# Instructions for Use - US

## Micromedical VisualEyes™ 505 by Interacoustics

Interacoustics

D-0115288 – C – 2018/02

# Table of Contents

# 1 Introduction

## 1.1 About this manual

This manual is valid for the VisualEyes™ 505 Software version 2.1. This product is manufactured by:

**Interacoustics A/S**
Audiometer Allé 1
5500 Middelfart
Denmark
Tel.: +45 6371 3555
Fax: +45 6371 3522
E-mail: info@interacoustics.com
Web: www.interacoustics.com

**Distribution and service:**

**Micromedical Technologies Inc.**
10 Kemp Drive
Chatham, IL 62629
USA
Tel.: 1 (800) 334-4154
Web: www.micromedical.com

## 1.2 Intended use

The VisualEyes™ 505 is a Video Frenzel system which provides information to assist in the evaluation, diagnosis and documentation of vestibular disorders. Nystagmus of the eye is recorded by use of a goggle mounted with cameras. These images are displayed and stored in the software.
This information then can be used by a trained medical professional to assist in diagnosing vestibular disorders. The target population for VisualEyes™ 505 is 5 years of age+.

The VisualEyes™ 505 is to be used by trained personnel only, such as audiologists, Physical therapists, ENT surgeons, doctors, hearing healthcare professionals or personnel with a similar level of qualifications. The device should not be used without the necessary knowledge and training to understand its use and how results should be interpreted.

**Federal law restricts the sale, distribution, or use of this device to, by, or on the order of a licensed medical practitioner**

NOTICE
VisualEyes™ 505 testing may be contrainidicated in patients who exhibit the following: blindness, broken nose or other face/head trauma, recent eye surgery and ptosis.

## 1.3 Product description

VisualEyes™ 505 consists of a goggle with one or two camers that are connected to a computer and dedicated software. Additional parts may also be included as specified in section 1.3.3.

### 1.3.1 System configurations

The VisualEyes™ 505 is available in 2 different configurations:

1. VisualEyes™ 505 monocular: One camera, eye images are displayed and stored for later replay. Option for external situation recording.
2. VisualEyes™ 505 binocular: Two cameras, eye images are displayed and stored for later replay. Option for external situation recording.

### 1.3.2 Minimum requirements to PC

Laptop PC: One 34 mm PCExpressCard slot available (for side mount FireWire® camera goggles only).
Desktop PC: One PCIExpress card available. (for side mount FireWire® camera goggles only).
Intel i5 processor 2.5 GHz or better.
Minimum 4 GB RAM or more.
Hard drive with min. 250GB space.
Minimum display of 1366X768 (Higher resolution recommended).

**Operating Systems supported:**
Windows®7 32-bit or 64-bit.
Windows® 8.1 64-bit.
Windows® 10 64-bit.

### 1.3.3 Included and optional parts

As standard, VisualEyes™ 505 system is delivered with the following:

| | USB camera systems | FireWire® camera systems |
|---|---|---|
| **Included parts** | Remote Control or Foot pedal<br>Instructions for Use<br>VisualEyes™ 505 installation media<br>OtoAccess™ Database media<br>VisualEyes™ 505 Quick Start Guide | |
| **Optional parts based on goggle type** | ***2D-VOGfw goggle w. side mounted cameras***<br>USB 2.0 Camera module (two modules in binocular configuration)<br>Disposable goggle foam pads – Box of 24 pcs<br>1.5 mm hexagon screwdriver for camera retaining screws<br>7-port USB 3.0 hub w. external power supply<br><br>***USBM2.1A goggle w. front mounted camera***<br>Adult mask for USB monocular camera<br>Camera module with 15' USB cable<br>7-port USB 3.0 hub w. external power supply<br><br>***USBM2.1P goggle w. front mounted camera***<br>Pediatric mask for USB monocular camera<br>Camera module with 15' USB cable A to Mini B<br>7-port USB 3.0 hub w. external power supply | ***2D-VOGfw goggle w. side mounted cameras***<br>FireWire® camera module (two modules in binocular configuration)<br>Disposable goggle foam pads – Box of 24 pcs<br>PCExpressCard Stabilization kit (laptop configuration)<br>PCExpressCard (for laptop configuration)<br>PCI ExpressCard (for tower PC configuration)<br>4-port USB hub |

| | | |
|---|---|---|
| | ***BG4.0KUSB goggle w. top mounted cameras***<br>Goggles USB Asian faceplate binocular<br>Two 15' USB cables A to Mini B<br>7-port USB 3.0 hub w. external power supply<br><br>***BG4.0USB goggle w. top mounted cameras***<br>Goggles USB binocular<br>Two 15' USB cables A to Mini B<br>7-port USB 3.0 hub w. external power supply | |

*Table 1. VisualEyes™ 505 included and optional parts*

## 1.4 Warnings and precautions

| | |
|---|---|
|  | **WARNING** indicates a hazardous situation which, if not avoided, could result in death or serious injury. |
|  | **CAUTION**, used with the safety alert symbol, indicates a hazardous situation which, if not avoided, could result in minor or moderate injury. |
| NOTICE | **NOTICE** is used to address practices not related to personal injury. |

