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Instructions for Use - US

Lyra



D-0119950-C – 2019/03

Interacoustics

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1 Introduction

1.1 About this manual

This manual is valid for the IA OAE Suite software version 1.0. The product is manufactured by:

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Denmark
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Fax: +45 6371 3522
E-mail: info@interacoustics.com
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1.2 Intended use

The Lyra with DPOAE software is intended for use in the audiologic evaluation and documentation of ear disorders using Distortion Product Otoacoustic Emissions. The target population for Lyra with DPOAE includes all ages.

The Lyra with TEOAE software is intended for use in the audiologic evaluation and documentation of ear disorders using Transient Evoked Otoacoustic Emissions. The target population for Lyra with TEOAE includes all ages.

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

1.3 Contraindications

Contraindications include the placement of the OAE probe in/on a patient's ear in case of a discharging ear, acute external auditory canal trauma, discomfort (e.g. severe otitis externa) or occlusion of the external auditory canal. Testing should not be performed on patients with such symptoms without a medical doctor's approval.

For US only: Federal law restricts the sale, distribution, or use of this device to, by, or on the order of a licensed medical practitioner.

1.4 Product description

The Lyra is a diagnostic device that interfaces with integrated audiologic software modules on a PC. Lyra can perform (license controlled):

- Distortion Product Otoacoustic Emissions
- Transient Evoked Otoacoustic Emissions

The system consists of the following included and options parts:

DPOAE	TEOAE
Included parts: Lyra unit with permanent OAE probe[1] BET25 Ear tips Test cavity 0.2 and 0.5cc IA OAE Suite software with DPOAE & TEOAE OtoAccess™ database software USB cable Carrying pouch	**Included parts:** Lyra unit with permanent OAE probe[1] BET25 Ear tips Test cavity 0.2 and 0.5cc IA OAE Suite software with DPOAE & TEOAE OtoAccess™ database software USB cable Carrying pouch

[1] Applied part according to IEC 60601-1

1.5 Warnings

Throughout this manual the following meanings of warnings, cautions and notices apply:



WARNING

The WARNING label identifies conditions or practices that may present danger to the patient and/or user.



CAUTION

The CAUTION label identifies conditions or practices that could result in damage to the equipment.

NOTICE

NOTICE is used to address practices not related to personal injury.

2 Unpacking and installation

2.1 Unpacking and Inspection

Check shipping box

As soon as the instrument is received, please check the shipping box for any sign of rough handling or damage. If the box is damaged, keep the shipping material as it may be required for inspection by the carrier regarding any potential insurance claim.

Keep carton

The Lyra comes in its own custom-made shipping carton. Please keep this carton as it will be needed if the instrument has to be returned for service or repair.

Inspect instrument before connection

Prior to connecting the product, it should once more be inspected for potential damage. The cabinet and the accessories should all be visually examined for scratches and missing parts.

Report immediately any concerns

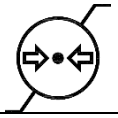
Any missing part or any mechanical or electrical malfunction should be reported immediately to your local distributor together with the invoice, serial number, and a detailed report of the problem.
Please refer to section 'Return report' in the back of this manual for information regarding Interacoustics returns procedure.

Storage

If you need to store the Lyra for a period, please ensure it is stored under the appropriate conditions as described in the Technical Specifications section, see chapter 'Lyra Hardware – Technical Specifications'.

2.2 Definition of symbols

The following symbols can be found on the instrument and/or accessories.

Symbol	Explanation
	Type B applied parts This is used for parts applied to the patient that require only ordinary electrical protection, e.g. headphones.
	Follow Instructions for Use
	Caution
	Refer to Instructions for Use
 0123	The CE-mark indicates that Interacoustics A/S meets the requirements of Annex II of the Medical Device Directive 93/42/EEC. TÜV Product Service, Identification No. 0123, has approved the quality system.
	Year of manufacture
	Manufacturer
	Serial number
	Reference number
	Do not re-use Ear tips and similar are for single use only
	Keep dry
	Transport and storage temperature range
	Transport and storage humidity limitations
	Transport and storage atmospheric pressure limitations

ETL CLASSIFIED Intertek 4005727 Conforms to ANSI/AAMI ES60601-1:2005/A1:2 Certified to CAN/CSA-C22.2 No. 60601-1:2(	ETL listing mark
Interacoustics	Company logo

LED light on	On (Power: connection to the USB power)
LED light off	Off (Power: disconnection from power)

2.3 Safety precautions



WARNING

When connecting the instrument to the computer, the following warnings must be observed:

1. This equipment is intended to be connected to other equipment thus forming a Medical Electrical System. External equipment intended for connection to signal input, signal output or other connectors 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 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 transformer to reduce the leakage currents. Any person who connects external equipment to signal input, signal output or other connectors has formed a Medical Electrical System and is therefore responsible for the system to comply with the requirements. If in doubt, contact qualified medical technician or your local representative. If the instrument is connect to a PC (IT equipment forming a system) ensure not to touch the patient while operating the PC.

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

2.3.1 Cautions - general



CAUTION

If the system is not functioning properly, do not operate it until all necessary repairs are made and the unit is tested and calibrated 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 and/or calibration. 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, distorted, or contaminated should be replaced immediately with clean, genuine replacement parts manufactured by or available from Interacoustics.

Equipment is not user repairable. Repairs must be performed by an authorized service representative only. No modifications of the equipment are allowed by anyone other than a qualified Interacoustics representative. Modification of the equipment could be hazardous.

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.

Connect only accessories purchased from Interacoustics to the instrument. Only accessories which have been stated by Interacoustics to be compatible are allowed to be connected to the device.

2.3.2 Environmental factors



CAUTION



Storage outside temperature range as specified in section 5.1 may cause permanent damage to the instrument and its accessories.

Do not use the device in the presence of fluid that can come into contact with any of the electronic components or wiring. Should the user suspect fluids have contacted the system components or accessories, the unit should not be used until deemed safe by an authorized service technician.

Do not place the instrument next to a heat source of any kind, and allow sufficient space around the instrument to ensure proper ventilation.

2.3.3 Electrical safety



WARNING

Do not disassemble or modify the product as this may impact on the safety and/or performance of the device. Refer servicing to qualified personnel.

For maximum electrical safety, turn off the power from a mains powered PC when it is left unused.

Do not use the equipment if it is showing visible signs of damage.

2.3.4 Electromagnetic compatibility (EMC)



CAUTION

Although the instrument fulfills the relevant EMC requirements, precautions should be taken to avoid unnecessary exposure to electromagnetic fields, e.g., from mobile phones, etc. If the device is used adjacent to other equipment it must be observed that no mutual disturbance appears. Please also refer to the appendix regarding EMC.

2.3.5 Explosion hazards



WARNING

Do not use in the presence of flammable anesthetics or other gases.

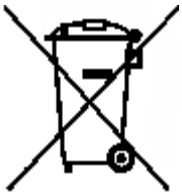
Do NOT use in the presence of flammable gaseous mixtures. Users should consider the possibility of explosions or fire when using this device in close proximity to flammable anesthetic gases.

Do NOT use the instrument in a highly oxygen-enriched environment, such as a hyperbaric chamber, oxygen tent, etc.

NOTICE

DO NOT connect the instrument to the computer before the software has been installed!

Great care should be exercised when handling OAE probe, as rough handling, for example dropping onto a hard surface may break or damage the parts.



Within the European Union it is illegal to dispose of electrical and electronic waste as unsorted municipal waste. Electrical and electronic waste may contain hazardous substances and therefore have to be disposed of separately. Such products will be marked with the crossed-out wheelie-bin image shown to the left. User cooperation is important in order to ensure a high level of reuse and recycling of electrical and electronic waste. Failure to recycle such waste products in an appropriate way may endanger the environment and consequently the health of human beings.

Outside the European Union, local regulations should be followed when disposing of the product after its useful life.

2.4 Connecting the Lyra to the PC/laptop

NOTICE

DO NOT connect the Lyra hardware to the computer before the software has been installed!

First ensure the PC/laptop has the IA OAE Suite software installed, where the driver is also located. Please refer to section 2.6 and 2.7.
Attach the USB cable to the Lyra device and to a free USB port on the PC/laptop.
The Lyra can be connected to a PC/laptop, where the software is installed.

2.4.1 Powering the Lyra

The Lyra is fully powered alone from the USB connection, no extra power or batteries are needed.
Ensure that the USB port can provide sufficient power to the Lyra, e.g. you may need to disable power save schemes.
When the Lyra is powered, the LED light on the device will turn on, and off when not powered/connected.

NOTICE

The Lyra takes approximately 2 seconds to boot up.

2.4.2 Data storage

Any recordings and patients are stored only on the PC/Laptop, the Lyra does not store any recording or patient data.

2.5 Safety precautions to take when connecting the Lyra to PC/laptop.

NOTICE

Please note that if connections are made to standard equipment like printers and networks, special precautions must be taken in order to maintain medical safety.
Please follow the instructions below.

Fig. 1. Lyra connected to the PC/Laptop running on battery.



Fig. 2. Lyra connected to the PC/Laptop connected to a medical approved transformer.



2.6 IA OAE Suite software installation

You must have administrative rights to the computer on which you are installing the IA OAE Suite software.

NOTICE

DO NOT connect the Lyra hardware to the computer before the software has been installed!

Important note on the use of Normative Data

The software have normative data available that can be displayed and compared to recordings made.
Further normative data can be created and the current ones can be edited.
Interacoustics claims no diagnostic consequence of degree of fit between the recorded results and whatever normative data examples the operator chooses to bring forward for comparison.

Further information about the normative data can be obtained from the Lyra Additional Information Manual and from Interacoustics.

PC minimum requirements

- Core i3 CPU or better (Intel recommended)
- 8GB RAM or more
- Hard drive with min 10 GB free space (Solid State Drive (SSD) recommended)
- Minimum display resolution of 1280x1024 pixels or higher recommended)
- DirectX 11.x compatible graphics (Intel/NVidia recommended)
- One USB ports, version 1.1 or higher

Supported operating systems

- Microsoft Windows® 7 32-bit and 64-bit
- Microsoft Windows® 8 64-bit
- Microsoft Windows® 10 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.

