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Instructions for Use - EN

VisualEyes™

515/525

Micromedical
by Interacoustics



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Interacoustics

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1 Introduction

1.1 About this manual

This manual is valid for the VisualEyes™ 515 and VisualEyes™ 525 software version 3.0. These products are manufactured by:

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Definitions:

VisualEyes™ 515 and VisualEyes™ 525 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 user manual refers to this document as 'Instructions for use'. The term 'VORTEQ™ IMU' refers to 2nd or latest generation of VORTEQ™ IMU. The term 'VORTEQ™ rate sensor' refers to 1st generation of VORTEQ™ head rotational rate sensor which works with VLink.

Instructions for Use/Additional information:

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

1.2 Intended use

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.

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.



1.3 Contraindications

VNG 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 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 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 VNG analysis software platform that is available in two different versions: VisualEyes™ 515 and VisualEyes™ 525.

The VisualEyes™ system can be configured with different hardware components/accessories (laptop/desktop PC, goggles, Orion Reclining/Comprehensive/Auto Traverse chair and etc.) based on the operator's needs to perform various tests as per the intended use (refer to section 1.4.2) for default and optional components of the product and 3.4 to learn more about individual hardware components).

The VisualEyes™ system extends support to existing users and is compatible with previous versions of components/accessories (e.g: Nydiag 200 reclining chair, System 2000 chair [Reclining/Comprehensive/Auto Traverse]) based on their license upgrade.

VisualEyes™ 515 does not utilize an external stimulus, thereby limiting the system to nystagmus and caloric testing. VisualEyes™ 525 utilizes an external stimulus for oculomotor testing and can be combined with accessories to perform additional test procedures. The available tests in the VisualEyes™ system are outlined in the following table. Please refer to Table 1.4-1 for details.

NOTICE The VisualEyes™ system can be provided with different test batteries and managed by user licenses. The user gets a license key for their hardware and configuration. This will enable the software to recognize the test battery assigned for the specific license. Refer to section 12.6 of '**Additional Information**' for more detail.



Table 1.4-1 Product description of VisualEyes™ System

Test	Availability	Additional Accessory Requirement	ENG*
Calibration	515 / 525	None	Yes
Spontaneous nystagmus	515 / 525	None	Yes
Dix Hallpike	515 / 525	Exam Table / Reclining Chair	Yes
Positional	515 / 525	Exam Table / Reclining Chair	Yes
Caloric	515 / 525	Exam Table / Reclining Chair, Caloric Irrigator	Yes
Gaze	525	None	Yes
Smooth Pursuit	525	None	Yes
Random Saccade	525	None	Yes
Saccadometry	525	None	Yes
Optokinetic	525	None	Yes
Sinusoidal Harmonic Acceleration	515 / 525	Reclining / Comprehensive / Auto Traverse Chair	Yes
Step Velocity	515 / 525	Reclining / Comprehensive / Auto Traverse Chair	Yes
VOR Suppression	515 / 525	Reclining / Comprehensive / Auto Traverse Chair	Yes
Visual VOR	515 / 525	Reclining / Comprehensive / Auto Traverse Chair	Yes
Subjective Visual Vertical (SVV)- Static	525	Comprehensive / Auto Traverse Chair	No
Subjective Visual Vertical (SVV)- Dynamic	525	Auto Traverse Chair	No
Video Frenzel	525	None	No
Ocular Counter Roll	525	None	No
VORTEQ™ AHR	525	VORTEQ™ IMU / VORTEQ™ rate sensor with VLink	No
vHIT for VORTEQ™	525		
Dynamic Visual Acuity (DVA)	515 / 525		
Dix Hallpike Advanced	515 / 525	VORTEQ™ IMU	No
Lateral Head Roll	515 / 525		
vHIT for EyeSeeCam - Lateral - LARP - RALP - SHIMP	515 / 525	EyeSeeCam camera with goggle and built-in IMU.	No

Note: The Orion AT/C chairs will not support caloric, Dix Hallpike/Dix Hallpike Advanced, Positional, DVA or VORTEQ™ vHIT testing inside the booth. However, these tests can be performed on an external examination table/chair with the provided extended goggle cables.
*** If the user has the ENG option, the tests marked as 'Yes' under ENG can be performed using electrodes.**



1.4.1 Minimum PC requirements

The user must ensure that the chosen PC is complying to minimum PC requirements to be compatible to the VisualEyes™ system. Please refer to section [6.1](#) for the recommended computer specifications.

NOTICE: As a part of data protection, ensure to be compliant with the following points

1. Use Microsoft supported operating systems
2. Ensure operating systems are security patched
3. Enable database encryption
4. Use individual user accounts and passwords
5. Secure psychical and network access to computers with local data storage
6. Use updated antivirus and firewall and anti-malware software
7. Implement appropriate backup policy
8. Implement appropriate log retention policy

1.4.2 Included and optional parts

The VisualEyes™ system is delivered with the following major items based on the system configuration. Please refer to [Table 1.4-2](#) for details.



Table 1.4-2 Detailed Description of Included and Optional components of VisualEyes™

	USB camera systems	FireWire® camera systems
Included parts*	VisualEyes™ 515/525 installation media OtoAccess® Database media Handheld RF remote control and/or foot pedal Certificates and reports: e.g: VNG test result report, license certificate, certificate of conformity and if applicable safety test report.	
Optional parts based on goggle type*	<p>2D-VOGfw goggle w. side mounted cameras¹ 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</p> <p>USBM2.1A goggle w. front mounted camera¹ Adult mask for USB monocular camera Camera module with 15' USB cable 7-port USB 3.0 hub w. external power supply</p> <p>USBM2.1P goggle w. front mounted camera¹ Pediatric mask for USB monocular camera Camera module with 15' USB cable A to Mini B 7-port USB 3.0 hub w. external power supply</p> <p>BG4.0KUSB goggle w. top mounted cameras¹ Goggles USB Asian faceplate binocular Two 15' USB cables A to Mini B 7-port USB 3.0 hub w. external power supply</p> <p>BG4.0USB goggle w. top mounted cameras¹ Goggles USB binocular Two 15' USB cables A to Mini B 7-port USB 3.0 hub w. external power supply</p>	<p>2D-VOGfw goggle w. side mounted cameras 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 PCI ExpressCard (for tower PC configuration) 4-port USB hub</p>
Optional parts based on the chair type*	<p>Orion Reclining Chair¹ Orion Rotary Chair USB cable Emergency stop button with Ethernet connector Power cord Tools and accessories for assembly</p> <p>Orion Comprehensive/Auto Traverse Chair¹ Orion Rotary Chair OKN Drum X-Y Laser assembly Off-axis stepper motor USB cable Emergency stop button with Ethernet connector Power cord</p>	

¹ Applied part according to IEC 60601-1



	USB camera systems	FireWire® camera systems
	<p>Booth and accessories Booth observation camera Intercom Remote control for SVV line Tools and accessories for assembly</p> <p>Pediatric option</p> <ul style="list-style-type: none">- Child seat¹- USBM2.1P goggle w. front mounted camera- Pole mounted patient observation camera <p>ENG on Chair option</p> <ul style="list-style-type: none">- Electrode skin prep pads¹- Set of 7 leadwires (40")- Disposable electrodes¹	
Optional parts based on ENG test*	DataLink Preamplifier EOG patient cable Lead wires 24' Electrodes ¹ USB cable Accessory kit (Alcohol prep pads and etc.)	
Optional parts based on vHIT module	vHIT camera with goggle/EyeSeeCam camera ¹ with goggle Built-in IMU USB cable	
Optional parts based on Caloric Irrigators*	Caloric Irrigators (Air Fx / Aqua Stim) Please refer to the respective product user manual for the irrigator system	
Note: The VisualEyes™ system also supports old systems such as VLink for VORTEQ™ rate sensor, System 2000 (reclining chair/Auto Traverse/comprehensive) chair or Nydiag 200 rotary chair		
*- the system may include other minor accessories like Digital Light Bar (DLB), custom cables, adapters, logo badges, cable wrap, cable tie and cleaning cloth for goggles etc., may be included in the package according to the choice of product configurations.		