1. A Separation Device (isolation device) is needed to isolate the equipment located outside the patient environment from the equipment located inside the patient environment. In particular such a Separation Device is required when a network connection is made. The requirement for the Separation Device is defined in IEC 60601-1, edition 3, clause 16.
2. The system must not be used in presence of explosive or flammable gases.
3. The goggle should not be worn by patients with strong defective vision and abnormal rare blink. Please consult a specialist in such circumstances before using the mask on these types of patients.
4. The system must be switched off before cleaning.
5. Do not use any additional multiple socket-outlet or extension cord.
6. No modification of this equipment is allowed without Interacoustics authorization.
7. The manufacturer will make available on request circuit diagrams, component part lists, descriptions, calibration instructions, or other information that will assist service personnel to repair those parts of this system that are designated by the manufacturer as repairable by authorized service personnel.
8. For maximum electrical safety, turn off the power from a mains powered instrument when it is left unused.
9. The instrument is not protected against harmful ingress of water or other liquids. If any spillage occurs check the instrument carefully before use or return for service.
10. Do not use the equipment if it is showing visible damage.

1. Use this device only as described in this manual.
2. The system must be serviced at least once a year. The service must verify system functionality.
3. Do not use the equipment if the equipment is broken. Have the equipment serviced.
4. Only personnel with proper training (skilled personnel) should operate the system.
5. Proper use of this device depends on careful reading of this manual and all additional instructions and labels.
6. Let the system obtain room temperature before turning it on. Extra time for obtaining room. temperature may be needed to avoid condensation if the system has been moved from a very cold location to a warmer one.
7. The patients or test persons should not wear any optical utilities such as glasses or contact lenses.
8. The patients or test persons should not wear make up around the eyes.

9. It is recommended that parts which are in direct contact with the patient (e.g. disposable goggle foam pads) should only be used with one patient, and should therefore be discarded after each session.
10. Be sure to use only stimulation movements that are acceptable to the patient.

## NOTICE

1. To prevent system faults take appropriate precautions to avoid PC viruses and similar.
2. Clean the camera lens and the infrared coated mirrors of the goggle regularly to avoid shadows on the displayed images.
3. Do not drop and avoid other undue impacts to this device. If the instrument is dropped or otherwise damaged, return it to the manufacturer for repair and/or calibration. Do not use the instrument if any damage is suspected.
4. Although the instrument 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 therefore has to be collected separately. Such products will be marked with the crossed-out wheeled bin shown below. The cooperation of the user is important in order 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.

# 2 Unpacking and inspection

## 2.1 Unpacking and inspection

**Check box and contents for damage**

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

**Keep carton for future shipment**

VisualEyes™ 505 comes in its own shipping carton, which is specially designed. Please keep this carton. It will be needed if the instrument has to be returned for service. If service is required, please contact your local distributor.

## 2.2 Reporting imperfections

**Inspect before connection**

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

**Report immediately any faults**

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

**Products returned for repair**

If the manufacturer requests that you return the product for evaluation or repair, pack the product well, preferably in the original shipping container with a Return Material Authorization (RMA) number provided by the manufacturer. Systems with optional rotational chairs will be serviced on-site by the local distributor.

## 2.3 Marking

The following marking can be found on the instrument:

| Symbol | Explanation |
|---|---|
|  | Type BF applied parts. |
|  | Type B applied parts. |
|  | Follow instructions for use. |
|  | WEEE (EU-directive).<br>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. |
|  <br>0123 | The CE-mark indicates that the manufacturer meets the requirements of Annex II of the Medical Device Directive 93/42/EEC for the quality system. |
|  | Year of Manufacturer. |
|  | Manufacturer |
|  | Do not re-use.<br>Parts like foam cushions and similar are for single use only. |
|  | Reference number used to denote the model of the equipment. |

*Legend of Symbols.*

# 3 Setup and installation

## 3.1 Introduction to VisualEyes™ VF 505 software suite

The VisualEyes™ 505 combines leading edge technology with touch screen capability in a new streamline software interface. The VisualEyes™ 505 provides information to assist in the evaluation, diagnosis and documentation of vestibular disorders. Eye movements are recorded by use of a goggle mounted with one or two infrared video cameras. The eye images are displayed in real time in large format on a computer monitor. External environments (room) are recorded by use of an integrated / external USB camera if desired. Patient interview is recorded separately for recording patient's medical history. This information can then be used by a trained medical professional to assess vestibular disorders.

## 3.2 Installation of OtoAccess™ database

The VisualEyes™ 505 software is accesssed through the Interacoustics OtoAccess™database. The Interacoustics OtoAccess™ database is used for storage of patient information and data recordings.
Your computer/ laptop will have OtoAccess and VisualEyes™ software pre-installed.
If you find that it is not already installed, or if a re-install is required please read the instructions for use to included with the OtoAccess™ installation media (CD or Flash drive) or contact your distributor.

## 3.3 Installation of VisualEyes™ 505 software

NOTICE
The OtoAccess™ database must be installed prior to installing VisualEyes™ software.

The VisualEyes™ software will be pre-installed on the computer purchased from the Interacoustics or Micromedical. In the event when the software must be re-installed, please follow these instructions.

1. Insert the VisualEyes™ Installation CD or thumb drive into the computer.
2. If the installation procedure does not start automatically, click **Start**, then go to **My Computer** and double click the **DVD/CD-RW drive** or **Flash Drive** to view the contents of the installation media.
3. Double click the **Micromedical VisualEyes™ Installer** file to initiate the installation.
4. The VisualEyes™ Setup Wizard will start.
5. Check the box to accept the terms and click Install.
6. After the installation completes, exit the installer.
7. Remove the installation media from the drive and store in a convenient place.