What you will need:

1. IA OAE Suite software Installation media
2. USB cable
3. Lyra hardware

To use the software in conjunction with a database (e.g. Noah 4 or OtoAccess™), make sure the database is installed prior to the IA OAE Suite software installation. Follow the manufacturer's installation instructions provided to install the relevant database.
Note that if you are using AuditBase System 5, you must ensure to launch this office system prior to this installation of the IA OAE Suite software.

Software installation on Windows® 7, Windows® 8 and Windows® 10
Insert the installation media and follow the steps below to install the IA OAE Suite software. If the installation procedure does not start automatically, click “Start”, then go to “My Computer” and double click the “setup.exe” file to initiate the installation.

1. Wait for the installation dialog to appear, agree to the license terms and conditions, then click **Install**.
2. Follow the onscreen Lyra Installer instructions until the installation has been completed. Click on “Close”. The software is now installed and ready to use.

   During installation, Windows® may:
   a) Ask if you want to allow changes to the computer. Click Yes if this happens
   b) Ask to download and install a new Windows Feature (e.g., .NET Framework 3.5). Download and install new features to ensure that the IA OAE Suite software works as intended
   c) Warn you that Windows cannot verify the publisher of this driver software. Install the driver software anyway to ensure the Lyra works as intended. If not installed, the Lyra will not be detected by the computer when connected via USB
3. Upon launching the software for the first time, you will be asked to choose your regional settings which activate a selection of factory protocols and the Instructions for Use (EN or US) of the IA OAE Suite software.



Note that all regional factory protocols will be available through the **show/hide protocols** option for each separate module. Refer to the Lyra Additional Information document for more details.

Note that the language can always be changed by selecting **Menu | Setup | Language** in the IA OAE Suite software after installation.

2.7 Installation of the driver

Now that the IA OAE Suite software is installed, you must install the driver for the Lyra.

1. Connect the Lyra via a USB connection (directly or via the cradle) to the PC.
2. The system will automatically detect the new hardware and a pop-up will appear on the task bar near the clock indicating that the driver is installed and the hardware is ready to use.

   To check that the driver has been installed properly, go to Device Manager and verify Lyra appears under Medical devices.



2.8 Standalone installation of IA OAE Suite software

If you do not want to run the IA OAE Suite software through Noah 4 or OtoAccess™ you can make a shortcut on the desktop to directly launch the IA OAE Suite software as a standalone module.

Go to Start | Programs | Interacoustics | IA OAE Suite software. Right click on IA OAE Suite software and select Send To | Desktop (create shortcut). A shortcut for the IA OAE Suite software will now appear on your desktop.

Note: Saving sessions in standalone mode will not link the measurements to a specific patient and cannot be transferred to a patient in the database later.

2.9 License

When you receive the Lyra product, it already contains the license including the software modules you have ordered. If you would like to add another module or function that is available in the IA OAE Suite software, please contact your dealer for a license.

3 Operating instructions

The instrument is switched on by a powered USB connection. When operating the instrument, please observe the following general precautions:



CAUTION

1. Use this device only as described in this manual.
2. Use only the disposable Sanibel ear tips designed for use with this instrument.
3. Always use a new ear tip for each patient to avoid cross-contamination. The ear tip is not designed for reuse.
4. Never insert the OAE probe tip into the ear canal without affixing an ear tip as omission may damage the patient's ear canal.
5. Keep the box of ear tips outside the reach of the patient.
6. Be sure to insert the OAE probe tip in a way which will assure an airtight fit without causing any harm to the patient. Use of a correct and clean ear tip is mandatory.
7. Be sure to use only stimulation intensities acceptable to the patient.
8. It is recommended to conduct an OAE probe test at the beginning of each day to ensure that the probe and/or cable is functioning correctly for DPOAE/TEOAE measurements.
9. Clean the probe tip regularly to ensure wax or other debris stuck in the probe tip does not affect the measurement.
10. The presence of tinnitus, hyperacusis or other sensitivity to loud sounds may contraindicate testing when high intensity stimuli are used.

.

NOTICE

1. Careful handling of the instrument whenever in contact with a patient should be given high priority. Calm and stable positioning while testing is preferred for optimal accuracy.

2. The Lyra should be operated in a quiet environment, so that measurements are not influenced by outside acoustic noises. This may be determined by an appropriately skilled person trained in acoustics. ISO 8253 Section 11, defines a quiet room for audiometric hearing testing in its guideline.

3. It is recommended that the instrument be operated within an ambient temperature range as specified in section 5.1.

4. Never clean the OAE probe housing with water or insert non-specified instruments into the OAE probe.

3.1 Handling and selection of ear tips

When using the Lyra probe, Sanibel™ OAE ear tips must be used.

The Sanibel™ ear tips are single use only and should not be reused. Reuse of ear tips can lead to the spread of infection from patient to patient.

The OAE probe must be fitted with an ear tip of a suitable type and size before testing. Your choice will depend on the size and shape of the ear canal and ear. Your choice may also depend on personal preference and the way you perform your test.



The umbrella shaped ear tips are **not** suitable for diagnostic OAE testings.



Use instead the mushroom shaped ear tips. Make sure that this ear tip inserts completely into the ear canal.

Refer to the “Selecting the Correct Ear Tip” Quick Guide included in the Lyra Additional Information document for an overview of ear tip sizes and selection.

3.2 Probe test for TEOAE

Probe performance is crucial to TEOAE test results. We recommend that you conduct a probe test at the beginning of each day before starting to test on patients to ensure that the probe is functioning correctly.

- Before conducting the probe test, ensure that the probe tip is clean and free of wax and/or debris
- Always conduct the probe test in a quiet test environment
- Only use the recommended cavity for testing. Using a different type of cavity may either not detect probe faults or may incorrectly indicate a faulty probe

3.2.1 Performing the Probe Test

1. Select the TEOAE 1-4kHz.protocol.
2. Insert the probe tip without an ear tip attached into the 2cc cavity provided with the Lyra.



3. Press the Start button and let the test run until it stops after 2 minutes. Do not stop the test manually.
4. If the probe is functioning correctly (no TE bands get a checkmark), it is possible to continue with daily testing.
5. If error messages appear during testing or if one or more of the TE bands has a checkmark above it at the end of the test, the probe test has failed. Check and clean the probe tip for wax or debris and redo the probe test. If the probe test fails a second time, the Lyra **must not be used to test on patients. Contact your local distributor for assistance**.

3.2.2 Functioning probe

If the probe is functioning correctly, none of the TE bands will have a checkmark above them when the test ends similar to Figure 1 below.



Figure 1 - Probe test has passed/functioning probe

3.2.3 Faulty probe

If error messages appear during testing or if one or more of the TE bands has a checkmark above it at the end of the test, the probe test has failed.

The most common cause of a probe test failure is wax or debris in the probe tip. Check and clean the probe tip for wax or debris and redo the probe test. If the probe functions correctly after removing wax or debris, continued use of the probe to test patients is ok.

If the probe status indicates “Too noisy”, this indicates that the environment is too noisy for testing or there is a probe fault. Stop the test, clean the probe and/or move to a quieter area and perform the test again.

If the probe test still indicates a faulty probe after a second test, the Lyra **must not be used to test on patients. Contact your local distributor for assistance**.

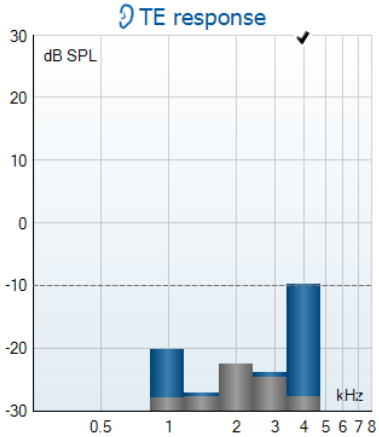


Figure 2 - Probe test has failed/faulty probe

4 The IA OAE Suite

4.1 PC power configuration

NOTICE
Allowing the PC to go into sleep mode or hibernation may cause the IA OAE Suite software to crash when the PC wakes up again. From the Start menu of your operating system, go to the **Control Panel** | **Power Options** to change these settings.

4.2 Compatible devices

The IA OAE Suite software is compatible with Interacoustics Lyra, Eclipse and Titan. This software can show recordings from all the devices, but protocol and patient upload/download to the handheld device Titan is only operated from the Titan Suite. However once saved to the database, the IA OAE Suite software can be used to open and display the recordings.

4.2.1 Starting from OtoAccess™

For instructions about working with the OtoAccess™ database, please see the instruction for use for OtoAccess™.

4.2.2 Starting from Noah 4

Ensure that the Lyra is connected before opening the software module. If the hardware is not detected, the IA OAE Suite software is opened in reader mode.

To start the IA OAE Suite software from Noah 4:

1. Open Noah 4.
2. Search for and select the patient you want to work with.
3. If the patient is not yet listed:
   - Click on the **Add a New Patient** icon
   - Fill in the required fields and click **OK**
4. Click on the **IA OAE Suite software module** icon at the top of the screen.

For further instructions about working with the database, please see the operation manual for Noah 4.

4.2.3 Simulation mode



You can enable simulation mode from Menu-Setup-Simulation mode.
In simulation mode you can simulate protocols and views before the actual testing on subject.
Print report previews can also be tested if needed.
When the software is launched, simulation mode is always disabled by default to ensure no “artificial recordings” are made by accident.
“Recordings” made in the simulation mode cannot be saved as the data are random and not patient related.

