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Technical Specifications

VisualEyes™

Micromedical
by Interacoustics



Interacoustics



License Overview (without Rotary Chairs)

	VisualEyes™ 505	VisualEyes™ 515	VisualEyes™ 525	VisualEyes™ EyeSeeCam
Video Frenzel	X		X	
Spontaneous Nystagmus	X	X	X	X
Gaze			X	
Dix Hallpike		X	X	
Positional		X	X	
Bithermal Caloric*		X	X	
Optokinetic			X	
Smooth Pursuit			X	
Self-Paced Saccades			X	
Smooth Pursuit Neck Torsion			X	
Cervical Gaze			X	
Saccade			X	
Ocular Counter Roll w. torsional tracking			X	
Saccadometry			X	
EyeSeeCam vHIT				X
ADD-ON: VORTEQ™ Assessment** - Dynamic Visual Acuity - Dix Hallpike Advanced - Lateral Head Roll - Gaze Stabilization Test - Functional Vision Head Impulse Test	X	X	X	
ADD-ON: VORTEQ™ Diagnostic** - Active Head Rotation - vHIT VORTEQ™			X	
ADD-ON: Research Module	X	X	X	X
ADD-ON: EOG Accessory kit for VNG		X	X	
ADD-ON: Static SVV module	X	X	X	
ADD-ON: External Sync	X	X	X	X

* Requires separate caloric irrigator

** Only compatible with top mount or side mount goggles



License Overview (with Rotary Chairs)

	Orion R + VE515	Orion R + VE525	Orion C Basic	Orion AT Basic	Orion C + VE525	Orion AT + VE525
Video Frenzel		X			X	X
Spontaneous Nystagmus	X	X	X	X	X	X
Gaze		X	X	X	X	X
Dix Hallpike	X	X			X	X
Positional	X	X			X	X
Bithermal Caloric*	X	X			X	X
Optokinetic		X	X	X	X	X
Smooth Pursuit		X	X	X	X	X
Saccade		X	X	X	X	X
Self-Paced Saccades		X			X	X
Smooth Pursuit Neck Torsion		X			X	X
Cervical Gaze		X			X	X
Ocular Counter Roll		X			X	X
Saccadometry		X			X	X
Step Velocity	X	X	X	X	X	X
Sinusoidal Harmonic Acceleration (SHA)	X	X	X	X	X	X
VOR Suppression	X	X	X	X	X	X
Visual VOR	X	X	X	X	X	X
Static SVV			X	X	X	X
Dynamic SVV				X		X
ADD-ON: VORTEQ™ Assessment** - Dynamic Visual Acuity - Dix Hallpike Advanced - Lateral Head Roll - Gaze Stabilization Test - Functional Vision Head Impulse Test	X	X			X	X
ADD-ON: VORTEQ™ Diagnostic** - Active Head Rotation - vHIT VORTEQ™		X			X	X
ADD-ON: Research Module	X	X	X	X	X	X
ADD-ON: Static SVV module	X	X				
ADD-ON: External Sync	X	X	X	X	X	X



	Orion R + VE515	Orion R + VE525	Orion C Basic	Orion AT Basic	Orion C + VE525	Orion AT + VE525
ADD-ON: EOG Accessory kit for VNG	X	X			X	X
ADD-ON: EOG Accessory kit for Orion C/AT			X	X	X	X
ADD-ON: Child Option Accessory kit for Orion C/AT			X	X	X	X