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 4.8 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 OKN 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 remains 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 OKN 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 OKN drum. Following, the operator shall exit the test or go to 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 shall 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 cause the chair to stop.





2 Unpacking and inspection

2.1 Unpacking and inspection

Check shipping containers and contents for damage

When the VisualEyes™ system is received, please check the shipping box for rough handling and damage. Ensure that you have received all the components on the shipping checklist. All the components should be checked visually for scratches and missing parts before use. All the contents of the shipment have to be checked for their mechanical and electrical functioning. If the equipment is found faulty, please contact your local distributor immediately. Keep the shipping materials for the carrier's inspection and insurance claim.

Keep carton for future shipment

The 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.






Reporting and returning procedure

Any missing part or malfunction should be reported immediately to the supplier/local distributor along with the invoice, serial number and a detailed report of the issue. For any on-site service-related information, please contact your local distributor. If the system / components are to be returned for service, please fill all the details related to product issues in the '**Return Report**', which is attached to this manual. It is very important that you describe all the known facts about the issue in the return report, as this will help the engineer to understand and solve the problem to your satisfaction. Your local distributor holds the responsibility for coordinating any service/return procedure and related formalities.














2.2 Marking

The following markings ([Table 2.2-1](#)) can be found on the equipment:



Table 2.2-1 Label markings and Explanations for VisualEyes™

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.
	The CE-mark indicates that Interacoustics A/S meets the requirements of Annex II of the Medical Device Directive 93/42/EEC. TÜV Product Service, Identification No. 0123, has approved the quality system



	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
	 <p>This product contains a component (Orion Comprehensive/Auto Traverse chair) of ‘Class 2 Laser beam’. Hence, do not look directly into the laser beam</p>
	Keep dry
	Transport and storage temperature range
	Transport and storage humidity limitations



<p>ETL CLASSIFIED</p>  <p>Intertek 4005727</p> <p>Conforms to AAMI ES60601-1 Certified to CSA-C22.2 No. 60601-1</p>	ETL listing mark
 <p>Interacoustics</p>	Logo





3 Setup and installation

3.1 Introduction to the VisualEyes™ software

The VisualEyes™ software combines cutting-edge technology with touch-screen capability in a streamlined software interface. The VisualEyes™ software is considered as the gold standard for testing the vestibular system and oculomotor function, a process known as vestibular assessment. It involves the use of infrared goggles or electrodes to record and analyze eye movements during visual stimulation, positional changes and caloric stimulation. The VisualEyes™ software can be configured with a rotary chair to test patients' vestibular-ocular reflex (VOR). This software can also be configured with VORTEQ™ IMU to test VOR, vHIT AHR and DVA.

3.2 Installation of the VisualEyes™ software

If the computer is purchased from Interacoustics, all the software / databases / drives (e.g: OtoAccess® Database, VisualEyes™, rotational chair drivers) are preinstalled. If the customer wants to install VisualEyes™ software in any other computer or in the event of re-installation, the following procedure is to be followed for successful installation.

Ensure that the chosen computer is compliant with all minimum PC requirements (refer to section 6.1) and that OtoAccess® Database is installed prior to the installation of the VisualEyes™ software. Consult the OtoAccess® Database instructions for use to install the software on computers bought outside Interacoustics. To install the VisualEyes™ software, run the **Micromedical VisualEyes™ Installer.exe** file from the VisualEyes™ installation media.

3.3 Installation of DAQ hardware driver for data acquisition components

NOTICE Ensure that the DAQ hardware software is installed for data acquisition from the hardware components such as rotational chairs, DataLink and VLink. Refer to the installation procedures below. After installation, the operator can refer to '**Additional Information**' for the settings to register these hardware components in the 'Remember to register these components' in the VisualEyes™ system.

3.3.1 Installing DAQ hardware driver for Orion Chair/System 2000 chair/DataLink/VLink

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 few seconds for all hardware to go through auto-discovery after connecting 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.



3.3.2 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.

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.

3.4 Hardware components

The VisualEyes™ system is composed of several hardware components to build the complete equipment setup. Its software is designed to be compatible with both Interacoustics A/S and Micromedical Technologies Inc. equipment.

3.4.1 Laptop/desktop PC

The customer can choose between a laptop or desktop PC from Interacoustics, which comes with pre-installed software ([Figure 3.4-1](#)). Laptop systems are configured with an externally powered USB hub to connect additional devices. Desktop PCs may be configured with a combination monitor stand to reduce desk space. The software also supports any other system of customer choice if the system is compliant with all pre-requirements to install the software.



Figure 3.4-1 Laptop/Desktop PC

3.4.2 Television/projector display/Digital Light Bar

The VisualEyes™ system can be configured with either a TV or a Projector or a DLB ([Figure 3.4-2](#)). The TV may be mounted on the wall or placed on a table with the TV feet. Windows Desktop can be extended across both displays. Digital Light Bar can be set up with desired height level by adjusting the tripod. Whenever the TV/projector/DLB is changed, the operator should calibrate the stimulus before taking the system for routine use. This helps the software to calculate the new hardware delay based on the patient's gain delay and accommodates for televisions and projectors. Refer to Section 8.2.4 of 'Additional information' for more detail on calibration.



Figure 3.4-2 TV, Projector Display and Digital Light Bar (DLB)

3.4.3 Side mounted camera goggles

The VisualEyes™ side mounted goggles (Figure 3.4-3) allow the recording of eye movements during various test conditions, both with and without visual stimulation. The VisualEyes™ side mounted goggles use either FireWire® or USB cameras to record eye images. The cameras use infrared light (IR), which is not visible to the naked eye.



Figure 3.4-3 The FireWire® or USB cameras are fixed on the sides of the goggles (Left). Side mounted camera goggles with replaceable foam pads (Right).



The side mounted 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.

The front cover plate of the side mounted goggle is magnetically fixed and can easily be removed for visual stimulation tests (i.e. oculomotor). The mask has an adjustable Velcro head strap that comfortably secures the goggles to the patient. The side mounted camera goggles can be configured with one camera and cover for monocular systems. In this configuration, the user would physically move the camera to the side of the goggles to record the desired eye, and the cover would be placed on the other side to block out light in vision-denied tests.

3.4.4 Top mounted camera goggles

The binocular video goggles (Figure 3.4-4) block out ambient light with the 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. There is a switch on the left side of the goggles to start and stop tests. The binocular video goggles have an adjustable Velcro head strap that secures the goggles while still providing patient comfort.



Figure 3.4-4 Top mounted camera goggles. Cover slips over front of goggles for vision-denied testing. The switch on the left side of the goggles starts and stops the test.

3.4.5 Front mounted camera goggles

The front mounted camera goggles (Figure 3.4-5) 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. 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 mounted camera goggles are typically used for smaller and younger patients.



Figure 3.4-5 Front mounted camera goggles. Left picture shows the standard goggles, and the right picture shows the small face goggles.

3.4.6 EyeSeeCam camera

The EyeSeeCam camera (Figure 3.4-6) 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. The camera can be mounted over either eye and a laser stimulus projects from the goggles in the vHIT test if selected.



Figure 3.4-6 EyeSeeCam camera and goggle with built-in IMU.

3.4.7 Pediatric observation camera

The AT/C rotational chairs may be configured with the pediatric observation camera. The provided infant car seat may be used for pediatric seating. This camera is mounted to a pole which fits into the bracket and sits on the footrest. The patient observation camera connects to the camera ports on the back of the chair frame and will observe the infant in the car seat (Refer to [Figure 3.4-7](#)).



Figure 3.4-7 Orion AT chair with infant seat (left) and pediatric observation camera (right)



3.4.8 Reclining rotary chair (optional)

The reclining rotary chair (Figure 3.4-8) provides sinusoidal harmonic acceleration (SHA) test and step test capability to the VisualEyes™ system. 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 3.4-8 Reclining rotary chair.

