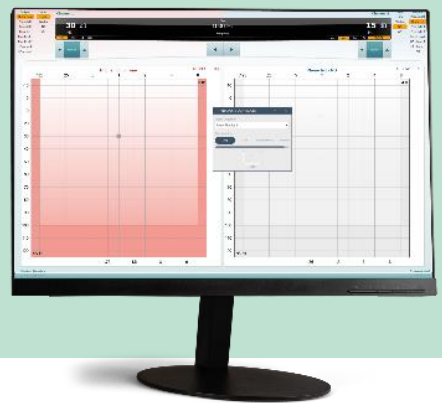
 Science **made** smarter

Instructions for Use - EN

VRA Pure



D-0132406-A – 2022/02

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1 Introduction

1.1 About this manual

This manual is valid for the Interacoustics VRA Pure. This product is distributed by Interacoustics A/S.

Interacoustics A/S

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1.2 Intended use

The Interacoustics VRA Pure is controlled from the clinics own PC and is therefore an integrated system in the workflow from the PC. VRA Pure works as an on-top mode when it is opened and is easy to control while using other test programs on the PC.

1.3 Contraindications

None known.

1.4 Product description

The Interacoustics VRA Pure provides the ability to support up to three visual reinforcement screens where motions and still pictures can be used as rewards.

The Playlist Creator software delivered with the VRA system makes it possible to adjust the default playlists provided and create playlists of you own.

Included parts:

- VRA Pure software

1.5 Minimum requirements

Screens

- Resolution 1024x768 (recomended 1920x1080)
- HDMI support



2 Installation

2.1 Reporting imperfections

Report any faults immediately

Any missing parts or malfunctions should be reported immediately to the supplier of the instrument together with the invoice, serial number, and a detailed report of the problem. At the end of this manual, you will find a "Return Report", where you can describe the problem.

Please use the "Return Report"

Use of the return report provides the service engineer with the relevant information to investigate the reported issue. Without this information, there may be difficulty in determining the fault and repairing the device.

2.2 Safety precautions

Read these instructions carefully and completely before using the product.

2.2.1 Cautions – general



If the system is not functioning properly, do not use it until all necessary repairs are made and the unit is tested for proper functioning in accordance with Interacoustics' specifications.

Do not drop or in any other way cause undue impact to this device. If the instrument is damaged, return it to the manufacturer for repair. Do not use the instrument if any damage is suspected.

This product and its components will perform reliably only when operated and maintained in accordance with the instructions contained in this manual, accompanying labels, and/or inserts. A defective product should not be used. Make sure all connections to external accessories are secured properly. Parts which may be broken or missing or are visibly worn or distorted should be replaced immediately with clean, genuine replacement parts manufactured by or available from Interacoustics.

Interacoustics will make available on request circuit diagrams, component part lists, descriptions, calibration instructions, or other information that will assist authorized service personnel to repair those parts of this instrument that are designated by Interacoustics as repairable by service personnel.

No parts of the equipment can be serviced or maintained while in use with the patient.

The instrument is not intended for use in environments exposed to fluid spills.

2.3 Malfunction



In the event of a product malfunction, it is important to protect patients, users, and other persons against harm. Therefore, if the product has caused, or potentially could cause such harm, it must be quarantined immediately.

Both harmful and harmless malfunctions, related to the product itself or to its use, must immediately be reported to the distributor where the product was acquired. Please remember to include as many details as possible e.g., the type of harm, serial number of the product, software version, connected accessories and any other relevant information.



In case of death or serious incident in relation to the use of the device, the incident must immediately be reported to Interacoustics and the local national competent authority.



3 Visual reinforcement audiometry (VRA)

VRA is a tool that can help keeping young patients stay focused during audiometric or other procedures by giving them a visual reward. The test is performed by an audiometer or another medical device. By using visual reinforcement, the child is trained to move their head to either side and indicate that they have heard the sound, thus giving the clinician an indication of the hearing level.

VRA is often done in a free field environment when it is infants/very young toddlers, and it is therefore not possible to determine which side the sound was heard at, at a specific sound level. If the child accepts it, headphones or foam tips with inserts can be used to make an ear specific audiometry.

In the VRA setup there are usually two screens, one on each side of the child. When the clinician is presenting a sound, the child is prompted to turn its head towards the sound. This can require some training at first. When the child moves its head towards the sound heard, the screen is activated by the operator, and an animation or image is presented as a reward.