4.2.4 Crash report



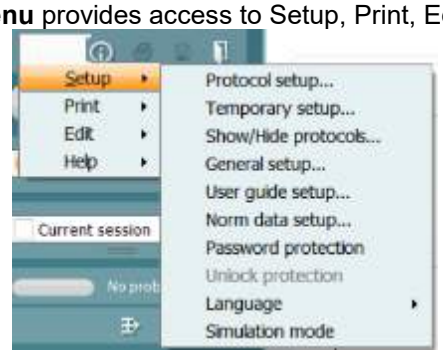
In the event that the IA OAE Suite software crashes and the details can be logged by the system, the Crash Report window will appear on the test screen (as shown below). The crash report provides information to Interacoustics about the error message and extra information can be added by the user outlining what they were doing before the crash occurred to assist in fixing the problem. A screen shot of the software can also be sent.

The “I agree to the Exclusion of Liability” check box must be checked before the crash report can be sent via the internet. For those users without an internet connection, the crash report can be saved to an external drive so it can be sent from another computer with an internet connection.

4.3 Using the menu

The following section describes the elements of the **Menu** which is accessible from both DPOAE and TEOAE module tab:

Menu provides access to Setup, Print, Edit and Help.



- **Menu | Setup | Protocol setup** create custom test protocols, or change the default protocols
- **Menu | Setup | Temporary setup** change protocols temporarily
- **Menu | Setup | Show/Hide protocols** hide or show protocols as preferred
- **Menu | Setup | General setup** Set specific OAE test parameters and automated print to pdf
- **Menu | Setup | Norm data setup** customize and import/export OAE norm data
- **Menu | Setup | Password protection** set a password for the setup
- **Menu | Setup | Language** allows selection of one of the available .languages. The language selection change will come into effect after the IA OAE Suite software is reopened
- **Menu | Setup | Simulation mode** activate the simulation mode, and trial out the protocols or see how data is visualized
- **Menu | Print** preview print, print wizard and print
- **Menu | Edit** export the data to an XML file
- **Menu | Help | About OAE software…** displays an information window showing the following:
    - IA OAE Suite software version
    - Hardware version
    - Firmware version
    - Copyright Interacoustics

  Further, you can reach the Interacoustics website from this window by clicking on the link to www.interacoustics.com
  By pressing the **License** button you are able to change the license keys of the device. The license keys for the device are specific for each serial number and define which modules, tests, protocol settings and other functionalities are available. Never change the license key without help of an authorized technician
- **Menu | Help | Documents…** launches digital version of the Instructions for Use Manual and Additional information manual (Adobe Reader required)

4.4 Using the DPOAE module

4.4.1 Preparing for the test

Patient instruction
Place the patient on a bed or comfortable chair or on an examination table if necessary. Small children may feel more comfortable sitting on a parent's or nurse's lap. Show the probe to the patient and then explain the following:

- The aim of the test is to screen the hearing organ for its functionality
- The tip of the probe will be inserted into the ear canal and has to make a good seal
- Multiple tones will be heard during the test
- No participation is expected from the patient
- Coughing, moving, talking and swallowing will disturb OAE test results

Visual inspection of the ear canal
Check the external ear canal for wax with an otoscope and remove excessive wax to prevent the probe opening from clogging which will inhibit testing. Excessive hairs may have to be cut.
If contraindications exist, the patient should be inspected by ENT or medical specialist.

Probe performance is crucial to OAE test results. We recommend that you conduct a probe test at the beginning of each day before starting to test on patients to ensure that the probe is functioning correctly.

Prepare the equipment

1. Turn on Lyra by connection the USB to the PC.
2. Open the OtoAccess™ or Noah database and enter new patient details.
3. Double click on the IA OAE Suite software. Icon to launch the software and click on the OAE module tab DP.
4. Select the desired test protocol from the dropdown list.
5. Select the ear for testing.

Before conducting the OAE test, ensure that the probe tip is clean and free of wax and/or debris.

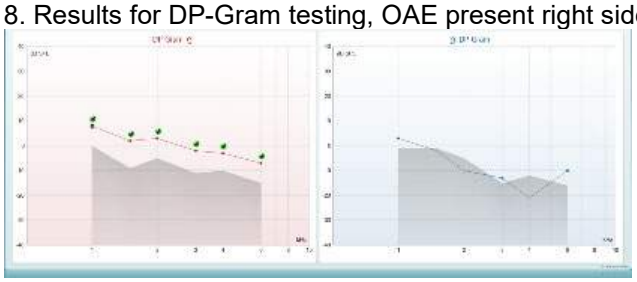
Test environment
Always conduct the OAE test in a quiet test environment, high ambient background noise will affect the OAE recording.

6. Select an ear tip size that will ensure a good seal in the ear canal.
7. Check the probe check status in the software to verify a good seal.



When the probe is detected to be **Out of ear** the color is red, **In ear** the color is green. When **Blocked** or **Too Noisy** the colored bar is amber.

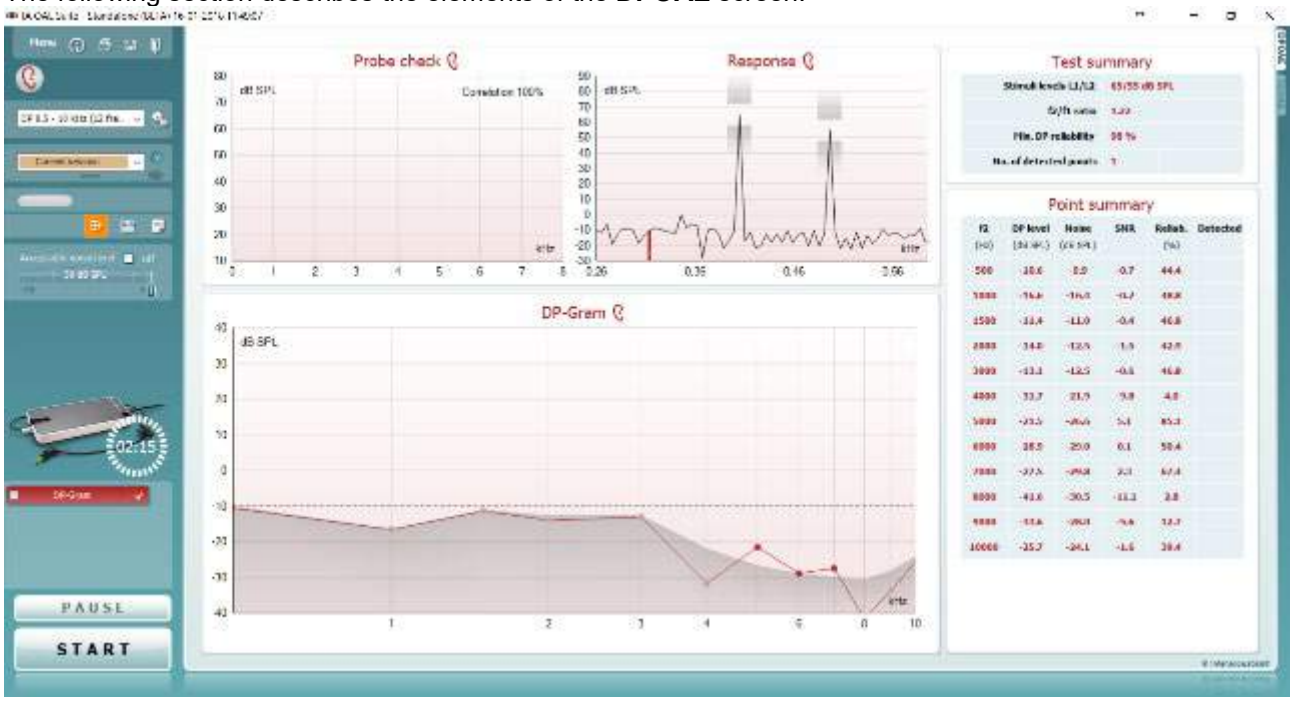
8. Results for DP-Gram testing, OAE present right side and no OAE response left side.



The type of test (DP-Gram or DP-IO) and ear side symbol and color is written on the top of the graph.
The green checkmarks indicates the DP points there have met the DP criteria as set in the protocol, as show above for the right ear.
The DP points having no checkmark did not meet the DP criterion and can be either below the noise or absent.
The DP points are line connected with the ear side color, to give an overall impression of the DPOAE levels.
The grey area is the background noise in the DP test.

4.4.2 Elements in the DPOAE module

The following section describes the elements of the **DPOAE** screen.





Menu provides access to Setup, Print, Edit or Help (refer to the Additional Information document for more details about the menu items).



Guidance button opens the user guide which shows instructions for testing within the module. The guidance can be personalized in the User guide setup window.



Print allows for printing the onscreen results directly to your default printer. You will be prompted to select a print template if the protocol does not have one linked to it (refer to the Additional Information document for more details about the print wizard).



Print to PDF icon appears when setup via the General Setup. This allows for printing directly to a PDF document that is saved to the PC. (Refer to the Additional Information document for setup information).



Save & New Session saves the current session in Noah 4 or OtoAccess™ (or to a commonly used XML file when running in standalone mode) and opens a new session.



Save & Exit saves the current session in Noah 4 or OtoAccess™ (or to a commonly used XML file when running in standalone mode) and exits the OAE software.



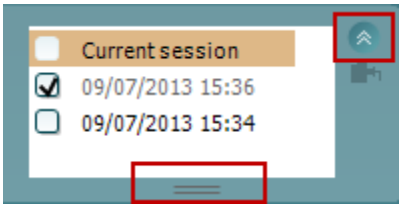
Toggle Ear changes from right to left ear and vice versa in all modules.



List of Defined Protocols allows for selecting a test protocol for the current test session (refer to the Additional Information document for more details about protocols).



Temporary setup allows for making temporary changes to the selected protocol. The changes will be valid for the current session only. After making the changes and returning to the main screen, the name of the protocol will be followed by an asterisk (*).



List of historical sessions accesses historical sessions for review or the **Current Session**.

The **historical session** box can be expanded by dragging downwards with the mouse or minimized/maximized by clicking on the arrow button.

The session highlighted in orange, is the selected session displayed on screen. Check the checkbox next to the session date to **overlay historic sessions** on the graph. **Go to current session** takes you back to the current session.