3.4.9 AT/C rotary chairs (optional)

The user gets the additional test options of sinusoidal harmonic acceleration (SHA) test and step test by choosing either of Orion (or existing System 2000) AT/C rotary chairs (Figure 3.4-9) as part of their VisualEyes™ system. The chair is enclosed in a light-tight booth. The laser projector is mounted on top of chair frame and this is used to project the target stimulus in oculomotor testing and VOR fixation tests. An optokinetic drum is mounted to the booth ceiling, which provides a full-field stripe stimulus. AT chairs have off-axis lateral movement capability used for subjective visual vertical testing. Optionally, the rotary chair can be configured with an electrode amplifier on the back of the chair frame to test patients with electrode lead wires for ENG evaluation.



Figure 3.4-9 AT/C rotary chair and booth enclosure.

3.4.10 Foot pedal (optional)

The foot pedal (Figure 3.4-10) allows you to begin testing by pressing the foot switch so you have both hands free to look after the patient (e.g. Dix-Hallpike) or to operate other devices (e.g. caloric irrigators). Connection with the PC is via a USB port.



Figure 3.4-10 VisualEyes™ foot pedal.

3.4.11 VisualEyes™ remote control (optional)

The remote control~~Error! Reference source not found.~~ provides a hand-held option for controlling and performing tests within the VisualEyes™ VNG suite, allowing ease of use when looking after the patient (e.g. positional tests) or centering the eyes. Connection to the PC is via a USB port.

The operator can get a standard remote control and can also use the SVV remote along with the Orion AT/C chairs.

Standard remote serves four functions (refer to Figure 3.4-11):

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

Typically, this can perform any command in VisualEyes which is selected (indicated with white background).



Please find the below example for better explanation:

Before calibration, one can command to select 'Calibration' option which is shown in white background.

After calibration, one can command to select 'START' option which is shown in white background.

This way, the operator can perform below listed actions.

- Goes forward in the software
- Launches 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.

The SVV remote's buttons (refer to figure no: [Figure 3.4-11](#)) 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 3.4-11 Standard RF remote (left) and SVV remote for AT/C chair (right)

3.4.12 External room camera and observation camera

The external room camera ([Figure 3.4-12](#)) may be an external device or integrated in the laptop. It serves to record and save the external environment and patient testing process from the beginning.



Figure 3.4-12 External room camera



The observation camera (Figure 3.4-13) is placed inside the booth of the AT/C chairs and the monitor is placed nearer to the operator. This enables the operator to monitor the patient inside the booth via the observation monitor screen. The observation video is not recorded or saved in the software.



Figure 3.4-13 Observation camera and monitor screen

3.4.13 VORTEQ™ IMU

The VORTEQ™ IMU sensor (Figure 3.4-14) connects to the laptop or mid-tower computer either by USB cable or wirelessly through Bluetooth with the accompanying Bluetooth receiver dongle. The VORTEQ™ IMU measures head position in space, allowing the VisualEyes™ software to determine where the patient's head is in space, and is used in active VOR testing, dynamic visual acuity, head roll testing, advanced Dix-Hallpike and advanced positional testing. This can be used with or without goggles depends on the test (Figure 3.4-15).



Figure 3.4-14 VORTEQ™ IMU

The inertial measurement unit (IMU) slides into the sensor mount on the top mounted or side mounted goggles. The USB cable from the IMU should be routed along the left side of the goggles if not used wirelessly. Visual acuity tests have the IMU placed on the DVA headband and route the USB cable along the right side of the headband. Patients should wear eyeglasses or contact lenses for best visual acuity with the DVA headband.

To turn on the VORTEQ™ IMU, slide the power switch on top of the unit to the right. The On light will then flash every four seconds. The Charging light will be lit when connected to USB. If using the IMU in Bluetooth mode, the BLE Connected light will blink every four seconds when the computer has successfully connected to the device.



Figure 3.4-15 IMU with Goggles / only with head band



3.4.14 DataLink

The operator can use Datalink (Figure 3.4-16) to perform the ENG tests (Spontaneous Nystagmus, Dix-Hallpike, Positional, Calorics, Gaze, Smooth Pursuit, Random Saccade, Saccadometry, Optokinetic, SHA, Step Velocity, VOR Suppression and Visual VOR) using electrodes. These options are controlled with the licenses. Patients who cannot be tested with the video goggles may be candidates for ENG tests. The DataLink is the component that receives the patient data (eye position) via electrode recording and sends to the computer via USB. Electrode lead wires are connected to the EOG Patient Cable that connects to the back of the DataLink.



Figure 3.4-16 DataLink and EOG Patient Cable

3.5 System configuration

3.5.1 Systems configured without a rotational chair

Hardware components will typically connect to the computer via USB. If the goggles use FireWire® cameras, the goggles will connect to a FireWire® plug-in card on the back of the mid-tower. The TV will connect via a HDMI cable to the back of the computer (which may require an adapter cable).

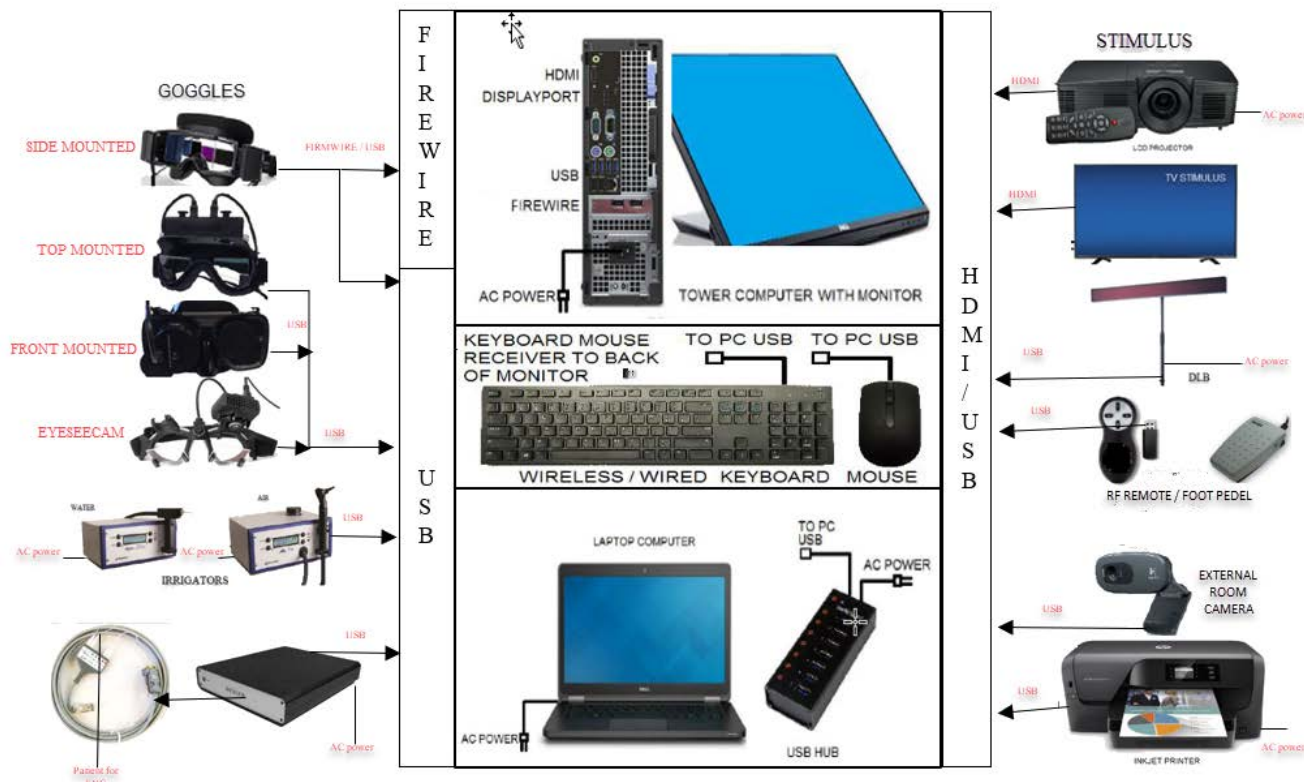


Figure 3.5-1 VisualEyes™ System Configuration Without a Rotational Chair



Laptop configurations will use a USB hub to connect devices that use an external power adapter. If a DataLink is connected to the system, it should connect either to a USB port on the monitor hub (tower computers) or directly to the laptop computer. Please refer to [Figure 3.5-1](#) to view pictorial representation of all the configuration available with the VisualEyes™ System without a rotational chair.