The VisualEyes™ 505 installation will configure OtoAccess™ for VisualEyes™ 505 testing. To use the VisualEyes™ 505 software, select the Micromedical VisualEyes™ instrument from OtoAccess.

## 3.4 Uninstall software

In Windows® 7 and 8.1, the VisualEyes™ software can be removed from Programs and Features.

1. Open Windows® Control Panel and then select Programs and Features. If the Category option is used, then under Programs choose Uninstall a program.
2. Select the **Micromedical VisualEyes™** entry. Click on Uninstall.
3. In the installer package, choose Uninstall. Once the program is uninstalled, close the installer and Control Panel.

In Windows® 10, the VisualEyes™ software can be removed from Settings.

1. From the start menu choose Settings.
2. Choose **System**, then select **Apps & features.**
3. In the sort box, choose Sort by name.
4. Select the Micromedical VisualEyes™ program in the list, then click on Uninstall.
5. Confirm the process by clicking on the Uninstall button.
   In the installer package, choose Uninstall. Once the program is uninstalled, close the installer and Settings.

## 3.5 Hardware setup

The VisualEyes™ 505 is composed of several selected pieces of equipment. The software is designed to be compatible with both Interacoustics a/s and Micromedical Technologies Inc. equipment.

Each piece of equipment, its function and installation is described below.

### 3.5.1 Laptop / PC

The VisualEyes™ 505 suite comes preloaded on a dedicated laptop or pc.

*Figure 3.5.1 VisualEyes™ Laptop*

### 3.5.2 The VisualEyes™ 505 video fenzel goggles

The Video Frenzel goggles allow for the recording of eye movements during various test conditions. In order to achieve this the goggle holds FireWire®/ USB cameras that are used to record the eye images. The FireWire® / USB cameras use infrared light (IR), which is not visible to the naked eye. The IR illumination enables sessions to be performed in complete darkness.

### 3.5.3 Side mount camera goggles

The USB or FireWire® cameras are fixed on the sides of the goggle.

*Figure 3.5.2 Side mount camera goggles*

The goggles come with replaceable foam cushions that are easily removed between patients by simply pulling the used foam cushion off of the Velcro pads on the inside of the mask and then aligning a new foam cushion on top of the Velcro.

The front cover plate of the Combi mask is magnetically fixed and can easily be removed for visual stimulation tests (i.e. oculomotor). The mask has an adjustable Velcro head strap that secures the goggles while still providing patient comfort.

Monocular configuration with the side mount camera goggles will have a camera module on one side, and the other side will be an empty camera module without adjustment knobs.

### 3.5.4 Top mount camera goggles

The top mount camera goggles block out ambient light with the removable cover over the portal for vision-denied testing. Side-lights on the goggle provide guidance/ illumination when placing the cover on the goggles. On the left side of the goggles is a switch to start and stop tests. The goggles have an adjustable Velcro head-strap that secures the goggles while still providing patient comfort.

*Figure 3.5.3 Top mount camera goggles*

### 3.5.5 Front mount camera goggles

The front mount camera goggles use a single USB camera pressed into the camera portal on the front of the goggles mask. The camera can be pressed into either camera portal to record the desired eye. The USB 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.

*Figure 3.5.4 Front mount camera goggles*

### 3.5.6 Foot Pedal

The foot pedal allows you to begin the measurement testing by pressing the foot switch so you have both hands free to look after the patient (e.g. Dix Hallpike). Connection with the PC is via a USB port.

*Figure 3.5.5 VisualEyes™ Foot pedal*

### 3.5.7 VisualEyes™ remote control

The remote control provides a hand held option for controlling and performing tests within the VisualEyes™ suite. The operator can operate the software using the remote control while remaining at the patient's side during testing. The remote control's receiver connects to the PC via a USB port, while the remote control connects to the receiver using 2.4 GHz rf transmission.


*Figure 3.5.6 VisualEyes™ Remote Control*

1. Top button:
    - Centers eyes (top mount goggles only)
2. Right button:
    - Goes forward in the software
    - 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:
    - Stops the test
4. Bottom button:
    - Turns on/off the fixation light during a test

### 3.5.8 External room camera

*Figure 3.5.7 USB room camera*

The room camera is an external device connected to the computer's USB port. It serves to record the external environment and patient testing process from the beginning. The external room camera provides additional flexibility in recording the testing procedure, though the laptop's integrated observation camera can be used with orienting the computer towards the patient.