By using the VRA setup it makes it more fun for the young child to participate in the examination and it does not seem so intimidating getting a hearing test, when cartoons and toys are used.



4 Getting started

The VRA Pure system only contains one part: the VRA Pure software.

4.1 The VRA software

Once the software is installed, the user is ready to create playlists and use the setup.

4.1.1 PC and connections

This version of VRA only contains software, therefore it will be the clinics own PC that is to be used to control the VRA.

4.1.2 Setup

Screens

The VRA Pure software can have up to three screens connected. It all depends on how many available HDMI/DP ports that are available on the clinics own PC.

4.1.3 Start-up

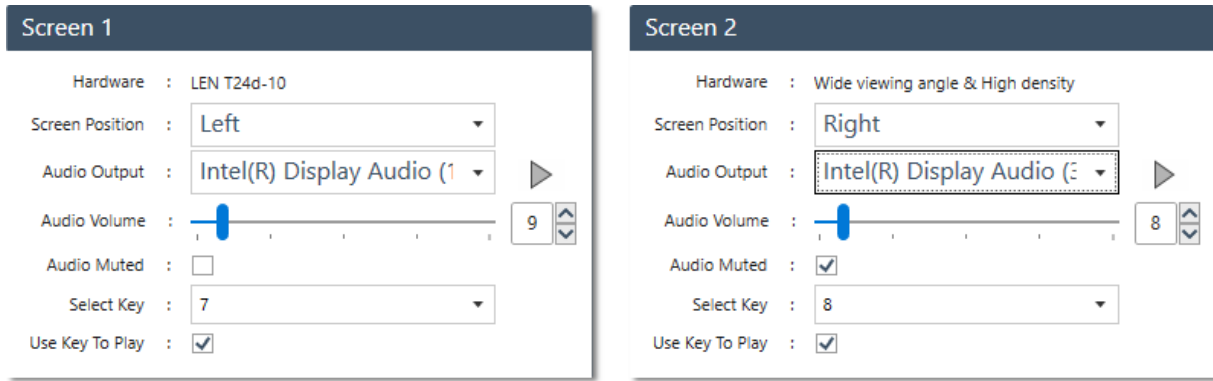
The VRA Pure is started from the clinics own PC by opening the program like any other program. If playlists have already been created, the software is ready to play, and the VRA Pure is activated on

the screens in the booth by pressing the play button. 

If playlists have not been created, please see section 4.2.

4.1.4 Setup window

The setup window is found in the top right corner.



Close Identify Screens

Hardware

In this field, information will be available about the screens connected.

Screen position

Possibility to select left, right or center

Audio output is where the speakers are selected. It is possible to send sound through the PC, or the connected loudspeaker. The play button to the right is to test that the sound is played through the correct media.

Audio volume gives the option to control how loud the sounds on the videos should be played. It will be set to 50 % as default.

Audio muted makes it possible to mute the sound on the videos and it is possible to mute one screen and have the sound on another if this is wanted.

Select key

Here it is possible to select 7, 8 or 9 that will activate the screens while in use. To activate the screens during a test, hold down “end” tap together with 7, 8 or 9.

Use key to play

To activate or deactivate the possibility to control the VRA Pure by using the keyboard.



4.2 Creating your own playlists

When receiving the system, the USB will contain the VRA Pure where you will have the possibility to create your own playlists and tailor the content from session to session in an easy and quick way.

4.2.1 PC requirements using the VRA Pure

PC minimum requirements

- Core i3 CPU or better (Intel recommended)
- 4GB RAM or more
- Hard drive with min 10 GB free space (Solid State Drive (SSD) recommended)
- Minimum display resolution of 1280x1024 pixels
- DirectX 11.x compatible graphics (Intel/NVidia recommended)
- One or more USB ports, version 1.1 or higher

Supported operating systems

- Microsoft Windows® 7 32-bit and 64-bit
- Microsoft Windows® 8 32-bit and 64-bit
- Microsoft Windows® 10 32-bit and 64-bit
- Windows® is a registered trademark of Microsoft Corporation in the United States and other countries.

Important: make sure you have the latest service packs and critical updates installed for the version of Windows® that you are running.

NOTICE: Using operating systems where Microsoft have discontinued software and security support will increase the risk for viruses and malware, which may result in breakdowns, data loss and data theft and misuse.

