during the head movement and to try not to resist the head movement. Instructing the patient to clench his or her teeth may help with the application of high acceleration head motion.

Place both hands on the jaw of the patient from behind. The correct technique for positioning the hands during the impulses is shown below.



Figure 4.4.9-2 Proper hand placements for impulses.



4.4.10 Start test

Select **Start** and begin doing lateral impulses.

The head of the patient should be turned horizontally to one side with high velocity, high acceleration, and small displacement. The direction should not be predictable for the patient and there should be different time intervals between the head impulses. After an impulse, the head should be held in the end position for a few seconds and then slowly rotated back to the initial position. Peak head velocity should be assessed right after each head impulse. If necessary, try relaxing the patient with slow head movements before starting the test for a better tolerance of the high peak head velocity necessary. It is important to avoid touching the goggles or stretching the patient's skin while applying the head impulse to avoid artifacts.

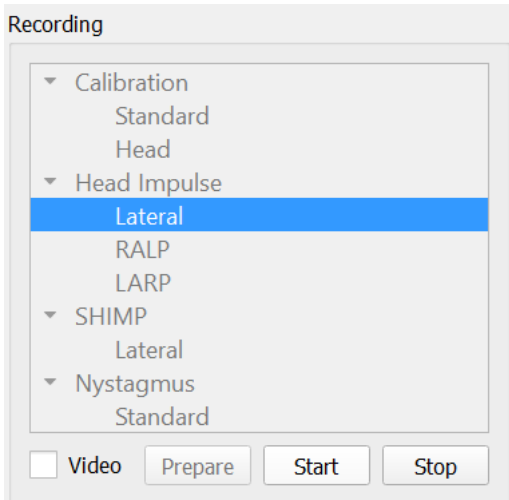


Figure 4.4.10-1 Start Data collection screen

4.4.11 Impulse counter

Each correct impulse you perform will generate an increasing count number in the upper left hand corner. This number will count every impulse you perform that produces a green check mark, but not the impulses that produce red X's. In the final report, the number of impulses will be the same as you see during the data collection unless there was artifact or noise present, and then the final algorithm will remove that tracing from the final report.

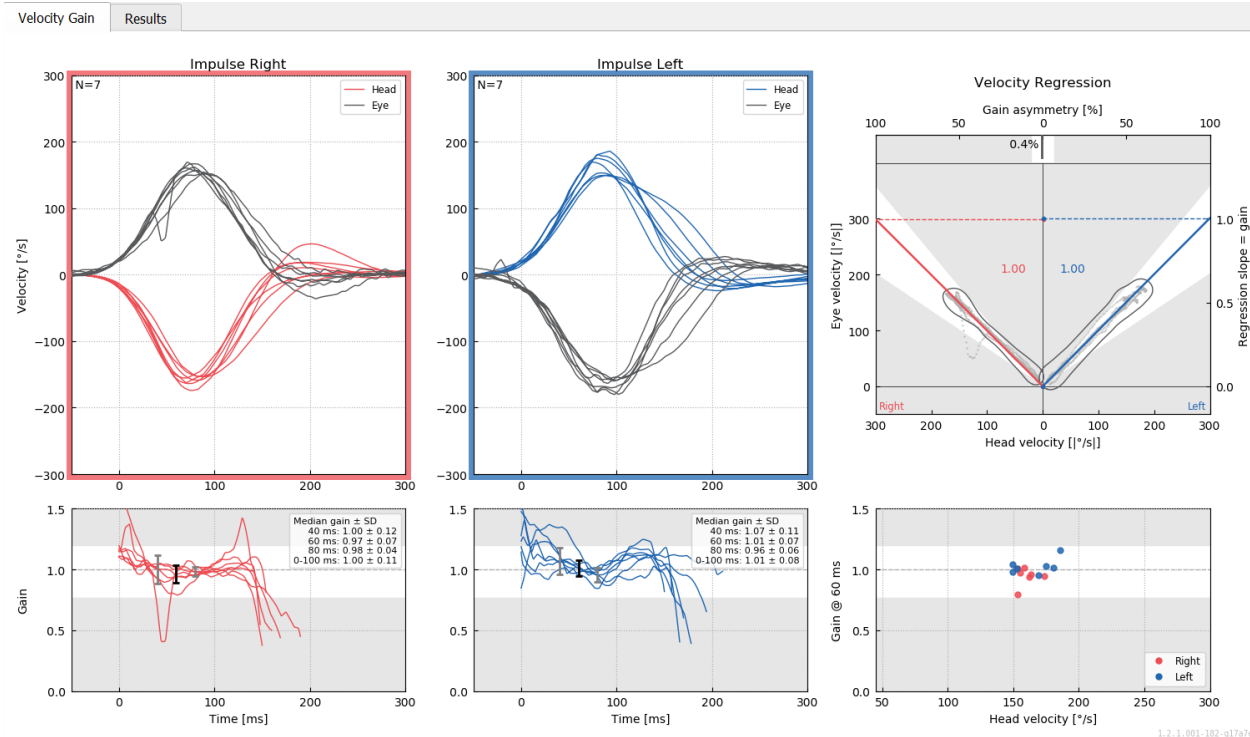


Figure 4.4.11-1 Data collection screen with Auto-Stop set to 7



4.5 Vertical impulses- RALP/LARP

For testing in the vertical planes you can select RALP and LARP protocols from the recording menu (right anterior/left posterior and left anterior/right posterior).

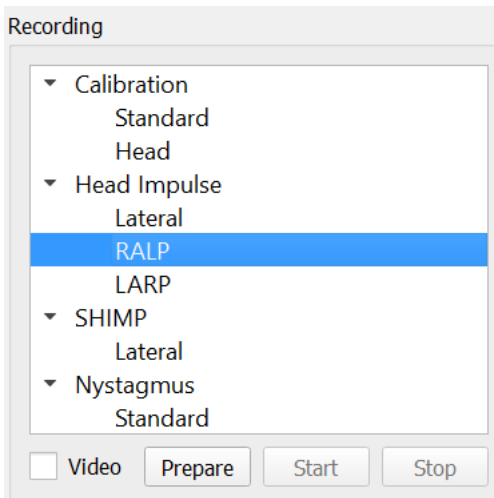


Figure 4.4.11-1 Head impulse testing – vertical canals

4.5.1 Background

The function of the horizontal VOR can be easily assessed with vHIT by rapidly rotating the head in the horizontal plane and measuring the resulting eye counter-rotation in the same plane. 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).

The EyeSeeCam protocol utilizes three well-documented properties of the VOR: 1) For fast head movements the axis of VOR eye rotation is head-fixed, i.e., independent of gaze direction, 2) the rotation axis can be separated into its horizontal, vertical, and torsional components, i.e., these components can be treated in isolation, and 3) the physiological frame of reference in which the VOR operates (the so-called “Listing’s” plane) is tilted backwards in pitch, i.e., it leaves the measurement of the vertical eye movement component unaffected. Even though EyeSeeCam records all three head velocity components, it eventually calculates the vertical VOR gain as the regression slope between solely the vertical components of eye and head velocities.

This usage of the vertical eye and head velocity components is best demonstrated in the following polar plot. The trace of a simulated head thrust with a velocity of 250 °/s in the RP direction (dark red) is plotted similar to how it would appear in the direction / plane guide. The thrust causes a VOR eye movement in the opposite direction (black). The isolated components of the head and eye movements along the vertical plane are shown in red and gray, respectively. It is the lengths of these two vertical components which are related to each other to calculate vertical VOR gain. Please note that the eye trace and the vertical components are just shown for clarification and that they do not appear in the direction / plane guide. Also, the eye trace is not in perfect opposition to the head trace because the VOR gain in the torsional plane is known to be less than unity (usually around 0.6). Nevertheless, the two vertical components (gray and red) are of the same length and would thus yield unity vertical VOR gain.

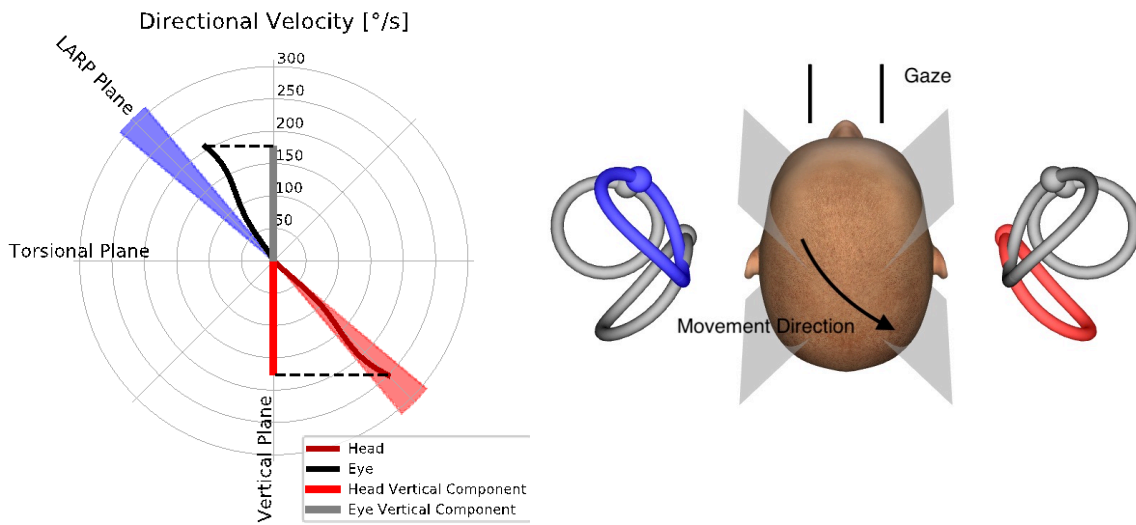


Figure 4.5.1-1 Direction / plane guide showing eye and head velocity as well as their respective vertical components during RP canal testing.

4.5.2 Eye Orientation

The correct eye orientation for the EyeSeeCam vertical canal testing protocol is straight-ahead along the midsagittal plane. This eye orientation ensures that the vertical pupil movement occurs within the calibrated range, where the measurement is optimal.

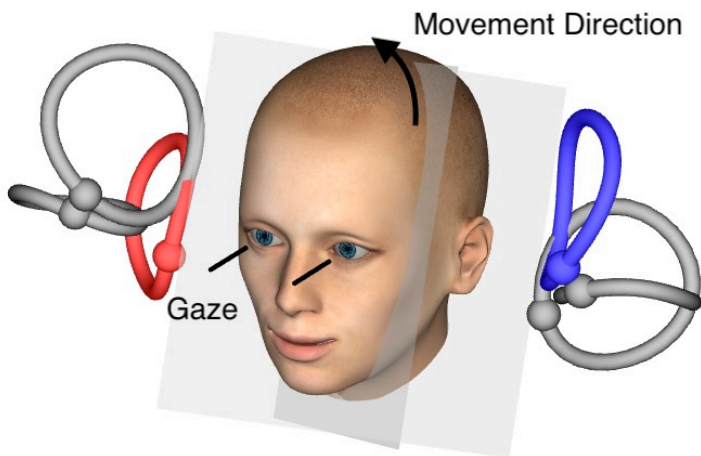


Figure 4.5.2-1 Vertical Head impulse testing – Orientation of semicircular canals, canal planes, and correct straight-ahead gaze in RP testing.



4.5.3 Head Orientation

Two head orientations with respect to the trunk are possible:

1. The head can be either straight (see below Figure 4.5.3-1, left), or
2. it can be rotated by
 - a. 45 degrees to the right for LARP testing (see below Figure 4.5.3-1, right) or by
 - b. 45 degrees to the left for RALP testing (not shown).

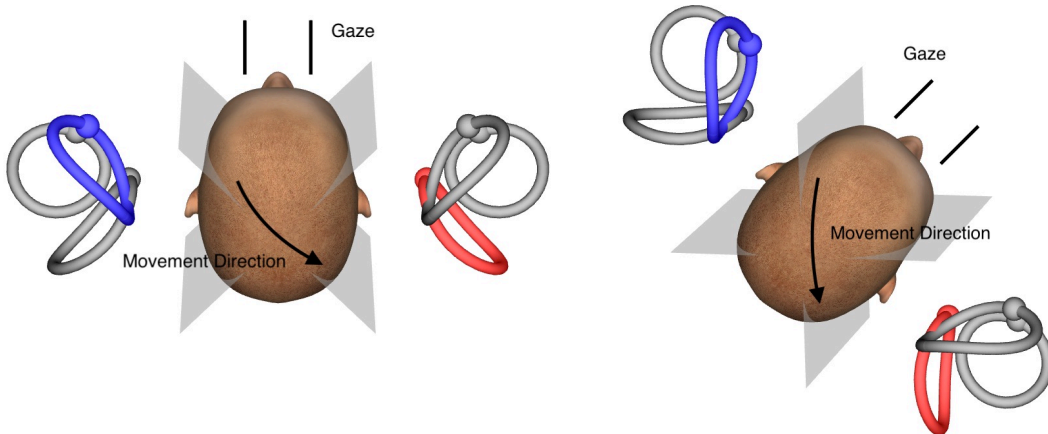


Figure 4.5.3-1 Vertical Head impulse testing – Two possible orientations of the head-on-trunk and correct straight gaze in RP canal testing.