Probe status is shown by a colored bar with description next to it.

When the probe status is **Out of ear** it will show the color of the selected ear (blue for left and red for right). When the probe is detected to be **In ear** the color is green. When **Blocked**, **Leaking** or **Too Noisy** the colored bar is amber. When **No probe** is detected the status bar is grey.



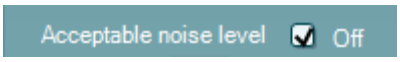
Summary view toggles between displaying result graph or result graph with test summary tables.



Monaural/Binaural view toggles between showing the results of a single ear or both ears.



Report editor button opens a separate window for adding and saving notes to the current or historic session.



Checking the **Acceptable noise level Off** box disables the rejection of any recording even when there is too much noise in the recording.



The **Acceptable noise level** slider allows setting the acceptable noise level limit between -30 and +30 dB SPL above which recordings are considered to be too noisy. The VU meter indicates the current noise level and becomes amber in color when exceeding the set level.



The hardware indication picture indicates whether the Lyra or Eclipse hardware is connected.
Simulation mode is indicated when operating the software in simulation mode (user chosen).



Before testing, the **Timer** symbol indicates after how much time the DPOAE test will automatically stop. During testing the timer counts down to zero. You can disable the countdown by clicking on the timer during testing. As a result the timer will begin counting up and indicate how much test time has passed. Then the test will continue until you manually press stop.

When the measurement is rejecting, the timer will stop counting. **Artifact rejection** is dependent upon the **Acceptable Noise Level** setting and **Level tolerance** level set in the protocol.



The **protocol listing** shows all tests that are part of the selected protocol. The test that is displayed in the test screen area is highlighted blue or red, depending on the chosen ear.



A **checkmark** in the box indicates that the test will run when **START** is pressed. During testing the tests which have been completed will automatically become unchecked. Uncheck the boxes of tests you do not wish to run under the selected protocol before pressing **START.**



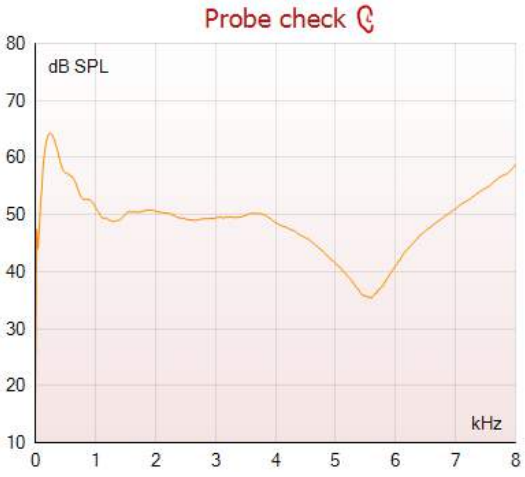
A **white checkmark** indicates that (at least some) data for this test is stored in the memory.



Pause becomes active after testing has started. It allows for pausing during a test.

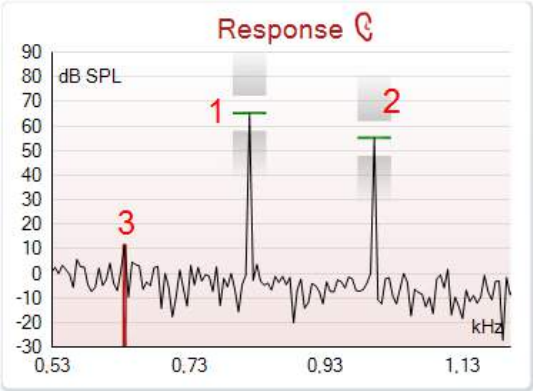


START (and **STOP**) button are used for starting and stopping the session.



The probe check graph provides a visual display of the probe fit in the patient's ear before and after testing.

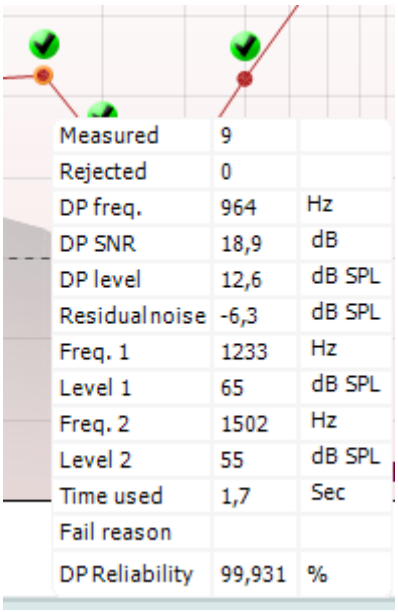
During testing, the probe check is not running and the graph will not display a curve.



The **response graph** shows the response recorded by the probe microphone (in dB SPL) as a function of the frequency (in Hz). Only the frequency range that is relevant for the currently measured or currently selected point is plotted.

1. The **two test stimuli** are easily recognized as the two peaks in the response graph.
2. The **stimulus tolerance range** is indicated by two shaded areas above and below the peak of the stimulus.
3. The red or blue line indicates the **DPOAE frequency** at which the main distortion product is expected.

See the Additional Information document for further details.



Measured	9	
Rejected	0	
DP freq.	964	Hz
DP SNR	18,9	dB
DP level	12,6	dB SPL
Residual noise	-6,3	dB SPL
Freq. 1	1233	Hz
Level 1	65	dB SPL
Freq. 2	1502	Hz
Level 2	55	dB SPL
Time used	1,7	Sec
Fail reason		
DP Reliability	99,931	%

Hovering the **mouse over** a measurement point shows details about the ongoing or finished measurement.

See the Additional Information document for more specific details of each item in the mouse over table.



The **DP found checkmark symbol**, a black checkmark in a green circle, indicates that this individual measurement met its specified criterion and no further testing at this frequency will occur.



The **DP found checkmark symbol**, a black checkmark, indicates that this individual measurement met its specified criterion, but testing will continue until the test time runs out or the test is manually stopped.



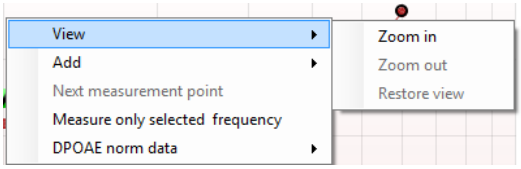
The **time out symbol**, a clock, indicates that the measurement has ended without reaching the specified criterion for the individual point within the time allowed. In the general setup it can be chosen whether or not this type of indication is shown.



The **noise floor symbol**, an arrow pointing at a line, indicates that the measurement has ended because the residual noise floor limit was reached. In the general setup it can be chosen whether or not this type of indication is shown.

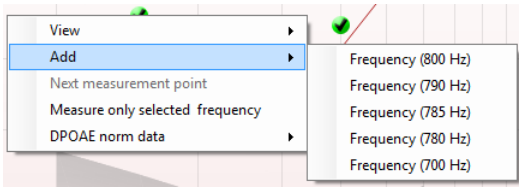


Pointing at the desired graph and then using the **scroll wheel** of your mouse allows **zooming in and out** on the Response and DP-Gram graph. Once zoomed in on, the graph then can be dragged in respect to the frequency axis.

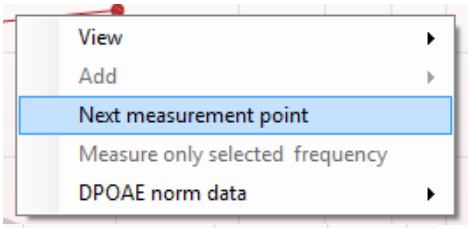


Right clicking on the DP-Gram graph provides the following options:

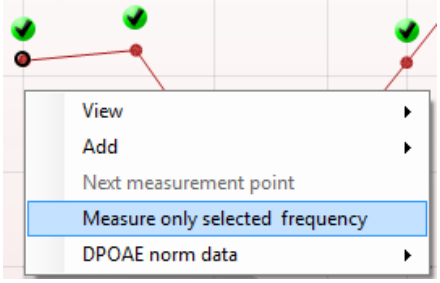
The **scroll wheel** of your mouse allows zooming in and out with respect to the frequency axis. Additionally you can **Zoom in**, **Zoom out** or **Restore view** by selecting the appropriate item from the right mouse click menu.



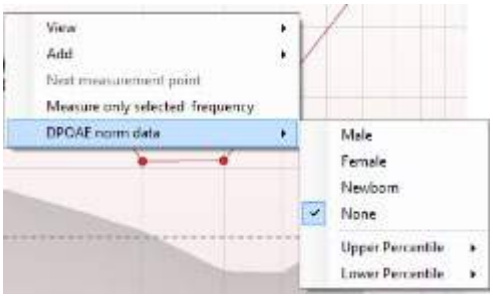
Add an additional frequency after testing of the original protocol has finished. Point and right click your mouse at the frequency that you would like to test. Click on **Add** then select an available frequency from the list to measure. After adding one or more frequencies you will notice that the **Start** button changes to say **Continue**. Clicking **Continue** will measure all inserted frequencies without a time limit. Press **Stop** when the additional points are sufficiently tested.



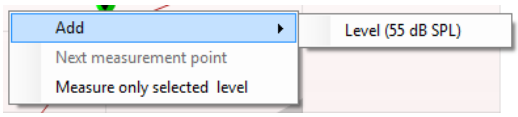
Next measurement point interrupts the automatic test procedure and forces the device to start testing the next frequency immediately. This function is available when max test point has been selected in the protocol.



Measure only selected frequency results in re-testing the currently selected measurement point only. Select a measurement point to re-test by right clicking on it. A black circle around the measurement point indicates that it is selected. After pressing **Continue** (where the **Start** button was) the selected point will be tested without a time limitation. Press **Stop** to stop testing.

