

Technical Specifications
Micromedical
VisualEyes™ 515
VisualEyes™ 525
by Interacoustics



Included and Optional Parts

The VisualEyes™ system is a sophisticated, videonystagmography analysis software platform that is available in two different versions: VisualEyes™ 515 and VisualEyes™ 525. Both systems consist of laptop/desktop PC, goggles (top mounted/ side mounted/ front mounted cameras) along with other parts as specified in the table on page 2.

The products vary in their testing capabilities. Tests included in VisualEyes™ 515 are Spontaneous Nystagmus, Dix-Hallpike, Positional and Calorics. VisualEyes™ 525 includes these tests with the addition of the oculomotor tests (Gaze, Smooth Pursuit, Random Saccade and Optokinetic). VisualEyes™ can also be used with the Reclining Rotary Chair, which includes the tests above, with the addition of Sinusoidal Harmonic Acceleration, Step Test, VOR Suppression, Visual VOR and Video Frenzel.

Tests	VisualEyes™ 515	VisualEyes™ 515 with Reclining Chair	VisualEyes™ 525	VisualEyes™ 525 with Reclining Chair
Calibration	Yes	Yes	Yes	Yes
Spontaneous nystagmus	Yes	Yes	Yes	Yes
Gaze	No	No	Yes	Yes
Smooth Pursuit	No	No	Yes	Yes
Random Saccade	No	No	Yes	Yes
Optokinetic	No	No	Yes	Yes
Dix Hallpike	Yes	Yes	Yes	Yes
Positional	Yes	Yes	Yes	Yes
Bithermal Caloric	Yes	Yes	Yes	Yes
Sinusoidal Harmonic Acceleration	No	Yes	No	Yes
Step Test	No	Yes	No	Yes
VOR Suppression	No	Yes	No	Yes
Visual VOR	No	Yes	No	Yes
Video Frenzel	No	No	Yes	Yes

As standard VisualEyes™ VNG system is delivered with the following:

	USB camera systems	FireWire® camera systems
Included parts	Hand held RF Remote Control and/or Foot pedal VisualEyes™ 515/525 installation media OtoAccess™ Database media Cleaning cloth for lens and goggle mirrors	
Optional parts based on goggle type	<p>2D-VOGfw goggle side mounted cameras USB 2.0 camera module (two modules in binocular configuration) Disposable goggle foam pads – Box of 24 pcs 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 camera 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 camera 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 cameras 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 cameras 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 PCExpressCard stabilization kit (laptop configuration) PCExpressCard (for laptop configuration) PCI ExpressCard (for tower PC configuration) 4-port USB hub</p>

<p>Optional parts based on reclining chair type</p>	<p><i>Using the Orion rotary chair</i> Orion rotary chair USB cable Emergency Stop button with Ethernet connector Power cord</p> <p><i>Using the System 2000 reclining chair</i> System 2000 reclining chair Chair controller USB cable Emergency Stop button Power cord</p>	<p><i>Using the Nydiag 200 rotary chair</i> Nydiag 200 rotary chair Ethernet to USB chair cable Emergency Stop button with Ethernet connector FireWire® cable</p>
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General Technical Specifications

Hardware and software

Laptop PC: One 34 mm PCIeExpressCard slot available (for side mount FireWire® camera goggles only).

Desktop PC: One PCIeExpress card available (for side mount FireWire® camera goggles only).

USB port required (expanded by USB hub)

Intel i5 processor 2.5 GHz or better, and not older than 2nd generation

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 32-bit and 64-bit.

Windows® 8.1 64-bit.

Windows® 10 64-bit.

Standards

EN 60601-1 2012	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
EN 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

Operation and storage specifications

Operation environment:

Temperature: 15° – 35° C

Relative Humidity: 30 – 90%

Transport:

Transport Temperature: -20° – 50° C

Rel. Humidity: 10% – 95% Non-Condensing, Keep Dry

Storage:

Temperature: 0° – 50° C

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 rotational chair, an isolation transformer is used to supply power to the components from power mains.

Component specifications

Component specifications top mount 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.

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 goggle foam pads.

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 mount 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.

Electromagnetic compatibility (EMC)


Electromagnetic compatibility (EMC) for top-mounted goggles

Medical electrical equipment needs special precautions regarding electromagnetic compatibility (EMC) and needs to be installed and put into service according to the EMC information provided.

 **Caution**

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

The VNG was tested for EMC compliance as a Group 1, Class B device.

 **Caution**

Use of accessories, transducers, and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation. Contact Micromedical for approved replacement parts.