It depends on examiner preferences whether the vertical head thrusts are easier to perform with the head straight or with the head rotated by 45 degrees. For some, testing in the rotated orientation might feel more natural because the neck anatomy is rotated in pitch only, not in the less usual diagonal direction. Whichever orientation you opt to use, the correct gaze is always straight along the midsagittal plane.

In order to provide fixation targets for all possible head orientations you can either place additional external targets at 45 degrees left and right on the wall or you can use the laser as described above in chapter 4.4.3 (“Display laser during HIT”). You can also adjust the 3D head model settings as described above in chapter 4.4.2 (“3D Head Modeling”) such that you can view it either from the “Top” position, if you opt for the straight orientation, or from the “Top 45°” position, if you opt for the rotated orientation. Depending on whether you select the RALP or LARP protocol, the 3D head model will be shown rotated 45 degrees to the left or right, respectively.

For testing in the vertical planes you can select RALP and LARP protocols from the recording menu (right anterior/left posterior and left anterior/right posterior).

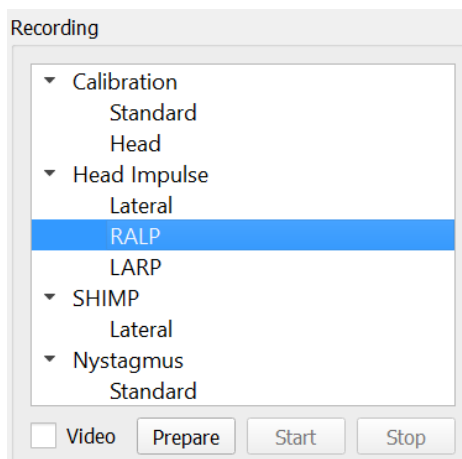


Figure 4.5.3-2 Head impulse testing – vertical canals



4.5.4 Prepare

Prepare will allow you to enter the practice mode just as in the prepare step for lateral canal impulses and to instruct the patient.

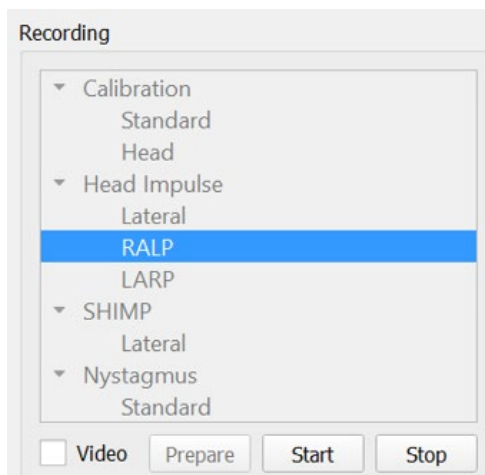


Figure 4.5.4-1 Recording menu prepare option

You can use the following or a similar instruction:

“I will be moving your head up and down in an angular pattern. Keep your eyes focused on the target on the wall the entire time. Please do not try to resist the head movements, as this will negatively impact the test results. Simply keep your neck loose to allow me to make the small movements.”

4.5.5 Direction/plane guide

This guide is shown to the right of the real-time data recording. You can also have the 3D head model present optionally.

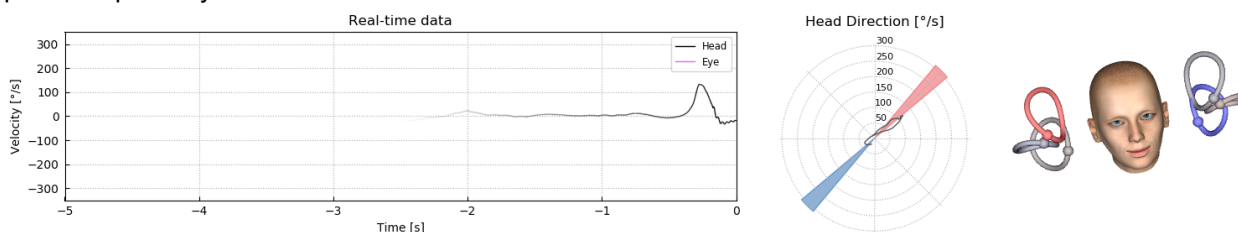


Figure 4.5.5-1 RALP Impulse Polar plot with impulse direction line shown in the red shaded area as an indication of correct thrust angle. The head model shows the right anterior canal activated and the left posterior canal inhibited.

The guide is there to show you if you are performing the impulses in the correct plane for that protocol. A line is plotted after each impulse that shows the angle measured for that thrust. Lines in the shaded area are within tolerance for an acceptable impulse angle.

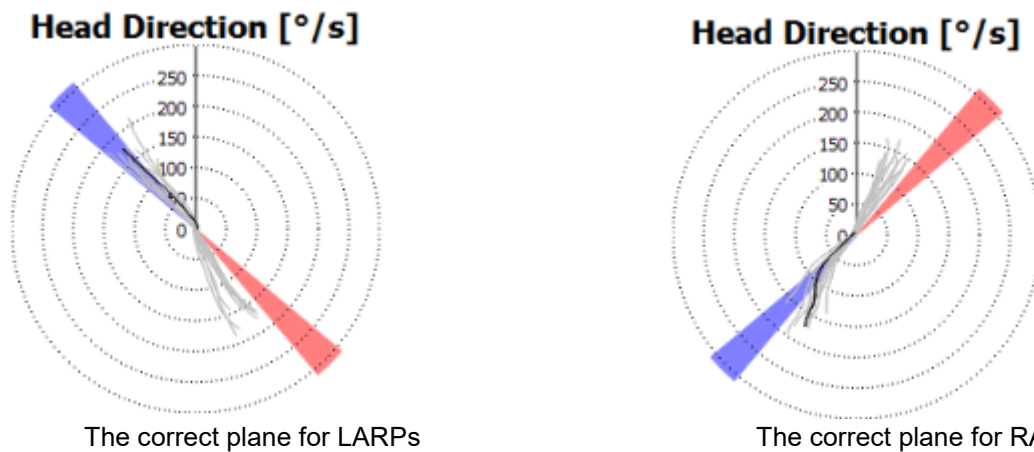


Figure 4.5.5-2 Direction/Plane guide

The last impulse performed is always shown with the darker black line. If your impulses are in the correct direction/plane you will see your response occur in the shaded areas. The blue shaded areas are for the LA or LP and the red shaded areas are for the RA or RP.

4.5.6 Start test

Select **Start** and begin performing RALP or LARP impulses.

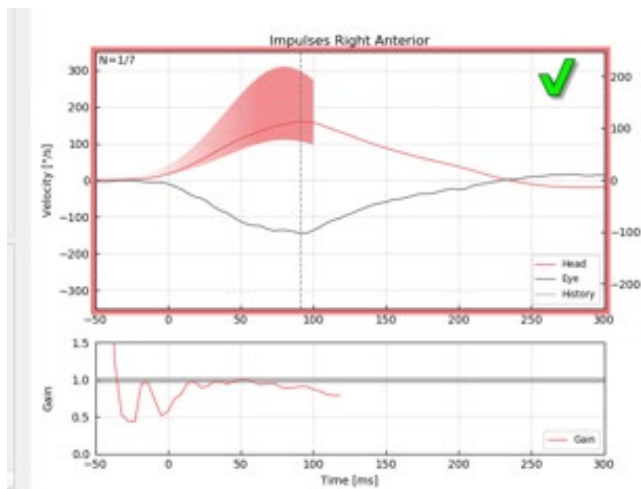


Figure 4.5.6-1 Data collection screen with an accepted Right Anterior Impulse

4.5.7 Stop

After a reasonable number of impulses are collected in both planes (7-10 anterior and 7-10 posterior) you can hit **Stop** which will end the data collection. Or you can use the auto stop as described in section 4.4.5.



4.6 Suppression Head Impulse Test (SHIMP)

When performing a SHIMP test select the default protocol in the Recording menu. The Prepare, Start and Stop functions are the same as in the impulse tests.

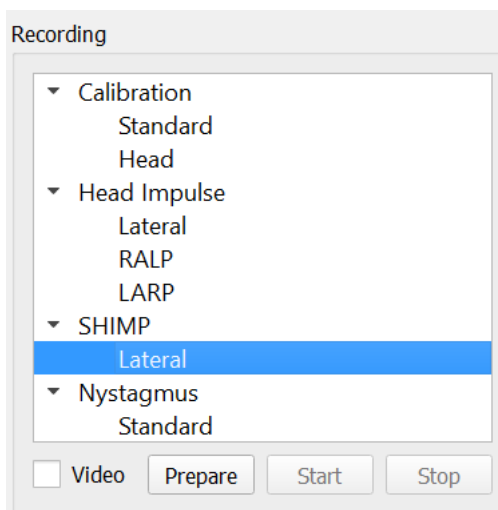


Figure 4.6-4.5.7-1 Recording Menu for SHIMP Test

In the SHIMP test the patient is instructed to follow the center laser dot as their head is thrust left or right. In a healthy subject with normal VOR function, the VOR will be active so the patient will temporarily lose the target (driving the eyes in the opposite direction to the head movement) and then they will need to make a corrective saccade to come back to the target.

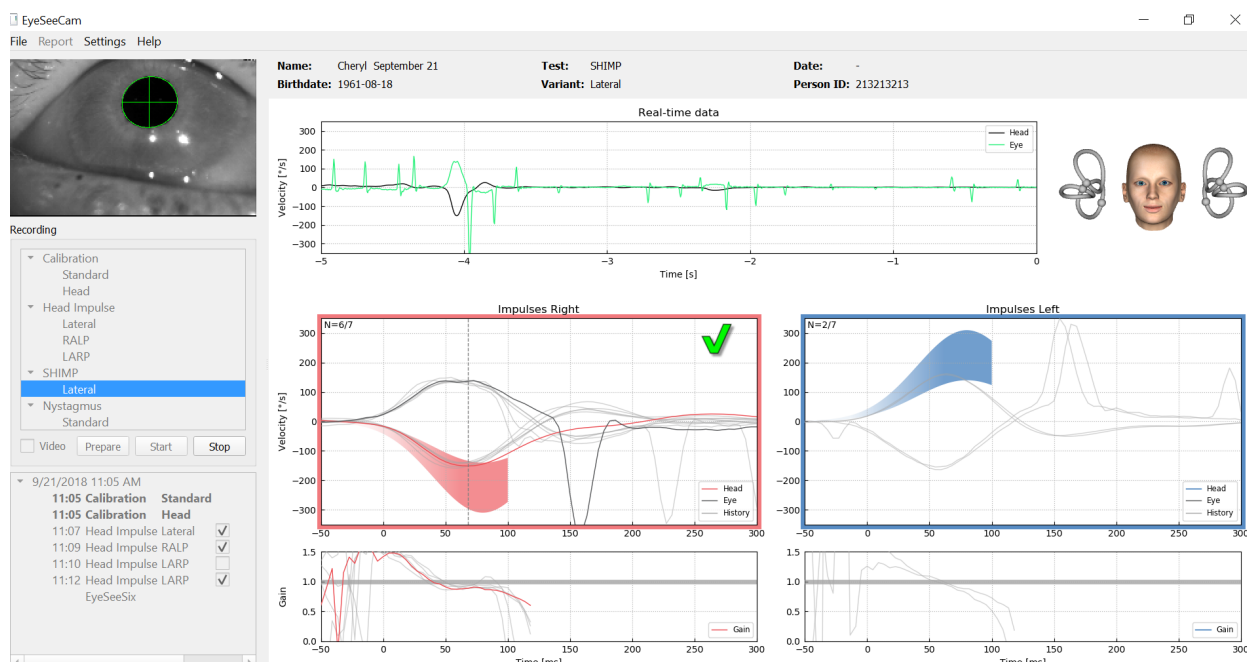


Figure 4.6-2 SHIMP test on a normal subject shows gains of near 1.0 and large corrective saccades.



4.7 Nystagmus test

There is a default protocol that allows you to measure nystagmus. This nystagmus can be video recorded and permanently documented in your patient records.

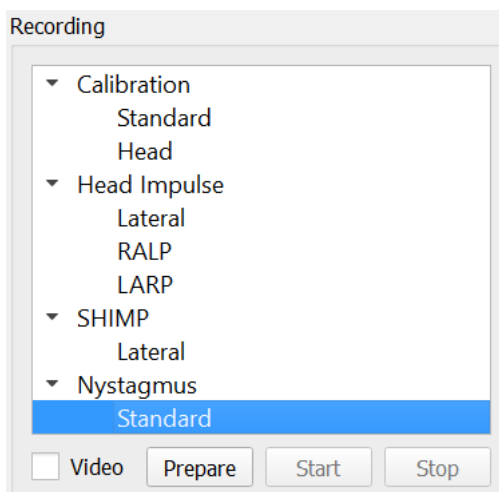


Figure 4.5.7-1 Recording menu Nystagmus Test

Prepare, start and stop work the same as in the Impulses tests. Once you start the recording you will see horizontal tracings in gray, vertical tracings in purple and if nystagmus is present the slope of the slow phase will be highlighted in green.