3.5.2 Systems configured with a rotational chair

The VisualEyes™ System can be configured with Reclining (Orion, System 2000 and Nydiag 200), and Auto Traverse/Comprehensive (Orion and System 2000) chairs as discussed below.



It is important to use an isolation transformer for electrical safety and/or step-down power supply for the VisualEyes™ systems with a rotational chair option. The isolation transformer is used to reduce equipment current leakage for all devices plugged into it. The supplied isolation transformer will step down an incoming 220, 230, or 240 VAC power supply to 115 VAC power used by the rotational chairs. VisualEyes™ systems without the rotational chair are also encouraged to use an isolation transformer for electrical separation, though it is not required. If an isolation transformer is used, all components of the VisualEyes™ system must be powered by the isolation transformer. Please refer #3 in the warning section [1.5](#).

3.5.3 Reclining chair setup

The 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 devices which uses an external power adapter and connects 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 should connect either a USB port on the monitor hub (tower computers) or directly to the laptop computer. Please refer to [Figure 3.5-2](#), [Figure 3.5-3](#) and [Figure 3.5-4](#) for pictorial representation of different chair types.

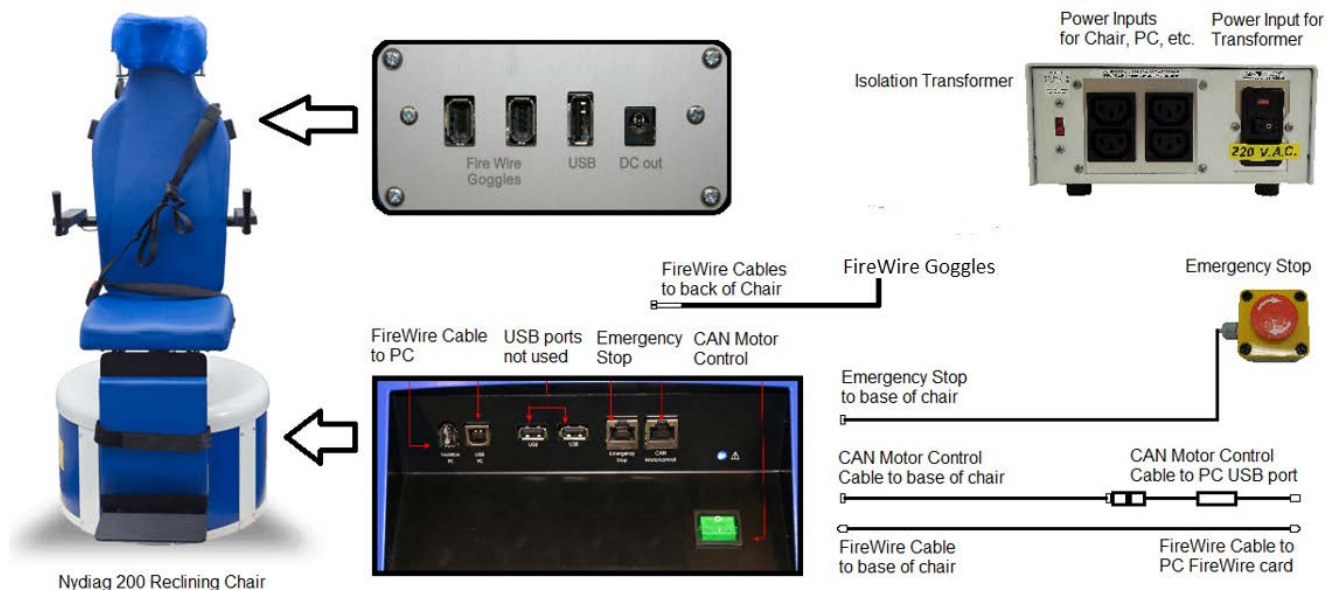


Figure 3.5-2 VisualEyes™ with NyDiag 200 rotary chair

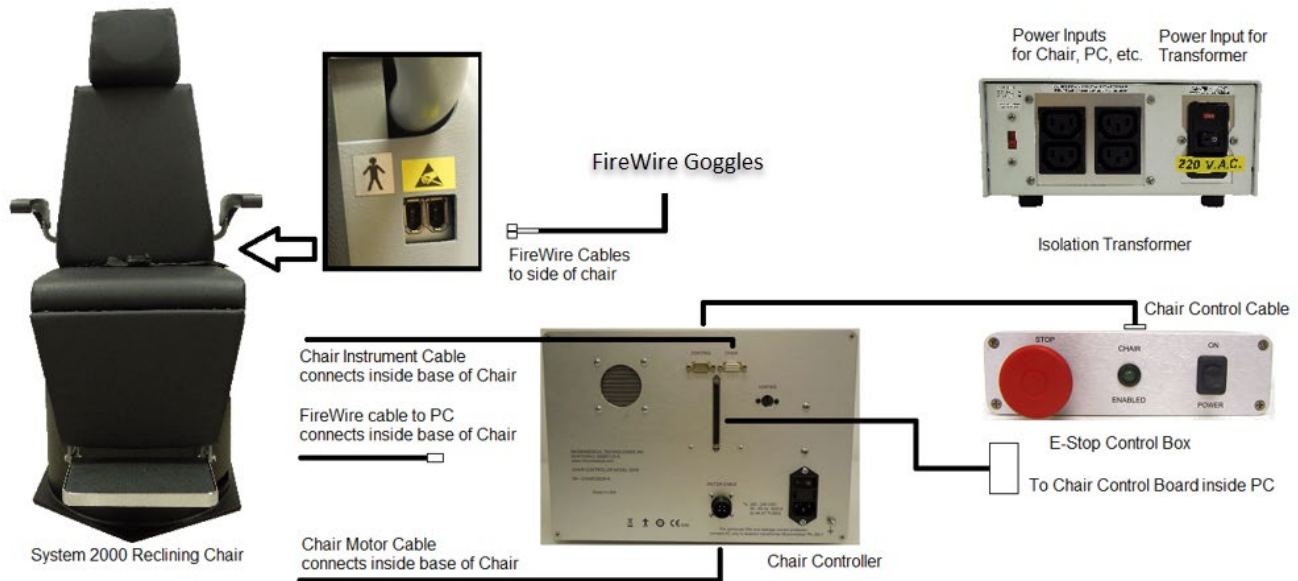


Figure 3.5-3 VisualEyes™ with System 2000 reclining chair

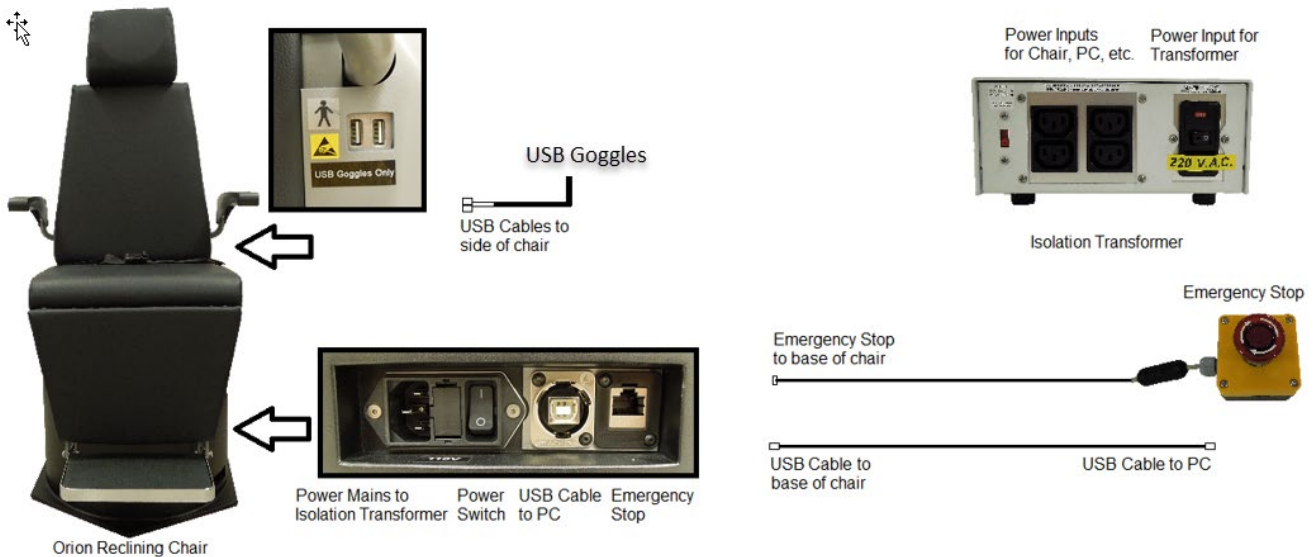


Figure 3.5-4 VisualEyes™ with Orion reclining chair

For complete installation instructions regarding the reclining rotational chairs, please refer to the NyDiag 200, Orion and System 2000 rotary chair installation manuals.

