# Instructions for Use - EN
# Virtual SVV™


Interacoustics

D-0116067–D – 2018/12

# Table of Contents

# 1 Introduction

## 1.1 About this manual

This manual is valid for the Virtual SVV™ software version 2.1. These products are manufactured by:

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## 1.2 Intended use

The Virtual SVV™ is intended for the measurement of subjective visual vertical. The system provides the means for the estimation of the gravitational vertical by the examined patient. The target population for the Virtual SVV™ is 8 years of age and over.

The Virtual SVV™ system is to be used by trained personnel only, such as physicians, audiologists, physical therapists, medical assistants, 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. The operator must comply with the instructions in this manual.

## 1.3 Contraindications

Virtual SVV™ testing may be contraindicated in patients who exhibit the following: blindness, broken nose or other face/head trauma, or recent eye surgery.

## 1.4 Product description

The Virtual SVV™ system provides a method to assess the patient's ability to adjust a line, in the absence of any other visible cues, to be parallel with gravity. The sensory information required to perform this task is provided predominantly by the vestibular system of the inner ear.

As standard Virtual SVV™ is delivered with the following

| | |
|---|---|
| **Included parts** | 1. Virtual Reality Goggle<br>2. Head Strap<br>3. Padded Face Cushions (24 units per package)<br>4. Handheld Remote<br>5. Base Station<br>6. Power Adaptor<br>7. Virtual SVV™ Software Installation Media<br>OtoAccess™ Database Media |


*Figure 1-1 Virtual SVV™ Hardware Components*

The notebook/PC does not make part of the device.

## 1.5 Warnings and precautions

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

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

# 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 shipping carton for future shipment**
The Virtual SVV™ comes in its own shipping carton, which is specially designed for the Virtual SVV™. 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 included parts should be checked visually for scratches and missing parts.

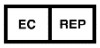
**Report immediately any faults**
Any missing part or malfunction should be reported immediately to the supplier of the instrument together with the invoice, serial number, and a detailed report of the problem. In the back of this manual you will find a "Return Report" where you can describe the problem.

**Please use "Return Report"**
Please use the Return Report to help to us guarantee that the correction of the problem will be to your satisfaction.

**Storage**
If you need to store the Virtual SVV™ for a period, please ensure it is stored under the conditions specified in the section for technical specifications.

## 2.3 Labeling

The following labeling can be found on the instrument:

| Symbol | Explanation |
|---|---|
|  | Type B applied parts.<br>Patient applied parts without electrical connection to the patient.<br>(Head unit, hand controller) |
|  | Refer to instruction manual. |
|  | 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. |
|  | 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 manufacture. |
|  | Manufacturer address. |
|   | Serial number. |
|   | European representative. |
|  | Non-ionizing radiation.<br>This device radiates non-ionizing radiation and can possibly interfere with other equipment in the vicinity. |
|  | To indicate on the rating plate that the equipment is suitable for direct current only. |

The following labeling can be found on the package of the face cushions:

| | |
|---|---|
|  | Do not re-use.<br>Parts like face cushions and similar are for single use only |

## 2.4 General warnings and precautions

**Intended purpose**

1. The Virtual SVV™ system is intended to be used exclusively for medical purposes. It is not intended for private or entertainment use.
2. The Virtual SVV™ system must only be operated according to the instructions described in this manual. The measurement of the subjective visual vertical is intended for use in the clinical diagnosis of vestibular disorders.
3. The operator is exclusively responsible if the equipment is used for any other purpose.
4. The equipment must only be operated by trained personnel. The operator is responsible for the familiarization and training of the operating personnel.

**Precautions during testing**

1. The virtual reality goggle occludes all ambient light such that the patient's visual perception is strongly restricted during testing. Therefore, the virtual reality goggle should only be placed on the patient when the patient is sitting.
2. Do not leave the patient unattended at any time during testing.
3. Terminate testing at any time if the patient suffers discomfort or requires assistance.
4. Do not leave the equipment unattended and do not use it without the presence of qualified personnel.

**Electrical safety**

1. The equipment operates with electrical energy and requires that appropriate caution be taken to use only the delivered power adaptor.
2. The operator and the patient should not touch the AC plug or the power adaptor with damp or wet hands.
3. If you wish to unplug the power adaptor from the AC outlet, grip and pull the AC plug. Never pull on the cable, as this could cause damage or breakage.
4. Take appropriate measures to avoid pinching or clampling the power cable in any way. Avoid any contact with sourses of heat.
5. Contact with any live cables or components (e.g. due to damage to isolation layer) can lead to electric shock and danger to life.
6. The base station should be set up so that the power cable is accessible and easy to disconnect from the AC outlet.
7. Any AC extension cables that are used should be appropriately rated for the required power consumption.
8. Do not use any extension cables with multiple socket outlets.
9. The voltage rating of the AC outlet employed for powering the equipment must match the specified voltage on the label of the power adaptor. Incorrect voltage could damage the equipment.
10. The base station does not possess an ON/OFF switch. Before cleaning or disinfecting the power adaptor must be disconnected from the AC outlet.
11. Never immerse any of the device in water or any other liquid.
12. Take measures to lie the AC power cable so that it does not represent a trip hazard.
13. Unplug the power adaptor from the AC when the batteries are fully loaded and the Virtual SVV™ device is not in use for a long period of time.

**Battery safety**

1. The Virtual SVV™ handheld remote contains two rechargeable AA NiMH batteries. Read the instructions in **Chaper 6 Exchanging Batteries** carefully before opening the battery compartment and exchanging the batteries.
2. Only the **VARTA Ready-to-use – NiMN AA 1.2V 2600mAh** battery type may be used.
3. During the battery charging process the housing of the handheld remote may become warm. This has no influence on the operation of the system, or on the operator or patient.

**Patient safety**

1. The base station is equipped with a USB interface for connection to a PC port. Note that the USB interface is not galvanically isolated.
2. “External equipment intended for connection to signal input, signal output or other connectors shall 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 – shall comply with the safety requirements stated in the general standard IEC 60601-1, edition 3, clause 16. Any equipment not complying with the leakage current requirements in IEC 60601-1 shall be kept outside the patient environment i.e. at least 1.5 m from the patient support or shall be supplied via a separation device to reduce the leakage currents.
3. 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 the requirements. If in doubt, contact qualified medical technician or your local representative.”

**Additional precautions**

1. Do not open the housing of the virtual reality goggle, the handheld remote or the base station. The Virtual SVV™ devices may only be opened by authorized personnel.
2. Avoid equipment contact with hot or cold surfaces, chemicals, heavy dust or strong vibrations or impacts. All Virtual SVV™ devices contain sensitivie electronic components that could be damaged.
3. The handheld remote draws current from the base station to charge the integrated battery and must therefore not come into contact with dampness. If this should occur, the cable connected to the virtual reality goggle must be disconnected and the handheld remote must be removed from the base station immediately and be dried throroughly.
4. The base station draws current from the power adaptor and must therefore not come into contact with dampness. If this should occur, the power adaptor must be disconnected immediately from the AC outlet and the base station should be dried throroughly.
5. Always use the safety loop to secure the handheld remote to the patient’s wrist to avoid any damage via dropping or impact.
6. No component of the equipment may be altered or modified without the express permission of the manufacturer.

Contact the manufacturer in case of suspected system fault or defect.

# 3 Setup and installation

## 3.1 The Virtual SVV™ system components

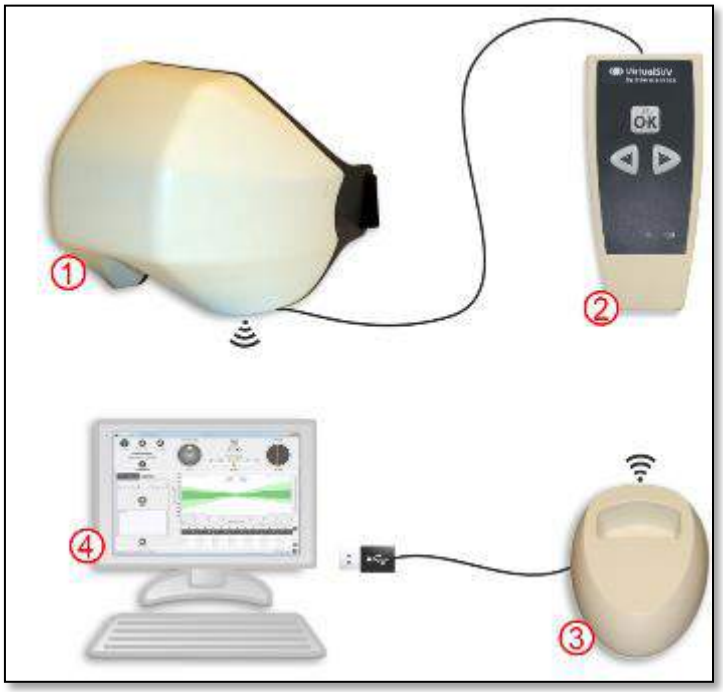
The Virtual SVV™ Device is comprised of four main components:

① **Virtual Reality Goggle**

② **Handheld Remote**

③ **Base Station**

④ **Virtual SVV™ Application Software**




### 3.1.1 Virtual reality goggle

The virtual reality goggle provides the patient with the display of the luminous line in otherwise full darkness. It is designed to be lightweight and comfortable. It is wired to the handheld remote to enable the patient to adjust the orientation of the line. Sensors are incorporated into the virtual reality goggle in order to measure continuously head orientation relative to gravity. This data are then compared with the orientation of the luminous line to achieve correct measurement. The medically approved foam padded face cushion facilitates fitting to the individual facial structure and ensures that the patient is in full darkness for the examination.