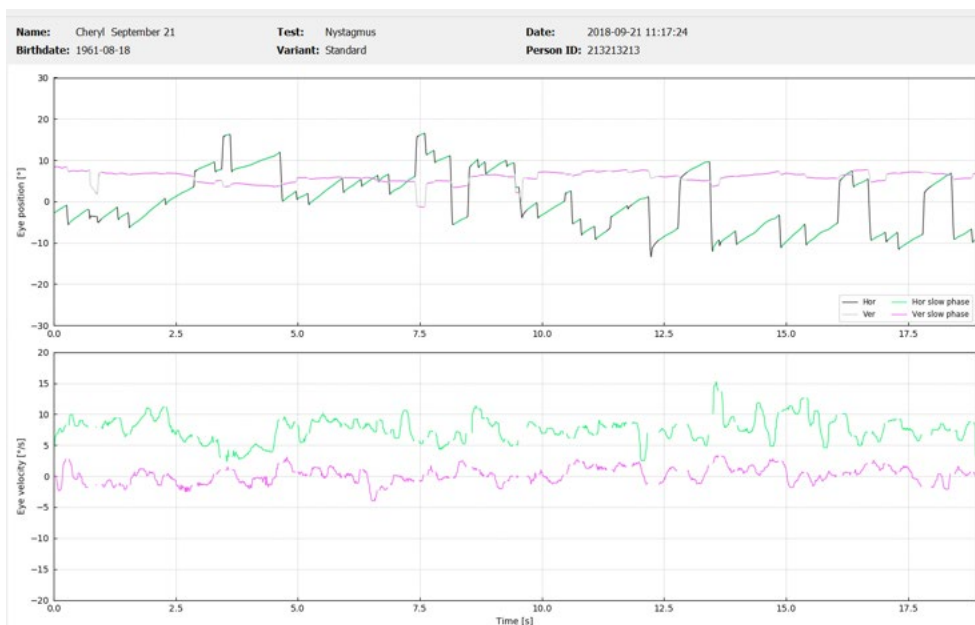


Figure 4.5.7-2 Nystagmus Measurement Screen



5 Reports

5.1 Report Menu Options

After you have completed a test a report will automatically be generated. You have several options available in the Report menu to help you edit and customize your reports.

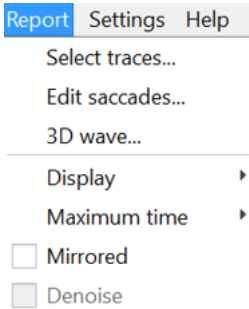


Figure 5.1-1 Report menu options

5.1.1 Select and Edit Traces

After you have finished your tests, in the Report menu you can **Select** traces to edit.

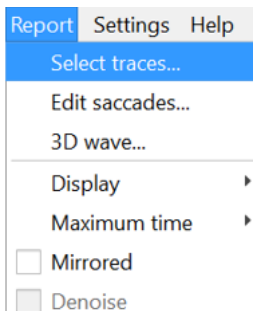


Figure 5.1.1-1 Report menu to Select traces

Once you opt to select traces, a new edit window will pop up called **Head Impulse Editor**. In this menu you can select individual or multiple data points to delete. If you click on an individual trace it will be bolded so you know it's active. If you hold down the control key you can click on multiple waveforms. After you have selected the waveforms that you want to delete, simply hit the delete key on the keyboard and these tracings will be removed from the analysis.

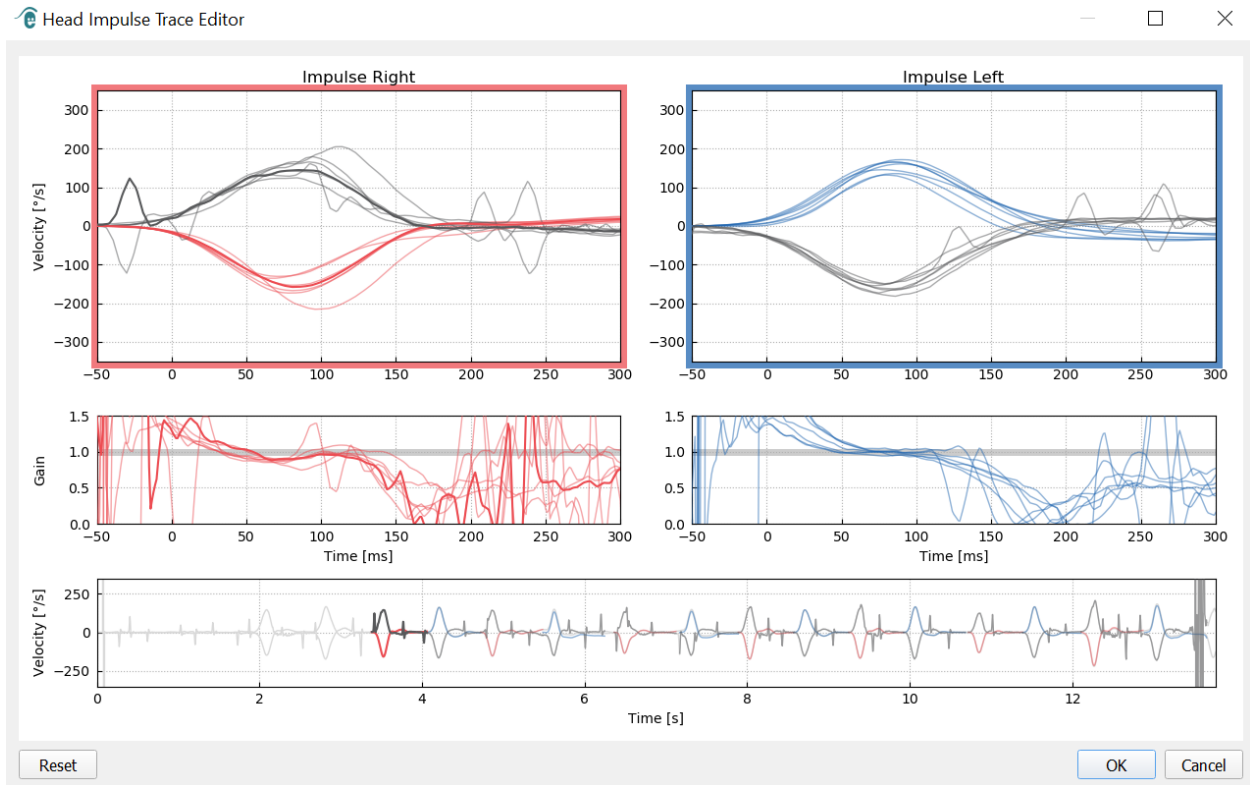


Figure 5.1.1-2 Head Impulse Trace Editor

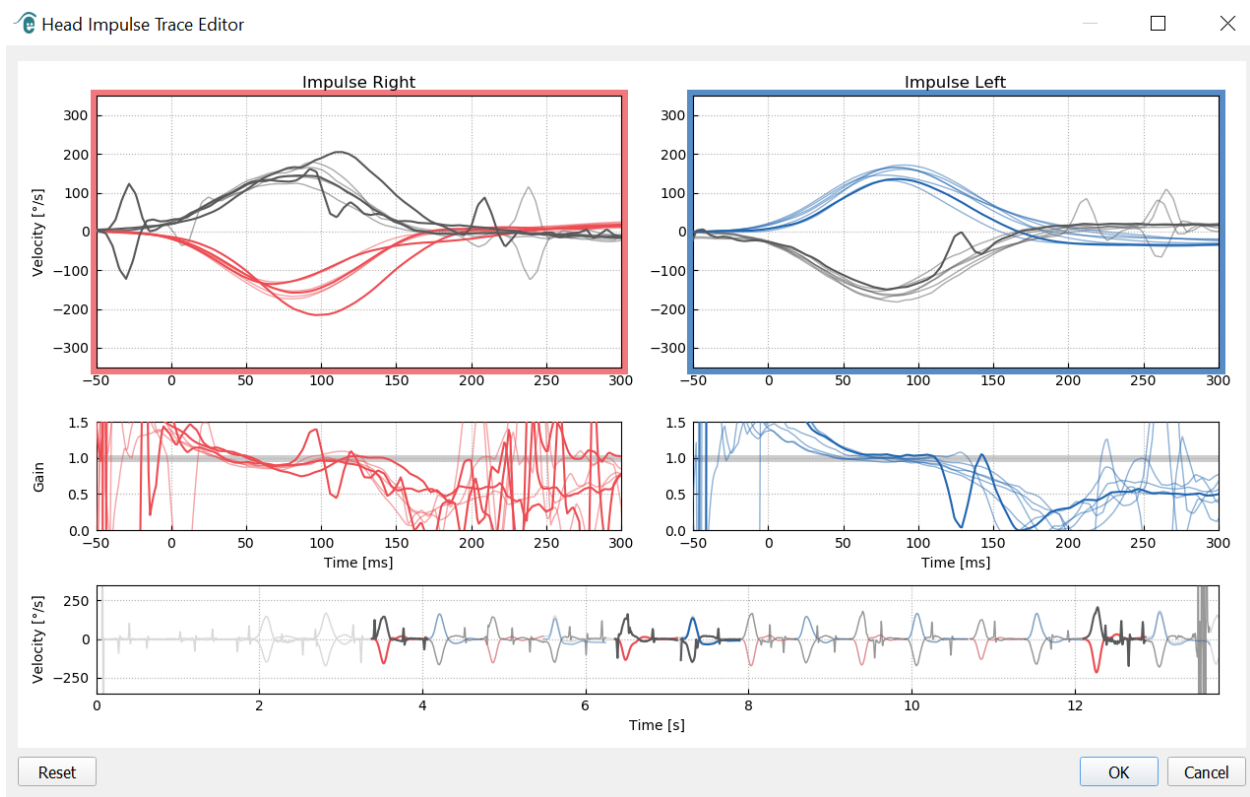


Figure 5.1.1-3 Head Impulse Editor with several waveforms highlighted to be deleted.

If you have deleted waveforms that you later decide you wanted to include in the analysis then you can use the **Reset** button in the bottom left-hand corner to reset the waveforms back to the original analysis.



5.1.2 Saccade Numerical Data Tables

Once you have completed your impulses click on the Results tab to open the saccade numerical data tables.

Name: Cheryl September 21	Test: Head Impulse
Birthdate: 1961-08-18	Variant: Lateral
Velocity Gain	Results

Figure 5.1.2-1 Results tab for saccade numerical summary data

For Velocity Gains, you will see mean, standard deviations, medians and inter-quartal range (iqr) values.

For Saccades you will see amplitude, latency, peak velocity and total number of saccades. If more than one saccade is generated by an individual head thrust then you will see first saccade, second saccade and so on.

Under the Data heading you will see individual saccade parameters including the peak, amplitude and latency for each saccade generated.

Name: Cheryl September 21	Test: Head Impulse	Date: 2018-09-21 11:07:42
Birthdate: 1961-08-18	Variant: Lateral	Person ID: 213213213
Velocity Gain	Results	

Summary

Velocity Gain

	Right (n=7)				Left (n=7)			
	mean	std	median	iqr	mean	std	median	iqr
Gain @ 40 ms	1.16	0.11	1.19	0.18	1.23	0.14	1.19	0.14
Gain @ 60 ms	0.99	0.04	0.99	0.06	1.13	0.08	1.12	0.06
Gain @ 80 ms	0.94	0.04	0.94	0.06	0.96	0.16	0.96	0.15
Median 0-100 ms	1.04	0.07	1.04	0.09	1.15	0.08	1.15	0.13
Regression	-1.05	0.02	-1.05	0.03	1.10	0.04	1.08	0.08

Saccades

	Right			Left		
	1st Saccade	2nd Saccade	3rd Saccade	1st Saccade	2nd Saccade	3rd Saccade
Amplitude [°]	0.82 ± 000.74	-0.72 ± 000.00	-	0.95 ± 000.41	-1.12 ± 000.54	2.30 ± 000.00
Latency [ms]	270.00 ± 108.45	617.00 ± 000.00	-	235.33 ± 122.11	567.50 ± 062.50	582.00 ± 000.00
Peak Velocity [°/s]	61.87 ± 059.18	-73.69 ± 000.00	-	79.10 ± 018.37	-104.63 ± 039.50	159.64 ± 000.00
Total	6	1	0	6	2	1

Data

Saccade Parameters

	Direction	Head Impulse		1st Saccade			2nd Saccade			3rd Saccade		
		Peak Time [ms]	Peak Velocity [°/s]	Latency [ms]	Peak Velocity [°/s]	Amplitude [°]	Latency [ms]	Peak Velocity [°/s]	Amplitude [°]	Latency [ms]	Peak Velocity [°/s]	Amplitude [°]
1	left	82.00	154.50	299.00	77.90	1.12	-	-	-	-	-	-
2	left	84.00	141.62	382.00	97.70	1.18	505.00	-144.13	-1.65	582.00	159.64	2.30
3	right	72.00	161.92	220.00	101.35	1.51	-	-	-	-	-	-
4	right	76.00	147.77	491.00	-69.25	-0.72	-	-	-	-	-	-
5	right	64.00	142.97	205.00	79.87	1.03	-	-	-	-	-	-
6	left	82.00	145.63	77.00	61.13	0.16	630.00	-65.13	-0.58	-	-	-
7	right	82.00	170.82	296.00	91.23	1.20	617.00	-73.69	-0.72	-	-	-

Figure 5.1.2-2 Saccade Numerical Data Table



5.1.3 Edit Saccades

If you have collected head impulses that have saccades present you can use the Saccade Editor to edit individual saccades or added saccades that were not identified by the software. You can access the Saccade Editor from the Report menu, Edit saccades.

