

**Additional Information** 

# Titan





## **Table of contents**

1	La	Launching software from databases1			
	1.1	Starting from OtoAccess®			
	1.2	Starting from Noah			
	1.3	Wireless PC controlled operation			
2		лР440			
_	2.1				
	2.2	Preparing for the test			
	2.2	2.2.1 Tympanometry patient instruction			
		2.2.2 Probe fit during Wideband Tympanometry and Absorbance Measurements			
		2.2.3 Visual inspection of the ear canal			
		2.2.4 Placement of the contralateral phones			
	2.3	The IMP440 menu items			
	2.4	General operation of IMP440			
	۷.٦	2.4.1 3D Tympanometry (license required)			
	Peak				
		size (minimum value of the v-shaped peak):	14		
	1 Can	2.4.2 Tympanometry			
		2.4.3 Reflex testing			
		2.4.4 Manual reflex testing			
		2.4.5 Reflex decay			
		2.4.6 Reflex latency			
		2.4.7 Eustachian tube function – non perforated eardrum			
		2.4.8 Eustachian tube function – non periorated eardrum			
		2.4.9 Eustachian tube function – periorated eardrum			
	2.5	Protocol setup & criterion			
	2.5	2.5.1 Protocol settings			
		2.5.2 3D tympanometry			
		2.5.2 SD tympanometry			
		2.5.4 Tympanometry settings			
		2.5.5 Standard reflex settings			
		2.5.6 Reflex decay			
		2.5.7 Reflex latency			
		2.5.8 Eustachian tube function – non perforated eardrum			
		2.5.9 Eustachian tube function – perforated eardrum			
		2.5.10 Eustachian tube function – patulous eustachian tube			
	2.6	2.5.11 Pause			
	2.0	The display wizard			
	0.7	2.6.1 Example of use of the display wizard			
	2.7	General setup			
	2.8	Temporary setup			
_	2.9	PC shortcuts			
3		BRIS440			
	3.1	About ABRIS440 module			
	3.2	Automated Auditory Brainstem Response (Automated ABR) testing			
		3.2.1 Automated ABR with Titan			
	0.0	3.2.2 Sensitivity and specificity			
	3.3	Preparing for the test			
		3.3.1 ABRIS patient preparation			
		3.3.2 ABRIS preparation of the skin			
		3.3.3 Electrode placement and cable connection			
	3.4	Electrode impedances			
		3.4.1 ABRIS default protocols			
	3.5	ABRIS440 menu items			
	26	Concret energtion of ARRISAAN	60		

		3.6.1	Main display structure	68		
		3.6.2	Transducer information area	69		
		3.6.3	Patient noise & EEG information area	70		
		3.6.4	Measurement information area	71		
	3.7	Protoco	ol setup and criterion			
		3.7.1	ABRIS protocol setup			
		3.7.2				
	3.8		al setup			
	3.9		uide 77			
	3.10		ortcuts	77		
4			10			
4	اط 4.1					
	4.2		ing for the test			
	4.3		POAE440 menu items			
	4.4		al operation of DPOAE440			
		4.4.1	Probe check			
		4.4.2	DP-Gram bar view			
		4.4.3	DP-Gram graph view			
		4.4.4	DP-I/O (DP-input/output)			
		4.4.5	Comparing DPOAE data (historic overlay)	86		
		4.4.6	Printing the overlaid sessions	87		
		4.4.7	Test summary table			
		4.4.8	Point summary table			
		4.4.9	Response and zoom graph			
		_	Probe status and stimuli tolerance			
			Pressurized DPOAE testing.			
	4.5		ol setup and criterion			
	4.5	4.5.1	DPOAE protocol setup			
		4.5.1	DP-Gram test settings			
		4.5.3	Common test settings for a DP-gram test			
		4.5.4	DP-I/O settings	97		
		4.5.5	Common test settings for a DP-I/O test			
	4.6		g a pass-refer DPOAE protocol			
	4.7		ıl setup	106		
	4.8		uide 108			
	4.9		rary setup			
	4.10	Norm o	lata setup	109		
	4.11	PC sho	ortcuts	110		
5	TE	EOAE44	0	111		
	5.1	About <sup>-</sup>	ГЕОАЕ440 module	111		
	5.2		ing for the test			
		5.2.1	Probe test			
		5.2.2	TEOAE patient instruction			
		5.2.3	Visual inspection of the ear canal			
	5.3		OAE440 menu items			
	5.4		al operation of TEOAE440			
	5.4					
		5.4.1	Probe check			
		5.4.2	TE response graph basic view			
		5.4.3	TE response graph advanced view			
		5.4.4	Comparing TEOAE data (historic overlay)			
		5.4.5	Printing the overlaid sessions			
		5.4.6	TE response graph FFT view			
		5.4.7	Stimulus graph			
		5.4.8	Response waveform graph	119		
		5.4.9	Test summary table			
		5.4.10	·			
		5.4.11				
		5.4.12	Pressurized TEOAE testing			
	5.5		ol setup and criterion			
			,			

		5.5.1 TEOAE protocol setup	123			
		5.5.2 TEOAE test settings	124			
		5.5.3 Common test settings for a TEOAE test	126			
	5.6	Creating a pass-refer TEOAE protocol	130			
	5.7	General setup	136			
	5.8	User guide 137				
	5.9	Temporary setup	137			
	5.10					
6	Protocol management					
	6.1	Renaming a protocol	139			
	6.2	Deleting a protocol	139			
	6.3	Exporting a protocol	139			
	6.4	Importing a protocol	139			
	6.5	Transferring protocols to Titan	140			
	6.6	Show/hide and reorder protocols in Titan Suite	142			
	6.7	Password protection				
7	Р	rinting and making reports	145			
	7.1	Using the thermal printer	145			
	7.2	The Print Wizard				
		7.2.1 Designing a customized print template	147			
	7.3	Design elements				
		7.3.1 Adding elements to the template	148			
		7.3.2 Moving and resizing elements	148			
		7.3.3 Customizing an element	148			
		7.3.4 General elements	149			
		7.3.5 IMP elements	151			
		7.3.6 DPOAE elements	153			
		7.3.7 TEOAE elements	154			
		7.3.8 ABRIS elements	156			
		7.3.9 Taskbar	157			
	7.4	Creating reports	158			
		7.4.1 Using the report editor with saved sessions				
		7.4.2 Operation of the report editor				
8	F.	AQ/troubleshooting	161			



### 1 Launching software from databases

#### 1.1 Starting from OtoAccess®

For instructions about working with the OtoAccess® database, please see the Instructions for Use for OtoAccess®.

#### 1.2 Starting from Noah

Ensure that the Titan is switched on and connected before opening the software module.

To start the Titan Suite from Noah:

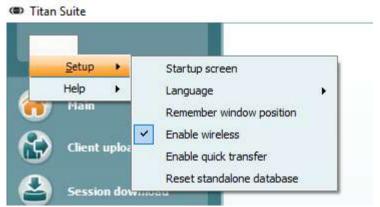
- 1. Open Noah
- 2. Search for and select the patient you want to work with.
- 3. If the patient is not yet listed:
  - Click on the Add a New Patient icon
  - Fill in the required fields and click **OK**
- 4. Click on the **Titan Suite module** icon at the top of the screen.