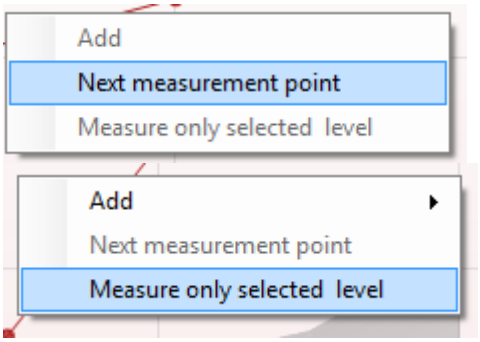


DPOAE norm data allows you to change which DP norm data is shown in the DP-Gram.



Right clicking on the DP-I/O graph provides the following options:

Add an additional level after testing of the original protocol has finished. Point and right click your mouse at the frequency that you would like to test. Click on **Add** then select an available level to additionally measure. After adding one or more levels you will notice that the **Start** button changes to say **Continue**. Clicking **Continue** will measure all inserted levels without a time limit. Press **Stop** when the additional points are sufficiently tested.



Next measurement point interrupts the automatic test procedure and forces the Lyra to start testing at the next intensity immediately. This function is available when max test point has been selected in the protocol.

Measure only selected level results in re-testing the currently selected measurement point only. Select a measurement point to re-test by right clicking on it. A black circle around the measurement point indicates that it is selected. After pressing **Continue** (where the **Start** button was) the selected point will be tested without a time limitation. Press **Stop** to stop testing.

The **minimum test requirements** as defined in the protocol are displayed beside some of the items in the **Test summary** table. These **numbers in parentheses** change to a **check mark** when the minimum requirement has been met during testing.

Point summary

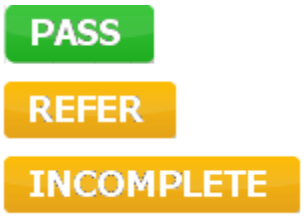
f2 (Hz)	DP level (dB SPL)	Noise (dB SPL)	SNR	Reliab.	Detected
1000	12.9	-4.4	17.3	99.5	✓
1500	8.6	-10.3	18.9	99.4	✓
2000	14.3	-15.2	29.5	100.0	✓
3000	0.6	-15.6	16.2	99.7	✓
4000	13.6	-17.0	30.6	100.0	✓
6000	22.9	-6.8	29.7	100.0	✓

The Point Summary table displays the f2 test frequencies, DP level, Noise, SNR and Reliability percentage. The **Detected** column displays a check mark when the specified frequency has met the criteria as setup in the protocol.

DP level, Noise and SNR values are rounded based on raw data. Therefore, the calculated SNR value displayed may not always equal the DP level minus the Noise.

When the stimulus level goes outside the tolerance set in the protocol setup, the **stimulus levels outside tolerance pop-up dialogue** will appear on screen.

Press **Stop** to stop testing.
Press **Skip** if you want to continue testing without the frequency for which this message appeared.



Screening protocol results can be PASS, REFER or INCOMPLETE and are indicated above the measurement.

The statistical significance of the detected result is dependent upon a combination of the following user defined settings in the protocol setup: Test time, Stimulus levels, SNR, Min DP level, DP tolerance, Reliability, Number of points required for a pass, Mandatory points required for a pass.

4.5 Using the TEOAE module

4.5.1 Preparing for the Test

Patient Instruction
Place the patient on a bed or comfortable chair or on an examination table if necessary. Small children may feel more comfortable sitting on a parent's or nurse's lap. Show the probe to the patient and then explain the following:

- The aim of the test is to screen the hearing organ for its functionality
- The tip of the probe will be inserted into the ear canal and has to make a good seal
- Multiple tones will be heard during the test
- No participation is expected from the patient
- Coughing, moving, talking and swallowing will disturb OAE test results

Visual inspection of the ear canal
Check the external ear canal for wax with an otoscope and remove excessive wax to prevent the probe opening from clogging which will inhibit testing. Excessive hairs may have to be cut.
If contraindications exist the patient should be inspected by ENT or medical specialist.

Probe performance is crucial to OAE test results. We recommend that you conduct a probe test at the beginning of each day before starting to test on patients to ensure that the probe is functioning correctly.

Prepare the equipment

1. Turn on Lyra by connection the USB to the PC.
2. Open the OtoAccess™ or Noah database and enter new patient details.
3. Double click on the IA OAE Suite software. icon to launch the software and click on the OAE module tab TE.
4. Select the desired test protocol from the dropdown list.
5. Select the ear for testing.

Before conducting the OAE test, ensure that the probe tip is clean and free of wax and/or debris.

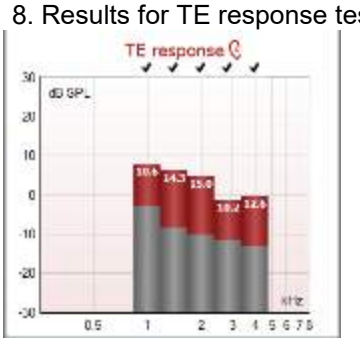
Test environment always conduct the OAE test in a quiet test environment, high ambient background noise will affect the OAE recording.

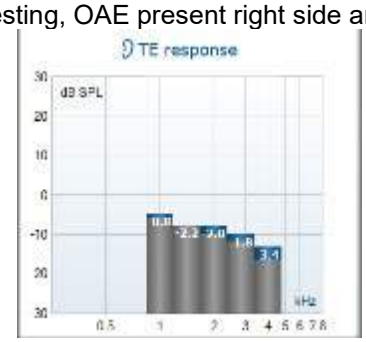
6. Select an ear tip size that will ensure a good seal in the ear canal.
7. Check the probe check status in the software to verify a good seal.



When the probe is detected to be **Out of ear** the color is red, **In ear** the color is green. When **Blocked** or **Too Noisy** the colored bar is amber.

8. Results for TE response testing, OAE present right side and no OAE response left side.

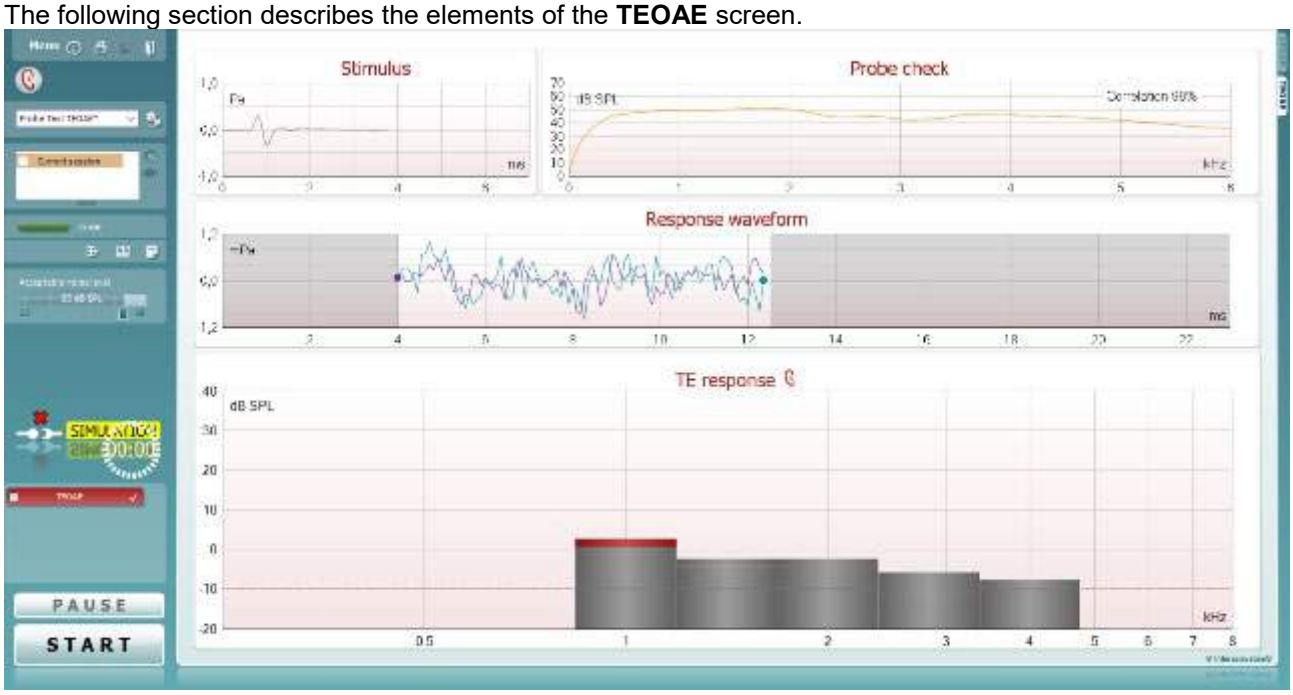




The ear side symbol and color is written on the top of the graph.
The checkmarks indicates the TE bars there have met the DP criteria as set in the protocol, as show above for the right ear.
The TE bars having no checkmark did not meet the TE criterion and can be either below the noise or absent.
The grey area is the background noise in the TE test.

4.5.2 Element in the TEOAE module

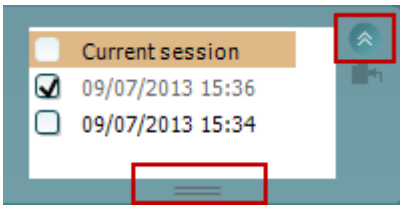
The following section describes the elements of the **TEOAE** screen.



Menu	**Menu** provides access to Setup, Print, Edit or Help (refer to the Additional Information document for more details about the menu items).
	Guidance button opens the user guide which shows instructions for testing within the module. The guidance can be personalized in the User guide setup window.
	Print allows for printing the onscreen results directly to your default printer. You will be prompted to select a print template if the protocol does not have one linked to it (refer to the Additional Information document for more details about the print wizard).
	Print to PDF icon appears when setup via the General Setup. This allows for printing directly to a PDF document that is saved to the PC. (Refer to the Additional Information document for setup information).
	Save & New Session saves the current session in Noah 4 or OtoAccess™ (or to a commonly used XML file when running in standalone mode) and opens a new session.
	Save & Exit saves the current session in Noah 4 or OtoAccess™ (or to a commonly used XML file when running in standalone mode) and exits the OAE software.
	Toggle Ear changes from right to left ear and vice versa in all modules.
TEOAE Test	**List of Defined Protocols** allows for selecting a test protocol for the current test session (refer to the Additional Information document for more details about protocols).