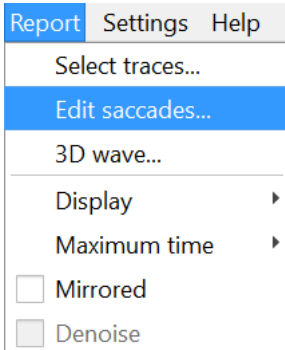


Figure 5.1.3-1 Report Menu Edit Saccades

In the Saccade Editor you will see each saccade identified with a green dot. When you select an individual impulse to review you will see each saccade for that impulse highlighted in gray. The start and stop of the saccade is marked with the small black lines on either side of the shading. You will see the latency and peak of each saccade.

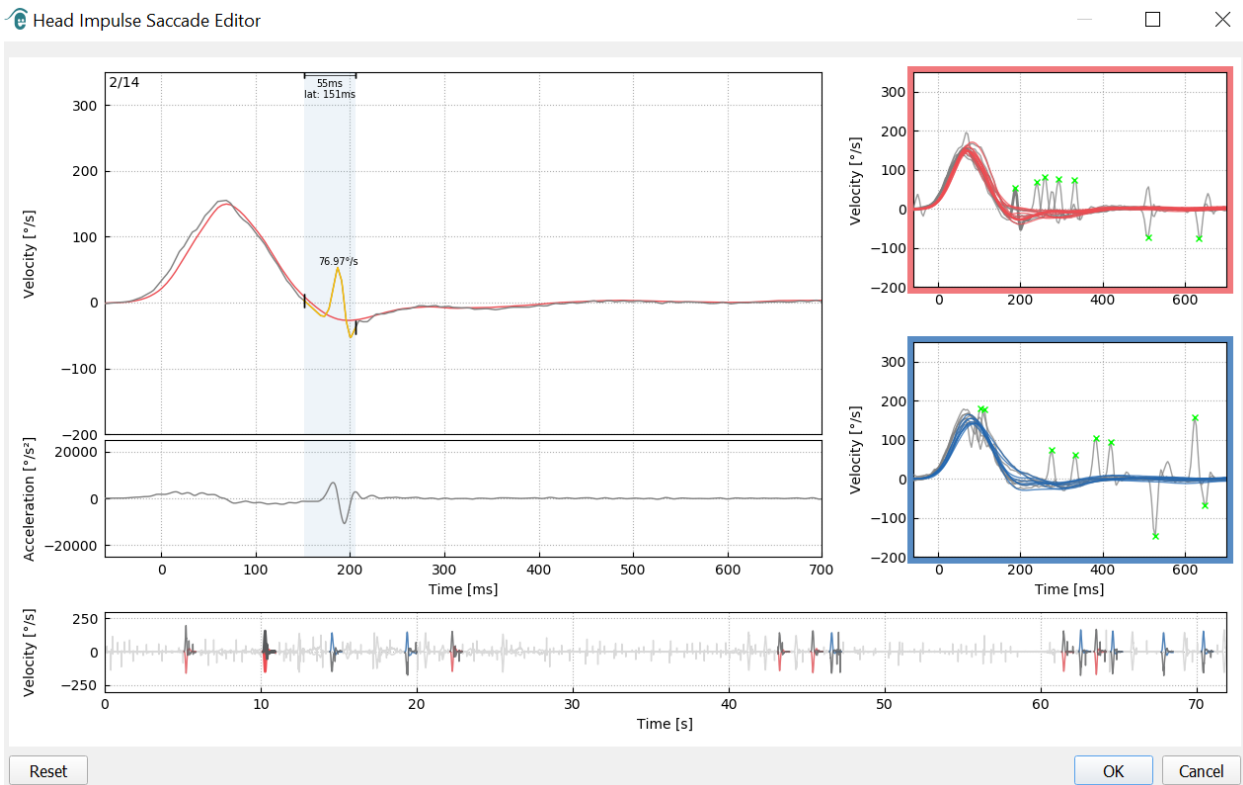


Figure 5.1.3-2 Saccade Editor



If you choose to delete a saccade simply right-click on the saccade you wish to remove and then click "Remove saccade". This will unmark this saccade.

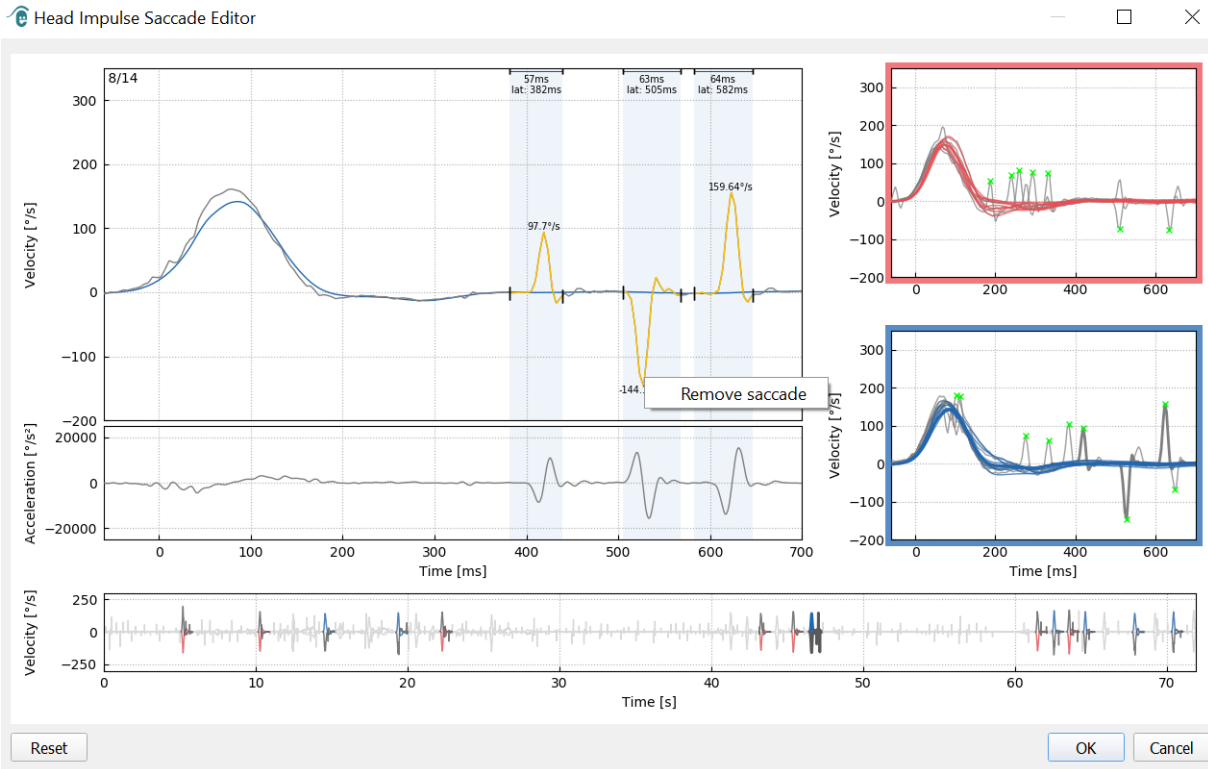


Figure 5.1.3-3 Remove saccade by right-clicking

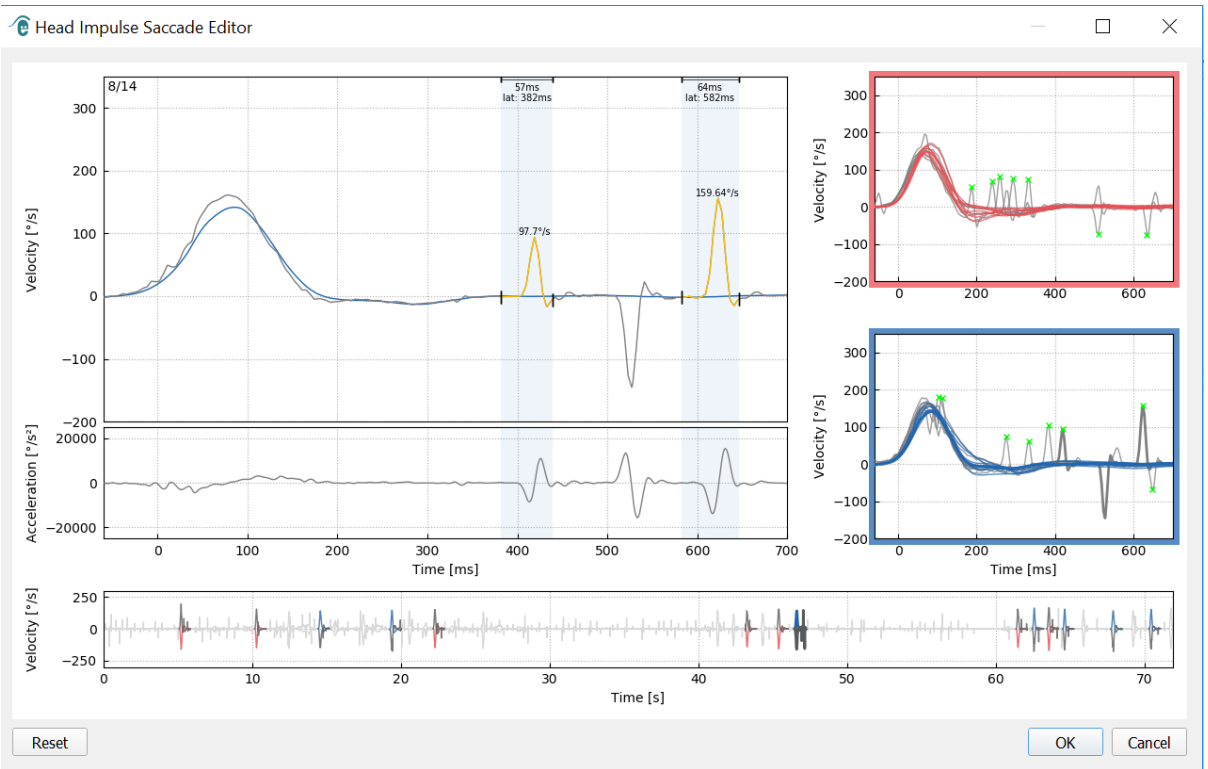


Figure 5.1.3-4 The second saccade has been removed



If you wish to add a saccade that is not marked, just right-click and select “Mark saccade here”.

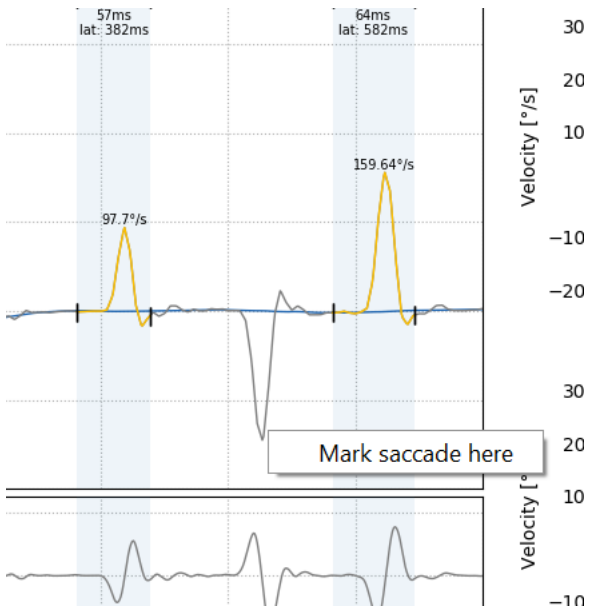


Figure 5.1.3-5 Add a saccade that is not already marked.

If you choose to change the start or ending point of the saccade simply click on one of the markers on the sides of the gray shading and drag the marker to its new location and drop there.