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

#### 1.3 Wireless PC controlled operation

PC operated measurements can be made while connecting wirelessly. Ensure that your PC allows the use of Bluetooth and that it is switched on.

- 1. Check that your Titan is set up to use its wireless function for connecting to a PC (and not to a printer). This is done by switching on the hand held unit and pressing **Protocol | My Titan | Titan...** Item **Wireless Connection** should be set to "PC".
- 2. Check that **Enable wireless** has been selected from the **Setup** menu on the **MAIN** tab.



3. When the Titan Suite is started, the dialog box below will be displayed and the software will search for Titan devices. When the Titan is found, a button will appear indicating the serial number (which can be viewed from the **My Titan | Setup | License** screen on the device. Press the button to initialize the wireless connection.







4. With a proper wireless connection, the message disappears, and the Titan will show the wireless icon next to the Titan picture in the control panel.



If the button grays out after pressing it, check the following:

- Is your Titan within a reasonable range of your PC?
- Is your Titan still switched on?
- Does your Titan match the serial number?
- Is the Titan setup to use wireless for a PC connection (instead of a printer)?

Refer to the Titan Instructions for Use for more information about wireless setup.





#### 2 IMP440

#### 2.1 About IMP440 module

The Titan with IMP440 Impedance System is an electroacoustic test instrument that produces controlled levels of test tones and signals intended for use in conduction diagnostic hearing evaluations and assisting in the diagnosis of possible otologic disorders, It features tympanometry and acoustics reflex. It also measures various acoustic properties of the ear, namely power reflectance, power absorption, transmittance, reflectance group delay, complex acoustic impedance and admittance, and equivalent ear canal volume. These measures allow the evaluation of the functional condition of the middle and outer ear. The target population for Titan with IMP440 includes all ages.

The Titan with IMP440 is designed to be used only by skilled personnel 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.

The IMP440 contains the following tests:

- > 3D tympanometry
- Wideband absorbance
- > Tympanometry 226, 678, 800 and 1000Hz
- Ipsilateral reflexes
- Contralateral reflexes
- Reflex decay
- Reflex latency
- > Eustachian Tube Function non-perforated
- Eustachian Tube Function perforated
- Eustachian Tube Function patulous
- eSRT (electrical stapedius reflex threshold)

Availability of these tests or specific settings within these tests on the hardware or in the software depend on the license purchased.

#### 2.2 Preparing for the test

#### 2.2.1 Tympanometry patient instruction

Place the patient on a 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 test the mobility of the eardrum
- The tip of the probe will be inserted into the ear canal and has to make a perfect seal
- A small amount of air will flow through the probe to move the eardrum; it produces a sensation equal to pressing a finger slightly into the ear canal
- One or more tones will be heard during the test
- No participation is expected from the patient
- Coughing, talking and swallowing will disturb test results





#### 2.2.2 Probe fit during Wideband Tympanometry and Absorbance Measurements

All Absorbance measures need to have a good probe fit to be reliable.

Evaluating Absorbance as provided by the 3D Tympanometry test ensures that a reasonably air tight probe seal was accomplished, as the air pressure sweep would not have been performed otherwise. In addition to an air tight probe seal, a deeper rather than a shallower probe insertion ensures the most accurate Absorbance measures. Shallow insertions tend to provide more elevated Absorbance readings at lower frequencies. This is somewhat similar to normal Tympanometry measures that are also influenced by probe fit and probe insertion depth.

#### 2.2.3 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.

#### 2.2.4 Placement of the contralateral phones

If the TDH39 is used, place the head band over the patient's head. The audiometric headphone is placed over the non test-ear (or contralateral reflex ear).

If the EARtone 3A insert phone is used, mount the proper foam tip on the end of the tubing before inserting in the non test-ear.





#### 2.3 The IMP440 menu items

From the main menu, the following options are available - **Setup**, **Print**, **Edit** or **Help**. The menu has the following structure:

**Menu | Setup | Protocol setup...** to enter the Titan Setup where the settings of all protocols can be viewed and changed. If data is measured before you enter the protocol setup, you are prompted to save or discard that data.

**Menu | Setup | Temporary setup...** to go into protocol settings and make changes which are only valid during the current session. If temporary changes are made to a protocol, its name appears ending with an asterisk. If data is measured before you enter temporary setup you are prompted to save or discard the data. In temporary setup the same options are available as in the normal protocol settings.

**Menu | Setup | Show/hide protocols...** to enter the setup to choose which protocols are available during the PC controlled measurements.

**Menu | Setup | General setup...** to enter the setup where PDF printing options are defined as well as which ear is selected by default when the suite starts up.

**Menu | Setup | Password protection...** to change and/or activate password protection for the complete Titan Suite. When activated users cannot enter the **Protocol setup**.

**Menu | Setup | Unlock protection...** to temporarily disable password protection.

**Menu | Setup | Language...** to change the language used in the software.

**Menu | Setup | Simulation mode...** to activate simulated testing with simulated hardware.

**Menu | Print | Print ...** to print the current protocol using the print template which is linked to the current protocol. You will enter the print window from where you can select your printer and change settings before printing. Note that you are prompted to select a template if the protocol did not include a template.

**Menu | Print | Print preview...** to see a print preview of the current measurement using the print template that is linked to the current protocol. Note that you are prompted to select a template if the protocol did not include a template.

**Menu | Print | Print wizard...** to open the print wizard window from where you can select a template to print the current measurement.

Menu | Edit | Export... to export the current measurement to an XML file.

Menu | Help | About brings you to an information window which showing the following:

- Titan Suite version
- Hardware version
- Firmware version
- Copyright Interacoustics 2009

Further, you can reach the Interacoustics website by pressing the link to <a href="www.interacoustics.com">www.interacoustics.com</a>.

By pressing the License button, you are able to change the license keys of the Titan Suite. The license keys for the Titan 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 | Instructions for use... to open the digital version of the Instructions for Use manual.

Menu | Help | Additional information... to open the digital version of the Additional Information manual.





#### 2.4 General operation of IMP440

#### 2.4.1 3D Tympanometry (license required)

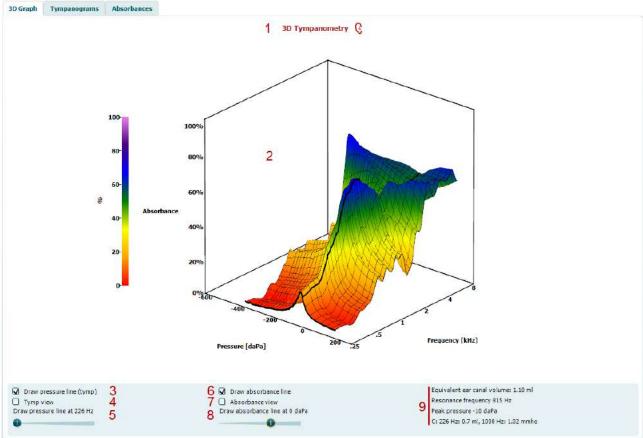
The display of 3D tympanometry test allows viewing results during or after testing in three ways by selecting the corresponding tab:

- i. A 3D graph (absorbance as function of pressure and frequency)
- ii. A set of tympanograms (compliance as function of pressure)
- iii. A set of absorbance graphs (absorbance as function of frequency)

