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Instructions for Use - US

VisualEyes™

Micromedical
by Interacoustics



Interacoustics

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1 Introduction

1.1 About this manual

This manual is valid for the VisualEyes™ 505, VisualEyes™ 515, VisualEyes™ 525, Orion Reclining, Orion Comprehensive (+ Basic), Orion Auto-Traverse (+ Basic), and VisualEyes™ EyeSeeCam with software version 3.0. These products are manufactured by:

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Definitions:
VisualEyes™ 505, VisualEyes™ 515, VisualEyes™ 525, and VisualEyes™ EyeSeeCam will be referred to as 'VisualEyes™ system' throughout this document. Wherever 'operator' is mentioned in this document, this refers to the clinician, technician or qualified personnel who operates the system. Rotational chair refers to all kinds of rotational chairs until a specific type is specified. Also, in the context of a rotational chair, Reclining, Auto-Traverse and Comprehensive are abbreviated as R, AT and C, respectively. The term 'VORTEQ™ IMU' refers to 2nd or latest generation of VORTEQ™ IMU.

Instructions for Use/Additional information:
'Instructions for use' contain all the information required to operate this system in a safe and effective manner but the **'Additional information'** guide is also available to the interested reader. The operator can find the Instructions for use and Additional information in the help menu in the software. The operator can also refer to these manuals on the manufacturer's official website.

1.2 Intended use

The VisualEyes™ system is to be used by trained personnel only, such as audiologists, ENT surgeons, physicians, hearing healthcare professionals or personnel with a similar level of education. The device should not be used without the necessary knowledge and training to understand its use and how results should be interpreted.

Videonystagmography (VNG):
The VisualEyes™ system provides information to assist in the nystagmographic evaluation, diagnosis and documentation of vestibular disorders. VNG testing evaluates nystagmus using goggles mounted with cameras. These images are measured, recorded, displayed and stored in the software. This information can then be used by a trained medical professional to assist in diagnosing vestibular disorders. The target population for videonystagmography is five years of age and above.

Electronystagmography (ENG):
The VisualEyes™ system also provides information to assist in the electronystagmographic evaluation, diagnosis and documentation of vestibular disorders. ENG testing evaluates nystagmus using electrodes. The eye movement analysis can be viewed, recorded and archived using this software. The target population for ENG testing includes all age groups.

Video head impulse testing (vHIT):
The VisualEyes™ 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.

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

1.3 Contraindications

VNG and vHIT testing may be contraindicated in patients who exhibit the following: blindness, broken nose or other face/head trauma, recent eye surgery and lazy eye.

ENG testing is not recommended for patients with a cardiac pacemaker or any other electric/magnetic implanted devices as the electrical equipment may interfere with the device's function.

Patients with strong defective vision, ptosis or abnormal blinks should be tested with caution as these conditions can lead to artefacts. Patients with severe back/neck problems may be excluded for positional and vHIT tests. Any other relevant clinical history or medication of an individual patient should be considered before starting a test. A medical specialist should be consulted for further information or guidance on clinical conditions that require additional attention before starting the test.

1.4 Product description

The VisualEyes™ system is a sophisticated software platform used for VNG, ENG, and vHIT testing.

1.4.1 Standard configurations without rotary chairs

VisualEyes™ systems is available in a number of different configurations with and without rotary chairs. The standard configurations without rotary chairs are *VisualEyes™ 505, VisualEyes™ 515, VisualEyes™ 525, and VisualEyes™ EyeSeeCam*. Refer to *Table 1.4-1* for an overview of the included tests with each of the systems.

- **VisualEyes™ 505**
  VisualEyes™ 505 is a Video Frenzel system including video recording as well as spontaneous nystagmus detection providing objective slow phase velocity data.

- **VisualEyes™ 515**
  VisualEyes™ 515 is a VNG system for evaluating spontaneous nystagmus, positional testing, and caloric testing. The system can also be combined with an Orion Reclining rotary chair for rotary chair testing.

- **VisualEyes™ 525**
  VisualEyes™ 525 is the full range VNG system including all tests from the VisualEyes™ 505 and VisualEyes™ 515 systems, with the addition of an advanced oculomotor test battery and ocular counter roll testing with torsional tracking. The system can also be combined with an Orion Reclining, Orion Comprehensive, or Orion Auto-Traverse rotary chair for rotary chair testing.

- **VisualEyes™ EyeSeeCam**
  VisualEyes™ EyeSeeCam is a vHIT system for quick and objective measurements of the vestibulo-ocular reflex (VOR) through lateral, RALP, LARP, and SHIMP testing. Furthermore, the system includes a protocol for spontaneous nystagmus providing objective slow phase velocity data. VisualEyes™ EyeSeeCam can be combined with any of the other VisualEyes™ systems, combining VNG and vHIT testing into the same software platform.

On top of the standard modules, different optional add-on modules can be added to some of the configurations:

- **VORTEQ™ Assessment (VisualEyes™ 505 / VisualEyes™ 515 / VisualEyes™ 525)**
  VORTEQ™ Assessment is an add-on module including the VORTEQ™ 2nd Generation IMU and headband for head position and velocity tracking.
  The module adds the following measurements on top of the extisting test battery:
  - BPPV Module
    - Advanced Dix Hallpike
    - Lateral Head Roll
  - Dynamic Visual Acuity

- **VORTEQ™ Diagnostic (VisualEyes™ 525)**
  VORTEQ™ Diagnostic is an add-on module including the VORTEQ™ 2nd Generation IMU for head position and velocity tracking.
  The module adds the following measurements on top of the extisting test battery:
  - vHIT VORTEQ™
  - Active Head Rotation

- **Research Module (VisualEyes™ 525)**
  The Research Module is an add-on module allowing for easy export of raw data along with adjustment of nystagmus detection parameters.

- **EOG Accessory kit for VNG (VisualEyes™ 515 / VisualEyes™ 525)**
  The EOG Accessory kit for VNG is an add-on module including the DataLink used for ENG testing.

Table 1.4-1 License Overview (without Rotary Chairs):

	VisualEyes™ 505	VisualEyes™ 515	VisualEyes™ 525	VisualEyes™ EyeSeeCam
Video Frenzel	X		X	
Spontaneous Nystagmus	X	X	X	X
Gaze			X	
Dix Hallpike		X	X	
Positional		X	X	
Bithermal Caloric*		X	X	
Optokinetic			X	
Smooth Pursuit			X	
Saccade			X	
Ocular Counter Roll w. torsional tracking			X	
Saccadometry			X	
EyeSeeCam vHIT				X
ADD-ON: VORTEQ™ Assessment** - Dynamic Visual Acuity - Dix Hallpike Advanced - Lateral Head Roll	X	X	X	
ADD-ON: VORTEQ™ Diagnostic** - Active Head Rotation - vHIT VORTEQ™			X	
ADD-ON: Research Module			X	
ADD-ON: EOG Accessory kit for VNG		X	X	

* Requires separate caloric irrigator
** Only compatible with top mount or side mount goggles

1.4.2 Standard configurations with rotary chairs

Rotary chairs can be combined with VisualEyes™ 515 and VisualEyes™ 525, as described below. The Orion Comprehensive and the Orion Auto-Traverse can furthermore be configured as Orion Comprehensive Basic and Orion Auto-Traverse Basic respectively. These include only the tests that can be performed inside the chair enclosure. Refer to *Table 1.4-2* for an overview of the included tests with each of the systems.

- **Orion Reclining**
  Orion Reclining is a rotary chair that can be reclined for calorics and positioning testing.

- **Orion Comprehensive**
  Orion Comprehensive is a rotary chair inside a chair enclosure, containing a built-in laser and an optokinetic drum for visual stimuli.

- **Orion Auto-Traverse**
  Orion Auto-Traverse is a rotary chair inside a chair enclosure, containing a built-in laser and an optokinetic drum for visual stimuli. The chair furthermore has off-axis lateral movement capability used for dynamic subjective visual vertical testing.

- **Other Rotary chairs**
  VisualEyes™ 3rd generation also supports the rotary chairs below:
  - System 2000 Reclining
  - System 2000 Comprehensive
  - System 2000 Auto-Traverse
  - Nydiag 200

Table 1.4-2: License Overview (with Rotary Chairs):

	Orion R + VE515	Orion R + VE525	Orion C Basic	Orion AT Basic	Orion C + VE525	Orion AT + VE525
Video Frenzel		X			X	X
Spontaneous Nystagmus	X	X	X	X	X	X
Gaze		X	X	X	X	X
Dix Hallpike	X	X			X	X
Positional	X	X			X	X
Bithermal Caloric*	X	X			X	X
Optokinetic		X	X	X	X	X
Smooth Pursuit		X	X	X	X	X
Saccade		X	X	X	X	X
Ocular Counter Roll		X			X	X
Saccadometry		X			X	X
Step Rotation	X	X	X	X	X	X
Sinusoidal Harmonic Acceleration (SHA)	X	X	X	X	X	X
VOR Suppression	X	X	X	X	X	X
Visual VOR	X	X	X	X	X	X
Static SVV			X	X	X	X
Dynamic SVV				X		X
ADD-ON: VORTEQ™ Assessment** - Dynamic Visual Acuity - Dix Hallpike Advanced - Lateral Head Roll	X	X			X	X
ADD-ON: VORTEQ™ Diagnostic** - Active Head Rotation - vHIT VORTEQ™		X			X	X
ADD-ON: Research Module		X	X	X	X	X
ADD-ON: EOG Accessory kit for VNG	X	X			X	X
ADD-ON: EOG Accessory kit for Orion C/AT			X	X	X	X
ADD-ON: Child Option Accessory kit for Orion C/AT			X	X	X	X

* Requires separate caloric irrigator
** Only compatible with top mount or side mount goggles

1.4.3 Included and optional parts

VisualEyes™ 505	VisualEyes™ 515	VisualEyes™ 525	EyeSeeCam vHIT
Included parts: • VNG goggle of choice • VisualEyes™ software • Remote control / foot switch • Full HD room camera • Cleaning cloth • Introduction guides • Certificates and reports: e.g. test result report, license certificate, certificate of conformity, and if applicable, safety test report.	**Included parts:** • VNG goggle of choice • VisualEyes™ software • Remote control / foot switch • Full HD room camera • Cleaning cloth • Introduction guides • Certificates and reports: e.g. test result report, license certificate, certificate of conformity, and if applicable, safety test report.	**Included parts:** • VNG goggle of choice • VisualEyes™ software • Remote control / foot switch • Full HD room camera • Cleaning cloth • Introduction guides • Certificates and reports: e.g. test result report, license certificate, certificate of conformity, and if applicable, safety test report.	**Included parts:** • EyeSeeCam vHIT goggle and camera • VisualEyes™ software • Full HD room camera • Cleaning cloth • Certificates and reports: e.g. test result report, license certificate, certificate of conformity, and if applicable, safety test report.
Optional parts: • TRV Chair • VORTEQ™ Assessment	**Optional parts:** • TRV Chair • VORTEQ™ Assessment • EOG Accessory kit for VNG • Orion Reclining • AquaStim • AirFx	**Optional parts:** • TRV Chair • VORTEQ™ Assessment • VORTEQ™ Diagnostic • Research Module • EOG Accessory kit for VNG • Orion Reclining • Orion Comprehensive • Orion Auto-Traverse • AquaStim • AirFx • Digital Lightbar	**Optional Parts:**

1.4.4 Additional parts based on VNG goggle type

Side Mount USB (2D-VOGFW)	Side Mount FireWire (2D-VOGFW)	Top Mount (BG4.0USB / BG4.0KUSB)	Front Mount (USBM2.1A / USBM2.1P)
Included parts: • USB 2.0 camera module (two modules in binocular configuration) • Disposable goggle foam pads – box of 24 pcs and foam insert case • 1.5 mm hexagon screwdriver for camera retaining screws • 7-port USB 3.0 hub w. external power supply	**Included parts:** • FireWire® camera module (two modules in binocular configuration) • Disposable goggle foam pads – box of 24 pcs and foam insert case • 1.5 mm hexagon screwdriver for camera retaining screws • 4-port USB 3.0 hub w. external power supply • PCI ExpressCard (for desktop PC configuration)	**Included parts:** • Binocular USB goggles • 7-port USB 3.0 hub w. external power supply	**Included parts:** • Adult (USBM2.1A) / Pediatric (USBM2.1P) mask for monocular USB camera • 7-port USB 3.0 hub w. external power supply

1.4.5 Additional parts based on rotary chairs

Orion Reclining	Orion Comprehensive / Orion Auto-Traverse
Included parts: • Orion Reclining rotary chair • USB cable • Emergency stop button with Ethernet connector • Power cord • Tools and accessories for assembly • Isolation transformer	**Included Parts:** • Orion Comprehensive / Auto-Traverse rotary chair • Optokinetic drum • X-Y laser assembly • Booth and accessories • USB cable • Emergency stop button with Ethernet connector • Power cord • Booth observation camera • Intercom • Remote control for SVV line • Tools and accessories for assembly • Isolation transformer
Optional parts:	**Optional Parts:** • EOG accessory kit for Orion C/AT • Child option accessory kit for Orion C/AT

1.4.6 Additional parts based on add-on modules

	VORTEQ™ Diagnostic	VORTEQ™ Assessment	Research Module
Compatible with:	• VisualEyes™ 525 (top mount / side mount goggles)	• VisualEyes™ 505 (top mount / side mount goggles) • VisualEyes™ 515 (top mount / side mount goggles) • VisualEyes™ 525 (top mount / side mount goggles)	• VisualEyes™ 525 • Orion Auto-Traverse Basic • Orion Comprehensive Basic
Included features/tests:	• Active Head Rotation • vHIT VORTEQ™	• Dynamic Visual Acuity • Dix Hallpike Advanced • Lateral Head Roll	• Adjustment of nystagmus parameters • Data export
Included parts:	• VORTEQ™ 2nd gen sensor • Bluetooth dongle • USB cable (for charging or wired connection) • Goggle mounts for side mount and top mount goggles	• VORTEQ™ 2nd gen sensor • Bluetooth dongle • USB cable (for charging / wired connection) • Goggle mounts for side mount and top mount goggles • Headband for Dynamic Visual Acuity	• License only

	EOG accessory kit for VNG	EOG accessory kit for Orion C/AT	Child option accessory kit for Orion C/AT
Compatible with:	• VisualEyes™ 515 • VisualEyes™ 525	• VisualEyes™ 525 + Orion C/AT • Orion Comprehensive Basic • Orion Auto-Traverse Basic	• VisualEyes™ 525 + Orion C/AT • Orion Comprehensive Basic • Orion Auto-Traverse Basic

Compatible features/tests (If system is licensed for the tests):	• 3-channel ENG testing compatible with below tests:
	  ○ Spontaneous Nystagmus
	  ○ Gaze
	  ○ Smooth Pursuit
	  ○ Saccade
	  ○ Optokinetic
	  ○ Positional
	  ○ Dix Hallpike
	  ○ Bithermal Caloric
	  ○ Saccadometry
		• 3-channel ENG testing compatible with below tests:
		  ○ Spontaneous Nystagmus
		  ○ Gaze
		  ○ Smooth Pursuit
		  ○ Saccade
		  ○ Optokinetic
		  ○ Step Rotation
		  ○ Sinusoidal Harmonic Acceleration
			• Rotary chair testing for children down to 1 year of age

Included parts:	• Datalink • 7x electrode cables (3 channels) • Snap electrodes (90 pcs for adults, 36 pcs for children) • Electrode skin prep pads (box of 100)	• ENG built into the back of the Orion C/AT rotary chairs • 7x electrode cables (3 channels) • Snap electrodes (90 pcs for adults, 36 pcs for children) • Electrode skin prep pads (box of 100)	• Pediatric front mount goggle (USBM2.1P) • Child seat • Pediatric observation camera

1.5 Warnings and precautions

The general warnings, precautions and points to be noticed for the VisualEyes™ system are discussed in this section with appropriate symbols. **Some of the specific warnings are discussed under respective sections to get the maximum attention from the user.**



Throughout this manual the following meaning of warnings, cautions and notices are used:

	**WARNING** identifies conditions or practices that may present danger to the patient and/or user.
	**CAUTION** label identifies conditions or practices that could result in damage to the equipment.
NOTICE	**NOTICE** is used to address practices not related to personal injury.

General warnings and precautions



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

1. Federal law restricts this device to sale by or on the order of a physician.
2. Do not disassemble or modify the product as this may impact on the safety and/or performance of the device. Always refer to qualified/authorized personnel for product service. No modification (if necessary) should be done to this equipment/its component without authorization from Interacoustics.
3. 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 62368-1 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 in the general standard IEC 60601-1, edition 3.1, 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 or shall be supplied via a separation transformer to reduce the leakage currents. Any person who connects external equipment to a 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 a qualified medical technician or your local representative.
4. 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 requirements for separation devices are defined in IEC 60601-1, edition 3, clause 16.
5. The system must not be used in the presence of explosive or flammable gases.
6. The system must be switched off before cleaning.
7. Do not use any additional multiple-socket outlet or extension cord.
8. For irrigators, to avoid the risk of electric shock, this equipment must only be connected to a supply main with protective earth.

9. The manufacturer will make available on request circuit diagrams, component part lists, descriptions, calibration instructions, or other information that will assist service personnel designated by the manufacturer to repair those parts of this system.
10. For maximum electrical safety, turn off the power to the equipment when it is left unused.
11. The equipment is not protected against harmful ingress of water or other liquids. If any spillage occurs, check the equipment carefully before use or contact the manufacturer for service.
12. Do not use the equipment before service, if it shows a visible or suspected damage.
13. Grade 2 laser stimulus is used in the Orion Auto Traverse / Orion Comprehensive chairs and the System 2000 Auto Traverse / System 2000 Comprehensive chairs against the booth enclosure. Both operator and patient should avoid looking into the laser beam. There are no user-serviceable components in the laser box assembly.





14. Do not service any part of the equipment while in use with a patient.



CAUTION, used with the safety alert symbol, indicates a hazardous situation which, if not avoided, could result in damage to the equipment.

1. Before using the system, it is mandatory to read the user manual, labels and other additional information. The system should be used as described in the user manual only.
2. The system should only be operated by qualified technicians with appropriate training.
3. The system must be serviced at least once a year. The service must include a safety test.
4. Handle the device components carefully to avoid system damage.
5. Allow the system to obtain room temperature before using the equipment. Any components that have been stored previously should be brought to room temperature before usage.
6. It is important to ensure that the rotational chair center is situated at least 1 meter (39 inches) from the center axis to any adjacent object to accommodate its reclined position.

NOTICE **NOTICE** is used to address practices not related to personal injury or damage to the equipment.

1. A CLASS 1 laser stimulus is used in the EyeSeeCam goggles. A CLASS 1 laser is safe under all conditions of normal use. This means the maximum permissible exposure (MPE) for this beam is not exceeded when viewed with the naked eye or with the aid of typical magnifying optics.



2. No other PC programs should be running or minimized while testing the patient with the software. This can interfere with the VisualEyes™ system's software.
3. To prevent system faults, take appropriate precautions to avoid PC viruses and similar.
4. Although the equipment fulfils the relevant EMC requirements, precautions should be taken to avoid unnecessary exposure to electromagnetic fields, e.g. from mobile phones etc. If the device is used adjacent to other equipment, it must be observed that no mutual disturbance appears.



Within the European Union it is illegal to dispose electric and electronic waste as unsorted municipal waste. Electric and electronic waste may contain hazardous substances and must therefore be collected separately. Such products will be marked with the crossed-out wheeled bin. The cooperation of the user is important to ensure a high level of reuse and recycling of electric and electronic waste. Failing to recycle such waste products in an appropriate way may endanger the environment and consequently the health of human beings. Users from countries not belonging to the European Union are entitled to follow the applicable local rules related to electric or electronic waste management.

1.6 Safety features and complaints handling

1.6.1 Complaints/safety reporting:



Please contact your local distributor in case of any incident related to product defects (hardware defects or software bugs) or adverse events (which does not necessarily have a causal association to the product). It is recommended for a user to report all the known facts about the incident. Upon receipt of any serious incident with serious health impact for the patient or user (serious adverse events), Interacoustics shall ensure that the regulatory authority in patient's home country is informed according to the vigilance requirements. Interacoustics shall handle all the product complaints and adverse events as per the internal procedure.

1.6.2 Safety features of the product

The VisualEyes™ system provides various safety features to ensure patient safety and various error messages as check points for the better performance of tests especially with all rotational chair options. Refer to section 4.3 for details on the error messages. Other safety features are described below.

1.6.3 All types of rotational chairs

All types of rotational chairs (Orion Reclining/Auto Traverse/Comprehensive, System 2000 Reclining/Auto Traverse/Comprehensive and Nydiag 200) have an **emergency stop button** which resides at the operator's station and the operator can manually override the system to stop the chair, laser, and optokinetic drum by pressing the button. Rotating the emergency stop button will release the devices and the system is ready for operation. The operator can restart the test from the software.

Rotational chair has seat belt to secure the patient from falling during the tests. Rotational chair tests do not respond to the RF remote as an additional patient safety measure. Refer to Additional information guide for more details.

1.6.4 Orion and System 2000 reclining chairs

The VisualEyes™ system does not allow a rotational chair to spin at the reclining position and the operator immediately gets an alert message from the software.

1.6.5 Orion Auto-Traverse/Comprehensive chairs

The Orion Auto-Traverse/Comprehensive chairs come with a booth enclosure. The booth enclosure is wired to ensure that the booth door is closed before testing. If the door is open, the test will not start. If you open the door during testing, the test will be stopped, and the operator gets an alert message.
Note: the chair, laser and drum are disabled for any test when the booth is open.

The patient-controlled stop button is secured on the right side of the head support of the Orion Auto-Traverse/Comprehensive chairs. The patient can press the stop button during testing. Pressing the button during a test will stop the chair, laser and optokinetic drum.

The chair has a built-in watchdog timer that checks if the software and chair are communicating. If there is no communication, the watchdog timer will stop the chair, laser and optokinetic drum. Following, the operator must exit the test or go to the home screen and restarting the test will reset the watchdog timer (refer to section 4.8.9 to know more). If the fault repeats, the operator must address the issue before proceeding with the test.

1.6.6 Nydiag 200 reclining chair

The patient-controlled stop button is located underneath the right armrest. Pressing the button during a test will stop the chair.

2 Unpacking and installation

2.1 Unpacking and inspection

Check shipping box
As soon as you receive the instrument, please check the shipping box for any sign of rough handling or damage. If the box is damaged, keep the shipping material as it may be required for inspection by the carrier regarding any potential insurance claim.

Keep carton
The VisualEyes™ system comes with shipping cartons, which are specifically designed for the components. It is recommended to keep the cartons for future shipments in case of any need for return or service.

Inspect instrument before connection
Inspect the product for potential damage before connecting it. Examine the cabinet and accessories for scratches and missing parts.

Report any concerns immediately
Report any missing part or any mechanical or electrical malfunction immediately to your local distributor 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.

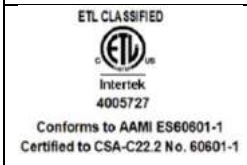
Please use “Return Report”
Please realize that if the service engineer does not know what problem to look for he may not find it, so using the Return Report will be of great help to us and is your best guarantee that the correction of the problem will be to your satisfaction.

Storage
If you need to store the VisualEyes™ system for a period, please ensure it is stored under the appropriate conditions as described for the different components in the Technical Specifications section 5: *General technical specifications.*

2.2 Markings and symbols

The following markings and symbols can be found on the instrument, accessories or packaging:

Symbol	Explanation
	Type BF applied parts
	Type B applied parts
	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.
 0123	The CE-mark in combination with MD symbol indicates that Interacoustics A/S meets the requirements of the Medical Device Regulation (EU) 2017/745. Approval of the quality system is made by TÜV – identification no. 0123.
	Medical device
	Manufacturer
	Date of Manufacture
	Indicates a component is intended for one use, or for use on a single patient during a single procedure. Cross contamination risk
	Reference number
	Do-not-push symbol used with components that could easily tip over, such as the Digital Light Bar
	Chinese RoHS compliance standard where the product contains less than the maximum concentration value of lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls and polybrominated diphenyl ethers

	CLASS 1 LASER PRODUCT. A CLASS 1 laser is safe under all conditions of normal use. This means the maximum permissible exposure (MPE) cannot be exceeded when viewing a laser with the naked eye or with the aid of typical magnifying optics
 	This product contains a component (Orion Comprehensive/Auto-Traverse chair) of **'Class 2 Laser beam'. Hence, do not look directly into the laser beam**
	Keep dry
	Transport and storage temperature range
	Transport and storage humidity limitations
	ETL listing mark
Interacoustics	Logo

2.3 To know before you start the installation

If the computer is purchased from Interacoustics, all the software / databases / drivers (e.g: OtoAccess® Database, VisualEyes™, rotational chair drivers, PC Power Settings) are preinstalled. Either a laptop or desktop computer can be selected for the VisualEyes™ systems. It is recommended to use the computers delivered by Interacoustics for VisualEyes™ systems as these have been tested to ensure compatibility.

NOTICE

1. You must have administrative rights to the computer on which you are installing the VisualEyes™ software.

2. Interacoustics will not make any guarantee for the functionality of the system if any other software is installed on the computer, with the exception of software delivered by Interacoustics and OtoAccess® Database.

3. Data from previous versions of VisualEyes™ can be reviewed and analyzed in VisualEyes™ 3rd generation. However, after being opened in VisualEyes™ 3rd generation, the data cannot be reopened in previous versions of VisualEyes™. This is especially important to consider in a server-client setup with multiple installations of VisualEyes™, where it is recommended to upgrade all installations to the newest software.

2.4 PC setup

Prior to the installation, ensure that the computer is compliant with all minimum PC requirements listed in the Technical Specifications in section 5: *General technical specifications*.

2.4.1 Power settings

In order to ensure sufficient power supply from the computer to the instrument, it is important to set up the PC power settings correctly. The PC must be set up for maximum performance. This includes settings in the BIOS, windows power options, and power management settings from the device manager as presented in Table 2.4-1. Configurations can differ between computer models, and below instructions should be seen as guidelines only.

Table 2.4-1: PC Power Settings

PC Power Settings	
BIOS Settings: *Navigate to the PC BIOS and search for similar settings*	
• Intel® SpeedStep technology:	Disabled
• Adaptive Thermal Management:	Scheme for AC: Maximum Performance Scheme for Battery: Maximum Performance
• CPU Power Management:	Disabled
• PCI Express Power Management:	Disabled
• USB 3.0 Mode	Disabled
• C-State Control:	Disabled

Windows Power Options: *Navigate to Control Panel > Power Options. Select the "High Performance" power plan, and open "change plan settings" and "Change advanced power settings".*	
• Hard disk > Turn off hard disk after:	On battery: Never Plugged in: Never
• Wireless Adapter Settings > Power Saving Mode:	On battery: Maximum Performance Plugged in: Maximum Performance
• USB Settings > USB selective suspend setting	On battery: Disabled Plugged in: Disabled
• Intel® Graphics settings > Intel® Graphics Power Plan:	On battery: Maximum Performance Plugged in: Maximum Performance
• PCI Express > Link State Power Management:	On battery: Off Plugged in: Off
Device Manager Settings: *Navigate to Device Manager and identify all USB Hubs and Host Controllers. Right click and go to properties, and apply below settings for all.*	
• Allow Computer to turn off this device to save power:	Unchecked

2.4.2 PCI Expresscard

If the VisualEyes™ system is ordered with FireWire® cameras, the PC needs a PCI Expresscard installed for FireWire® connection. This should be installed following below instructions.



Close the open windows and shut down the computer. Make sure the power cable and the power supply for PC are disconnected.

Plug the PCI expresscard into a free PC slot and insert the power adapter F3-14/SATA-16 between power supply to the PC and PCI expresscard. Reconnect the power cable and the PC, and then start the computer.

Windows automatically installs the necessary drivers.

2.4.3 USB connection

The VisualEyes™ system is delivered with a 4-port or 7-port USB hub depending on the configuration. This is an active USB hub that must be supplied with power from the included 12V power supply. The VNG and vHIT goggles must be connected through this externally powered USB hub to ensure that the devices are supplied with sufficient power.

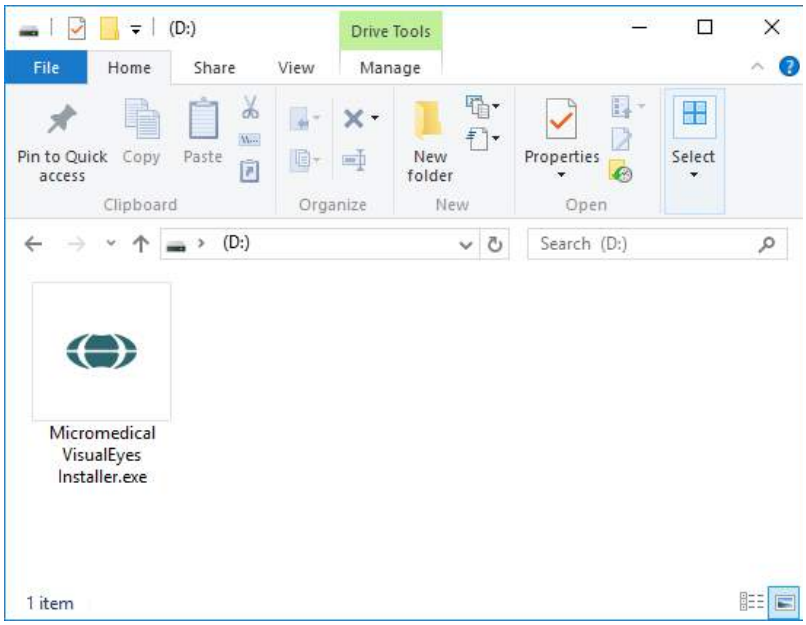
2.5 Software installation

Ensure that OtoAccess® Database is installed before installing the VisualEyes™ software. Consult the OtoAccess® Database Instructions for Use to install the software.

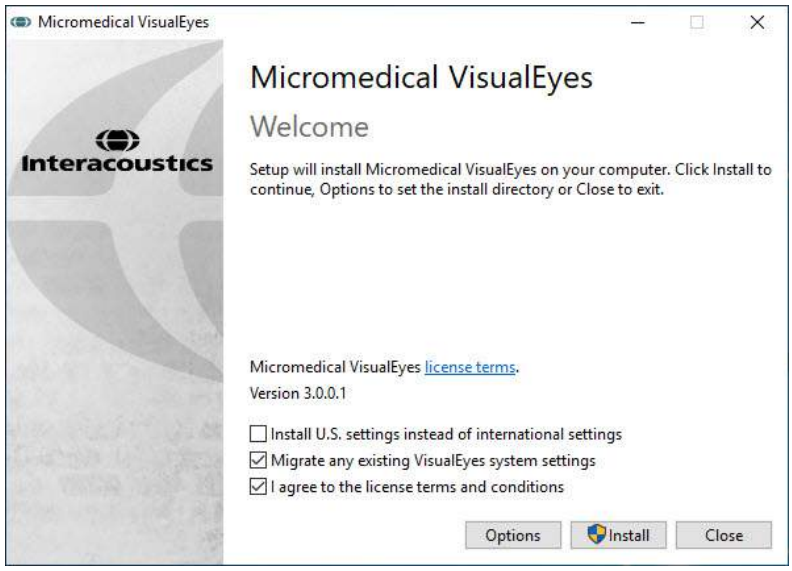
If a previous version of VisualEyes™ is installed on the computer, uninstall this before installing the new version, following the instructions in section 2.5.2: *Uninstalling VisualEyes™*.

Insert the *VisualEyes™* installation flash drive into the computer.

If the installation procedure does not start automatically, click *Start*, then go to *My Computer* and click the *Flash Drive* to view the contents of the installation media.



Click the *Micromedical VisualEyes™ Installer* to initiate the installation.



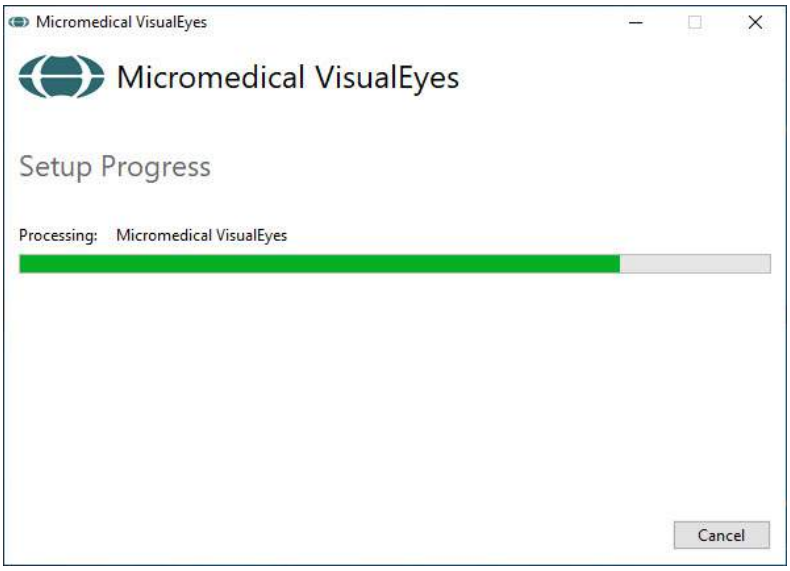
The *VisualEyes™ Setup Wizard* pops up.

Check the box to accept the license term and conditions for use.

If a previous version of VisualEyes™ has been installed on the computer, checking the “Migrate existing VisualEyes™ system settings” box will transfer any existing system settings during the installation. This includes protocols, stimuli settings, rotational chair settings, threshold levels and more.

Checking the “Install U.S. settings instead of international settings” box will set up the software with local settings specified for U.S.

Click Install.



Wait for the installation process to complete.



When the installation is complete, exit the installer by clicking *Close.*

The installation media can now be removed from the drive and be stored in a convenient place.

2.5.1 Demo patients

The VisualEyes™ software includes demo patients that can be imported into OtoAccess® Database for demonstration purposes.
The demo patients are available at the following path after the VisualEyes™ software installation:
C:\Program Files (x86)\Interacoustics\Micromedical VisualEyes™\Demo data

Please refer to the OtoAccess® Database documentation for further instructions on how to import patients into the database.

2.5.2 Uninstalling VisualEyes™

Windows® 7, Windows® 8.1 and Windows® 10	
VisualEyes™ software removal is possible from *Programs and Features.*	
1	Open *Windows® Control Panel* and then select *Programs and Features*. If the option *Category* is used, then select *Uninstall a program* in *Programs*.
2	Select *Micromedical VisualEyes™*. Click *Uninstall*.
3	In the installer package, select *Uninstall*. Once the program is uninstalled, close both installer and control panel.

2.6 Hardware components and installation

A VisualEyes™ system can, depending on the configuration, contain a lot of hardware components, and it is important that these are all connected and installed correctly. This section will cover the installation of the different hardware components. Most components connect to the computer via USB. If the goggles use FireWire® cameras, the goggles will connect to the FireWire® plug-in card on the computer. The TV or projector will connect via HDMI.

Please refer to Figure 2.6-1 for a pictorial representation of all the configurations available with the VisualEyes™ system without a rotational chair.

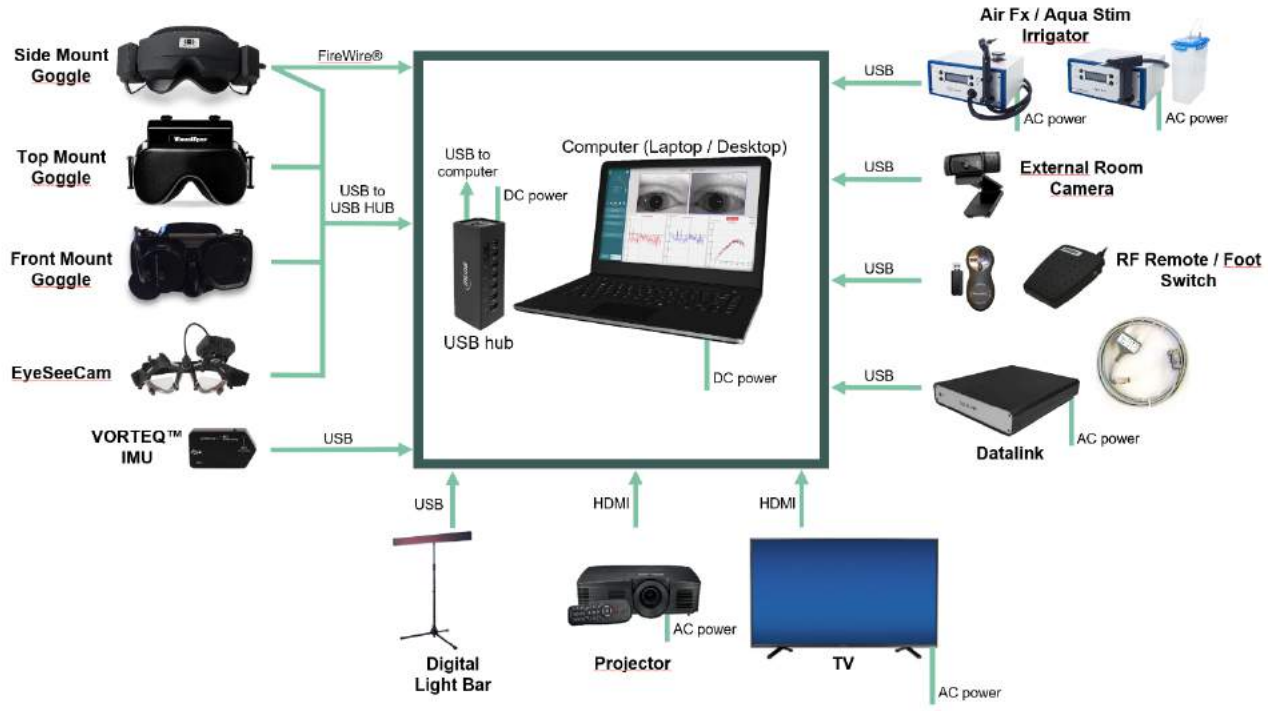


Figure 2.6-1: Configuration of VisualEyes™ systems without rotary chairs

2.6.1 VNG and vHIT goggles

VisualEyes™ comes with a variety of VNG and vHIT goggles. VisualEyes™ EyeSeeCam comes with the EyeSeeCam goggle, Orion Auto-Traverse Basic and Orion Comprehensive Basic comes with the Top Mount goggle, while VisualEyes™ 505/515/525 comes with either the Side mount, top mount, or front mount goggles.

2.6.1.1 Side mount goggles

The VisualEyes™ side mount goggles allow the recording of eye movements during various test conditions, both with and without visual stimulation. The goggles can be configured with either one or two cameras, and with either FireWire® or USB connection. The goggle comes with a removable cover for light occlusion. This is magnetically fixed, and can easily be removed for oculomotor testing. The mask has an adjustable Velcro head strap that comfortably secures the goggles to the patient.

The side mount goggles come with replaceable foam pads that are meant for single use as reuse of foam pads can cause cross contamination. This should be changed after every single use by pulling the used foam pad off of the hook and loop pads on the inside of the mask and then aligning a new foam pad on top of the hook and loop.



Figure 2.6-2: Side mount goggle with removable cover (left), and replaceable single-use foam pads (right)

The cameras are fixed on the side of the goggle. The cameras are fixed using magnets, along with fixation screws on the top and bottom of the goggle. The fixation screws can be loosened or tightened using the included hexagon screwdriver.

If the goggle only has one camera, this can be moved to either side of the goggle in order to record either the left or right eye. You can insert a cover into the camera slot in the opposite side to block out light in vision-denied tests.



Figure 2.6-3: Hexagon fixation screws on the top and bottom of the side mount goggle, used for fixation of a camera or fixation of a cover (in picture)

Each camera on the side mount goggle contains three knobs for image adjustment:

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

For further image adjustment, the mirrors on the goggles can also be rotated into two positions to help adjust for different interpupillary distances.



Figure 2.6-4: Adjustable IR mirrors for interpupillary distance adjustment (left), and knobs for 1) vertical camera adjustment, 2) horizontal camera adjustment, 3) camera focus adjustment (right)

Hardware setup:

1. Insert the camera(s) into the camera slot(s) on the goggle and tighten the fixation screws using the supplied screw driver, until the camera is properly fixated.
2. If monocular, attach a cover into the camera slot in the opposite side of the attached camera.
3. Connect the camera(s) to the computer:
    a. If USB – connect the USB cable(s) to the supplied USB hub. Ensure that the hub is powered through the external power supply.
    b. If FireWire – connect the FireWire cable(s) to the PCI Express card in the computer.
    c. If used with a rotary chair, the goggle plugs in to the connectors on the chair.
4. Mount a replaceable foam pad on the goggle.
5. Register the side mount goggles as ”Side Mount Monocular” or ”Side Mount Binocular” in the the VisualEyes™ software, following the instructions in section 2.8: *Hardware registration and licensing*.

2.6.1.2 Top mount goggles

The VisualEyes™ top mount binocular goggles come with an easy-to-place cover over the portal for vision-denied testing. Side-lights on the goggles are programmed to flash to remind the operator which ear to irrigate during the caloric test and are also used to provide illumination when placing the cover on the goggles. The knobs on the top side of the goggle can be used to adjust the focus for the optimal image, and the switch on the left side of the goggles can be used to start and stop tests. The top mount goggles have an adjustable velcro head strap that secures the goggles while still providing patient comfort.



Figure 2.6-5: Top mount goggle with cover (left), without cover (middle), and start/stop switch on goggle (right)

Hardware setup:

1. Connect the USB mini-B connectors to the connectors on the top side of the goggle.
2. Connect the other end of the USB cables to the supplied USB hub. Ensure that the hub is powered through the external power supply. If used with a rotary chair, the goggles plug in to the connectors on the chair.
3. Register the top mount goggles as ”Top Mount Camera” in the the VisualEyes™ software, following the instructions in section 2.8: *Hardware registration and licensing*.

2.6.1.3 Front mount goggles

The front mount goggles use a single USB camera pressed into the camera portal on the front of the goggle’s mask. The camera can be placed into either camera portal to record the desired eye, and the focus can be adjusted for the optimal image using the knob in the center of the camera. The cable is secured in the cable clip above the portal. Each portal has a swivel cover plate to provide vision-denied testing. The goggles have an adjustable head-strap that secures the goggles while still providing patient comfort. The front mount goggle is furthermore available in a version designed for smaller and younger patients.



Figure 2.6-6: Standard front mount goggle (left), and small face front mount goggle (right)

Hardware setup:

1. Insert the camera into the portal on the mask. Ensure that the camera is placed in the correct orientation by placing the camera with the “UP” label pointing upwards.
2. Connect the USB mini-B connector to the connector on the camera.
3. Connect the other end of the USB cable to the supplied USB hub. Ensure that the hub is powered through the external power supply.
4. Register the front mount goggles as ”Front Mount Camera” in the the VisualEyes™ software, following the instructions in section 2.8: *Hardware registration and licensing*.