* Requires separate caloric irrigator

** Only compatible with top mount or side mount goggles

Included and optional parts

VisualEyes™ 505	VisualEyes™ 515	VisualEyes™ 525	VisualEyes™ EyeSeeCam	Orion AT/C Basic
Included major parts: - VNG goggle of choice - VisualEyes™ software - Remote control / foot switch - Full HD room camera - Cleaning cloth - Introduction guides - Certificates and reports: e.g. test result report, license certificate, certificate of conformity, and if applicable, safety test report.	Included major parts: - VNG goggle of choice - VisualEyes™ software - Remote control / foot switch - Full HD room camera - Cleaning cloth - Introduction guides - Certificates and reports: e.g. test result report, license certificate, certificate of conformity, and if applicable, safety test report.	Included major parts: - VNG goggle of choice - VisualEyes™ software - Remote control / foot switch - Full HD room camera - Cleaning cloth - Introduction guides - Certificates and reports: e.g. test result report, license certificate, certificate of conformity, and if applicable, safety test report.	Included major parts: - EyeSeeCam vHIT goggle and camera - VisualEyes™ software - Full HD room camera - Cleaning cloth - Introduction guides - Certificates and reports: e.g. test result report, license certificate, certificate of conformity, and if applicable, safety test report.	Included major parts: - Orion Auto-Traverse or Comprehensive chair - Top mount goggle - VisualEyes™ software - Remote control / foot switch - Full HD room camera - Cleaning cloth - Introduction guides - Certificates and reports: e.g. test result report, license certificate, certificate of conformity, and if applicable, safety test report



VisualEyes™ 505	VisualEyes™ 515	VisualEyes™ 525	VisualEyes™ EyeSeeCam	Orion AT/C Basic
Optional parts: • Pediatric goggle • TRV Chair • VORTEQ™ Assessment • Research Module • Static SVV Module • External Sync.	Optional parts: • Pediatric goggle • TRV Chair • VORTEQ™ Assessment • Research Module • Static SVV Module • EOG Accessory kit for VNG • Orion Reclining • AquaStim • AirFx • External Sync.	Optional parts: • Pediatric goggle • TRV Chair • VORTEQ™ Assessment • VORTEQ™ Diagnostic • Research Module • EOG Accessory kit for VNG • Orion Reclining • Orion Comprehensive • Orion Auto-Traverse • AquaStim • AirFx • Digital Lightbar • Static SVV module • External Sync.	Optional Parts: • Research Module • External Sync.	Optional Parts: • Research Module • Appropriate optional parts for the chosen chair (1.4.4)



Additional parts based on VNG goggle type

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

Additional parts based on rotary chairs

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



Additional parts based on add-on modules

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



	EOG accessory kit for VNG	EOG accessory kit for Orion C/AT	Child option accessory kit for Orion C/AT
Compatible with:	• VisualEyes™ 515 • VisualEyes™ 525	• VisualEyes™ 525 + Orion C/AT • Orion Comprehensive Basic • Orion Auto-Traverse Basic	• VisualEyes™ 525 + Orion C/AT • Orion Comprehensive Basic • Orion Auto-Traverse Basic
Compatible features/tests (If system is licensed for the tests):	• 3-channel ENG testing compatible with below tests: ○ Spontaneous Nystagmus ○ Gaze ○ Smooth Pursuit ○ Saccade ○ Optokinetic ○ Positional ○ Dix Hallpike ○ Bithermal Caloric ○ Saccadometry	• 3-channel ENG testing compatible with below tests: ○ Spontaneous Nystagmus ○ Gaze ○ Smooth Pursuit ○ Saccade ○ Optokinetic ○ Step Velocity ○ Sinusoidal Harmonic Acceleration	• Rotary chair testing for children down to 1 year of age
Included major parts:	• Datalink • 7x electrode cables (3 channels) • Snap electrodes • Electrode skin preparation accessory	• ENG built into the back of the Orion C/AT rotary chairs • 7x electrode cables (3 channels) • Snap electrodes • Electrode skin preparation accessory	• Pediatric front mount goggle (USBM2.1P) • Child seat • Pediatric observation camera



General technical specifications

Minimum computer requirements

Desktop PC: One PCI Express card available (FireWire® systems only).

USB port required (expanded by USB hub)

Intel i5 processor 2.5 GHz or better, and not older than 5th generation. Minimum 4 cores (4 threads).

Minimum 8 GB RAM or more.

Hard drive with min. 250 GB space.

Minimum display of 1366x768 (Higher resolution recommended).

Touch monitor or laptop with touch screen is highly recommended though not required.

Operating systems supported:

Windows® 10 64-bit.

Windows® 11 64-bit.

Standards

IEC 60601-1:2005, AMD1: 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 S3.45:2009	Standard Procedures For Testing Basic Vestibular Function

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.