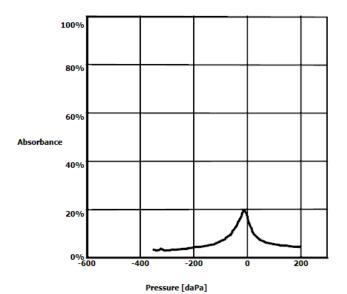


#### 3D Graph

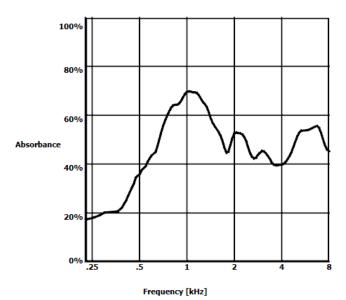
The following information and controls are found in the display of 3D graphs:



- 1. Name of test and ear which is tested.
- 2. The 3D graph contains all resulting data points of the pressure sweep. The graph can be rotated with the mouse by pressing the left mouse button and then dragging it to the direction in which it is wanted to rotate.
- 3. Activating **Draw pressure line (tymp)** highlights a tympanogram in the 3D graph at the frequency which is selected with the slider from item nr. 5. In the above example the 226 Hz tympanogram is highlighted.
- 4. Activating **Tymp view** results in the 3D graph automatically rotating to the 2 dimensional view in which absorbance is displayed as function of pressure. The surface of the 3D graph is then hidden so that only the tymp at the selected frequency is seen, like in the example below.



- 5. This slider is used to select at which frequency a tympanogram is highlighted in the 3D graph.
- 6. Activating **Draw absorbance line** highlights a absorbance slice in the 3D graph at the pressure which is selected with the slider from item nr. 8. In the above 3D example the slice at ambient pressure (0 daPa) is highlighted.
- 7. Activating **Absorbance view** results in the 3D graph automatically rotating to the 2 dimensional view in which absorbance is displayed as function of frequency. The surface of the 3D graph is then hidden so that only the absorbance measure at the selected pressure is seen, like in the example below.

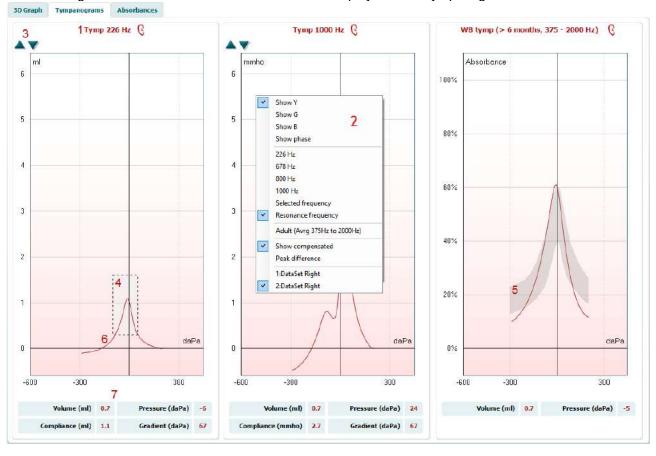


- 8. The slider is used to select at which pressure an absorbance slice is highlighted in the 3D graph.
- 9. The following numerical information is shared:
  - The equivalent ear canal volume
  - The lowest available resonance frequency at peak pressure. The tympanogram found at this resonance frequency can be interesting for differentiating between some pathologies (for example to distinguish between a flaccid eardrum and a discontinuity of the ossicular chain).
  - Peak pressure as found in the frequency averaged tympanogram (see paragraph 0)
  - The peak compliance for both tympanograms at 226 Hz (in ml) and 1000 Hz (in mmho).



#### 3D Tympanograms

The following information and controls are found in the display of these tympanograms:



- 1. The ear which is tested and for which frequency the tympanogram is displayed.
- 2. Using right mouse click in the tympanogram window gives a pop up window. This gives following options:
  - **Show Y** to show the acoustic admittance
  - **Show G** to show the acoustic conductance (the real part of the admittance vector)
  - **Show B** to show the acoustic susceptance (the imaginary part of the admittance vector)
  - **Show Phase** to show the phase (the angle of the admittance vector)
  - **226Hz** to display the 226 Hz tympanogram from the 3D Tympanometry measure
  - **678Hz** to display the 678 Hz tympanogram from the 3D Tympanometry measure
  - 800Hz to display the 800 Hz tympanogram from the 3D Tympanometry measure
  - 1000Hz to display the 1000 Hz tympanogram from the 3D Tympanometry measure
  - Selected frequency allows you to view the tympanogram of each frequency from 200-4000 Hz in a 50 Hz step resolution. The information below the tympanogram is always from the admittance curve Y
  - Resonance Frequency to display the tympanogram from the 3D Tympanometry measure that is found at the lowest resonance frequency at peak pressure
  - Adult (Avrg 375Hz to 2000Hz) to display the averaged tympanogram between 375 and 2000
    Hz which is only available when the protocol uses calibration values valid for 6 months and
    older

**Child (Avrg 800Hz to 2000Hz)** to display the averaged tympanogram between 800 and 2000 Hz which is only available when the protocol uses calibration values valid up to an age of 6 months





- Show compensated to show the tympanogram baseline compensated. When measuring tympanograms with higher probe tone frequencies, it is common to have the low pressure tail of the tympanogram much lower than the high pressure tail. To see those tympanograms completely, it is recommended to view them noncompensated
- **Peak difference** brings up two markers on the tympanogram that can be moved pulling the arrows at the x-axis. By moving the arrows you can indicate the peaks on the curve and read out the peak difference (P. diff.) and the compliance difference (C.diff.) in the table below the tympanogram. The information below the tympanogram is for the selected curve
- 1: Dataset or 2: Dataset or 3: ... etc. to show one of the available datasets. When a test is repeated, more datasets are available for reviewing. Remember that when saving a session, only the dataset displayed in the graph is saved
- 3. **Up** and **down** buttons to scale the y-axis of the tympanogram.
- 4. The normative box which shows where the peak of the tympanogram is expected in normal middle ear functioning. The size of the normative box can be customized in the protocol setup for a 226 Hz and 1000 Hz tympanogram.
- 5. The normative area of the wideband averaged tympanogram indicates what shape and highest absorbance values are expected for normal middle ear function. This normative shows to be different at different age groups.
- 6. The tympanometry curve(s). The numerical values of the curve should be read from the left Y-axis. For tympanometry performed at 226 Hz the scaling is in ml. For all other probe frequencies, the unit at the Y-axis is mmho. When plotting an averaged tymp the unit will be % of absorbance.
- 7. The table with measurement values. Here you will find
  - V or Volume, the equivalent ear canal volume
  - C or Compliance, the peak compensated static acoustic admittance, or in other words: When
    the tympanogram is shown baseline compensated, C is the compliance value at the peak. A
    peak compliance (or peak absorbance) for the averaged tymp is not calculated P or Pressure,
    the pressure at which the peak (or highest compliance) is detected
  - G or Gradient. If it is chosen to show gradient in pressure values, it gives the tympanogram width at half the height of the peak compensated static acoustic admittance. If it is chosen to show gradient as a compliance value it gives the average of the two compensated admittance values which are 50 daPa away from the peak pressure. Gradient is not calculated for averaged tymps
- Note that the table will not show all data if the test is manually stopped

#### Interpretation of 3D tympanograms

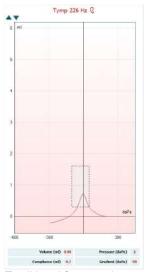
Wideband tympanometry provides information about the amount of energy being absorbed by the middle ear, and thereby gives you detailed information about the condition of the middle ear. All the information is provided is one measure.