Interacoustics A/S cannot be held liable for your data. Some Interacoustics A/S products support or may work with operating systems unsupported by Microsoft. Interacoustics A/S recommends you to always use Microsoft supported operating systems that are kept fully security updated.

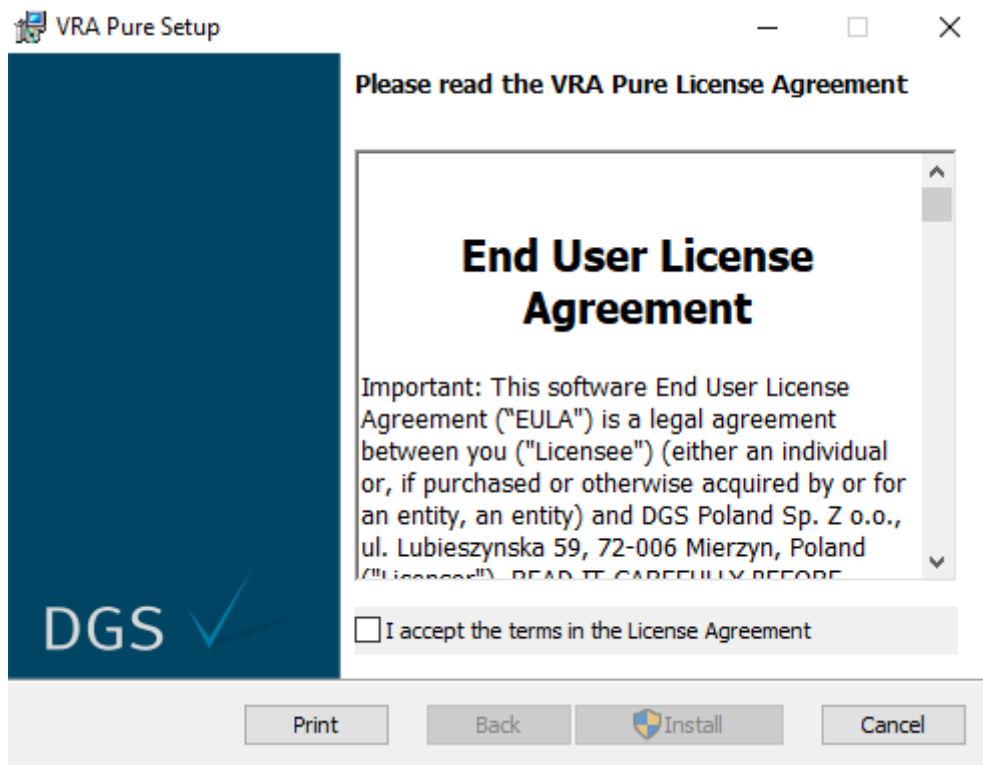
4.2.2 Software Installation

Software installation on Windows® 7, Windows® 8 and Windows® 10

Insert the installation USB and follow the steps below to install the VRA Pure. Click **Start**, then go to **My Computer** and double click the USB drive to view the contents of the installation USB. Double click the **setup.exe** file to initiate the installation. Wait for the dialog shown below to appear, agree to the license terms and conditions, then click **Install**.

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

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



Follow the onscreen VRA Pure Installer instructions until the installation has been completed. Click on **Close**. The software is now installed and ready to use.

During installation, Windows® may:

- Ask if you want to allow changes to the computer. Click **Yes** if this happens
- Ask to download and install a new Windows Feature (e.g., .NET Framework 3.5). Download and install new features to ensure that the software works as intended
- Warn you that Windows cannot verify the publisher of this driver software. Install the driver software anyway to ensure the VRA Pure works as intended

Open the program from desktop shortcut or from **Start**.