Important

The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

Guidance and manufacturer’s declaration – electromagnetic emissions		
<i>The VNG is intended for use in the electromagnetic environment specified below. The customer or the user of the VNG should assure that it is used in such an environment.</i>		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The VNG uses RF energy only for its internal functions. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The VNG is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class B	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	complies	

Guidance and manufacturer’s declaration – electromagnetic immunity			
<i>The VNG is intended for use in the electromagnetic environment specified below. The customer or the user of the VNG should assure that it is used in such an environment.</i>			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge immunity (ESD) IEC 61000-4-2	+/- 6 kV contact +/- 8 kV air	+/- 6 kV contact +/- 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Radiated RF Immunity IEC 61000-4-3	Stress 4.5 V/M	Stress 4.5 V/M	Not Applicable

Electrical fast transient/burst IEC 61000-4-4	+/- 2 kV for power supply lines +/- 1 kV for input/output lines	+/- 2 kV for power supply lines. No input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge immunity IEC 61000-4-5	+/- 1 kV line(s) to line(s) +/- 2 kV line(s) to earth	+/- 1 kV line(s) to line(s) +/- 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Conducted RF Immunity IEC 61000-4-6	Stress 3 V and 10 V	Stress 3 V and 10 V	Not applicable
Power Frequency Magnetic Immunity 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 hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% U_T 10 ms 40% U_T 100 ms 70% U_T 500 ms 0% U_T 5000 ms	0% U_T 10 ms 40% U_T 100 ms 70% U_T 500 ms 0% U_T 5000 ms	Mains power quality should be that of a typical commercial or hospital environment. If the user of the VNG requires continued operation during power mains interruptions, it is recommended that the VNG be powered from an uninterruptible power supply or battery.
NOTE: U_T is the mains voltage prior to application of the test level.			

Electromagnetic compatibility (EMC) for side-mounted goggles

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

VisualEyes™ has been tested for EMC emissions and immunity as a standalone VisualEyes™. Do not use VisualEyes™ adjacent to or stacked with other electronic equipment. If adjacent or stacked use is necessary, the user should verify normal operation in the configuration.

The use of accessories, transducers and cables other than those specified, with the exception of servicing parts sold by Interacoustics as replacement parts for internal components, may result in increased EMISSIONS or decreased IMMUNITY of the device.

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

Guidance and manufacturer’s declaration - electromagnetic emissions		
VisualEyes™ is intended for use in the electromagnetic environment specified below. The customer or the user of VisualEyes™ should assure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	VisualEyes™ 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. VisualEyes™ is suitable for use in all commercial, industrial, business, and residential environments.
RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Not Applicable	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Not applicable	


Recommended separation distances between portable and mobile RF communications equipment and VisualEyes™.			
VisualEyes™ is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of VisualEyes™ can help prevent electromagnetic interferences by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and VisualEyes™ as recommended below, according to the maximum output power of the communications equipment.			
Rated Maximum output power of transmitter [W]	Separation distance according to frequency of transmitter [m]		
	150 kHz to 80 MHz $d = 1.17\sqrt{P}$	80 MHz to 800 MHz $d = 1.17\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.23\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.70	3.70	7.37
100	11.70	11.70	23.30
For transmitters rated at a maximum output power not listed above, the recommended separation distance <i>d</i> in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where <i>P</i> 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			
VisualEyes™ is intended for use in the electromagnetic environment specified below. The customer or the user of VisualEyes™ should assure that it is used in such an environment.			
Immunity Test	IEC 60601 Test level	Compliance	Electromagnetic Environment-Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	+6 kV contact	+6 kV contact	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be greater than 30%.
	+8 kV air	+8 kV air	
Electrical fast transient/burst IEC61000-4-4	+2 kV for power supply lines	Not applicable	Mains power quality should be that of a typical commercial or residential environment.
	+1 kV for input/output lines	+1 kV for input/output lines	
Surge IEC 61000-4-5	+1 kV differential mode	Not applicable	Mains power quality should be that of a typical commercial or residential environment.
	+2 kV common mode		
Voltage dips, short interruptions and voltage variations on power supply lines IEC 61000-4-11	< 5% <i>UT</i> (>95% dip in <i>UT</i>) for 0.5 cycle	Not applicable	Mains power quality should be that of a typical commercial or residential environment. If the user of VisualEyes™ requires continued operation during power mains interruptions, it is recommended that VisualEyes™ be powered from an uninterruptable power supply or its battery.
	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		

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

Guidance and manufacturer’s declaration — electromagnetic immunity

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

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

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 **VisualEyes™** is used exceeds the applicable RF compliance level above, **VisualEyes™** should be observed to verify normal operation, If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating **VisualEyes™** .
^(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:

EUT Support Equipment

ITEM	MANUFACTURER	MODEL
DC Power Supply	UE	UE15WCP1
Firewire® PCIExpress Card	n/a	n/a

EUT Support Cables

Description	Length	Screened	Connector
DC Power Supply	2m	Yes	FireWire 1394a
Firewire® PCIExpress Card	2	No	DC Power

This VisualEyes™ is suitable in hospital environments except for near active HF surgical equipment and RF shielded rooms of systems for magnetic resonance imaging, where the intensity of electromagnetic disturbance is high.

Use of accessories, transducers and cables, other than those specified or provided by the manufacturer of this equipment, could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation. The list of accessories, transducers and cables can be found in the EMC appendix of this instruction.

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 VisualEyes™, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.