3.5.4 Auto Traverse and Comprehensive chair setup

The VisualEyes™ System can be configured with Orion Auto Traverse/Comprehensive and System 2000 Auto Traverse/Comprehensive chairs. Both the systems have 3 main components as vestibular booth, rotary chair and equipment cart. These systems are configured in the same way except few variations. The pictorial representations for these two different chair setups are shown below in the pictures [Figure 3.5-5](#) (Orion AT/C) and [Figure 3.5-6](#) (System 2000 AT/C).

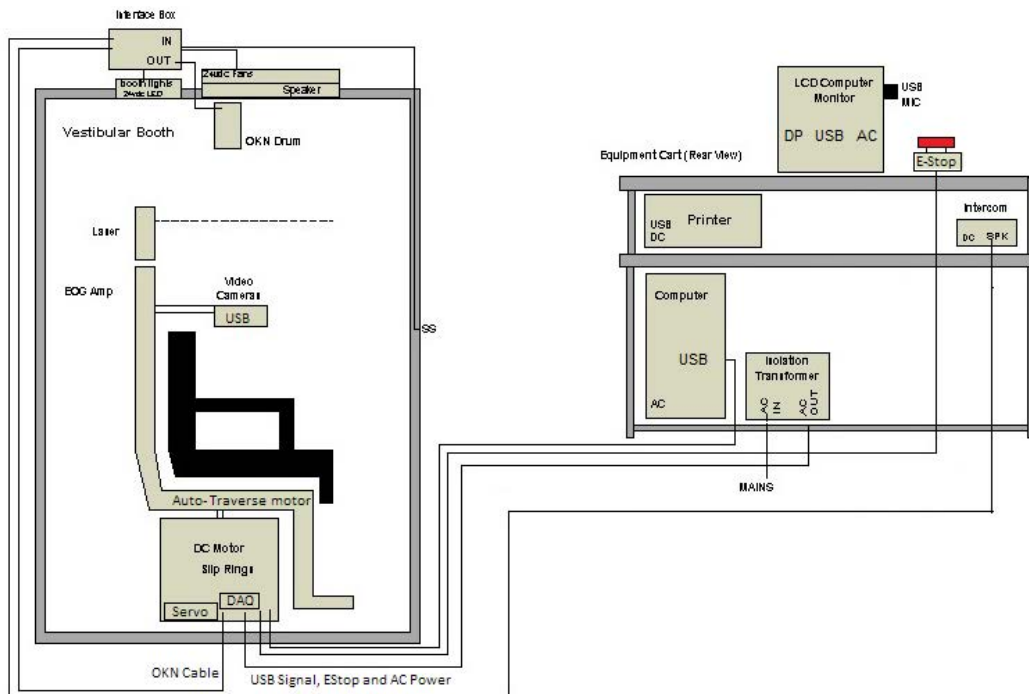


Figure 3.5-5 VisualEyes™ with Orion Auto Traverse/Comprehensive Chair

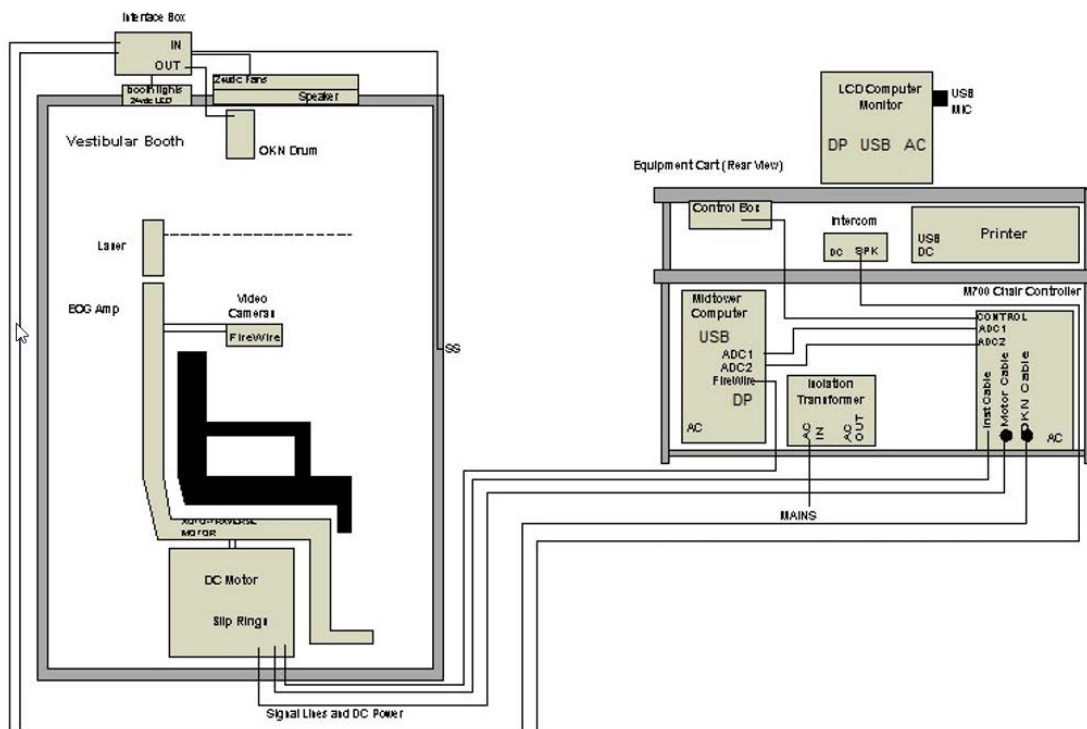


Figure 3.5-6 VisualEyes™ with System 2000 Auto Traverse/Comprehensive Chair





4 Operating instructions

4.1 System startup

4.1.1 Turn on power sources

Ensure that the laptop/PC systems and USB hub are power connected. Isolation transformers should be turned on using the power switch in case Orion rotational chair (R/AT/C) is in use.

4.1.2 Turn on accessories

Goggles: Ensure that the goggle cameras (binocular or monocular) are connected to the computer, USB hub or rotational chair, depending on the license/choice of the operator.

Chair: Ensure that the rotational chair is power connected and that the power switch is turned on. The power switch is located on the back of the chair controller for System 2000 chairs (R/AT/C) and at the base of all other kinds of rotational chairs. Turn on the observation monitor **if the observation camera** is used for AT/C chairs.

Emergency button: Ensure that the Emergency Stop button is disengaged (turn clockwise to disengage the button).

DataLink: If the DataLink is used for ENG evaluations, turn on the power using the power switch on the back of the device.

VORTEQ™ IMU / VLink (head rotational rate sensor): Ensure that the VORTEQ™ IMU/VLink is connected and powered via USB hub.

Caloric Irrigators: Ensure that the irrigator (Air Fx air irrigator/Aqua Stim water irrigator) is turned on using the power switch on the back of the irrigator (Please refer to user manual of irrigators for detailed instruction for operation).

4.1.3 Turn on stimulus then 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 a second display.

4.2 Entering patient information

Please refer to the OtoAccess® Database Instructions for Use on how to enter/access the patient information.

4.3 Starting the VisualEyes™ software

Launch the VisualEyes™ software from OtoAccess® Database.

4.4 Room recording

The operator can set up a room video recording on the computer's main screen to record and save the patient session during patient interview and test procedures. The operator can also pause and restart the recording as many times as he/she wishes. Refer to section 5.1 of '**Additional Information**' to know more detail.