The virtual reality goggle transfers all data via a wireless link to the base station, and in turn to the PC application. The use of a wireless link provides maximum freedom of movement of the patient during the examination.

### 3.1.2 Handheld remote

The handheld remote enables the patient to adjust the orientation of the projected luminous line to the perceived visual vertical and to confirm the setting. The capacity of the integrated batteries provides for normal usage over several hours. The batteries are charged automatically when the handheld remote is inserted into the cradle on the Base Station.

### 3.1.3 Base station

The Base Station Incorporates the wireless transceiver for communication between the patient's handheld remote and the USB interface to the PC. This permits real-time transfer of the patient's settings and the data from the virtual reality goggle sensors to the application software.

### 3.1.4 Application software

The application provides the operator with control of the test routine and continuous monitoring of all parameters (e.g. angle of head tilt, angle of luminous line). The graphic display elements indicate continuously the movements of the luminous line as the patient adjusts it to the perceived visual vertical and monitors the orientation of the virtual reality goggle. After confirmation by the patient, the set values are stored and presented in the on-screen results chart. In this way the operator can track how well the patient is performing with reference to the threshold range. The software also generates a test report sheet containing all measurement data. This can be output to electronic or hardcopy media.

## 3.2 Installation of OtoAccess™ database

The Virtual SVV™ software is accessed through the Interacoustics OtoAccess™ database. The Interacoustics OtoAccess™ database is used for storage of patient information and data recordings. OtoAccess™ should be installed prior to installing the Virtual SVV™ software. Please refer to the instructions for use included with the OtoAccess™ installation media (CD or Flash drive) or contact your distributor.

## 3.3 Installation of Virtual SVV™ software

NOTICE

The OtoAccess™ database must be installed prior to installing Virtual SVV™ software.

To install the Virtual SVV™ application on a Windows PC initiate the Setup program in the correct directory on the installation media delivered with the device. Note that either the 32 bit or the 64 bit version must be installed according to which Windows operating system is installed on the host PC.

An installation setup assistant guides installation.

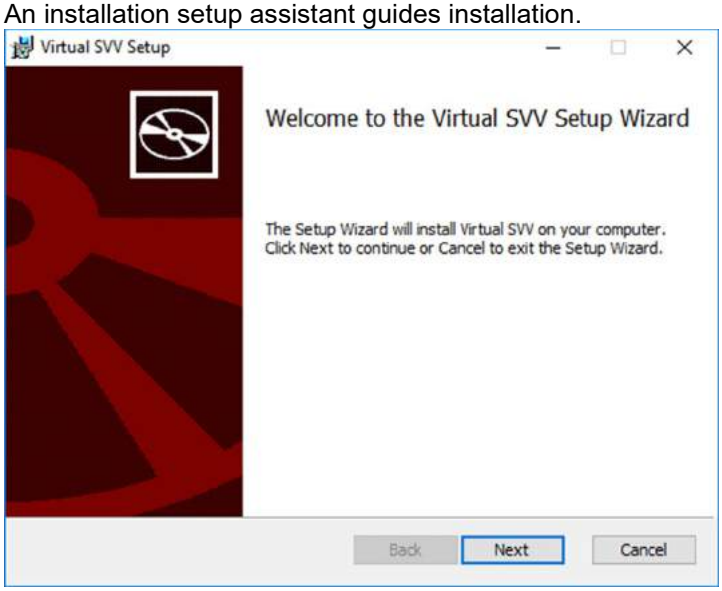



*Figure 3-1 First step in Virtual SVV™ installation setup*

A valid user license in the form of a license file is included with the purchase of a Virtual SVV™ device. The name of the license file is generated as the combination of "**device number**.**license**".

The setup requires the location of the valid license file. This is illustrated in the figure below.

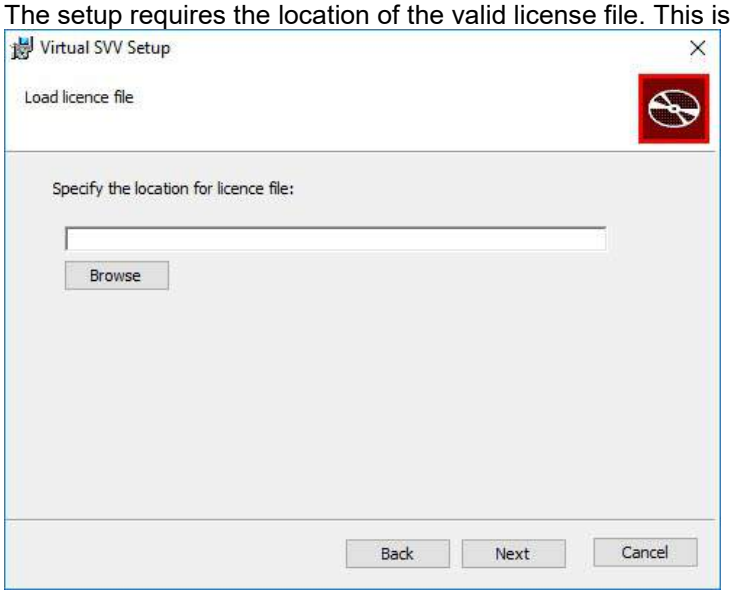



*Figure 3-2 Selection of directory path for license file*

The license file is to be found in the directory **/License** on the Virtual SVV™ installation media. Press "**Browse**" to select the path as shown in the dialogue box. The installation can only be completed after the license file has been identified.

Note that a valid license permits installation of the Virtual SVV™ application on more than one PC.

Accept the terms in the license agreement to continue with installation.

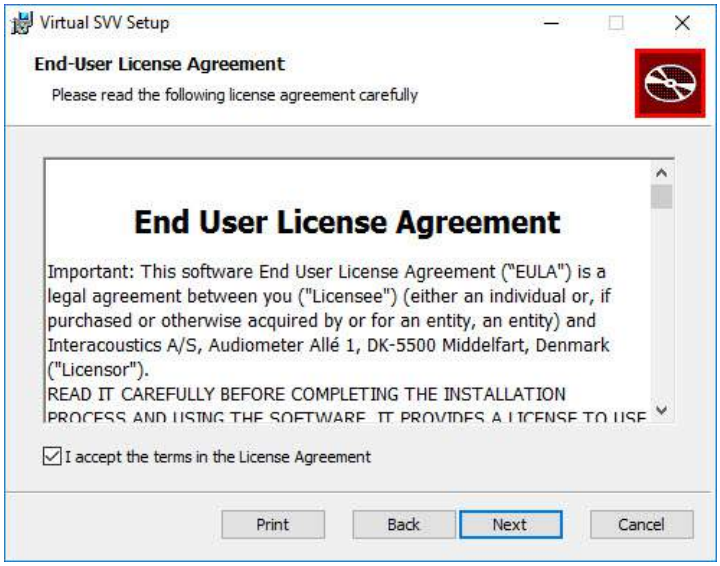



*Figure 3-3 Software license agreement*

The following default directory path will be selected for the installation procedure.

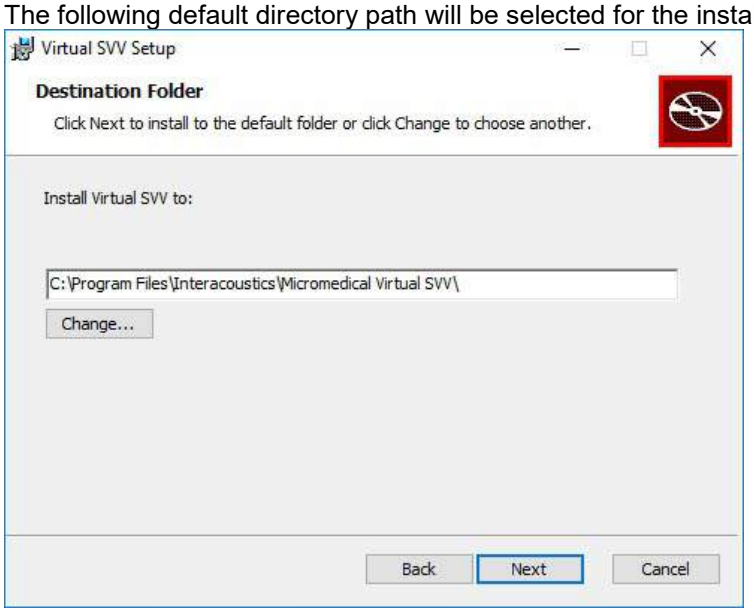



*Figure 3-4 Selecting directory path for Virtual SVV™ installation*

If a previous software version has been installed, an option to import previous settings will appear during installation.

Select “Next” to proceed with installation. Upon successful installation, the setup assistant may be closed by selecting “Finish”.