2.6.1.4 EyeSeeCam goggle

The EyeSeeCam camera acquires the eye position and head position data during video head impulse tests (vHIT). Along with vHIT, VisualEyes™ can now use the EyeSeeCam goggle for standard VNG tests where applicable, and if the EyeSeeCam is combined with VNG system. The camera is connected through USB, and can be mounted into the spherical socket over the eye. A laser stimulus projects from the goggles in the vHIT test.



Figure 2.6-7: EyeSeeCam goggle

The camera is mounted in a spherical ball-and-socket joint over either the right or left eye. This allows for recording the eye better suited for the examination. This feature is particularly useful in patients with either a glass eye or with a ptosis. The ball-and-socket joint allows the user to adjust the angle of the camera in order to center the eye in the image, and the lens of the camera module can be turned to adjust the focus of the image. A focused image is a precondition of stable eye tracking and noise-free data.



Figure 2.6-8: Focus adjustment on the EyeSeeCam goggle

The calibration laser, on the bridge 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.

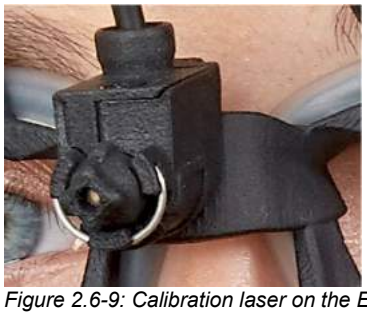


Figure 2.6-9: Calibration laser on the EyeSeeCam goggle.

Hardware setup:

1. Connect the USB mini-B connector to the connector on the EyeSeeCam camera.
2. Connect the other end of the USB cable to the supplied USB hub. Ensure that the hub is powered through the external power supply.
3. Mount the camera on the goggle using the spherical ball-and-socket joint.
4. Mount the calibration laser on the bridge of the goggle.
5. Register the EyeSeeCam goggle as ”EyeSeeCam” in the the VisualEyes™ software, following the instructions in section 2.8: *Hardware registration and licensing*.
6. Ensure that the calibration laser is in horizontal/vertical alignment, and adjust if necessary.

2.6.2 External room camera

All VisualEyes™ systems are delivered with an external room camera. This can be used to record the environment, for example to see how the patient was positioned during measurements, or to record patient interviews. The room recordings are synchronized with the eye recordings.



Figure 2.6-10: External room camera

Hardware setup:

1. Place the camera on a location where the environment can be properly recorded.
2. Connect the USB cable to a USB port on the computer or on the USB hub.
3. Navigate to *Configuration* > *System Default Settings* > *Input*, and select the connected camera in the list under *Room Camera*.



Figure 2.6-11: Selection of room camera under System Default Settings > Input

2.6.3 Foot switch and RF remote control

VisualEyes™ 505/515/525, Orion Comprehensive Basic, and Orion Auto-Traverse Basic are all delivered with either a foot switch or a remote control. These can be used to start/stop the tests away from the computer. The RF remote can also be used to restart, turn the fixation light on/off, or to center the camera image (if used with the top mounted camera goggle):

1. Top button:
    - Centers eyes (top mounted goggles)
    - Centers traces (side mounted goggles)
2. Right button:

Typically, this can perform any selected command in VisualEyes™ (indicated by white background). Please find the below example for better explanation:

Before calibration, you can select the ‘Calibration’ option which is shown with a white background.

After calibration, you can select the ‘START’ option which is shown with a white background.



This way, the operator can perform below listed actions.

- Go forward in the software
- Launch calibration
- Following calibration, button will start the test
- If the test is running, it stops the test
- If in playback mode, the button will advance to the next test in the list

3. Left button:
    - Aborts the test
4. Bottom button:
    - Turns the fixation light on/off during a test

NOTICE The right and left buttons are not active during rotary chair tests for safety reasons.



Figure 2.6-12: Foot switch (left), and RF remote control (right)

Hardware setup:

1. Connect the USB cable/dongle to a USB port on the computer or on the USB hub.

2.6.4 Caloric irrigators (optional)

AquaStim and AirFx can be added to the VisualEyes™ 515/525 system for water or air stimulation for the caloric test. The caloric irrigators can be controlled through the VisualEyes™ software.



Figure 2.6-13: AquaStim for water irrigation (left), and AirFx for air irrigation (right)

For fill- and installation instructions, please refer to separate documentation for AquaStim or AirFx.

Setup in software:

1. Connect the USB type B connector to the connector on the rear panel of the irrigator. Connect the other end of the USB cable to the computer or externally powered USB hub.
2. Launch the VisualEyes™ software, and navigate to *Configuration* > *Protocol Management* > *Caloric* > *Edit Test*. Go to the *Irrigator* tab in the panel to the left, and select the *Irrigator Type* matching the connecting irrigator.

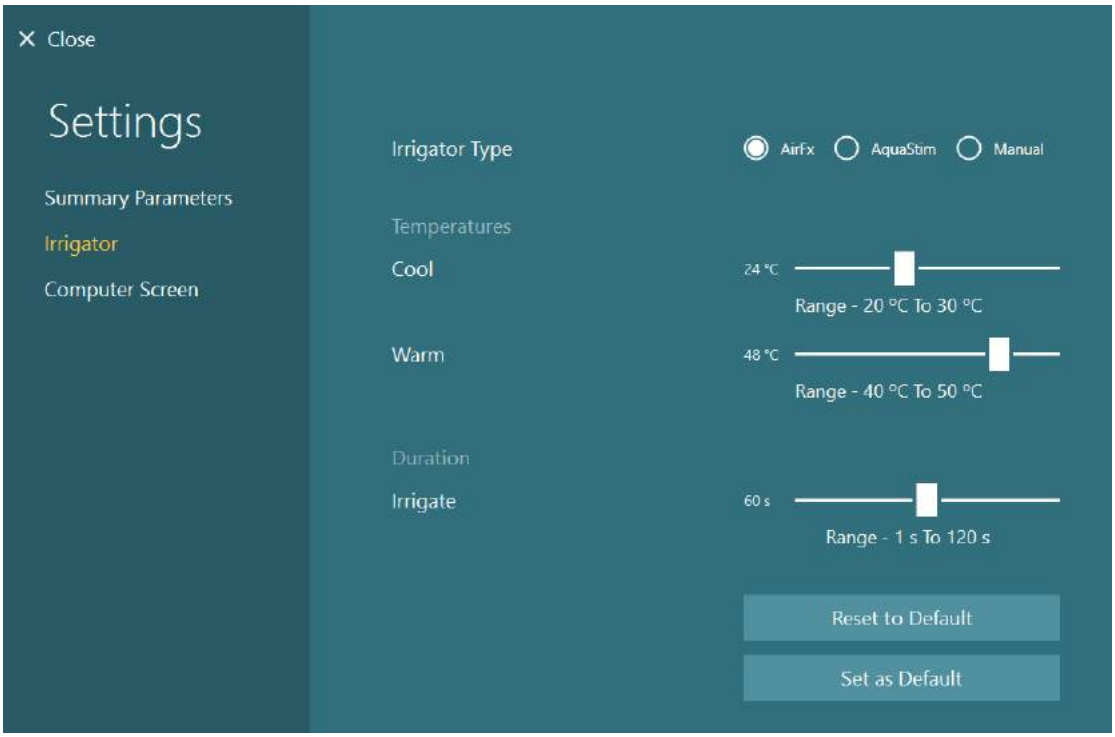


Figure 2.6-14: Irrigator settings for the caloric test

2.6.5 Digital Light Bar (optional)

The Digital Light Bar can be added to the VisualEyes™ 525 system. This can be used as visual stimuli for oculomotor tests. The Digital Light Bar is attached to a tripod that can be adjusted in height, and the direction of the stimuli can be altered between horizontal and vertical by rotating the Digital Light Bar via the hinge connected to the tripod. The Digital Light Bar must be model DLB7.2 or newer in order to be compatible with the system.



Figure 2.6-15: Digital Light Bar

Hardware setup:

1. Attach the Digital Light Bar to the tripod.
2. Connect the USB cable to a USB port on the computer or on the USB hub.
3. Launch the VisualEyes™ software, and navigate to *System Default Settings* > *Stimuli.* Select “Digital Light Bar” in the drop down menu for *Stimulus Type.*

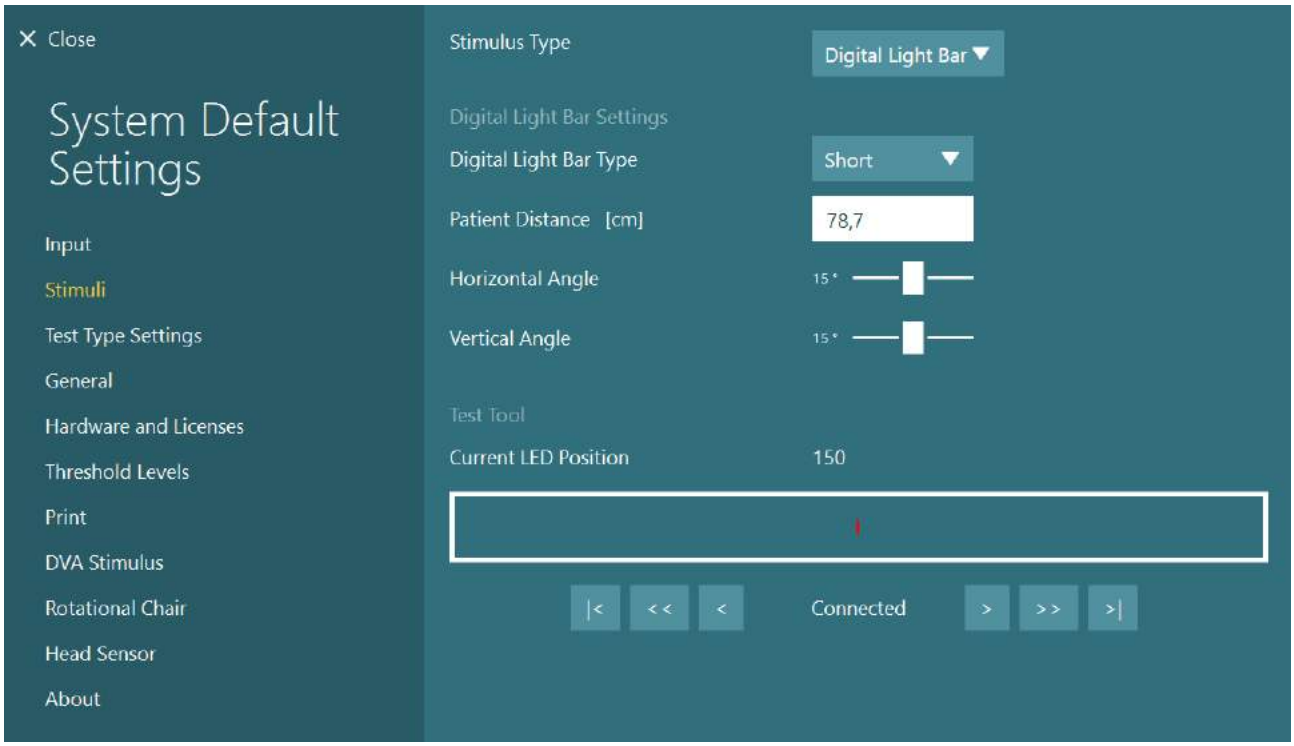


Figure 2.6-16: Configuration of Digital Light Bar in System Default Settings > Stimuli

4. Select the *Digital Light Bar Type* according to the model.
5. Measure and enter the patient distance.
6. Adjust the vertical angles. If you are not able to reach the desired angles, you may need to reduce the patient distance.

2.6.6 VORTEQ™ 2nd eneration IMU (optional)

The VORTEQ™ 2nd Generation IMU is delivered with the VORTEQ™ Assessment and VORTEQ™ Diagnostic modules, and is used to measure the patient's head movement and positioning in space during testing. The VORTEQ™ Assessment module can be added to VisualEyes™ 505, 515, and 525, and the VORTEQ™ Diagnostic module can be added to VisualEyes™ 525.
The VORTEQ™ 2nd Generation IMU can be connected to the computer either by USB cable or wirelessly through Bluetooth with the accompanying Bluetooth receiver dongle.
The IMU can be attached to the VNG goggle by sliding the IMU into the goggle mount. The VORTEQ™ 2nd Generation IMU is not compatible with the front mounted goggle.
VORTEQ™ Assessment also comes with a headband used for *Dynamic Visual Acuity* testing. This has a similar mount for the IMU as the one attached to the VNG goggles.



Figure 2.6-17: VORTEQ™ 2nd Generation IMU being mounted on a side mount goggle (left), and mounted on the headband for Dynamic Visual Acuity (right)

The VORTEQ™ 2nd Generation IMU has four LEDs that describe the status of the device:

- **ON**: Flashes yellow when powered on
- **CHARGING**: Lights blue when the battery is charging through the connected USB cable
- **BLE Broadcasting**: Flashes yellow when bluetooth is broadcasting
- **BLE Connected**: Flashes red when the computer has successfully connected to the device.



Figure 2.6-18: VORTEQ™ 2nd Generation IMU with LEDs turned on

Hardware setup:

1. Connect the USB cable to VORTEQ™ 2nd Generation IMU.
2. Connect the other end of the USB cable to the computer or the USB hub.
3. Power on the IMU by sliding the power switch.
4. Register the VORTEQ™ 2nd Generation IMU as ”VORTEQ™ 2nd Gen” in the the VisualEyes™ software, following the instructions in section 2.8: *Hardware registration and licensing*.
   NOTICE: The VNG goggles must be registered and licensed before the VORTEQ™ 2nd Generation IMU. If prompted for a license when registering the VORTEQ™ 2nd Generation IMU, leave this empty and click ”close”.
5. Go to *System Default Settings* > *Head Sensor*, and ensure the *Head Sensor Type* is set as ”Micromedical VORTEQ™ 2nd Generation IMU”.

   Set the *Connection Type* to ”USB”. If the device is properly connected, the *Board Status* should be green.

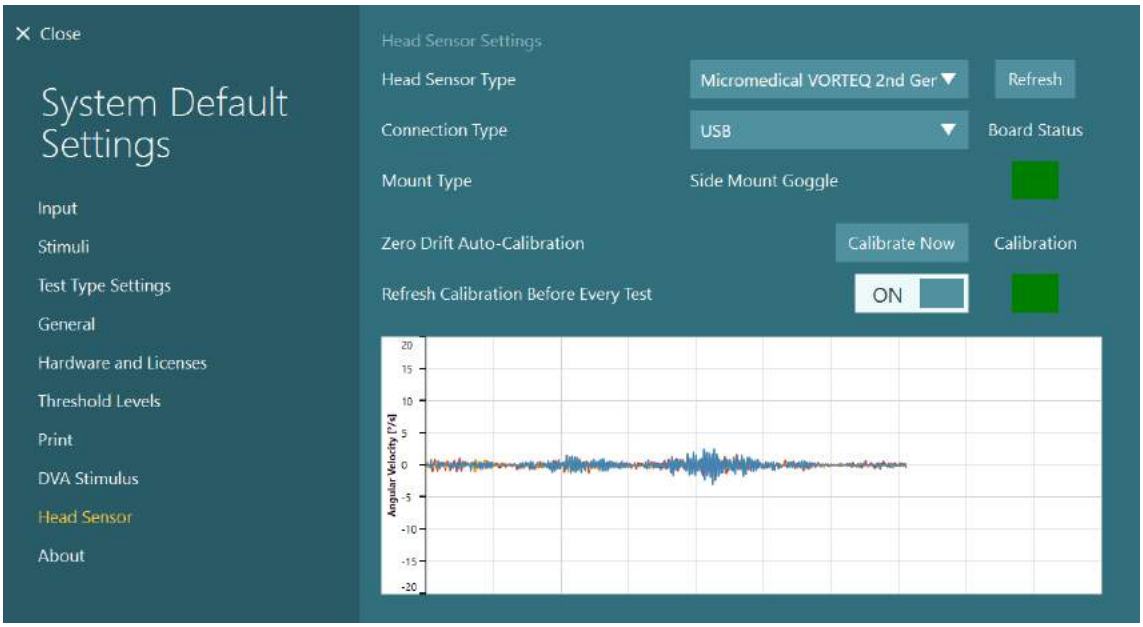


Figure 2.6-19: Configuration of VORTEQ™ 2nd Generation IMU in System Default Settings > Head Sensor

6. If wireless connection is desired, connect the USB dongle to a USB port on the computer or on the USB hub, and select ”Bluetooth” as the *Connection Type*.
7. The sensor can be calibrated by clicking ”Calibrate Now”.
   If the ”Refresh Calibration Before Every Test” is set to ”ON”, the software will calibrate the sensor before every test. This setting is enabled as default.

During installation, Windows Security may request permission to install the device software from Kvaser AB. Check the box to always trust software from 'Kvaser AB', then choose Install.

2.6.7 Rotary chairs (optional)

Several different rotary chairs can be added to the VisualEyes™ system.
The VisualEyes™ software supports below rotary chairs:

- Orion Reclining
- Orion Auto-Traverse
- Orion Comprehensive
- Nydiag 200
- System 2000 Reclining
- System 2000 Auto-Traverse
- System 2000 Comprehensive

For complete instructions for the hardware installation, please refer to the separate installation instructions.

Hardware setup:

1. Follow the instructions in the separate installation instructions for the specific rotary chair to set up and connect the chair correctly.
2. Make sure the rotary chair is powered and connected to the PC.
3. Install the DAQ hardware driver according to the instructions in section 2.7: *Installation of DAQ hardware drivers for Rotary chairs and DataLink.*
4. Perform the rotary chair calibration and validation according to section 2.6.7.4: *Rotary Chair Calibration & Validation.*

2.6.7.1 Reclining rotary chair

VisualEyes™ 515 and VisualEyes™ 525 can be used with the reclining rotary chairs. The system supports the Orion Reclining, Nydiag200, and System 2000 Reclining. The reclining rotary chair allows for sinusoidal harmonic acceleration (SHA) velocity step testing. The reclining rotary chair can also be used as the exam table for positional and caloric testing. The backrest can be reclined to 30˚ from horizontal for caloric irrigations. Positional tests can be performed with the backrest reclined to 0˚ horizontal. For Dix-Hallpike tests, the headrest can be removed on the System 2000 and Orion chairs to allow the clinician to bring the head below the frame. When a top-mounted goggle is used, the velcro straps on the headrest (located on the back of the System 2000 and Orion chairs) can help to stabilize the patient's head by attaching to the goggle strap on the top-mounted MMT goggle.



Figure 2.6-20: Orion Reclining rotary chair in upright position (left), and in reclined position (right)

Reclining chair configuration
The VNG goggles can be connected directly to the reclining rotational chair. FireWire® cards are used with FireWire® side mounted and FireWire® top mounted camera goggles and with the System 2000 Reclining and Nydiag 200 chairs. Connect the power supply connector from the laptop PC Express card to power mains when used with laptops. If the card must be removed later, the computer must be turned off before removing the card. The TV stimulus will connect via a HDMI cable to the back of the computer (which may require an adapter cable). Laptop configurations will use a USB hub to connect to devices which use an external power adapter and connect to the back of the laptop, though the USB cable from the chair will connect directly to the computer (not through the USB hub if present). If a DataLink is connected to the system, it must be connected to a USB port on the externally powered USB hub or directly on the computer.

NOTICE The DataLink cannot be used for rotary chair tests with the reclining chairs.

Please refer to Figure 2.6-21, Figure 2.6-22, and Figure 2.6-23 for pictorial representations of the configurations for the different chair types.

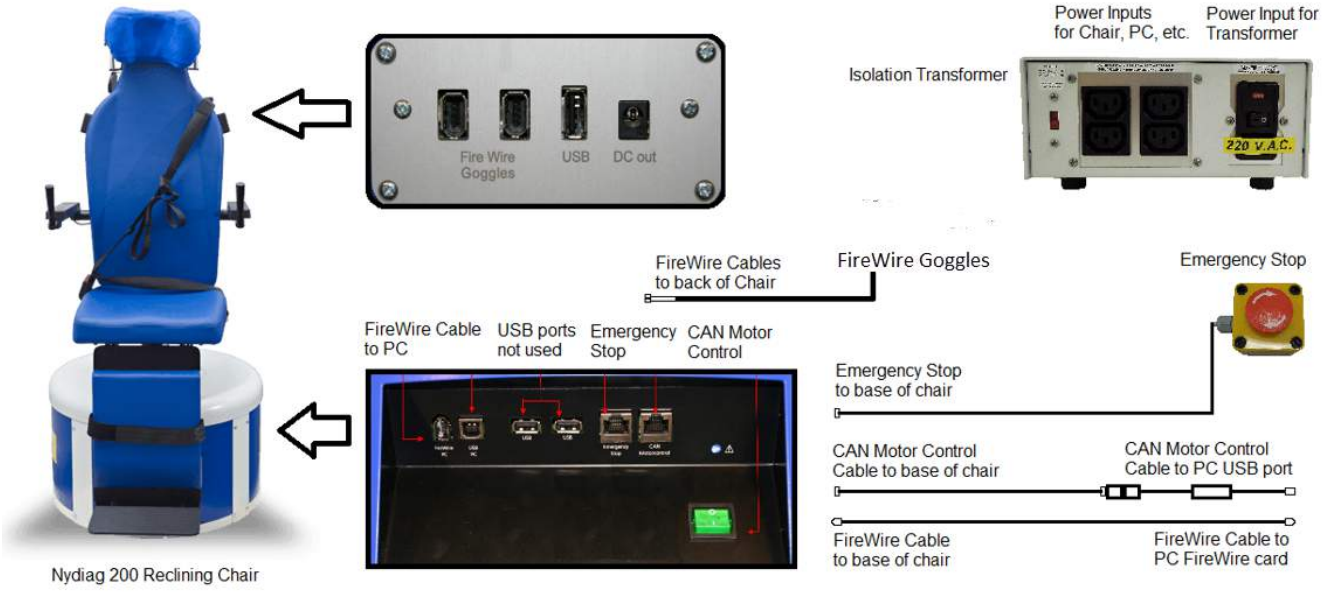


Figure 2.6-21: Configuration of Nydiag 200 Reclining Chair

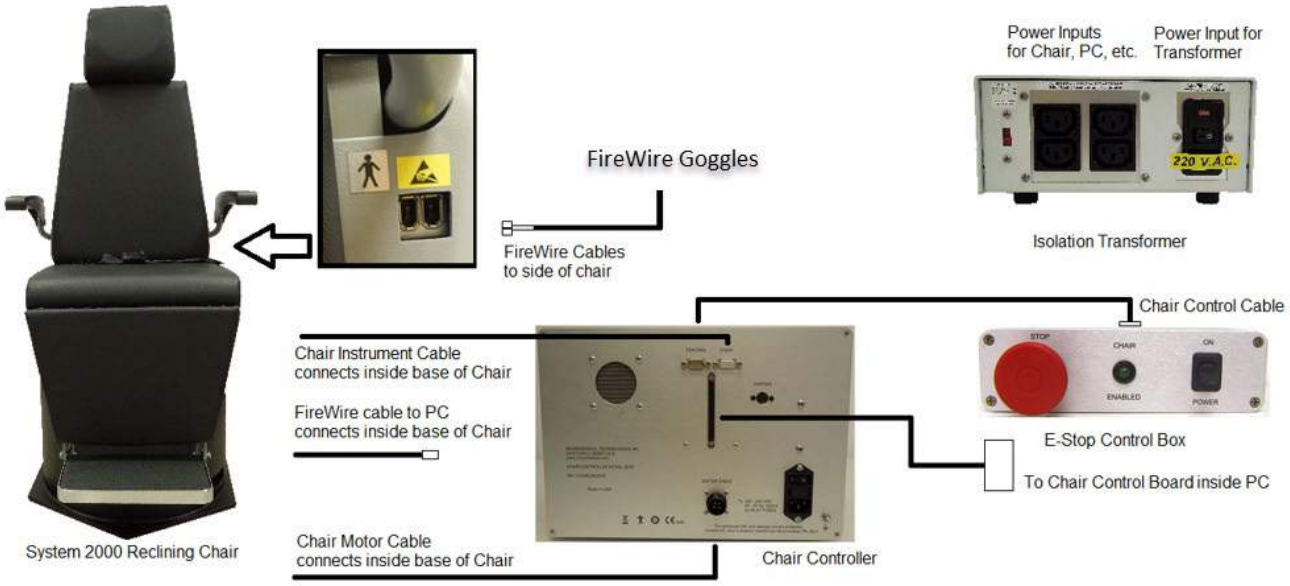


Figure 2.6-22: Configuration of System 2000 Reclining Chair

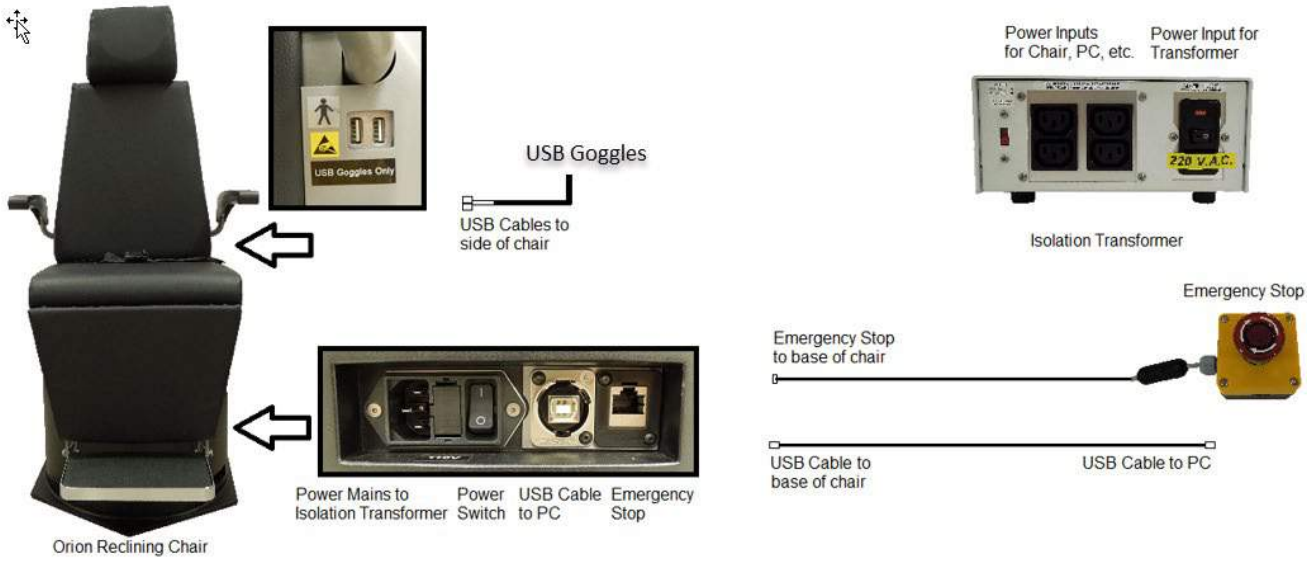


Figure 2.6-23: Configuration of Orion Reclining Chair

2.6.7.2 Auto-Traverse & Comprehensive rotary chairs

The Auto-Traverse & Comprehensive rotary chairs are available with VisualEyes™ 525, Orion Comprehensive Basic, and Orion Auto-Traverse Basic.
The user gets the additional test options of the sinusoidal harmonic acceleration (SHA) test and the step test by combining the system with Orion Auto-Traverse/Comprehensive or System 2000 Auto-Traverse/Comprehensive rotary chairs. The chair is enclosed in a light-tight booth. The laser projector is mounted on top of the chair frame and this is used to project the target stimulus in oculomotor testing, VOR fixation tests, or SVV tests. An optokinetic drum is mounted to the booth ceiling, which provides a full-field stripe stimulus. Auto-Traverse chairs have off-axis lateral movement capability used for subjective visual vertical testing.



Figure 2.6-24: Orion Auto-Traverse/Comprehensive rotary chair

For SVV testing, the patient will use the SVV remote. This will rotate the SVV line by 0.1° counter clockwise (left button) or clockwise (right button). The buttons can be held down as well to rotate the SVV line incrementally until the button is released.



Figure 2.6-25: SVV remote for Orion Auto-Traverse/Comprehensive rotary chair

The observation camera for the Orion Auto-Traverse/Comprehensive chair is placed inside the chair enclosure, and the monitor is placed near the operator. This allows the operator to monitor the patient inside the booth via the observation monitor screen. The video from the observation camera is not recorded or saved in the software.



Figure 2.6-26: Observation camera and monitor screen

Auto-Traverse and Comprehensive chair setup

The Orion Auto-Traverse/Comprehensive and the System 2000 Auto-Traverse/Comprehensive chairs have 3 main components: vestibular booth, rotary chair, and equipment cart. These systems are configured in the same way except for a few variations. The pictorial representations for these two different chair setups are shown below in Figure 2.6-27 (Orion Auto-Traverse/Comprehensive) and Figure 2.6-28 (System 2000 Auto-Traverse/Comprehensive).

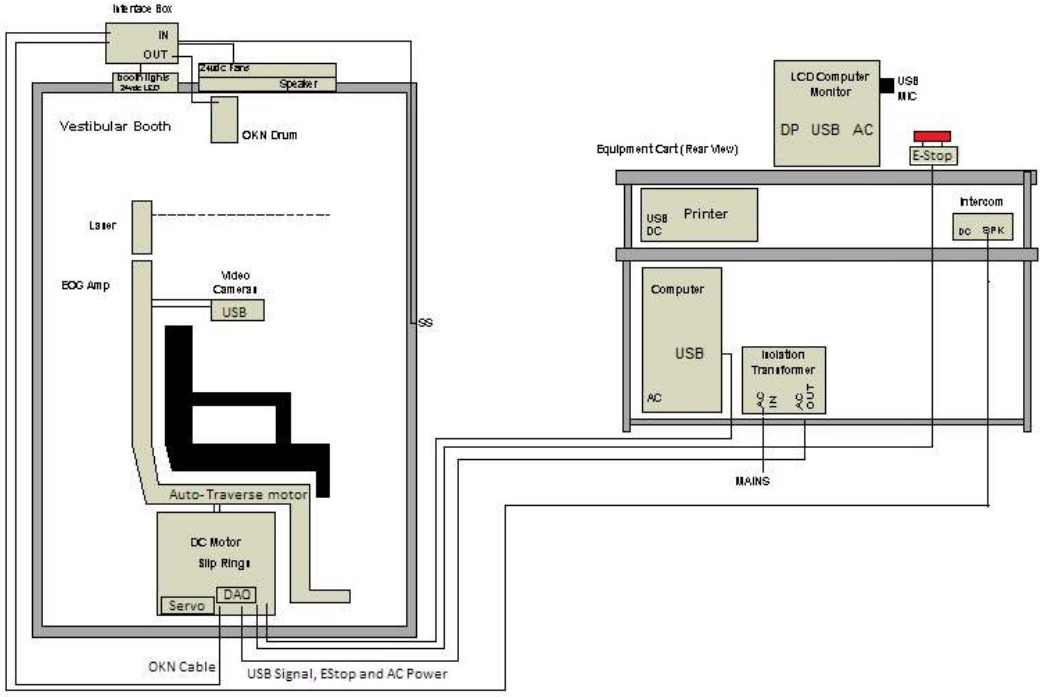


Figure 2.6-27: Configuration of Orion Auto-Traverse/Comprehensive

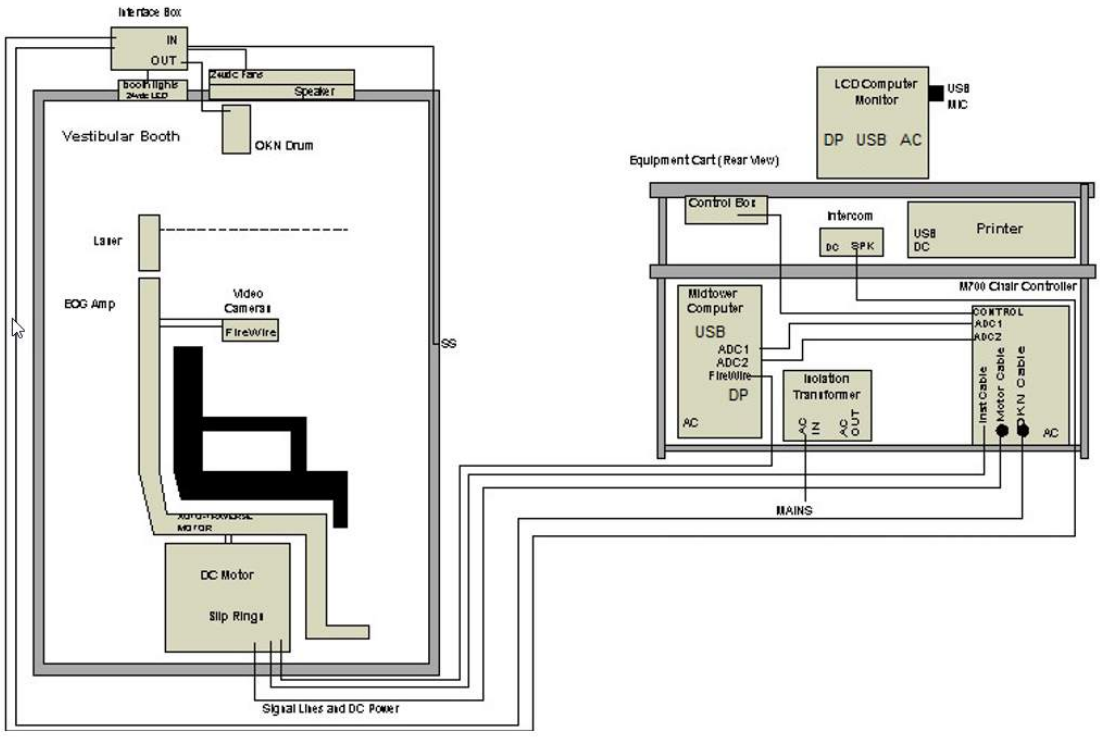


Figure 2.6-28: Configuration of System 2000 Auto-Traverse/Comprehensive

2.6.7.3 Auto-Traverse & Comprehensive rotary chairs optional add-ons

The Auto-Traverse and Comprehensive chairs have two optional add-ons.

Child Option Accessory kit for Orion Comprehensive/Auto-Traverse
The Auto-Traverse/Comprehensive rotational chairs can be configured with a child option accessory kit including an infant car seat and a pediatric observation camera. The pediatric observation camera is mounted to a pole which fits into the bracket at the footrest. The pediatric observation camera will observe the infant in the car seat.
NOTICE the pediatric observation camera offers no eye-tracking in the software. It is strictly for observation and recording of the patient in the chair.

Hardware setup (car seat):

1. Unscrew the head support on the chair to remove it.
2. Slide the hook through the seat belt slot of the safety seat, so that a hook is available on each side of the infant seat.
3. Secure the infant seat and foam on top of the chair seat by attaching the hooks to the eye bolts on the chair frame.
4. The chair's lap belt and shoulder belts may be left disconnected.
5. The patient must be secured using the infant seat's harness.



Figure 2.6-29: Sequential images of infant car seat fitting on Auto-Traverse/Comprehensive Chair (left to right)

Hardware setup (pediatric observation camera):

1. Attach the camera to the pole and attach this to the bracket at the footrest of the rotary chair.
2. Connect the USB cables to the ports on the back of the chair frame.
3. Register the pediatric observation camera as "Pediatric Observation Camera" in the the VisualEyes™ software, following the instructions in section 2.8: *Hardware registration and licensing*.
   NOTICE: The VNG goggles must be registered and licensed before the pediatric observation camera.



Figure 2.6-30: Pediatric observation camera attached to the Orion Auto-Traverse/Comprehensive chair and connected to the USB ports on the back of the chair

EOG Accessory kit for Orion Comprehensive/Auto-Traverse
The Auto-Traverse/Comprehensive rotational chairs can optionally be configured with an electrode amplifier built into the back of the chair frame to test patients with electrode lead wires for ENG evaluations.
This can, unlike the separate DataLink, be used for rotary chair testing. For instructions on electrode montage and impedance testing, please refer to section 3.5.3.

The ENG in Chair option is compatible with below tests, if the VisualEyes™ system has the required licenses:

- Spontaneous Nystagmus
- Gaze
- Smooth Pursuit
- Saccade
- Optokinetic
- Step Rotation
- Sinusoidal Harmonic Acceleration

Hardware setup:

1. Ensure the EOG board is
2. Register the EOG board as ”ENG in Chair” in the the VisualEyes™ software, following the instructions in section 2.8: *Hardware registration and licensing*.
   NOTICE: The VNG goggles must be registered and licensed before registering the ENG in Chair.

2.6.7.4 Rotary chair calibration & validation

After installation of the DAQ hardware driver for the rotary chair, launch OtoAccess® Database and the VisualEyes™ software.
Go to *Configuration>System Default Settings* and select *Rotational Chair* in the left panel.

The user can select the chair type from the drop-down menu. The user can see the Controller board status and can also adjust the zero position of the chair.



Figure 2.6-31: Selection of rotary chair type

As part of installation checks, the operator can validate and calibrate the system. Once the installation is done, the operator must validate the system. By choosing the Validation option under Maintenance Routines, the operator can perform Sine Wave Validation.

Click Go on the Sine Wave Validation screen. The chair should rotate back and forth slowly. Watch the sine wave. There should be two colored sine waves that are superimposed into one curve. If the curves match, there is no need to calibrate.

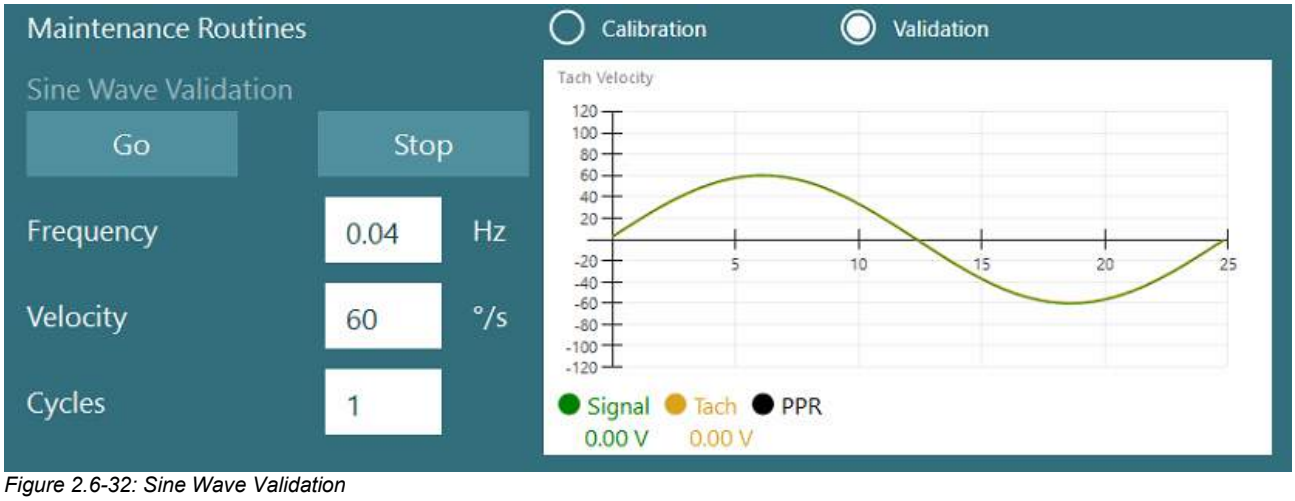


Figure 2.6-32: Sine Wave Validation

If the curves do not match, then switch to the Calibration Maintenance Routines. Click Go under Drift Calibration. The chair should be stopped and not drifting. If the chair is moving slowly, remove the drift using the Drift Offset left / right arrow buttons. Once the chair stops moving, click Stop. Then click Go under Velocity Tach Calibration. The chair will spin clockwise. Two lines will appear and eventually be superimposed. The calibration will stop automatically.



Figure 2.6-33: Drift and Velocity Tach Calibration

2.6.7.5 Additional steps for Auto-Traverse and Comprehensive chairs

For otolith function testing, a 0 to 7 cm micro-centrifuge option is available. The chair seat should be centered laterally on the chair base. If the scale shows the chair is off-center, enter the current chair off-center position under ”Current Lateral Position (cm)”, then select the direction the chair is from center (Left / Right). Click on the Center Laterally button to move the chair to center.

Caution: Do not attempt to move the chair frame laterally by pushing on the chair frame or damage may occur.

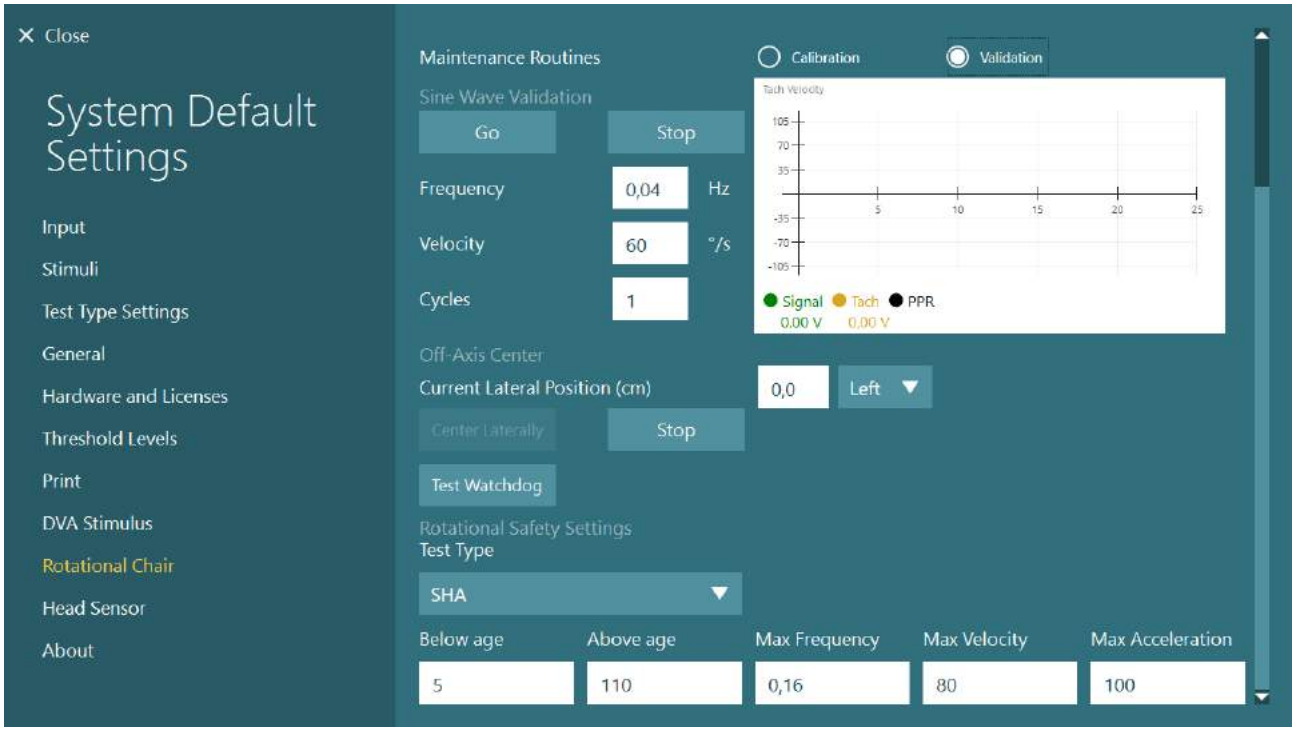


Figure 2.6-34: Additional Off-Axis Center settings for Auto-Traverse and Comprehensive chairs

Laser check

Select the stimulus type as Laser and Drum from the drop-down menu. For *Settings and Calibration*, select ”Laser”.