Temporary setup allows for making temporary changes to the selected protocol. The changes will be valid for the current session only. After making the changes and returning to the main screen, the name of the protocol will be followed by an asterisk (*).



List of historical sessions accesses historical sessions for review or the **Current Session**.

The **historical session** box can be expanded by dragging downwards with the mouse or minimized/maximized by clicking on the arrow button.

The session highlighted in orange, is the selected session displayed on screen. Check the checkbox next to the session date to **overlay historic sessions** on the graph.



Go to current session takes you back to the current session.



Probe status is shown by a colored bar with description next to it. When the probe status is **Out of ear** it will show the color of the selected ear (blue for left and red for right). When the probe is detected to be **In ear** the color is green. When **Blocked**, **Leaking** or **Too Noisy** the colored bar is amber. When **No probe** is detected the status bar is grey.



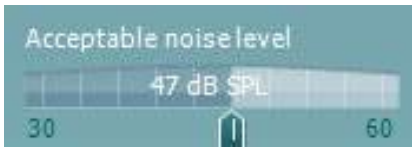
Summary view toggles between displaying result graph or result graph with test summary tables.



Monaural/Binaural view toggles between showing the results of a single ear or both ears.



Report editor button opens a separate window for adding and saving notes to the current or historic session.



The **Acceptable noise level** slider allows setting the acceptable noise level limit between +30 and +60 dB SPL. Sweeps recorded above the set acceptable noise level are considered to be too noisy and are rejected.

The VU meter indicates the current noise level and becomes amber in color when exceeding the set level.

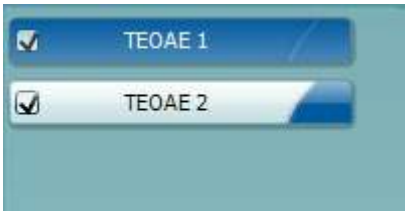


The hardware indication picture indicates whether the Lyra or Eclipse hardware is connected.
Simulation mode is indicated when operating the software in simulation mode (user chosen).



Before testing, the **Timer** symbol indicates after how much time the TEOAE test will automatically stop. During testing the timer counts down to zero. You can disable the countdown by clicking on the timer during testing. As a result the timer will begin counting up and indicate how much test time has passed. Then the test will continue until you manually press stop.

When the measurement is rejecting, the timer will stop counting. **Artifact rejection** is dependent upon the **Acceptable Noise Level** setting and **Level tolerance** level set in the protocol.



The **protocol listing** shows all tests that are part of the selected protocol. The test that is displayed in the test screen area is highlighted blue or red, depending on the chosen ear.



A **checkmark** in the box indicates that the test will run when **START** is pressed. During testing the tests which have been completed will automatically become unchecked. Uncheck the boxes of tests you do not wish to run under the selected protocol before pressing **START.**



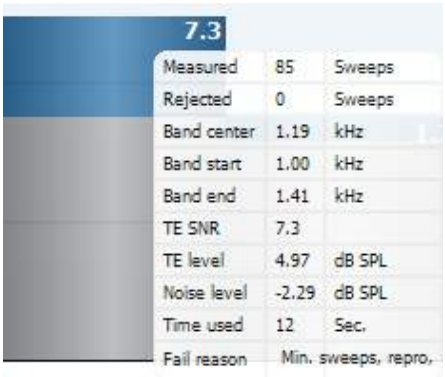
A **white checkmark** indicates that (at least some) data for this test is stored in the memory.



Pause becomes active after testing has started. It allows for pausing during a test.



START (and **STOP**) button are used for starting and stopping the session.

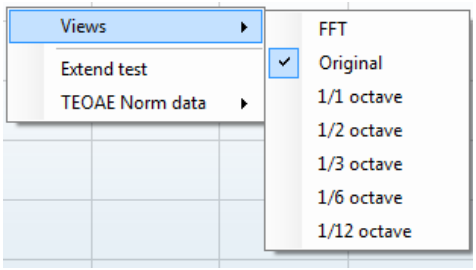


The **SNR (Signal-to-noise ratio)** is displayed within each of the frequency bands tested and is calculated in dB.

Hovering the **mouse over** a frequency band shows details about the ongoing or finished measurement.



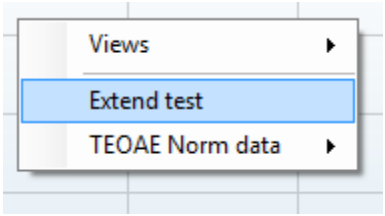
Pointing at the desired graph and then using the **scroll wheel** of your mouse allows **zooming in and out** on all graphs.



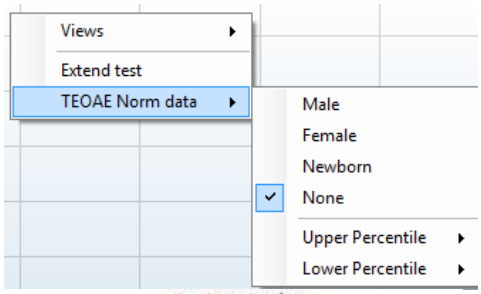
It is possible to change the view of the TE response graph by right clicking. The dropdown menu gives the following options:

View allows you to change from the **Original view to FFT view, 1/1, 1/2, 1/3, 1/6 and 1/12** octave band display.

Extend test allows continued testing after the test has ended on its own or been manually stopped. The counter will revert to 0 and start counting without a time limitation. Press **Stop** to stop testing.



Norm data allows you to change which TE norm data is displayed in the TE response graph.





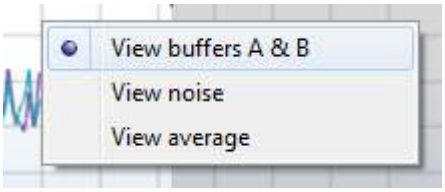
The **response waveform** along with the **recording window** and **response reproducibility** range are shown.

The arrows indicate the **recording window** start and stop time. The area outside the recording window is grayed out. The **recording window** start and stop time can be changed prior to starting a test by moving the arrows on the graph with the mouse,

The **waveform reproducibility window range** is indicated by a **black line** on the x axis. Only the waveform within this range accounts for the calculation of the **waveform reproducibility percentage**.

Clicking on the aqua or purple circles at the end of each waveform and moving the mouse, allows for separation of the curves within the graph

Right clicking on the **response waveform graph** allows for changing the display.



View buffers A & B is the default view showing the two superimposed averaged OAE waveforms.
View noise displays the noise in the waveform (Noise = A buffer – B buffer).
View average displays the mean of the A and B waveforms.

Test summary

Average stimulus level	-	
Stimulus type	-	
Stimulus stability	-	
No. of accepted sweeps	-	(240)
No. of rejected sweeps	-	
Response reproducibility	-	(80)
Total OAE	-	(0)
A & B mean	-	
A - B diff	-	
MEP	-	
No. of detected bands	-	

The **minimum test requirements** as defined in the protocol are displayed beside some of the items in the **Test summary** table. These **numbers in parentheses** change to a **check mark** when the minimum requirement has been met during testing.

Band summary

Frequency (kHz)	TE level (dB SPL)	Noise (dB SPL)	SNR	Detected
1.00	7.7	-5.3	13.0	✓
1.50	7.3	-4.3	11.6	✓
2.00	-2.8	-8.9	6.1	✓
3.00	7.0	-6.0	13.0	✓
4.00	6.2	-7.8	14.0	✓

The **Band Summary** table displays the test frequencies, TE level, Noise, SNR. The **Detected** column displays a check mark when the specified frequency has met the criteria as setup in the protocol.

TE level, Noise and SNR values are rounded based on raw data. Therefore, the calculated SNR value displayed may not always equal the TE level minus the Noise.

When the stimulus level goes outside the tolerance set in the protocol setup, the **stimulus levels outside tolerance pop-up dialogue** will appear on screen.

Press **Stop** to stop testing.
Press **Skip** if you want to continue testing without the frequency for which this message appeared.



Screening protocol results can be PASS, REFER or INCOMPLETE and are indicated above the measurement.

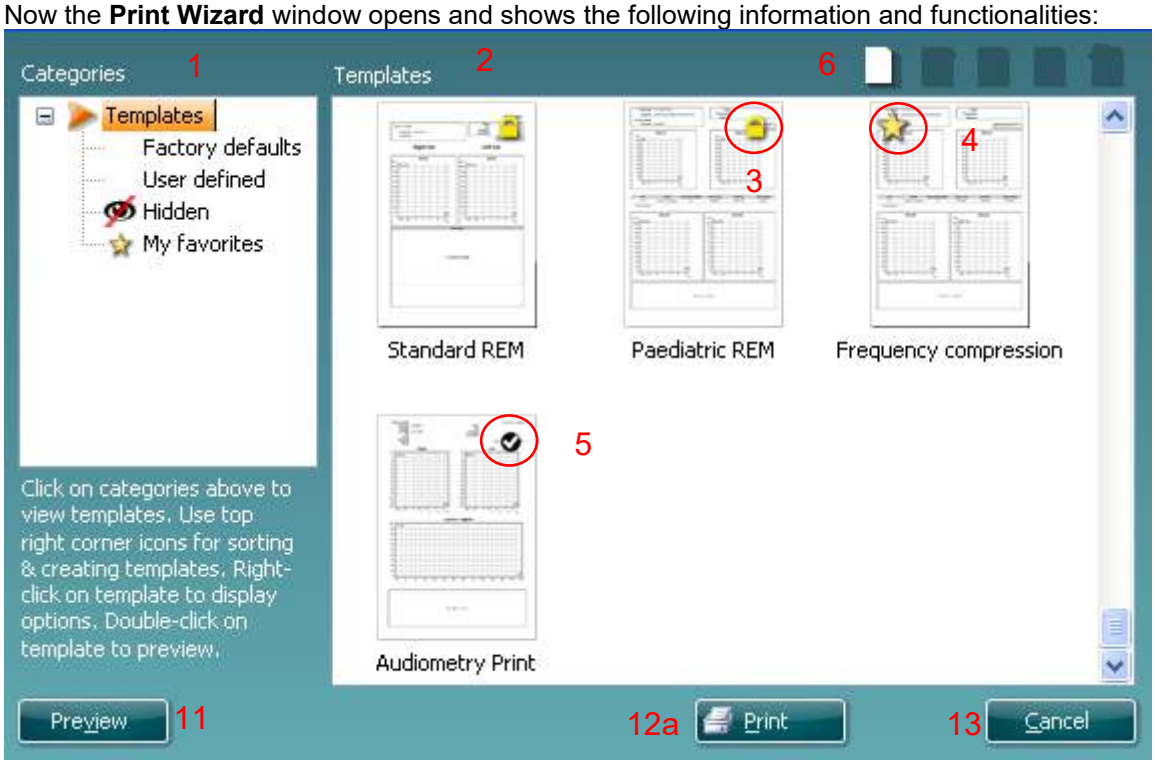
The statistical significance of the detected result is dependent upon a combination of the following user defined settings in the protocol setup: Test time, Stimulus levels, SNR, Min DP level, DP tolerance, Reliability, Number of points required for a pass, Mandatory points required for a pass.