## 3.6 Connection layout

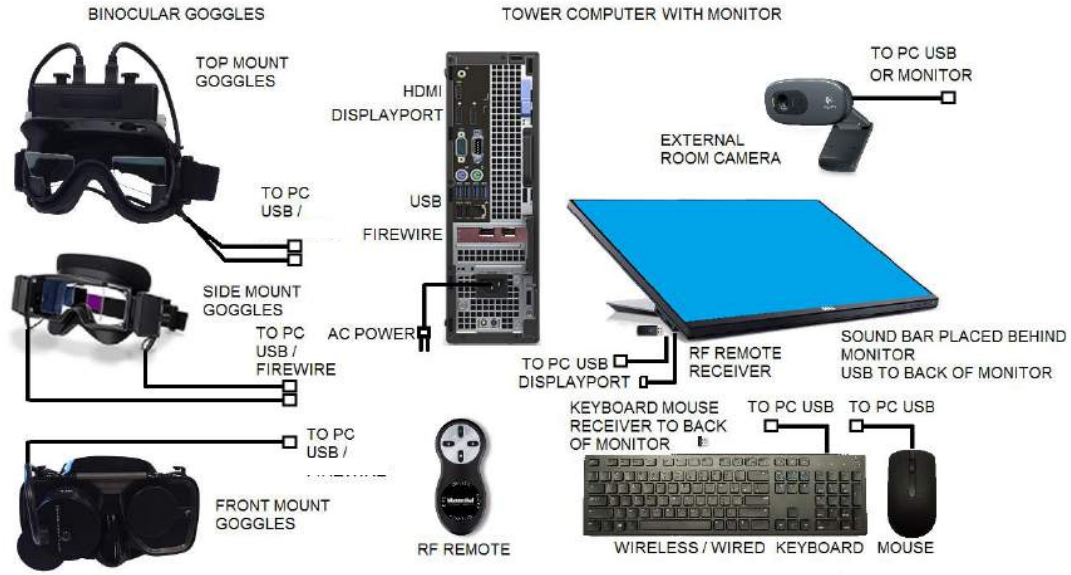


*Figure 3.6.1 Tower PC connection diagram*


*Figure 3.6.2 Laptop PC connection diagram*

NOTICE

Always connect other IT-equipment before powering up the computer.
Power on all connected IT-equipment before starting the VisualEyes™ software.
Always power off the FireWire® card before removing the card from the PC.

 (Valid for all configurations).
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 must comply with the relevant product standard e.g. IEC 60950-1 for IT equipment and the IEC 60601-series for medical electrical equipment. In addition, all such combinations – Medical Electrical Systems – must 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 must be kept outside the patient environment i.e. at least 1.5m from the patient support or must be supplied via a separation transformer to reduce the leakage currents. Any person who connects external equipment to signal input, signal output or other connectors has formed a Medical Electrical System and is therefore responsible for the system to comply with these requirements. If in doubt, contact a qualified medical technician or your local representative. When the instrument is connected to a PC, or other similar items, beware of not touching the PC and patient simultaneously.

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

# 4 Patient entry

## 4.1 Entering patient information

1. Open **OtoAccess™** (Figure 4.1.1).
2. If the patient has already been entered, then select the patient in the table; it will highlight blue to indicate selection.
3. If the patient is not yet listed:
    - press the **New client** button 
    - fill in at least the mandatory fields which are marked with a red square (squares are displayed after the New Client button is pressed)
    - save the patient details by pressing the **Save client** button 

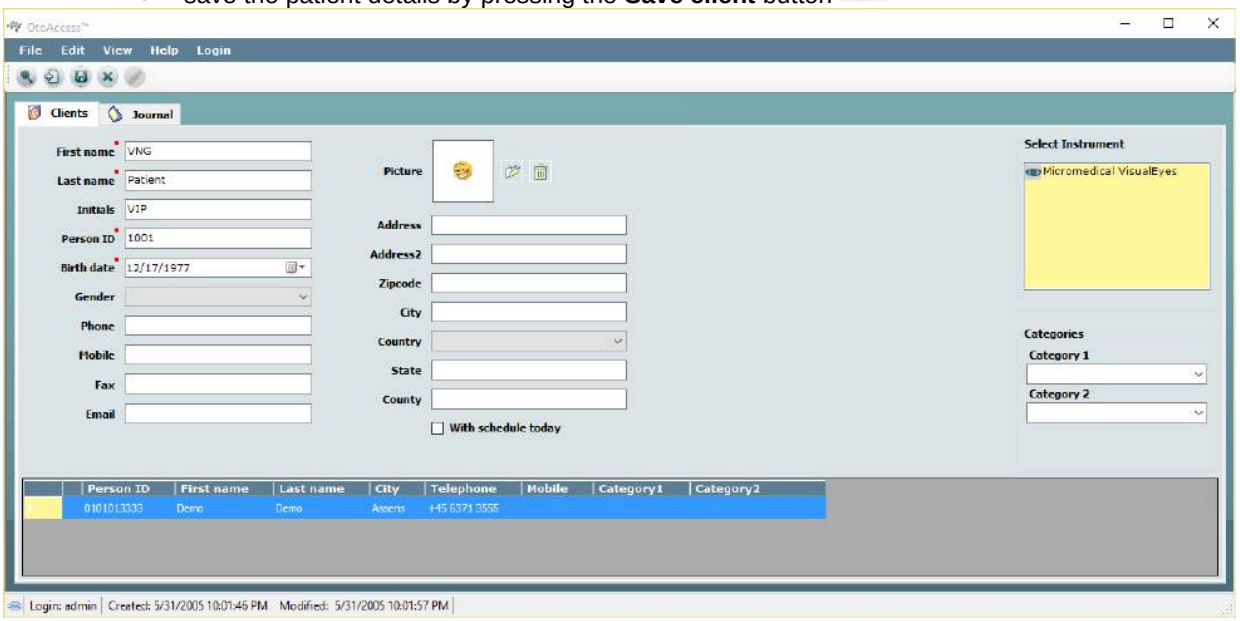


*Figure 4.1.1 OtoAccess™ main screen*

4. Double click **Micromedical VisualEyes™** in the **Select Instrument** box. (Figure 4.1.2).

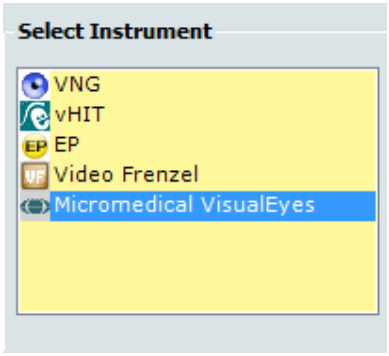


*Figure 4.1.2 Micromedical VisualEyes™ instrument*

NOTICE
For further instructions about working with the OtoAccess™ database, please see the operation manual for OtoAccess™.