4.5 Patient preparation



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

1. 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 precaution, adverse effects etc. Especially, additional care should be given for irrigation and positional tests (e.g. caloric test, rotary chair tests, etc.).
2. It is also important to consider the patient's clinical condition/history before testing. 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).
3. 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.
4. 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.
5. Ensure that the rotary chair is locked in the desired position before starting any test using a rotational chair to avoid unintended turns.
6. The operator should ensure that there are no objects placed that will potentially interfere when the chair is reclining or spinning. It is also recommended that the testing room be darkened for all vision-denied tests.
7. 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.
8. Patients cannot use corrective eyeglasses during testing but corrective contact lenses can be worn to improve visual acuity.
9. 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.
10. Ensure that the goggles are sanitized with appropriate procedure. 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. Front mounted camera goggles and top mounted camera goggles should be disinfected with approved cleansing wipes as described in section 5.1.
11. 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.
12. Before starting any test involving the Orion AT/C chairs, a set of safety checks (Figure 4.5-1) 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.

To ensure the safety of the patient before rotating the patient in the chair, please use this checklist as a guide to ensure the patient's safety during the test.

- ☐ Are ALL patient seat belts securely fastened?
- ☐ Is the patient's head restrained to the head support?
- ☐ Has the ankle restraint been fastened?
- ☐ Does the patient have access to the patient stop button?

OK

Cancel

Figure 4.5-1 Safety Checklist for Orion AT/C chairs.



4.5.1 Seat the patient in the reclining chair (Orion/System 2000/Nydiag 200)

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 4.5-2](#)) 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 4.5-2](#)). 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 as same as the Orion Reclining chair except System 2000 reclining chairs can rotate freely and can be locked manually by depressing the foot brake to prevent the chair from unintended turns whereas the Nydiag 200 chair can be locked using the software.



Figure 4.5-2 Sequential images of patient seating procedure with Orion reclining Chair (left to right)

4.5.2 Seat the patient in the AT/C chairs (Orion/System 2000)

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 4.5-3](#)). **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 4.5-3 Sequential images of patient seating procedure with Orion/System 2000 Auto Traverse and Comprehensive Chair (left to right)



4.5.3 Seat the infant patient in the AT/C chairs

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 4.5-4](#)).



Figure 4.5-4 Sequential images of infant car seat fitting on AT/C Chair (left to right)

4.5.4 Electrode placement and impedance test for ENG evaluation

When a patient is decided to be 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 4.5-5](#)).

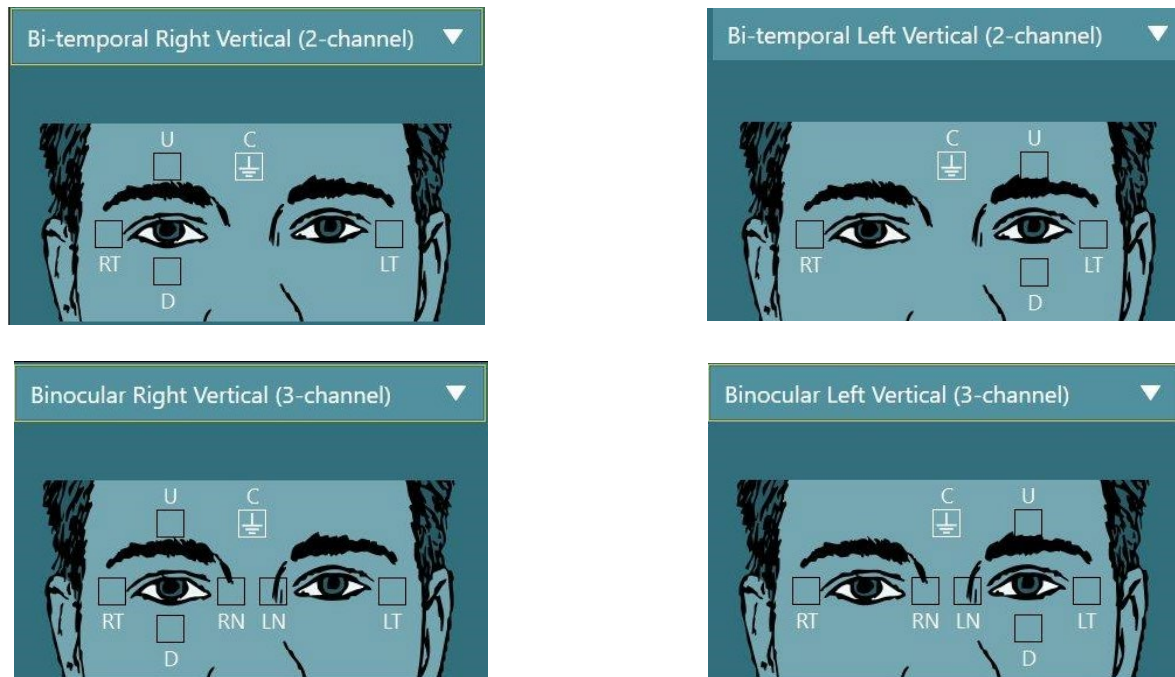


Figure 4.5-5 Electrode Montage Positions for ENG Evaluation



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 do the impedance test (refer to section 2.1 of additional information guide) to verify proper electrode signal reception. Once the operator gets the acceptable level of impedance (refer to section 2.1 of additional information guide), she/he can proceed with the calibration (refer to section 4.6) for the individual test of a test battery followed by the actual test.

4.5.5 Placing the goggles on the patient

When a patient is decided to be tested using 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 back 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.

4.5.6 Eye image adjustment

After placing the goggle on every individual patient, if necessary, the operator adjusts the eye image in order to track the patient's pupils adequately. Tap the 'BEGIN TESTING' button from the main screen, which will open the first test and display the eye images on the test screen. Center the eyes so that they appear in the middle of the image window (refer to Figure 4.5-6). If using the side mounted camera goggles, use the alignment knobs on the sides of the cameras (top knob for vertical adjustment, front knob for horizontal adjustment). If using the top mounted camera goggles, use the center eyes button found in the tools between the eye images or remote to adjust the eye image. If using the front mounted camera goggles, use both the center eyes button and manual adjustment of the camera in the goggle viewport to center and align the eye image. Use the focus knobs on the front and top mounted goggles to bring the eye image(s) into focus. The infrared reflections will be the smallest when the cameras are in optimal focus.



Figure 4.5-6 Center eyes button

4.6 Calibration

It is important to do the standard calibration on every individual patient before starting any test in the VisualEyes™ system. In general, 5-point calibration is performed as the standard calibration method.

Note: If a rotational 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.

From the left menu panel of the test, tap 'Calibration' to open the calibration screen. The calibration target will be displayed on the TV, projector screen or booth wall. The calibration target and calibration source hardware can be changed from the selection boxes when switching between tests with different hardware (e.g. EyeSeeCam goggle for EyeSeeCam vHIT). Use the 'Target Center position' slider to adjust the target's center position on the TV or projector to the patient's eye level. The target center in the booth enclosure can be manually adjusted by adjusting the laser box. Tap Start Calibration and instruct the patient to follow the target as it moves to the five calibration points. If the calibration is useable, the circles will be filled with green checkmarks. If the calibration is not optimal, the circles will be filled with red x marks. Calibration should be repeated if green check marks are not obtained for all five calibration points.



If the 5-point calibration is not achieved, the operator can use the 'Default Calibration' option to use the default calibration values. These values will provide an approximate calibration scaling; however, the accuracy of the measurements will be reduced when default calibration values are used. In general, the operator can accept the partially achieved calibration based on the clinical interest of evaluation (e.g. if all three horizontal calibration points are achieved, the operator can accept the calibration for vestibular tests. For oculomotor tests, all the five points are to be calibrated). Please refer to [Figure 4.6-1](#) for the pictorial reference.

Standard calibration is not mandatory for tests that require a torsion calibration (e.g. Dix-Hallpike test, Ocular Counter Roll and Lateral Head Roll) unless it becomes a first test/only test of the test battery.