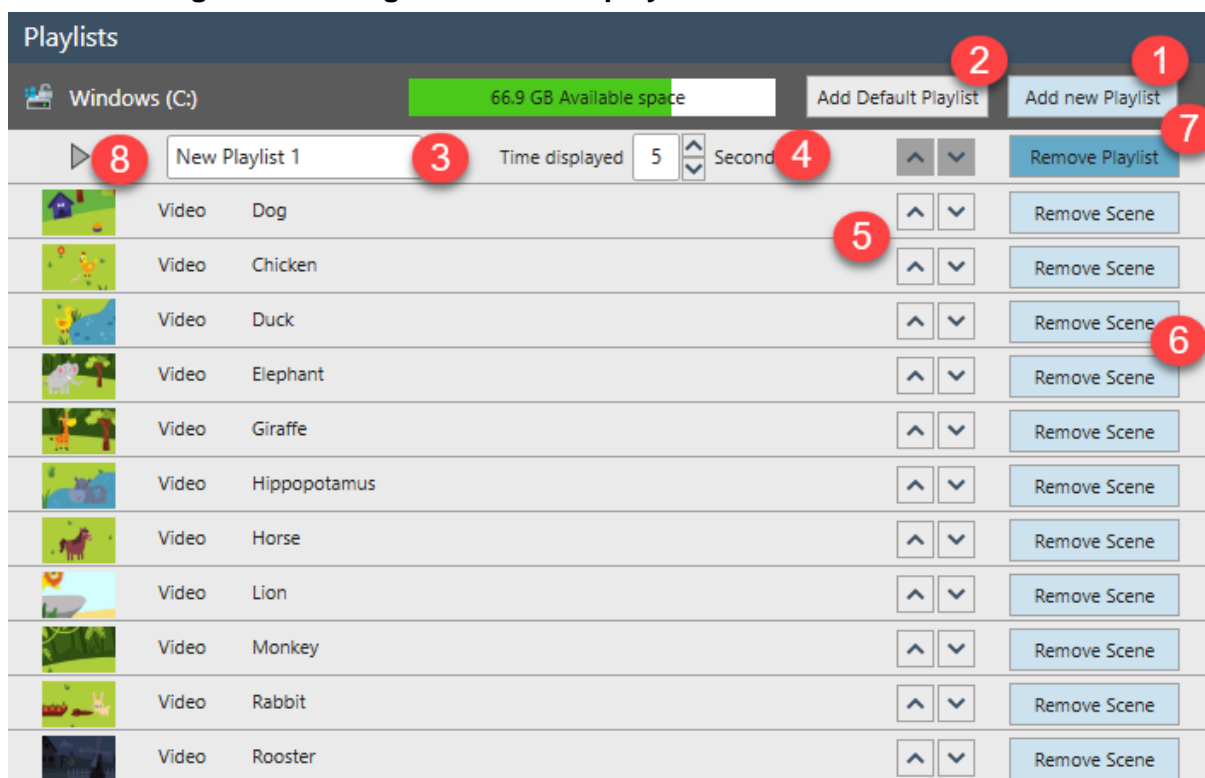
Supported files are:

- **images:** .jpeg, jpg, png, bmp
- **videos:** .mp4, .m4a, .m4v

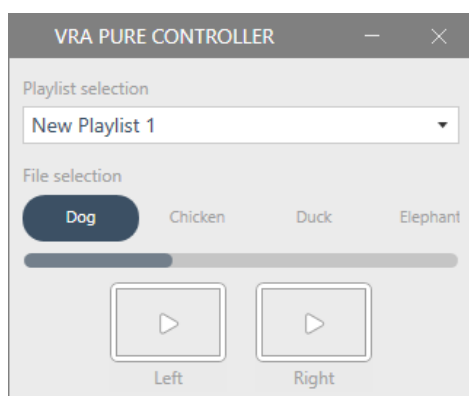
Only supported files are visible when looking through folders on the local PC.