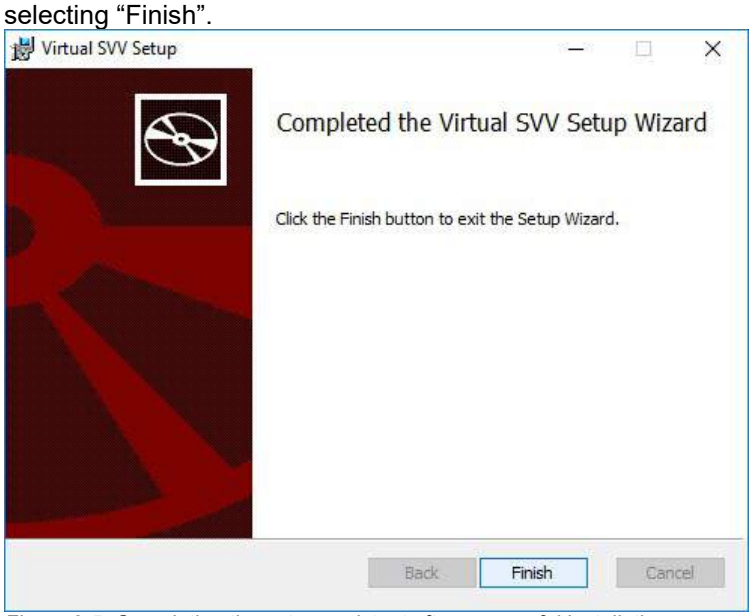
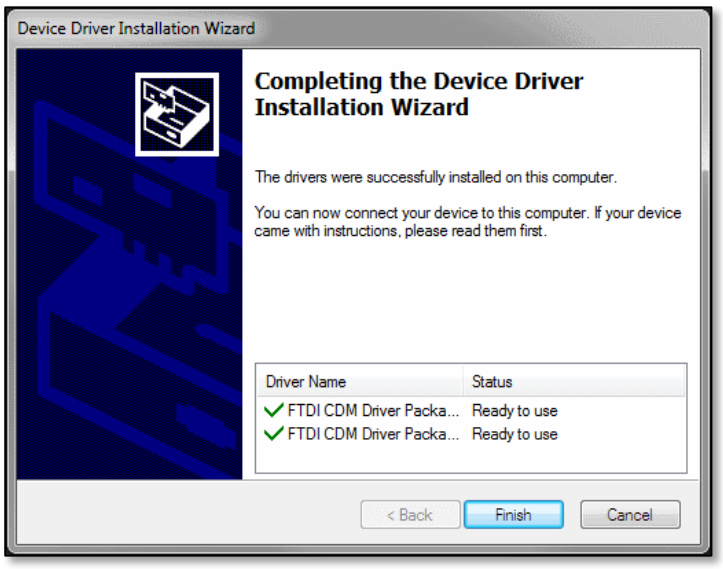



*Figure 3-5 Completing the setup assistant after successful installation*

## 3.4 Installation of Virtual SVV™ drivers

Connect the base station of the Virtual SVV™ to a USB port on the PC or laptop. The installation procedure identifies whether the necessary driver software is already installed on the PC. If this is not the case, these are installed automatically. If the necessary drivers are not installed on the PC, a Windows error message will appear and a corresponding warning in the Device Manager is indicated. In order to install the drivers manually, select the file **FTDI-Setup.exe** from the directory **/FTDI Driver** on the delivered installation media. Select “Extract” to perform driver setup. Successful completion is notified by the message shown in the figure below.




## 3.5 Configuring Virtual SVV™ in OtoAccess™

In order to setup Virtual SVV™ as an instrument within OtoAccess™, the database must be configured appropriately. Open OtoAccess™ and select “File” and proceed to “Setup”. Select the “Instruments” tab. Enter Virtual SVV™ in the “New Instrument Name” field. Select Virtual SVV™ in both the software and hardware fields. Select “Create” to confirm Virtual SVV™ as a new instrument in OtoAccess™. Select “Apply Settings” to keep changes. Select “OK” to exit setup.

NOTICE

Please note that OtoAccess™ must be restarted before the new instrument will appear in the Select Instrument field.

## 3.6 Hardware setup

The Virtual SVV™ system is composed of several components. Each component, its function and installation is described below.

### 3.6.1 Attaching the face cushion to the virtual reality goggle

**Step 1**

Align the face cushion to the virtual reality goggle, with the side with black fabric towards the virtual reality goggle. To facilitate this, fold the face cushion slightly, as shown in Figure 3-6. Center it against the virtual reality goggle. The face cushion should be positioned so that the upper section of the cutaway is aligned with the upper edge of the viewing aperture of the virtual reality goggle as illustrated below. Ensure that the face cushion does not occlude the viewing aperture of the virtual reality goggle.

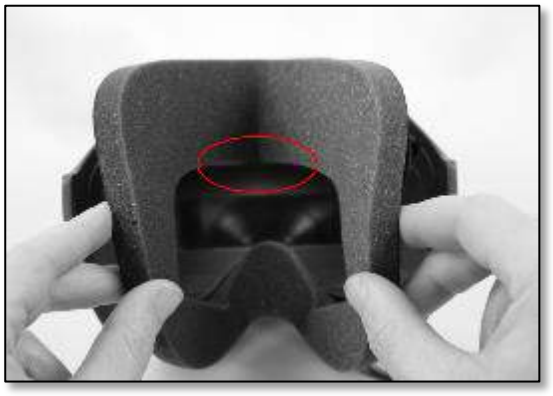


*Figure 3-6 Aligning the face cushion to the virtual reality goggle*

**Step 2**

The lower section of the face cushion is intended to fit snugly around the nose. This section should be aligned with the lower edge of the viewing aperture as shown in Figure 3-7. When correctly aligned, the face cushion can be pressed firmly to adhere to the virtual reality goggle.

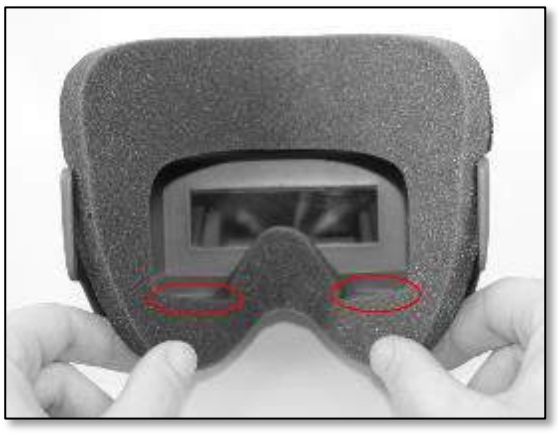


*Figure 3-7 Fastening the face cushion*

**Step 3**
Press the face cushion to the virtual reality goggle, beginning in the center (see Figure 3-8) and working towards the outer edges. Ensure that the entire interface between face cushion and virtual reality goggle is bonded. This is necessary to occlude any light sources from the surroundings while the virtual reality goggle is worn. The finished product is shown in Figure 3-8.

*Figure 3-8 Correctly attached face cushion*

### 3.6.2 Attaching the head strap

The head strap is fastened and adjusted using the hook-and-loop tape. Unfold both ends of the head strap and proceed as follows:

**Step 1**
Take the shorter end of the head strap and slip it through the slot on the right of the virtual reality goggle (as viewed in Figure 3-9). Ensure that the rougher side of the head strap is facing outwards. Continue to slip the head strap through the left-hand side of the virtual reality goggle.

*Figure 3-9 Attaching the head strap*

**Step 2**
Fold the left-hand end of the head strap around the slot and fixate the Velcro hooks and loops. This end of the head strap remains fastened throughout the examination.

The head strap can now be pulled through the right-hand slot from right to left. The head strap can be adjusted in length to fit each patient's head, and then secured with the Velcro pads. The complete virtual reality goggle with face cushion and head strap is illustrated in Figure 3-10.

*Figure 3-10 Complete virtual reality goggle with head strap*

### 3.6.3 Handheld remote

Attach the black tape cable to the handheld remote at the top of the device as shown in Figure 3-11.


*Figure 3-11 Plug connection on handheld remote*

The control elements for the adjustment of the luminous line by the patient are incorporated into the handheld remote.

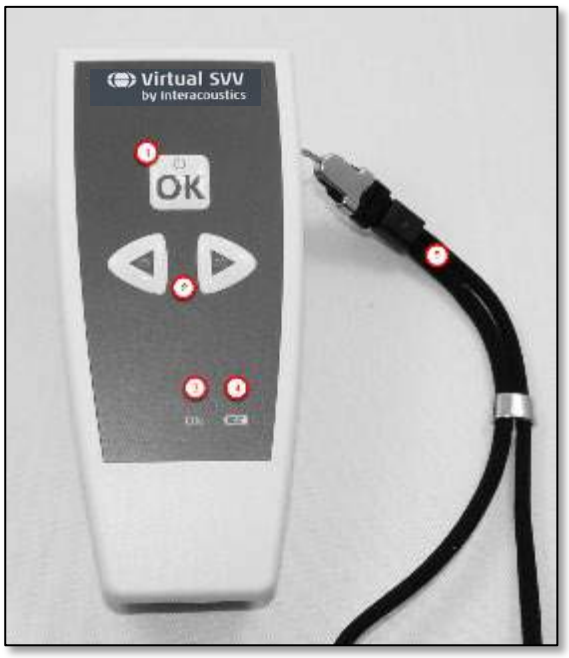



*Figure 3-12 Elements of the handheld remote*

① OK button for confirming completion of adjustment

② Buttons for left / right rotation of the luminous line

③ LED indicating power ON (green)

④ LED indicating charge status (yellow)

⑤ Armband for securing handheld remote

### 3.6.4 Preparing the base station

Connect the AC power adaptor to the socket on the back of the base station so that it latches.

*Figure 3-13 Connecting the AC power adaptor to the base station*

Connect the AC power adaptor to a standard (110/230 VAC) outlet. Note the safety warnings in Chapter 2, as well as the technical specifications.

NOTICE

**Positioning the base station**

To ensure a reliable wireless transmission it is important that a free line-of-sight is maintained between the virtual reality goggle and base station. It is recommended that the base station is positioned in the vicinity of the patient. To avoid electrical interference it should not be positioned close to the PC or monitor or any other equipment likely to generate high frequency radiation.