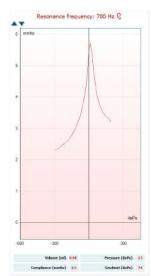
When viewing the tympanograms from the wideband tympanometry the information about the condition of the middle ear can be interpreted from the flowing tympanograms.

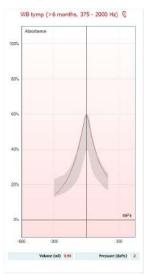
The **Tympanograms tab** displays different tympanograms retrieved from the 3D measurement. It provides a display of the tympanograms for the **Traditional frequencies** (226,678, 800 and 1000 Hz), the **Resonance frequency**, a **Wide Band Tympanogram**, or the view can be set to **Selected frequency**.

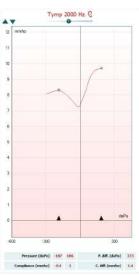












Traditional frequencies 226, 678, 800 and 1000 Hz

Resonance frequency Wie

Wide Band tympanogram

Selected frequency

#### **Traditional frequencies**

226 Hz is the traditional frequency used in tympanometry on adults, while the 1000 Hz frequency has shown useful with better sensitivity and specificity in the assessment of the middle ear on children younger than 6 months of age (Carmo, Costa, & Momensohn-Santos, 2013¹). The higher frequencies 678 and 800 Hz has historically been used in the more advanced assessment of middle ear (Janet E. Shanks, 1984²).

#### Resonance frequency

The resonance frequency is easy to obtain with wideband tympanometry. The resonance frequency is clinically relevant because the resonance frequency tympanogram should be sensitive to middle ear disorders affecting both mass and stiffness.

At resonance frequency a system oscillates with greater amplitude because the system stores vibration energy for this frequency. This happens if the presented energy is in phase with the system. Similarly the resonance frequency of the middle ear is defined as the lowest available frequency for which it is in phase with the presented stimuli. Hence, it is the lowest frequency at which the spring and mass elements of the outer and middle ear structures contribute equally to the admittance. Note that the resonance frequency of the ear is detected at middle ear pressure.

Theoretically, a probe frequency close to the resonance frequency will be sensitive to a change both in mass and stiffness, hence sensitive to all middle ear diseases. The resonance frequency will move upwards or downwards according to outer and middle ear pathologies that affects the mass and stiffness differently. An increase in the stiffness increases the resonance frequency while an increase in mass decreases the resonance frequency.

Resor	nance Frequ	inecy
Mass	Hz	Stiffness
dominated		dominated

#### Calculation of the resonance frequency

There are several ways in which the resonance frequency can be calculated in admittance terminology (Y, B or G components of the tympanogram. The method used in Titan relates to analysis of susceptance (B) at peak pressure (i.e. pressure where absorbance is highest).

The B component tympanogram should be 0 mmhos; when the stiffness elements (positive mmhos) and mass (negative mmhos) are equal. Hence the lowest frequency at which B is zero mmhos (at peak pressure) is the resonance frequency.

<sup>&</sup>lt;sup>2</sup> Janet E. Shanks. (1984). Tympanometry. Ear & Hearing, 5(5), 268–280.



<sup>&</sup>lt;sup>1</sup> Carmo, M. P., Costa, N. T. de O., & Momensohn-Santos, T. M. (2013). Tympanometry in infants: a study of the sensitivity and specificity of 226-Hz and 1,000-Hz probe tones. *International Archives of Otorhinolaryngology*, *17*(4), 395–402



#### Interpret the resonance frequency

The purpose of identifying the resonance frequency is that it can be useful in the diagnosis of ossicular chain abnormalities. For instance, the middle ear resonance frequency tends to shift to lower frequencies with mass dominating pathologies (like ossicular chain discontinuities) and shift to higher frequencies with abnormal stiffness (like with otosclerosis).

The resonance of the human middle ear system typically falls between 800-1200 Hz (adults) / 250-600 Hz (neonates).

It is reported that the resonance frequency might differ too much on individual basis for direct comparison to group normative data. However, monitoring ones resonance frequency seems promising for monitoring progression of otosclerosis (stiffness dominated).

Also, a resonance frequency tympanogram is helpful in differentiating an ossicular chain fixation (RF increase) from a flaccid eardrum (RF decrease).

#### Wide Band Tympanogram

The Wide Band Tympanogram is the average curve in a range of the measurement. For babies under the age of 6 months the curves from 800 to 2000 Hz are averaged. For older children and adults the average is taken from 375 to 2000 Hz; such frequency data are used to detect middle ear effusions. They are minimally noise-sensitive, yielding clean traces from even noisy patients such as on infants. A comparison between WBT at 1250 Hz and static admittance at 226 Hz found that WBT best distinguished between healthy ears and those with a middle ear effusion.

High-frequency tympanometry yields better results in younger infants, and low-frequency tympanometry better results in older infants. However, the optimal frequencies detecting middle ear problems in infants aged 4-8 months remain unclear. WBT yields tympanograms at both 226 and 1000 Hz, allowing clinicians to compare low- and high-frequency data.

It has been shown that WB tympanograms perform better than 1000 Hz tympanograms in explaining why an OAE screening has resulted in a refer, particularly in infants.

Sanford et al.<sup>3</sup> recommend considering the implementation of the WB tympanogram in the follow up diagnostics of neonatal screening programs.

#### **Select Frequency**

Select Frequency allows you to view the tympanogram of each frequency from 200-4000 Hz in a 50 Hz step resolution. Together with the opportunity to view the Y (admittance), B (substance), and G (conductance) curve this allows you to get out detailed information about the condition in the middle ear.

In particular the ability to view the admittance and conductance curve around 2000 Hz has proven useful in identifying ears of e.g. Meniere's (Darrouzet, Dulon, & Franco-Vidal, 2007; Franco-Vidal et al., 2005; Ishizu et al., 2018; Sugasawa et al., 2013) <sup>4</sup>. Here enabling the display of the peak difference will allow you to see the peak difference and compliance difference between two points of the tympanogram selected.

Sugasawa, K., Iwasaki, S., Fujimoto, C., Kinoshita, M., Inoue, A., Egami, N., ... Yamasoba, T. (2013). Diagnostic usefulness of multifrequency tympanometry for Ménière's disease. *Audiology & Neuro-Otology*, *18*(3), 152–160.



<sup>&</sup>lt;sup>3</sup> Sanford et al., (2009). Sound-conduction effects on distortion-product otoacoustic emission screening outcomes in newborn infants: Test performance of wideband acoustic transfer functions and 1-kHz tympanometry. *Ear & Hearing, 30*, 635-652.

<sup>&</sup>lt;sup>4</sup> Carmo, M. P., Costa, N. T. de O., & Momensohn-Santos, T. M. (2013). Tympanometry in infants: a study of the sensitivity and specificity of 226-Hz and 1,000-Hz probe tones. *International Archives of Otorhinolaryngology*, *17*(4), 395–402.