## 4.2 Licensing

The VisualEyes™ 505 system is licensed and will require specific license key or keys to be put into the software upon its initial launch to make the Video Frenzel available.

The VisualEyes™ licenses are not time limited, and the same license can be installed on more than one computer, allowing you to move the cameras between two or more workstations.

NOTICE
The computer set up from the factory will already have the camera serial numbers and license keys registered in the software.

- Prior to starting the VisualEyes™ software suite, make sure that the cameras are connected to the computer and turned on
- The software will automatically detect the cameras and display a Setup License screen (Figure 4.2.11)
- For each camera an empty field allows the entry of a new license key
- Beside each license key field is an ignore button. If the serial number should be ignored, click on the ignore button beside it. If there is no camera detected, the ignore button is automatically selected
- License keys are not case sensitive. License/s must be entered for the camera/s to use the camera hardware
- Once entered, click **Save** to store the new license


*Figure 4.2.1 Setup License screen*

## 4.3 Micromedical VisualEyes™ main screen

When the Micromedical VisualEyes™ software is launched, the main screen will appear. Patient information is retrieved from the OtoAccess database and is displayed on the main screen (highlighted in Figure 4.3.1). The patient name will be displayed in all test screens.

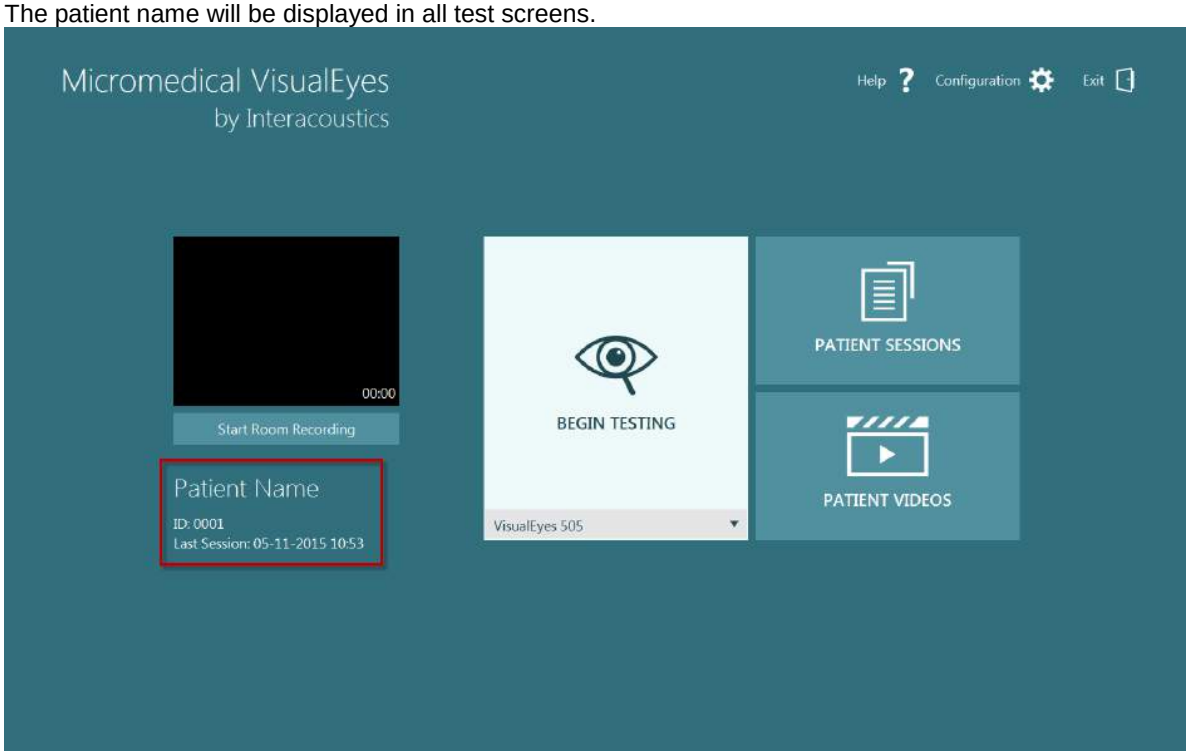


*Figure 4.3.1 Micromedical VisualEyes™ main screen with patient information circled*

## 4.4 Room recording

A patient interview video recording can be created from the Main screen. Recording can be started and stopped an unlimited number of times during a patient session. The video will be saved once BEGIN TESTING has been selected or the user leaves the main screen.