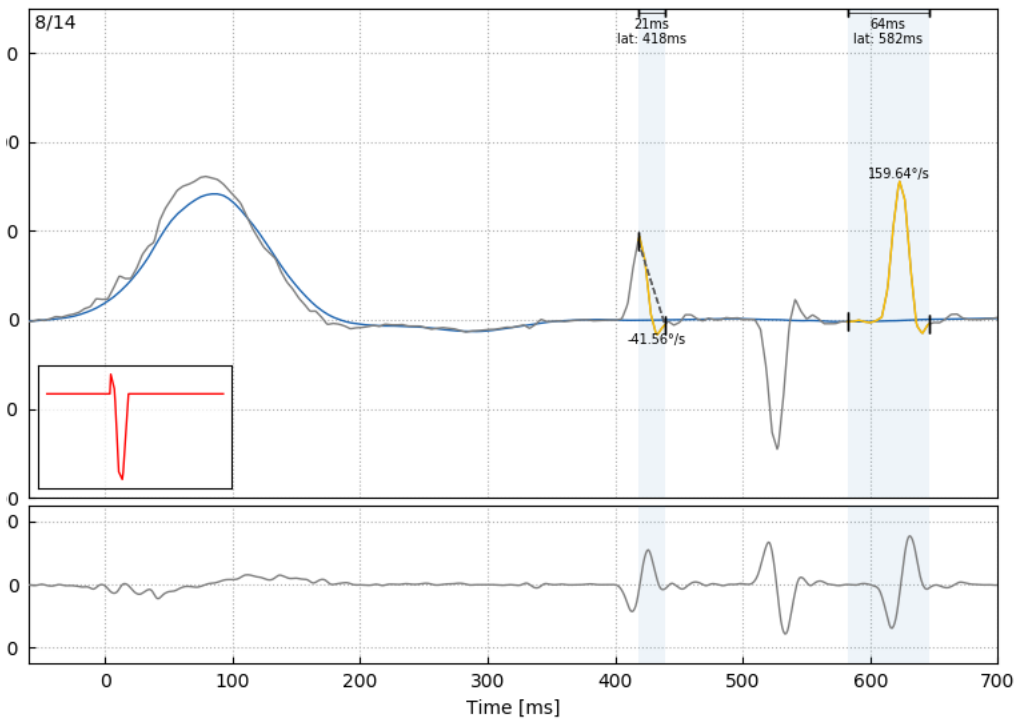


Figure 5.1.3-6 Changing the start and stop time of the saccades.



If you wish to reset the marked saccade back to the default values click on reset and the values will return to the original state.

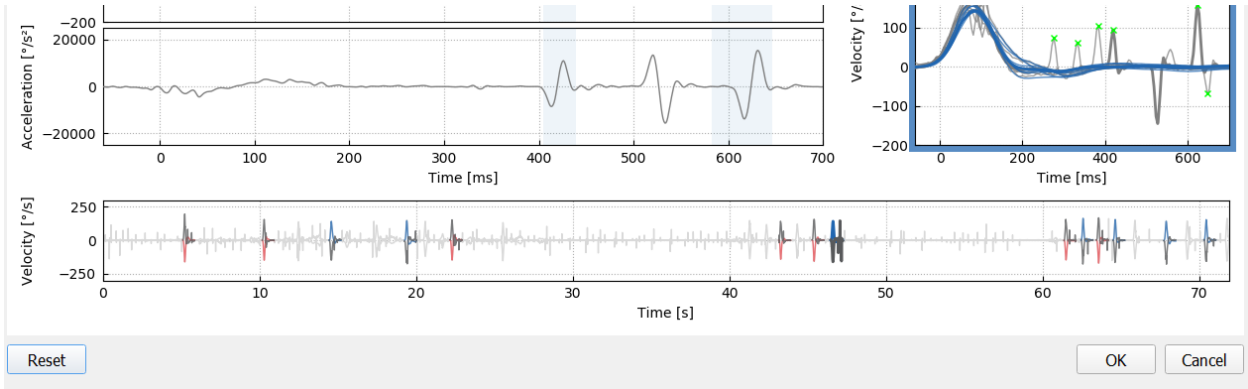


Figure 5.1.3-7 Reset Saccades back to default values

5.1.4 3D wave

If you would like to see the data expressed using a 3D waveform then from the Report menu choose the 3D wave option.

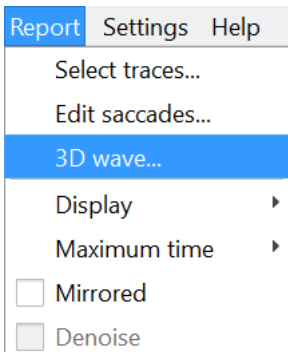


Figure 5.1.4-1 Report menu item to select 3D waveform

In this view you will see the saccades colored in orange.

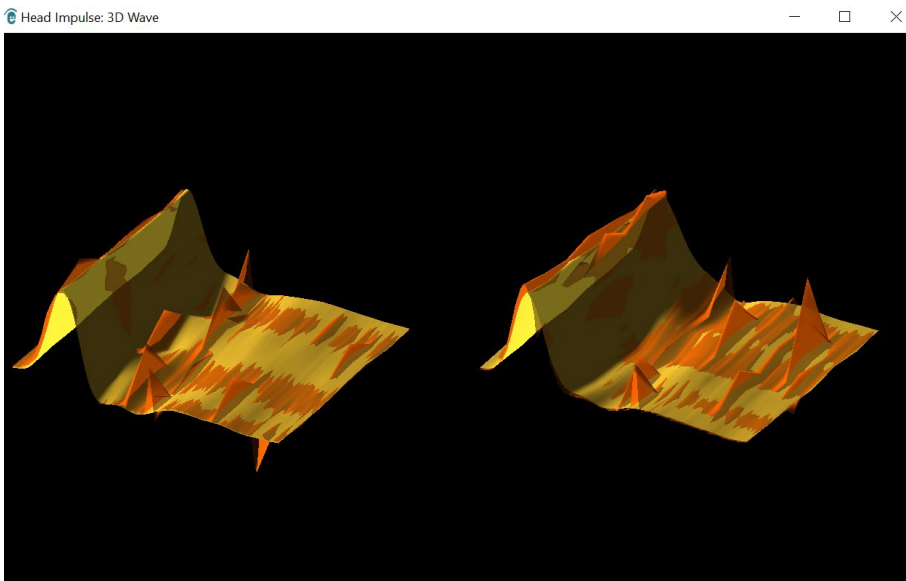


Figure 5.1.4-2 3D waveform view of impulse data



You can click on the individual waveforms and turn them to see the saccades from different directions.

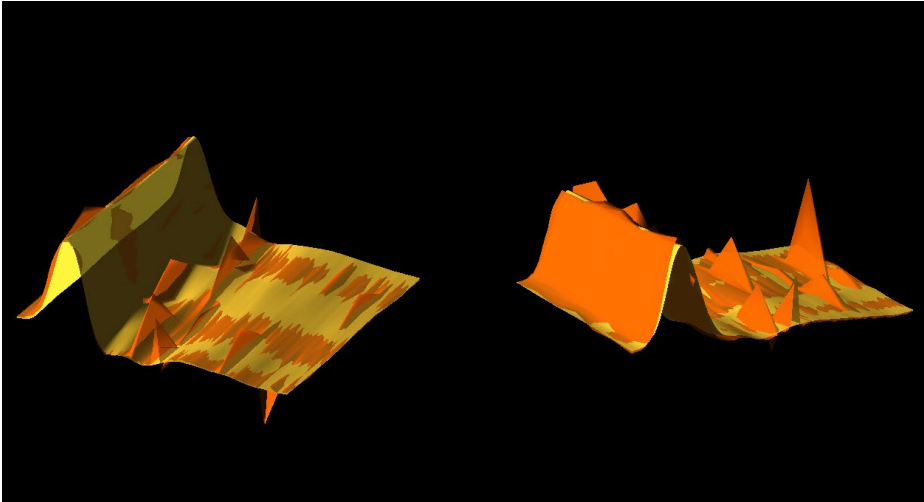


Figure 5.1.4-3 Different views of the 3D waveform

5.1.5 Display

You can change the display colors under the Report menu Display.

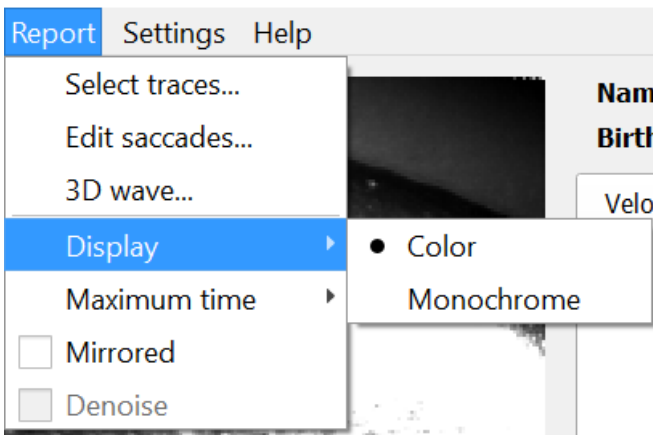


Figure 5.1.5-1 Report menu Display option

You can display the data in monochrome if you have a non-color printer. You will see different symbols to identify the different directions of the head impulses. Stars represent right head impulses and diamonds represent left impulses.



Figure 5.1.5-2 Monochrome symbols for left and right head impulses

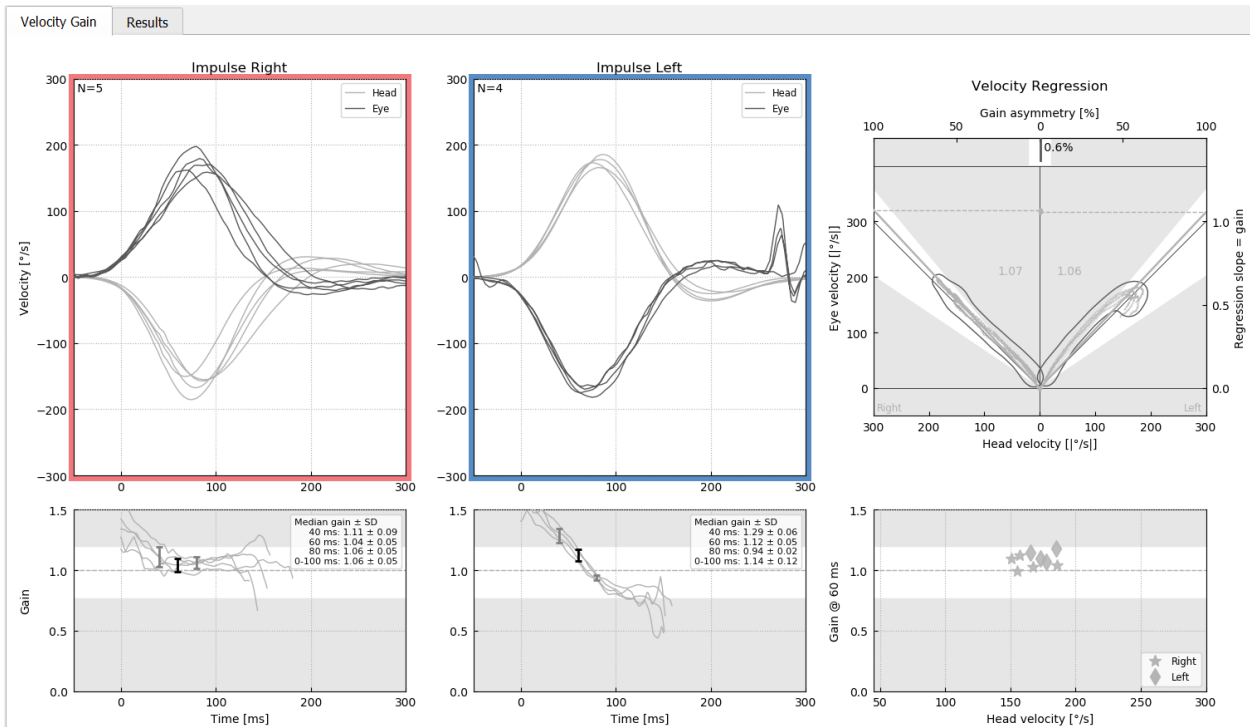


Figure 5.1.5-3 Monochrome display of results

5.1.6 Maximum time

The time scale can be extended from 300 – 700 ms by selecting Maximum time from the Report menu.

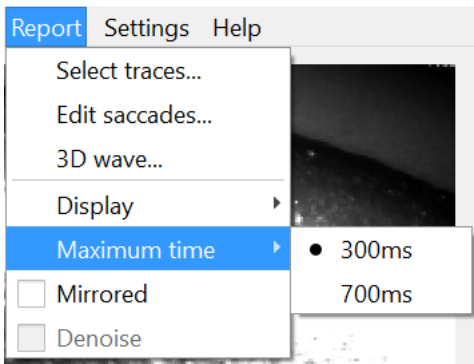


Figure 5.1.6-1 Report menu for Maximum time scale

This will allow you to view later overt saccades if they are present.