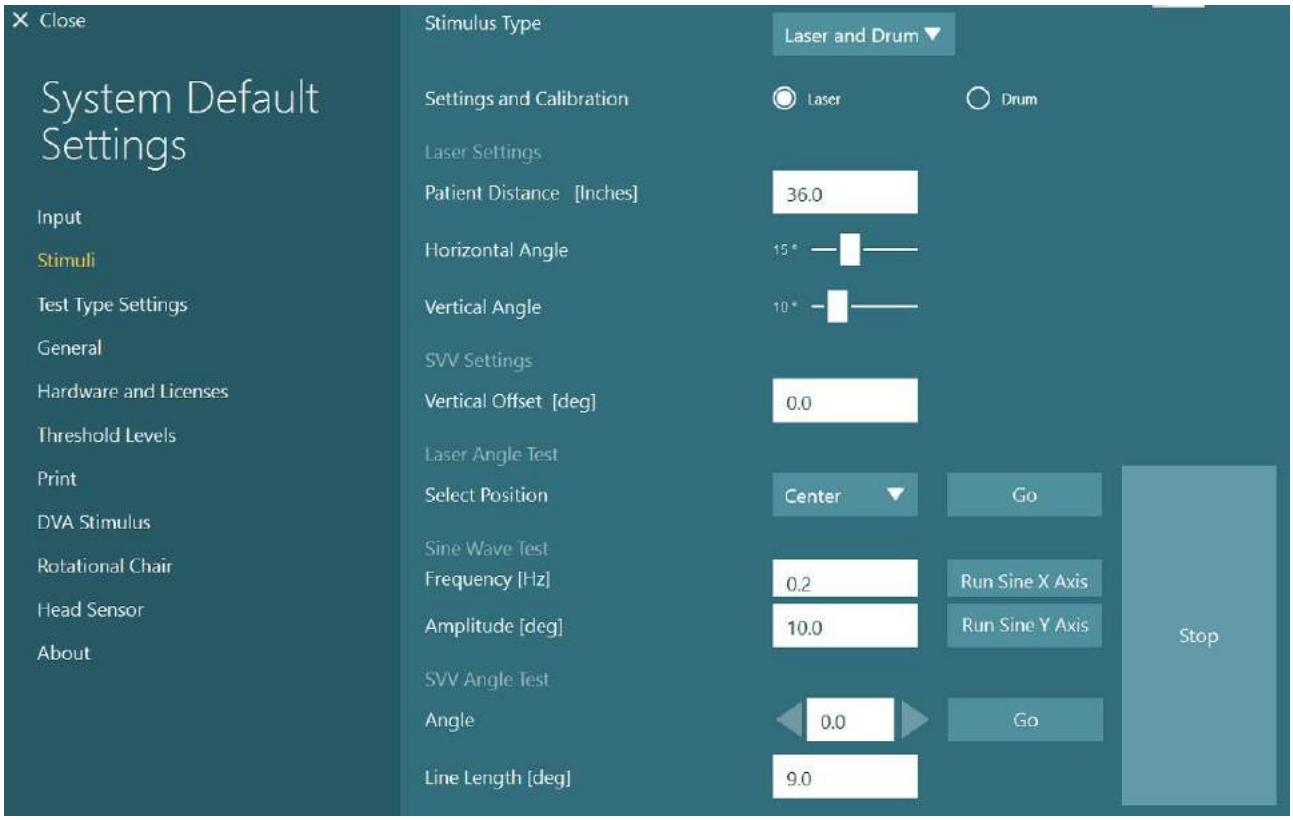


Figure 2.6-35: Laser stimuli settings for the Auto-Traverse/Comprehensive chair

Select the Center position and click ’Go’ under the Laser Angle Test. The laser light should put a red target on the booth wall depending on the position selected (Center, Left 15, Right 15, Left 25, Right 25 etc.). Then perform the Sine Wave Test using ’Run Sine X Axis or Run Sine Y Axis’ and observe that the laser moves in a smooth pattern. Click Stop to stop the Sine Wave Test.

Under SVV Angle Test, click Go to check that the SVV line is rendered. Use the left / right arrow buttons to change the line angle and to confirm smooth movement of the line.

Optokinetic drum check

Select the stimulus type as Laser and Drum from the drop-down menu. For *Settings and Calibration*, select ”Drum”, and select the validation option. Click on ’Go’ for Sine Wave validation. The optokinetic lamp should turn on and stripes will appear on the booth wall. The drum should rotate first one way then the other with a symmetrical sine wave. The drum will stop automatically after completing the number of cycles set in the validation parameters.

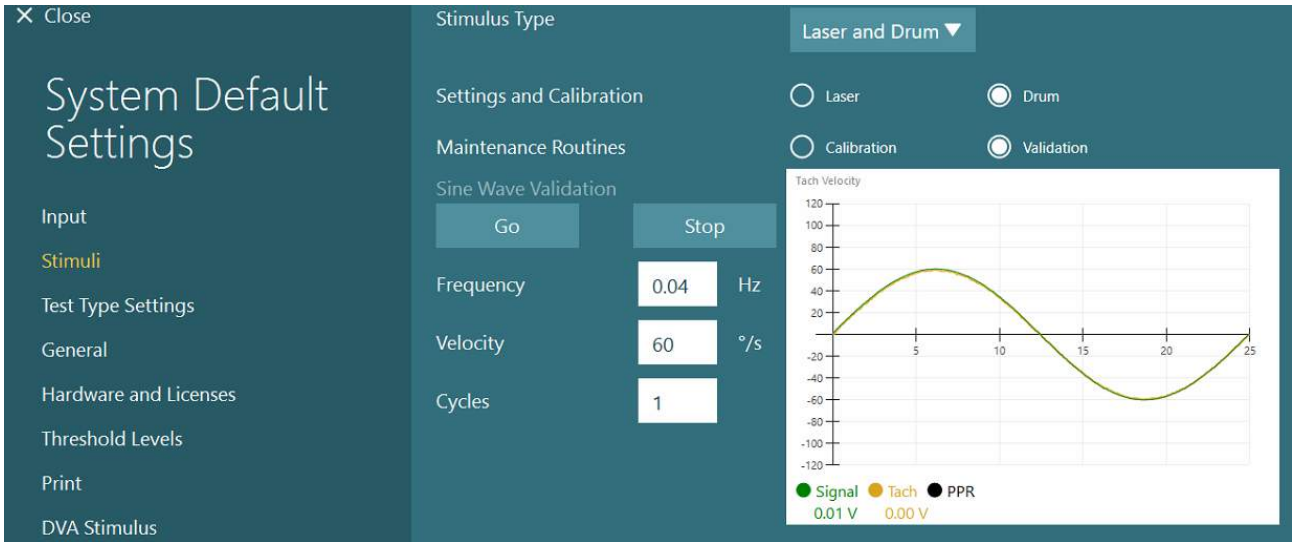


Figure 2.6-36: Drum stimuli settings for the Auto-Traverse/Comprehensive chair

If the sine wave does not show superimposed lines, select the 'Calibration' option. Click the Go button under Drift Calibration and adjust the drift using the left / right arrow buttons to stop any drum movement. Click Stop. Then click on Go button under Velocity Tach calibration. The drum will begin to rotate. Make sure the direction is counter clockwise. Two lines will appear and eventually be superimposed. The calibration will stop automatically.

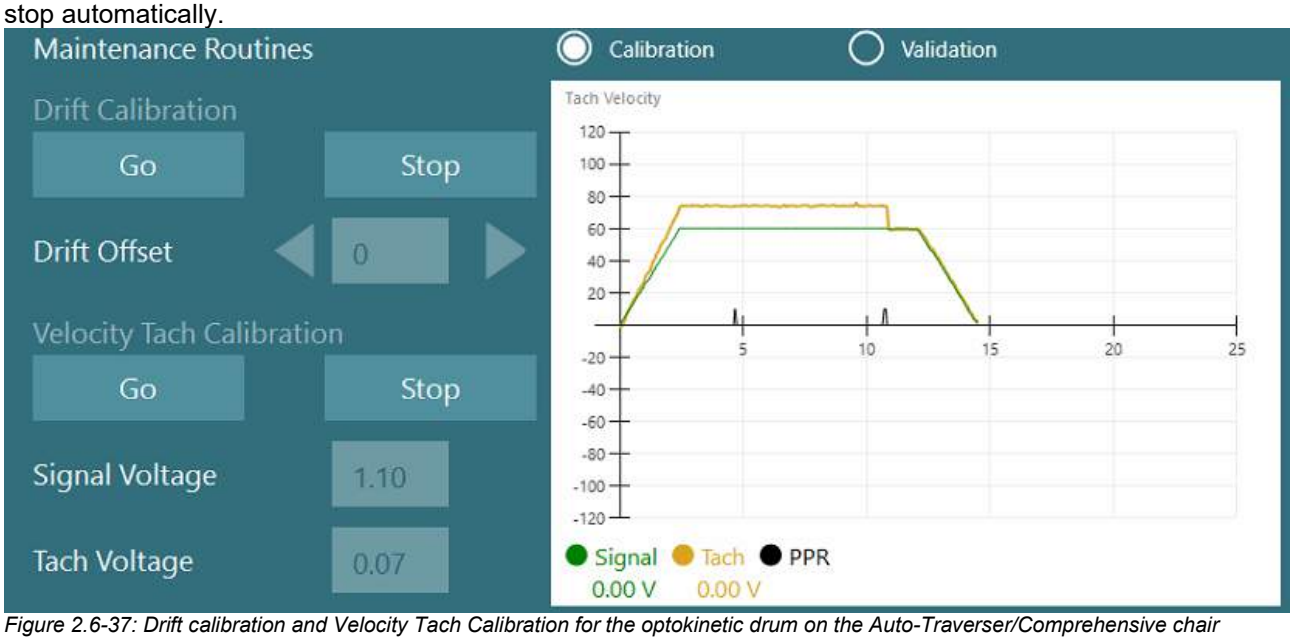


Figure 2.6-37: Drift calibration and Velocity Tach Calibration for the optokinetic drum on the Auto-Traverser/Comprehensive chair

Safety checks

Before beginning the test in the chair system, certain safety tests must be done as described below.

Safety checks for for Orion Auto-Traverse and Orion Comprehensive

- Watchdog safety: Make sure the E-stop has been disengaged. The E-stop will remain off until one enters the VisualEyes™ software and clicks on Begin Testing or goes into *System Default Settings* > *Rotational Chair* and selects "Orion A/C". Exiting VisualEyes™ will turn off the E-stop light after a few seconds. This ensures the Watchdog safety is working.
- Booth door safety: Click Begin testing with the booth door open. You should receive a message alerting that the booth door needs to be closed to continue testing. Close the booth door and go to a rotational chair test. You will get a safety checklist. The list needs to be checked before test can begin.

2.6.8 DataLink (optional)

DataLink can be added to VisualEyes™ 515 and VisualEyes™ 525 through the “EOG Accessory kit for VNG”. This can be used to perform ENG tests for patients who cannot be tested with the VNG goggles. The DataLink measures the eye position via electrode recordings from electrodes attached to the patient. The EOG Patient Cable connectes to the DataLink, and the color coded lead wires connect to the EOG Patient Cable and snap on the electrodes attached to the patient. For instructions on electrode montage and impedance testing, please refer to section 3.5.3.

DataLink is compatible with below tests, if the VisualEyes™ system has the required licenses:
NOTICE the DataLink is not compatible with any rotary chair tests.

- Spontaneous Nystagmus
- Gaze
- Smooth Pursuit
- Saccade
- Optokinetic
- Positional
- Dix Hallpike
- Bithermal Caloric
- Saccadometry

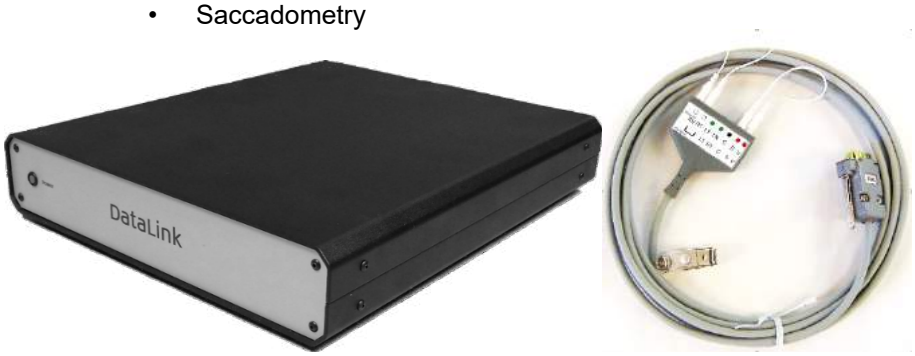


Figure 2.6-38: DataLink and EOG Patient cable

Hardware setup:

1. Connect the 9-Pin connector from the EOG Patient cable to the *EOG* connector on the rear panel of the DataLink.
2. Connect the USB type B connector to the *USB PC* port on the back of the DataLink, and connect the other end to the computer or the USB hub. The green *A/D Status* LED next to the USB port on the DataLink should turn on.
3. Connect the mains cable to the power entry on the back of the DataLink.
4. Power on the DataLink using the power switch on the rear panel. The green *Power* LED on the front panel of the DataLink should turn on.
5. Install the
6. Register the DataLink as ”DataLink” in the VisualEyes™ software, following the instructions in section 2.8: *Hardware registration and licensing*.
   NOTICE: The VNG goggles must be registered and licensed before registering the DataLink.

2.6.8.1 Installing DataLink in combination with Orion Reclining, System 2000 Reclining, or System 2000 Comprehensive

When configuring a DataLink in combination with an Orion Reclining, a System 2000 Reclining, or a System 2000 Comprehensive chair, sometimes the DataLink board (minilab 1008) is detected first and becomes board#0 in Instacal. This can conflict with the communication between the chair and the VisualEyes™ software.

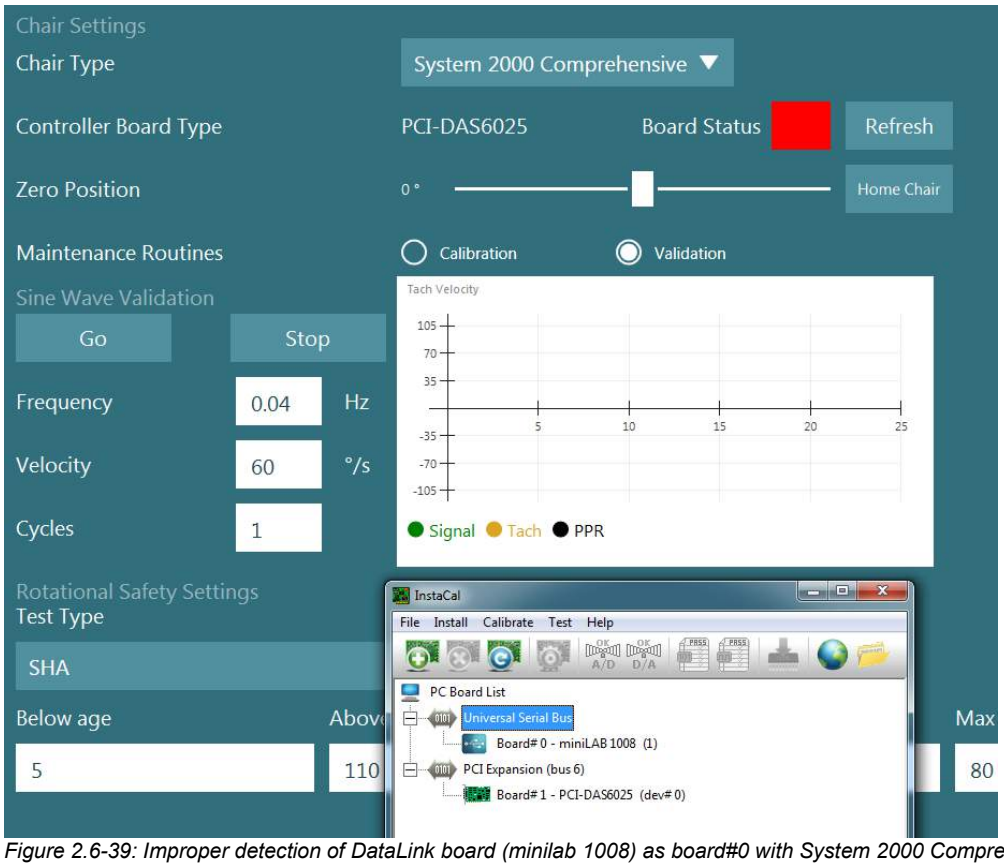


Figure 2.6-39: Improper detection of DataLink board (minilab 1008) as board#0 with System 2000 Comprehensive/Reclining chair

To solve this, change the board number by right clicking on the board in Instacal and click “Change Board#...”
Configure instacal so the DataLink (miniLAB 1008) is Board#1, and the chair (USB-231 / PCI-DAS6025) is Board#0.

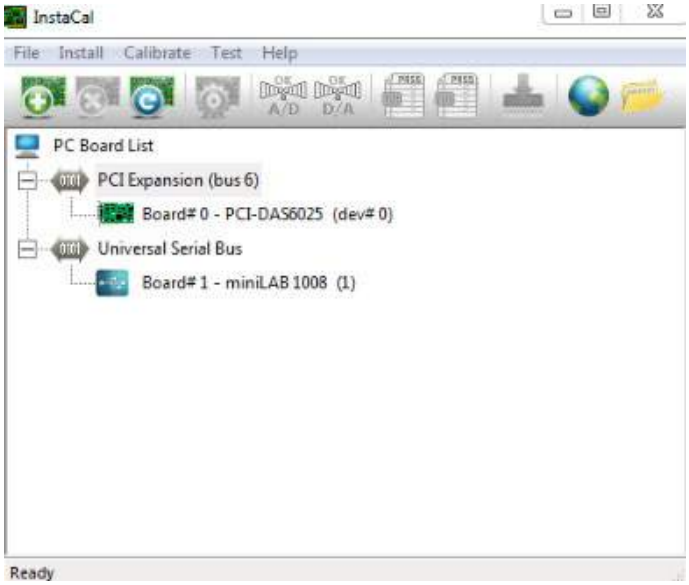


Figure 2.6-40: Correct detection of DataLink board (minilab 1008) with System 2000 Comprehensive/Reclining chair

2.6.9 TRV Chair (optional)

The TRV chair can be added to VisualEyes™ systems with FireWire® connection.
Please see separate instructions regarding installations and usage of the TRV chair.



Figure 2.6-41: TRV Chair

2.7 Installation of DAQ hardware drivers for rotary chairs and DataLink

Rotary chairs and DataLink require additional installations of DAQ hardware drivers for successful data acquisition from the hardware components. Follow below instructions for the relevant drivers:

NOTICE

When upgrading from a previous version of the software the drivers must be updated to the drivers supplied with the new software installation.

Installing DAQ hardware driver for Orion chair, System 2000 chair, and DataLink

Open Windows® Explorer. Navigate to the following location:
C:\Program Files (x86)\Interacoustics\Micromedical VisualEyes™\Driverfiles and run the program **icalsetup.exe**.
Click on Setup to begin installing InstaCal.
Choose to install InstaCal to the default location of C:\Program Files (x86)\Measurement Computing\DAQ\.
When asked which program features should be installed, choose the default option to install the Universal Library Examples.
During installation, Windows Security may request permission to install the device software from Measurement Computing. Check the box to always trust software from 'Measurement Computing', then choose Install. The computer will need to be rebooted after the InstaCal setup is complete.

After the computer has been restarted, launch the InstaCal software. Before launching the Instacal software, ensure that the USB cable from the chair is connected to the system and the rotational chair is powered on. Give a few seconds for all hardware to go through auto-discovery after connecting the USB cable. You can find the software at the below-mentioned locations.
In Windows® 7 / 8.1, click on Start > All Programs > Measurement Computing > InstaCal.
In Windows® 10, click on Start > All apps > Measurement Computing > InstaCal.

When the InstaCal software is launched, the software will detect the hardware as the board type described in Table 2.7-1 (provided the hardware is powered and connected to the PC). Click on the OK button to register the device in the program. In the case of the System 2000 Auto-Traverse chair, click on the Configuration button for each board and change the Board Configuration settings for the Counter 1 Clock Source to be 10 MHz Clock.

Table 2.7-1: Board Type detection in the InstaCal software for the different Hardware Models.

Hardware Model	Board Type	Number of Boards
Orion Reclining	USB-231	1
Orion Comprehensive	USB-231	2
Orion Auto-Traverse	USB-231	2
System 2000 Reclining	PCI-DAS6025	1
System 2000 Comprehensive	PCI-DAS6025	1
System 2000 Auto-Traverse	PCI-DAS6025	2
DataLink	miniLAB-1008	1

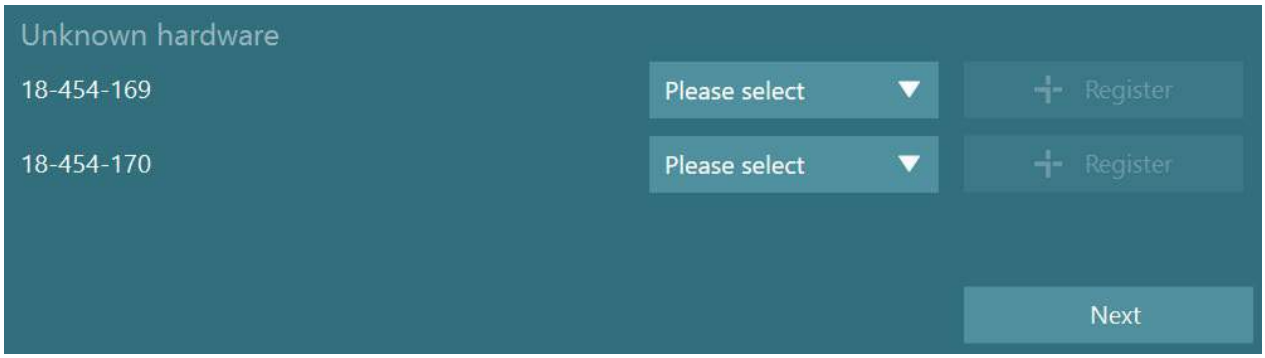
Installation of DAQ hardware driver for Nydiag 200 rotary chair

Ensure that the CAN motor control cable from the Nydiag 200 chair is connected to the computer's USB port.
Open Windows® Explorer. Navigate to the following location:
C:\Program Files (x86)\Interacoustics\Micromedical VisualEyes™\Driverfiles and run the program **kvaser_drivers_setup.exe**.
When asked which components should be installed, choose the default selections for installing the drivers (32/64-bit x86), Start Menu Shortcuts, and GUI tools.
When asked for the destination folder for installing the drivers, choose the default location of C:\Program Files\Kvaser\Drivers.

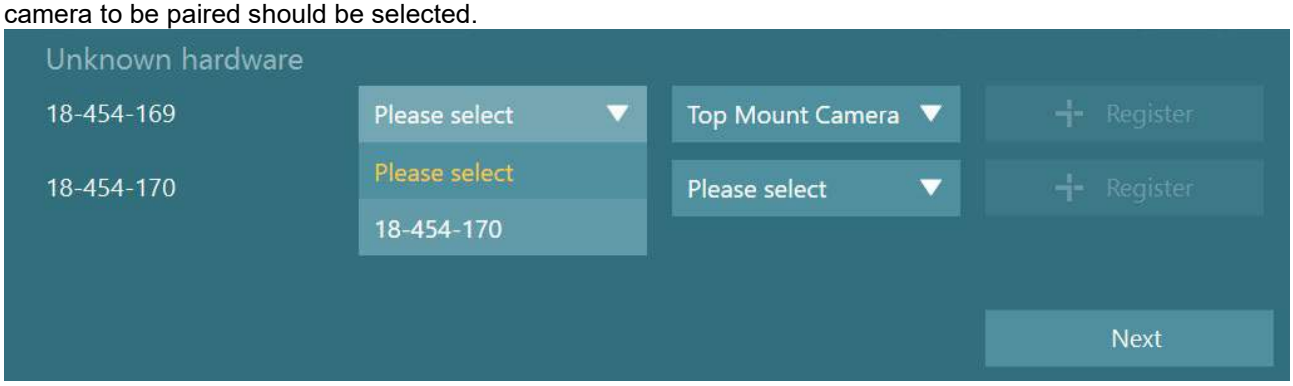
2.8 Hardware registration and licensing

When new hardware is connected to the VisualEyes™ system, this needs to be registered in the software to be recognized correctly. The VNG and vHIT goggles also need to be licensed in the system.

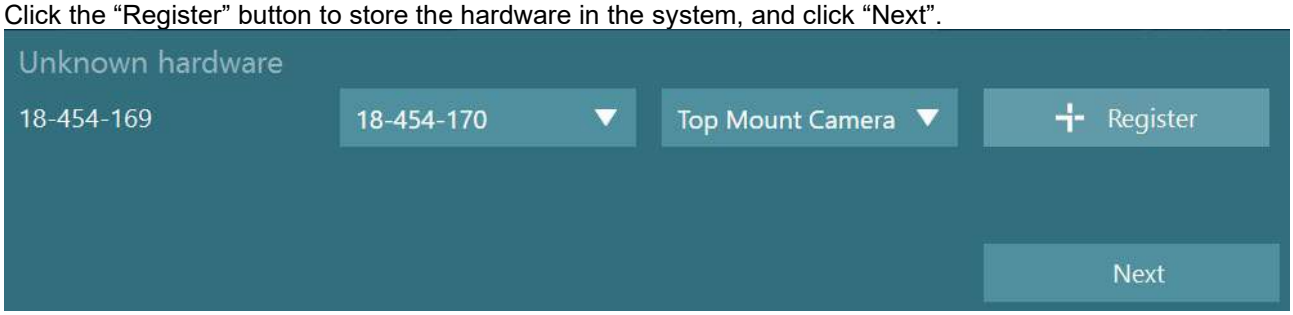
When launching the VisualEyes™ software with new hardware connected, the software automatically detects the new hardware and below pop up will appear in the software. This presents the unique hardware numbers for the specific hardware connected. The user must specify the type of hardware connected in the drop-down selection menu. It's important that the VNG goggle is registered and licensed before the rest of the hardware.



If the selected hardware is a binocular goggle, another drop-down menu will appear to the left, where the camera to be paired should be selected.

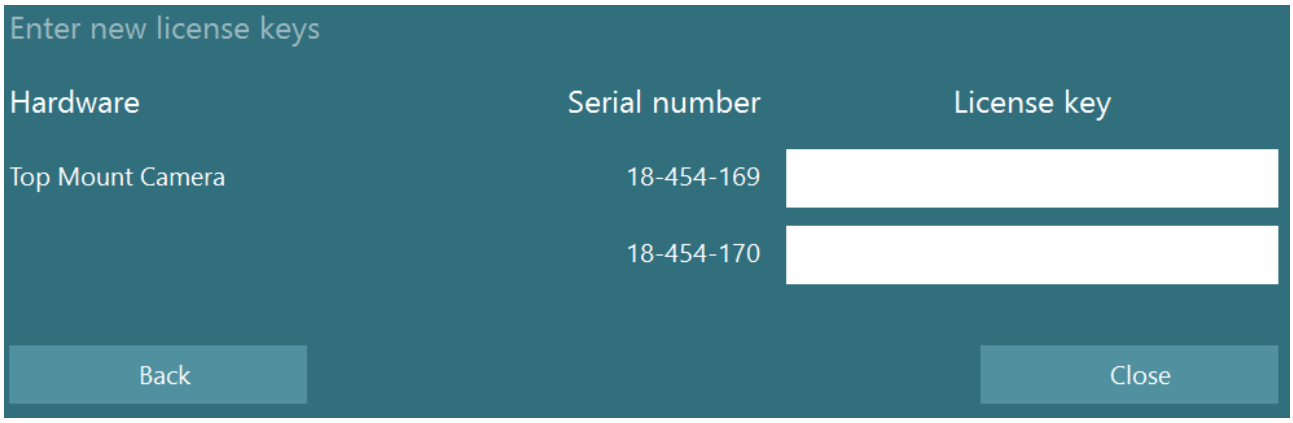


Click the "Register" button to store the hardware in the system, and click "Next".

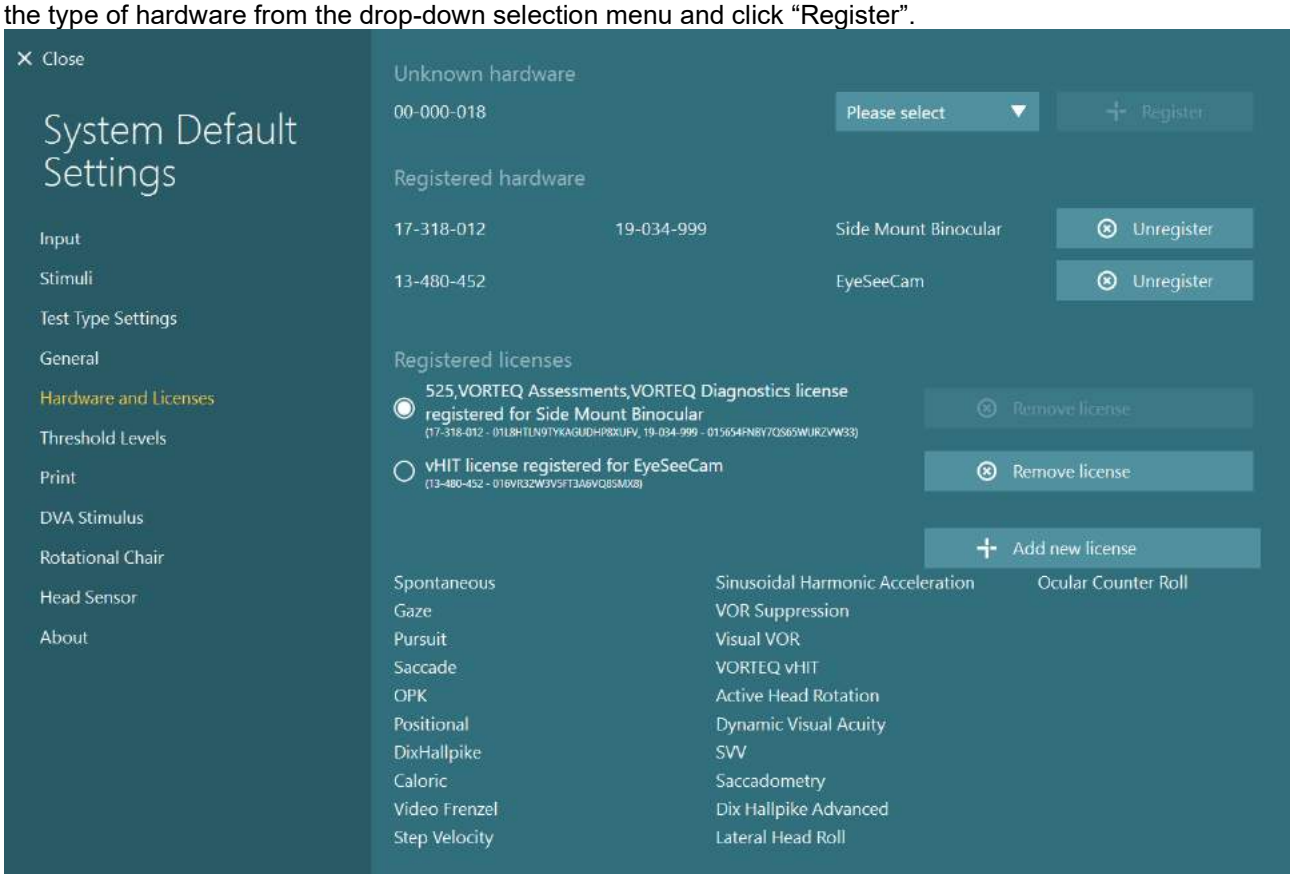


A new window for entering license keys will appear. Enter the license delivered with the system for the newly registered hardware.

NOTICE Only the main VNG goggle and the EyeSeeCam goggle should hold licenses. These are the licenses that are delivered with the VisualEyes™ system. For all other types of hardware (ENG in Chair / DataLink / Pediatric Observation Camera / VORTEQ 2nd gen), the user should simply leave the license entry empty, and click "Close". The hardware will then function using the same license as entered for the VNG goggle.



After the registration and licensing of the VNG goggle, any additional hardware can be registered.
This can be done by restarting the software with the new additional hardware connected, which will result in the pop-up window stating that there is unknown hardware and it can then be registered following the steps described in the procedure above.
Alternatively, the user can connect the new hardware and navigate to *System Default Settings* > *Hardware and Licenses*. This presents an overview of all registered hardware along with the registered licenses. If there is any unknown hardware this will be presented in the top of the screen as well. The user can select the type of hardware from the drop-down selection menu and click “Register”.



2.9 Display configuration

VisualEyes™ requires precise TV/projector configuration to present the visual stimuli properly, and to calibrate the eye tracking to the correct angles. When using a display for presentation of visual stimuli, it is therefore important to ensure that this is configured correctly according to the following instructions.

2.9.1 TV considerations

It's important that the screen dimensions are large enough for the software to present the visual stimuli at the desired angles.

If the connection distance exceeds 7.5m to hide the cable behind the wall or go through the ceiling, a powered HDMI extension hub/cable must be used. Wireless HDMI connections are not supported.

When setting up the TV, this should be set to "Computer" or "Game" mode to correct for HDMI scaling and digital image processing potentially delaying the presented stimuli signal.

It is recommended to use a Full HD (1080p) TV.

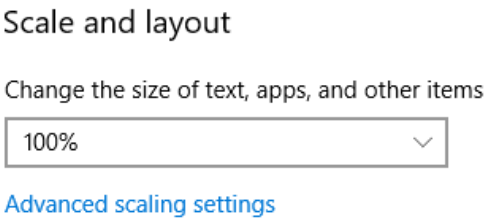
2.9.2 Windows display settings

The display must be set correctly up in the windows display settings under *Windows Settings* > *System* > *Display*:

- The displays must be set up as extended displays, and the computer monitor must be selected as the main display. The TV/projector cannot be selected as the main display.



- The scale must be set at 100% for the TV/projector.

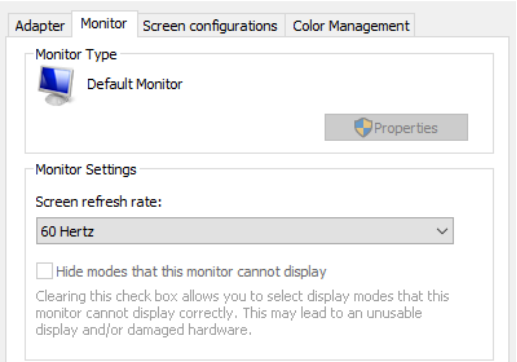


- The resolution should be set to 1920 x 1080.
  When using a UHD 4K TV, the resolution must be set to 1920 x 1080 with a refresh rate of 60 Hz.

  To set the refresh rate to 60 Hz, go to *Advanced display settings,* select the display, and click *"Display adapter properties for Display X"*.



Then select the “Monitor” tab in the top of the window, and select “60 Hertz” in the drop down selection under *Screen refresh rate*.



2.9.3 VisualEyes™ software settings

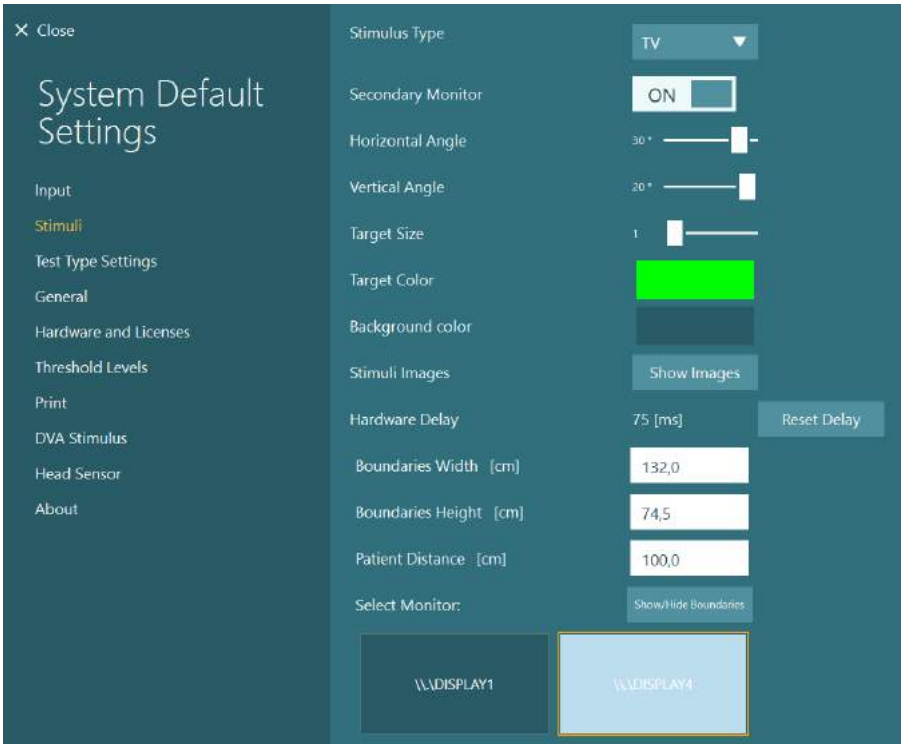
When the TV and Windows settings are configured correctly, launch the VisualEyes™ software, and configure the displays in the software using the following instructions.

NOTICE: Even if *“Migrate any existing VisualEyes™ system settings”* was checked during installation, it is highly recommended to remeasure the display size. Different versions of VisualEyes™ have used different measurement methods. It is therefore important to validate the dimensions of the display.

2.9.3.1 Stimuli

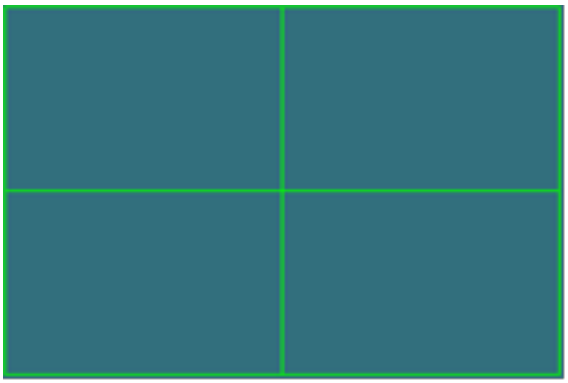
Navigate to *System Default Settings* and select “Stimuli” in the panel on the left side of the screen.

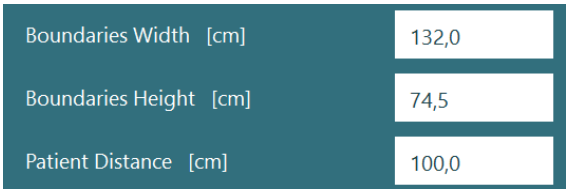
- Select TV as Stimulus type if using a TV or projector.
- Ensure that *Secondary Monitor* is set to “ON”.
- Select the TV/monitor for the visual stimuli to be presented on, in the bottom of the page.
  The monitors are sized relative to their respective pixel resolutions.
- Click on *Show/Hide Boundaries* to display gridlines on the selected monitor.



- Measure and enter the width and height of the horizontal and vertical gridlines

- Measure and enter the distance from the screen to the patient.





NOTICE:
The specified units to be entered in the software are determined by the Windows Regional format, and can be either cm or inches.

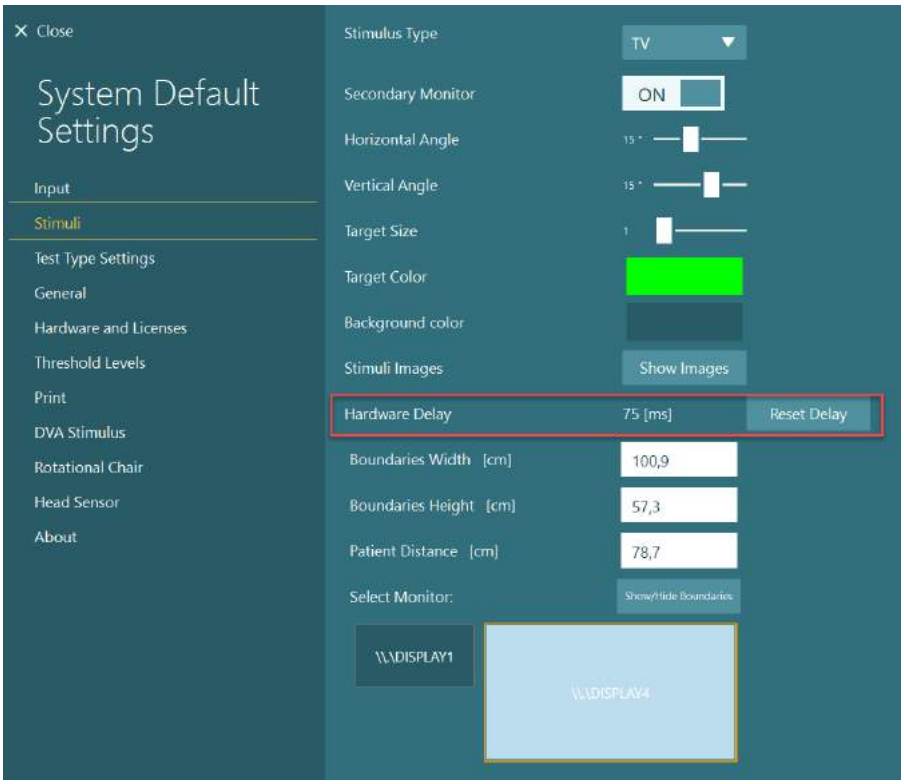
- Adjust the horizontal and vertical angles, using the sliders, determining the maximum angle that can be used for the visual stimuili.