The radio reception quality between the head unit and the base station can be controlled in Settings under General. The signal bar with the percentage display indicates the connection quality. In case of poor signal strength, it is useful to vary the position of the base station and possibly to reduce the distance from the head unit. The radio reception indicator should be monitored in order to identify improvements and so automatically find the optimum orientation and arrangement of the examination setup.

The base station also functions as a charger for the handheld remote. For this purpose it should be positioned so that the handheld remote can be inserted and held securely.

During charging in the base station the unit should be arranged so that the charge indicator LED can be observed.

Access to the AC Power Adaptor must be ensured so that the AC Power cable can be pulled at any time.
Do not expose the device to direct sunlight or high heat supply.

### 3.6.5 Battery charging

During initial charging it is important that the handheld remote is kept continuously in the base station until the yellow indicator LED extinguishes. Do not disconnect the base station from the AC power outlet during this procedure.

**Charging process**

In order to charge the battery of the handheld remote insert it into the base station as shown in the figure below. Charging is initiated automatically, and is indicated by the illuminated yellow LED on the handheld remote. When charging is complete the indicator LED extinguishes.


*Figure 3-14 Handheld remote in base station*

During normal use the green ON LED blinks when the battery capacity has reached a critically low level after 4 hours of continuous use. When this occurs, the handheld remote must be inserted into the base station for recharging. Depending on battery capacity, recharging can take up to 5 hours.

## NOTICE

If it is necessary to replace the batteries, please read and follow the safety instructions in Chapter 6.

# 4 Operational instructions

## 4.1 System startup

**Enabling and disabling the Virtual SVV™ system**

To enable the Virtual SVV™ system press the OK button on the handheld remote for approximately 2 seconds until the green ON LED indicator begins to blink, then release the button. The system initiates after a further 3 seconds and the green ON LED ceases to blink and remains illuminated.

To disable the Virtual SVV™ system, press the two buttons ◁ and ▷ simultaneously for approximately five seconds until the green ON LED extinguishes.

If the Virtual SVV™ system is not disabled manually, the handheld remote includes an internal timer that is programmed to disable the system automatically after a predetermined interval. The standard factory-set interval is 10 minutes. This interval can be set under the Preferences tab of the application software to a value up to 30 minutes. The application software notifies the operator of automatic disabling of the system with the following message box:


*Figure 4-1 Message indicating automatic system disable after prolonged inactivity*

The device can be re-enabled by pressing the OK button until the green ON LED lights up again.

NOTICE

To avoid total discharge and possible damage to the batteries the Virtual SVV™ device will also disable automatically when the battery voltage reduces to a critical level. This condition is signaled to the operator by the application software. If this occurs, the handheld remote must be recharged in the base station cradle.

Once enabled, from the Windows® desktop, click or touch the OtoAccess™ database icon to launch OtoAccess.

## 4.2 Entering patient information

From the Windows® desktop, tap the OtoAccess™ database icon to launch OtoAccess.  The database will be populated with a list of all patients previously entered, which will be shown in the grid at the bottom of the screen.

Select the New Client icon  to create a new client record. The fields marked with a red dot indicate the fields that are mandatory. These include the patient's first and last name, birth date, and person ID. Enter the patient information and use the mouse or [Tab] key and [Shift] + [Tab] combination to move between fields.

Tap the Save Client icon  to save the information to the OtoAccess™ database.

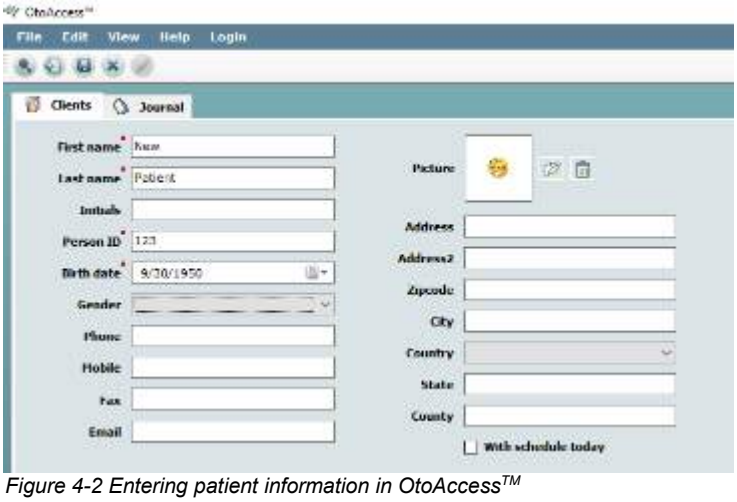



*Figure 4-2 Entering patient information in OtoAccess™*

If the patient is returning for a repeat visit, select the client record from the list at the bottom of the screen, or select the Search Client icon to use the patient information fields as search parameters.

## 4.3 Starting the Virtual SVV™ software

Select the desired patient in the OtoAccess™ database, then double-click on Virtual SVV™ from the Select Instrument box in the upper right corner of OtoAccess™ to launch the software.

## 4.4 Navigating the Virtual SVV™ user interface

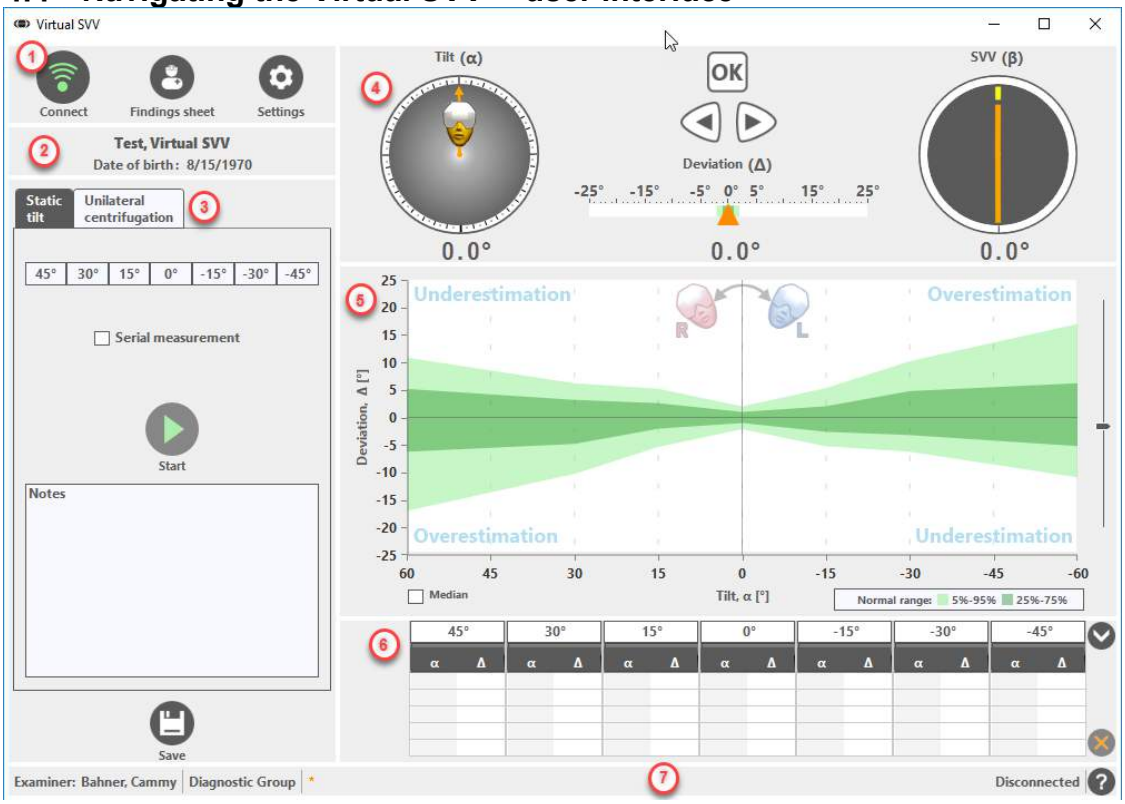



*Figure 4-3 Virtual SVV™ User Interface*

① Located on the upper left are the buttons for establishing communication with the base station, printout of test report and application preferences.

② Panel with patient demographic information. More detailed patient information can be displayed, but not altered.

③ This panel permits selection of the “Static tilt” or “Unilateral centrifugation” test mode. The corresponding test sequence is selected and the measurement sequence is initiated. Relevant notes can be entered and stored.

④ The upper right-hand area displays the real-time monitoring information on the luminous line, the patient’s button activity and the head sensor data. The left dial indicates the current angle of head tilt, while the right dial indicates the angle of the luminous line. The deviation of the patient’s SVV estimate from the actual head tilt is visualized in the form of a slider. The displayed angle is calculated as follows:

**SVV Deviation = SVV Estimate + Tilt Angle**

The polarity of the angles is defined from the point of view of the patient, i.e.:

**Right (or Clockwise)** = positive

**Left (or Counterclockwise)** = negative

However the animation of the angle displays in the software application are configured according to the clinical diagnostic tradition, i.e. inversely. Details on these conventions are included in the Additional Information Manual.

⑤ The center of the screen displays the results chart for each measurement performed by the patient. Results are plotted against the normal reference range. An optional display for the median value in each tested position can be selected.

⑥ The individual test results (head tilt, SVV estimate) are entered in the table below the chart.

⑦ The status bar contains information on the current test sequence and on the battery capacity. The help function, designated by the question mark in the lower right corner opens the PDF user manual.