Darrouzet, V., Dulon, D., & Franco-Vidal, V. (2007). Multifrequency immittancemetry in experimentally induced stapes, round window and cochlear lesions. *Audiology and Neurotology*, *12*(2), 85–100.

Franco-Vidal, V., Legarlantezec, C., Blanchet, H., Convert, C., Torti, F., & Darrouzet, V. (2005). Multifrequency admittancemetry in Ménière's disease: A preliminary study for a new diagnostic test. *Otology and Neurotology*, *26*(4), 723–727.

Ishizu, K., Tamae, A., Kubo, K., Yoshida, T., Matsumoto, N., Yasui, T., & Nakagawa, T. (2018). Diagnosis and following up of Ménière's disease using multifrequency tympanometry—Cutoff values and temporal changes in measurements. *Auris Nasus Larynx*, *45*(1), 170–174.

Janet E. Shanks. (1984). Tympanometry. Ear & Hearing, 5(5), 268–280.

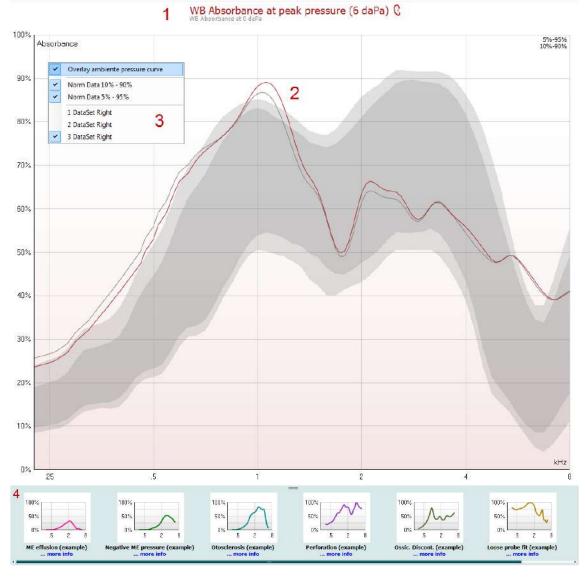
Merchant, G. R., Röösli, C., Niesten, M. E. F., Ulku, H., Rosowski, J. J., Ph, D., & Merchant, S. N. (2015). Power Reflectance as a Screening Tool for the Diagnosis of Superior Semicircular Canal Dehiscence. *Otology & Neurotology:* Official Publication of the American Otological Society, American Neurotology Society [and] European Academy of Otology and Neurotology, 36(1), 172–177.



A dedicated protocol is made to extract the essential information needed in the interpretation of the tympanograms. The protocol WBT2000 is setup, so the resonance frequency, 2000 Hz G and 2000 Hz Y is visible directly after the measure.

#### **3D Absorbances**

The tab with absorbance graphs retrieved from the 3D measurement can show the absorbance at ambient pressure and/or at peak pressure. The following information and controls are found in the display of these absorbance slices:



- 1. The ear which is tested and for which pressure the absorbance is displayed. The indication can be shown as peak pressure and ambient pressure.
- 2. The absorbance curves as function of frequency. By matching the curve to a normative data set one can obtain a quick impression of the middle ear status.
- 3. Using right mouse click in the tympanogram window gives a pop up window. This gives following options:
  - Overlay peak pressure/ambient pressure curve which overlays the absorbance curve at the peak pressure with the curve at ambient pressure
  - Norm Data 10% 90% to show the interval of the norm data that includes 10% to 90% of the normal population
  - **Norm Data 5% 95%** to show the interval of the norm data that includes 5% to 95% of the normal population





- 1: Dataset or 2: Dataset or 3: ... etc. to show one of the available datasets. When a test is repeated, more datasets are available for reviewing. Remember that when saving a session, only the dataset displayed in the graph is saved
- 4. The sketched examples show how an absorbance measurement could look like for certain

pathological cases. They are shown by pressing in the left panel. These examples can be resized by dragging the mouse up or down between the examples and the absorbance graph. When an example is selected it gets displayed with the measurement to make comparison easier. Examples are shown or hidden by pressing the following button in the left panel.

#### Absorbance difference

Calculating the absorbance difference relative to the 50% percentile can be a help in providing an accurate result in cases where an increase in absorbance relative to the norm is observed as the calculation provides a better predictor relative to eyeballing. This for instance in cases on SCD (Merchant et al., 2015).

#### Setup

In order to make use of the absorbance difference calculation from the norm you need to create a protocol including the calculation.

- 1. Enter the Menu Setup Protocol setup and create a protocol with 3D tympanometry.
- 2. Enter the settings of the protocol and go to the Absorbance tab.
- 3. Enable Absorbance difference parameters and save the protocol.

Note: the calculation is always based on the absorbance peak pressure.



#### Test screen

Enter the protocol you have created. On the screen you will see the absorbance measure and in addition the absorbance difference from the norm. The graph 'Absorbance difference from norm' provides a view of what the absorbance obtained is relative to the norm. Obtain a WBT measure using the protocol.

#### Interpretation

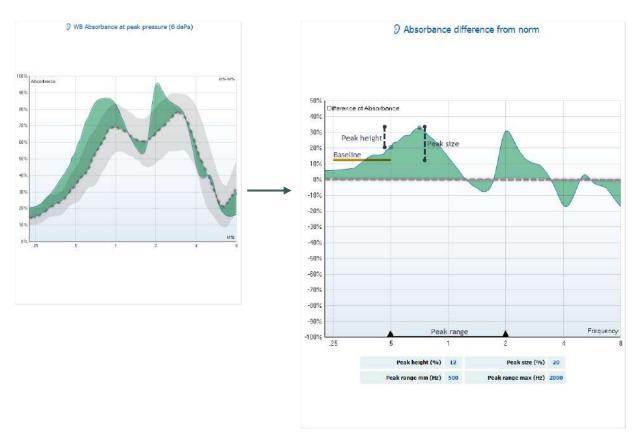
Peak: A peak is provide in the **frequency interval** indicated. If a peak is detected in the set frequency interval. The interval can be adjusted using the mouse to pull in the two arrows in the frequency-axis.

From there the minima on each side of the peak is detected within the frequency interval.

- There has to be at least 10 measure points at each side lower than the detected peak for it to be true (graph is 107 points)
- The height has to be at least 2%







Peak height: The peak height is the lower of the two surrounding minima of the peak detected.

#### Peak - highest of two surrounding minima = Peak height

- Peaks that are too wide are eliminated by comparison of the minima found within a designated peak frequency range
- Is a criteria to ensure a significant difference is present appearing as a peak. A point on each side of the peak is detected and the greatest of the two is disregarded. The lower of the two is indicated and the difference from this point to the peak is defined as the peak height

Peak size (minimum value of the v-shaped peak): Is sufficient relative to the average of the absorbance over a **baseline range** comprising frequencies from 1.5 to 0.5 octaves below the notch frequency. The baseline controls for variations of the low frequency absorbance value in different ears.

#### Peak - baseline = Peak size

#### General:

Calculated peak height and peak size has to be at least 10% for the values to appear below graph

- The display of the values thereby senses, if the peak is high and steep enough to be considered a
  peak within the indicated frequency internal
- The Peak size is meaningful in optimizing the peak detection in ears with SCD, cauterized by an increase in the absorbance of energy relative to the norm

Peak frequency range set to 585 to 1876 Hz and a peak size >9.7% and a peak height of 5% suggests indication of SCD ears from normal ears with a sensitivity of 92.5% and specificity of 69% (Merchant et. al, 2015<sup>5</sup>).