2.9.3.2 Hardware delay

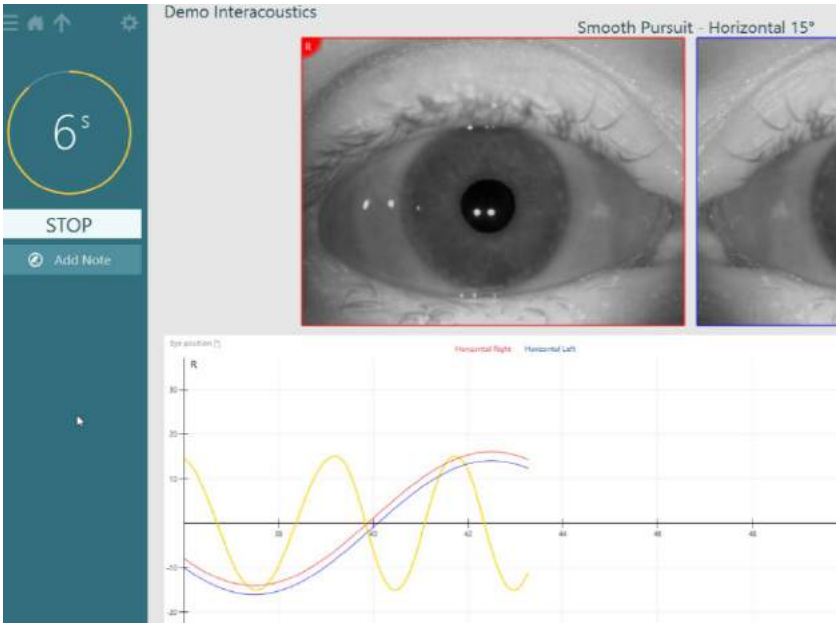
In order to compensate for any potential delay for the presentation of the visual stimuli on the connected screen, the hardware delay can be adjusted from the software. If this is not adjusted correctly for the connected stimuli monitor, this may lead to abnormal latency values for oculomotor tests. It is therefore recommended to adjust the hardware delay for any installation using visual stimuli, and should be readjusted if the monitor for visual stimuli is later replaced.

The value currently set for the hardware delay can be found under *System Default Settings > Stimuli*.
Clicking *"Reset Delay"*, will set the hardware delay to 0 ms.



To adjust the hardware delay for the connected monitor for visual stimuli, the below instructions should be followed:

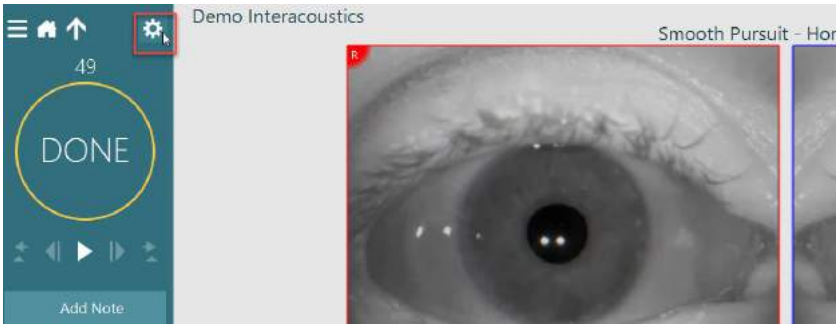
1. Perform a "Smooth Pursuit" test on a person known to have a normal response.



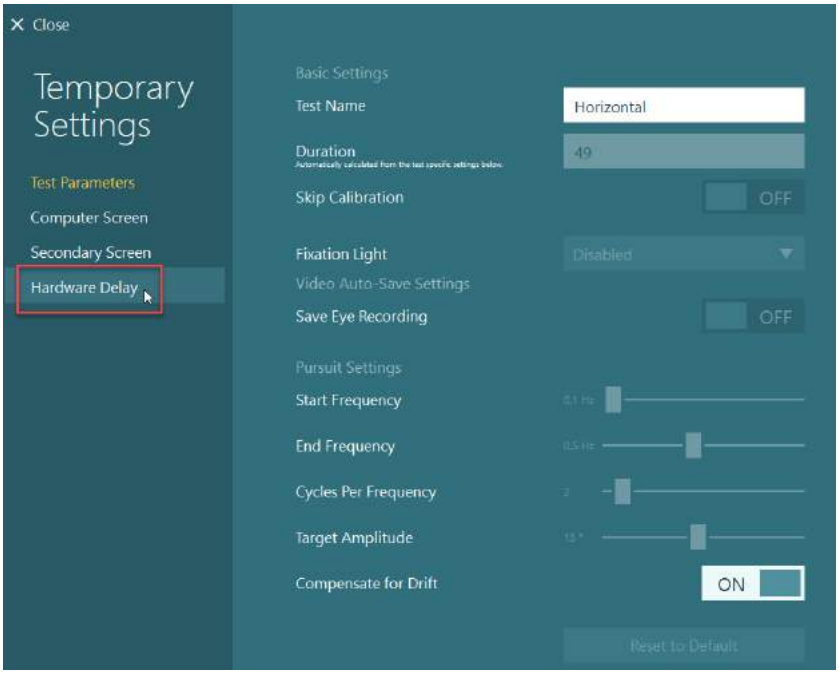
2. After completion of the test, click on the subtest.



3. Go to *Temporary Setup.*



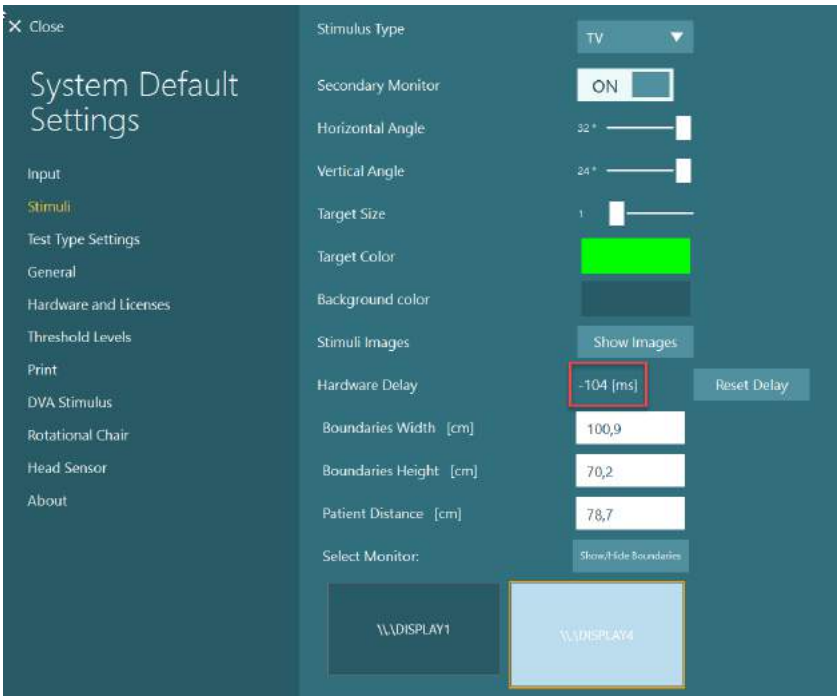
4. From *Temporary Settings*, click on *Hardware Delay* in the left panel.



5. The suggested adjustment for the hardware delay will be presented as *Current Delay*. Clicking on "*Adjust Hardware Delay*" will adjust the hardware delay value accordingly.



6. After clicking *“Adjust Hardware Delay”,* the adjusted value will be visible in *System Default Settings > Stimuli.*



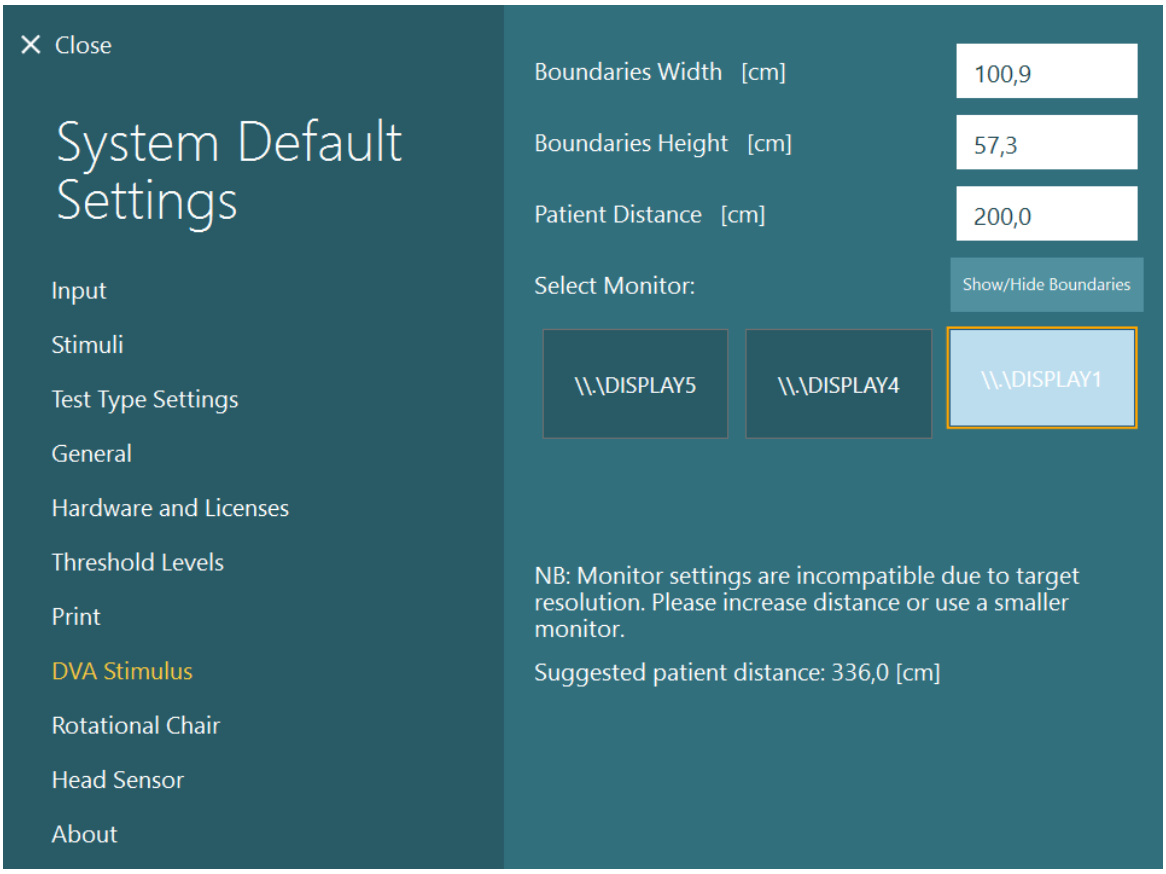
7. In order to validate the new value for the hardware delay, perform another “Smooth Pursuit” test on a person known to have a normal response.

   The suggested adjustment, should then be close to 0 ms.



2.9.3.3 DVA stimulus

If VORTEQ™ Assessment is added to the software, the stimulus must be configured under *System Default Settings > DVA Stimulus*. The DVA Stimulus settings screen provides the separate screen measurements for the stimulus used for the DVA tests. If the TV screen is too large for DVA testing, then the computer monitor can be selected for the DVA test stimulus. Select the monitor to be used for DVA testing, then confirm the measurements for the display (as this can be the primary laptop / desktop screen, the boundaries must be entered for the display selected). If the Patient Distance value is not adequate for displaying on the display selected, the optotype will be drawn as much as possible, but may not be discernable at the lowest logMAR values.



2.10 Language settings

The language in the software can be set up by navigating to *System Default Settings* > *General*, and selecting the appropriate language in the drop-down selection menu (see Figure 2.6-1). The software will have to be restarted when the program language is changed.
The languages available in the software are below:

- English (United States)
- French (France)
- German (Germany)
- Greek (Greece)
- Italian (Italy)
- Japanese (Japan)
- Korean (Korea)
- Polish (Poland)
- Portugese (Brazil)
- Russian (Russia)
- Slovene (Slovenia)
- Spanish (Spain)
- Swedish (Sweden)
- Turkish (Turkey)

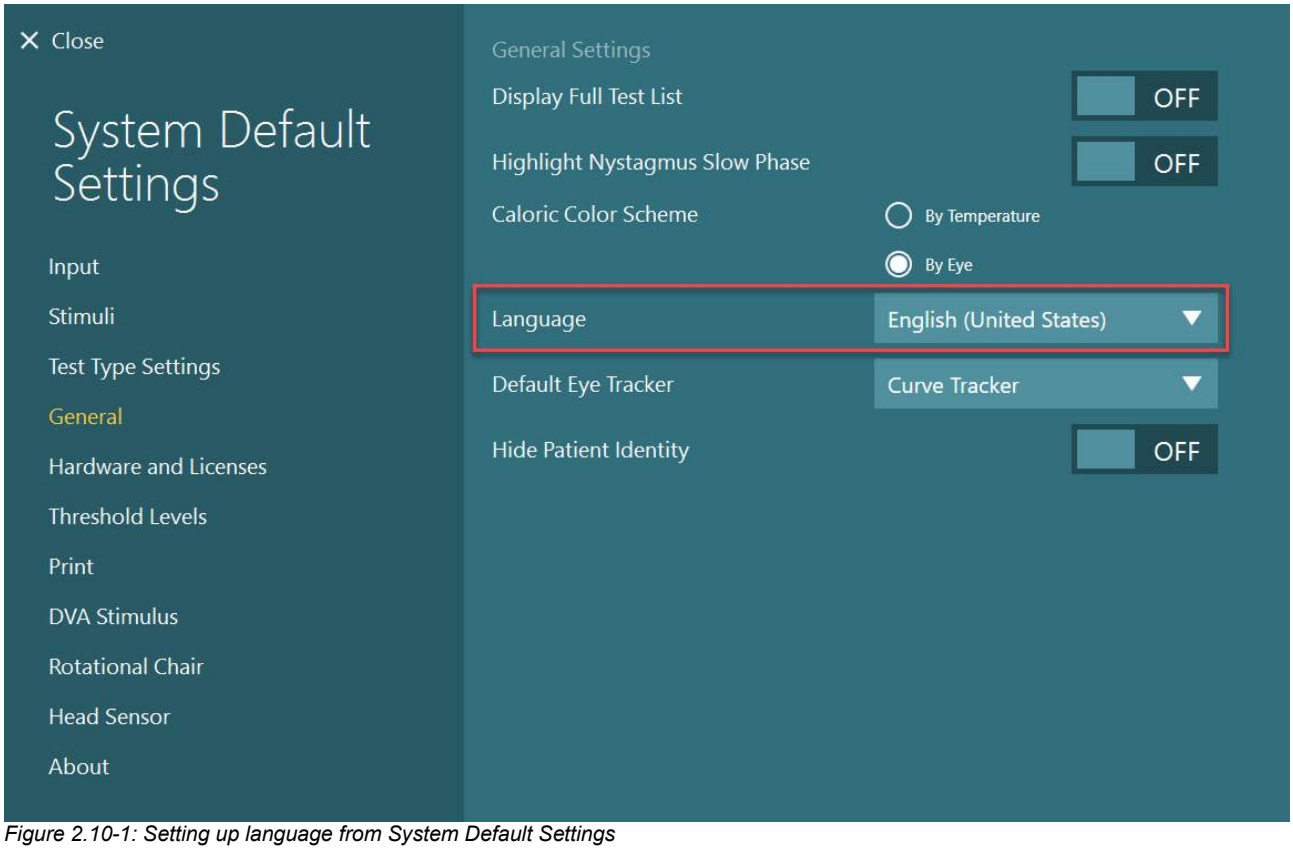


Figure 2.10-1: Setting up language from System Default Settings

2.11 Data and video storage

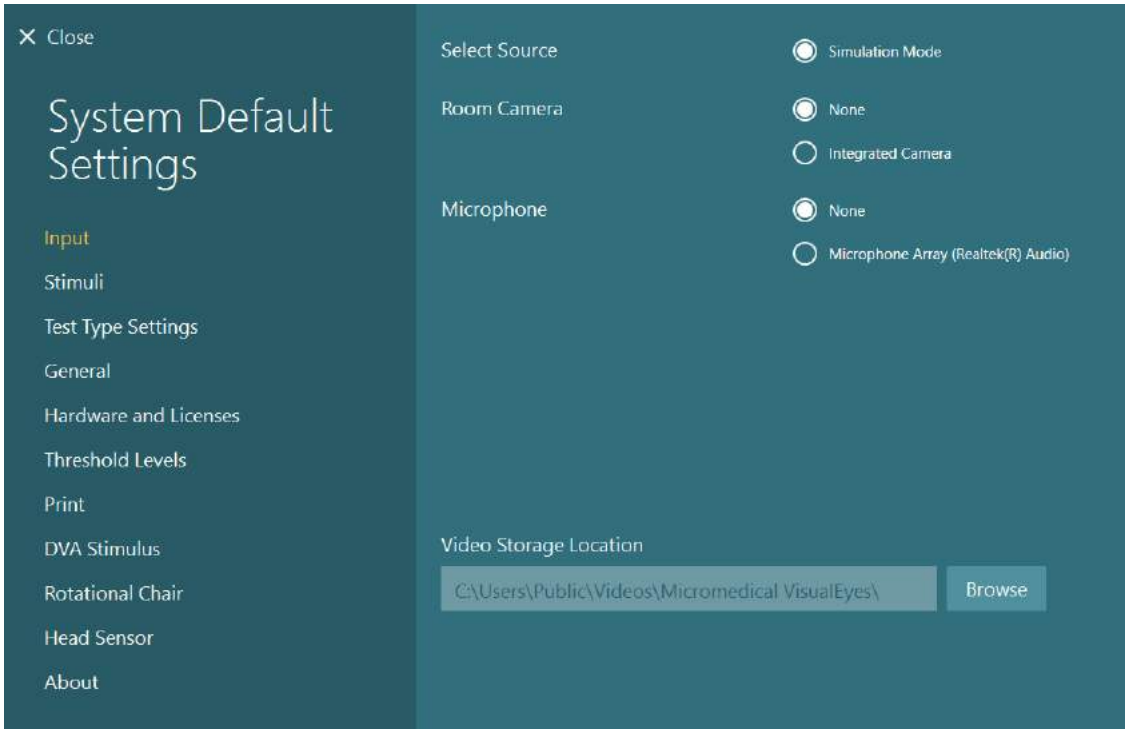
2.11.1 Session data

VisualEyes™ can store session data through OtoAccess® Database. The session data will be stored automatically when VisualEyes™ is opened through OtoAccess® Database, and the session data will be stored on the patient selected in the database.

2.11.2 Video recordings

VisualEyes™ can record videos from the VNG or vHIT goggles, as well as the video from the external room camera. These video files will be linked to the specific patient and sessions, but are not stored in the OtoAccess® Database. The video storage location can be specified in *System Default Settings* under Input. Click *Browse*, and navigate to the desired folder.
The default location is *C:\Users\Public\Videos\Micromedical VisualEyes*.

NOTICE: **Ensure that the specified path for video storage is accessible for all installations if the system is installed in a server/client configuration.**



2.11.3 Session reports



Print to Database
OtoAccess® Database can store session reports in pdf for fast and easy access without the need to launch the VisualEyes™ software for session reviews. To use this function, the operator must click “Print to Database” in the *Session Review* after each completed session.

Create PDF
It is also possible to enable PDF printing directly from VisualEyes™ for archiving PDF prints outside of OtoAccess® Database.
This is possible from *System Default Settings* > *Print* under *PDF Configuration*. From here set “Save PDF Document” to *ON*, and specify the storage location for the PDF reports, by blicking “Browse”, and selecting the desired folder. The PDF filename can be customized by selecting the fields the operator wants included in the filename from the *Field Selections* drop-down selection menu. The fields will be separated in the PDF filename by the specified *Field Delimiter*.

NOTICE: **Ensure that the specified data location is accessible for all installations if the system is installed in a server/client configuration.**

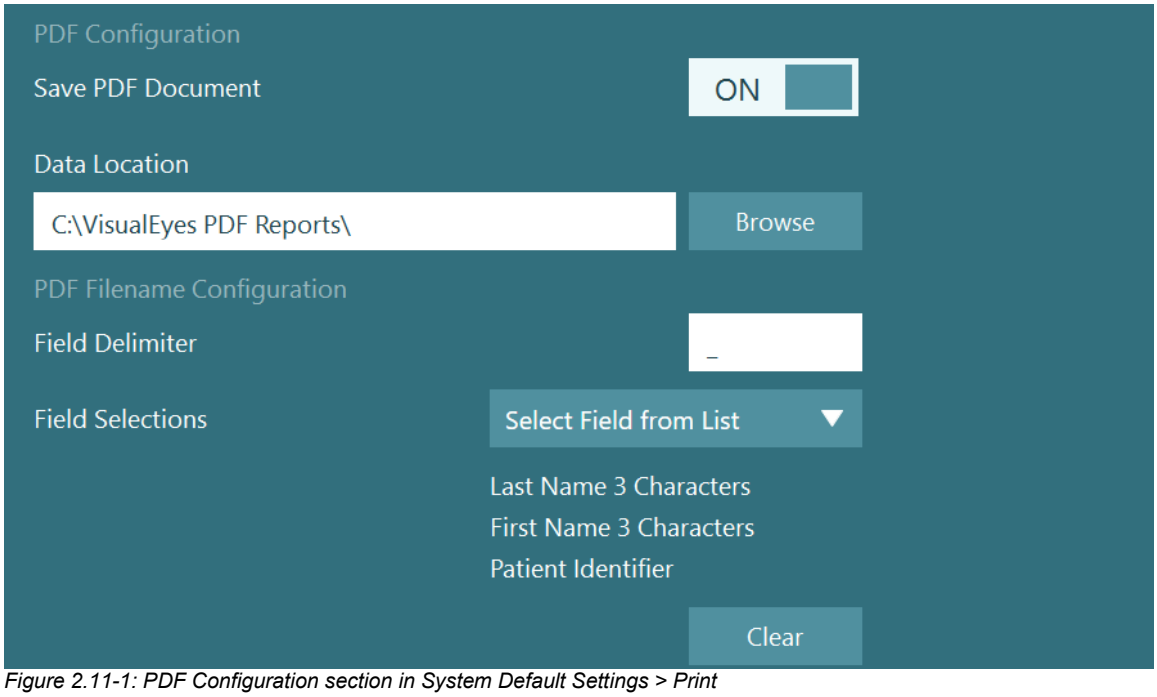
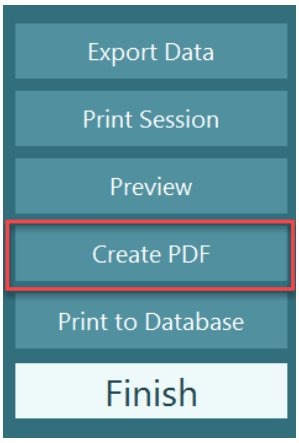


Figure 2.11-1: PDF Configuration section in System Default Settings > Print

After following above instructions, a new “Create PDF” button will appear in the *Session Review* after a completed session. Clicking *Create PDF* will generate a PDF report in the selected data location, with the configured PDF filename.



3 Operating instructions

3.1 System startup

When starting the VisualEyes™ system, below instructions should be followed:

1. Turn on power sources:
   Ensure that the PC systems and USB hub are power connected. If any components are connected through an isolation transformer, this must be turned on using the power switch.

2. Turn on accessories:
   - VNG/vHIT goggles:
     Ensure that the goggles are connected to the USB hub or rotational chair.

   - Rotary chair (optional):
     Ensure that the rotational chair is connected to power and is switched on using the power switch. The power switch is located at the base of the rotational chair for the Orion and Nydiag200 rotary chairs and at the back of the chair controller for System 2000 chairs.
     - Ensure the emergency stop button is disengaged (turn clockwise to disengage the button).

   - DataLink (optional):
     Ensure that the DataLink is connected to power and connected to the computer through the USB connection. Power on the device using the power switch on the back.

   - Caloric irrigators (optional):
     Ensure that the AirFx or AquaStim is connected to power and connected to the computer through the USB connection (please refer to user manual of irrigators for detailed instruction for operation).

   - VORTEQ™ 2nd Generation IMU:
     Ensure that the device is powered and connected to the computer either via USB or bluetooth.

   - Digital Light Bar (optional):
     Ensure the device is connected to the computer via the USB connection.

3. Turn on stimulus before the computer:
   Switch on the TV or projector using its power button. Then, turn on the computer and ensure that the TV/projector stimulus is configured as an extended display.

4. Launch OtoAccess® Database, and enter the patient information. Refer to OtoAccess® Database Instructions for Use for further information.

5. Launch VisualEyes™ from OtoAccess® Database.

3.2 Main screen

When launching the VisualEyes™ software, it will start on the main screen (see Figure 3.2-1). The patient information retrieved from OtoAccess® Database will be visible below the room camera image.
From the main screen there are several options:

1. **Start Room Recording:**
   Clicking ”Start Room Recording” will start a recording from the external room camera. This can be used to record a session with the patient before doing any measurements e.g. a patient interview. This recording is linked to the selected patient.

2. **Select Protocol:**
   The drop-down selection menu is used to set the protocol to be used in the patient session. For further information on protocol management, refer to section 3.4.

3. **Begin Testing:**
   Clicking ”BEGIN TESTING” will start the patient session with the selected protocol. For further information on testing, see sections 3.8 and 3.9.

4. **Patient Sessions:**
   This will take the operator to an overview of previous patient sessions that can be reviewed in detail, exported, or printed. For further information see section 3.11.

5. **Patient Videos:**
   Clicking on ”PATIENT VIDEOS” will take the operator to an overview of any previously recorded patient videos. This includes both patient interviews and measurement recordings. For further information see section 3.12.

6. **Help:**
   The ”Help” button will open up the ”Instructions for Use” and ”Additional Information” documents. These documents can also be found from the Windows File Explorer by navigating to *” C:\Program Files (x86)\Interacoustics\Micromedical VisualEyes\Operation Manual”*. This folder also contains relevant quick guides.

7. **Configuration:**
   This will take the operator to the settings menus. This includes *Protocol Management,* and *System Default Settings*.

8. **Exit:**
   The ”Exit” button will close the VisualEyes™ software.

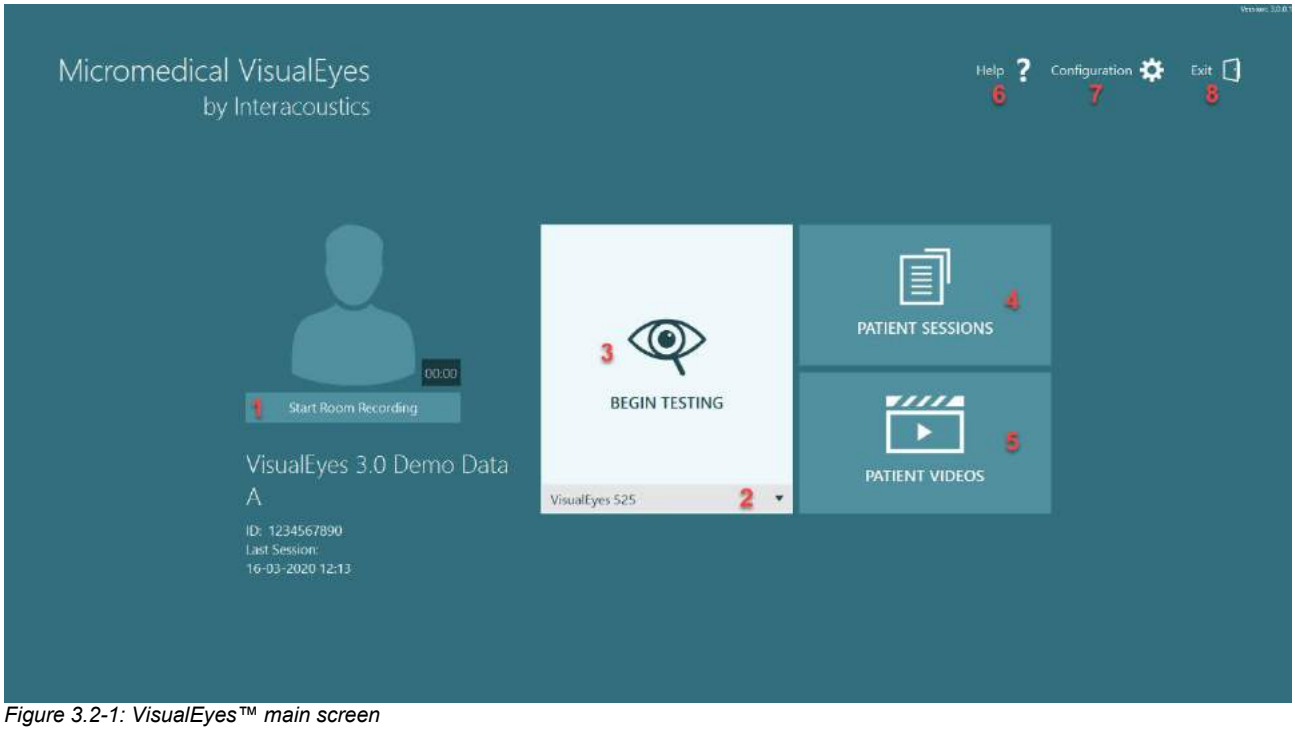
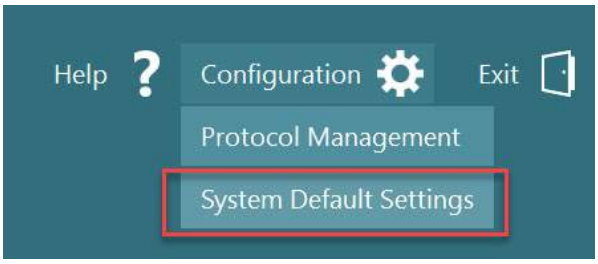


Figure 3.2-1: VisualEyes™ main screen

3.3 System default settings

Clicking on *"Configuration"* from the main screen, and selecting *"System Default Settings"* will take the operator to the menu shown in Figure 3.3-1.
This menu is used for setting up the system components and accessories, and general software settings, such as *language* and *Video Storage Location.*



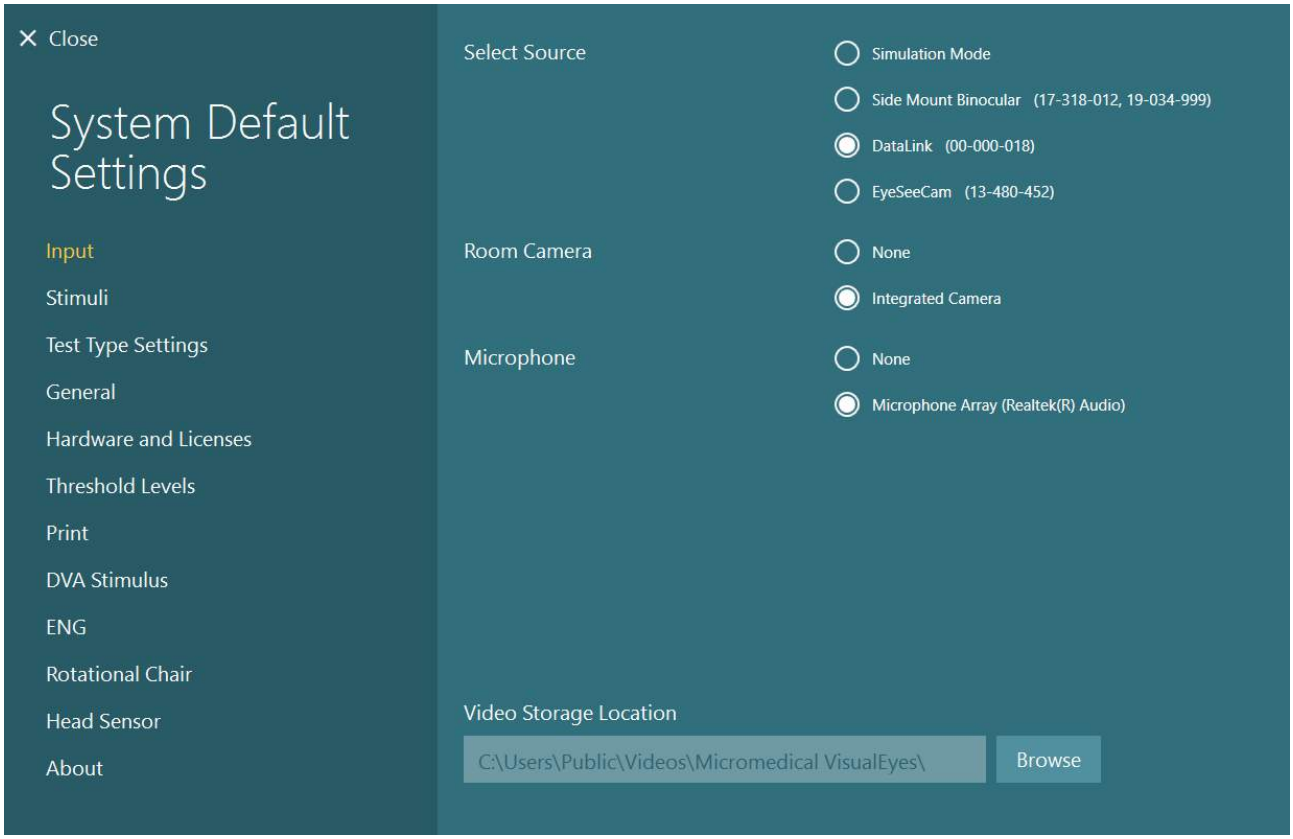
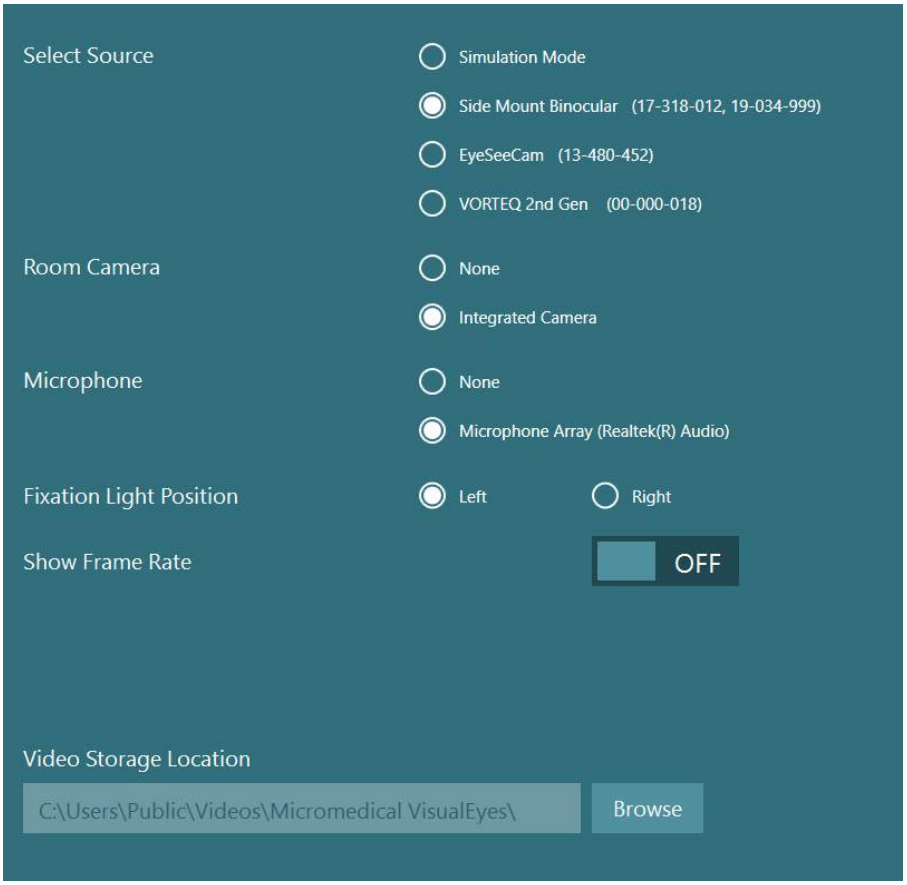


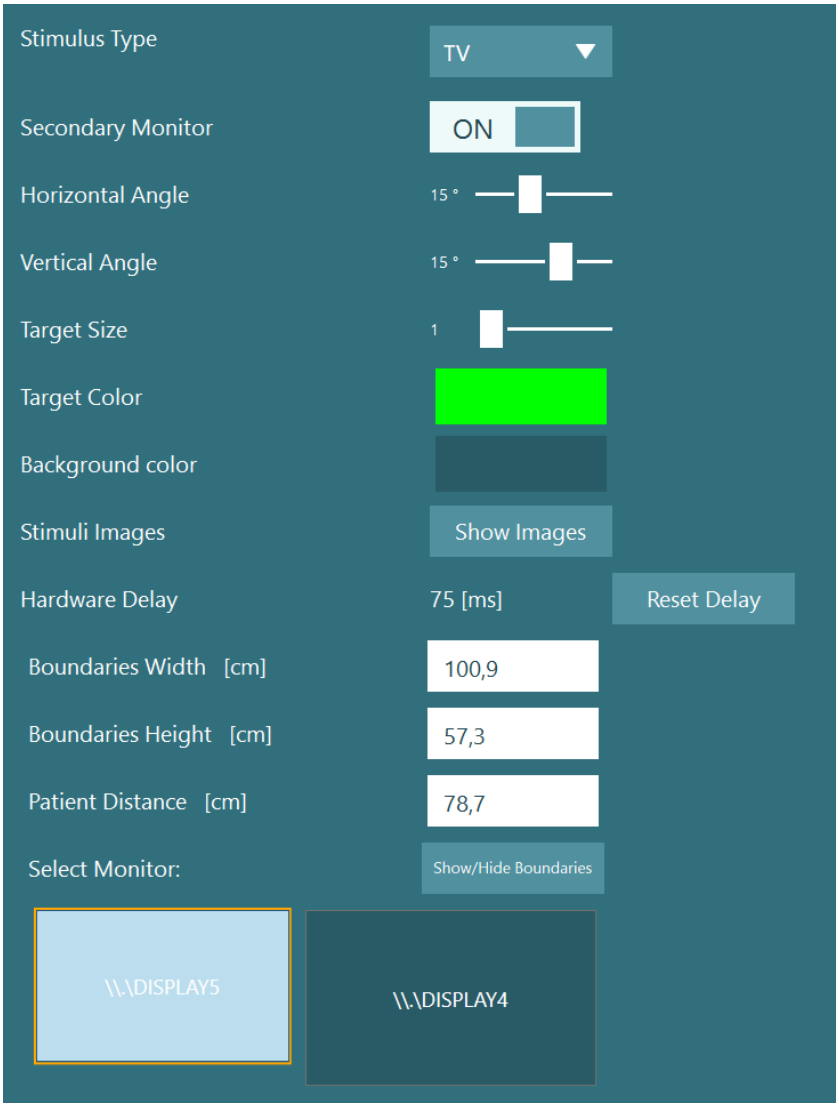
Figure 3.3-1: System Default Settings menu

The *System Default Settings menu* contains several sub-menus selected from the panel on the left side of the screen. For a detailed description of each of these menus and the available settings, refer to the *Additional Information.*

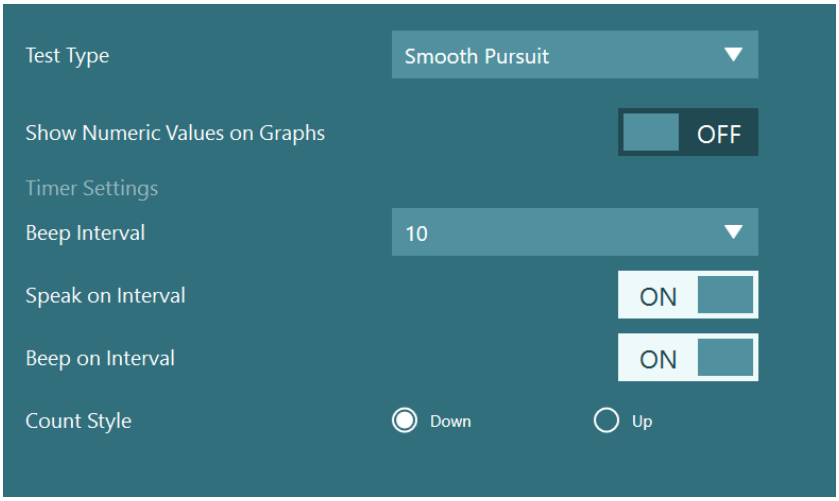
Input:
The *Input* settings screen provides access to the recording hardware. The operator can select from the registered hardware e.g. vHIT/VNG goggles, ENG devices, or a simulation mode. The operator can also select the Room Camera and Microphone and set up the Video Storage Location.



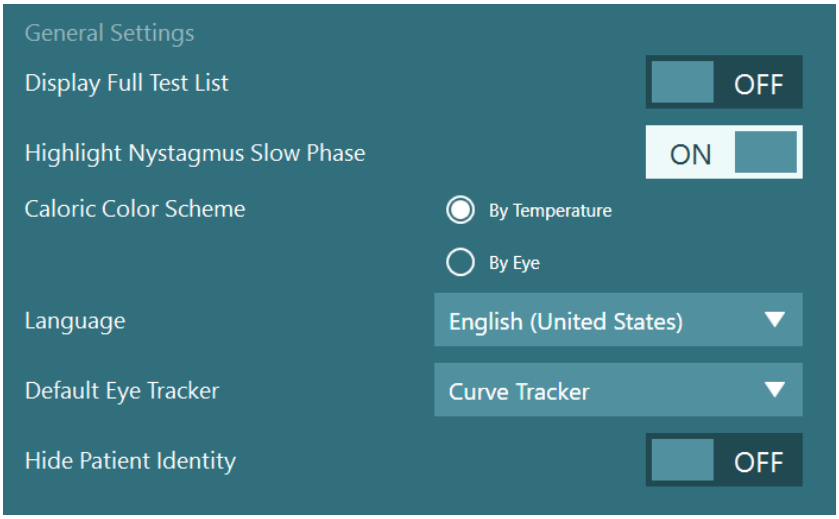
Stimuli
From the *Stimuli* settings screen, the operator can set up the stimulus source. This will be relevant for VisualEyes™ 525 systems and users of the Auto-Traverse or Comprehensive rotary chairs. The settings include selection of stimulus type (TV, Digital Light Bar, Laser and Drum), monitor dimensions, patient distance, target angles, target size, and target and background colors.



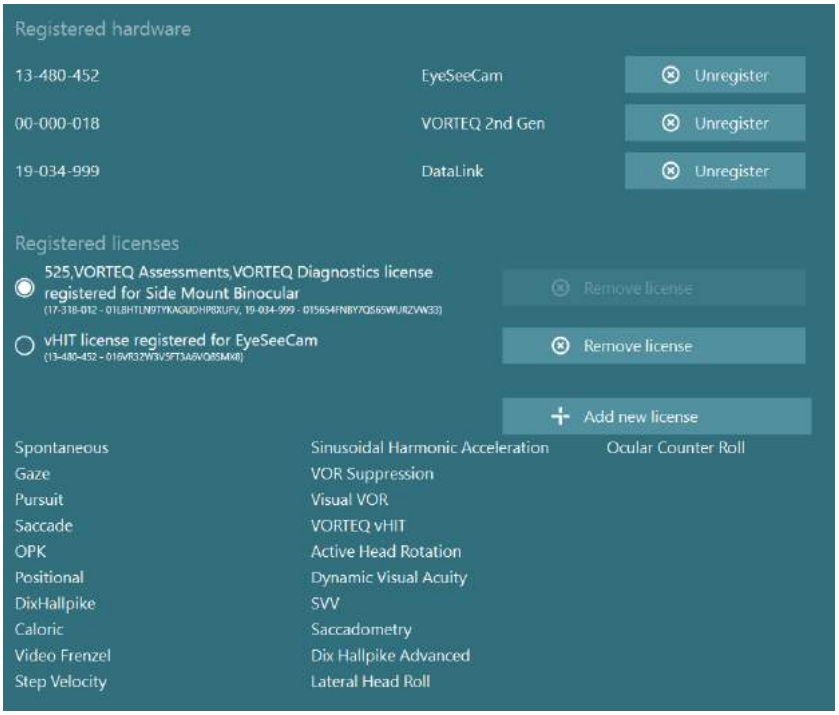
Test type settings
The *Test Type Settings* menu contains options to customize test-specific settings such as setting the *Count style* and *Beep Interval* or enabling *timer* functions between between caloric irrigations.