Goggles



Side Mount (2D-VOGFW)

Quick Description:		Goggle with side mounted cameras. This goggle is highly versatile and will be able to fit the use of most clinics as it can be configured with either FireWire or USB connection and either monocular or binocular.
Technical Specifications:		
Standards:	Applied Part Type: BF according to IEC 60601-1	
Operation Environment:	Temperature:	15 – 35°C
	Relative Humidity:	30 – 90%
Transport & Storage Environment:	Transport Temperature:	-20 – 50°C
	Storage Temperature:	0 – 50°C
	Relative Humidity:	30 – 80%, Non-condensing
Interface:	FireWire / USB 2.0	
Cable Length:	4.5m (3m for Orion Reclining)	
Camera Configuration:	Monocular / Binocular	
Removable Cover:	Yes	
Eye Movement Resolution:	0.22°	
Dynamic Range:	±30° Horizontal	
	±35° Vertical	
Capture Resolution (per camera):	640x480 @100fps	
Video Resolution:	Monocular: 320x240 @25fps	
	Binocular: 640x240 @25fps	
Dimensions (L x W x H):	302 x 216 x 131 mm	
Weight:	Monocular: 240g (320g with cover)	
	Binocular: 305g (385g with cover)	
Dual IR LED infrared illumination:	940 nm @ 65 mW/sr	
Face Cushion:	Single-use Disposable Soft Foam Pads	
VORTEQ™ Compatibility:	Yes	
Max. Magnetic DC field:	1210 µT	



Top Mount (BG4.0USB)

Quick Description:

Goggle with top mounted cameras.
This binocular goggle includes start/stop button on goggle, along with software controlled image centering.
Also available with Asian Faceplate (BG4.0KUSB).

Technical Specifications:

Standards:	Applied Part Type: BF according to IEC 60601-1	
Operation Environment:	Temperature:	15 – 35°C
	Relative Humidity:	30 – 90%
Transport & Storage Environment:	Transport Temperature:	-20 – 50°C
	Storage Temperature:	0 – 50°C
	Relative Humidity:	30 – 80%, Non-condensing
Interface:	USB 2.0	
Cable Length:	4.5m (3m for Orion Reclining / 0.9m for Orion Auto-Traverse/Comprehensive)	
Camera Configuration:	Binocular	
Removable Cover:	Yes	
Eye Movement Resolution:	0.3°	
Dynamic Range:	±45° Horizontal ±25° Vertical	
Capture Resolution (per camera):	320x240 @100fps	
Video Resolution:	Binocular: 640x240 @25fps	
Dimensions (L x W x H):	165 x 165 x 89 mm	
Weight:	345g (with cover)	
Single IR LED infrared illumination:	950 nm at 1.5 mW/cm ²	
On-goggle Start/Stop Button:	Yes	
Software image centering:	Yes	
Face Cushion:	Soft Rubber	
VORTEQ™ Compatibility:	Yes	
Max. Magnetic DC field:	90 µT	



Front Mount (USBM2.1A)

Quick Description:

Goggle with front mounted camera.

This monocular goggle includes a camera that can easily be interchanged between right and left eye.

Also available as a smaller pediatric version (USBM2.1P)

Technical Specifications:

Standards:	Applied Part Type: BF according to IEC 60601-1	
Operation Environment:	Temperature:	15 – 35°C
	Relative Humidity:	30 – 90%
Transport & Storage Environment:	Transport Temperature:	-20 – 50°C
	Storage Temperature:	0 – 50°C
	Relative Humidity:	30 – 80%, Non-condensing
Interface:	USB 2.0	
Cable Length:	4.5m (3m For Rotary Chair Version)	
Camera Configuration:	Monocular (Interchangeable between right and left eye)	
Removable Cover:	Yes	
Eye Movement Resolution:	0.31°	
Dynamic Range:	±20° Horizontal	
	±20° Vertical	
Capture Resolution (per camera):	640x480 @50fps	
Video Resolution:	Monocular: 320x240 @25fps	
Dimensions (L x W x H):	165 x 165 x 89 mm	
Dual IR LED infrared illumination:	950 nm at 1 mW(cm ²)	
Face Cushion:	Soft Rubber	
VORTEQ™ Compatibility:	No	
Max. Magnetic DC field:	160 µT	



EYESEECAM vHIT

Quick Description:

Lightweight monocular goggle for EyeSeeCam vHIT.
The camera can be interchanged between right and left eye.
Fits both pediatric and adult faces.
Also available with Asian goggle frame version (EyeSeeCam vHIT ASIA).