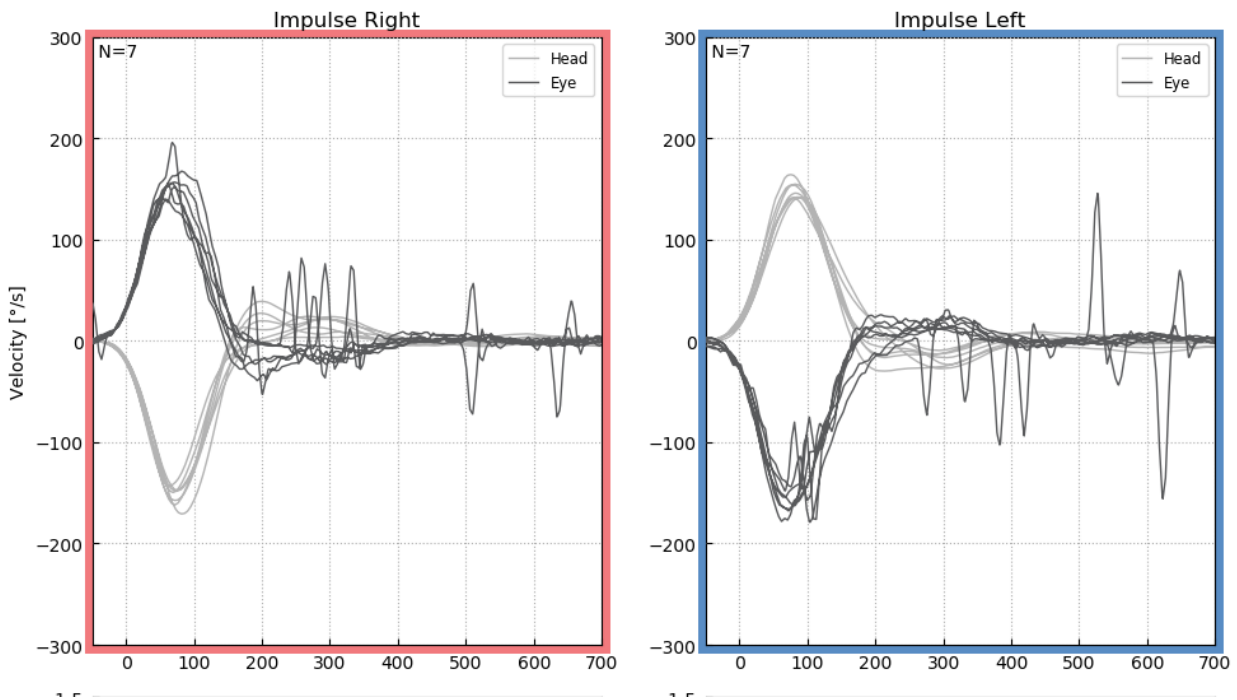


Figure 5.1.6-2 Impulses with time scale expanded to 700 ms

5.1.7 Mirrored

If you choose to view your waveforms in the mirrored arrangements you can select Mirrored under the Report menu and this will invert the eye tracings so they overlap the head tracings.

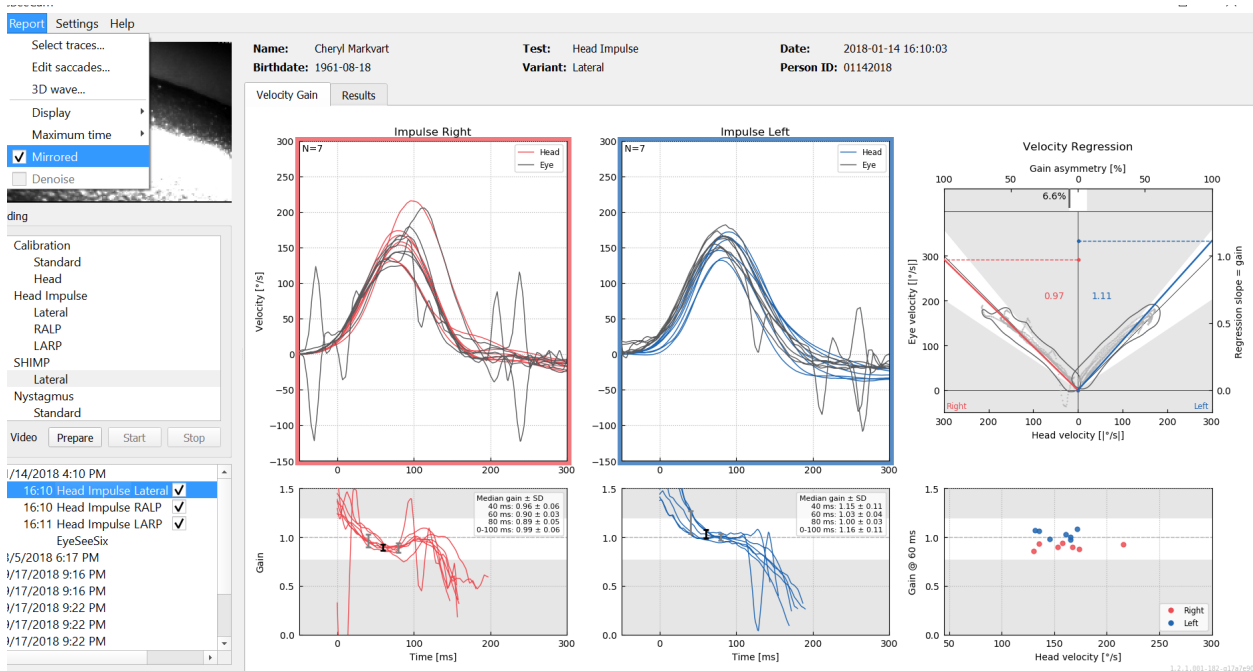


Figure 5.1.7-1 Mirrored tracings



5.1.8 Denoise

Denoise can only be applied to vertical impulses and it is used to remove artifact.

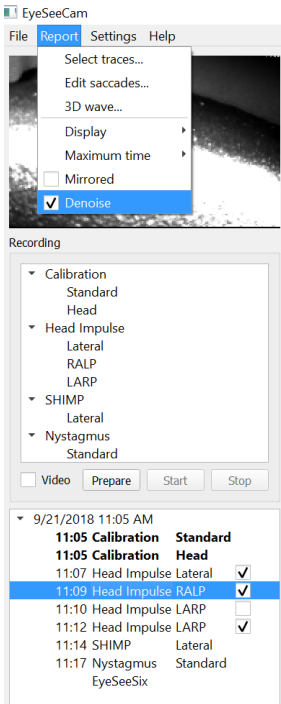


Figure 5.1.8-1 Denoise option for vertical impulses



5.2 Generate reports

Reports are automatically generated at the completion of test protocols.

5.2.1 Individual Test Reports

After each test is completed the full test report will be generated automatically. You can opt to see the other test reports by selecting them in the left hand test completed menu.

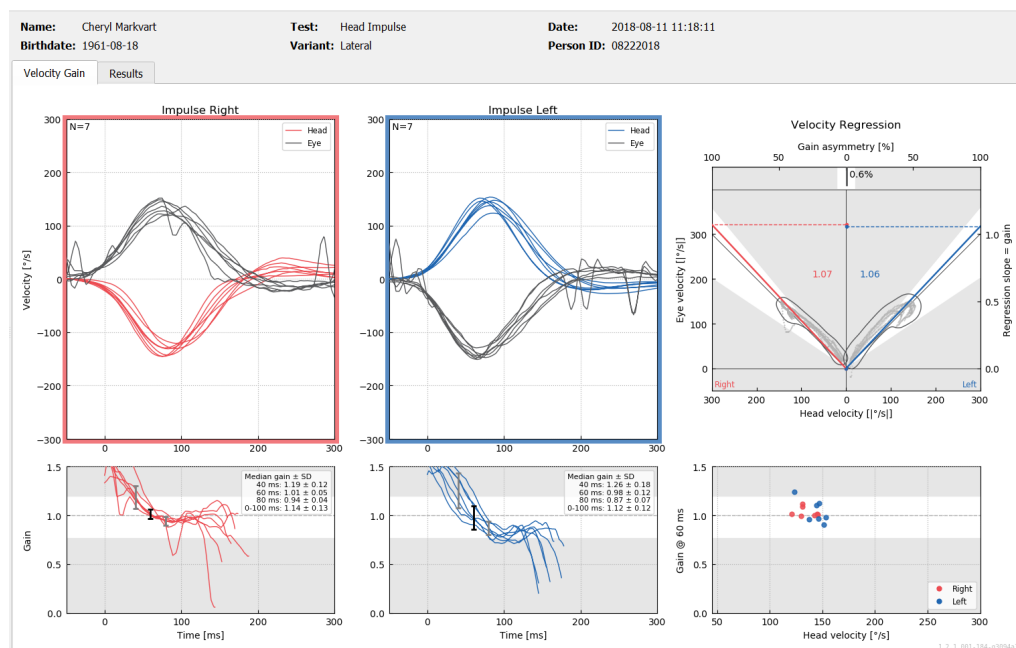


Figure 5.2.1-1 Full Report

5.2.2 EyeSeeSix report

Once Lateral, RALP and LARP tests are completed, an EyeSeeSix summary graph will automatically be generated.

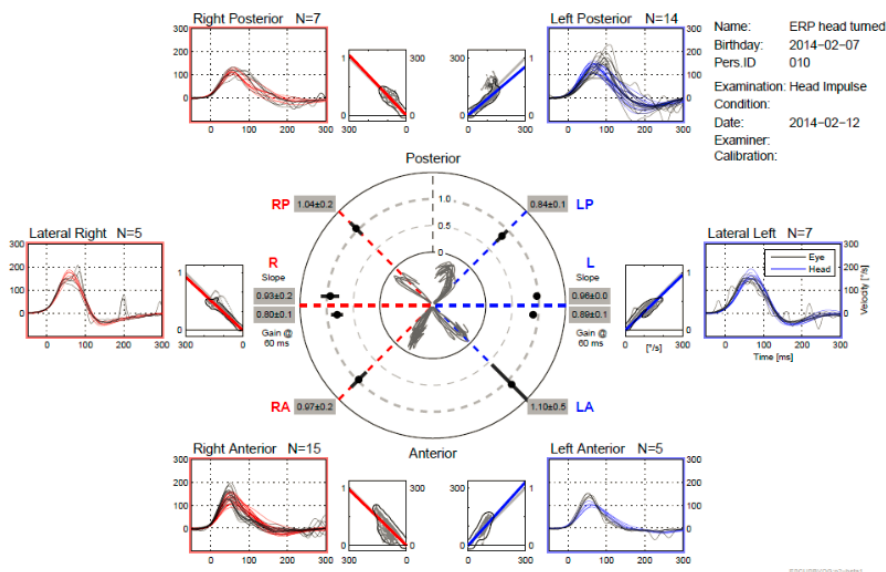


Figure 5.2.2-1 EyeSeeSix Report

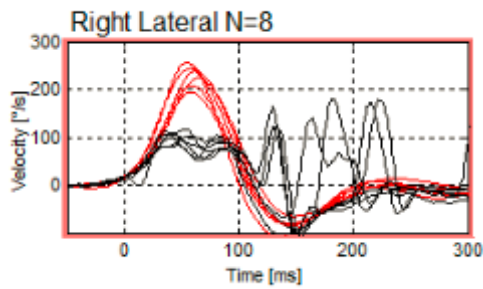


You need to complete at least one run of each protocol, Lateral, RALP and LARP. If you choose to run a protocol more than one time, then you can use the check marks to decide which run from each protocol you wish to display in your EyeSeeSix Report. You are only allowed to have one check mark per protocol (RALP, LARP and Lateral) if you want to generate an EyeSeeSix Report.

What you see in the report are 5 main things:

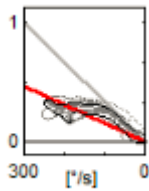
1. Raw tracings

Raw tracings show the impulse data overlaying the eye head movements. The impulses are shown in red if they stimulate a right sided canal (R-lateral, R-posterior and R- anterior) and blue if they stimulate a left sided canal (L-lateral, L-posterior and L-anterior).



2. Regression plots

Allows for graphical data analysis over the entire velocity range of the head impulses



3. Gain calculations

Lateral gains are shown for both the 60 ms calculation and the average regression plot slope gain calculation.

RL
Slope
0.47±.02
0.40±.07
Gain @
60 ms

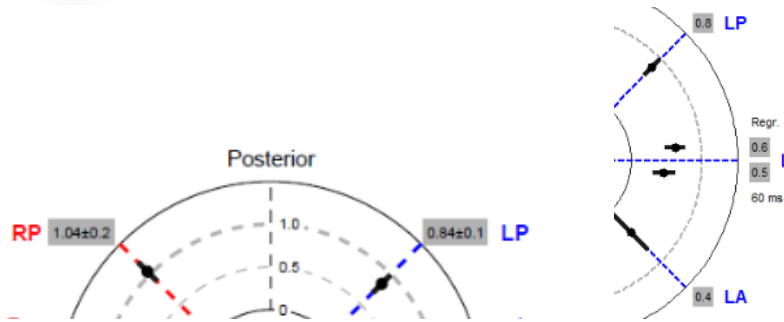
Vertical gains are shown as the average regression slope gain.

Slope
RP 0.70±.07



4. Circular gain plot

This plot gives an overall visual of where each of the gain calculations is plotted. It has dotted grid lines that can help you easily see how close to unity gain of 1.0 the results are. In a normal healthy vestibular system you would expect to see gains near 1 and an impaired vestibular system may show gains of less than 0.7. The black dot represents the actual gain value and the black bar around the dot represents the standard deviation for the measure.