## 4.5 Patient preparation

The patient should remove any eye makeup prior to testing. Soft contact lenses may be worn with the goggles, but eyeglasses must be removed. Sanitize the goggles prior to testing each patient. It is recommended that the testing room be darkened for all vision-denied tests.

Remove the vision-denied cover to allow vision during goggles placement. Place the goggles on the patient's face and adjust the strap for a snug fit. For vision-denied testing, place the cover back on the goggles. Confirm with the patient that there is no light leakage. If the patient still sees light, adjust the goggles position and tightness of the strap as needed.

## 4.6 Testing the Patient

### 4.6.1 Starting the test

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.

### 4.6.2 Pausing the test

During the recording of the test, the test can be paused by using the Pause button or pressing the RF Remote, side switch, or foot pedal. The test can be resumed with the Unpause button or pressing the RF Remote, side switch, or foot pedal.

### 4.6.3 Ending the test

To end the test, click or touch the Stop button.

### 4.6.4 Additional Functions

During the test procedure click or touch the Add Note button to add a comment during the test. The fixation light inside the video goggles can be turned on and off using the Fixation Light button or using the Fixation button on the RF Remote. If the test needs to be restarted, press the ESC key on the RF remote or the escape key on the keyboard.

## 4.7 Session Review and Write Report

Once all of the tests have been completed, the software will show the Session Review screen. By clicking or touching Write Report, the user can create a report for the video frenzel tests performed and any findings seen during testing. When the report is printed, the written report and any notes taken during the tests will be printed.

## 4.8 Additional information

For more information about the VisualEyes™ software, please consult the Additional Information manual that can be accessed from the Help menu within the software.

# 5 Care and maintenance

## 5.1 General maintenance procedures

1. Camera lenses and IR coated mirrors must be checked regularly for stains and dust, and should be cleaned with lens cleaning cloth.
2. Goggles cushions for the side mount cameras are single use only and must be exchanged between patients. This is necessary to avoid the possibility of cross infection.
3. Goggles frame should be cleaned with a Sani-Cloth™ disinfectant wipe.
4. Side mount camera goggle 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.

## 5.2 How to clean the VisualEyes™ system

If the surface of the instrument or parts of it are contaminated, it can be cleaned using Sani-Cloth™ disinfectant wipes. Goggles mirrors and computer touch screens should be cleaned using the provided lens cleaning cloth to remove dust and fingerprint smudges.

- Before cleaning always switch off and disconnect from power
- Use a soft Sani-Cloth™ to clean all exposed surfaces
- Do not allow liquid to enter into the components of the VisualEyes™ system
- Do not autoclave, sterilize or immerse the instrument or accessory in any fluid
- Do not use hard or pointed objects to clean any part of the instrument or accessory

**Recommended cleaning and disinfection solutions:**

- Sani-Cloth™ disinfectant wipes

**Procedure:**

- Clean the touch screen on PC with the lens cleaning cloth when the computer and monitor are turned off
- If the touch screen needs further cleaning, use a Sani-Cloth™ disinfectant wipe to clean the surface. Allow the cleaning solution to completely dry before turning on the computer and monitor.

## 5.3 Warranty and Service

Micromedical Technologies, Inc. (“Micromedical”) warrants the products it manufactures to be free from defects caused by faulty materials or poor workmanship for a period of twelve months from date of shipment from Micromedical. This warranty applies only to the original purchaser and is not transferable. Micromedical's liability is limited to replacing or repairing, at its option, any of its products that are returned during the warranty period. Micromedical's liabilities on any claim for loss or damage arising out of the sale, resale or use of any of its products shall in no event exceed the selling price of the unit. Computer hardware, application software or operating system software purchased from other vendors is not warranted, supported or repaired by Micromedical. This warranty excludes normal component wear and tear.

Micromedical Technologies computerized systems are considered to be medical equipment and are warranted as such. Installation of any non-Micromedical software by user shall render this warranty null and void unless such installation has been approved in advance in writing by Micromedical Technologies. This disclaimer shall also apply if the computer is used or found to have been used for general Internet access or as an E-mail client. Furthermore, the warranty shall be declared null and void if it is determined that the operating system has been affected by a software virus or similar corruption of the supplied hardware or software.

### 5.3.1 PRODUCT LIFE

Micromedical products utilize hardware and software technology that changes rapidly. Micromedical will support new products and make every effort to repair or replace with same or similar components for a period of seven years from date of original purchase. This policy does not apply to refurbished components or systems. If repaired or replacement components are no longer available, then upgrades may be possible but are not guaranteed to be available.

### 5.3.2 PRODUCT SERVICE

***Domestic***

If a problem occurs with equipment purchased from Micromedical, whether it is software or hardware related, the buyer should first contact the distributor who installed the equipment. If directed by the distributor, the customer can contact Micromedical Technical Support directly online at www.micromedical.com or by telephone (217-483-2122) to isolate and identify the problem. If Micromedical Technical Support determines a system component is defective, then (1) the defective component or part should be return shipped to Micromedical for repair, or (2) at Micromedical’s discretion a replacement component will be sent to and installed by the distributor or customer.

If Micromedical requests that you return the product for evaluation or repair, pack the product well, preferably in the original shipping container, addressed to: Micromedical Technologies, 10 Kemp Drive, Chatham, IL 62629 with the RMA number given by Micromedical. Insure the product with the shipper and choose the shipping method (ground, 2nd day air, next day air) to meet your required schedule. The customer will be responsible for paying shipping charges to Micromedical, as well as any repairs that result from shipping damage due to packaging problems. Packaging materials can be requested from Micromedical if needed for a nominal fee.