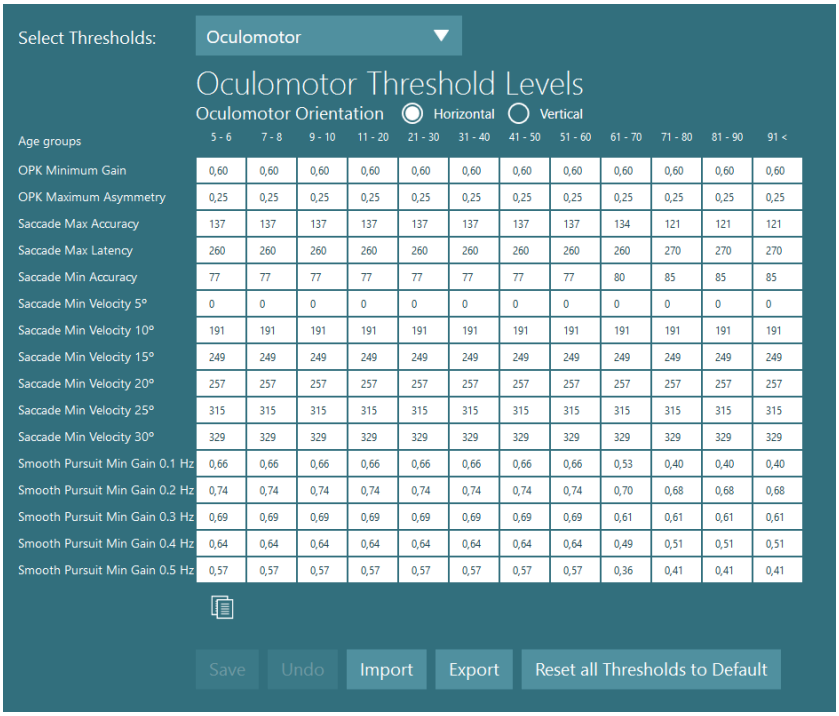
General
The *General* settings menu contains general software settings, such language settings, and selection of the default eye tracker.



Hardware and licenses
In the *Hardware and Licenses* menu the operator can get an overview of the registered hardware and the registered licenses.
The bottom section will present the tests available from the highlighted license.

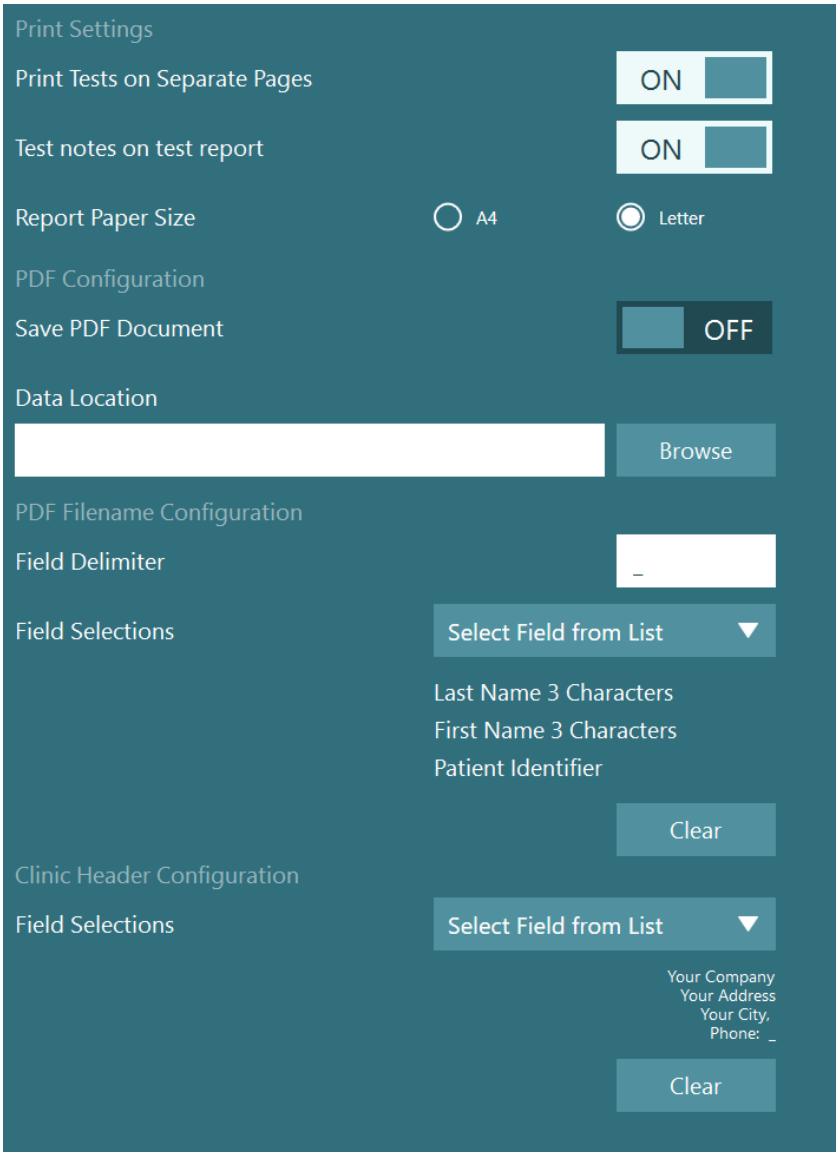


Threshold levels
The *Threshold Levels* menu presents the threshold tables for specific tests. The tables are used by the software during testing, presenting the grey shaded area in test graphs. If the test values fall outside the suggested thresholds, the measurement will be marked with an out-of-threshold symbol (red diamond).
The operator can customize the threshold levels by changing the values in the tables.



Age groups	5 - 6	7 - 8	9 - 10	11 - 20	21 - 30	31 - 40	41 - 50	51 - 60	61 - 70	71 - 80	81 - 90	91 <
OPK Minimum Gain	0,60	0,60	0,60	0,60	0,60	0,60	0,60	0,60	0,60	0,60	0,60	0,60
OPK Maximum Asymmetry	0,25	0,25	0,25	0,25	0,25	0,25	0,25	0,25	0,25	0,25	0,25	0,25
Saccade Max Accuracy	137	137	137	137	137	137	137	137	134	121	121	121
Saccade Max Latency	260	260	260	260	260	260	260	260	260	270	270	270
Saccade Min Accuracy	77	77	77	77	77	77	77	77	80	85	85	85
Saccade Min Velocity 5°	0	0	0	0	0	0	0	0	0	0	0	0
Saccade Min Velocity 10°	191	191	191	191	191	191	191	191	191	191	191	191
Saccade Min Velocity 15°	249	249	249	249	249	249	249	249	249	249	249	249
Saccade Min Velocity 20°	257	257	257	257	257	257	257	257	257	257	257	257
Saccade Min Velocity 25°	315	315	315	315	315	315	315	315	315	315	315	315
Saccade Min Velocity 30°	329	329	329	329	329	329	329	329	329	329	329	329
Smooth Pursuit Min Gain 0.1 Hz	0,66	0,66	0,66	0,66	0,66	0,66	0,66	0,66	0,53	0,40	0,40	0,40
Smooth Pursuit Min Gain 0.2 Hz	0,74	0,74	0,74	0,74	0,74	0,74	0,74	0,74	0,70	0,68	0,68	0,68
Smooth Pursuit Min Gain 0.3 Hz	0,69	0,69	0,69	0,69	0,69	0,69	0,69	0,69	0,61	0,61	0,61	0,61
Smooth Pursuit Min Gain 0.4 Hz	0,64	0,64	0,64	0,64	0,64	0,64	0,64	0,64	0,49	0,51	0,51	0,51
Smooth Pursuit Min Gain 0.5 Hz	0,57	0,57	0,57	0,57	0,57	0,57	0,57	0,57	0,36	0,41	0,41	0,41

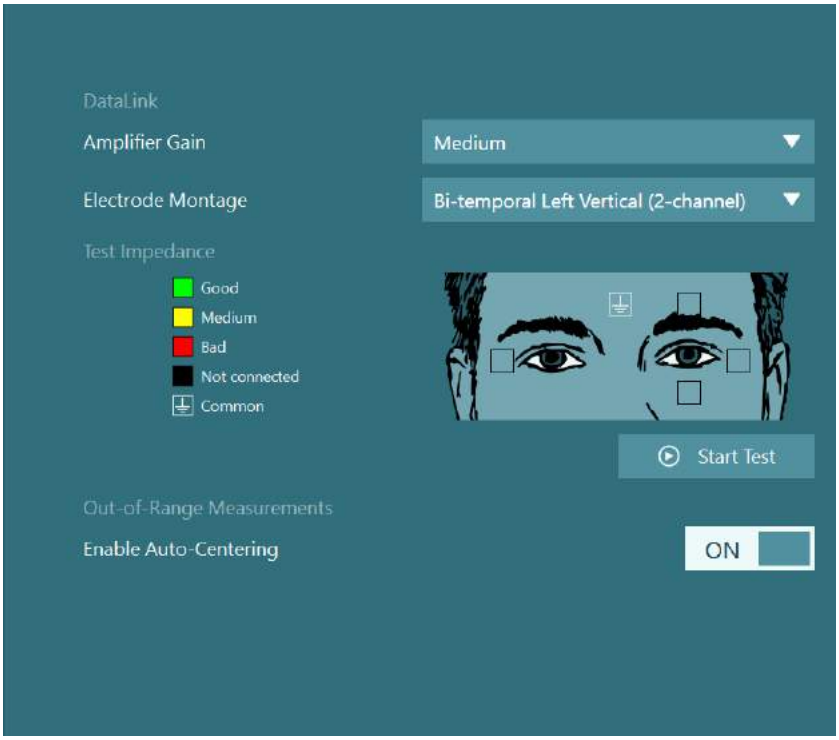
Print
The *Print* menu contains settings for the printed report. From here it is also possible to enable PDF printing to a specified data location, and configure the Clinic Header on the printed report with facility information from OtoAccess® Database.



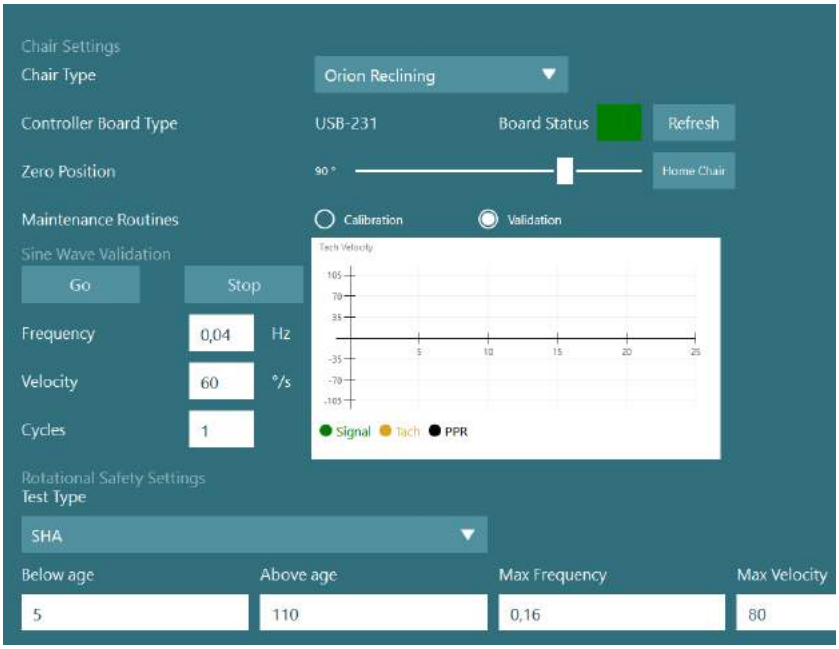
DVA stimulus
If *VORTEQ™ Assessment* is added to the VisualEyes™ system, the *DVA Stimulus* menu must be used to configure the stimulus. Refer to section 2.9.3.3: *DVA Stimulus* or the *Additional Information* for further information.



ENG
If “ENG in Chair” or “DataLink” is registered and selected as input source, the *ENG* menu will appear. This settings menu provides access to the default settings for recording electrode signals, along with instructions for electrode montage in the selected configuration, and the ability to test the impedance of the electrodes.

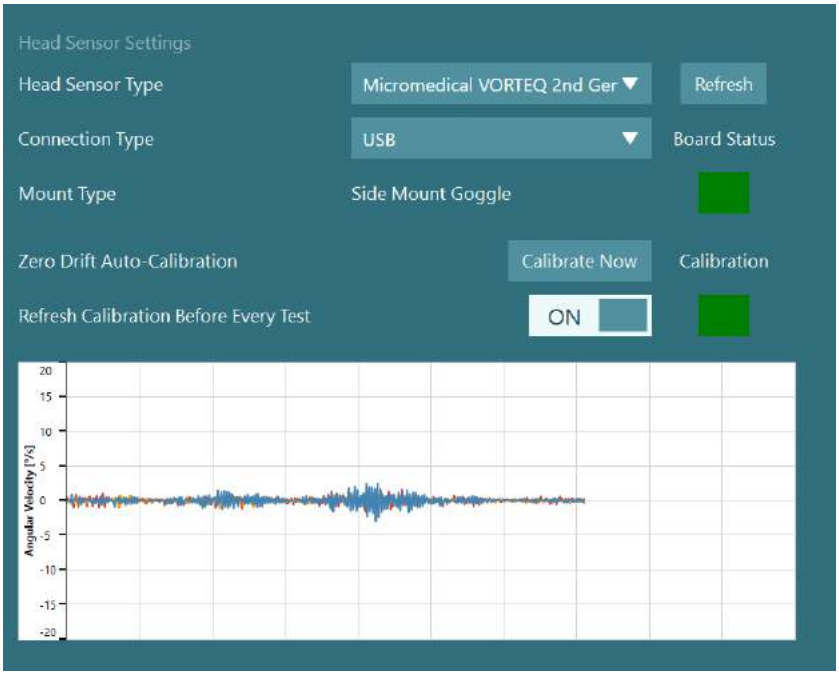


Rotational chair
The *Rotational Chair* menu provides access to relevant rotational chair settings. The available settings depends on the connected chair type.
The board status is presented for the Orion and System 2000 chairs. The status will be green if the software can communicate with the chair, and red if there is an error.
The zero position can be used to align the chair with the center of the TV or projection screen for oculomotor testing, or the booth door in booth enclosures.
It is also possible to perform calibration and validation of the chairs from the *rotational chair* menu. Refer to section 2.6.7.4: *Rotary Chair Calibration & Validation* and the *Additional Information* for instructions.



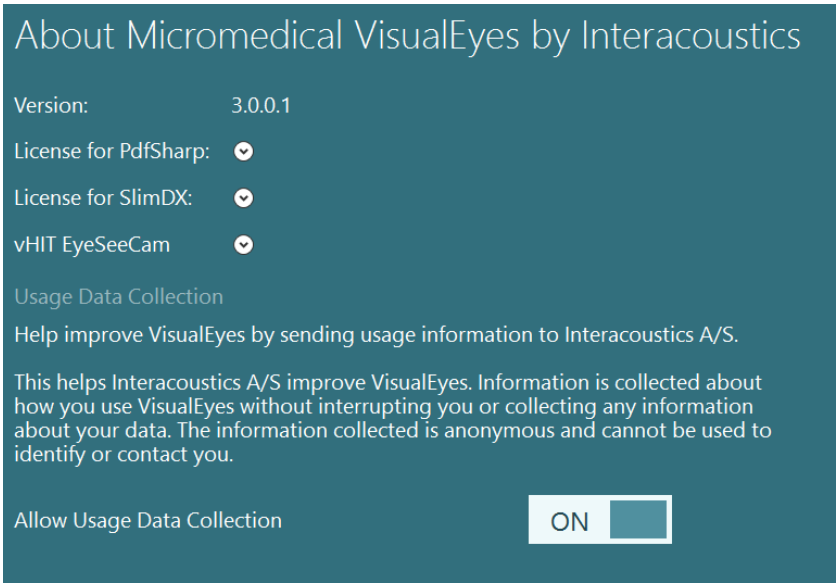
The Rotational Safety Settings specify test-specific safety limitations for patients above and below specified values.

Head sensor
If *VORTEQ™ Assessment* or *VORTEQ™ Diagnostic* is added to the VisualEyes™ system, the *Head Sensor* menu provides access to the relevant settings for the VORTEQ™ sensor. Refer to section 2.6.6: *VORTEQ™ 2nd Generation IMU (optional)* or *Additional Information* for instructions.



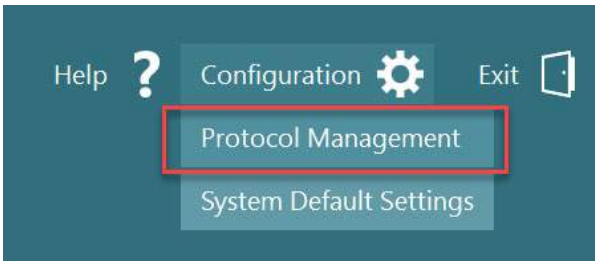
About
The *About* menu contains information about the software, including software version, and licenses used by the software.

The VisualEyes™ software will collect data about how the software is used to improve the software. This option will send back the system configuration information, test configuraton information for each test performed (no personal identifiable information is reported other than the patient's age), and any unhandled exceptions in the software from testing anomalies. This will require data transmitted along ports 80 and 443 on the testing computer.
The usage data collection can be enabled or disabled by setting "Allow Usage Data Collection" to *ON* or *OFF* respectively.



3.4 Protocol management

Clicking on *"Configuration"* from the main screen, and selecting *"Protocol Management"* will take the operator to the menu shown in Figure 3.4-1.
This menu is used for managing the protocols in the system. Protocols are composed of a list of tests and designated to be performed in a specific order at the preference of the clinician or clinic.



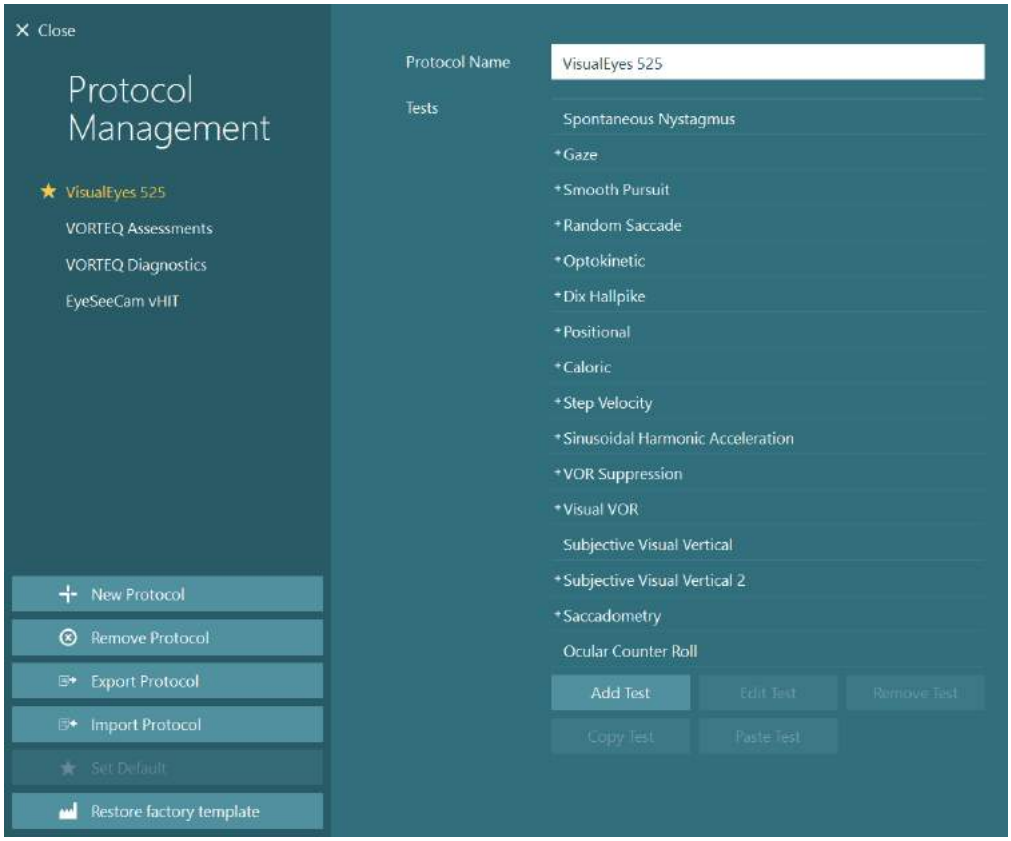


Figure 3.4-1: Protocol Management menu

3.4.1 Default protocols delivered with VisualEyes™ systems

After registering and licensing the components of the VisualEyes™ system, the software will automatically generate one or more protocols depending on the licenses added. An overview of the automatically generated protocols is presented in *Table 1.4-1*.
The *Dix Hallpike* and *Headshake* tests presented in the *VisualEyes™ 505* protocol are all based on the Video Frenzel test. This means that the Dix Hallpike test available in the *VisualEyes™ 505* protocol is different than the dedicated Dix Hallpike test available in the *VisualEyes™ 515 and VisualEyes™ 525* protocols, which include eye tracking and where the test can be divided in different sections for Sitting and Supine positions.

Table 3.4-1: Default protocols with VisualEyes™ systems.

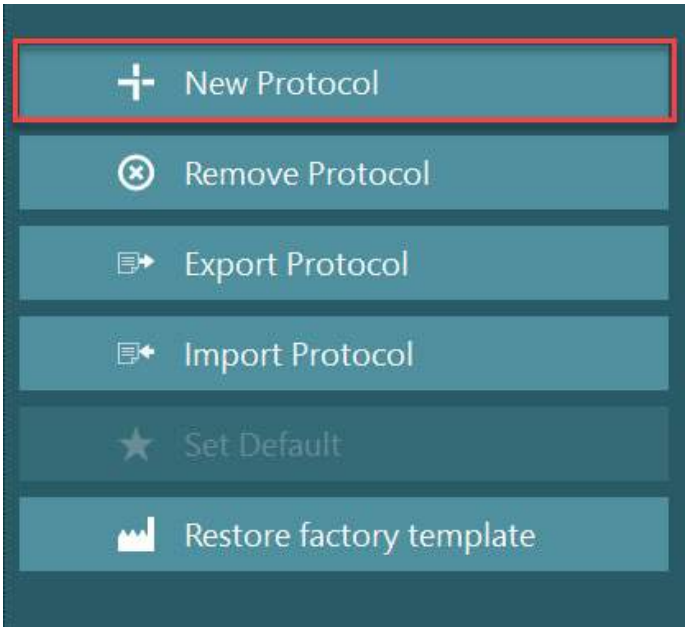
VisualEyes™ 505	VisualEyes™ 515	VisualEyes™ 525	VORTEQ™ Assessments	VORTEQ™ Diagnostics	VisualEyes™ EyeSeeCam
• Dix Hallpike Left* • Dix Hallpike Right* • Headshake* • Spontaneous Nystagmus	• Spontaneous Nystagmus • Dix Hallpike • Positional • Caloric • Step Velocity** • Sinusoidal Harmonic Acceleration** • VOR Suppression** • Visual VOR**	• Spontaneous Nystagmus • Gaze • Smooth Pursuit • Random Saccade • Optokinetic • Dix Hallpike • Positional • Caloric • Step Velocity** • Sinusoidal Harmonic Acceleration** • VOR Suppression** • Visual VOR** • Subjective Visual Vertical** • Saccadometry • Ocular Counter Roll	• Dynamic Visual Acuity • Lateral Head Roll • Dix Hallpike Advanced	• vHIT for VORTEQ™ • VORTEQ™ AHR	• Spontaneous Nystagmus • vHIT for EyeSeeCam

* Customized Video Frenzel test
** Only present with the addition of the relevant rotary chair.

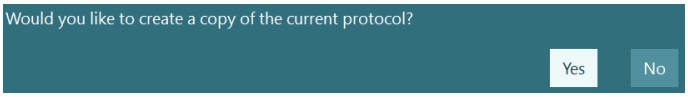
3.4.2 Customized protocols

Protocols can be customized to the desired settings of the operator.

The operator can generate a new protocol by clicking “New Protocol” in the *Protocol Management* menu.

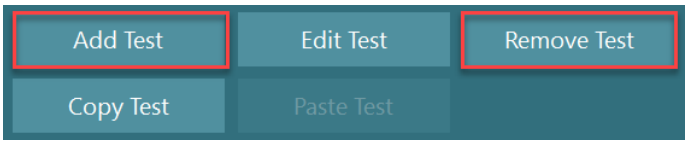


When clicking “New Protocol”, the operator can choose to create a copy of the currently selected protocol by clicking “Yes” in the popup dialogue box, or choose to create a new empty protocol by clicking “No”.

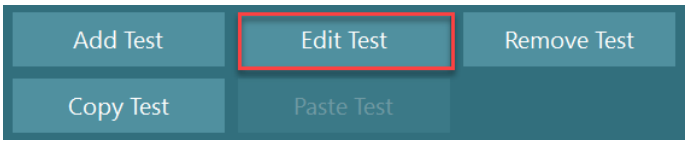


Any protocol sequence can be customized by the operator by adding or removing tests using the buttons below the list of tests.

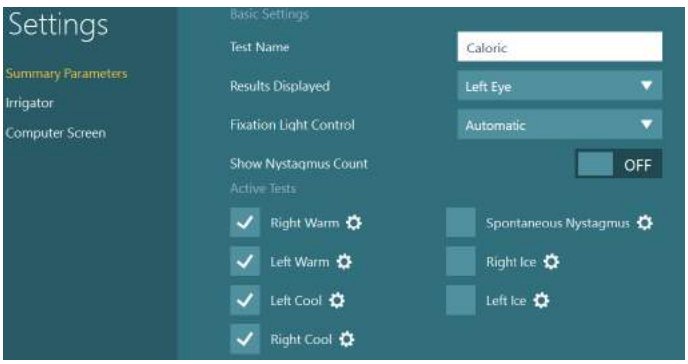
The order of the tests can also be altered by clicking, and holding, on a test in the list and dragging it to the desired position in the test sequence.



Clicking “Edit Test” with a test selected will open the test-specific settings.



The test-specific settings available are dependent on the selected test, and include the selection of different subtests to be performed, duration, target settings, and selection of graphs and values to be presented in the results. For a detailed description of the configuration options for each tests, refer to *Additional Information*.



3.5 Patient preparation



The operator and the patient should be aware of the below-listed points before starting a test.

General:

1. Ensure that the goggles are sanitized. Disposable foam pads used with the side mounted camera goggles are meant for single use and should be replaced after testing every single patient to avoid cross infection. Equipment should be cleaned and disinfected following the instructions in section 4.1: *How to clean the VisualEyes™ system*.
2. It is important to consider the patient's clinical condition/history before testing and ensure compliance according to the contraindications described in section 1.3: *Contraindications*.
3. Patients should remove any eye makeup before starting a test. Cosmetic tattoos or permanent makeup may interfere with eye tracking and should be disclosed by the patient to the testing facility prior to testing.
4. Patients cannot use corrective eyeglasses during testing but corrective contact lenses can be worn to improve visual acuity.
5. Before starting a test, it is very important that the patient is provided with all the relevant information about a test and what he/she/guardian can expect out of a test such as general precautions, adverse effects etc. Especially, additional care should be given for irrigation and positional tests (e.g. caloric test, rotary chair tests, etc.).
6. Always remove the vision-denied cover to allow vision during the placement of goggles.
7. Place the goggles on the patient's face and adjust the strap for a snug fit. For vision-denied testing, place the cover back on the goggles. Confirm with the patient that there is no light leakage. If the patient still sees light, adjust the goggles' position and tightness of the strap as needed.
8. Headband straps should be checked with each patient for the best fit. If the headband strap does not remain fastened, then it should be replaced. Replacement headband straps are available from the manufacturer.
9. It is recommended that the testing room is darkened for all vision-denied tests.
10. Be sure to only use stimulation movements that are acceptable to the patient.

Additional for rotary chair systems:

1. The operator should be aware of all emergency stop options and safety features if available with the product (refer to section 1.6 for more details).
2. Ensure that the patient is informed about the emergency stop feature, which is accessible to her/him. The patient can stop the test if she/he cannot tolerate the test.
3. Patients with a history of motion sickness should be informed if the test battery includes rotary tests and the patient should be monitored with additional care during the test. If the patient feels any discomfort, the technician/clinician should stop the test either using this software or using the Emergency Stop button to stop the chair.
4. Ensure that the rotary chair is locked in the desired position before starting any test using a rotational chair to avoid unintended turns.
5. The operator should ensure that there are no objects placed that will potentially interfere when the chair is reclining or spinning.
6. The operator should pay attention to alerts from the software if he/she tries to spin the rotational chair when it is reclined. However, the safety feature available in the Orion / System 2000 reclining chair will not allow the rotary chair to spin in the reclining position.

7. Before starting any test involving the Orion Auto-Traverse/Comprehensive chairs, a set of safety checks (Figure 3.5-1) will appear on the software to confirm safety precautions have been taken. Each box in the safety checklist must be checked before testing can begin.

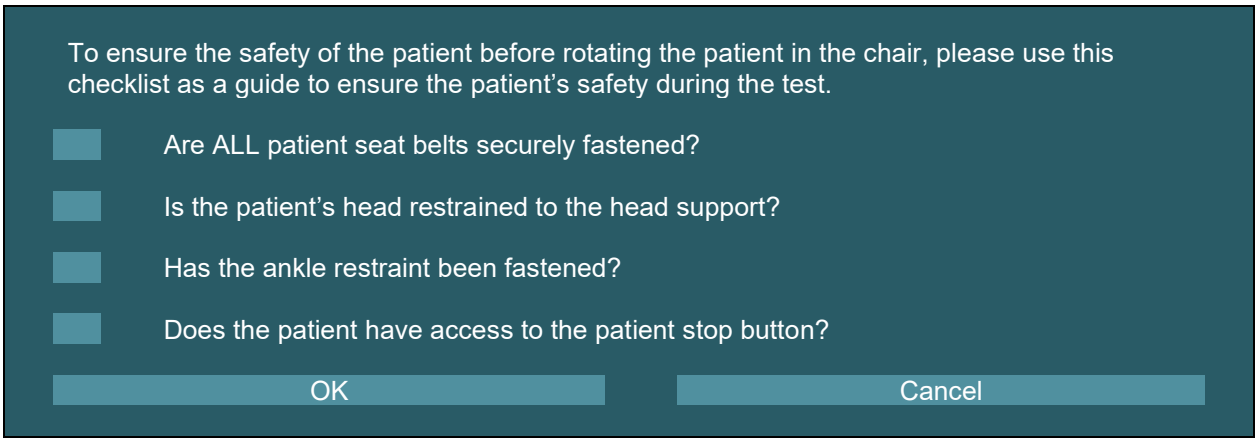


Figure 3.5-1: Safety checklist for Orion Auto-Traverse/Comprehensive chairs

3.5.1 Seat the patient in the reclining rotary chair

If the rotational chair is to be used for a test, the patient must be seated appropriately as follows.
Orion Reclining chair: The chair can be rotated using the electronic locking mechanism (ELM) switch (refer to Figure 3.5-2) to control the chair movement. Press and hold the ELM switch to disengage the ELM and rotate the chair to a position to facilitate patient seating. Lift the appropriate chair arm. Guide the patient to sit down in the chair from the side (refer to Figure 3.5-2). Guide the patient to swing his/her legs around the chair to face forward in the chair with the feet resting on the footrest. Have the patient fasten the seat belt. Lower the chair arm back down. **Note:** If needed, the patient can recline the chair back partially for comfort using either of the recline handles found on the sides of the chair frame and this is up to the operator to decide considering the test requirements. The footrest should not be used as a step to enter the chair. Release the ELM switch and rotate the chair (manually or through software) until it locks in the desired place to start with the test. The software locks the chair automatically once the operator starts the test as an additional safety feature to the Orion chair.

System 2000 reclining and Nydiag 200 chairs: Patient seating instructions are the same as the Orion Reclining chair except System 2000 reclining chairs can rotate freely and can be locked manually by de-pressing the foot brake to prevent the chair from unintended turns whereas the Nydiag 200 chair can be locked using the software.

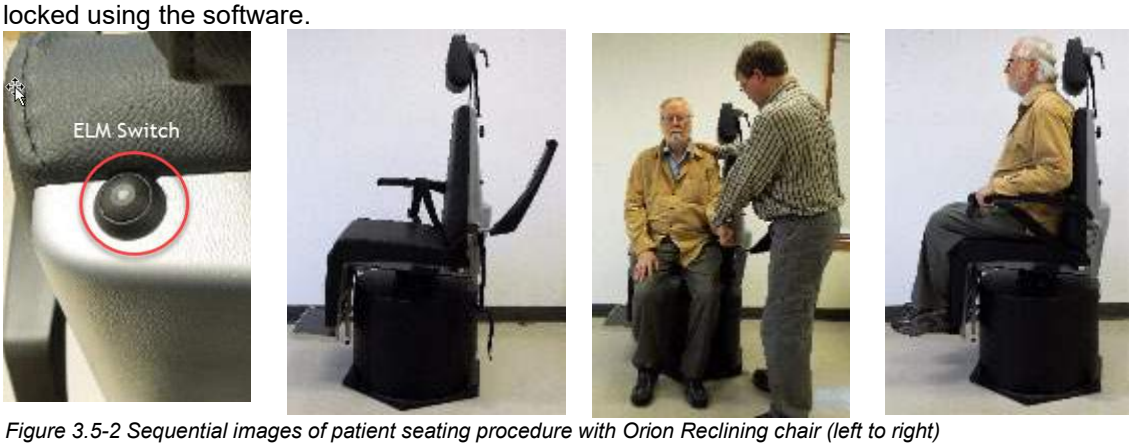


Figure 3.5-2 Sequential images of patient seating procedure with Orion Reclining chair (left to right)

3.5.2 Seat the patient in the Auto-Traverse/Comprehensive chair

Open the door to the booth enclosure. Unscrew the head support and move it up and out of the way. Guide the patient to sit and push into chair while avoiding the footrest (refer to Figure 3.5-3). **Note** that the footrest should not be used as a step to enter the chair. Guide the patient to adjust the seating position having the patient backed up into the chair. If needed, the armrests can be widened by using the adjustment levers underneath the armrests of the Orion chairs or adjustment knobs underneath the armrests of the System 2000 chairs. Fasten the lap belt and shoulder belts. Adjust the head support for patient comfort. Secure the patient's feet with the ankle restraint.

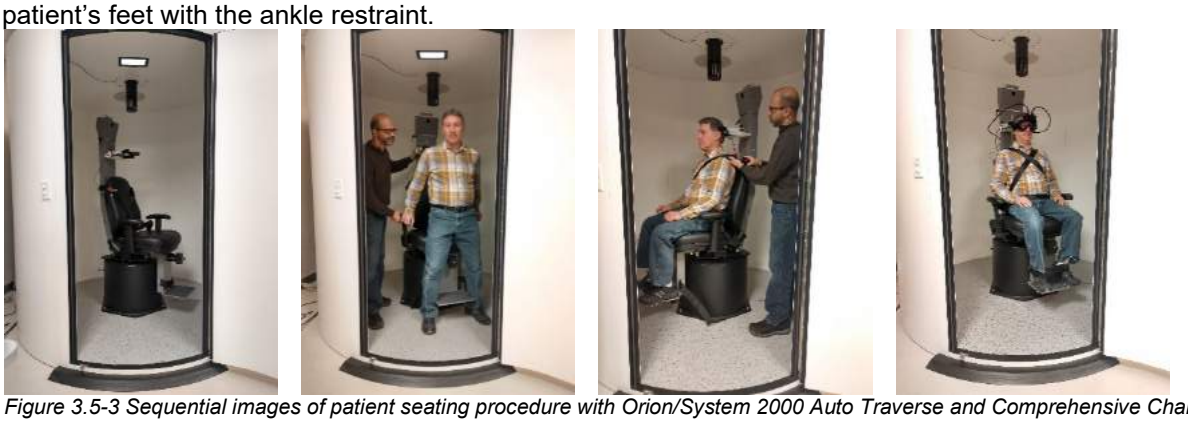


Figure 3.5-3 Sequential images of patient seating procedure with Orion/System 2000 Auto Traverse and Comprehensive Chair (left to right)

3.5.2.1 Seat the infant patient in the Auto-Traverse/Comprehensive chair

Open the door to the booth enclosure. Unscrew the head support and remove it. Slide the hook through the seat belt slot of the safety seat so that a hook is available on each side of the infant seat. Secure the infant seat and foam on top of the chair seat by attaching the hooks to the eye bolts on the chair frame. The chair's lap belt and shoulder belts may be left disconnected. Place the patient into the seat and secure the child with the infant seat's harness (refer to Figure 3.5-4).



Figure 3.5-4 Sequential images of infant car seat fitting on AT/C Chair (left to right)

3.5.3 Electrode placement and impedance test for ENG evaluation

When a patient is tested using electrodes (ENG evaluation), he/she should be prepared with the appropriate electrode montage. The operator should either have DataLink or the ENG option as part of the Orion/System 2000 AT/C chairs to proceed with the tests.

There are two montage options: bi-temporal and binocular. In general, bi-temporal montages are the standard method for ENG evaluations. If the patient exhibits disconjugate eye movement, the binocular montage can be used for the ENG evaluation. Based on these methods, the operator has four different montage options in the software as shown below (Figure 3.5-5).

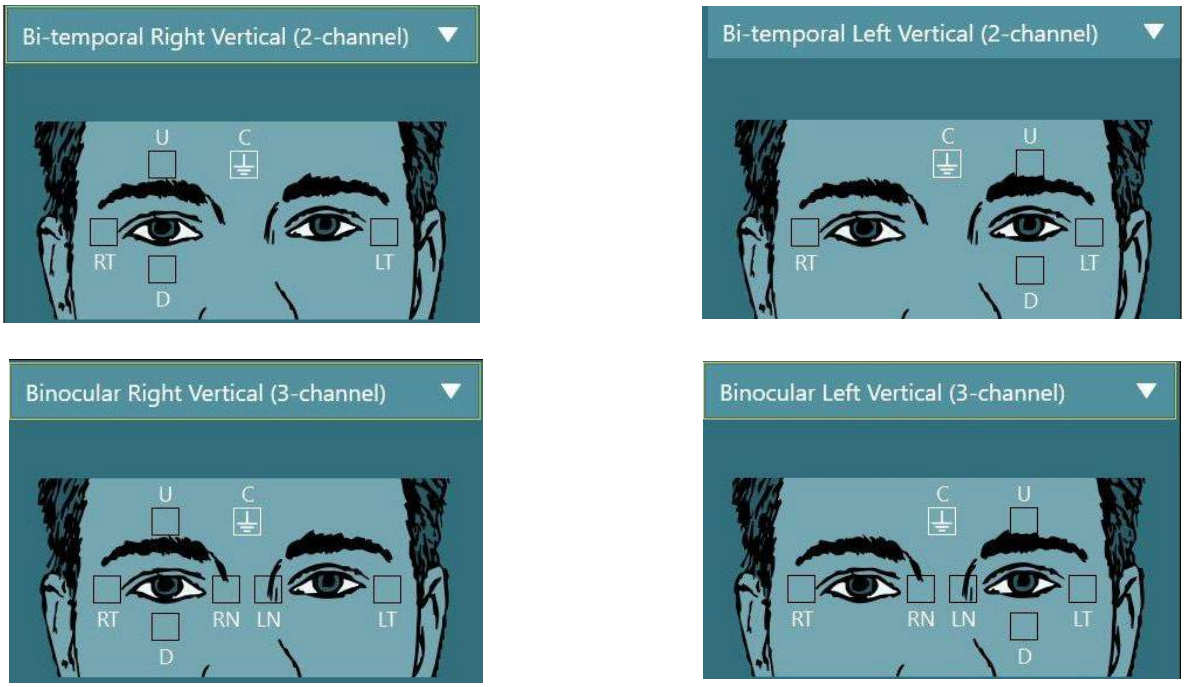


Figure 3.5-5 Electrode montage positions for ENG evaluations

The patient must be prepared with the electrodes based on the chosen montage type. The operator can verify the electrode placement against the labels on the pictures shown in the software. The default montage can be set from *Configuration* > *System Default Settings* > *ENG*. The patient's skin has to be abraded with alcohol-free pumice pads and dried before placing the electrodes. Before starting the test, it is important to perform an impedance test to verify proper electrode signal reception (see section 3.5.3 or refer to *Additional Information*). Once the operator gets the acceptable level of impedance she/he can proceed with the calibration for the individual test of a test battery followed by the actual test.

3.5.4 Placing the goggles on the patient

When a patient is tested using one of the goggles, the goggles must be placed appropriately. Ensure that the goggle cover is taken off while you place the goggle on the patient's face. Adjust the strap for a snug fit. For vision-denied testing, place the cover on the goggles. Confirm with the patient that there is no light leakage. If the patient still sees light, adjust the goggle's position and tightness of the strap as needed.

3.6 Eye image adjustment

After placing the goggle on every individual patient, and before performing any tests, it is important to ensure that the camera image is configured properly to track the patient's pupils adequately.
Go to the test screen by clicking "BEGIN TESTING" on the main screen. The camera eye images will then be visible from the test screen.

3.6.1 Eye image centering:

The eyes should be centered so that the pupils appear in the center of the image window with the patient looking straight ahead.
NOTICE: If the image if not optimally centered, the eye tracker may fail to record eye movements in certain positions.

Side mount goggle:
If using the side mount goggle, use the mirror adjustment and the alignment knobs on the sides of the cameras for vertical and horizontal adjustment, as described in section 2.6.1.1.

Top mount goggle:
If using the top mount goggle, the images can be centered from the software by using the center eyes button from the eye tools menu described in section 3.6.3.

Front mount goggle:
If using the front mount goggle, use the center eyes button in the eye tools menu and manually adjust the camera in the goggle viewport. Ensure that the “UP” sticker on the camera is pointing upwards.