Technical Specifications:

Standards:	Applied Part Type: BF according to IEC 60601-1	
Operation Environment:	Temperature:	15 – 35°C
	Relative Humidity:	30 – 90%
	Ambient Pressure:	98 – 104 kPa
Transport & Storage Environment:	Transport Temperature:	10 – 50°C
	Storage Temperature:	10 – 35°C
	Relative Humidity:	30 – 80%
Interface:	USB 2.0	
Cable Length:	2.95m	
Camera Configuration:	Monocular (Interchangeable between right and left eye)	
Capture Resolution:	376x120 @220fps	
Video Resolution:	188x120 @25fps	
Dimensions (L x W x H):	Goggle: 139 x 60 x 56 mm	
	Camera: 48 x 42 x 35 mm	
	Combined: 139 x 82 x 81	
Weight:	Goggle: 40g	
	Camera: 32g	
	Combined: 72g	
Head Tracking Sensor:	Inertial Measurement Unit (IMU) with 6 degrees of freedom	
Laser:	Class 1	
Face Cushion	Cleanable silicone	
Max. Magnetic DC field:	150 μ T	



Accessories



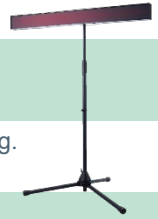
VORTEQ™ IMU

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

DATALINK & ENG in Chair



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



DIGITAL LIGHTBAR

Quick Description:

Digital Lightbar presenting visual stimuli for oculomotor testing.

Technical Specifications:

Interface:	USB 2.0
Dimensions (L x W x H):	83.8 x 8.9 x 4.4 cm
Weight:	1.2 kg
Power:	5 VDC supplied by PC USB



TRV Chair



TRV CHAIR

Quick Description:	Unique chair with 2-axis 360° rotation for diagnosis and treatment of Benign Paroxysmal Positional Vertigo (BPPV) in all semi-circular canals.	
Technical Specifications:		
Standards:	Applied Part Type: B according to IEC 60601-1	
Operation Environment:	Temperature:	5 – 40°C
	Relative Humidity:	30 – 90%
Transport & Storage Environment:	Transport Temperature:	-15 – 40°C
	Storage Temperature:	-15 – 40°C
	Relative Humidity:	30 – 80%
Rotation Control:	Mechanical	
Interface	USB	
Maximum Patient Weight:	150 kg	
Dimensions (L x W x H):	160 x 120 x 190cm	
Weight:	640 kg	
Patient Fixation:	4-point harness for body Shoulder supports Leg strap Ankle strap Head support with headstrap	
Degrees of freedom:	2-axis 360°	
Shipping info:	Shipping crate dimensions (LxWxH):	193 x 183 x 165 cm
	Shipping Weight:	1100 kg



Rotary chairs



ORION RECLINING ROTARY CHAIR

Quick Description:	Rotary chair with reclining options, for caloric, Dix Hallpike, and positional tests.	
Technical Specifications:		
Standards:	Applied Part Type: B according to IEC 60601-1” “Protection class: Class I according to IEC 60601-1	
Operation Environment:	Temperature:	15 – 35°C
	Relative Humidity:	30 – 80%
Transport & Storage Environment:	Transport Temperature:	0 – 50°C
	Storage Temperature:	0 – 50°C
	Relative Humidity:	30 – 80%, Non-condensing
Rotation Control:	Software controlled	
Available rotary tests (on top of standard VisualEyes™ Tests):	Step Rotation (up to 200°/s) Sinusoidal Harmonic Acceleration (0.01 – 0.64 Hz) VOR Suppression (0.01-0.64 Hz)	
Interface:	USB	
USB Cable Length:	3m	
Power Cable Length:	2.5m	
Maximum Chair Speed:	200°/s	
Maximum Chair Acceleration:	100°/s²	
Maximum Patient Weight:	160kg	
Dimensions (L x W x H):	Upright: 94 x 69 x 183 cm Reclined: 198 x 69 x 152 cm	
Weight:	170 kg	
Patient Fixation:	Safety belt for body Head strap (Only for TopMount goggle)	
Headrest:	Yes (Detachable for Dix Hallpike test)	
Footrest:	Yes	
Emergency Stop:	Yes	
Reclining range:	90° (upright) - 0° (flat) w/ 30° indication label for caloric irrigation	
Shipping info:	Shipping crate dimensions (LxWxH):	123 x 100 x 180 cm
	Shipping Weight:	323 kg
Power supply:	110VAC, 220VAC step down to 110VAC through included isolation transformer	



ORION AUTO-TRAVERSE / COMPREHENSIVE ROTARY CHAIR

Quick Description:

Rotary chair in enclosure with built-in laser and optokinetic drum for visual stimuli.