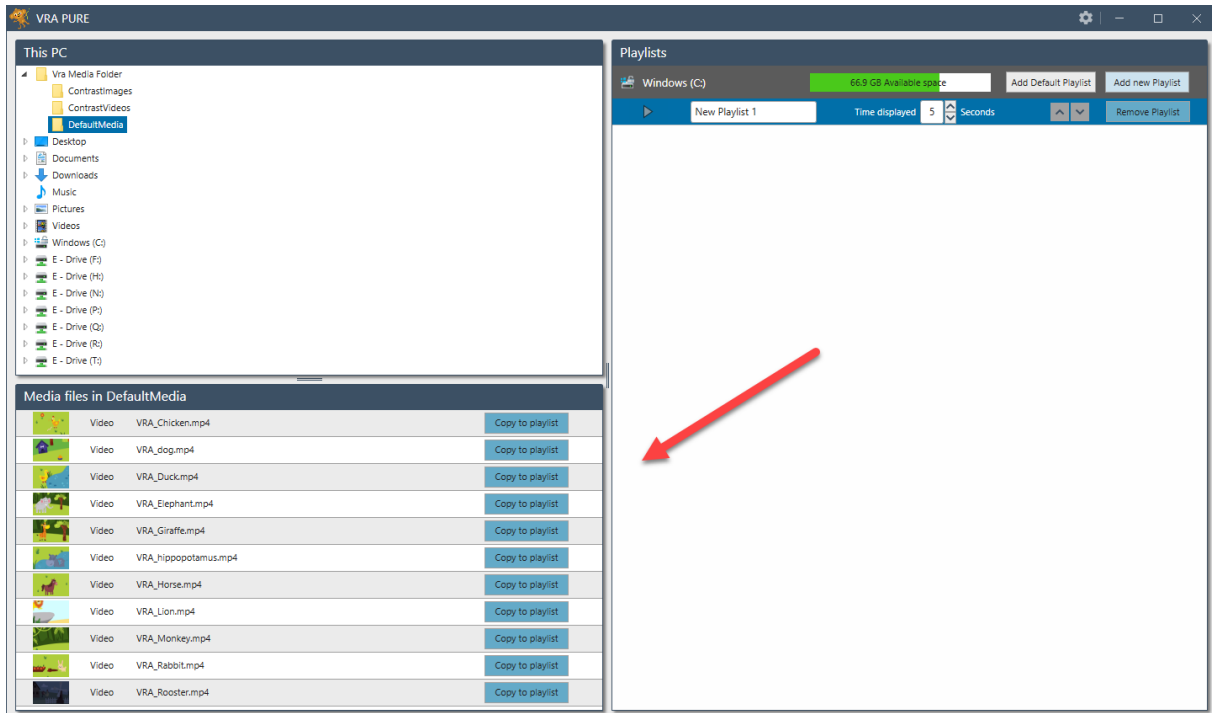
4.2.3 Getting started using the VRA Pure playlist creator



1. **Add new playlist:** Create new playlists.
2. **Add default playlist:** The default playlists with cartoon animals will be added.
3. **Rename the playlist:** Choose the name of the playlist. The playlist name will only be visible in the left bottom corner of the screen when changing through playlists in use.
4. **Time displayed:** Set the time to how long the image or video should be visible on screen. From 0 to 99 seconds.
5. **Shuffle arrow:** Replace the image or video on the playlist.
6. **Remove Scene:** Remove an image or video from the playlist.
7. **Remove playlist:** Remove entire playlist from USB. Default playlist can always be removed and added again when needed.
8. **Start playlist:** When the play button is pressed, a small on-top window will appear and allow the user to play the selected playlist on the chosen screen



A new playlist is created by using **Add new playlist**. Open the folders of the content in the upper left corner. The supported files in the folder will be available in the lower left corner of the screen. Choose the image or video to add to playlist and press **Copy to Playlist** or drag the content over to the playlist on the right side of the screen.



Press **Copy to playlist** or drag the image or video to playlist.

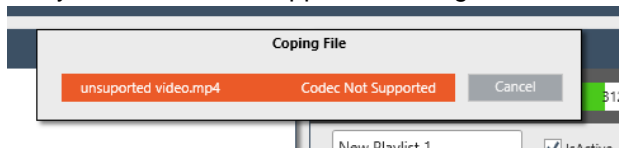
When multiple playlists are created, remember to choose the right one before adding images or video to the playlist. This is done by clicking in the line with playlist name and time displayed.

The selected playlist will appear dark blue.

When dragging the content from the media files list, the playlist where the image or video will be added will appear light blue.

During transfer of the image or video, a box will appear to indicate the status of transfer.

If the status bar turns orange during transfer, this means that the image or video is not supported by the system, or an error appeared during transfer.