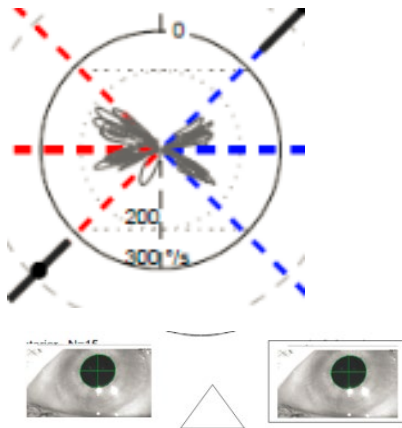


Normal gains

Abnormal Gain

5. Information on the vertical plane impulses

This plot helps you verify that your vertical impulses were performed in the correct directions, indicating that you have stimulated the canal for which you had intended to measure the performance.





5.3 Printing Reports

5.3.1 De-identify Patient Information

If you want to remove the patient's personal information from the screen and the report, use the De-identify Patient Information option under the File menu.

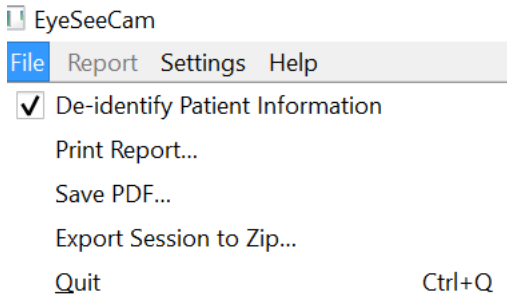
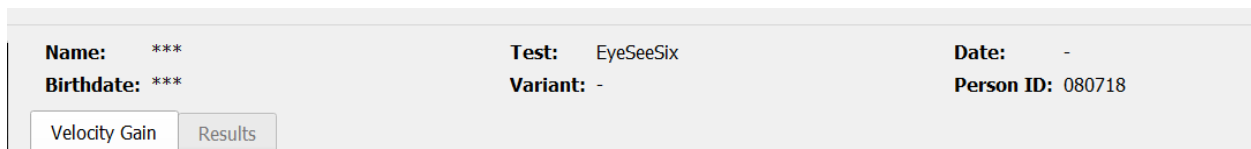


Figure 5.3.1-1 File menu option to de-identify information

The personal information will be replaced with ***. The only personal information that is not removed is the Person ID.



5.3.2 Print to external printer or PDF

From the File menu, select Print Report.

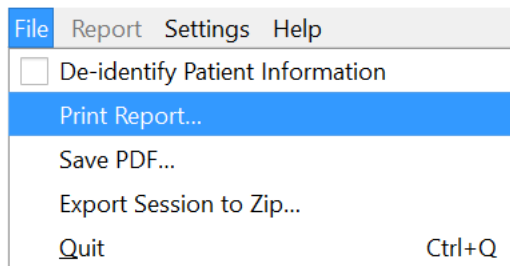


Figure 5.3.2-1 File menu option to Print Report

You can also print to PDF.



EyeSeeCam	Name:	John Petrak	Test:	Head Impulse	Date:	2018-09-18 13:51:11
	Birthdate:	1976-09-04	Variante:	RALP	Person ID:	09182018

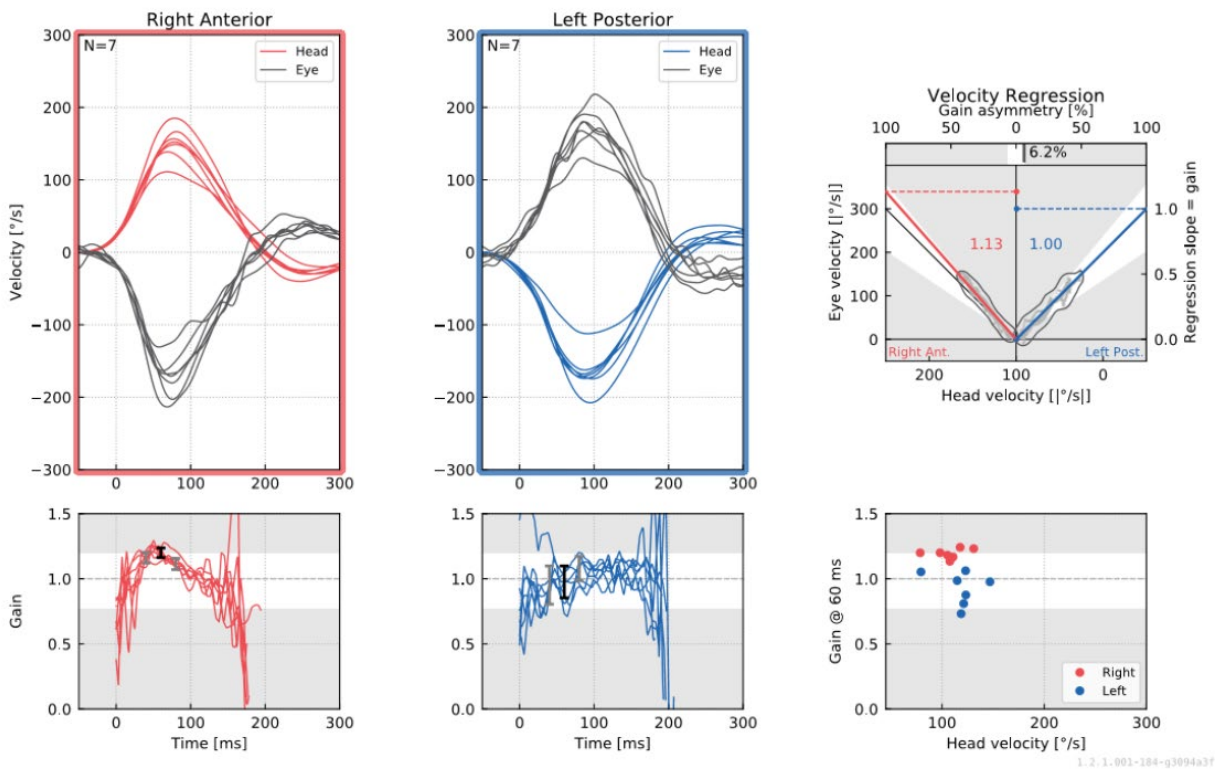


Figure 5.3.2-2 Final report for RALP test.

5.4 Export completed session data

This feature is used to export previously collected sessions for troubleshooting if necessary. When you select to export a session to a zip file from your file drop down menu it will then automatically save a zip file into your compressed files folder.

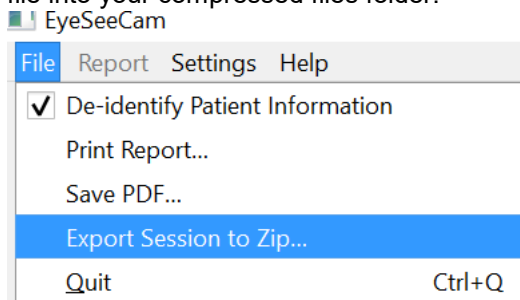


Figure 5.3.2-1 Export session to Zip File

The file will be given a file name with “.zip” as the suffix and you will choose where you want the file to be saved on your computer.

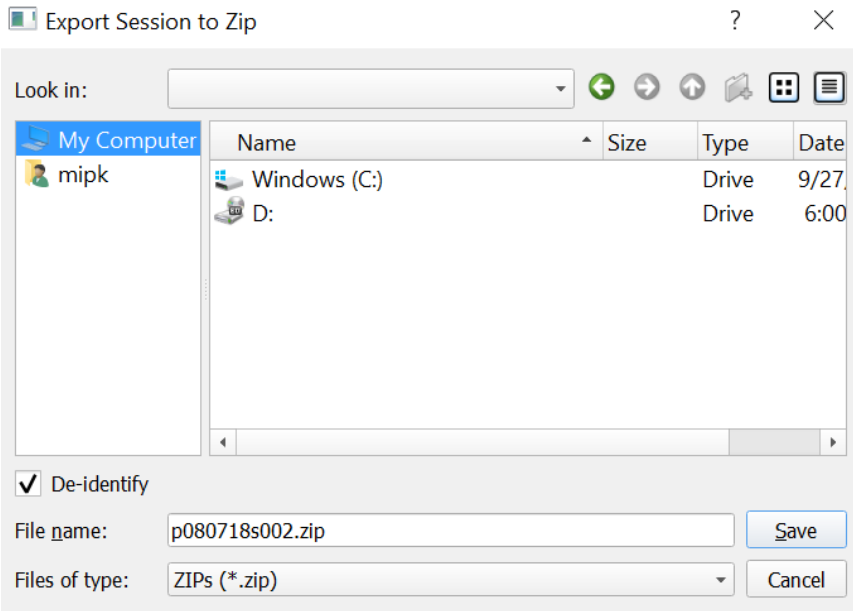


Figure 5.3.2-2 Export session to zip

5.5 Video Recording

To record a video, simply tick the video record check box on your test screen before you begin testing for the current session. The default is video record mode off, so you have to select video record to activate this feature.



Figure 5.3.2-1 Select Video Record Option by ticking box next to Video

Once you have completed your testing, you can select **Recordings** tab to review your session data, both graphical and video. If a video was recorded you will see a file next to the test name. You can choose to open the video in Media Player or Show in Explorer.

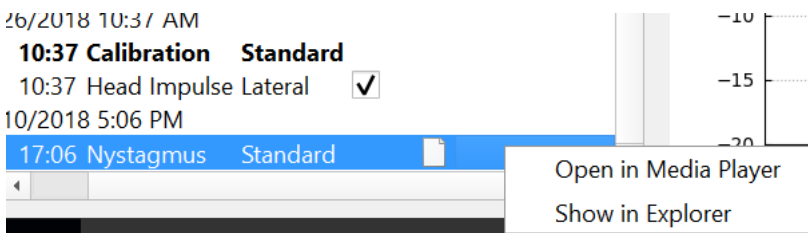


Figure 5.3.2-2 Select Test Sessions and Videos for Playback.

The video files are saved in your videos files folder where they can be played back, renamed or exported.

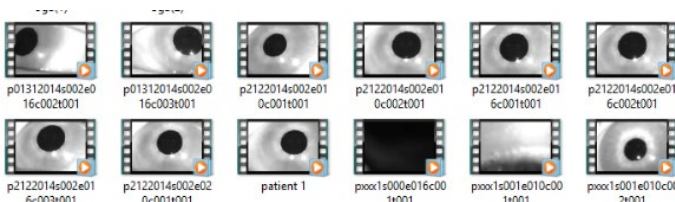


Figure 5.3.2-3 Previously Collected Videos





6 Licensing

There are 2 separate methods to license your new software.

6.1 New Systems

If you buy a new system the license key will come pre-assigned to the serial number of your camera. You will not need to do anything unless you need to replace your camera for some reason.

6.2 Upgrade existing systems

If you are upgrading an existing system then you will need to locate your serial number using a small command line tool called `list_esc_cameras` provided with the software upgrade files. This tool should be transferred to your computer and then run from your computer while your camera is plugged in. Once you have that serial number you can then contact your local distributor and they will provide you with a new license key.

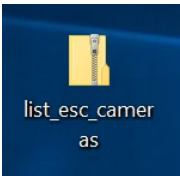


Figure 5.3.2-1 command line tool to locate esc camera serial number in predicate software releases

Once you have that license key you can install the new software upgrade.

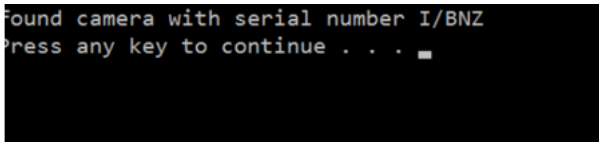


Figure 5.3.2-2 Serial number for camera identified

If you need further assistance on how to run this program or install the software upgrade, please refer to the ESC software installation guide.

When the software is launched with an unregistered camera connected you will receive a pop-up licensing box that will ask you to enter the license key (given to you by the local distributor) for that specific camera serial number.

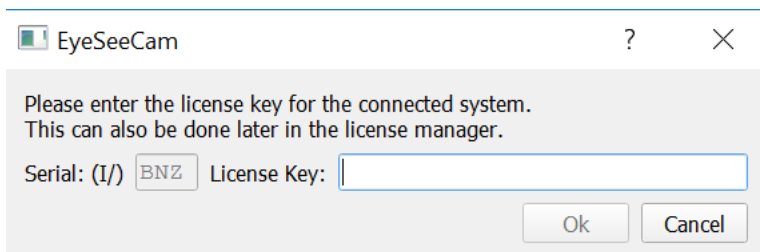


Figure 5.3.2-3 Pop-up menu for adding the license number for your camera.

Once you have entered your license key, hit “Ok” and the software installation will start to run. If you hit cancel you can still use the software as a viewer for existing recordings.

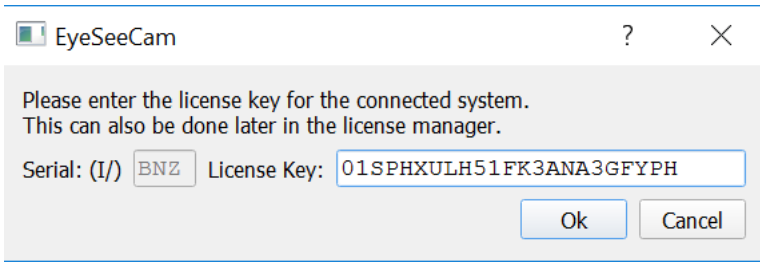


Figure 5.3.2-4 Enter license key

If at a later time you receive a new camera for some reason, you can enter that camera's license key from the Help menu, Manage Licenses.