***International***

If a problem occurs with equipment purchased from Micromedical, whether it is software or hardware related, the buyer should first contact the distributor who installed the equipment. If directed by the distributor, the customer can contact Micromedical Technical Support directly online at www.micromedical.com or by telephone (217-483-2122) to isolate and identify the problem. If Micromedical Technical Support determines a system component is defective, then (1) the defective component or part should be return shipped to Micromedical for repair, or (2) at Micromedical’s discretion a replacement component will be sent to and installed by the distributor or customer.

If Micromedical requests that you return the product for evaluation or repair, pack the product well, preferably in the original shipping container, addressed to: Micromedical Technologies, 10 Kemp Drive, Chatham, IL 62629 with the RMA number given by Micromedical. Insure the product with the shipper and choose the shipping method to meet your required schedule. The customer will be responsible for paying shipping charges to Micromedical, as well as any repairs that result from shipping damage due to packaging problems.

### 5.3.3 PRODUCTS RETURNED FOR REPAIR

When returning product, whether in warranty or out of warranty, approval must first be obtained from Micromedical in the form of a Return Material Authorization (RMA) number. Credit will not be given, nor repairs made for products returned without such approval or if packaging is not labeled in accordance with RMA instructions. When approved for return to Micromedical, products must be returned freight and insurance prepaid by the customer.

### 5.3.4 WARRANTY DETERMINATION

If upon Micromedical's examination of the product, a warranted defect exists, then the product(s) will be repaired or replaced and return shipped via ground service at no charge to the buyer. Warranty repairs do not extend the original warranty period. If the product is out of warranty or if the products have been subjected to misuse, accident or improper installation or application, or have been repaired or altered by others without written consent by Micromedical, then non-warranty repair charges apply.

### 5.3.5 EXTENDED WARRANTY

An extended warranty can be purchased before the original warranty expires to extend the warranty an additional 12 months. Extended Warranty agreements include telephone consultation and component exchange or if necessary on-site repair. An extended warranty is available for VisualEyes™, irrigators, and rotational chair systems.

### 5.3.6 SERVICE CONTRACT

A Service Agreement for a period of one year may be purchased by the customer for rotational chair systems. This Service Contract includes telephone consultation, component exchange or if necessary on-site repair, and one on-site preventive maintenance visit to be agreed upon by the customer and Micromedical and its representatives.

### 5.3.7 NON-WARRANTY FACTORY REPAIRS

After Micromedical has run diagnostics on the component or system, the buyer shall be notified of the repair cost. At such time the buyer must issue a written purchase order to cover the cost of the repair plus return freight, or authorize the product(s) to be shipped back, as is, at the buyer's expense. Failure to provide a purchase order within (30) days of notification will result in the product(s) being returned, as is, at the buyer's expense. Labor and replacement parts are warranted for (90) days from date of repair.

**Micromedical Technologies' policies and charges are subject to change without notice.**

# 6 General technical specifications

## 6.1 PC Hardware and Software

Laptop: 34mm PCExpressCard slot (for side mount FireWire® goggles only).
Desktop: 1 free PCI Express slot (for side mount FireWire® goggles only).
Intel i5 processor 2.5 GHz or better.
Minimum 4 GB RAM or more.
Hard drive with min. 250GB space.
Minimum display of 1366X768 (Higher resolution recommended).

**Operating systems supported:**
Windows® 7 32-bit and 64-bit.
Windows® 8.1 64-bit.
Windows® 10 64-bit.

Power supply: Use only UE15WCP1 for side mount FireWire® VNG goggle with Laptop computer.

## 6.2 Operation and storage specifications

| | | |
|---|---|---|
| Operation environment: | Temperature: | 15 – 35 °C |
| | Relative Humidity: | 30 – 90% |
| Transport & Storage: | Storage Temperature: | 0 – 50°C |
| | Transport Temperature: | -20 – 50 °C |
| | Rel. Humidity: | 10 – 95% |

Systems can operate on 100 to 240 VAC at frequencies of 50/60Hz.. Only power cables supplied should be used with the equipment.

## 6.3 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 |
| IEC 60825-1 or<br>IEC 62471 | Safety of laser products<br>Photobiological safety of lamps and lamp systems |
| ANSI S3.45. | Performance standard |

## 6.4 Component specifications

**Component Specifications Top mount VNG goggle**
Binocular video eye tracking goggles.
Removable eye cover for vision enabled or vision denied recording.
USB 2.0, 4.5m dual cables to PC.
Resolution: 320 x 240 Pixels @ 100 Hz.
Images: 100 images per second.
Dimensions (L x W x H) 165 x 165 x 89mm.
Horizontal and Vertical Eye movement measurement resolution: approx. 0.33 degrees.
Single IR LED infrared illumination: 950 nm at 1.5 mw/cm2.

**Goggle Weight:**
**Binocular VNG cameras**
345g (occluded view) without cables.

**Component Specifications Front mount VNG goggle**
Monnocular video eye tracking goggles.
Swivel eye portal cover for vision enabled or vision denied recording.
USB 2.0, 4.5m cable to PC.
Resolution: 640 x 480 Pixels @ 30 Hz.
Images: 30 images per second.
Dimensions (L x W x H) 165 x 165 x 89mm.
Horizontal and Vertical Eye movement measurement resolution: approx. 0.25 degrees.
Dual IR LED infrared illumination: 950 nm at 1 mW/cm2.