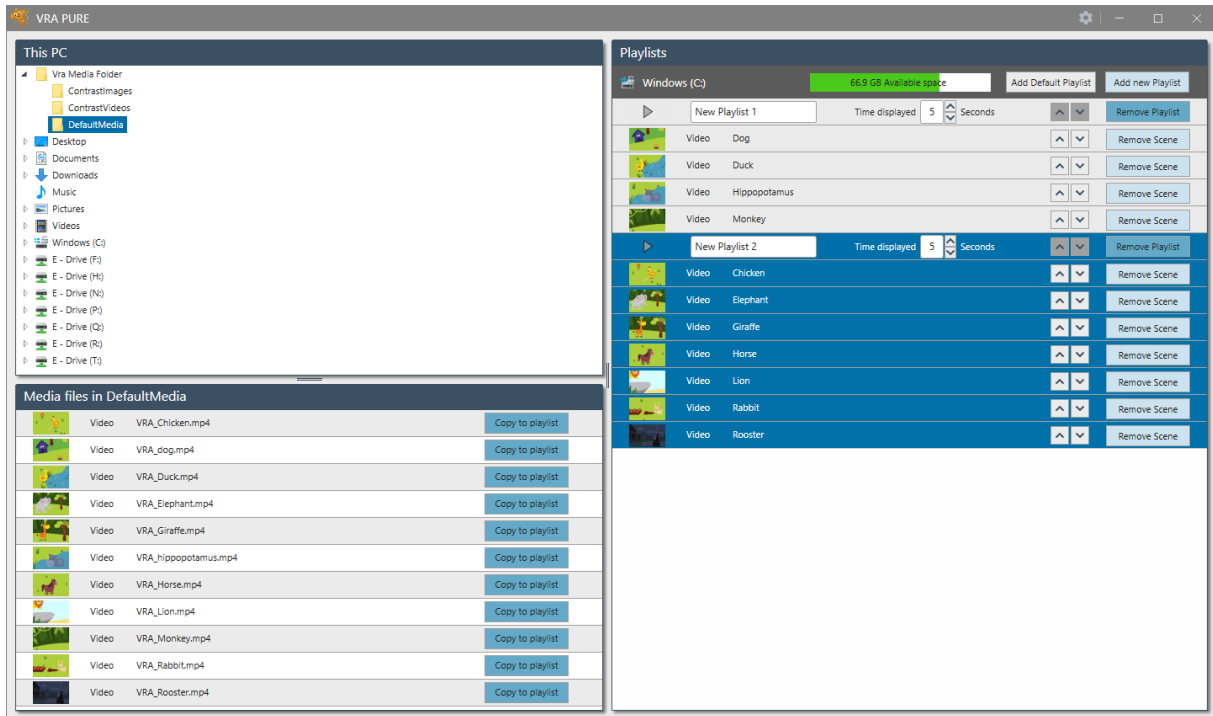


When a playlist is created there are multiple options to customize the content. For example, the time shown on screen, which image should appear on what playlist, should a single video or image be shown multiple times in a row etc.

4.3 Drag and drop

It is possible to create as many playlists as needed. When having more playlist, the user can drag images and videos between the different playlists by holding down on the item and dragging it to the desired place on the playlist or to another playlist. The list the image or video are being dragged to, will be marked by a bold line.

To copy an image or video from one playlist to another, hold down CTRL when dragging the item. This can also be used for copying an image or video to the same playlist.



When the desired playlists are added and customized, the play button is pressed, and the selected screens are blacked out and the VRA Pure is ready to use.



5 Care and maintenance

5.1 Repair

DGS Diagnostics A/S 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.

The customer shall reach out to the local distributor to determine the service/repair possibilities including onsite service/repair. It is important that the customer (through local distributor) fills out the **RETURN REPORT** every time when the component/product is sent for service/repair to Interacoustics.

This should also be done every time an instrument is returned to Interacoustics. (This of course also applies in the unlikely worst-case scenario of death or serious injury to a patient or user).

This device is manufactured by:

DGS Diagnostics A/S
Audiometer Allé 1
5500 Middelfart
Denmark

5.2 Warranty

Interacoustics guarantees that:

- The Interacoustics VRA Pure is free from defects in material and workmanship under normal use and service for a period of 24 months from the date of delivery by Interacoustics to the first purchaser
- Accessories are free from defects in material and workmanship under normal use and service for a period of ninety (90) days from the date of delivery by Interacoustics to the first purchaser

If any product requires service during the applicable warranty period, the purchaser should communicate directly with the local Interacoustics service center 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 the purchaser's risk.

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 opinion, to affect its stability or reliability;
- subject to misuse or negligence or accident, or that has had the serial or lot number altered; defaced or removed; or
- improperly maintained or used in any manner other than in accordance with the instructions provided by Interacoustics.

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 warranty is in lieu of all other warranties, express or implied, and of all other obligations or liabilities of Interacoustics. 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.

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Return Report – Form 001



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

Company: _____

Address: _____

Phone: _____

Fax or e-mail: _____

Address

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

Contact person: _____ Date: _____

Following item is reported to be:

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

Item: _____ **Type:** _____ **Quantity:** _____
Serial No.: _____ Supplied by: _____
Included parts: _____

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

Description of problem or the performed local repair:

Returned according to agreement with: Interacoustics, Other : _____

Date : _____ Person : _____

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

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

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

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

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