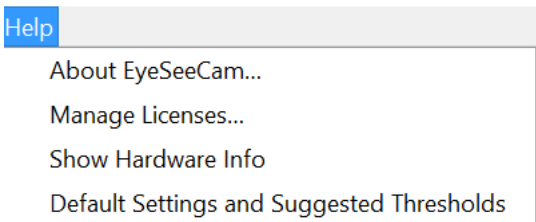


Figure 5.3.2-5 Help menu Manage Licenses

Here you can add the new camera license key and begin using that camera also.

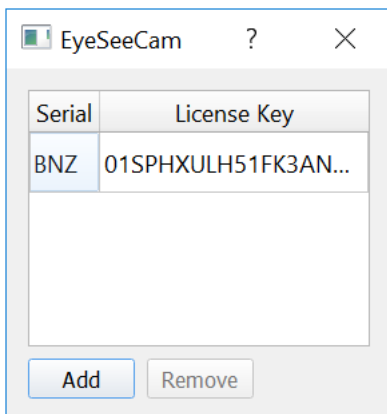


Figure 5.3.2-6 Help menu "add a new license key"



7 Maintenance

7.1 General maintenance procedures

The operator is responsible for the perfect state of the instrument.

Immediate maintenance is required if:

- The instrument was subjected to extreme mechanical stress (impact, defective cable due to inadmissible traction);
- Fluid gets into the instrument;
- Cables and/or connectors are defective;
- Rubber-joints have developed cracks.

For further details please contact your Interacoustics representative.

7.2 How to clean Interacoustics Products

If the surface of the instrument or parts of it are contaminated, it can be cleaned using a soft cloth moistened with a mild solution of water and dish washing cleaner or similar. The use of organic solvents and aromatic oils must be avoided. Always disconnect the USB cable during the cleaning process, and be careful that no fluid is entering the inside of the instrument or the accessories.



- Before cleaning always switch off and disconnect from power
- Use a soft cloth lightly dampened with cleaning solution to clean all exposed surfaces
- Do not allow liquid to enter the camera housing
- Do not autoclave, sterilize or immerse the instrument or accessory in any fluid
- Do not use hard or pointed objects to clean any part of the instrument or accessory

Recommended cleaning and disinfection solutions:

- Warm water with mild, nonabrasive cleaning solution (soap)

Procedure:

- Clean the instrument by wiping outer case with a lint free cloth lightly dampened in cleaning solution

7.3 Concerning repair

Interacoustics is only considered to be responsible for the validity of the CE marking, effects on safety, reliability and performance of the equipment if:

1. Assembly operations, extensions, readjustments, modifications or repairs are carried out by authorised persons,
2. A 1 year service interval is maintained
3. The electrical installation of the relevant room complies with the appropriate requirements, and
4. The equipment is used by authorised personnel in accordance with the documentation supplied by Interacoustics.



It is important that the customer (agent) fills out the RETURN REPORT every time a problem arises and sends it to **Interacoustics, 10393 West 70th Street, Eden Prairie, MN 5534, USA.**

This should also be done every time an instrument is returned to Interacoustics. (This of course also applies in the unthinkable worst case of death or serious deterioration to patient or user).

7.4 Warranty

INTERACOUSTICS warrants that:

- The vHIT is free from defects in material and workmanship under normal use and service for a period of 12 months from the date of delivery by Interacoustics to the first purchaser
- Accessories are free from defects in material and workmanship under normal use and service for a period of ninety (90) days from the date of delivery by Interacoustics to the first purchaser

If any product requires service during the applicable warranty period, the purchaser should communicate directly with the local Interacoustics service centre to determine the appropriate repair facility. Repair or replacement will be carried out at Interacoustics' expense, subject to the terms of this warranty. The product requiring service should be returned promptly, properly packed, and postage prepaid. Loss or damage in return shipment to Interacoustics shall be at purchaser's risk.

In no event shall Interacoustics be liable for any incidental, indirect or consequential damages in connection with the purchase or use of any Interacoustics product.

This shall apply solely to the original purchaser. This warranty shall not apply to any subsequent owner or holder of the product. Furthermore, this warranty shall not apply to, and Interacoustics shall not be responsible for, any loss arising in connection with the purchase or use of any Interacoustics product that has been:

- repaired by anyone other than an authorized Interacoustics service representative;
- altered in any way so as, in Interacoustics judgement, to affect its stability or reliability;
- subject to misuse or negligence or accident, or which has had the serial or lot number altered, effaced or removed; or
- improperly maintained or used in any manner other than in accordance with the instructions furnished by Interacoustics.

This warranty is in lieu of all other warranties, express or implied, and of all other obligations or liabilities of Interacoustics, and Interacoustics does not give or grant, directly or indirectly, the authority to any representative or other person to assume on behalf of Interacoustics any other liability in connection with the sale of Interacoustics products.

INTERACOUSTICS DISCLAIMS ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FOR FUNCTION OF FITNESS FOR A PARTICULAR PURPOSE OR APPLICATION.



8 Technical information

Medical CE-mark:	The CE-mark indicates that Interacoustics A/S meets the requirements of Annex II of the Medical device Directive 93/42/EEC. Approval of the quality system is made by TÜV – Identification no. 0123	
Standards:	Safety:	IEC 60601-1, Class II, Type B, applied parts
	EMC:	IEC 60601-1-2
Operating environment	Temperature:	15 - 35 °C
	Relative Humidity:	30 – 90%
	Ambient Pressure:	98 kPa – 104 kPa
Transport & Storage	Storage Temperature:	0 - 50 °C
	Transport Temperature:	-20 - 50 °C
	Relative Humidity:	10 – 95%

PC Interface	USB 2.0
USB supply	5VDC ±0.25VDC
Camera	Monocular camera, interchangeable between left and right eye
Goggle	Molded, flexible frame with snug fit, cleanable silicone contact areas. Fits pediatric and adult faces.
Weight	Goggle: 40g Camera: 32g Combined weight: 72g
Calibration	Goggle mounted laser with 5-point calibration
Sample rate	220 Hz
Head tracking sensor	Inertial Measurement Unit (IMU) gyroscope with 6 degrees of freedom
Gain	Instantaneous gain at 40, 60 and 80 ms – equivalent to scleral search coil method.
Data Analysis	Velocity Regression Plot, Gain Plot

System Requirements:

PC Hardware	Intel Core i3 processor 2.53 GHz or better
	Minimum 8 GB RAM
	One USB 2.0 port available
	Windows®10 (32-bit or 64-bit)
PC Software	Windows®8 (32-bit or 64-bit) Professional
	Windows®7 (32-bit or 64-bit) Professional



8.1 Appendix A: Electromagnetic compatibility (EMC)

- This instrument is suitable in hospital environments except for near active HF surgical equipment and RF shielded rooms of systems for magnetic resonance imaging, where the intensity of electromagnetic disturbance is high
- Use of this instrument adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this instrument and the other equipment should be observed to verify that they are operating normally
- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation. The list of accessories, transducers and cables can be found in this appendix.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of this instrument, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result

NOTICE ESSENTIAL PERFORMANCE for this instrument is defined by the manufacturer as:

- This instrument does not have an ESSENTIAL PERFORMANCE Absence or loss of ESSENTIAL PERFORMANCE cannot lead to any unacceptable immediate risk
- Final diagnosis shall always be based on clinical knowledge There are no deviations from the collateral standard and allowances uses
- This instrument is in compliance with IEC60601-1-2:2014, emission class B group 1

NOTICE: There are no deviations from the collateral standard and allowances uses NOTICE: All necessary instruction for maintaining compliance with regard to EMC can be found in the general maintenance section in this instruction. No further steps required.



Portable and mobile RF communications equipment can affect the **EyeSeeCam**. Install and operate the **EyeSeeCam** according to the EMC information presented in this chapter.

The **EyeSeeCam** has been tested for EMC emissions and immunity as a standalone **EyeSeeCam**. Do not use the **EyeSeeCam** adjacent to or stacked with other electronic equipment. If adjacent or stacked use is necessary, the user should verify normal operation in the configuration. The use of accessories, transducers and cables other than those specified, with the exception of servicing parts sold by Interacoustics as replacement parts for internal components, may result in increased EMISSIONS or decreased IMMUNITY of the device. Anyone connecting additional equipment is responsible for making sure the system complies with the IEC 60601-1-2 standard.

Guidance and manufacturer's declaration - electromagnetic emissions		
The EyeSeeCam is intended for use in the electromagnetic environment specified below. The customer or the user of the EyeSeeCam should assure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The EyeSeeCam uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The EyeSeeCam is suitable for use in all commercial, industrial, business, and residential environments.
Harmonic emissions IEC 61000-3-2	Complies Class A Category	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

Recommended separation distances between portable and mobile RF communications equipment and the EyeSeeCam .			
The EyeSeeCam is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the EyeSeeCam can help prevent electromagnetic interferences by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the EyeSeeCam as recommended below, according to the maximum output power of the communications equipment.			
Rated Maximum output power of transmitter [W]	Separation distance according to frequency of transmitter [m]		
	150 kHz to 80 MHz $d = 1.17\sqrt{P}$	80 MHz to 800 MHz $d = 1.17\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.23\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.70	3.70	7.37
100	11.70	11.70	23.30
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. Note 1 At 80 MHz and 800 MHz, the higher frequency range applies. Note 2 These guidelines may not apply to all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			


Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The EyeSeeCam is intended for use in the electromagnetic environment specified below. The customer or the user of the EyeSeeCam should assure that it is used in such an environment.			
Immunity Test	IEC 60601 Test level	Compliance	Electromagnetic Environment-Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	+6 kV contact +8 kV air	+6 kV contact +8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be greater than 30%.
Electrical fast transient/burst IEC61000-4-4	+2 kV for power supply lines +1 kV for input/output lines	+2 kV for power supply lines +1 kV for input/output lines	Mains power quality should be that of a typical commercial or residential environment.
Surge IEC 61000-4-5	+1 kV differential mode +2 kV common mode	+1 kV differential mode +2 kV common mode	Mains power quality should be that of a typical commercial or residential environment.
Voltage dips, short interruptions and voltage variations on power supply lines IEC 61000-4-11	< 5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT	< 5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for	Mains power quality should be that of a typical commercial or residential environment. If the user of the EyeSeeCam requires continued operation during power mains interruptions, it is recommended that the EyeSeeCam be powered from an uninterruptible power supply or its battery.



	(>95% dip in <i>UT</i>) for 5 sec	5 cycles 70% <i>UT</i> (30% dip in <i>UT</i>) for 25 cycles <5% <i>UT</i>	
Power frequency (50/60 Hz) IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or residential environment.
Note: <i>UT</i> is the A.C. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration — electromagnetic immunity

The **EyeSeeCam** is intended for use in the electromagnetic environment specified below. The customer or the user of the **EyeSeeCam** should assure that it is used in such an environment,

Immunity test	IEC / EN 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC / EN 61000-4-6	3 Vrms 150kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any parts of the EyeSeeCam , including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1,2\sqrt{P}$ $d = 1,2\sqrt{P}$ 80 MHz to 800 MHz $d = 2,3\sqrt{P}$ 800 MHz to 2,5 GHz Where <i>P</i> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <i>d</i> is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, (a) should be less than the compliance level in each frequency range (b) Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC / EN 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies
 NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

^(a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the **EyeSeeCam** is used exceeds the applicable RF compliance level above, the **EyeSeeCam** should be observed to verify normal operation, If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the **EyeSeeCam**.
^(b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Return Report – Form 001



Opr. dato: 2014-03-07 af: EC Rev. dato: af: MSt Rev. nr.: 4

Company: _____

Address: _____

Phone: _____

Fax or e-mail: _____

Address

10393 West 70th Street
Prairie
MN 55344
USA

Phone

(+1) 800 947 6334

Fax

(+1) 952 903 4200

E-mail

rmd@interacoustics-us.com

Contact person: _____ Date: _____

Following item is reported to be:

- returned to INTERACOUSTICS for: repair, exchange, other: _____
- defective as described below with request of assistance
- repaired locally as described below
- showing general problems as described below

Item: _____ **Type:** _____ **Quantity:** _____
Serial No.: _____ Supplied by: _____
Included parts: _____

Important! - Accessories used together with the item must be included if returned (e.g. external power supply, headsets, transducers and couplers).

Description of problem or the performed local repair:

Returned according to agreement with: Interacoustics, Other : _____

Date : _____ Person : _____

Please provide e-mail address or fax No. to whom Interacoustics may confirm reception of the returned goods:

The above mentioned item is reported to be dangerous to patient or user ¹

In order to ensure instant and effective treatment of returned goods, it is important that this form is filled in and placed together with the item.
Please note that the goods must be carefully packed, preferably in original packing, in order to avoid damage during transport. (Packing material may be ordered from Interacoustics)

¹ EC Medical Device Directive rules require immediate report to be sent, if the device by malfunction deterioration of performance or characteristics and/or by inadequacy in labelling or instructions for use, has caused or could have caused death or serious deterioration of health to patient or user. Page 1 of 1