EyeSeeCam goggle:
If using the EyeSeeCam goggle, 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. Only rotate the camera in one of these three possible directions at a time. 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 is shown below:

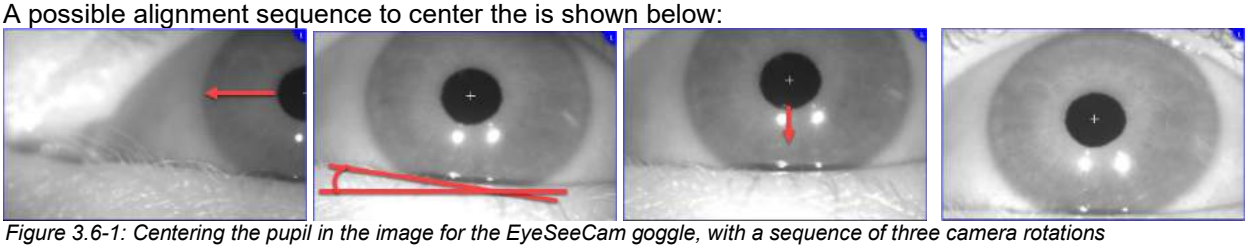


Figure 3.6-1: Centering the pupil in the image for the EyeSeeCam goggle, with a sequence of three camera rotations

3.6.2 Focus adjustment

To optimize the pupil detection the camera should be focused. This is done by turning the knobs/lens as described for the selected goggles in section 2.6.1, and shown in Figure 3.5-6. Turn the knob clockwise or counterclockwise while watching the image on the screen. Stop turning the knob when the pupil outline and iris pattern is clear, even if the eye surroundings may be blurry at this point. The infrared reflections will be the smallest when the cameras are in optimal focus. With binocular goggles, each camera must be adjusted separately.

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



Figure 3.6-2: Focus adjustment on the different VNG and vHIT goggles

3.6.3 Eye tools menu

When touching or hovering the mouse over the eye images in the test screen, the *Eye tools menu* will appear. The Eye tools menu contains five buttons:

1. **Toggle Right Eye:** Enable/disable image and eye tracking for the right eye.
2. **Click to center eyes:** Centers the eyes in the images (only available with the top mount and front mount goggle).
3. **Click to select eye tracker:** Allows the operator to select the eye tracker to be used.

4. **Toggle threshold sliders:** Allows the operator to adjust the image contrast using the appearing scrollbars. The contrast should be adjusted so the eye tracking crosshair appears in the middle of the pupil when the patient is looking center, up, down, left, and right. The contrast will be adjusted automatically by default, and can be reset to automatic threshold adjustment clicking the A icon below each slider.

5. **Toggle Left Eye:** Enable/disable image and eye tracking for the left eye.



Figure 3.6-3: Eye tools menu

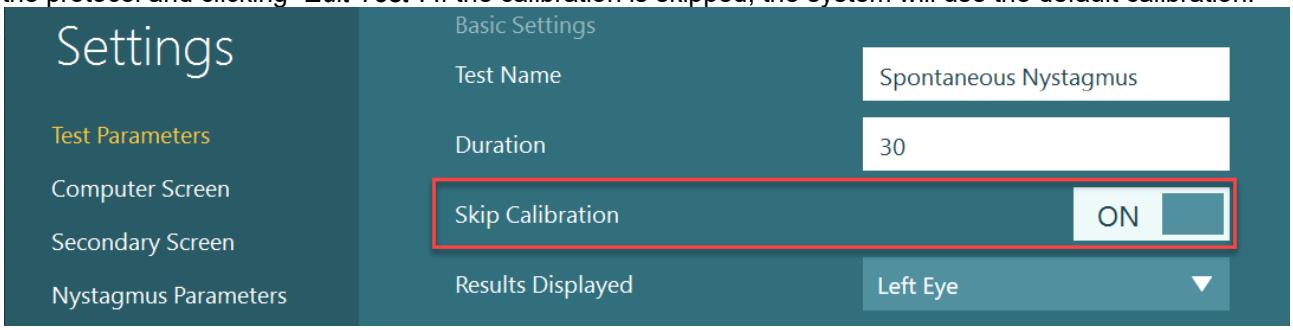
3.7 Calibration

For all tests including eyetracking, it is recommended to perform a calibration to ensure accurate measurements of the position of the eyes, and the velocity of the nystagmus. Calibrations are particularly important in tests where eye movements are compared with a given stimulus of a known position and/or velocity (e.g. Saccade, Smooth Pursuit, Gaze etc.).
NOTICE: A calibration should be performed anytime the goggle/camera is changed, or the goggles or cameras are moved.

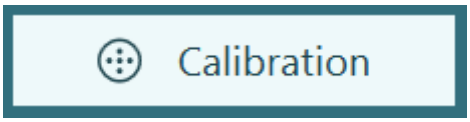
For VisualEyes™ 505, VisualEyes™ 515, and VisualEyes™ 525, a stimuli monitor/TV or projector is required to perform the calibration. When using the Orion Comprehensive or Auto-Traverse chairs, the built-in laser will be used for the calibration. For EyeSeeCam it is recommended to always use the laser attached on the goggle.

NOTICE: If a reclining rotary chair is used for the test, the operator has to ensure that the chair is faced towards the television screen/projection image, that the patient is centered in front of the stimulus and that the chair is locked to avoid unintended turns before starting the calibration.

VisualEyes™ 505 and VisualEyes™ 515 systems do not use visual stimuli for the tests, and therefore these systems might not have the required monitor, TV, or projector to perform the calibration. In this case the user can disable the calibration step for the tests by turning ON “Skip Calibration” in the Test Parameters under specific tests. The test parameters can be found by navigating to *Protocol Management*, selecting a test in the protocol and clicking “*Edit Test*”. If the calibration is skipped, the system will use the default calibration.



The Calibration screen can be opened from the test screen, by clicking on the ”Calibration” button in the left panel. The calibration screen can also be entered by clicking the foot switch or the right button on the remote control when Calibration button is highlighted in white.



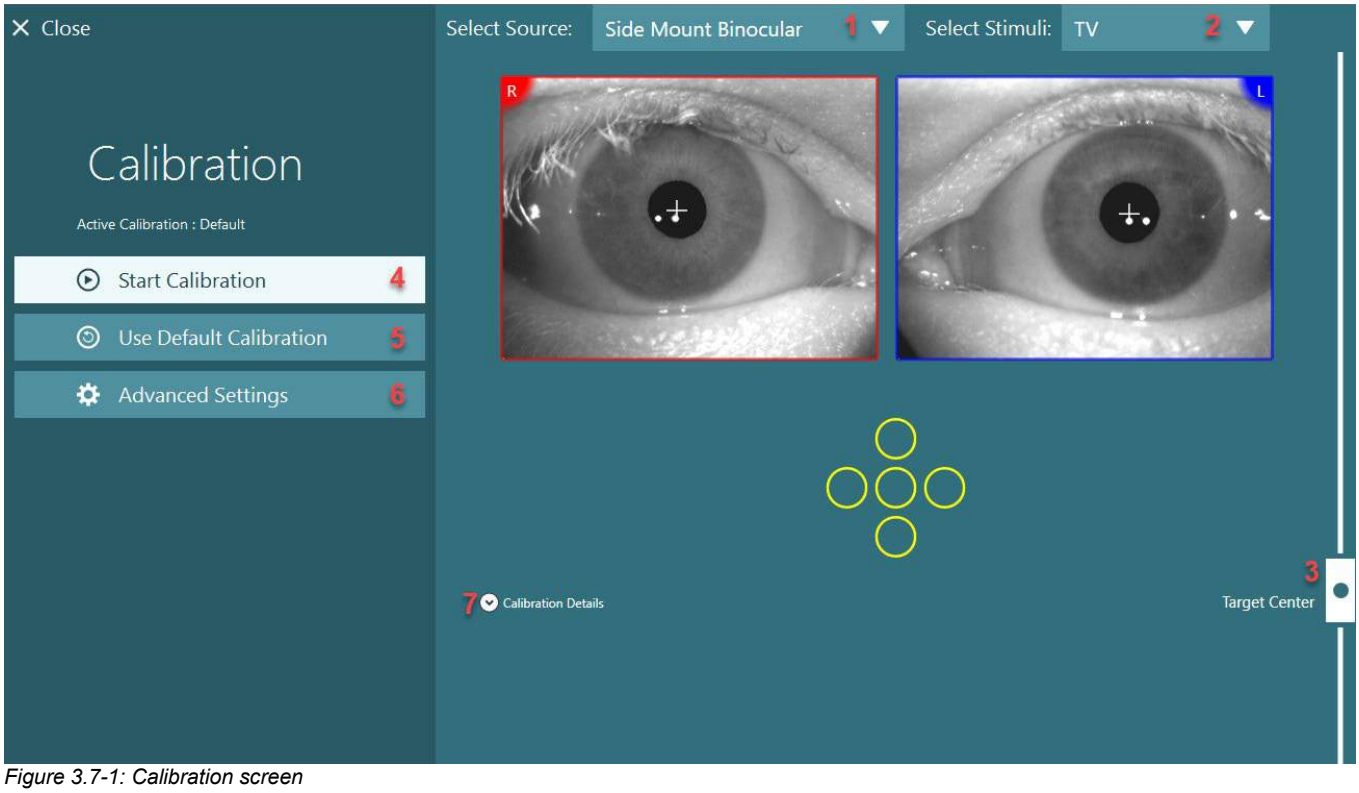


Figure 3.7-1: Calibration screen

After entering the calibration screen, the operator should ensure that the source and stimuli are selected properly. This is done by first selecting the source in the drop down selection menu (1 in Figure 3.7-1), and afterwards selecting the stimuli in the drop down selection menu (2 in Figure 3.7-1).

Center the calibration stimulus for the patient using the target center slider (3 in Figure 3.7-1). Vertical tests will still display the target from the center of the screen, but horizontal tests will display the target centered at the target center position specified by the target center slider. If using the Auto-Traverse or Comprehensive chair, the target can be adjusted by manually adjusting the laser on the back of the chair.

If the patient distance differentiates from the patient distance entered in System Default Settings, this can quickly be adjusted for the specific calibration by entering the Advanced Settings (6 in Figure 3.7-1). From here the target size can also be adjusted, if for instance the patient is visually impaired and not able to see the default target size.

The calibration can be started by pressing ”Start Calibration” (4 in Figure 3.7-1). Refer to the instructions in section 3.7.1 - 3.7.5 for instructions for performing the calibration.

If you cannot complete the calibration, use the default calibration by clicking “Use Default Calibration” (5 in Figure 3.7-1). This sets the VisualEyes™ system to use default calibration settings which provide only an approximate calibration value. Be aware that results for oculomotor tests and nystagmus velocities need to be interpreted with caution.

Further calibration details can be presented in either graphical or tabular form by pressing “Calibration Details” (7 in Figure 3.7-1).

3.7.1 Standard calibration

The standard calibration is a 5-point calibration, where the patient is instructed to hold their head still facing the stimuli screen, and look at each of the 5 targets as they appear on the stimuli screen. The calibration screen will show a large yellow dot representing the current target point that the patient is looking at. The software will by default automatically accept the fixation points after a few seconds and move on to the next target. Automatic fixation detection may not be achieved successfully in some patients. In such cases, by observing the video image of the calibrated eye on the screen if the calibration point has been fixated upon, clicking the "*Accept point"* button will manually accept the value and move to the next target position. When a target has been accepted by the software, a yellow check mark will appear on the calibration screen at the specific target position.

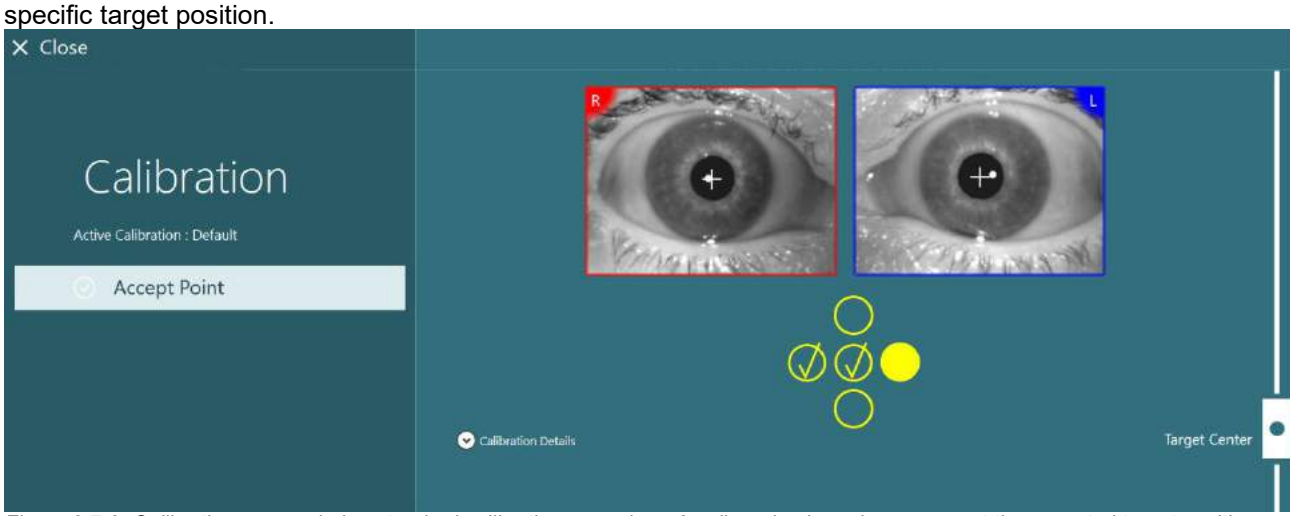


Figure 3.7-2: Calibration screen during standard calibration procedure. A yellow check marks appears at the accepted target positions

After completion of the calibration, the check marks will turn green if the calibration values are within acceptable ranges (Figure 3.7-3). If the calibration values are not acceptable the check marks will turn red, and the calibration should be repeated for these points.
Once all target points are green, press "Accept and Close". This will close the calibration screen, and the system is ready to perform the tests.

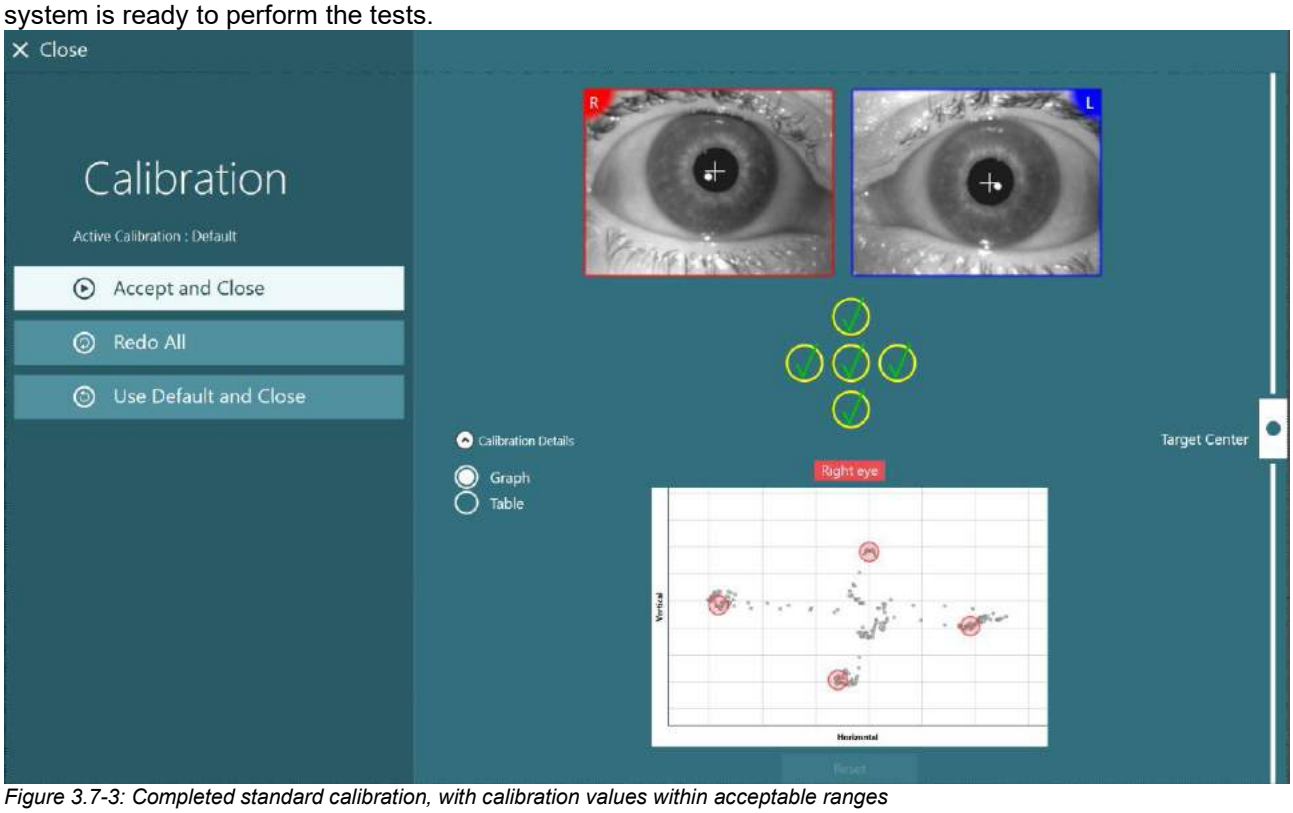


Figure 3.7-3: Completed standard calibration, with calibration values within acceptable ranges

3.7.2 Torsion calibration

Tests that include torsion tracking (e.g. *Advanced Dix Hallpike*, *Ocular Counter Roll, and Lateral Head Roll*) will need to perform a torsion calibration before use. For these tests, a *Torsion* calibration button will be present in the calibration screen (Figure 3.7-4). Clicking this will open the Torsion Calibration screen.

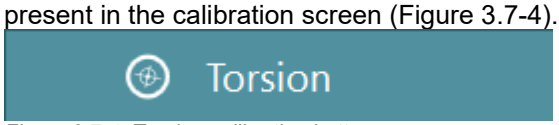


Figure 3.7-4: Torsion calibration button

Have the patient look straight ahead, then click on the Auto Detect button. The software will select an iral segment with good contrast to track rotation. The tracking area can be adjusted using the sliders below the eyes.
If the torsion tracker is to be utilized in the dark with dilated pupils, it is very important to perform the torsion calibration in the dark with dilated pupils. If possible, ask the patient to look slightly up – this will make the iris more visible.

The white circle indicating the tracking area must never be filled out by the pupil, this will lead to unstable torsion tracking (Figure 3.7-5).

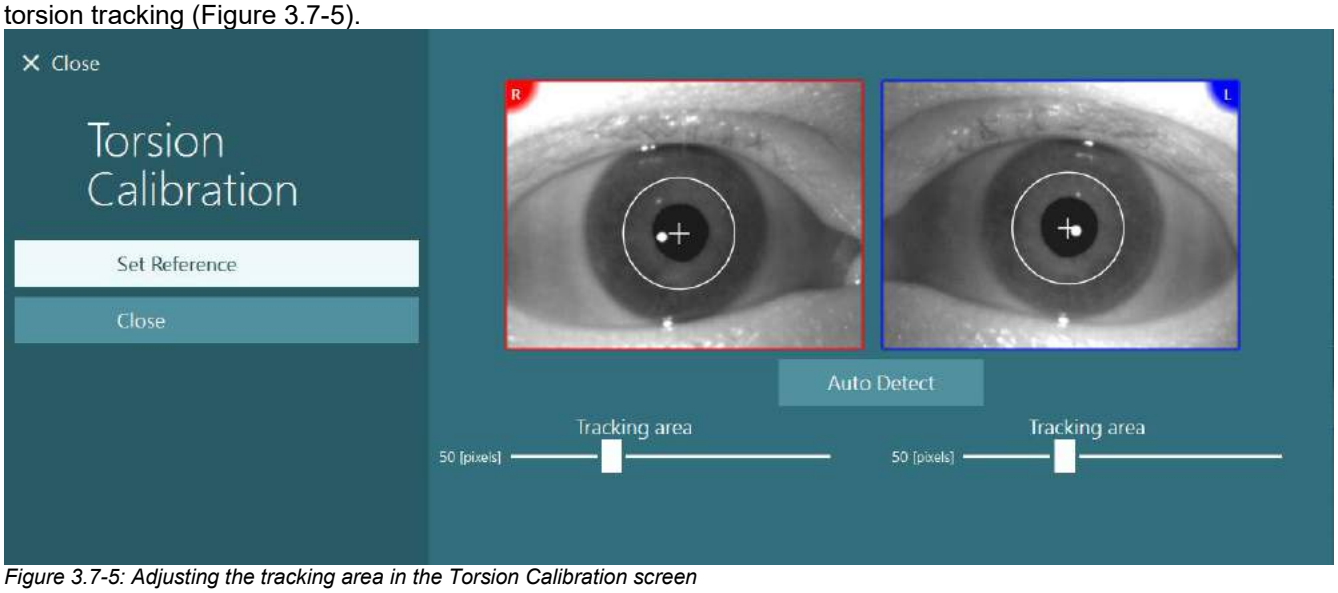


Figure 3.7-5: Adjusting the tracking area in the Torsion Calibration screen

Once the adjustments have been made, click on the Set Reference button. The crosshair will now show a circle with a crosshair. Confirm that the torsion angle is responding to the patient's eye movements, otherwise adjust the tracking area and click on Set Reference to update. To return to the calibration settings, click on the Close button (Figure 3.7-6).

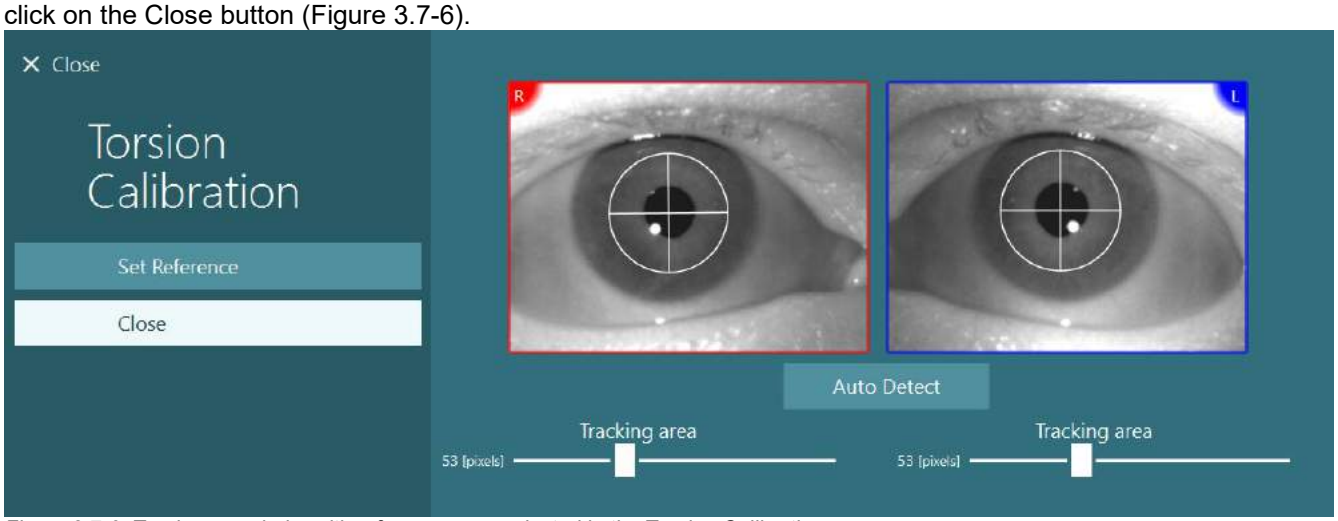
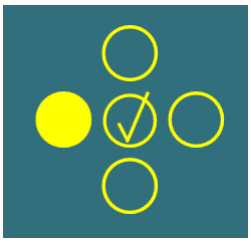


Figure 3.7-6: Torsion crosshairs with reference area selected in the Torsion Calibration screen

3.7.3 EyeSeeCam calibration



For the EyeSeeCam goggle, the standard calibration should be peformed first. Open the calibration screen, and select *EyeSeeCam* as input source, and *EyeSeeCam Laser* as stimuli, and click start calibration. The standard calibration follows the same procedure as described in section 3.7.1, except that the EyeSeeCam laser always presents 5 stationary dots, so the operator must instruct the patient to focus on only one dot at a time. The large yellow dot on the calibration screen presents the target that the patient should be instructed to focus on.

NOTICE: Automatic fixation detection is not available with the EyeSeeCam goggle, so the points must be accepted manually by clicking ”Accept Point” in the left panel.

After the standard calibration has been completed, a head calibration must be performed. Whenever EyeSeeCam is selected as input source, the *Head Calibration* button will appear (Figure 3.7-7). Clicking this will open the Head Calibration screen.

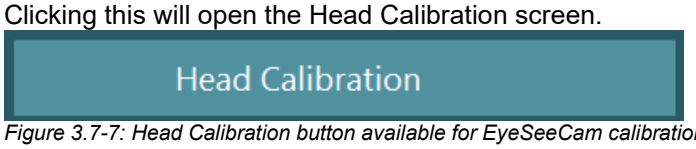


Figure 3.7-7: Head Calibration button available for EyeSeeCam calibration

Ask the patient to fixate at a point, and click ‘Start’ to start the head calibration. Ask the patient to shake the head slowly in a horizontal direction. The head velocity guide indicates the correct speed for the head movement. When the bar is green, the correct speed is achieved and the system can track the head movement. After a few seconds, the system moves to vertical calibration, and you must ask the patient to move his/her head slowly in a vertical direction.

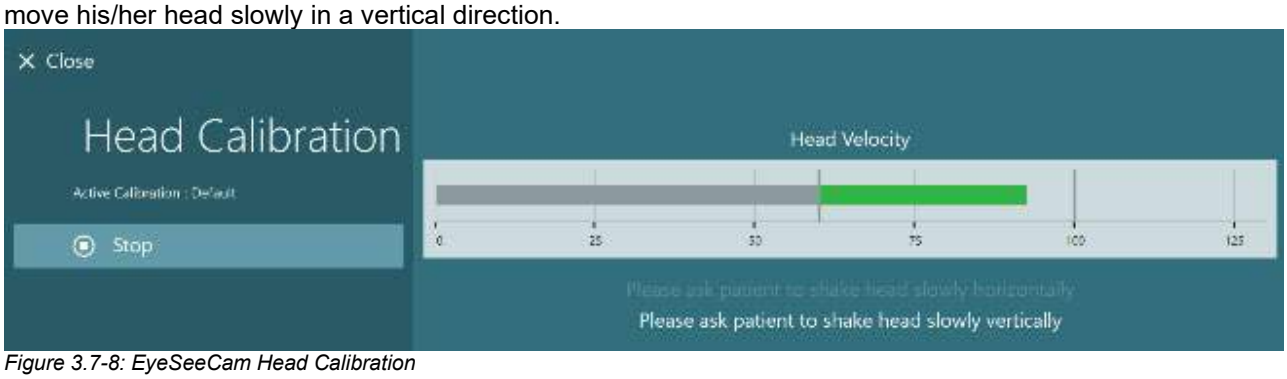


Figure 3.7-8: EyeSeeCam Head Calibration

Once both planes have been completed, the head calibration results will appear. The graphs should present a cross with vertical and horizontal lines as shown in Figure 3.7-9. The operator can then Accept and Close, or redo the calibration. Once clicking ‘Accept and Close’ the system is ready for the tests.

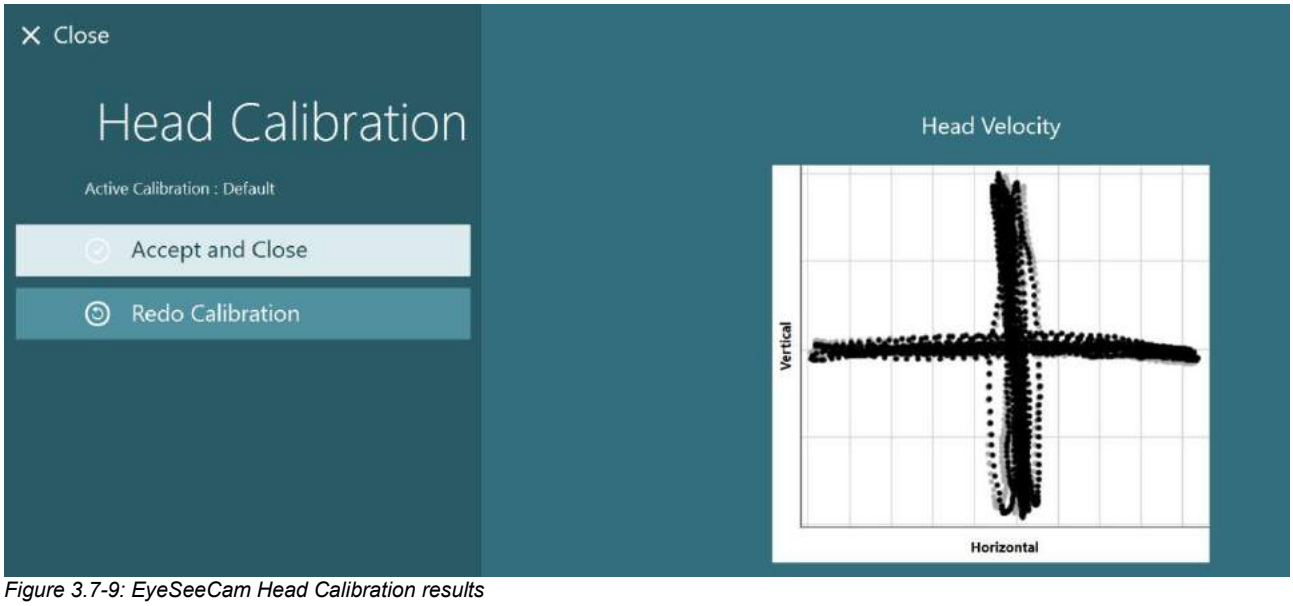


Figure 3.7-9: EyeSeeCam Head Calibration results

3.7.4 ENG calibration and impedance test



With 'DataLink' or 'ENG in Chair' selected as input source, the 'Impedance Test' button and the 'Center Traces' button will appear in the left panel on the calibration screen . Clicking the Impedance Test button will open the Impedance test screen (Figure 3.7-10). The impedance test can also be performed from *System Default Settings* > *ENG*.

The Imedance Test screen allows the operator to select the desired electrode montage from the drop down selection menu. The image will present instructions for how to place the electrodes on the patient.

Clicking on the 'Start' button will check each electrode and report the impedance.
If the impedance is measured as 10 kOhm or less, the electrode will be marked as 'Good' indicated by green coloring. If the impedance is between 11 kOhm and 15 kOhm the electrode will be marked as 'Medium' indicated by yellow coloring. If the impedance is between 16 kOhm and 20 kOhm the electrode will be marked as 'Bad' indicated by red coloring.
Sometimes there may not be any clean ENG signals. This will be marked as 'Not connected' indicated by black coloring.

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

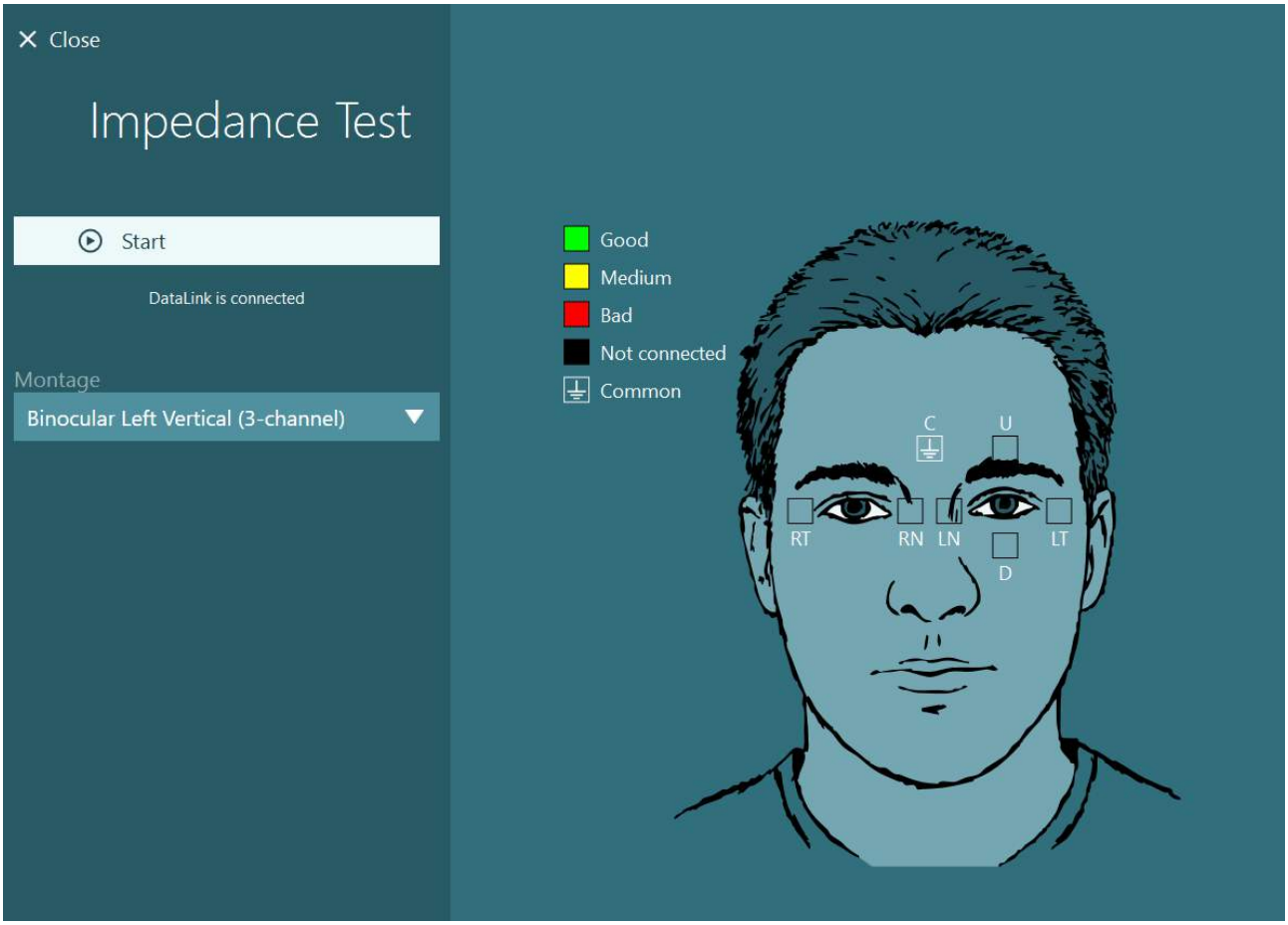


Figure 3.7-10: Impedance Test screen.

When the impedance test has been performed, a standard calibration can be performed following the procedure in section 3.7.1.

If the electrode traces for horizontal and vertical traces show drift, the traces can be manually centered using the **Center Traces** button. If the patient's eye movements are not shown in the electrode traces, then the Amplifier Gain can be adjusted below the traces to magnify the patient's electrode signals (Figure 3.7-11).

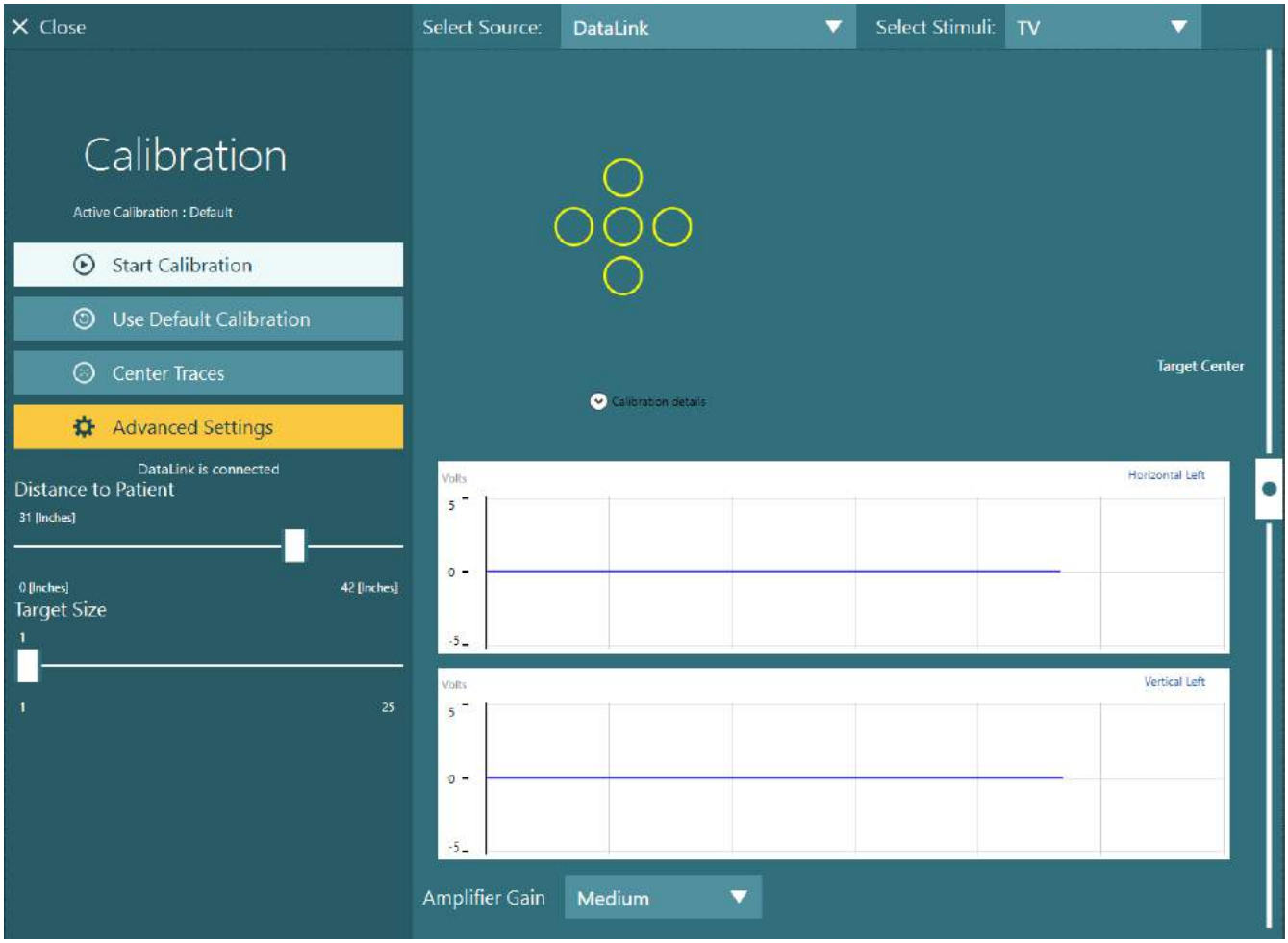


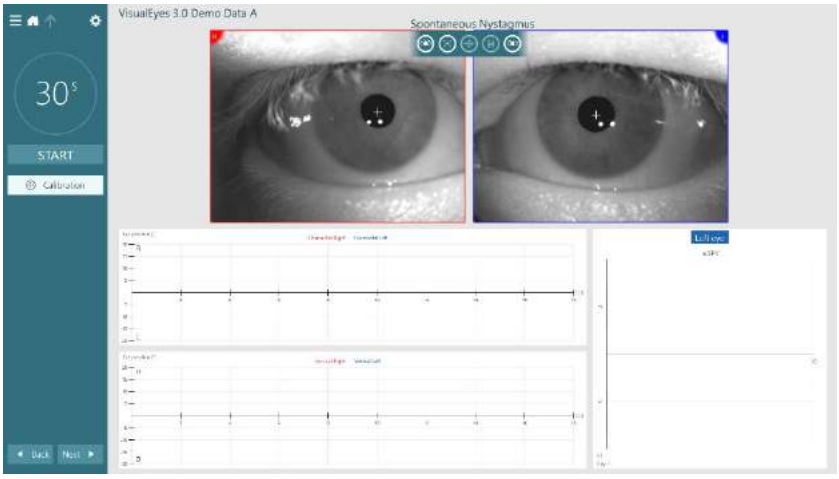
Figure 3.7-11: Standard calibration with ENG

3.8 The test screen

When the system and the patient have been prepared, the tests can be performed. To enter a test session, select the desired protocol and click on ”BEGIN TESTING” from the main screen.



After clicking “BEGIN TESTING”, the software will open a test session starting with the first test in the selected protocol.
If a session was already created on today’s date with the same protocol for the selected patient, the software will continue from where the previous session was left.



The test screen will present the images from the cameras, a counter presenting the duration of the test, as well as test-specific graphs and controls.

The left side panel contains buttons for operator controls. The buttons in the panel vary for each test. Some of the most general controls are the following:

Test menu, will open the session tree allowing the operator to view the current test session.



Home button, will return to the main screen.



Up arrow, will exit the current subtest and go to the individual subtest summary screen.



Temporary settings, will open the temporary settings for the specific test, allowing the operator to change the parameters temporarily.



Back and **Next** will go to the previous or next test/subtest in the protocol test list.



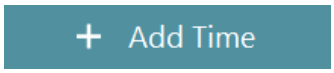
START, will start the selected test.



Timer, displays the time remaining/elapsed based on the selecting count style.



Add Time, will add 30 seconds to the time remaining on the counter.



3.9 Performing the tests

This section contains a short description on how to perform the tests available with the VisualEyes™ systems. For a detailed description, please refer to *Additional Information*.

3.9.1 VisualEyes™ 505, VisualEyes™ 515 and VisualEyes™ 525

3.9.1.1 Video Frenzel

The Video Frenzel test is available with *VisualEyes™ 505* and *VisualEyes™ 525*. Video Frenzel is a basic test, which can record patient eye movement without any analytical assessments. There is no time limit for eye recording in this test and there is no calibration requirement to perform this test.

3.9.1.2 Spontaneous Nystagmus

Spontaneous Nystagmus is available with all VisualEyes™ systems. This is a vision-denied test and the patient will look straight ahead with the goggle cover on. The operator will be able to watch the patient's eyes either from the computer screen or from the TV or projector screen. When the test is started, the eye position graphs will be displayed. Nystagmus beats will be marked with triangles displayed at the onset of the fast phase. When significant nystagmus is detected, the average slow phase velocity (a.SPV) will be displayed in the bar graph on the right side of the eye position recordings. When the test ends, the software will color-code the nystagmus slow phase velocities in green.