## 4.5 Virtual SVV™ settings

Settings can be accessed via the gear icon located in the upper left panel of the user interface. Default parameters can be adjusted as described below.

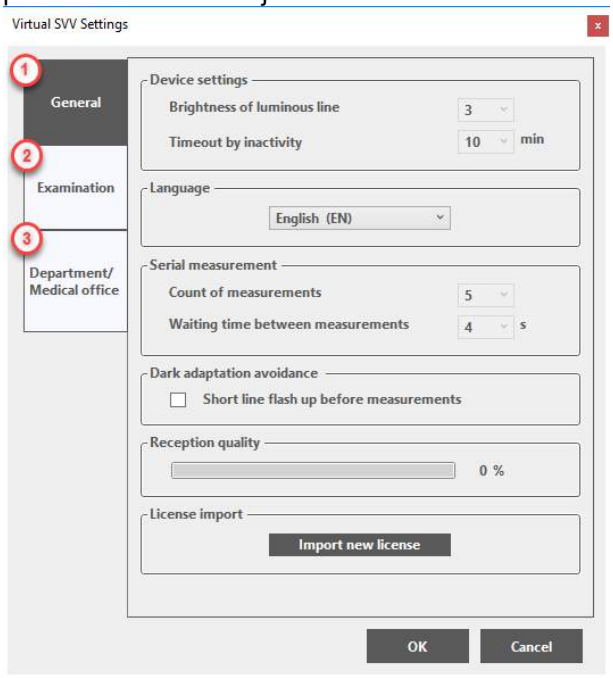



*Figure 4-4 Settings Dialogue*

① **General**
Options for selection of brightness of luminous line, definition of disable-timer interval, and application language. Language options include German (DE), English (EN), French (FR), Italian (IT), Spanish (ES), Portuguese (PT), Russian (RU), and Chinese (ZH). Number of measurements and pause duration for the serial measurement can be configured. The 'short line flash up before measurement' option can be activated to prevent patients' eyes adaptation to darkness during long examinations. Radio reception quality of the connected device is displayed.

② **Examination**
Selection of "Static Tilt" or Unilateral Centrifugation" mode of stimulation.

③ **Department / Medical Office**
Display of clinic information stored in the OtoAccess™ database.

## 4.6 Virtual SVV™ findings sheet

The findings for each examination are collated and stored on a findings report sheet in PDF format. Optionally, this can be printed as a hard copy. In addition, the measurement data from each examination is stored and can be exported in CSV format.


*Figure 4-5 Findings Sheet*

# 5 Test procedures

Open OtoAccess™, select a patient, and double-click the Virtual SVV™ instrument in the select instrument box in the upper right corner of the database client screen.

Enable the Virtual SVV™ system by holding the OK button on the handheld remote for approximately two seconds until the green ON LED begins to blink. After approximately three seconds the system is activated and the LED remains illuminated. The start logo with four red boundary dots will appear on the display inside of the virtual reality goggle.

## 5.1 Test mode selection

The Virtual SVV™ application permits two different test modes for the measurement of the subjective visual vertical:

**Static Tilt** and **Unilateral Centrifugation**

The desired test mode can be selected from the tabs in the left side panel.

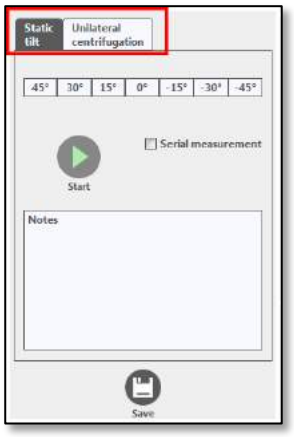



*Figure 5-1 SVV Test Mode Selection*

## 5.2 Patient preparation

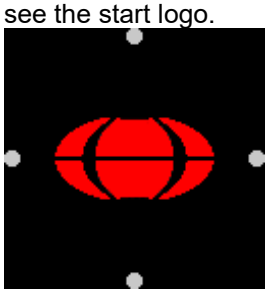
Prior to testing the, inform the patient of the test procedure, and familiarize the patient with the virtual reality goggle and the handheld remote.

Be aware that the patient is in the dark throughout the examination and may suffer from disorientation. It is therefore important that the patient understands clearly how to perform the tasks required.

Make sure that the exchangeable components (face cushion, head strap) are correctly mounted on the virtual reality goggle and are fully functional. The head strap should be exchanged if the Velcro hook-and-loop fasteners are worn or are prone to slippage.

### 5.2.1 Mounting the virtual reality goggle

Loosen the head strap and instruct the patient to hold the virtual reality goggle with fitted face cushion to his/her face so that it is comfortable. Ensure that the patient can now see all four boundary dots on the display. The dots mark the working area of the luminous line. Tighten the head strap carefully so that the virtual reality goggle is fitted securely to the patient's head without pinching hair and ears. The patient will see the start logo.



### 5.2.2 Securing the handheld remote

Give the patient the handheld remote and secure the safety loop with the metal slider to avoid dropping.


*Figure 5-2 Applying the safety loop*

### 5.2.3 Connecting the device

Press the Connect button in the upper left corner in the application software to establish wireless communication with the base station. When communication is established the symbol text changes from Connect to Disconnect.

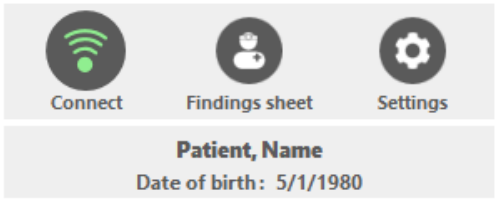
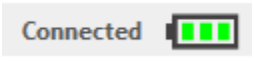



*Figure 5-3 Connecting with the base station*

In the lower right corner of the software application the word **Connected** will appear, along with a battery symbol to indicate amount of remaining battery life.



### 5.2.4 Patient instructions

1. The luminous line will appear at an arbitrary angle. Using the ◁ and ▷ buttons rotate the luminous line to be parallel to gravity (“*as rain falls*”). The short red tip should point upwards (“*like a candle*”).
2. Confirm the setting with the [OK] button.

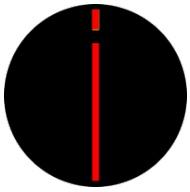


*Figure 5-4 Example of the luminous line as seen by the patient*

## 5.3 Starting measurements

Click on the Start button to begin test measurement. Familiarize the patient with the operation of the device.

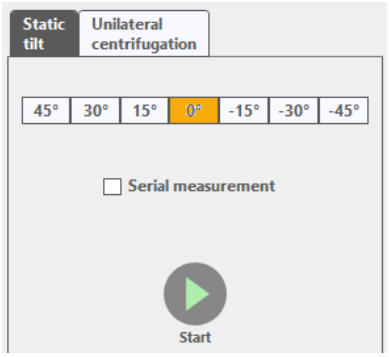



*Figure 5-5 Start button*

When the Start button is clicked the luminous line appears at a random angle on the patient’s display. Instruct the patient to use the left and right buttons on the handheld remote to rotate the line to be vertical. Remind the patient that the yellow end of the luminous line should point upwards.

During this procedure, the longer the left or right button is pressed, the faster the line will rotate. A short press rotates the line by 0.1°. Thus the luminous line can be set with a resolution of 0.1°. During the test ensure that the patient maintains his head in an upright position. This can be monitored on the effective tilt dial in the application software. When the patient is convinced that the luminous line is gravity-vertical, he/she should confirm this by pressing the OK button on the handheld remote.

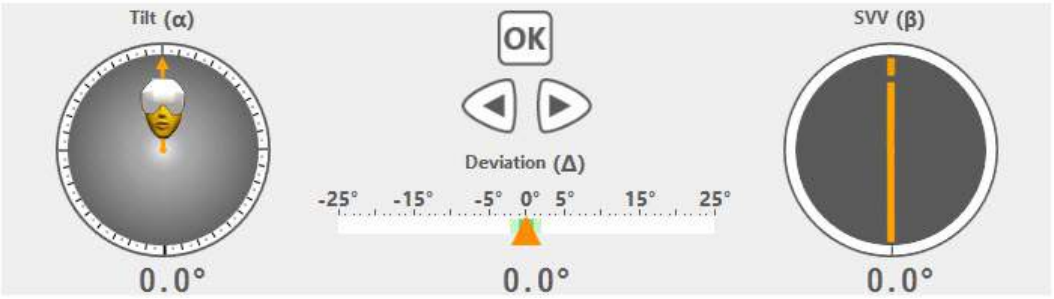



*Figure 5-6 Real-time display of effective head tilt, SVV dial, and patient activity buttons*

The application software provides the operator with comprehensive real-time information regarding the patient’s activity. The angle of the head tilt and of the luminous line, as well as the patient activity buttons are displayed in real-time.

**Serial measurements**
The serial measurement function is intended to simplify the procedure when several measurements are to be made in one head position. This optional mode is configured by two parameters within the General tab in Settings.

1. Number of measurements – definable from 3 to 10 trials
2. Waiting time between measurements – definable from 3 to 10 seconds

The serial measurement mode is enabled by checking the box located above the start button.
During serial measurements each trial is preceded by a countdown. In this manner the examiner is freed from initiating each trial and can focus attention on monitoring the patient.

The serial measurement mode can be disabled at any time by unchecking the serial measurement box above the start button, or by clicking cancel. The serial measurement can be started several times until the maximum number of 10 trials per position have been collected.

## 5.4 Testing with static tilt

### 5.4.1 Configuration and operation

Additional test trials can be performed with the patient's head tilted at varying degrees to the left and right as deemed necessary by the examiner. In the static tilt mode, the patient is first tested in the upright position and then at a number of head tilt angles.