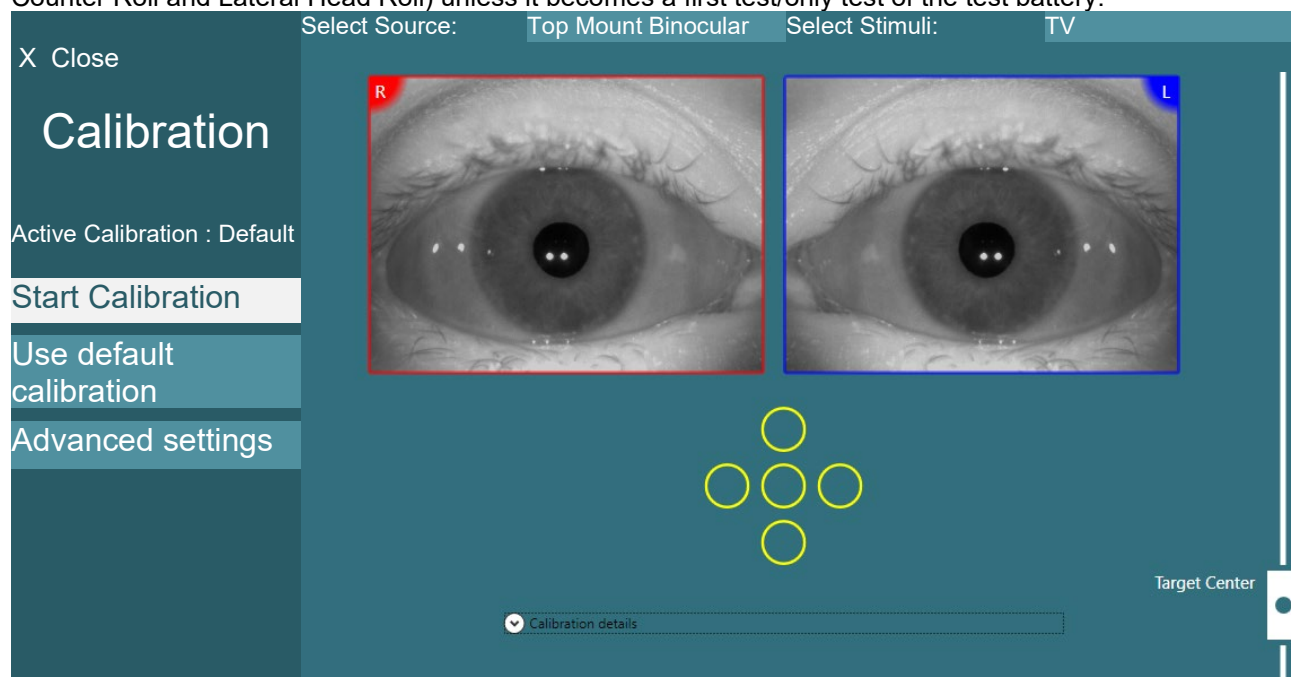


Figure 4.6-1 Calibration menu.

4.7 Testing the patient

4.7.1 Performing tests

Tests can be started in one of three ways:

- Tap on the START button on the test screen. This option is available for all tests
- Press the foot pedal or ENTER button on the RF remote. This option is ideal for starting tests when not at the computer. This option is also available for all tests.
- Press the switch on the side of the top mounted camera goggles. The switch is ideal for starting tests when positioned next to the patient, such as Dix-Hallpike and Positional tests.

Tests can be aborted in the following ways:

- Holding down the side switch for three seconds on the top mounted binocular goggles
- Pressing the ESC key on the RF remote or keyboard
- Pressing the patient stop button on the bottom of the right armrest of the Nydiag 200 chair or movable patient stop button on the Orion AT/C chairs

4.7.2 Video Frenzel

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.



4.7.3 Spontaneous nystagmus

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.

4.7.4 Dix-Hallpike / Advanced Dix-Hallpike

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 reclined fully (refer to [Figure 4.7-1](#)). 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 feet off on either side of the exam chair for balance. Use the recline handle to recline the chair to be supine. In the advanced version of the test, the VORTEQ™ IMU attaches to the goggles and provides feedback to the clinician to show if the patient has the head in the appropriate position and records torsion. 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.



Figure 4.7-1 Chair in supine position for Dix-Hallpike with head support removed (Orion and System 2000).

4.7.5 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 4.7-2](#)). 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 4.7-2 Supine positional test.

4.7.6 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 OKN 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.

4.7.7 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 or VORTEQ™ rate sensor to the binocular goggles. If using the VORTEQ™ rate sensor, make sure the sensor is manually fixed in the correct orientation for testing. 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.

4.7.8 Dynamic Visual Acuity

This test does not require any goggle. Ensure the chair is in the sitting position and locked. Attach the VORTEQ™ IMU or VORTEQ™ rate sensor 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. If the test is performed with a wrong orientation of the VORTEQ™ rate sensor, the operator gets a warning message from the software.



4.7.9 Video Head Impulse Testing (vHIT for VORTEQ™ and EyeSeeCam)

vHIT for 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 VORTEQ™ rate sensor is connected to the binocular goggles and manually oriented for the desired subtest (horizontal/vertical). In the use of VORTEQ™ rate sensor, the VLink will connect to the computer and the cable will have to stretch to the patient seated in the chair. If the VORTEQ™ IMU is used, it is wireless and make sure the IMU is switched on prior to starting the test.

vHIT for EyeSeeCam:

Ensure that the patient is seated in an upright position with arm rest and low back rest. The test can be done with the EyeSeeCam goggle with camera and built-in IMU. Ensure that the standard calibration and the head calibration is done before starting the test. The operator can then proceed with the subtests (Lateral, LARP, RALP and SHIMP). Please refer to '**Additional information**' for more detail.

4.7.10 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. Prior to 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.

4.7.11 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 4.7-3](#)). 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 4.7-3 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 or Freyss diagram or Claussen graph or Haid stoll graph or 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.

4.7.12 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 50°/second and 180°/second by default, and 100°/second as a standard option. In addition, there are options to test at velocities between 10 and 200°/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.

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 OKN 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 to the left 4 cm, back to center, then to the right 4 cm, 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.



4.8 Rotational chair error messages

4.8.1 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 as shown in [Figure 4.8-1](#). 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.

Figure 4.8-1 Chair speed error message.

4.8.2 Patient safety error (applicable for all type of rotational chairs)

If the patient's age lies outside the required age range for performing a rotary chair test, the software will give an error ([Figure 4.8-2](#)) 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.

Figure 4.8-2 Patient safety error message.

4.8.3 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 an error message ([Figure 4.8-3](#)). 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.

Figure 4.8-3 Emergency stop button pressed error message.

4.8.4 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 ([Figure 4.8-4](#)). 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.

Figure 4.8-4 Chair servo error state error message.



4.8.5 Rotary chair reclined position error (applicable for Orion/System 2000 reclining chair)

If the Orion Reclining or System 2000 Reclining chair is reclined during a rotary chair test, the software will present an error message (Figure 4.8-5) to the operator. 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.

Figure 4.8-5 Chair reclined error message.

4.8.6 Booth door open error (applicable for Orion AT/C 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 following message (Figure 4.8-6) that the door must be closed to resume testing.

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

Figure 4.8-6 Booth door open error.

4.8.7 Patient safety switch error (applicable for Orion AT/C chair)

If the patient pushes the abort switch provided with Orion A/C chairs, the software will display the following message (Figure 4.8-7) 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.

Figure 4.8-7 Patient safety switch error

4.8.8 Chair control board error (applicable for Orion AT/C chair)

If the Orion AT/C chair's USB cable disconnects during the test, the chair, laser and OKN drum will turn off and gradually come to a stop. The software will present the following error message (Figure 4.8-8) 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.

Figure 4.8-8 Chair control board error.

4.8.9 Watchdog timeout error (applicable for Orion AT/C chair)

If the system with an Orion AT/C chair stops responding, the Emergency Stop circuit will activate and the chair, laser and OKN drum will turn off and gradually come to a stop. Following, the operator shall exit the test or go to home screen and restarting the test will reset the watchdog timer. This will be indicated with the E-Stop lights up again.



4.9 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 the main USB cable from the computer and leave it unplugged for 20 seconds.
- Plug the main USB cable back into the computer.
- Once all the USB devices have been initialized, restart the VisualEyes™ software.