<sup>&</sup>lt;sup>5</sup> Merchant, G. R., Röösli, C., Niesten, M. E. F., Ulku, H., Rosowski, J. J., Ph, D., & Merchant, S. N. (2015). Power Reflectance as a Screening Tool for the Diagnosis of Superior Semicircular Canal Dehiscence. *Otology & Neurotology:* 



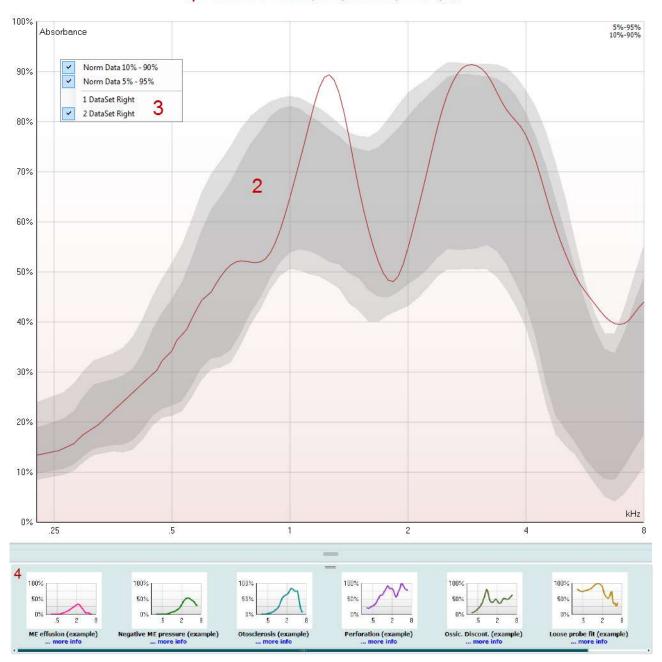




#### Absorbance

The absorbance test allows measuring the absorbance as function of frequency at ambient pressure (0 daPa) or when known at peak pressure. The following information and controls are found in the display of these absorbance slices:

#### 1 WB Absorbance at peak pressure (-4 daPa) ©



- 1. The ear which is tested and for which pressure the absorbance is displayed. The indication can be shown as peak pressure or ambient pressure.
- 2. The absorbance curves as function of frequency. By matching the curve to a normative data set one can obtain a quick impression of the middle ear status.

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- 3. Using right mouse click in the tympanogram window gives a pop up window. This gives following options:
  - **Norm Data 10% 90%** to show the interval of the norm data that includes 10% to 90% of the normal population
  - **Norm Data 5% 95%** to show the interval of the norm data that includes 5% to 95% of the normal population
  - 1: Dataset or 2: Dataset or 3: ... etc. to show one of the available datasets. When a test is repeated, more datasets are available for reviewing. Remember that when saving a session, only the dataset displayed in the graph is saved
- 4. The sketched examples show how an absorbance measurement could look like for certain

pathological cases. They are shown by pressing in the left panel.- These examples can be resized by holding the mouse button between the examples and the absorbance graph and dragging the mouse up or down.

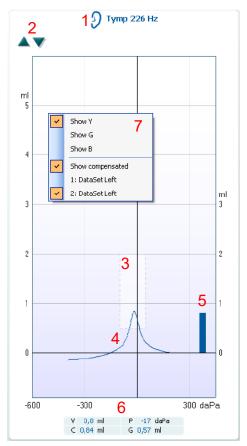




#### 2.4.2 Tympanometry

The default display of tympanometry tests shows both graphs for left and right ear. The following information and controls are found in the display:

- 1. Name of test and ear which is tested.
- 2. **Up** and **down** buttons to scale the y-axis of the tympanogram.
- 3. The normative box which shows where the peak of the audiogram is expected in normal middle ear functioning. The size of the normative box can be customized in the protocol setup. Be aware that the placement of the normative box is dependent on the ear canal volume. This means that when the



- curves are shown in non-compensated view, the box will only be placed correctly after the ear canal volume is determined.
- 4. The tympanometry curve(s). The numerical values of the curve should be read from the left Y-axis. For tympanometry performed at 226 Hz the scaling is in ml. For all other probe frequencies the unit at the Y-axis is mmho.
- 5. The equivalent ear canal volume. In automated tympanometry the acoustic admittance (Y) at the start pressure is taken as the reference value. In manually performed tympanometry it takes the acoustic admittance at the highest recorded pressure as a reference. Be aware that at other probe frequencies than 226 Hz, the equivalent ear canal volume is read from right Y-axis. It displays a measure in ml where the left Y-axis displays the curve measures in mmho.
- 6. The table with measurement values. Here you will find
  - **V**, the equivalent ear canal volume (see also item 5).
  - C, the peak compensated static acoustic admittance, or in other words: When the tympanogram is shown compensated for the ear canal volume, C is the compliance value at the peak.
  - **P**, the pressure at which the peak (or highest equivalent volume) is detected.
  - **G**, the gradient. If it is chosen to show gradient in pressure values, it gives the tympanogram width at half the height of the peak compensated static acoustic admittance. If it is chosen to show gradient as a compliance value it gives the average of the two

compensated admittance values which are 50 daPa away from the peak pressure. If the automated measurement for some reason did not reach the end pressure as set in the protocol setup, the table will only show the equivalent ear canal volume.

- 7. Using right mouse click in the tympanogram window gives a small pop up window. This gives following options:
  - **Show Y** to show the acoustic admittance.
  - **Show G** to show the acoustic conductance (the real part of the admittance).
  - **Show B** to show the acoustic susceptance (the imaginary part of the admittance).
  - **Show compensated** to show the tympanogram compensated for the equivalent ear canal value. When measuring tympanograms with higher probe tone frequencies, it is quite common to have the low pressure tail of the tympanogram much lower than the high pressure tail. To see those tympanograms completely, it is recommended to view them non-compensated. Manual tympanometry will always show non-compensated during the test because the compensation value (ear canal volume) is not yet known.
  - 1: Dataset or 2: Dataset or 3: ... etc. to show one of the available datasets. When a test is repeated, more datasets are available for reviewing. Remember that when saving a session, only the dataset displayed in the graph is saved.





#### Label of gradient



When measurering the tympanomgram it is possible to choose how the gradient should be presented. The three options are Compliance (mmhm)
Pressure (daPa)

Ratio (No unit)

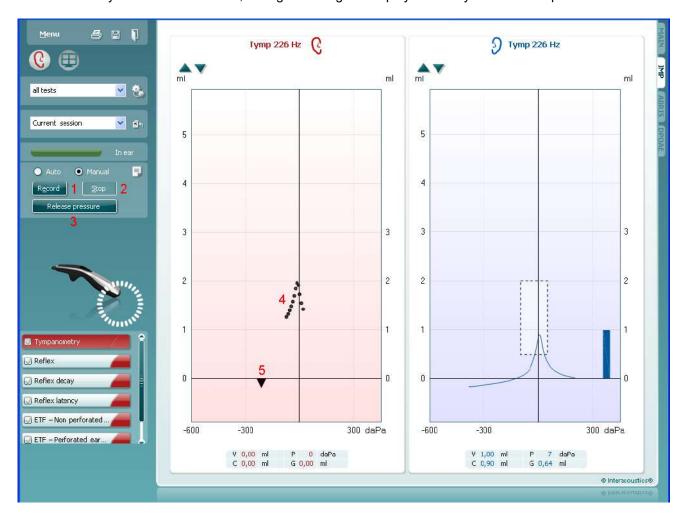
The option to change the gradient gives the user a larger freedom to choose which measuring type is relevant for the individual clinic.