3.9.1.3 Dix Hallpike

The dedicated Dix Hallpike test is available with *VisualEyes™ 515* and *VisualEyes™ 525.* This is a vision-denied test and the test can be performed on an examination table/reclining chair. With the patient seated in the upright reclining chair, remove the Orion or System 2000 head support and set it aside. Unlock the chair with the ELM button (Orion) or release the foot brake (System 2000) and rotate the chair as needed to allow the chair and patient to be fully reclined (refer to Figure 3.9-1). Have the patient unfasten the seatbelt. When maneuvering the patient into the standard Dix Hallpike body position, the head will hang past the chair frame supported by the examiner. Position the patient (depending on patient height) so the patient's head will hang while supported off the end of the chair. If comfortable, keep the patient seated with his/her feet off on either side of the exam chair for balance. Use the recline handle to recline the chair to be supine. The patient will look straight ahead with the goggle cover on in a vision-denied condition. Lower the patient into the Dix Hallpike position while supporting the head and the goggles in place. Use the RF remote, foot pedal, or side switch to start recording the eye movements. A double beep will sound when the test is scheduled to raise the patient back up to a sitting position, however using the RF remote, foot pedal, or side switch will end the supine portion early and play the double beep and allow the operator to finish the test earlier if desired.

It is also possible to add the advanced version of the test with the VORTEQ™ Assessment bundle available for *VisualEyes™ 505*, *VisualEyes™ 515,* and *VisualEyes™ 525.* This includes feedback to the clinician regarding correct head position, and recording of torsional eye movement. Refer to section 3.9.2.2 for further information of the *Dix Hallpike Advanced* test.



Figure 3.9-1 Chair in supine position for Dix-Hallpike with head support removed (Orion and System 2000)

3.9.1.4 Positional

This is a vision-denied test and the test can be performed on an examination table/reclining chair. If the reclining chair is used for the test, install the head support on the chair (Orion and System 2000). Lock the chair with the foot brake if using the System 2000 reclining chair. If applicable, leave the hook and loop straps (Orion and System 2000) from the head support detached from the goggles because the patient's head will be in different positions during this test. The seatbelt should be unfastened. While the operator supports the weight of the chair, lower the chair and patient to a supine position (refer to Figure 3.9-2). Proceed with each subtest, assisting the patient into each new head and body position as required. Use the RF remote, foot pedal, or side switch to begin recording after moving the patient's head or body into each position. When testing is complete, have the patient return to laying on his / her back, then push down on the chair recline lever and physically lift the chair back with the patient into an upright position.



Figure 3.9-2 Supine positional test

3.9.1.5 Caloric test

Caloric testing is completed with the goggle cover on for vision-denied testing. If using the System 2000 reclining chair, engage the foot brake to prevent the chair from rotating. Recline the chair to be thirty degrees above horizontal to perform the caloric tests. On the Orion rotary and System 2000 reclining chairs, there is a marker below the seat that shows the correct reclined orientation (refer to Figure 3.9-3). For the Nydiag 200 rotary chair, there is an inclination dial that displays the current chair angle near the top of the chair frame.



Figure 3.9-3 Reclined chair for caloric testing with caloric angle marker and inclination dial

When the caloric test is selected, VisualEyes™ will initialize the irrigator for the selected warm or cool temperature. The irrigator status will be displayed in the left menu panel. When the appropriate temperature has been reached, the status will change to 'Ready' and a beep will sound to alert the user. To begin recording, press the button on the AirFx or AquaStim irrigator handle. To abort the test, hold down the button on the irrigator handle for three seconds. Alerting tasks should be administered during the caloric tests to prevent the patient from suppressing the nystagmus.

A spontaneous nystagmus test can also be performed as a caloric subtest, which is recommended when spontaneous nystagmus is present in the caloric position. When spontaneous nystagmus is detected, the average SPV value can be used to correct the caloric summary by toggling the Spontaneous Correction option in the left menu panel.

If the wrong ear or wrong temperature was tested by mistake, a message will appear at the end of the subtest asking if the wrong test was performed. Options for switching to the appropriate ear or temperature will be available when this message appears. This change is only available upon completing the test and cannot be changed thereafter.

Caloric tests can display the eye position tracings, pods diagram and optional bar graph, Freyss diagram, Claussen graph, Haid stoll graph, total amplitude, or result table. Unilateral weakness, directional preponderance and cumulative slow phase velocity information will be present in the upper right corner of the summary screen.

3.9.1.6 Oculomotor tests

The oculomotor tests include Gaze, Smooth Pursuit, Random Saccade, Saccadometry, and Optokinetic tests. These tests are performed with the goggle cover removed so that the patient can follow targets as they move around on the TV, projector screen, or with the laser projected on the booth enclosure wall. During Gaze tests, the patient will fixate on stationary targets that are positioned at center, right, left, up and down. Random Saccade tests allow the target to move randomly in a horizontal, vertical or mixed pattern while the patient follows the target with his/her eyes. Smooth Pursuit tests the patient's ability to track a target that moves in a sinusoidal pattern across the screen. The target speed will increase from 0.1 Hz to 0.5 Hz in 0.1 Hz steps. The Optokinetic test is used to examine eye movements during stimulation from a large moving checkerboard pattern or stripe pattern produced by the optokinetic drum along the booth wall. All oculomotor tests will display real-time graphical data to help the clinician interpret the results for each individual test.

3.9.1.7 Ocular counter roll

This is a vision-denied test. Side mounted/front mounted/top mounted goggle with camera can be used for the test. Ensure that the patient is seated in the upright position. Before starting the test, the clinician will need to enter 'Calibration' and then go to 'Torsion Calibration' to establish the iris signature. The test will then have the patient hold his/her head in the center, then roll the head to the left and hold, and then roll to the right and hold.

3.9.1.8 Rotary chair tests

The VisualEyes™ system with the optional rotary chair can perform additional tests, including Sinusoidal Harmonic Acceleration (SHA), Step Test, VOR Suppression and Visual VOR. Rotary chair testing is completed with the goggle cover on or in the booth enclosure for vision-denied testing. The rotary chair is set in the upright position to perform the rotary tests. Ensure that the foot brake is disengaged if using the System 2000 reclining chair. Alerting tasks should be administered during the SHA and Step tests to prevent the patient from suppressing the nystagmus.

Sinusoidal Harmonic Acceleration is a vision-denied test. In this test, the patient is rotated in a sinusoidal pattern alternating from left to right at octave frequencies from 0.01 Hz to 0.64 Hz for System 2000 and Orion chairs and 0.01 Hz to 0.32 Hz for the Nydiag 200 rotary chair. Gain, phase and (a)symmetry graphs are displayed, along with tracings for eye velocity and eye position.

The Velocity Step Test is vision-denied test. This involves rotating the patient in one direction at a constant velocity for several seconds, then stopping the chair while recording continues. The same process is completed in the opposite direction. The four steps are then observed for gain, time constants and (a)symmetry. Step tests are performed at 50º/second and 180º/second by default, and 100º/second as a standard option. In addition, there are options to test at velocities between 10 and 200º/second. To include spontaneous nystagmus correction, a spontaneous nystagmus sub test can be added to the step test to provide a baseline nystagmus value. Eye velocity and eye position tracings are displayed.

The VOR Suppression test can be performed in the same manner as SHA except that the fixation light within the goggles is illuminated so that the patient can fixate on the target during rotation in order to suppress the response. Goggle cover is on all reclining chairs and goggle cover is always left off when the test is performed inside the light tight booth of Orion/System 2000 AT/C Chair. Visual VOR is also like SHA but is performed with the goggle cover removed even for reclining chair. The patient is instructed to focus on a target on the TV for reclining chair, a projector screen or stationary optokinetic drum stripes (laser) on the booth wall for Orion/System 2000 AT/C chair. Visual VOR is typically performed only at 0.32 Hz.

The Orion/System 2000 AT/C chairs include the subjective visual vertical test for measuring otolith function. During the test, the goggles are removed from the chair and the patient's head is strapped to the head support. In the static SVV test, the patient establishes a static visual vertical value by rotating the laser line to orient the line with the patient's perceived vertical. In the dynamic SVV test (this can be done only with Auto-Traverse chair), the chair rotates at 300 dps while the chair is aligned at the center axis. The chair is then moved 4 cm to the left, back to center, then 4 cm to the righ, and then the chair is returned to center and slowed down to a stop. The patient must adjust the laser line at each chair position using the SVV remote to perceived vertical.

3.9.2 VORTEQ™ assessment

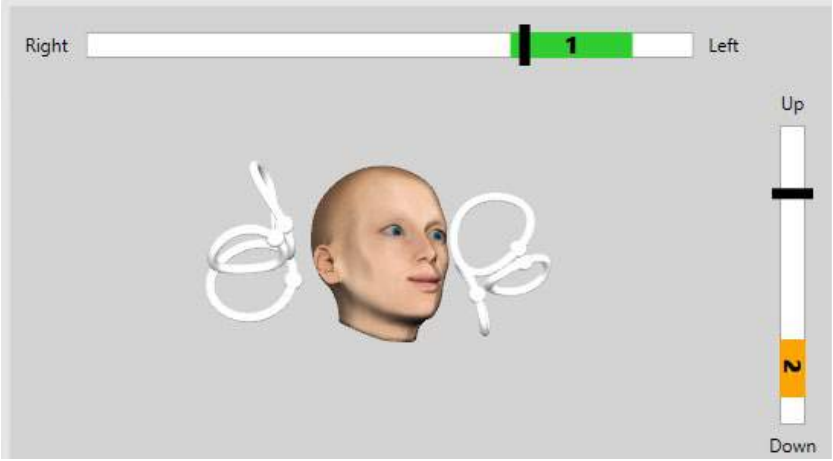
VORTEQ™ Assessment can be added to *VisualEyes™ 505, VisualEyes™ 515* and *VisualEyes™ 525*, and includes the *Dynamic Visual Acuity*, *Dix Hallpike Advanced,* and *Lateral Head Roll* tests. The tests all require the use of the VORTEQ™ IMU.

3.9.2.1 Dynamic visual acuity

This test does not require any goggle. Ensure the chair is in the sitting position and locked. Attach the VORTEQ™ IMU to the DVA headband. Before starting the test, the patient will establish his/her static acuity by correctly defining the C character without shaking the head. The test will then proceed with testing each direction while the patient shakes his/her head to the sound of a metronome. Have the patient smoothly shake his/her head side to side for horizontal testing or up and down for vertical testing.

3.9.2.2 Dix Hallpike advanced

The Dix Hallpike Advanced is performed similarly to the Dix Hallpike test described in section 3.9.1.3, however the Dix Hallpike Advanced furthermore allows the clinicial to record torsional eye movements, and use the VORTEQ™ IMU to get feedback for the patients head position through the 3D head model guide to show if the patient has the head in the appropriate position. The spatial position of the head will be presented with a black bar on the two position sliders. The shaded areas on the position sliders present the desired position of the head. When the head is positioned in the desired angle the shaded area will turn green instead of orange.

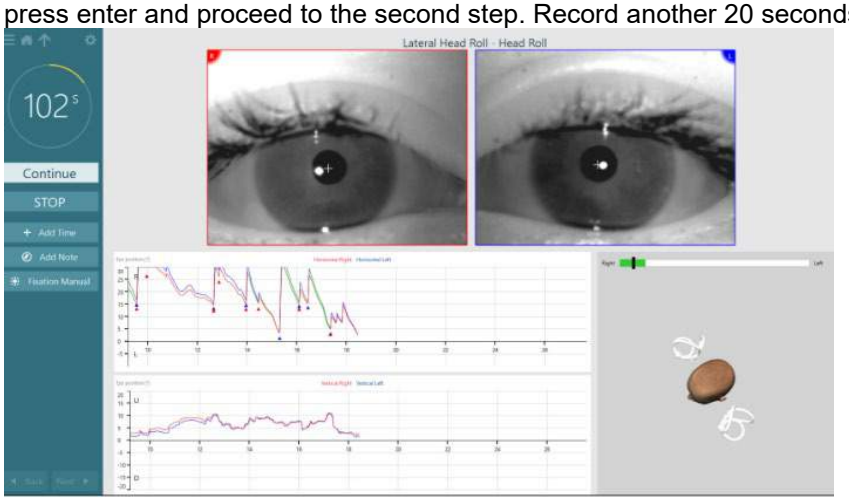


3.9.2.3 Lateral head roll

The Lateral Head Roll test is performed to identify horizontal canal BPPV, and includes the 3D head model guide to assist in proper head placement during the test.
Make sure the VORTEQ™ IMU is attached to the goggle and turned on. The test is performed with the patient supine (laying down).

1. Step 1 is to turn the patient's head 45 degrees towards the right.
2. Step 2 is to turn the patient's head 45 towards the left.

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



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

3.9.3 VORTEQ™ diagnostic

VORTEQ™ Diagnostic can be added to *VisualEyes™ 525*, and includes *Active Head Rotation, and vHIT VORTEQ™*. The tests all require the use of the VORTEQ™ IMU.

3.9.3.1 Active head rotation

Ensure the chair is in the sitting position and locked. If applicable, leave the hook and loop straps (Orion and System 2000) from the head support detached from the goggles. Attach the VORTEQ™ IMU to the binocular goggles. The start of the test will have the patient shake his/her head to the sound of a metronome at the low frequency of the test for ten seconds as practice then the test will begin. Have the patient smoothly shake his/her head side to side for horizontal testing or up and down for vertical testing. If the test is performed with a wrong orientation, the operator gets a warning message from the software.

3.9.3.2 vHIT VORTEQ™

Ensure that the patient is seated in an upright position and the head rest of the rotational chair is taken off. Ensure the calibration is done before starting the test. Side mounted/top mounted goggle with camera can be used for this test. Make sure the IMU is connected and switched on before starting the test.

3.9.4 EyeSeeCam vHIT

The test is performed with the EyeSeeCam goggle, and includes subtests for Lateral, RALP, and LARP vHIT testing, along with the SHIMP test. Ensure that the patient is seated in an upright position with arm rest and low back rest, 1.5 meters from a wall where the red laser dots are projected on to. Prior to performing the vHIT tests, conduct the calibration as described in section 3.7.3.

3.9.4.1 Lateral VHIT

The Lateral vHIT test assesses the function of the lateral semicircular canals. For this test, hold the patient's jaw while standing behind the patient (Figure 3. 6-7). During the test, the patient's teeth should be clenched so the hand thrust will be transferred to the patient's head. Practice a few impulses before beginning the recording. This will also familiarize the patient with the stimulus. Do **not** allow the hands to touch or move the goggles during head impulses as that movement will affect the gain measurement.



Figure 3.9-4 Lateral vHIT hand placement

3.9.4.2 Left Anterior Right Posterior (LARP) / Right Anterior Left Posterior (RALP) vHIT

The LARP and RALP tests assess the function of the vertical semicircular canals. For assessing the function of the vertical semicircular canals, the head is rotated right-downward to left-upward in the plane of the right anterior and left posterior canals (RALP) or left-downward to right-upward in the plane of the left anterior and right posterior canals (LARP). Alternatively, the head can be rotated 45 degrees to the right for LARP testing and 45 degrees (Figure 3. 6-8) to the left for RALP testing. Regardless of setup the patient must always gaze straight ahead.

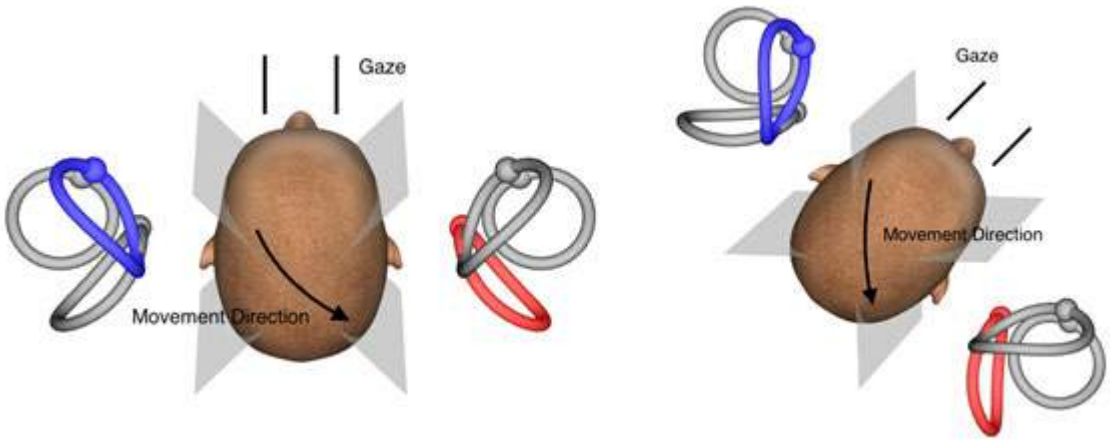


Figure 3.9-5 vHIT testing with head-on gaze and corrected straight gaze in LARP testing

3.9.4.3 Performing the test

A three-dimensional head model with the semicircular canals (Figure 3. 6-9) is displayed in the upper right corner of the screen. The EyeSeeCam head sensor will automatically reset if the sensor is left still. At the start of the test, have the patient look straight ahead and keep the head still. The EyeSeeCam head sensor will then reset and the head model should appear looking forward. As the head impulses are performed, the activated semicircular canal pair are highlighted in blue and red depending on the direction of the impulse.

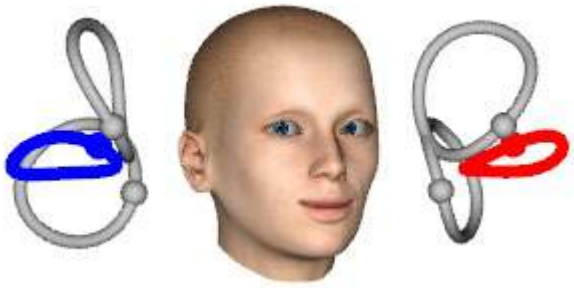


Figure 3.9-6 Head model with highlighted semicircular canals

When the operator performs the head impulse, the software will display the head movement and eye movement in the appropriate impulse graph depending on the impulse direction. If the head movement fits the swoosh velocity profile, the head impulse will be accepted and show a green check mark in the upper right corner of the impulse graph (Figure 3. 6-10). Rejected head impulses will display a red x in the upper right corner.

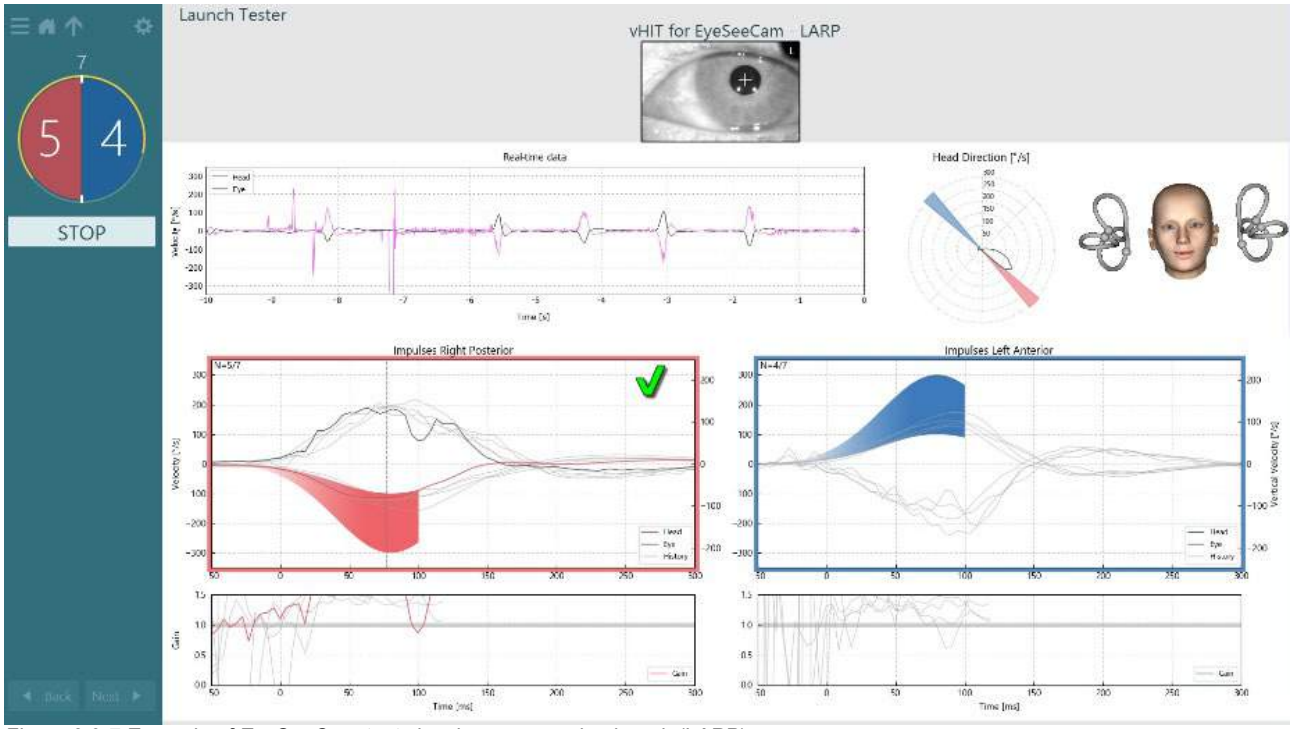


Figure 3.9-7 Example of EyeSeeCam test showing a green checkmark (LARP)

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

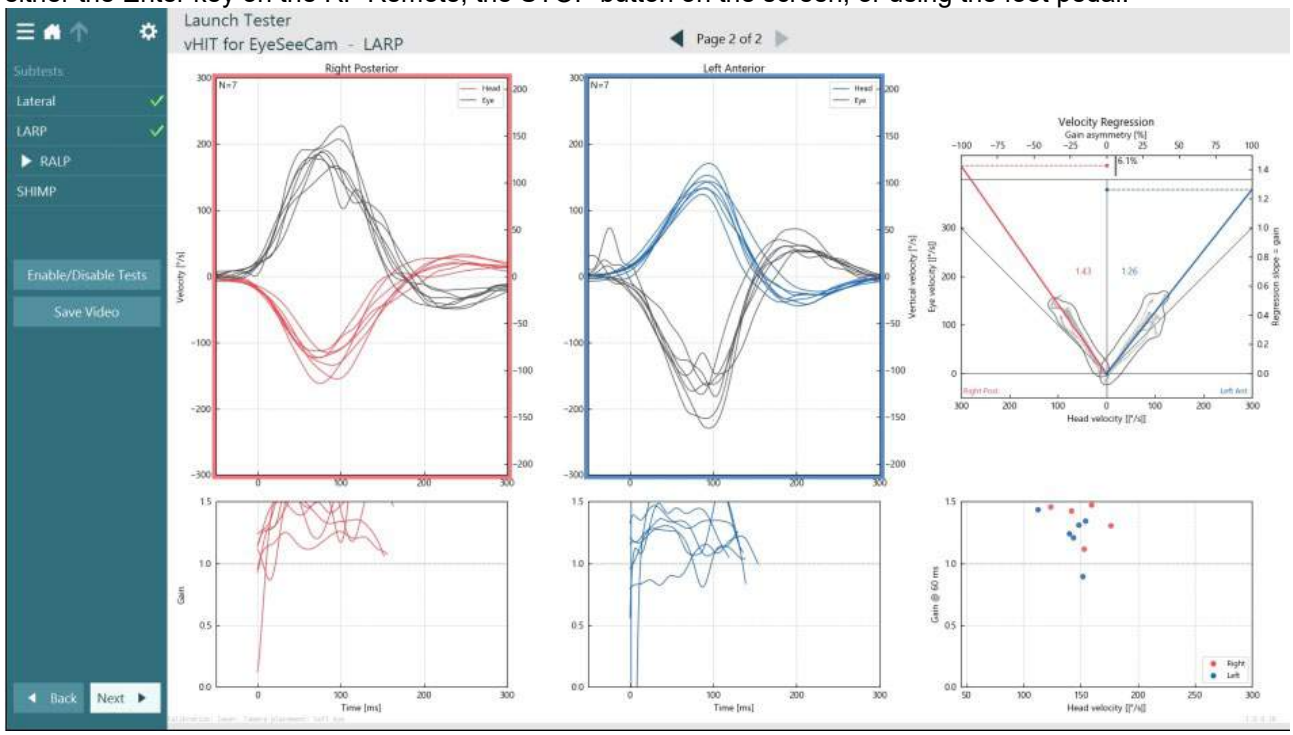


Figure 3.9-8 VHIT EyeSeeCam analysis

As each subtest is performed, the software displays each subtest's analysis on a page (Figure 3. 6-11). The analysis displayed is defined by the page navigation at the top of the screen. Once the Lateral, LARP, and RALP tests have been performed, the EyeSeeSix report can be created from the vHIT for EyeSeeCam summary's side panel. If a subtest is repeated, the desired subtest can be selected from the combo boxes at the top of the EyeSeeSix report (Figure 3. 6-12).

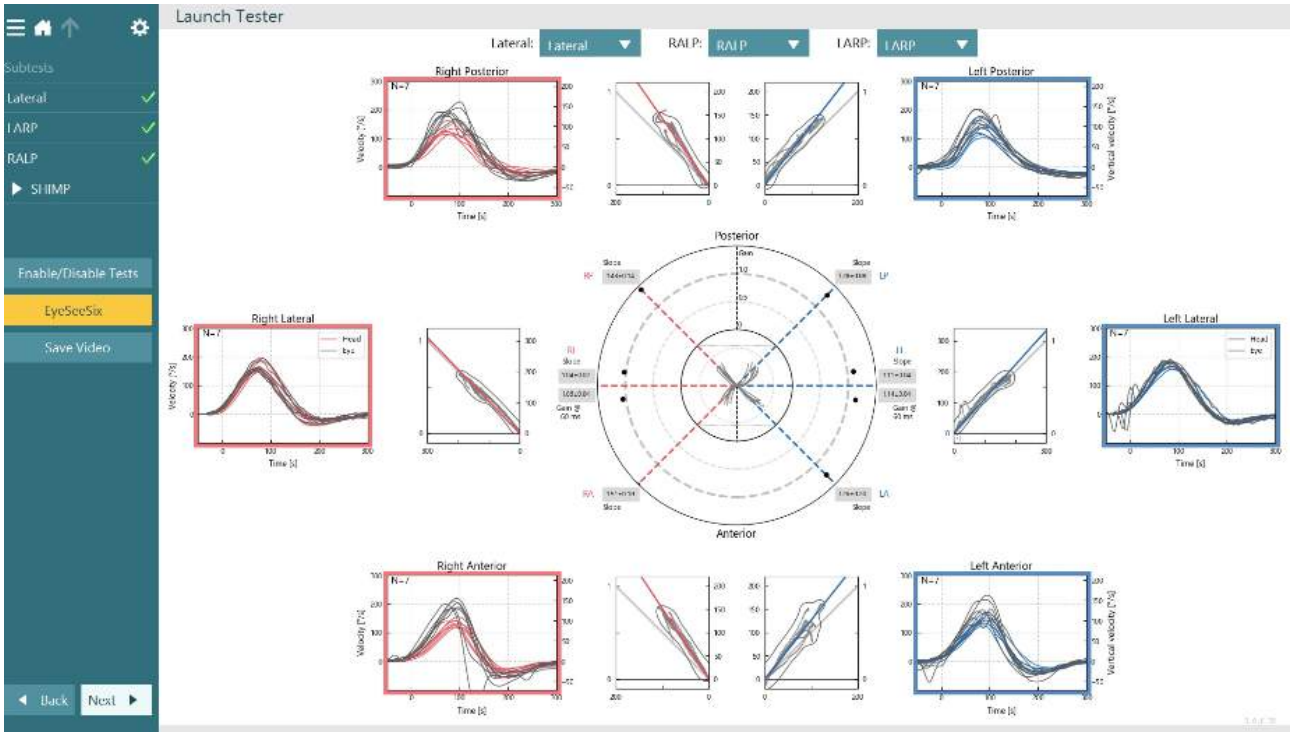


Figure 3.9-9 VHIT EyeSeeSix report

To view the information in a tabular form, click on the Numerical Results button (Figure 3. 6-13). The text can be copied (click and drag or by using Ctrl + A on the keyboard) and pasted into Excel or other spreadsheet software.

Summary

Velocity Gain

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

Saccades

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

Data

Saccade Parameters

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

Figure 3.9-10 Numerical Results

Clicking on the 3D Waves button will toggle the display of the waveforms in 3D space (Figure 3. 6-14).

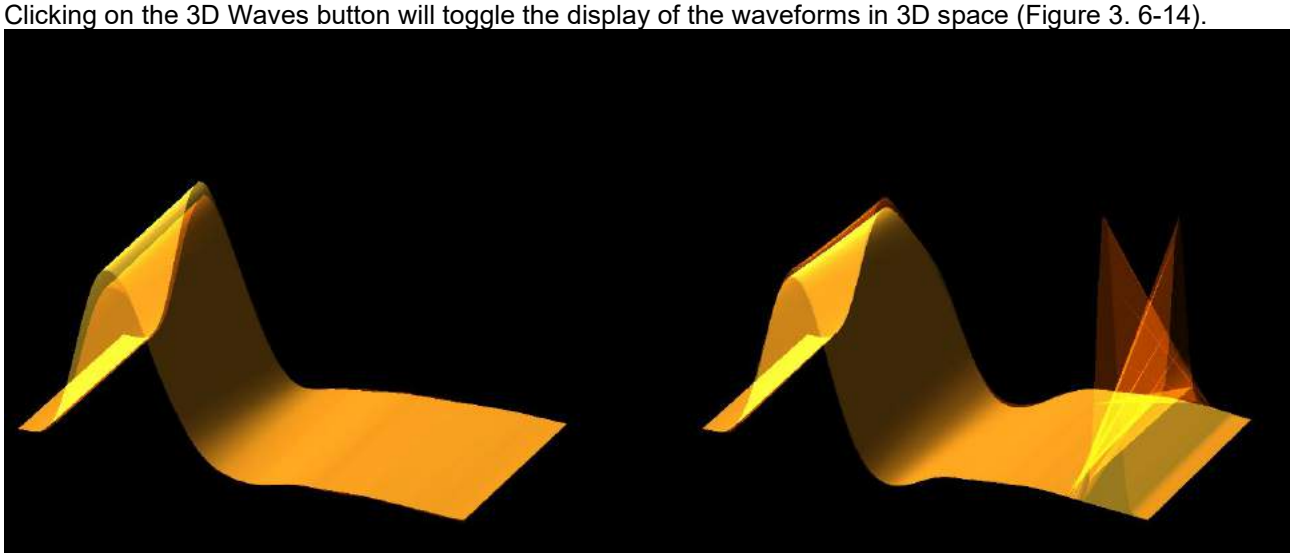


Figure 3.9-11 Eye movements rendered in 3D space

Suppression Head IMpulse Paradigm (SHIMP) test

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

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

Test preparation:

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

Performing test:

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

The VOR gains should be similar in vHIT and SHIMP tests. However, the pattern of saccades generated is different. vHIT rarely generates compensatory saccades in normal patients, while in SHIMP testing, healthy subjects will make a large anti-compensatory saccade at the end of the head turn (Figure 3.9-12). This is referred to as a "SHIMP saccade". This pattern of result is exactly opposite for impaired patients. An impaired VOR system will lead to a catch-up saccade on the vHIT but no (or very few) compensatory SHIMP saccades. Sample test and result screens are provided below (Figure 3. 6-15 and Figure 3. 6-16).

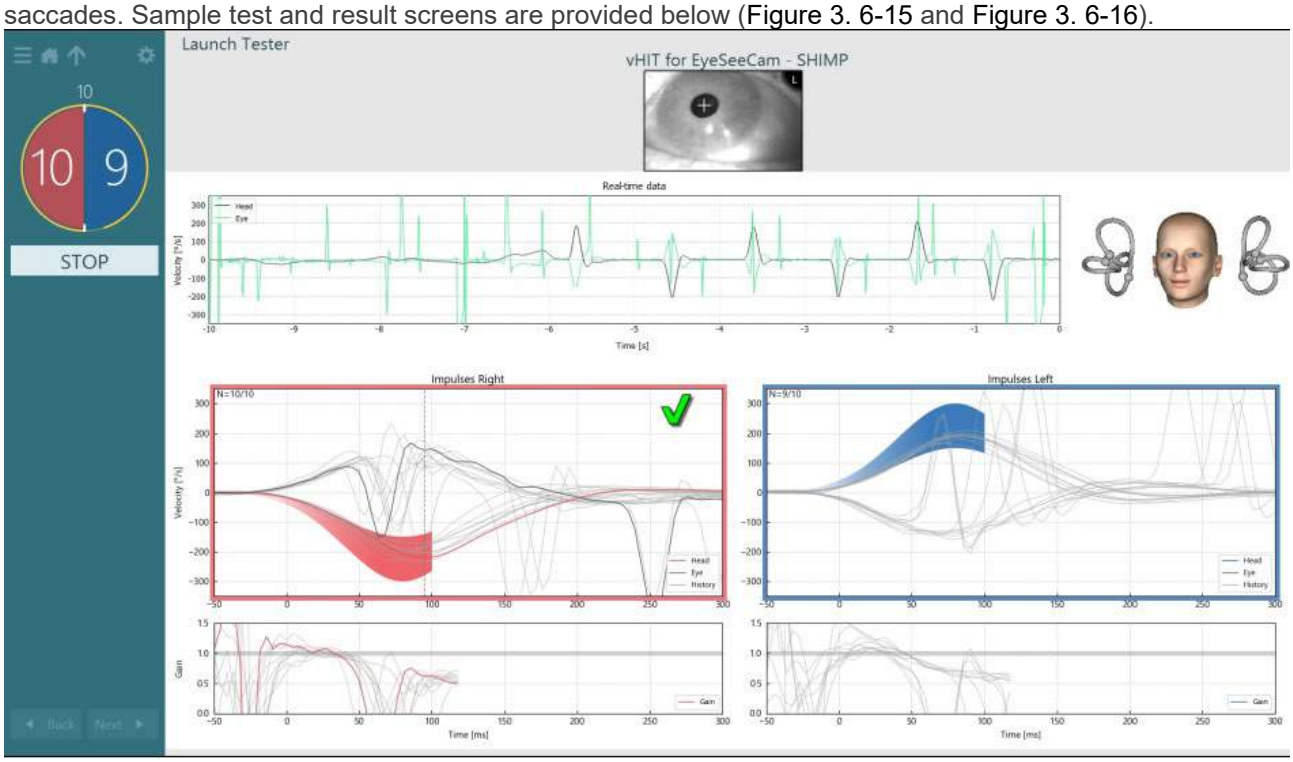


Figure 3.9-12 Test screen for SHIMP test

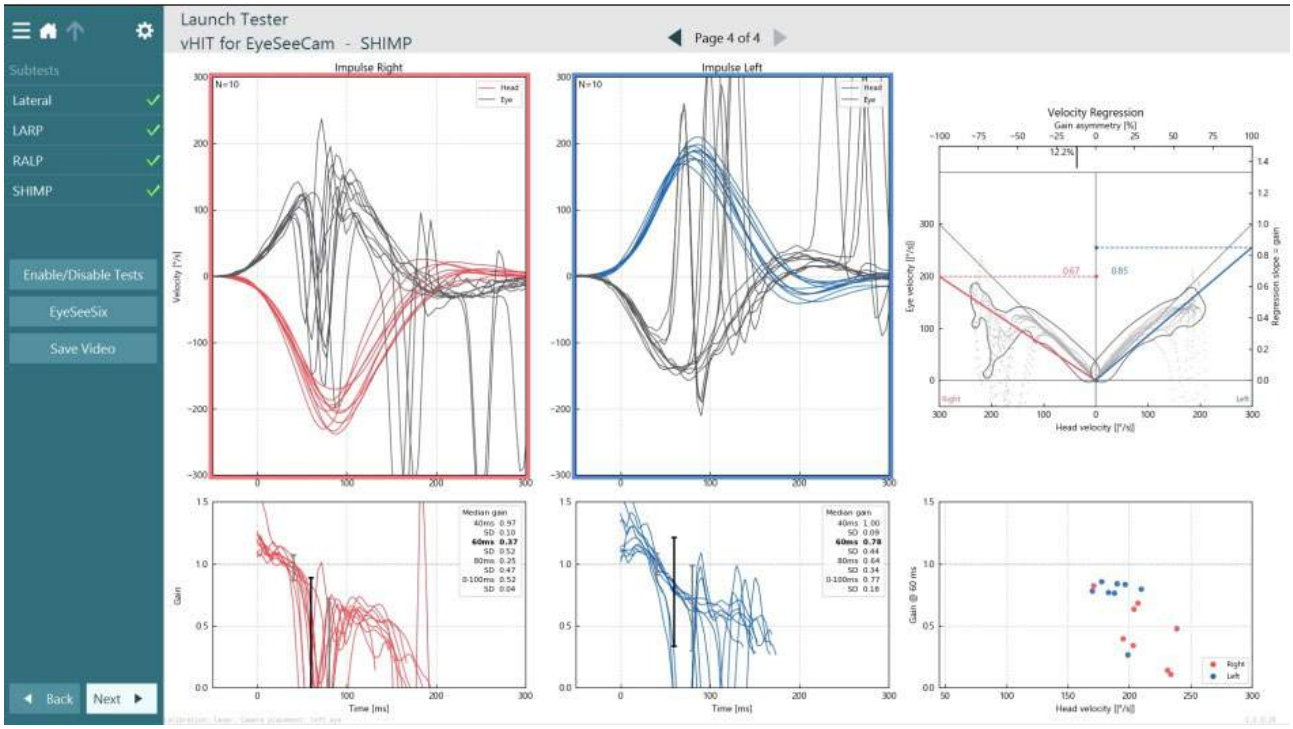


Figure 3.9-13 Result screen for SHIMP test

3.10 Test review screen

Once the operator has ended the test, the software will allow the operator to review the patient's response during the test. The test review screen (Figure 3.10-1) contains the playback menu, timeline, eye and room video recordings. The eye videos and room camera video are played synchronously from the Test Review screen. The playback will begin by clicking on the play button in the playback menu. As the test plays back, a yellow circle will show the current position of the video on both the timeline and the playback timer. This circle can be grabbed or dragged with the mouse to jump to a new location in the video playback. The size slider is available during the test review, allowing the user to make the eyes or the room camera video larger dynamically to focus on the selected video during playback.

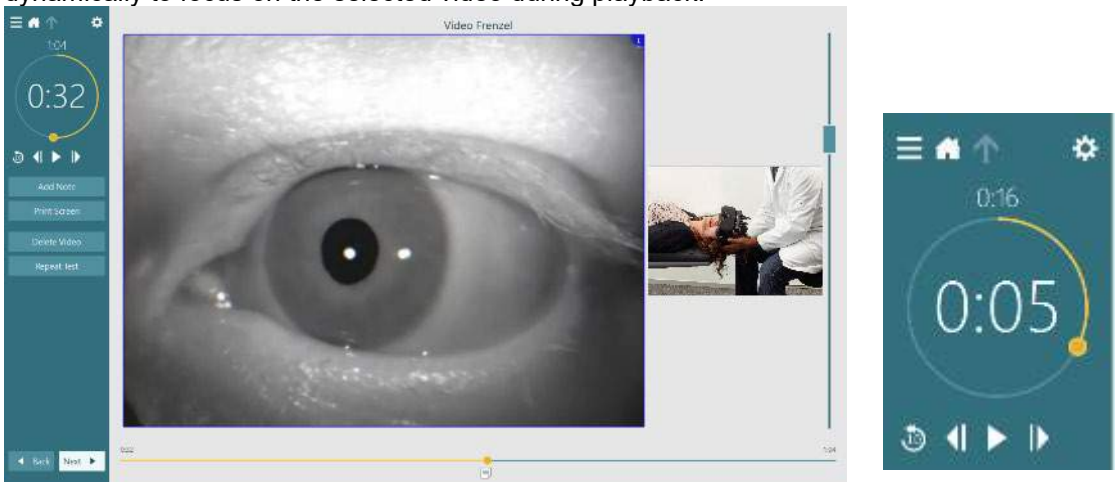


Figure 3.10-1: Test Review screen



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

Play/pause.

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

Go back 10 secs in video playback.

3.10.1 Edit tools

For most test types edit tools are available from the Test Review screen. The tools available are highly dependent on the test type. For a detailed description of editing tools for specific tests, refer to Additional information.

3.11 Review previous sessions

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

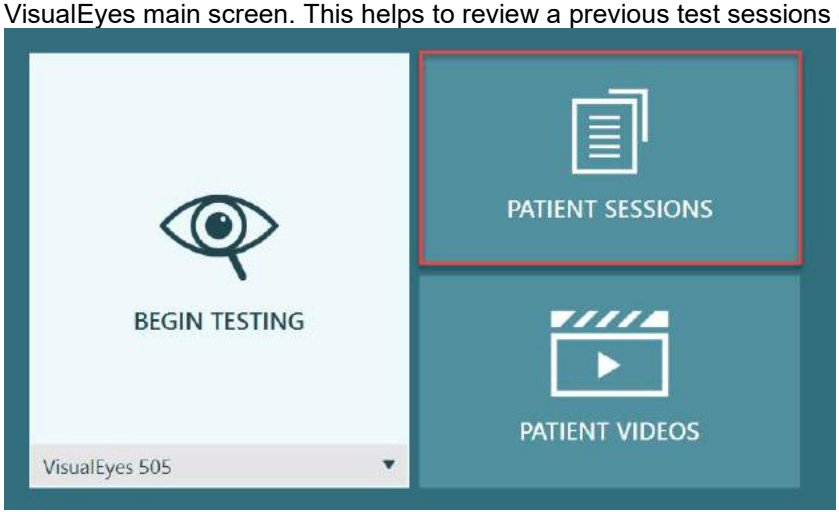


Figure 3.11-1: Patient Sessions button

The Patient Sessions screen (Figure 3.11-2) displays a list of all previous test sessions in the side panel menu. Selection of a specific session date will display all the tests performed on that date and an indication of whether the test results were completed (green checkmark). When completed and the test is outside of threshold, it will be marked with a red diamond.



Figure 3.11-2 Patient Sessions screen

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

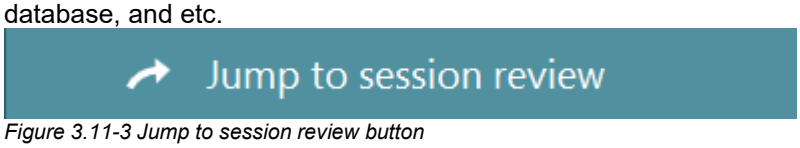


Figure 3.11-3 Jump to session review button

3.11.1 Session review

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



A drop down menu will appear with the ‘Review Session’ button displayed at the bottom.

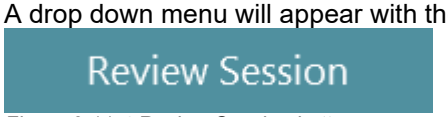


Figure 3.11-4 Review Session button

Review Session will list the tests within the protocol that have been or are yet to be completed (Figure 3.11-5). A symbol will be present next to completed test names indicating whether the test resulted in a within-threshold-outcome (green tick) or an outside-of-threshold-outcome (red diamond). Tests can be reviewed, clinical report can be written, and the tests can be printed from the Session Review screen.