With add-on packages it is possible to do ENG testing in the rotary chair and perform tests in pediatric patients.

With the Orion Auto-Traverse, it is also possible to do off-axis rotation for dynamic SVV.

Technical Specifications:

Standards:	Applied Part Type: B according to IEC 60601-1" "Protection class: Class I according to IEC 60601-1	
Operation Environment:	Temperature:	15 – 35°C
	Relative Humidity:	30 – 80%
Transport & Storage Environment:	Transport Temperature:	0 – 50°C
	Storage Temperature:	0 – 50°C
	Relative Humidity:	30 – 80%, Non-condensing
Rotation Control:	Software controlled	
Available rotary tests (on top of standard VisualEyes™ Tests):	Step Rotation (up to 350°/s) Sinusoidal Harmonic Acceleration (0.01 – 1.28 Hz) VOR Suppression (0.01 – 1.28 Hz) Static SVV Dynamic SVV (only Auto-Traverse)	
Interface:	USB 2.0	
Maximum Chair Speed:	350°/s	
Maximum Chair Acceleration:	200°/s	
Maximum Patient Weight:	180kg	
Dimensions (L x W x H):	Chair: 61 x 61 x 165 cm Booth Enclosure: 206 x 206 x 239 cm	
Required minimum ceiling height:	245 cm	
Weight:	Chair:	170 kg (375 lbs)
	Booth Enclosure:	295 kg (650 lbs)
Patient Fixation:	Safety belt for body Ankle belt Head strap	
Headrest:	Yes	
Footrest:	Yes	
Emergency Stop:	Yes	
Laser:	Class:	2
	Wavelength:	680 nm
	Beam divergence:	0.35 mrad
	Pulse pattern:	Not pulsed, solid on state
	Maximum Power Output:	<1 mW
EOG built in:	See technical specifications for DATALINK (EOG/ENG) under Accessories	



Lateral Movement:	-7cm to +7cm (only Auto-Traverse)
Lateral Movement Speed:	0.8 cm/sec (only Auto-Traverse)

Shipping info:	Shipping crate dimensions (LxWxH):	Enclosure crate: 236x118x133 cm Chair crate: 119x175x100 cm Accessories pallet: 122x60x115 cm
Power supply:	110VAC, 220VAC step down to 110VAC through included isolation transformer	

Orion Auto-Traverse/Comprehensive accessories



PEDIATRIC OBSERVATION CAMERA

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

Caloric irrigators

Please see separate datasheets for AquaStim and AirFx.



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.

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.

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 result in improper operation.

This equipment complies with IEC60601-1-2:2014+AMD1:2020, 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.

NOTICE: If Non-Medical Electronic Equipment (Typical information technology equipment) is attached, it is the responsibility of the operator to ensure that this equipment comply to applicable standards and the system as whole complies to the EMC requirements. Commonly used standards for EMC testing information technology equipment and similar equipment¹ are:

Emissions testing

EN 55032 (CISPR 32)
EN 61000.3.2

EN 61000.3.3

Electromagnetic Compatibility Of Multimedia Equipment – Emission Requirements
Electromagnetic compatibility (EMC) – Limits for harmonic current emissions
(AC mains only, Equipment input current less than or equal to 16 A per phase)
Electromagnetic compatibility (EMC) – Limits – Limitation of voltage changes,
voltage fluctuations and flicker in public low-voltage supply systems (AC mains only,
Equipment input current less than or equal to 16 A per phase)

Immunity testing

EN 55024 (CISPR 24)

Information technology equipment – Immunity characteristics – Limits and methods
of measurement

¹ Products include personal computer, PC, tablet, laptop, notebook, mobile device, PDA, Ethernet hub, router, WiFi, computer peripheral, keyboard, mouse, printer, plotter, USB storage, Hard drive storage, solid-state storage and many more.