The desired tilt angles can be individually defined in the Examination tab within Virtual SVV™ settings. Up to four head tilt positions between 1° and 60° to the left and to the right can be entered. The input window displays the previously defined tilt angles. Old tilt angles can be deleted after marking with the mouse.

Use the effective tilt dial in the application software to ensure that the patient's head is tilted in the appropriate degree and direction.

As an alternative to the raw measurement data in each position, the median value can be calculated and display on the results chart. This also allows outliers beyond a set permissible tolerance range to be excluded. This tolerance range defines how many degrees any individual measurement data point may deviate in order to be considered in the median calculation and can be defined within Virtual SVV™ settings.

Any setup changes can be confirmed by clicking OK.

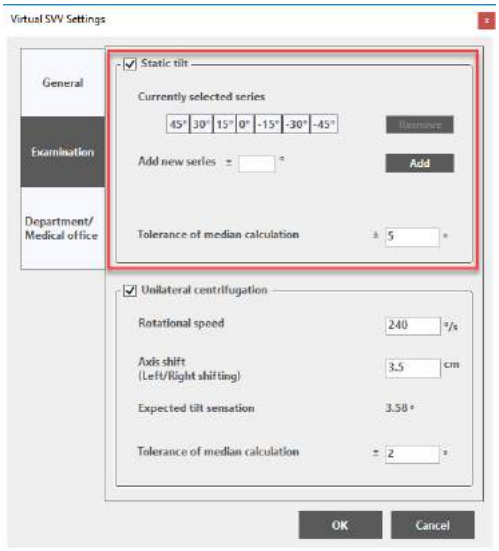



*Figure 5-7 Configuring tilt sequence and median tolerance*

### 5.4.2 Viewing the sequence of measurement positions

The Static Tilt planned measurement sequence can be viewed in the upper left area in the application software. Normally the 0° head upright position is preselected and the corresponding block for that measurement is shaded orange. The order of positions can be altered by checking the desired block. In addition to the current measurement position marked in orange, the pending measurement position is displayed below the block diagram.

In each position up to ten measurements can be performed. No further measurements are possible in a given position.

### 5.4.3 Adjusting the patient

Before commencing with the measurements in any one position, the patient must be secured correctly with the head set to the specified tilt angle as accurately as possible. To assist with the adjustment, the tolerance range for the respective head tilt is indicated green on the tilt angle indicator. The center of the dial remains green as long as the head tilt is within the tolerance range. The green marked frame range can be configured by changing the median tolerance settings.


*Figure 5-8 Green indicators in head tilt dial to help maintain desired head tilt*

### 5.4.4 Performing measurements

When the patient is secured in the selected tilt position, measurement can be started by clicking the Start button. As an additional operator cue, the outer rings of the two dials are illuminated in orange until the patient has confirmed his/her estimate.

As soon as the Start button is activated the luminous line appears at an arbitrary angle in the virtual reality goggle. The patient is then instructed to rotate the line to gravity-vertical.

The device monitoring elements in the application software provide the operator with real-time information for the head tilt angle, the angle of the luminous line and the button activation. Each button symbol illuminates orange when the corresponding button the handheld remote is pressed by the patient.

NOTICE

Note that the two dials for head tilt angle (α) and SVV (β) are configured from the viewpoint of the examiner.

IMPORTANT

Maintain observation of the patient throughout the entire procedure in order to respond quickly in case of any discomfort. If the patient is tested in a tilted position or rotated on a rotary chair ensure that he/she is held securely.

### 5.4.5 Angle of deviation

The angle of deviation (Δ) between the angle of the head tilt and the set angle of the luminous line is presented graphically and as a numerical value.

**Angle of Deviation (Δ) = SVV Angle + Angle of Head Tilt**

The scale covers a range of -25° to +25°. The orange-colored arrow indicates continuously the angle of deviation while the patient is adjusting the luminous line. The normal range is modified according to the current head-tilt angle. This display component permits continuous insight into how well the patient is performing and able to adjust the luminous line vertically.

For additional orientation the optimal SVV angle is indicated by a small black triangular marker on the outer ring of the SVV dial.

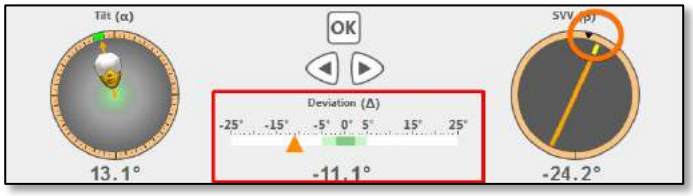



*Figure 5-9 Indication of optimal SVV setting*

### 5.4.6 Results diagram and measurement data table

The head-tilt angle (α) and the SVV deviation (Δ) are plotted on the results graphical diagram after completion of each measurement confirmation by the patient with the OK button. The ordinate scale (angle of deviation Δ) can be user-adjusted by the slider on the right-hand edge of the chart.

To assist in interpretation of the results, the threshold response range is indicated in the graphical diagram. The dark green shaded region represents the 25 – 75% threshold range, while the light green shaded region represents the 5 – 95% threshold range. These values are based on data from a population of normal subjects tested in the Vestibular Research Lab of the Charité Berlin, Campus Benjamin Franklin.

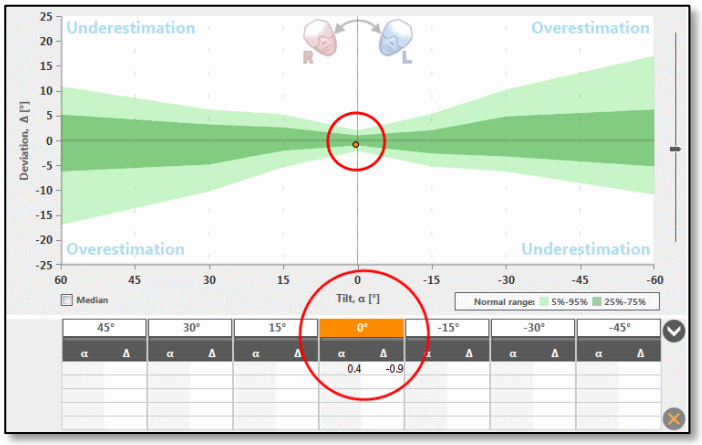



*Figure 5-10 Results diagram and table with a single exemplary data point*

The measurement data (α and Δ) are also entered in the appropriate column of the table below the graphical diagram. If desired, the table can be minimized to provide a larger image of the results diagram.

### 5.4.7 Swapping measurement sequences

After each individual measurement the operator has the choice to remain with the current measurement position or to switch to another. It is, however, recommended to perform 3 to 5 measurements at each postion.

### 5.4.8 Static tilt – step procedure

The following is a shortform procedure for the static tilt test mode:

1. Instruct the patient on the examination procedure and provide a hands-on explanation of the operation of the virtual reality goggle and handheld remote.
2. Mount the virtual reality goggle on the patient's head and check for fit and comfort. Secure the handheld remote with the safety loop and give the patient the handheld remote.
3. Select the first desired tilt position and secure the patient accordingly. Check for correct orientation on the basis of the tilt indicator, the green tolerance range and the green dial center.
4. Start the first measurement by clicking on the Start button.
5. Allow the patient to set the luminous line to his/her subjective vertical and to confirm the setting. Monitor the patient's activity with the aid of the software application device displays.
6. Repeat the measurement procedure for the current tilt position 3 to 5 times. The use of the serial measurement function is recommended.
7. Secure the patient in the next tilt position and perform the 3 to 5 measurements in this position. Repeat this procedure in all required tilt positions.
8. Remove the virtual reality goggle and handheld remote from the patient. Be aware that the patient may be disorientated for the next few minutes.
9. Store the recorded data and the resulting test report document.

During the examination the patient has been in total darkness for several minutes. After removing the virtual reality goggle be aware that the ambient room light may be disturbing to the patient. Allow a few minutes for the patient to readjust to the lighting in the room.

## 5.5 Testing with unilateral centrifugation

The unilateral centrifugation test protocol requires a motor-driven rotary chair fitted with a lateral shift mechanism to shift the chair 3.5-4.0 cm off center in both directions. In order to generate an adequate unilateral centrifugation stimulus, a contant angular velocity of at least 240º/second is required. For a complete desription of the unilateral centrifugation test procedure, please refer to the Virtual SVV™ Additional Information .

## 5.6 Discarding data

When the test trials are completed the stored measurement data can be erased by marking the measurement entry in the table and activating the delete icon on the lower right side of the data table. This erase function can be used throughout the examination if for any reason a measurement needs to be discarded.

*Figure 5-11 Delete icon*

# 6 Care and maintenance

## 6.1 General maintenance procedures

The operator of the Virtual SVV™ system is responsible for maintaining the medical product in faultless condition. The functionality and condition of all components should be checked regularly. The disposable items (face cushions, head strap and safety loop) should be exchanged or discarded as described.

In each delivered system the three component devices – base station, handheld remote and virtual reality goggle – are factory-matched and carry the same serial number. Exchanging any of these components should be carried out by the manufacturer. Each Virtual SVV™ system is calibrated at the manufacturer's facility. Under normal usage conditions recalibration is not necessary.

**Damage to devices**

In the following situations the Virtual SVV™ system should not be used until a qualified inspection has been performed:

1. One or more devices have been mechanically damaged (e.g. through impact).
2. A liquid has penetrated into one or more of the devices.
3. A cable or connector is defective.

In these or comparable situations, contact the distributor.