4.6 Using the Print Wizard

In the Print Wizard you have the option to create customized print templates which can be linked to individual protocols for quick printing. The Print Wizard can be reached in two ways.

a. If you want to make a template for general use, or select an existing one for printing: Go to **Menu | Print | Print wizard…** in any of the IA OAE Suite software tabs (DPOAE, TEOAE)
b. If you want to make a template or select an existing one to link to a specific protocol: Go to Module tab (DPOAE, TEOAE) relating to the specific protocol and select **Menu | Setup | Protocol setup**. Select the specific protocol from the drop down menu and select **Print Wizard** at the bottom of the window

Now the **Print Wizard** window opens and shows the following information and functionalities:



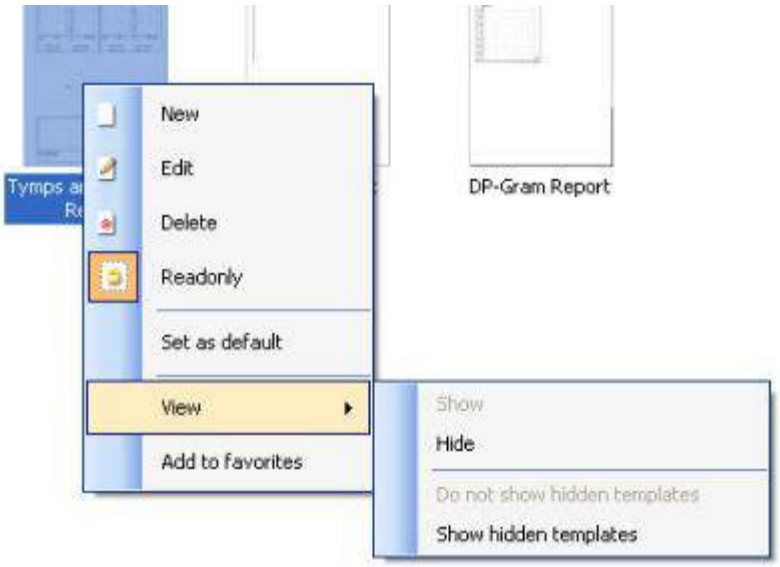
1. **Categories** you can select:



   - **Templates** to show all available templates
   - **Factory defaults** to show only standard templates
   - **User defined** to show only custom templates
   - **Hidden** to show hidden templates
   - **My favorites** to show only templates marked as a favorite
2. Available templates from the selected category are shown in the **Templates** viewing area.
3. Factory default templates are recognized by the lock icon. They ensure that you always have a standard template and do not need to create a customized one. However, they cannot be edited according to personal preferences without resaving with a new name. **User defined**/created templates can be set to **Read-only** (showing the lock icon), by right clicking on the template and selecting **Read-only** from the drop down list. **Read-only** status can also be removed from **User defined** templates by following the same steps.
4. Templates added to **My favorites** are marked with a star. Adding templates to **My favorites** allows quick viewing of your most commonly used templates.
5. The template that is attached to the selected protocol when entering the print wizard via the **DPOAE** or **TEOAE** window is recognized by a checkmark.
6. Press the **New Template** button to open a new empty template.

7. Select one of the existing templates and press the **Edit Template** button to modify the selected layout.
8. Select one of the existing templates and press the **Delete Template** button to delete the selected template. You will be prompted to confirm that you want to delete the template.
9. Select one of the existing templates and press the **Hide Template** button to hide the selected template. The template will now be visible only when **Hidden** is selected under **Categories**. To unhide the template, select **Hidden** under **Categories**, right click on the desired template and select **View**/**Show**.
10. Select one of the existing templates and press the **My Favorites** button to mark the template as a favorite. The template can now be quickly found when **My Favorites** is selected under **Categories**. To remove a template marked with a star from My Favorites, select the template and press the **My Favorites** button.
11. Select one of the templates and press the **Preview** button to print preview the template on screen.
12. Depending how you reached the Print Wizard, you will have the option to press
    a. **Print** for using the selected template for printing or press
    b. **Select** for dedicating the selected template to the protocol from which you got into the Print Wizard
13. To leave the Print Wizard without selecting or changing a template press **Cancel**.

Right clicking on a specific template provides a drop down menu offering an alternative method for performing the options as described above:



More detailed information about the Print Wizard can be found in the Lyra Additional Information document.

5 Maintenance

5.1 General maintenance procedures

The performance and safety of the instrument will be maintained if the following recommendations for care and maintenance are observed:

1. It is recommended that the instrument go through at least one annual service, to ensure that the acoustical, electrical and mechanical properties are correct. This should be carried out by an authorized technician in order to guarantee proper service and repair.
2. Observe that no damage is present to the insulation of the mains cable or the connectors and that it is not exposed to any kind of mechanical load that could involve damage.
3. To ensure that the reliability of the instrument is maintained, we recommend that the operator at short intervals, for instance once a day, performs a test on a person with known data. This person could be the operator.
4. If the surface of the instrument or parts of it is contaminated, it can be cleaned using a soft cloth moistened with a mild solution of water and detergent or similar. Always disconnect the USB connection during the cleaning process, and be careful that no fluid enters the inside of the instrument or accessories.
5. After each patient examination, ensure that there has been no contamination to the parts touching the patient. General precautions must be observed in order to avoid cross-contamination of disease from one patient to another. Water should be used for frequent cleaning, but in the case of severe contamination it may be necessary to use a disinfectant.

5.2 General maintenance procedures



- Before cleaning always switch off and disconnect from the power supply (PC)
- Use a soft cloth lightly dampened with cleaning solution to clean all exposed surfaces
- Do not allow liquid to come in contact with the inner parts inside the OAE probe
- Do not autoclave, sterilize or immerse the instrument or accessory in any fluid
- Do not use hard or pointed objects to clean any part of the instrument or accessory
- Do not let parts that have been in contact with fluids dry before cleaning
- Rubber ear-tips or foam ear-tips are single use components
- Ensure that isopropyl alcohol does not come into contact with any connection parts or rubber parts

Recommended cleaning and disinfection solutions:

- Warm water with mild, nonabrasive cleaning solution (soap)
- 70% isopropyl alcohol only on hard cover surfaces

5.3 Cleaning the probe tip

In order to secure correct measurements it is important to make sure that the probe system is kept clean at all times. Therefore please follow the below illustrated instructions on how to remove e.g. cerumen from the small acoustic and air pressure channels of probe tip.

OAE probe

1. Unscrew the probe cap.



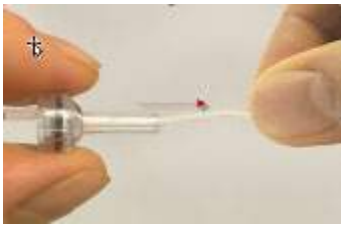
2. Remove the probe tip.



3. Thread the stiff end of the cleaning floss into one of the tubes.



4. Pull the cleaning floss completely through the probe tip tube. Clean each of the tubes as required. Discard floss after use.



5. Assemble the probe again.





Notice:

Do not use the cleaning tool to clean the probe base. This will destroy the acoustic filters.





5.4 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. a 1 year service interval is maintained
3. the electrical installation of the relevant room complies with the appropriate requirements, and
4. 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. 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).

5.5 Warranty

Interacoustics guarantees that:

- The Lyra is free from defects in material and workmanship under normal use and service for a period of 12 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 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 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

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.

INTERACOUSTICS DISCLAIMS ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FOR FUNCTION OF FITNESS FOR A PARTICULAR PURPOSE OR APPLICATION.