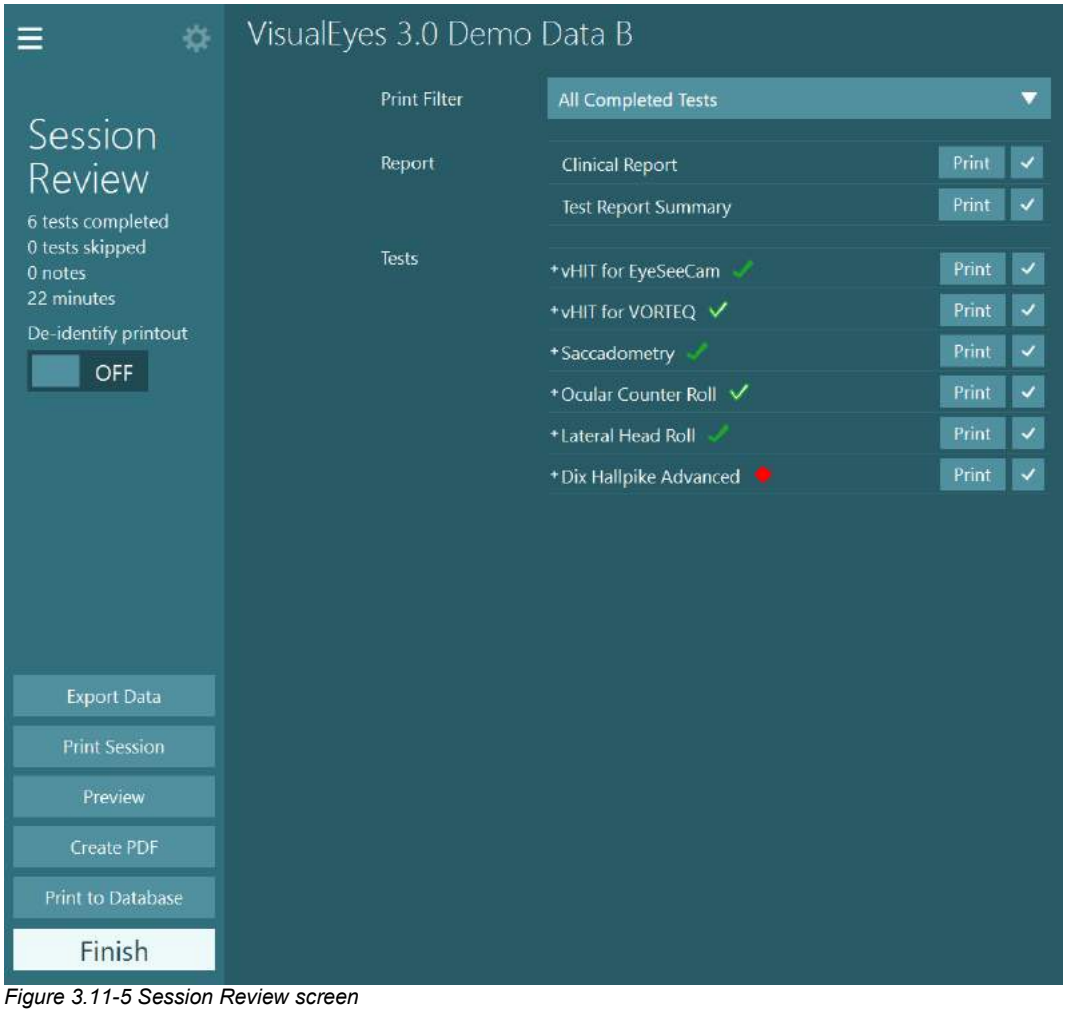


Figure 3.11-5 Session Review screen

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

3.12 Review patient videos

If video recording has been enabled during the patient sessions, the videos may be reviewed after testing. The recorded videos are available from the **PATIENT VIDEOS** menu from the main screen (Figure 3.12-1).

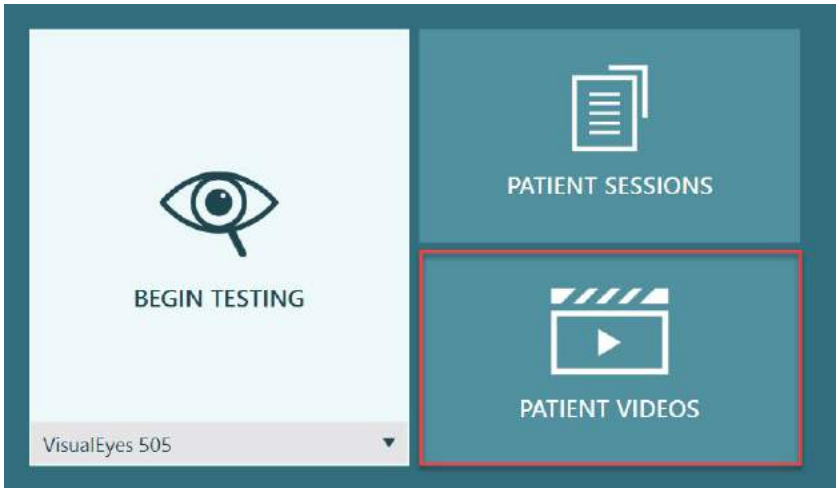


Figure 3.12-1: PATIENT VIDEOS button

In the Patient Videos menu, the videos are categorized by date and test type.

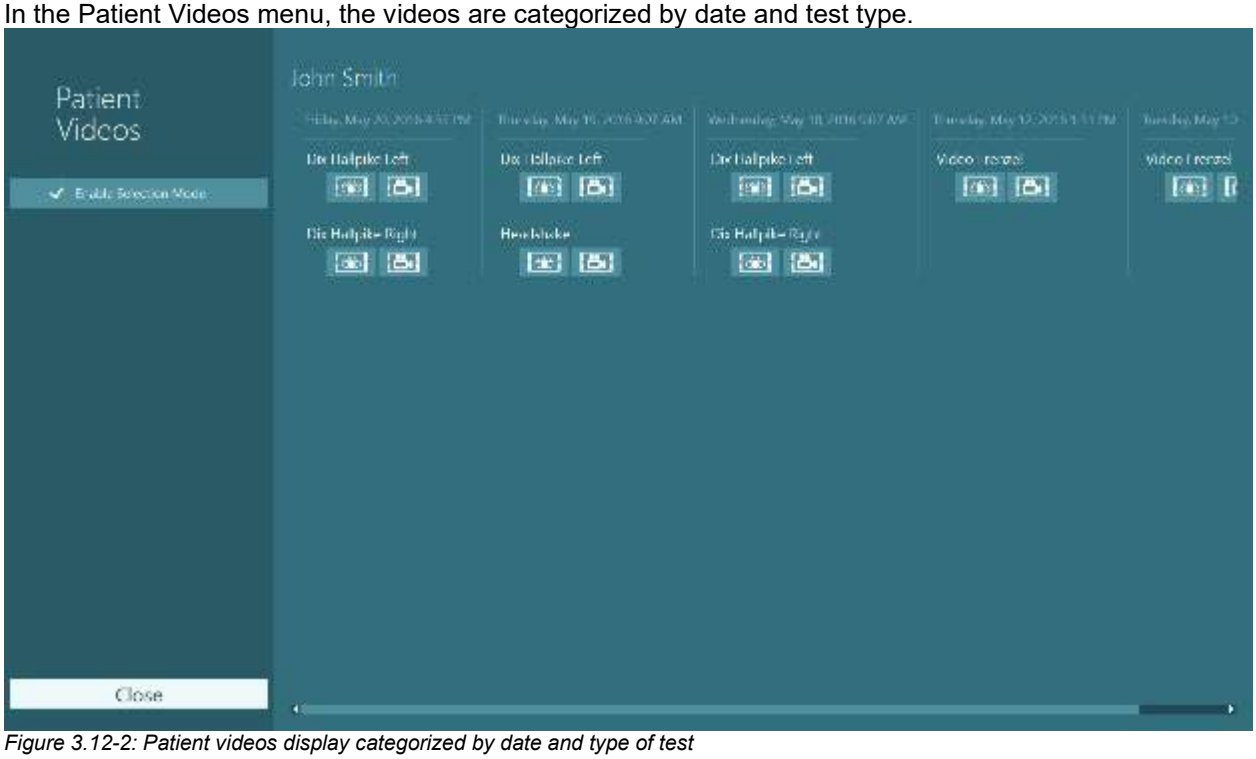


Figure 3.12-2: Patient videos display categorized by date and type of test

To playback the video click on the video file of interest. It will be launched in a compatible video player.



Video of eye recordings (no raw data).



Videos of room recording.

By selecting the **Enable Selection Mode** in the left side panel, it is possible to select videos to be deleted or exported.

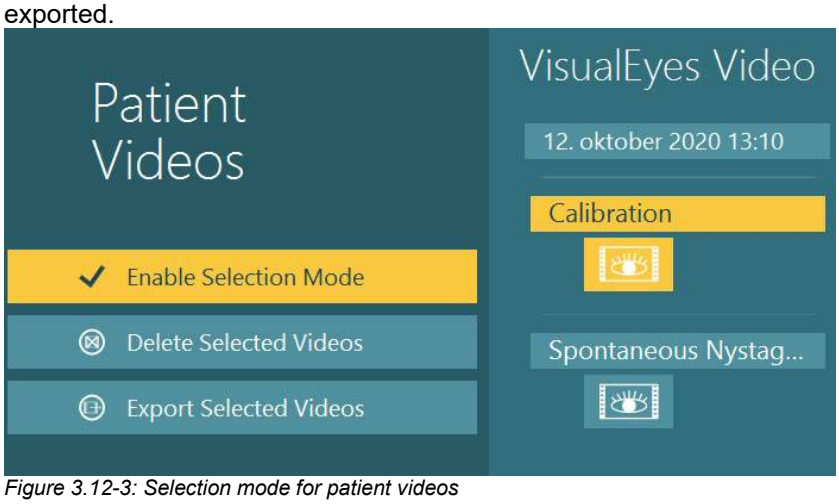


Figure 3.12-3: Selection mode for patient videos

When selecting and exporting both eye and room videos for the same session, it is possible to combine these into one video by checking the **Combine eye and room videos** in the Export Video Files menu that will be presented when clicking Export Selected Videos.



Figure 3.12-4: Export Video Files menu. Destination folder can be selected and it is possible to combine eye and room videos

3.13 Research module

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

3.13.1 Nystagmus parameters

This feature will work with any completed test with recorded eye movements.

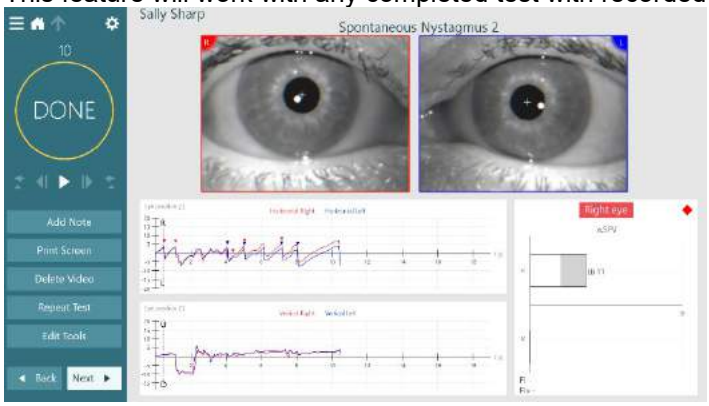


Figure 3.13-1 Nystagmus test screen

For example, for the above test, you can enter the temporary settings menu and adjust the parameters to accommodate your research protocol.

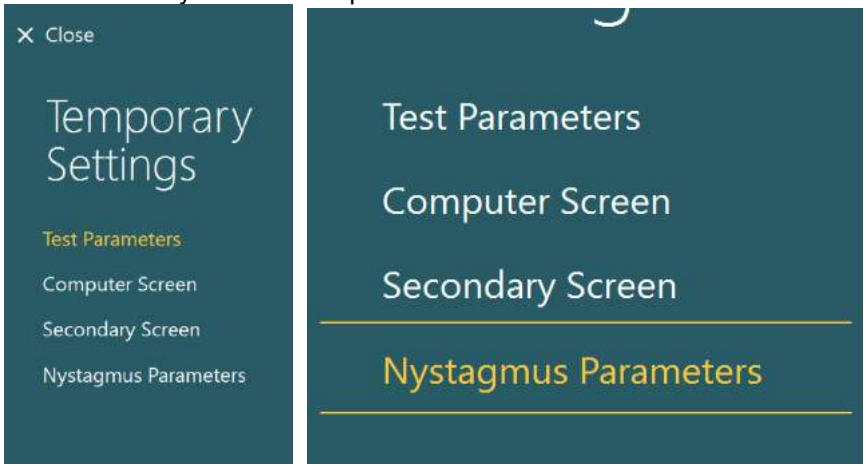


Figure 3.13-2 Nystagmus parameter settings

Once in the settings menu, you can adjust the parameters that are used in the nystagmus detection algorithm.

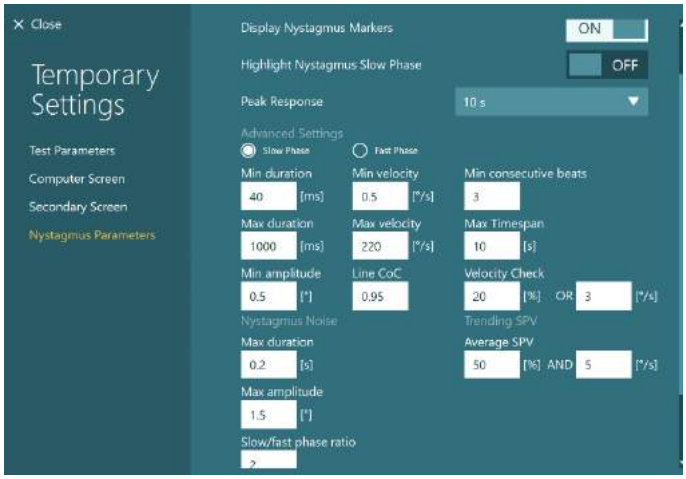


Figure 3.13-3 Nystagmus parameters in the Research Module

3.13.2 Data export

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

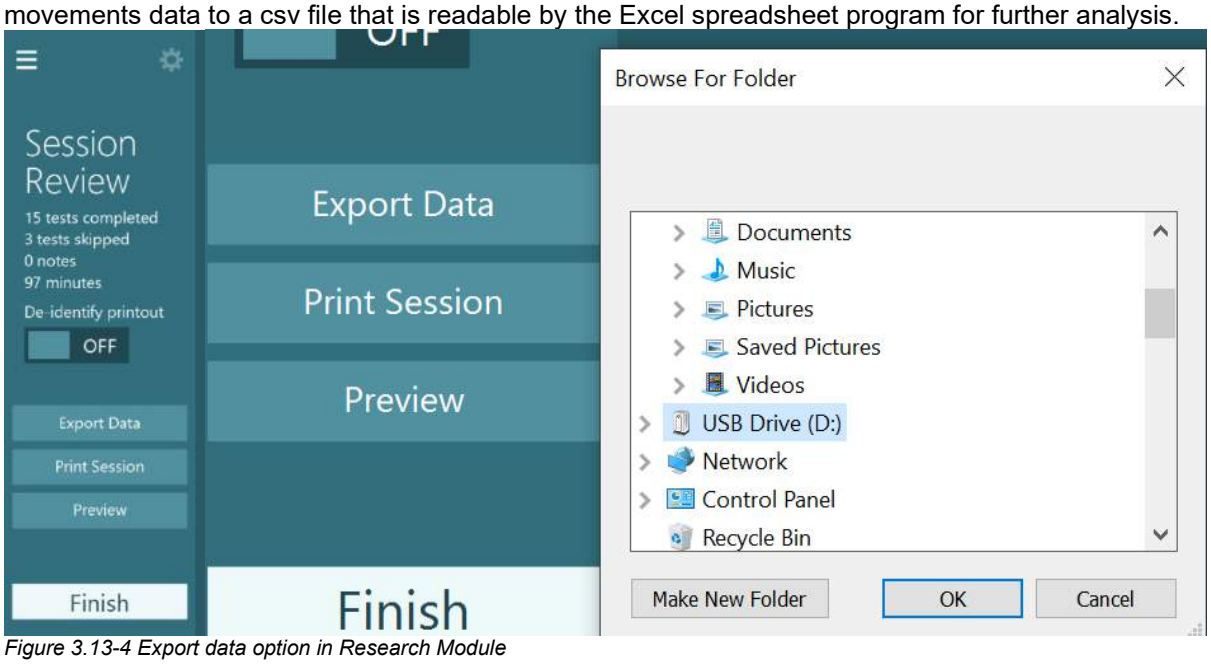


Figure 3.13-4 Export data option in Research Module

3.14 System shutdown

- **Turn off computer**

Firstly, close the VisualEyes™ software by returning to the main screen and selecting the Exit button. Close the OtoAccess® Database software. Shut down the computer using Start > Shut down.

- **Turn off stimulus**

Turn off the TV/projector.

- **Turn off accessories**

If the Orion Reclining Chair or Nydiag 200 Reclining Chair is used, turn off the power switch in the base of the chair. Turn the VORTEQ™ IMU off if applicable. If the System 2000 chair is used, turn off the power to the chair controller using the power switch on the back of the controller. If the DataLink is used, turn off the power using the power switch on the back of the device. If the AirFx air irrigator or AquaStim water irrigator is used, verify the irrigator is in the standby state first, then switch off the irrigator from the power switch on the back of the irrigator. If the observation camera for the Orion Auto-Traverse/Comprehensive chair is used, turn off the observation monitor.

- **Turn off power sources**

The USB hub should be disconnected from power by turning off the USB hub using the button on the hub, or turning off the power source powering the USB hub.
This will remove power from the cameras when not in use. Isolation transformers should be turned off using the power switch after any other devices have been powered off.

4 Care and maintenance

4.1 How to clean the VisualEyes™ system

Before you clean:



- Always switch off and disconnect from the power before you start cleaning
- Do not allow liquid to enter the components of the VisualEyes™ system
- Do not autoclave, sterilize or immerse the equipment or accessory in any fluid
- Do not use hard or pointed objects to clean any part of the equipment or accessory

Cleaning procedure:
Recommended cleaning and disinfectant solutions
Lens cleaning cloth (microfiber), damp cloth, Sani-Cloth AF3 disinfectant wipes

NOTICE: **Please follow the instructions on the label of Sani-Cloth AF3 disinfectant wipes for usage and disposal**.

Procedure:

- Video goggles and goggle straps should be cleaned with a Sani-Cloth AF3 disinfectant wipe between patients
- Goggle mirrors, camera lenses and IR coated mirrors must be cleaned regularly with microfiber lens cleaning cloth to remove stains and dust and this helps to avoid shadows on the displayed images
- Side mounted camera goggles straps can be machine washed at 40°C using normal washing detergents. Do not tumble dry. Please note that the elastic qualities may deteriorate after more than 10 washing cycles, after which the straps should be replaced
- Foam pads used in the side mounted camera goggles must be replaced after every single patient to avoid cross infection. Refer to 2.6.1.1 to know how to replace these foam pads
- The touch screen on PC can be cleaned by the microfiber lens cleaning cloth when the monitor is turned off. If the touch screen needs further cleaning, use a Sani-Cloth AF3 disinfectant wipe to clean the surface**.** Allow the cleaning solution to completely dry before turning on the computer and monitor
- All other external / exposed surface of the equipment and accessories can be regularly cleaned with a soft damp cloth. This includes rotational chair, booth wall, projector, keyboard, mouse, mouse pad, remote, emergency switch etc.

4.2 Warranty and service

- **Product warranty**

Interacoustics warrants that:

- The VisualEyes™ system 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 component requires service during the applicable warranty period, the purchaser should communicate directly to the local distributor 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 with proper packing, 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. Directly or indirectly, Interacoustics does not give/grant the authority to any representative or other person to assume on behalf of Interacoustics for 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.

Concerning product repair / service
Interacoustics is responsible for the validity of the CE marking, effects on safety, reliability and performance of the equipment if:

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

The customer shall reach out to the local distributor to determine the service/repair possibilities including onsite service/repair. It is important that the customer (through local distributor) fills out the **RETURN REPORT** every time when the component/product is sent for service/repair to Interacoustics.

4.3 Rotational chair error messages

- **Rotary chair speed error (applicable for Orion and System 2000 rotational chairs)**

If the rotary chair has not been calibrated previously, then the chair's tachometer and signal traces will not align, resulting in the chair spinning slower or faster than intended. The operator gets the error message below. The operator should calibrate the chair from the System Default Settings screen.

Chair Speed Error Occurred. (> 20 d/s). Perform calibration from System Default Settings.

- **Patient safety error (applicable for all types of rotational chairs)**

If the patient's age lies outside the required age range for performing a rotary chair test, the software will give the error below stating the patient cannot perform the test if the velocity or frequency exceeds the allowable limit for the patient's age.

Velocity is set to 100 which exceeds the recommended value for a patient below 5 years.

- **Emergency stop error (applicable for Orion and System 2000 rotational chairs)**

If the operator presses the Emergency Stop button during the rotary chair test, the chair will stop, and the software will present the error message below. The operator can resume rotary chair testing by disengaging the emergency stop and restarting the test.

Emergency stop button was engaged or Chair Controller was powered off. Turn on the Chair Controller and disengage the Emergency Stop in order to perform rotational testing.

- **Chair servo error state error (applicable for Orion and System 2000 rotational chairs)**

If the Orion or System 2000 reclining chairs try to spin and fail due to obstruction, chair brake (System 2000) or hardware failure, the software will detect the error as an emergency stop error first, and when the test is restarted, the software will give the chair servo error state message below. The operator can resume rotary chair testing with the Orion chair by pressing the Emergency Stop button until the light turns off in the switch (approximately 20 seconds), then disengage the emergency stop and restart the test. The operator can resume rotary chair testing with the System 2000 reclining chair by switching off the chair power switch for approximately 20 seconds, then turn on the power switch and restart the test.

Chair is not moving due to servo error state. Press the emergency stop till the red light in the switch goes off. Then try again.

- **Rotary chair reclined position error (applicable for Orion and System 2000 reclining chair)**

If the Orion Reclining or System 2000 Reclining chair is reclined during a rotary chair test, the software will present the error message below. The operator can resume rotary chair testing by setting the chair upright and restarting the test.

Chair is reclined or powered off. Set the chair to an upright position and check that chair is powered.

- **Booth door open error (applicable for Orion Auto-Traverse/Comprehensive chair)**

If the Orion Auto-Traverse or Orion Comprehensive chair's booth enclosure has the door opened before or during testing, the software will display the below error message saying that the door must be closed to resume testing.

Booth door is open. Close the door to continue testing.

- **Patient safety switch error (applicable for Orion Auto-Traverse/Comprehensive chair)**

If the patient pushes the abort switch provided with Orion Auto-Traverse/Comprehensive chairs, the software will display the following message and stop the rotational chair, laser and drum hardware. The test can be restarted after the operator has addressed patient concerns.

Patient pressed the safety switch error.

- **Chair control board error (applicable for Orion Auto-Traverse/Comprehensive chair)**

If the Orion Auto-Traverse chair's USB cable disconnects during the test, the chair, laser and optokinetic drum will turn off and gradually come to a stop. The software will present the following error message to the operator. Reconnect the USB cable from the chair to resume testing. This error condition will also happen if there is no power to the chair base.

Chair control board not detected. Please check configuration and cable connections then try again.

- **Watchdog timeout error (applicable for Orion Auto-Traverse/Comprehensive chair)**

If the system with an Orion Auto-Traverse/Comprehensive chair stops responding, the Emergency Stop circuit will activate and the chair, laser and optokinetic drum will turn off and gradually come to a stop. Following, the operator shall exit the test or go to the home screen and restarting the test will reset the watchdog timer. This is indicated by the Emergency Stop lighting up again.

4.4 Cameras disconnecting

If unusual behavior is experienced such as camera images dropping out and not coming back, USB device disconnects, or software not running as expected, perform the follow sequence to recover:

- Shut down the VisualEyes™ software completely.
- Unplug all USB devices from the computer and leave it unplugged for 20 seconds.
- Plug USB devices back into the computer.
- Once all the USB devices have been initialized, restart the VisualEyes™ software.

5 General technical specifications

5.1 Minimum computer requirements

Desktop PC: One PCI Express card available (FireWire® systems only).
USB port required (expanded by USB hub)
Intel i5 processor 2.5 GHz or better, and not older than 5th generation. Minimum 4 cores (4 threads).
Minimum 8 GB RAM or more.
Hard drive with min. 250 GB space.
Minimum display of 1366x768 (Higher resolution recommended).
Touch monitor or laptop with touch screen is highly recommended though not required.

Operating systems supported:
Windows® 7 64-bit.



Using operating systems where Microsoft have discontinued software and security support will increase the risk for viruses and malware, which may result in breakdowns, data loss and data theft and misuse. Interacoustics A/S cannot be held liable for your data. Some Interacoustics A/S products support or may work with operating systems unsupported by Microsoft. Interacoustics A/S recommends you to always use Microsoft supported operating systems that are kept fully security updated.
Windows® 8.1 64-bit.
Windows® 10 64-bit.

5.2 Standards

IEC 60601-1: 2012	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2: 2014	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests
ANSI S3.45	Performance standard

Systems can operate on 100 to 240 VAC at frequencies of 50/60 Hz. A grounded plug can be used for the intended voltage, frequency and socket style used in the customer's region. Only power cables supplied should be used with the equipment. When used with the rotary chair, an isolation transformer is used to supply power to the components from power mains.

5.3 Goggles



Side Mount (2D-VOGFW)

Quick Description:	Goggle with side mounted cameras. This goggle is highly versatile and will be able to fit the use of most clinics as it can be configured with either FireWire or USB connection and either monocular or binocular.	
Technical Specifications:		
Standards:	IEC 60601-1 Type BF	
Operation Environment:	Temperature: Relative Humidity:	15 – 35°C 30 – 90%
Transport & Storage Environment:	Transport Temperature: Storage Temperature: Relative Humidity:	-20 – 50°C 0 – 50°C 30 – 80%, Non-condensing
Interface:	FireWire / USB 2.0	
Cable Length:	4.5m (3m for Orion Reclining)	
Camera Configuration:	Monocular / Binocular	
Removable Cover:	Yes	
Eye Movement Resolution:	0.1°	
Dynamic Range:	±30° Horizontal ±35° Vertical	
Capture Resolution (per camera):	640x480 @100fps	
Video Resolution:	Monocular: 320x240 @25fps Binocular: 640x240 @25fps	
Dimensions (L x W x H):	302 x 216 x 131 mm	
Weight:	Monocular: 240g (320g with cover) Binocular: 305g (385g with cover)	
Dual IR LED infrared illumination:	940 nm @ 65 mW/sr	
Face Cushion:	Single-use Disposable Soft Foam Pads	
VORTEQ™ Compatibility:	Yes	
Max. Magnetic DC field:	1210 µT	

Top Mount (BG4.0USB)



Quick Description:	Goggle with top mounted cameras. This binocular goggle includes start/stop button on goggle, along with software controlled image centering. Also available with Asian Faceplate (BG4.0KUSB).	
Technical Specifications:		
Standards:	IEC 60601-1 Type B	
Operation Environment:	Temperature: Relative Humidity:	15 – 35°C 30 – 90%
Transport & Storage Environment:	Transport Temperature: Storage Temperature: Relative Humidity:	-20 – 50°C 0 – 50°C 30 – 80%, Non-condensing
Interface:	USB 2.0	
Cable Length:	4.5m (3m for Orion Reclining / 0.9m for Orion Auto-Traverse/Comprehensive)	
Camera Configuration:	Binocular	
Removable Cover:	Yes	
Eye Movement Resolution:	0.33°	
Dynamic Range:	±45° Horizontal ±25° Vertical	
Capture Resolution (per camera):	320x240 @100fps	
Video Resolution:	Binocular: 640x240 @25fps	
Dimensions (L x W x H):	165 x 165 x 89 mm	
Weight:	345g (with cover)	
Single IR LED infrared illumination:	950 nm at 1.5 mW/cm^2	
On-goggle Start/Stop Button:	Yes	
Software image centering:	Yes	
Face Cushion:	Soft Rubber	
VORTEQ™ Compatibility:	Yes	
Max. Magnetic DC field:	90 µT	

Front Mount (USBM2.1A)



Quick Description:	Goggle with front mounted camera. This monocular goggle includes a camera that can easily be interchanged between right and left eye. Also available as a smaller pediatric version (USBM2.1P)	
Technical Specifications:		
Operation Environment:	Temperature: Relative Humidity:	15 – 35°C 30 – 90%
Transport & Storage Environment:	Transport Temperature: Storage Temperature: Relative Humidity:	-20 – 50°C 0 – 50°C 30 – 80%, Non-condensing
Interface:	USB 2.0	
Cable Length:	4.5m (3m For Rotary Chair Version)	
Camera Configuration:	Monocular (Interchangeable between right and left eye)	
Removable Cover:	Yes	
Eye Movement Resolution:	0.25°	
Dynamic Range:	±20° Horizontal ±20° Vertical	
Capture Resolution (per camera):	640x480 @50fps	
Video Resolution:	Monocular: 640x480 @25fps	
Dimensions (L x W x H):	165 x 165 x 89 mm	
Dual IR LED infrared illumination:	950 nm at 1 mW(cm^2)	
Face Cushion:	Soft Rubber	
VORTEQ™ Compatibility:	No	
Max. Magnetic DC field:	160 µT	

EYESEECAM vHIT



Quick Description:	Lightweight monocular goggle for EyeSeeCam vHIT. The camera can be interchanged between right and left eye. Fits both pediatric and adult faces. Also available with Asian goggle frame version (EyeSeeCam vHIT ASIA).	
Technical Specifications:		
Operation Environment:	Temperature: Relative Humidity: Ambient Pressure:	15 – 35°C 30 – 90% 98 – 104 kPa
Transport & Storage Environment:	Transport Temperature: Storage Temperature: Relative Humidity:	10 – 50°C 10 – 35°C 30 – 80%
Interface:	USB 2.0	
Cable Length:	2.95m	
Camera Configuration:	Monocular (Interchangeable between right and left eye)	
Capture Resolution:	376x120 @220fps	
Video Resolution:	188x120 @25fps	
Dimensions (L x W x H):	Goggle: 139 x 60 x 56 mm Camera: 48 x 42 x 35 mm Combined: 139 x 82 x 81	
Weight:	Goggle: 40g Camera: 32g Combined: 72g	
Head Tracking Sensor:	Inertial Measurement Unit (IMU) with 6 degrees of freedom	
Laser:	Class 1	
Face Cushion	Cleanable silicone	
Max. Magnetic DC field:	150 µT	

5.4 Accessories



VORTEQ™ IMU (2nd generation)

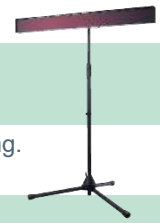
Quick Description:	Inertial Measurement Unit used to track head movement and position. The VORTEQ™ IMU is used with both the VORTEQ™ Assessment and VORTEQ™ Diagnostic modules, and is compatible with the side mount and top mount goggles.
Technical Specifications:	
Interface:	Wireless / USB 2.0
Velocity Range:	±500°/s
Sensitivity:	65.5 LSB/(°/s)
Dimensions (without cable) (L x W x H):	5.0 x 2.8 x 2.2 cm
Weight (without cable):	0.02 kg
Power:	5 VDC supplied by PC USB

DATALINK & ENG in Chair



Quick Description:	Amplifier used for EOG/ENG measurements. Is available as the DataLink through the *EOG Accessory kit for VNG* or built into the Orion Auto-Traverse / Orion Comprehensive chairs through the *EOG Accessory kit for Orion C/AT*.
Technical Specifications:	
Standards:	ISO 60601-1 Class II, Type B
Interface:	USB 2.0
Number of channels:	2 or 3
Dimensions (L x W x H):	25 x 29.5 x 5.1 cm
Weight:	1.9 kg
Internal Noise:	<4 µV RMS inputs shorted, bandwidth DC-40 Hz
Input DC withstand:	300 mW
Programmable Gains:	1250, 2500, 5000, 10000
Common mode rejection:	>100 dB measured at 10 Hz measured with 5k imbalance
Isolation mode rejection:	>130 dB measured at 10 Hz
Impedance test:	Impedance test circuit for individual electrodes up to 20 kΩ
Power:	110-220 VAC, 50-60 Hz, 1000W

DIGITAL LIGHTBAR



Quick Description:	Digital Lightbar presenting visual stimuli for oculomotor testing.
Technical Specifications:	
Interface:	USB 2.0
Dimensions (L x W x H):	83.8 x 8.9 x 4.4 cm
Weight:	1.2 kg
Power:	5 VDC supplied by PC USB

5.5 TRV chair



TRV CHAIR		
Quick Description:	Unique chair with 2-axis 360° rotation for diagnosis and treatment of Benign Paroxysmal Positional Vertigo (BPPV) in all semi-circular canals.	
Technical Specifications:		
Standards:	IEC 60601-1:2005, A1:2012 Type B apllied parts	
Operation Environment:	Temperature: Relative Humidity:	5 – 40°C 30 – 90%
Transport & Storage Environment:	Transport Temperature: Storage Temperature: Relative Humidity:	-15 – 40°C -15 – 40°C 30 – 80%
Rotation Control:	Mechanical	
Interface	FireWire	
Maximum Patient Weight:	150 kg	
Dimensions (L x W x H):	160 x 120 x 190cm	
Weight:	640 kg	
Patient Fixation:	4-point harness for body Shoulder supports Leg strap Head support with headstrap	
Degrees of freedom:	2-axis 360°	
Shipping info:	Shipping crate dimensions (LxWxH): Shipping Weight:	193 x 183 x 165 cm

5.6 Rotary chairs



ORION RECLINING ROTARY CHAIR		
Quick Description:	Rotary chair with reclining options, for caloric, dix hallpike, and positional tests.	
Technical Specifications:		
Standards:	IEC 60601-1 Class I, Type B	
Operation Environment:	Temperature: Relative Humidity:	15 – 35°C 30 – 80%
Transport & Storage Environment:	Transport Temperature: Storage Temperature: Relative Humidity:	0 – 50°C 0 – 50°C 30 – 80%, Non-condensing
Rotation Control:	Software controlled	
Available rotary tests (on top of standard VisualEyes Tests):	Step Rotation (up to 200°/s) Sinusoidal Harmonic Acceleration (0.01 – 0.64 Hz) VOR Suppression (0.01-0.64 Hz)	
Interface:	USB	
USB Cable Length:	3m	
Power Cable Length:	2.5m	
Maximum Chair Speed:	200°/s	
Maximum Chair Acceleration:	100°/s^2	
Maximum Patient Weight:	160kg	
Dimensions (L x W x H):	Upright: 94 x 69 x 183 cm Reclined: 198 x 69 x 152 cm	
Weight:	170 kg	
Patient Fixation:	Safety belt for body Ankle belt Head strap	
Headrest:	Yes (Detachable for Dix Hallpike test)	
Footrest:	Yes	
Emergency Stop:	Yes	
Reclining range:	90° (upright) - 0° (flat) w/ 30° indication label for caloric irrigation	
Shipping info:	Shipping crate dimensions (LxWxH): Shipping Weight:	123 x 100 x 180 cm 323 kg
Power supply:	110VAC, 220VAC step down to 110VAC through included isolation transformer	

ORION AUTO-TRAVERSE / COMPREHENSIVE ROTARY CHAIR



Quick Description:	Rotary chair in enclosure with built-in laser and optokinetic drum for visual stimuli. With add-on packages it is possible to do ENG testing in the rotary chair and perform tests in pediatric patients. With the Orion Auto-Traverse, it is also possible to do off-axis rotation for dynamic SVV.	
Technical Specifications:		
Standards:	IEC 60601-1 Class 1, Type B	
Operation Environment:	Temperature: Relative Humidity:	15 – 35°C 30 – 80%
Transport & Storage Environment:	Transport Temperature: Storage Temperature: Relative Humidity:	0 – 50°C 0 – 50°C 30 – 80%, Non-condensing
Rotation Control:	Software controlled	
Available rotary tests (on top of standard VisualEyes Tests):	Step Rotation (up to 350°/s) Sinusoidal Harmonic Acceleration (0.01 – 1.28 Hz) VOR Suppression (0.01 – 1.28 Hz) Static SVV Dynamic SVV (only Auto-Traverse)	
Interface:	USB 2.0	
Maximum Chair Speed:	350°/s	
Maximum Chair Acceleration:	200°/s	
Maximum Patient Weight:	180kg	
Dimensions (L x W x H):	Chair: 61 x 61 x 165 cm Booth Enclosure: 206 x 206 x 239 cm	
Required minimum ceiling height:	245 cm	
Weight:	Chair: Booth Enclosure:	170 kg (375 lbs) 295 kg (650 lbs)
Patient Fixation:	Safety belt for body Ankle belt Head strap	
Headrest:	Yes	
Footrest:	Yes	
Emergency Stop:	Yes	
Laser:	Class: Wavelength: Beam divergence: Pulse pattern: Maximum Power Output:	2 680 nm 0.35 mrad Not pulsed, solid on state <1 mW
EOG built in:	See technical specifications for DATALINK (EOG/ENG) under Accessories	
Lateral Movement:	-7cm to +7cm (only Auto-Traverse)	
Lateral Movement Speed:	0.8 cm/sec (only Auto-Traverse)	
Shipping info:	Shipping crate dimensions (LxWxH):	Enclosure crate: 236x118x133 cm Chair crate: 119x175x100 cm Accessories pallet: 122x60x115 cm

Power supply:	110VAC, 220VAC step down to 110VAC through included isolation transformer

5.7 Orion Auto-Traverse/Comprehensive accessories

PEDIATRIC OBSERVATION CAMERA	
Quick Description:	Camera mounted on a unipod that can be attached to the Orion Auto-Traverse / Comprehensive. Can be used when doing measurements in babies who can't wear goggles.
Technical Specifications:	
Interface:	Dual USB 2.0
Cable Length:	1.8m
Capture Resolution:	640x480 @50fps
Video Resolution:	320x240 @25fps
Dimensions (L x W x H):	Camera: 54 x 69 x 62 mm Unipod: 978 x 84 x 79 mm
IR LED infrared illumination:	940 nm @ 252.6 mW/sr

5.8 Caloric irrigators

Please see separate datasheets for AquaStim and AirFx.

5.9 Electromagnetic compatibility (EMC)

This section is valid for the VisualEyes™ system including all variant of goggles.
This equipment is suitable in hospital and clinical 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 equipment adjacent to other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Use of accessories 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 and cables can be found in this section.

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 equipment, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could occur.

NOTICE ESSENTIAL PERFORMANCE for this equipment is defined by the manufacturer as:
This equipment 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.

This equipment complies 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 instructions for maintenance comply with EMC and can be found in the general maintenance section in this instruction. No further steps required.

Portable and mobile RF communications equipment can affect the ***ORION.*** Install and operate the ***ORION*** according to the EMC information presented in this chapter.
The ***ORION*** has been tested for EMC emissions and immunity as a standalone ***ORION.*** Do not use the ***ORION*** 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, except for servicing parts sold by Interacoustics A/S 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 ***ORION*** is intended for use in the electromagnetic environment specified below. The customer or the user of the ***ORION*** should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The ***ORION*** 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 ***ORION*** 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 *ORION*.			
The ***ORION*** is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ***ORION*** can help prevent electromagnetic interferences by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ***ORION*** 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 = 1.17P	**80 MHz to 800 MHz** d = 1.17P	**800 MHz to 2.7 GHz** d = 2.23P
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 ***ORION*** is intended for use in the electromagnetic environment specified below. The customer or the user of the ***ORION*** 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	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 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 100 kHz repetition frequency ± 1 kV Line-to-line 100 kHz repetition frequency	± 2 kV ± 1 kV	Mains power quality should be that of a typical commercial or residential environment.
Surge IEC 61000-4-5	± 1 kV Line-to-line ± 2 kV Line-to-ground	± 1 kV ± 2 kV	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	0% *U*T for 0.5 cycle 0 % UT for 1 cycle and 70% *U*T for 25/30 cycles Single phase: at 0°	0% *U*T for 0.5 cycle 0 % UT for 1 cycle and 70% *U*T for 25/30 cycles Single phase: at 0°	Mains power quality should be that of a typical commercial or residential environment. If the user of the ***ORION*** requires continued operation during power mains interruptions, it is recommended that the ***ORION*** be powered from an uninterruptable power supply or its battery.
Power frequency (50/60 Hz) IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or residential environment.
Note: *U*T is the A.C. mains voltage prior to application of the test level.			

Guidance and Manufacturer's Declaration — Electromagnetic Immunity			
The ***ORION*** is intended for use in the electromagnetic environment specified below. The customer or the user of the ***ORION*** should assure that it is used in such an environment,			
Immunity test	**IEC / EN 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
			Portable and mobile RF communications equipment should be used no closer to any parts of the ***ORION,*** including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:**
Conducted RF IEC / EN 61000-4-6	3 Vrms 150kHz to 80 MHz 6 Vrms in ISM bands 150kHz to 80 MHz 80 % AM at 1 kHz	3 Vrms 6 Vrms	$d = 1{,}2\sqrt{P}$
Radiated RF IEC / EN 61000-4-3	3 V/m 80 MHz to 2,7 GHz 80 % AM at 1 kHz	3 V/m	$d = 1{,}2\sqrt{P}$ 80 MHz to 800 MHz $d = 2{,}3\sqrt{P}$ 800 MHz to 2,7 GHz Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* 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: 

NOTE1 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 ***ORION*** is used exceeds the applicable RF compliance level above, the ***ORION*** should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the ***ORION.*** [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

To ensure compliance with the EMC requirements as specified in IEC 60601-1-2, it is essential to use only the following accessories:

Item	**Manufacturer**	**Model**	**Cable**	
			Length [meter]	Screened [Y/N]
Camera System for Vestibular Analysis	Interacoustics	2D-VOGfw (Side Mount)	4,5	Y
Goggles USB Binocular 4.0	Interacoustics	BG4.0USB (Top Mount)	1,8	Y
Goggles USB Monocular Adult Mask or Pediatric Mask	Interacoustics	USBM2.1A (Front Mount)	1,8	Y

Conformance to the EMC requirements as specified in IEC 60601-1-2 is ensured if the cable types and cable lengths are as specified below:

Item	**Manufacturer**	**Model**	**Cable**	
			Length [meter]	Screened [Y/N]
Mains cable (Grey)	-	IEC C13/C14	2,9	Y
USB cable	-	USB A/B	2,9	Y
Emergency switch	Interacoustics	-	4,4	N

6 Return procedure

If the product is faulty or damaged in some way, it is important that you report this immediately to your local distributor together with the invoice and serial number. If it is decided that it is necessary to return the instrument to Interacoustics, you must fill out a detailed report of your concern. In the delivery box and also at the end of this manual you will find a Return Report form, where you can describe the problem.

Please use the Return Report form
Please note that it is important that you provide as much relevant information as possible in the Return Report regarding the problem in order to facilitate the task of the service engineer and ensure a successful outcome.

This procedure should be complied with in all cases where an instrument is returned to Interacoustics.