**Exchanging the padded face cushion**

The padded face cushions are intended as single-use, disposable items. They must be exchanged before each new patient is tested.

Replacing face cushion pads for each use is necessary to avoid the possibility of cross-infection.

The face cushion is bonded to the virtual reality goggle by a number of small Velcro® hook points. The face cushion can, therefore, be simply removed. Perform the procedure as described in chapter 3.

**Exchanging the head strap**

The head strap is subject to wear and tear after repeated use. It should be exchanged when this becomes apparent. The instructions provided in chapter 3 for attaching the strap can be performed in reverse to remove the used item.

**Battery care**

Follow the instructions for battery use and care to ensure long life.

- The built-in NiMH batteries are rechargeable. Under no circumstances should alkaline (non-rechargeable) batteries be used
- Only charge the batteries within the specified temperature range
- Use only the delivered power adaptor. Using other power sources could damage the batteries
- Take into consideration that a new battery reaches its full capacity after several charging cycles
- Never short-circuit the contacts on the handheld remote or in the cradle of the Base Station. This would damage the device!

- Avoid interrupting the charging cycle before the yellow LED extinguishes
- The integrated inactivity-timer in the handheld remote powers the system down after prolonged inactivity in order to save battery capacity. The standard period of inactivity is set to 10 minutes. This period can be increased (up to 30 minutes) if needed.
- Avoid discharging the batteries so completely that the system closes down. This can shorten battery life. Charge the batteries regularly when the charge indicator on the Operator GUI changes to yellow or red.
- Charge the batteries regularly, even during periods when seldom used
- Do not expose the device to direct sunlight or high temperatures. This would, under certain circumstances, affect the temperature-dependent charge control and the batteries would not be charged completely.
- The batteries should be exchanged if the capacity is so low such that SVV testing is unable to be performed correctly. Follow the instructions in below on exchanging batteries.

**Exchanging the built-in batteries**

The batteries should be exchanged when its operative life becomes so short that examinations cannot be performed in full. Proceed as follows:

**Step 1**
Switch off the handheld remote by pressing both right and left buttons for at least 5 seconds. The device is powered down when the ON-LED extinguishes. Disconnect the cable to the virtual reality goggle.

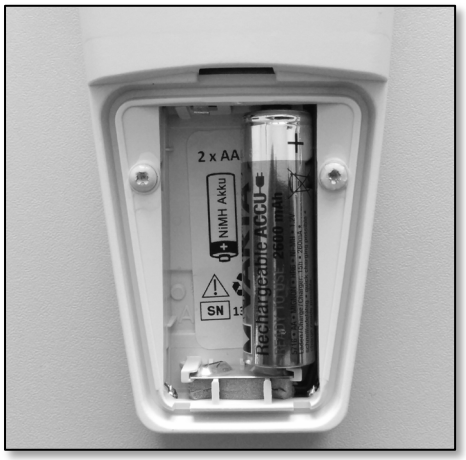
**Step 2**
Slide the securing clip on the battery compartment cover downwards in order to open the cover.


**Step 3**

Only the following battery type may be used:
**2 x VARTA Ready to use – NiMH AA 1,2 V 2600 mAh**


Under no circumstances should non-rechargeable (alkaline) batteries be used. The permissible battery type can be read from the label inside the battery compartment. Using a non-rechargeable battery will void the device warranty. Polarity markings should be followed. Address any questions in this matter to your distributor.

When inserting the new batteries pay attention to the correct polarity. This is indicated clearly inside the battery compartment for each battery.



**Step 4**
Replace the battery compartment cover as shown in the figure below. Slide the securing clip upwards.

NOTICE

After inserting new batteries it is important that the charging process is continued until the yellow LED charge indicator extinguishes. Do not disconnect the base station from the AC outlet during this procedure.

## 6.2 How to clean Interacoustics products

Always remove the face cushion before cleaning the virtual reality goggle. Wipe the surface of the virtual reality goggle and handheld remote with a soft, clean cloth or tissue. The cloth may be slightly dampened with water, mild cleaning liquid (e.g. dish washing cleaner or similar).

- Before cleaning always switch off and disconnect from AC outlet
- Do not use solvents or aggressive cleaning liquids or pastes
- Do not use disinfectant sprays
- Do not use saturated cloths or tissue
- Do not soak or immerse any of the connectors in liquid. Avoid getting the device wet
- Do not autoclave, sterilize or immerse the instrument or included parts in any fluid
- Use a soft cloth lightly dampened with cleaning solution to clean all exposed surfaces
- Do not use hard or pointed objects to clean any part of the instrument or included parts
- Face cushions are single use components. They must be exchanged before each new patient

**Recommended cleaning and disinfection solutions:**

- Warm water with mild, nonabrasive cleaning solution (soap)
- 70% isopropyl alcohol

NOTICE

**Cleaning the head strap**

The elastic head strap can be machine-washed at 40° C with regular washing powder. However, do not dry in the dryer. Note that the elasticity can deteriorate after 4-5 wash cycles. The head strap must be discarded and exchanged at this point in order to ensure a comfortable and tight fit during testing.

## 6.3 Concerning repair

Interacoustics is only considered to be responsible for the validity of the CE marking, effects on safety, reliability and performance of the equipment if:

1. assembly operations, extensions, readjustments, modifications or repairs are carried out by authorized persons,
2. the electrical installation of the relevant room complies with the appropriate requirements, and
3. the equipment is used by authorized personnel in accordance with the documentation supplied by Interacoustics.

It is important that the customer (agent) fills out the RETURN REPORT every time a problem arises and sends it to Interacoustics, along with the complete SVV system (all three components plus power supply). This should also be done every time an instrument is returned to Interacoustics for repair. (This of course also applies in the unthinkable worst case of death or serious deterioration to patient or user).

Interacoustics will make necessary diagrams and part lists available for authorized Interacoustics service personnel.

## 6.4 Warranty

Interacoustics warrants that:

- The Virtual SVV™ system is free from defects in material and workmanship under normal use and service for a period of 24 months from the date of delivery by Interacoustics to the first purchaser
- Included parts are free from defects in material and workmanship under normal use and service for a period of ninety (90) days from the date of delivery by Interacoustics to the first purchaser

If any product requires service during the applicable warranty period, the purchaser should communicate directly with the local Interacoustics service centre to determine the appropriate repair facility. Repair or replacement will be carried out at Interacoustics' expense, subject to the terms of this warranty. The product requiring service should be returned promptly, properly packed, and postage prepaid. Loss or damage in return shipment to Interacoustics shall be at purchaser's risk.

In no event shall Interacoustics be liable for any incidental, indirect or consequential damages in connection with the purchase or use of any Interacoustics product.

This shall apply solely to the original purchaser. This warranty shall not apply to any subsequent owner or holder of the product. Furthermore, this warranty shall not apply to, and Interacoustics shall not be responsible for, any loss arising in connection with the purchase or use of any Interacoustics product that has been:

- Repaired by anyone other than an authorized Interacoustics service representative
- Altered in any way so as, in Interacoustics judgement, to affect its stability or reliability
- Subject to misuse or negligence or accident, or which has had the serial or lot number altered, effaced or removed
- Improperly maintained or used in any manner other than in accordance with the instructions furnished by Interacoustics

This warranty is in lieu of all other warranties, express or implied, and of all other obligations or liabilities of Interacoustics, and Interacoustics does not give or grant, directly or indirectly, the authority to any representative or other person to assume on behalf of Interacoustics any other liability in connection with the sale of Interacoustics products.

Interacoustics disclaims all other warranties, expressed or implied, including any warranty of merchantability or for function of fitness for a particular purpose or application.

# 7 Troubleshooting

## 7.1 Troubleshooting table

| Problem | Possible Cause | Solution |
|---|---|---|
| Communication between base station and handheld remote is interrupted | Timeout | Switch on handheld remote |
| | Battery low | Insert handheld remote in cradle on base station. Recharged when yellow LED extinguishes |
| | Poor wireless transmission | Check for free “line-of-sight” between handheld remote and base station. Alter the position of patient and/or base station. Control the reception quality in Settings-General. |
| Connection to device cannot be established | Base Station not connected to PC | Check USB connection |
| | Handheld remote not activated | Switch on handheld remote |
| | Battery low | Insert handheld remote in cradle on base station. Recharged when yellow LED extinguishes. |
| | Poor wireless transmission | Check for free “line-of-sight” between handheld remote and base station. Alter the position of the patient and/or base station. Control the reception quality in Settings-General. |
| Error while reading the calibration parameters! Error while reading the serial number! Error while requesting system state! The state of the luminous line could not be set! | Base station not connected | Check USB connection |
| | Handheld remote not activated | Switch on handheld remote |
| | Battery low | Insert handheld remote in cradle on base station. Recharged when yellow LED extinguishes. |

| | | |
|---|---|---|
| The measurement could not be started. Please check the connection. | Poor wireless transmission | Check for free “line-of-sight” between handheld remote and base station.<br>Alter the position of the patient and/or base station.<br>Control the reception quality in Settings-General. |
| You have no valid license for this software version. Please contact your distributor. | License invalid | Your license does not match your software. Please uninstall the current Virtual SVV™ software and install Virtual SVV™ from the included media and use the license included. |
| | | Contact your distributor to obtain a valid license |
| The serial number of the connected Virtual SVV™ system does not match your license | License invalid<br><br>No license in the folder “License” in the Virtual SVV™ installation directory that matches to your serial number | If the valid license is available, copy this to the folder “License” in the Virtual SVV™ installation directory |
| | | Contact your distributor to obtain a valid license |
| The data could not be exported | Another process is accessing the SVV data | Determine which program is accessing the data. Terminate this program. |

## 7.2 System function check

Before patient testing it is recommended that a quick check of the main system functions be performed.