When the ratio presents itself with no unit it is because it is a ratio between the gradient and tympanometric width and the unit is therefore non existing and the value will be between 0 and 1 as it is fractions.

#### Manual tympanometry testing

When choosing to test tympanometry manually the following additional information and controls become available:

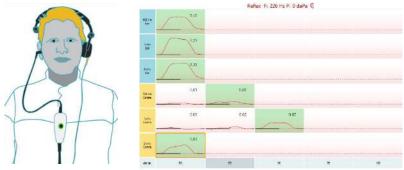
- 1. The **Record** button to start recording the tympanogram.
- 2. The **Stop** button to stop the recording of the tympanogram.
- 3. The Release Pressure button to have the pressure released and brought back to 0 daPa.
- 4. The pressure cursor which is dragged by the mouse and changes the desired pressure.
- 5. The measurement trail showing what the (non-compensated) acoustic admittance is. It is only shown when not recording. If you choose to view the compliance compensated for the equivalent ear canal volume, it is only shown after the recording is finished because only the compensation value can be correctly used. In other words, during recording the display will always be non-compensated.





#### 2.4.3 Reflex testing

The default displays of reflex tests show a matrix of reflexes, which will be measured in the order of appearance on the screen. The reflexes are indicated by the probe ear. Meaning that when the probe is placed on the right ear and the contra headphone is placed on the left ear, the reflexes for the right ear is obtained.



When the probe is placed in the left ear with the contra headphone placed on the right ear, the reflexes for the left ear is optianed.



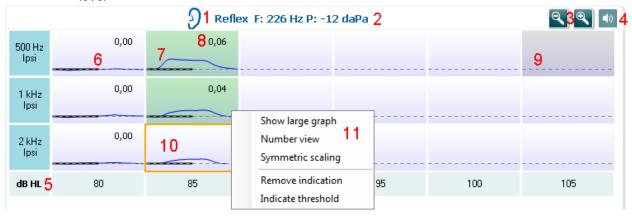
The following information and controls are found in the display:

- 1. Name of test and ear which is tested.
- The used probe tone frequency and pressure at which the selected reflex (see number 9) is measured.
- 3. The **Zoom in** and **Zoom out** button to change the size of the reflex matrix. By default the display shows the complete matrix.
- 4. The **Manual stimulus** button which is only available when testing manually (see next paragraph).
- 5. The reflex matrix shows graphs of equal stimulus types in the rows and equal stimulus levels in the columns.
- 6. Within the graph, the x-axis is the time scale on which the black bar indicates when the stimulus was given
- 7. A green graph indicates that (automatically or manually) the reflex threshold is set at the chosen stimulus level. The indication is a guideline to the user of when a reflex is detected based on the reflex parameters in the settings. With a change in threshold criteria, the reflex can be detected as more or less robust. A professional judgement of the results is mandatory regardless of the indication.
- 8. The **Deflection value** is shown when this option is activated through the protocol settings.
- 9. A grayed graph belongs to a stimulus level that is not available for that stimulus type.
- 10. The orange square shows which graph of the matrix is selected or is currently being measured.
- 11. A right mouse click on the reflex graph allows a small pop up window. This gives following options:
  - **Show large graph** gives a window (always in front) showing the selected graph and allows you to see more details and numerical information at the axes
  - Number view (or graphical view) toggles the matrix between showing graphs like above and only numbers indicating the stimulus levels
  - Symmetric scaling which changes the Y-axis to show a symmetric range around zero for those
    instances that the reflex curves are measured on both sides of the Y-axis (which is not
    uncommon when measuring with another probe tone than 226 Hz)





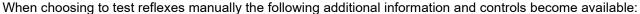
- Remove Indication takes out the indication that the reflex threshold was measured.
- **Indicate Threshold** puts the reflex threshold level for that stimulus type at the chosen stimulus level

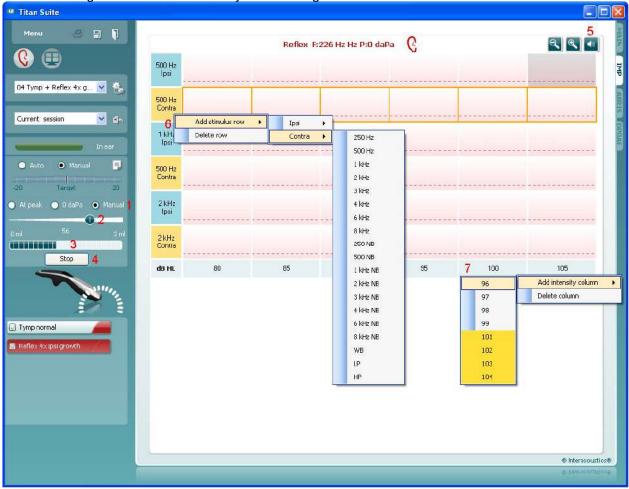






#### 2.4.4 Manual reflex testing





- 1. Here you select at which pressure the reflex is measured at. Choosing **At peak** results in using the peak pressure of the last available tympanogram with the same probe tone frequency. Choosing **0 daPa** of course results in a measurement at zero pressure. Choosing **Manual** results in having items 3 to 5 available for setting the pressure manually.
- 2. This pressure handle can be dragged by clicking it with the left mouse button. When selected you can also use the left and right arrows to adjust pressure more precisely.
- 3. While changing the pressure here the non-compensated admittance is indicated as an equivalent ear volume.
- 4. This **Start** (and **Stop**) button is used to start and stop the manual pressure changing. When stopped, Titan will try to keep the pressure constant.
- 5. After the **Manual stimulus** button is pressed, press the loudspeaker icon on the top right corner and turn the curser in to a loudspeaker. When clicking on one of the graphs that reflex measurement is started. When clicking again it will stop the measurement (Which is, e.g., used if the measurement does not start correctly due to a bad probe fit). Press the loudspeaker in the upper right corner to turn the curser back to normal.
- 6. Using the right mouse button on one of the stimulus labels gives the opportunity to
  - a. Add Stimulus Row.
  - b. Delete Row.
- 7. Using the right mouse button on one of the stimulus levels gives the opportunity to
  - a. Add Intensity Column.
  - b. Delete Column



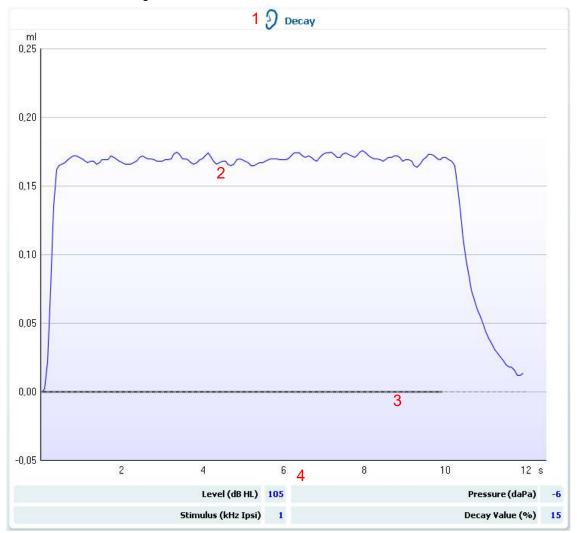


#### 2.4.5 Reflex decay

After pressing the **Start** button, the decay test will be automatically performed. A reflex threshold is determined automatically, using default reflex growth settings which are described in protocol setup of reflexes and decay reflexes. If within the protocol a decay test is preceded by a reflex test, the thresholds found during the reflex test will be used for the decay test, but only if they were measured using specific conditions.