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

Item	Manufacturer	Model
Goggle, 2-D VOGfw	Interacoustics	2D VOGfw
Goggle, BG4.0USB	Interacoustics	BG4.0USB
Goggle, USB2.1A	Interacoustics	USB2.1A
Goggle, USB2.1P	Interacoustics	USB2.1P
Emergency switch	Interacoustics	Emergency switch
Goggle, EyeSeeCam USB cable	Interacoustics	EyeSeeCam

Anyone connecting additional equipment is responsible for making sure the system complies with the IEC 60601-1-2 standard.

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:

Description	Length	Screened (Yes/No)
Goggle, 2-D VOGfw	4,5	Yes
Goggle, BG4.0USB	1,8	Yes
Goggle, USB2.1A	1,8	Yes
Goggle, USB2.1P	1,8	Yes
Goggle, EyeSeeCam USB cable	2,9	Yes
Goggles USB Monocular Adult Mask or Pediatric Mask	1,8	Yes
Emergency switch	4,4	No



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 *Instrument*.

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 $d = 1.17\sqrt{P}$	80 MHz to 800 MHz $d = 1.17\sqrt{P}$	800 MHz to 2.7 GHz $d = 2.23\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.70	3.70	7.37
100	11.70	11.70	23.30

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1 At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2 These guidelines may not apply to all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.



Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The 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%.
Immunity to proximity fields from RF wireless communications equipment IEC 61000-4-3	Spot freq. 385-5.785 MHz Levels and modulation defined in table 9	As defined in table 9	RF wireless communications equipment should not be used close to any parts of the Instrument .
Electrical fast transient/burst IEC61000-4-4	+2 kV for power supply lines +1 kV for input/output lines	+2 kV for power supply lines +1 kV for input/output lines	Mains power quality should be that of a typical commercial or residential environment.
Surge IEC 61000-4-5	+1 kV Line to line +2 kV Line to earth	+1 kV Line to line +2 kV Line to earth	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> (100% dip in <i>UT</i>) for 0.5 cycle, @ 0, 45, 90, 135, 180, 225, 270 and 315° 0% <i>UT</i> (100% dip in <i>UT</i>) for 1 cycle 40% <i>UT</i> (60% dip in <i>UT</i>) for 5 cycles 70% <i>UT</i> (30% dip in <i>UT</i>) for 25 cycles 0% <i>UT</i> (100% dip in <i>UT</i>) for 250 cycles	0% <i>UT</i> (100% dip in <i>UT</i>) for 0.5 cycle, @ 0, 45, 90, 135, 180, 225, 270 and 315° 0% <i>UT</i> (100% dip in <i>UT</i>) for 1 cycle 40% <i>UT</i> (60% dip in <i>UT</i>) for 5 cycles 70% <i>UT</i> (30% dip in <i>UT</i>) for 25 cycles 0% <i>UT</i> (100% dip in <i>UT</i>) for 250 cycles	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.
Radiated fields in close proximity — Immunity test IEC 61000-4-39	9 kHz to 13.56 MHz. Frequency, level and modulation defined in AMD 1: 2020, table 11	As defined in table 11 of AMD 1: 2020	If The Orion contains magnetically sensitive components or circuits, the proximity magnetic fields should be no higher than the test levels specified in Table 11

Note: *UT* 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 6 Vrms In ISM bands (and amateur radio bands for Home Healthcare environment.)	3 Vrms 6 Vrms	Portable and mobile RF communications equipment should be used no closer to any parts of the Instrument , including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = \frac{3,5}{V_{rms}} \sqrt{P}$
Radiated RF IEC / EN 61000-4-3	3 V/m 80 MHz to 2,7 GHz 10 V/m 80 MHz to 2,7 GHz Only for Home Healthcare environment	3 V/m 10 V/m (If Home Healthcare)	$d = \frac{3,5}{V/m} \sqrt{P} \text{ 80 MHz to 800 MHz}$ $d = \frac{7}{V/m} \sqrt{P} \text{ 800 MHz to 2,7 GHz}$ 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 **Instrument**.

^{b)} Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.