**Head tilt sensors**
Tilt the virtual reality goggle to the right and to the left and check that a corresponding reading appears on the software application device displays.

**Virtual reality display**
Initiate a measurement. Check that the luminous line is displayed in the virtual reality goggle.

**Luminousline**
Using the ◁ and ▷ buttons on the handheld remote, check that the luminous line rotates correspondingly in the virtual reality goggle and in the application software.

**Response confirmation**
After a measurement has been initiated, press the OK button on the handheld remote to check that the luminous line in the virtual reality goggle display extinguishes. Check that the measurement data is entered in the results table and that the measurement data point appears in the graphical display.

# 8 General technical specifications

## 8.1 System requirements

**Hardware**

| | |
|---|---|
| **Processor** | Intel i5 processor 2.5 GHz or better |
| **RAM** | Minimum 8 GB |
| **Ports** | One USB 2.0 port |
| **HD** | 250 GB or more |
| **Drive** | not required |
| **Monitor resolution** | 1366x768 or higher |
| **Med-PC** | Acc. DIN EN 60601-1 |

**Software**

| | |
|---|---|
| **Operating system** | Windows® 7 (32/64bit)<br>Windows® 8 (32/64bit)<br>Windows® 10 (32/64 bit) |
| **Framework** | Microsoft .NET Framework 4.0 (provided on software CD) |
| **PDF Viewer** | Adobe Reader X recommended<br>(provided on software installation media) |
| **Database** | OtoAccess™ Version 1.4 or later |

**Environmental Conditions**

| | | |
|---|---|---|
| **Operation** | Temperature: | 15 ° – 35 °C 59º - 95ºF |
| | Rel. humidity: | 35 % – 95 % |
| | Pressure: | 800 hPa – 1050 hPa |
| **Storage** | Temperature: | 0 °C – 50 °C 32º - 122ºF |
| | Rel. humidity: | 10 % – 95 % RH |
| **Ingress Protection rating** | IP40 | |

**Transporting the system**
The Virtual SVV™ system should be switched off prior to transport.

The device should be transported in the original package or in a suitable transport case. The device should be protected from impact, humidity, dust, and electrical interference during transport.

Avoid changes in temperature and/or relative humidity during operation of the system.
Avoid positioning the devices in direct sunshine or in the neighborhood of radiators or other sources of heat.

**Storage**
If the Virtual SVV™ system is not used for any length of time, keep it stored in a dry, dust-free area out of sunlight. The batteries should be removed if the device is not being used for a longer period. The device should preferably be stored in the original packaging.

**Operation mode**
The duration of operation is limited by the capacity of the rechargeable batteries. When battery capacity reduces below a critical level, a warning is signaled to the operator and the devices power down automatically. In addition a timer monitors the device activity. If no user/patient activity occurs the timer powers down the device after 10 minutes. This timeout period can be user-modified up to a maximum of 30 minutes.

## 8.2 Virtual SVV™ hardware specifications

| | |
|---|---|
| **Angular Resolution** | 0,1 ° |
| **Accuracy +/- 60**° tilt | +/- 0,5° |
| **Accuracy +/- 2**° tilt | +/- 0,19° |
| **Weight** | Virtual reality goggle: 384 g<br>Handheld remote: 184 g |
| **Dimensions (packed)** | 33 x 15 x 27 cm (WB x H x D) |
| **Electrical Device Classification** | IEC/EN 60601-1,Battery powered, Applied part Type B |
| **Transmission Frequency** | 2450 MHz ISM (Industrial, Scientific & Medical) |
| **Transmission Range** | 10m inside building |
| **AC Power Adaptor** | VEP15US05 (Manufacturer: XP Power) |
| **Input Voltage** | 100-240 Vac 0.5 A, 50/60 Hz |
| **Output Voltage** | 5.0 Vdc 2.0 A |

## 8.3 Electromagnetic compatibility (EMC)

**CAUTION**

- This instrument 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 this instrument adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this instrument and the other equipment should be observed to verify that they are operating normally
- Use of included parts, 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 included parts, 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 instrument, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

**NOTICE**

- Essential performance for this instrument is defined by the manufacturer as:
  This instrument 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. There are no deviations from the collateral standard and allowances uses.
- This instrument is in compliance with IEC60601-1-2:2014, emission class B group 1
  NOTICE: There are no deviations from the collateral standard and allowances uses
- NOTICE: All necessary instruction for maintaining compliance with regard to EMC can be found in the general maintenance section in this instruction. No further steps required.

| **Guidance and manufacturer's declaration - electromagnetic emissions** | | |
|---|---|---|
| ***Virtual SVV*™ is intended for use in the electromagnetic environment specified below. The customer or the user of *Virtual SVV*™ should assure that it is used in such an environment.** | | |
| **Emissions Test** | **Compliance** | **Electromagnetic environment - guidance** |
| RF emissions<br>CISPR 11 | Group 1 | ***Virtual SVV*™** 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 | ***Virtual SVV*™** 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 *Virtual SVV*™.** | | | |
|---|---|---|---|
| ***Virtual SVV*™** is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of ***Virtual SVV*™** can help prevent electromagnetic interferences by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and ***Virtual SVV*™** 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** | | | |
|---|---|---|---|
| ***Virtual SVV™*** is intended for use in the electromagnetic environment specified below. The customer or the user of ***Virtual SVV™*** 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 | ±2kV air/contact<br><br>±4kV air/contact<br><br>±6kV contact<br><br>±8kV air/contact<br><br>±15kV air | ±2kV air/contact<br><br>±4kV air/contact<br><br>±6kV contact<br><br>±8kV air/contact<br><br>±15kV 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 ***Virtual SVV™*** requires continued operation during power mains interruptions, it is recommended that ***Virtual SVV™*** be powered from an uninterruptable power supply or its battery. |
| Power frequency (50/60 Hz)<br><br>IEC 61000-4-8 | 30 A/m | 30 A/m | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or residential environment. |
| **Note:** *U*T is the A.C. mains voltage prior to application of the test level. | | | |

<table>
<tr><th colspan="4">Guidance and manufacturer's declaration — electromagnetic immunity</th></tr>
<tr><td colspan="4">Virtual SVV™ is intended for use in the electromagnetic environment specified below. The customer or the user of Virtual SVV™ should assure that it is used in such an environment,</td></tr>
<tr><td>Immunity test</td><td>IEC / EN 60601<br>test level</td><td>Compliance level</td><td>Electromagnetic environment – guidance</td></tr>
<tr><td>Conducted RF<br>IEC / EN 61000-4-6<br><br><br><br>Radiated RF<br>IEC / EN 61000-4-3</td><td>3 Vrms<br>(150kHz to 80 MHz)<br>6 Vrms<br>(ISM Band)<br><br>3 V/m<br>80 MHz to 2,5 GHz</td><td>3 Vrms<br><br>6 Vrms<br><br>3 V/m</td><td>Portable and mobile RF communications equipment should be used no closer to any parts of Virtual SVV™, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.<br><br>Recommended separation distance<br>$d = 1{,}2\sqrt{P}$<br>$d = 1{,}2\sqrt{P}$ 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>  </td></tr>
<tr><td colspan="4">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.</td></tr>
<tr><td colspan="4">[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 Virtual SVV™ is used exceeds the applicable RF compliance level above, Virtual SVV™ should be observed to verify normal operation, If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating Virtual SVV™ .<br>[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</td></tr>
</table>

| **Guidance and manufacturer's declaration —** Immunity to RF wireless communication | | | | | | |
|---|---|---|---|---|---|---|
| **Test frequency** (MHz) | **Band** (MHz) | **Service** | **Modulation** | **Maximum power** | **Distance** | **Immunity test level** |
| 385 | 380 – 390 | TETRA 400 | 18 Hz Pulse modulation | 1,8 W | 0,3 m | 27 V/m |
| 450 | 430 – 470 | GMRS 460, FRS 460 | FM ±5 kHz deviation 1kHz sine | 2 W | 0,3 m | 28 V/m |
| 710, 745, 780 | 704 – 787 | LTE Band 13, 17 | 217 Hz Pulse modulation | 0,2 W | 0,3 m | 9 V/m |
| 810, 870, 930 | 800 – 960 | GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5 | 18 Hz Pulse modulation | 2 W | 0,3 m | 28 V/m |
| 1720, 1845, 1970 | 1700 – 1990 | GSM 1800, CDMA 1900, GSM 1900, DECT, LTE Band 1, 3, 4, 25; UMTS | 217 Hz Pulse modulation | 2 W | 0,3 m | 28 V/m |
| 2450 | 2400 – 2570 | Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7 | 217 Hz Pulse modulation | 2 W | 0,3 m | 28 V/m |
| 5240, 5500, 5785 | 5100 – 5800 | WLAN 802.11 a/n | 217 Hz Pulse modulation | 0,2 W | 0,3 m | 9 V/m |

## 8.4 Safety regulations

CE

**Declaration of conformity**
The CE marking confirms that the Virtual SVV™ system conforms to the relevant requirements of the guideline 93/42/EEC. The Virtual SVV™ system is classified accordingly as a Class 1 medical device.

**Safety standards**
This device is specified to comply with the international standards, IEC/EN/ES 60601-1 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.

**RoHS compliance – 2011/65/EU**
The Virtual SVV™ system fulfils the European guidelines for the limited use of dangerous materials in electrical and electronic equipment.