4.10 System shutdown

4.10.1 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.

4.10.2 Turn off stimulus

Turn off the TV using the remote control. Turn off the projector with the power button on the remote control and follow the instructions on the projection image.

4.10.3 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 Air Fx air irrigator or Aqua Stim 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 is used, turn off the observation monitor.

4.10.4 Turn off power sources

Laptop systems should have the USB hub power disconnected either from the hub or by turning off the power strip that powers the 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.





5 Care and maintenance

5.1 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 section 3.4.3 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.

5.2 Warranty and service

5.2.1 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 **24 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.

5.2.2 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.



6 General technical specifications

6.1 Computer specifications

Hardware and software

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.

6.2 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

6.3 Operation and storage specifications

Operation environment:

Temperature: 15° – 35° C (59°F - 95°F)

Relative Humidity: 30 – 90%

Transport:

Transport Temperature: -20° – 50° C (-4°F - 122°F)

Rel. Humidity: 30% – 80% Non-Condensing, Keep Dry

Storage:

Temperature: 0° – 50° C (32°F - 122°F)

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.



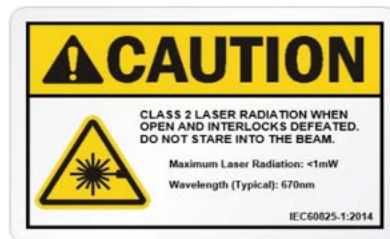
6.4 Component specifications

Orion Reclining Chair Specifications

Dimensions (L x W x H): 78 x 27 x 60 inches (198 x 69 x 152 cm)
Weight: 375 lbs (170 kg)
Maximum rotation: 200 degrees/second
Maximum patient weight: 350 lbs (160 kg)
Power required: 900W, 110 VAC (provided by isolation transformer)
IEC 60601-1 Class I, Type B

Orion Auto Traverse / Comprehensive Specifications

Booth Enclosure Dimensions (L x W x H): 81 x 81 x 94 inches
Booth Enclosure Weight: 650 lbs (295 kg)
Chair Dimensions (L x W x H): 24 x 24 x 65 inches (61 x 61 x 165 cm)
Chair Weight: 375 lbs (170 kg)
Maximum rotation: 350 degrees/second
Maximum patient weight: 400 lbs (181 kg)
Power required: 1000W
Laser specifications:
 Class: 2
 Wavelength: 670nm
 Beam divergence 0.35 mrad
 Pulse pattern: not pulsed, solid on state
 Maximum power output: 1 mW
IEC 60601-1 Class I, Type B



VLink Specifications

Dimensions: 4.8 x 4.0 x 1.5 inches (12 x 10 x 3 cm)
Weight: 0.65 lbs (0.30 kg)
Power: 5 VDC supplied by PC USB

DataLink Specifications

Dimensions (L x W x H): 7.3 x 9.8 x 2.0 inches (25 x 29.5 x 5.1 cm)
Weight: 4.2 lbs (1.9 kg)
Power: 110 – 220 VAC, 50 – 60 Hz, 1000 W
IEC 60601-1 Class II, Type B

DLB Specifications

Dimensions (L x W x H): 33 x 3.5 x 1.75 inches (83.8 x 8.9 x 4.4 cm)
Weight: 4.5 lbs (1.2 kg)
Power: 5 VDC supplied by PC USB

VORTEQ™ Inertial Measurement Unit (IMU) Specifications

Dimensions without cable (L x W x H): 2 x 1.1 x 0.9 inches (5.0 x 2.8 x 2.2 cm)
Weight without cable: 0.05 lbs (0.02 kg)
Power: 5 VDC supplied by PC USB

Component specifications top mounted VNG goggles

Binocular video eye tracking goggles.
Removable eye cover for vision-enabled or vision-denied recording.
USB 2.0, 4.5 m dual cables to PC.
Capture Resolution: 320 x 240 Pixels @ 100 fps.
Video Resolution: 640 x 240 Pixels @ 25 fps
Dimensions (L x W x H) 165 x 165 x 89 mm.
Horizontal and vertical eye movement measurement resolution: approx. 0.33 degrees.



Single IR LED infrared illumination: 950 nm at 1.5 mw/cm².
IEC 60601-1 Type B

Goggles weight:

Binocular VNG cameras

345g (occluded view) without cables.

Component specifications side mount VNG goggles

Monocular/binocular video eye tracking goggles.
Removable eye cover for vision-enabled or vision-denied recording
USB 2.0 or FireWire® 400, 4.5m cables to PC.
Capture Resolution: 640 x 480 Pixels @ 100 fps.
Video Resolution: 640 x 240 Pixels @ 25 fps
Images: 100 frames per second.
Dimensions (L x W x H): 302 x 216 x 131 mm.
Dispensing box with 24 pcs of disposable goggles foam pads.
IEC 60601-1 Type BF

Goggles weight:

Monocular VNG camera

240 g (non-occluded view).

320 g (occluded view).

Binocular VNG cameras

305 g (non-occluded view).

385 g (occluded view).

Component specifications front mounted VNG goggles

Monocular video eye tracking goggles.
Swivel eye portal cover for vision-enabled or vision-denied recording.
USB 2.0, 4.5 m cable to PC.
Capture Resolution: 640 x 480 Pixels @ 50 fps.
Video Resolution: 640 x 480 Pixels @ 25 fps
Dimensions (L x W x H) 165 x 165 x 89 mm.
Horizontal and vertical eye movement measurement resolution: approx. 0.25 degrees.
Dual IR LED infrared illumination: 950 nm at 1 mW/cm².

Component specifications EyeSeeCam camera and goggles

Monocular video eye tracking goggles, camera can track either eye.
Molded flexible frame with snug fit, cleanable silicone contact areas, and fits pediatric and adult faces
Inertial Measurement Unit (IMU) gyroscope with 6 degrees of freedom
Instantaneous gain measured at 40, 60, and 80 ms – equivalent to scleral search coil method
USB 2.0, 5 VDC ±0.25 VDC
Weight: 72g (40g from goggles, 32g from camera)
Sample rate: 220 Hz
Laser specification: Class 1



Component specifications Pediatric Observation camera

Monocular video eye tracking camera
USB 2.0, 2 6ft (1.8m) cables, 5 VDC 0.5 A per cable
IR LED infrared illumination: 252.6 mW/sr



6.5 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. The ORION is suitable for use in all commercial, industrial, business and residential environments.
RF emissions CISPR 11	Class B	
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% <i>UT</i> for 0.5 cycle 0 % <i>UT</i> for 1 cycle and 70% <i>UT</i> for 25/30 cycles Single phase: at 0°	0% <i>UT</i> for 0.5 cycle 0 % <i>UT</i> for 1 cycle and 70% <i>UT</i> 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: <i>UT</i> 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
Conducted RF IEC / EN 61000-4-6	3 Vrms 150kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any parts of the ORION , including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = 1,2\sqrt{P}$
	6 Vrms in ISM bands 150kHz to 80 MHz 80 % AM at 1 kHz	6 Vrms	
	Radiated RF IEC / EN 61000-4-3	3 V/m 80 MHz to 2,7 GHz 80 % AM at 1 kHz	
			$d = 1,2\sqrt{P}$ 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

Return Report – Form 001



Opr. dato: 2014-03-07	af: EC	Rev. dato: 2015-04-15	af: MSt	Rev. nr.: 4
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Company: _____

Address: _____

Phone: _____

Fax or e-mail: _____

Address

DGS Diagnostics Sp. z o.o.
ul. Słoneczny Sad 4d
72-002 Doluje
Polska

Contact person: _____ Date: _____

Following item is reported to be:

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

Item:

Type:

Quantity:

Serial No.: _____

Supplied by: _____

Included parts: _____

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

Description of problem or the performed local repair:

Returned according to agreement with: ☐ Interacoustics, ☐ Other : _____

Date : _____

Person : _____

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

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

In order to ensure instant and effective treatment of returned goods, it is important that this form is filled in and placed together with the item.

Please note that the goods must be carefully packed, preferably in original packing, in order to avoid damage during transport. (Packing material may be ordered from Interacoustics)

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