**Goggle Weight:**
**Binocular VNG cameras**
254g without cable.

**Component Specifications Side mount VNG goggle**
Monocular/ Binocular video eye tracking goggles.
Removable eye cover for vision enabled or vision denied recording.
USB2.0 IEEE1394 FireWire®.
Resolution: 640 x 240 Pixels @ 100 Hz.
Images: 100 or 105 images per second.
Dimensions (L x W x H):302 x 216 x 131mm.

**Goggle Weight:**
**Monocular VNG Camera**
240g (non-occluded view).
320g (occluded view).
**Binocular VNG cameras**
305g (non-occluded view).
385g (occluded view).
Dispensing box with 24 pcs of disposable goggle foam pads.

**Isolation transformer:**
Standard: IEC60601-1
Power: Please ensure the isolation transformer is rated for at least the total power of the supplied equipment e.g. LCD screen, video projector, computer, LCD monitor, printer etc.

## 6.5 Electromagnetic compatibility (EMC)

### 6.5.1 Electromagnetic compatibility (EMC) for top-mounted goggles

The VNG was tested to IEC60601-1-2 standards regarding EMC. This allows you to install and use the VNG in classic environments, but it does not allow you to use it in harsh environments like operating rooms where there are many devices producing electromagnetic fields.

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 closed 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 | | |
|---|---|---|
| *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.* | | |
| **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 | | | |
|---|---|---|---|
| *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.* | | | |
| **Immunity Test** | **IEC 60601 test level** | **Compliance Level** | **Electromagnetic environment – guidance** |
| Electrostatic discharge immunity (ESD) IEC 61000-4-2 | +/- 6 kV contact<br>+/- 8 kV air | +/- 6 kV contact<br>+/- 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<br>+/- 1 kV for input/output lines | +/- 2 kV for power supply lines.<br><br>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)<br>+/- 2 kV line(s) to earth | +/- 1 kV line(s) to line(s)<br>+/- 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 3V and 10V | Stress 3V and 10V | 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% $U_T$ 10ms<br>40% $U_T$ 100ms<br>70% $U_T$ 500ms<br>0% $U_T$ 5000ms | 0% $U_T$ 10ms<br>40% $U_T$ 100ms<br>70% $U_T$ 500ms<br>0% $U_T$ 5000ms | 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. | | | |

### 6.5.2 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<br>CISPR 11 | Group 1 | ***VisualEyes™*** uses RF energy only for its internal function.<br>Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. |
| RF emissions<br>CISPR 11 | Class B | ***VisualEyes™*** is suitable for use in all commercial, industrial, business, and residential environments. |
| Harmonic emissions<br>IEC 61000-3-2 | Not Applicable | |
| Voltage fluctuations / flicker emissions<br>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<br>$d = 1.17\sqrt{P}$ | 80 MHz to 800 MHz<br>$d = 1.17\sqrt{P}$ | 800 MHz to 2.5 GHz<br>$d = 2.23\sqrt{P}$ |
| **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.<br>**Note 1** At 80 MHz and 800 MHZ, the higher frequency range applies.<br>**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)<br><br>IEC 61000-4-2 | +6 kV contact<br><br>+8 kV air | +6 kV contact<br><br>+8 kV air | Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be greater than 30%. |
| Electrical fast transient/burst<br><br>IEC61000-4-4 | +2 kV for power supply lines<br><br>+1 kV for input/output lines | Not applicable<br><br>+1 kV for input/output lines | Mains power quality should be that of a typical commercial or residential environment. |
| Surge<br><br>IEC 61000-4-5 | +1 kV differential mode<br><br>+2 kV common mode | Not applicable | Mains power quality should be that of a typical commercial or residential environment. |
| Voltage dips, short interruptions and voltage variations on power supply lines<br><br>IEC 61000-4-11 | < 5% *U*T<br>(>95% dip in *U*T)<br>for 0.5 cycle<br><br>40% *U*T<br>(60% dip in *U*T)<br>for 5 cycles<br>70% *U*T<br>(30% dip in *U*T)<br>for 25 cycles<br><br><5% *U*T<br>(>95% dip in *U*T)<br>for 5 sec | 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. |
| Power frequency (50/60 Hz)<br><br>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:** *U*T 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 |
| Conducted RF<br>IEC / EN 61000-4-6 | 3 Vrms<br>150kHz to 80 MHz | 3 Vrms | 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.<br><br>Recommended separation distance<br>$d = 1{,}2\sqrt{P}$ |

| | | | |
|---|---|---|---|
| Radiated RF<br>IEC / EN 61000-4-3 | 3 V/m<br>80 MHz to 2,5 GHz | 3 V/m | $d = 1{,}2\sqrt{P}$ 80 MHz to 800 MHz<br>$d = 2{,}3\sqrt{P}$ 800 MHz to 2,5 GHz<br><br>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).<br><br>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)<br><br>Interference may occur in the vicinity of equipment marked with the following symbol:<br>  |
| NOTE1 At 80 MHz and 800 MHz, the higher frequency range applies.<br>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 reorienting or relocating ***VisualEyes™*** .<br>[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 environment 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.