6 General technical specifications

6.1 Lyra Hardware – technical specifications

Medical CE-mark	The CE-mark indicates that Interacoustics A/S meets the requirements of Annex II of the Medical Device Directive 93/42/EEC. Approval of the quality system is made by TÜV – identification no0123	
Standards	**Safety:**	IEC 60601-1:2005, A1:2012 Type B applied parts
	EMC:	IEC 60601-1-2:2014
	Test signal:	IEC 60645-1:2012 /ANSI S3.6 , IEC 60645-3: 2007
	OAE:	TEOAE IEC 60645-6:2009, Type 1 & 2 Otoacoustic emissions DPOAE IEC 60645-6:2009, Type 2 Otoacoustic emissions
Operation environment	**Temperature:**	15°-35°C
	Relative humidity:	30-90%
	Ambient pressure:	98 kPa-104 kPa
	Boot time	Less than 2 seconds
	Warm-up time:	Less than 2 seconds
Transport & Storage	**Storage temperature:** **Transport temperature:** **Relative humidity:**	0°C-50°C -20°-50 °C 10-95%
Power		Powered trough USB 5V Minimum 330 mA Typical 420 mA Maximum 470 mA
PC control	**USB:**	Input/output for computer communication. Lyra is fully operated from a PC.
Dimensions		8 x 18 x 2 cm (cable length 112 cm)
Lyra weight		165 gram incl. OAE probe

DPOAE		
Stimulus	**Frequency range:**	500 to 10000 Hz
	Nominal frequency:	f2
	Frequency step:	1 Hz
	Level:	30 to 70 dB SPL (30 to 65 dB SPL for 8 kHz to 10 kHz)
	Level step:	1 dB
Recording	**Analysis time:**	1 second to unlimited time
	A/D resolution:	24 bit, 5.38 Hz resolution
	Artifact rejection system:	-30 to +30 dB SPL or off
	Stimulus tolerance:	Adjustable between 1 and 10 dB
	SNR criteria:	Adjustable between 3 and 25 dB
	DP criteria:	SNR, Min DP level, DP tolerance, Residual noise, mandatory points, DP reliability
	Probe check window:	256 points frequency response of the ear canal due to a click stimulus.
	DP-response window:	4096 points frequency response
	Residual noise:	A RMS average measurement in the DP-bin frequency area (26 bins at frequencies < 2500 Hz & 60 bins ≥ 2500 Hz).
Display	**Other information:**	In ear status (before/after test) and noise rejection level
		Basic or advanced view of the DP-Gram, test summary table, point summary table
Probe specifications	**Lyra OWA probe:**	Combined DPOAE and TEOAE OWA probe
		Replaceable probe tip

TEOAE		
Stimulus	**Frequency range:**	500 to 5500 Hz
	Frequency step:	1 Hz (Custom bands)
	Stimulus type:	Non-Linear (according to IEC 60645-3)
	Level:	30 to 90 dB peSPL, peak to peak calibrated, AGC controlled
	Level step:	1 dB
	Click rate:	43.5 or 80 Hz
	Stimulus tolerance:	Adjustable between 1 and 3 dB
Recording	**Analysis time:**	30 seconds to 30 minutes or 300 to 30000 sweeps
	A/D Resolution:	24 bit
	Artifact rejection system:	0 to +60 dB SPL
	SNR criteria:	Adjustable between 5 and 25 dB
	TE criteria:	SNR, min sweeps, min Total OAE, min TE level, mandatory bands
	Stimulus time window:	128 points instant recording of first click in sequence of clicks
	Probe check window:	256 points frequency response of the ear canal recorded click stimulus
	Time recording window:	4-23 msec (max). A and B buffer time-samples @ sampling rate 11025 Hz
	Frequency response window:	256 points frequency response, bin spacing 43 Hz
	Residual noise:	A RMS value for each octave band, based on the Bayesian weighted average for the defined OAE time window
Display	**Other information:**	In ear status (active before, during & after test) and noise rejection level
		Basic or advanced view, FFT view, test summary table, band summary table
Probe specifications	**Lyra OWA probe:**	Combined DPOAE and TEOAE OWA probe
		Replaceable probe tip

Table 1: Frequencies and intensity ranges for DPOAE

Lyra Maximums DPOAE		
	IPSI	*ch2*
	Reading	*Reading*
Center Freq. [Hz]	*Tone [dB SPL]*	*Tone [dB SPL]*
500	70	70
750	70	70
1000	70	70
1500	70	70
2000	70	70
3000	70	70
4000	70	70
6000	70	70
8000	65	65
10000	65	65

Lyra Maximum TEOAE level
Maximum TEOAE Click Intensity: 90 dB peSPL.

Specification of input/output connections

Inputs	**Connector type**	**Electrical properties**
Data I/O		
USB	USB type”B”	USB port for communication

6.2 Calibration properties

Calibrated Transducers

	Probe system:	Probe frequency transmitter and receiver are integrated in the probe system
Accuracy	General:	Generally the instrument is made and calibrated to be within and better than the tolerances required in the specified standards:
	DPOAE levels:	±1.5 dB for 1000 to 4000 Hz and ±3 dB outside range
	TEOAE levels:	±2 dB for click stimulus

Coupler types used for calibration

DPOAE:
Probe stimuli L1 and L2 are calibrated individually in SPL values using the IEC 711 ear simulator coupler made in accordance to IEC 60318-4.
TEOAE:
Probe stimuli are calibrated in peSPL values using the IEC 711 ear simulator coupler made in accordance to IEC 60318-4.

General information about specifications

Interacoustics continuously strives to improve its products and their performance. Therefore the specifications can be subject to change without notice.
The performance and specifications of the instrument can only be guaranteed if it is subject to technical maintenance at least once per year. This should be carried out by a workshop authorized by Interacoustics.

Interacoustics puts diagrams and service manuals at the disposal of authorized service companies.

Enquiries about representatives and products may be sent to:

Interacoustics A/S	Phone:	+45 63713555
Audiometer Allé 1	Fax:	+45 63713522
5500 Middelfart	E-mail:	info@interacoustics.com
Denmark	http:	www.interacoustics.com

6.3 Electromagnetic compatibility (EMC)

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

Portable and mobile RF communications equipment can affect the ***Lyra***. Install and operate the ***Lyra*** according to the EMC information presented in this chapter.
The ***Lyra*** has been tested for EMC emissions and immunity as a standalone ***Lyra***. Do not use the ***Lyra*** adjacent to or stacked with other electronic equipment. If adjacent or stacked use is necessary, the user should verify normal operation in the configuration.
The use of accessories, transducers and cables other than those specified, with the exception of servicing parts sold by Interacoustics as replacement parts for internal components, may result in increased EMISSIONS or decreased IMMUNITY of the device.
Anyone connecting additional equipment is responsible for making sure the system complies with the IEC 60601-1-2 standard.

Guidance and manufacturer's declaration - electromagnetic emissions		
The *LYRA* is intended for use in the electromagnetic environment specified below. The customer or the user of the *LYRA* should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The ***LYRA*** uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The ***Lyra*** is suitable for use in all commercial, industrial, business, and residential environments.
Harmonic emissions IEC 61000-3-2	Complies Class A Category	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

Recommended separation distances between portable and mobile RF communications equipment and the *Lyra*.			
The ***Lyra*** is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ***Lyra*** can help prevent electromagnetic interferences by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ***Lyra*** as recommended below, according to the maximum output power of the communications equipment.			
Rated Maximum output power of transmitter [W]	**Separation distance according to frequency of transmitter [m]**		
	150 kHz to 80 MHz $d = 1.17\sqrt{P}$	80 MHz to 800 MHz $d = 1.17\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.23\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.70	3.70	7.37
100	11.70	11.70	23.30
For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. **Note 1** At 80 MHz and 800 MHZ, the higher frequency range applies. **Note 2** These guidelines may not apply to all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The ***Lyra*** is intended for use in the electromagnetic environment specified below. The customer or the user of the ***Lyra*** should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test level**	**Compliance**	**Electromagnetic Environment-Guidance**
Electrostatic Discharge (ESD) IEC 61000-4-2	+6 kV contact +8 kV air	+6 kV contact +8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be greater than 30%.
Electrical fast transient/burst IEC61000-4-4	+2 kV for power supply lines +1 kV for input/output lines	+2 kV for power supply lines +1 kV for input/output lines	Mains power quality should be that of a typical commercial or residential environment.
Surge IEC 61000-4-5	+1 kV differential mode +2 kV common mode	+1 kV differential mode +2 kV common mode	Mains power quality should be that of a typical commercial or residential environment.
Voltage dips, short interruptions and voltage variations on power supply lines IEC 61000-4-11	< 5% *U*T (>95% dip in *U*T) for 0.5 cycle 40% *U*T (60% dip in *U*T) for 5 cycles 70% *U*T (30% dip in *U*T) for 25 cycles <5% *U*T (>95% dip in *U*T) for 5 sec	< 5% *U*T (>95% dip in *U*T) for 0.5 cycle 40% *U*T (60% dip in *U*T) for 5 cycles 70% *U*T (30% dip in *U*T) for 25 cycles <5% *U*T	Mains power quality should be that of a typical commercial or residential environment. If the user of the ***Lyra*** requires continued operation during power mains interruptions, it is recommended that the ***Lyra*** be powered from an uninterruptable power supply or its battery.
Power frequency (50/60 Hz) IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or residential environment.
Note: *U*T is the A.C. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration — electromagnetic immunity			
The ***Lyra*** is intended for use in the electromagnetic environment specified below. The customer or the user of the ***Lyra*** should assure that it is used in such an environment,			
Immunity test	IEC / EN 60601 test level	Compliance level	Electromagnetic environment – guidance
			Portable and mobile RF communications equipment should be used no closer to any parts of the ***Lyra***, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Conducted RF IEC / EN 61000-4-6	3 Vrms 150kHz to 80 MHz	3 Vrms	Recommended separation distance $d = 1{,}2\sqrt{P}$
Radiated RF IEC / EN 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	$d = 1{,}2\sqrt{P}$ 80 MHz to 800 MHz $d = 2{,}3\sqrt{P}$ 800 MHz to 2,5 GHz Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, (a) should be less than the compliance level in each frequency range (b) Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE1 At 80 MHz and 800 MHz, the higher frequency range applies NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the ***Lyra*** is used exceeds the applicable RF compliance level above, the ***Lyra*** should be observed to verify normal operation, If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the ***Lyra***. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Conformance to the EMC requirements as specified in IEC 60601-1-2 is ensured if the cable types and cable lengths are as specified below:

Description	Length	Screened
OAE cable	2.0 m	Screened
USB Cable	2.0 m	Screened

Return Report – Form 001

Interacoustics

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

Company: _____

Address: _____

_____

Phone: _____

Fax or e-mail: _____

Address

10393 West 70th Street
Prairie
MN 55344
USA

Phone
(+1) 800 947 6334

Fax
(+1) 952 903 4200

E-mail
rmd@interacoustics-us.com

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.