The default display of the reflex decay tests shows the graphs of the decay measurements which are measured on the selected ear. The following information is found in the display:

- 1. Name of test and ear which is tested.
- 2. The tympanometry curve.
- 3. Within the graph, the x-axis is the time scale on which the black bar indicates when the stimulus was given.
- 4. The table with measurement values which are only calculated if the measurement could be completed.
  - Level, stimulus level
  - **Pressure**, the pressure at which the decay reflex is measured. Usually the Decay test will be set up to use the peak pressure of a preceding tympanogram
  - Stimulus, stimulus frequency
  - Decay Value, the decay value is the percentage difference of the two reflex deflection values taken half a second after the stimulus started and half a second before the stimulus stopped. If decay is present, the percentage shows as a negative number. When the calculation results in numbers larger than 125% or smaller than -115% the outcome is invalid and will not be shown







When choosing to test decay reflexes manually you have the possibility to change the ear canal pressure before starting a measurement. The following additional information and controls become available:

- 1. Here you select at which pressure the reflex is measured. Choosing **At peak** results in using the peak pressure of the last available tympanogram with the same probe tone frequency. Choosing **0 daPa** results in a measurement at zero pressure. Choosing **Manual** results in having items 3 to 5 available for setting the pressure manually.
- 2. This pressure handle can be dragged by clicking it with the left mouse button. When selected, you can also use left and right arrow to adjust pressure more precise.
- 3. While changing the pressure the non-compensated admittance is indicated as an equivalent ear volume.



- 4. This **Start** (and **Stop**) button is used to start and stop the manual pressure changing. When stopped, Titan will try to keep the pressure constant.
- 5. With the slider you can set the stimulus length to 10, 15, 20, 25 or 30 seconds.

#### 2.4.6 Reflex latency

After pressing the **Start** button, the reflex latency test will be automatically performed. Automatically a reflex threshold is determined using default reflex growth settings which are described in protocol setup of reflexes and reflex latency. If within the protocol a reflex latency test is preceded by a reflex test, the thresholds found during the reflex test will be used for the decay test, but only if they were measured using specific conditions.

The default display of the reflex latency test, shows the graphs of the latency measurements which are measured on the selected ear. The following information is found in the display:

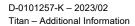
- 1. Name of test and ear which is tested.
- 2. The first 300 ms of the tympanometry curve.
- 3. The table with measurement values which are only calculated if the measurement could be completed.
  - Level, stimulus level
  - Pressure, the pressure at which the decay reflex is measured.
     Usually the Decay test will be set up to use the peak pressure of a preceding tympanogram
  - **Stimulus**, stimulus frequency
  - Latency Value, the latency value is the time interval between onset of the stimulus and the point where 10% of the reflex deflection value is reached. The reflex deflection value is measured as the average of the deflection between 250 and 300 ms after stimulus onset

#### Manual reflex latency testing

When choosing to test reflex latencies manually you are given the option to change the ear canal pressure before starting a measurement. The following additional information and controls become available:

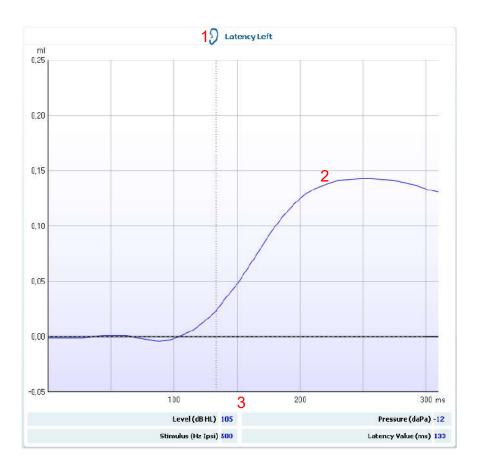
- Here you select at which pressure the reflex is measured. Choosing At peak results in using the
  peak pressure of the last available tympanogram with the same probe tone frequency. Choosing 0
  daPa results in a measurement at zero pressure. Choosing Manual results in having items 3 to 5
  available for setting the pressure manually.
- 2. This pressure handle can be dragged by clicking it with the left mouse button. When selected you can also use left and right arrow to adjust pressure more precisely.
- 3. While changing the pressure, the non-compensated admittance is indicated as an equivalent ear volume.
- 4. This **Start** (and **Stop**) button is used to start and stop the manual pressure changing. When stopped, Titan will attempt to keep the pressure constant.







## MMMM

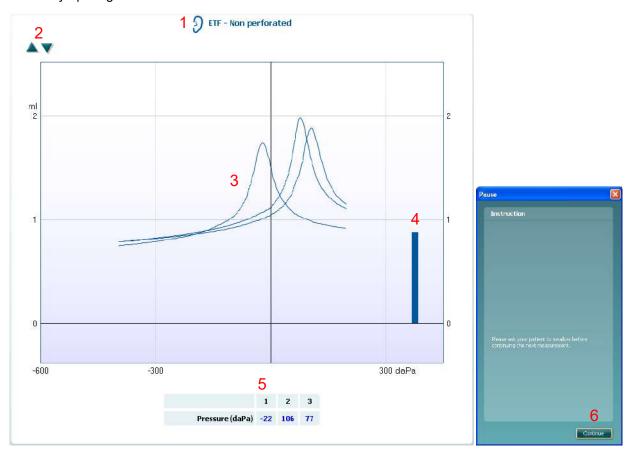






#### 2.4.7 Eustachian tube function – non perforated eardrum

The display of the Eustachian tube function test for the non perforated eardrum shows graphs for the selected ear in which the three tympanograms of the adapted Williams procedure are plotted. The Williams procedure keeps the pressure in between the first and second tympanogram at stop pressure and between the second and third tympanogram at the start pressure. In between all tympanograms the original Willams procedure is to ask the patient to swallow. In order to get a bigger displacement of tympanograms we advise to ask the patient to perform a Valsalva's maneuver after the first tympanogram and to swallow after the second tympanogram.



The following information is available during testing:

- 1. Name of test and ear which is tested.
- 2. **Up** and **down** buttons to scale the y-axis of the tympanogram.
- 3. The non-compensated tympanometry curves.
- 4. The equivalent ear canal volume where the acoustic admittance (Y) at the starting pressure of the first tympanogram is taken as the reference value.
- 5. The table shows the pressure values at which the three peaks are detected (or the highest equivalent volume if there is no peak).
- 6. In between the three tympanograms an instruction pops up to tell you how to instruct the patient. Press **Continue** to continue.

#### Manual ETF Testing - Non Perforated Eardrum

Choosing to test manually does not change any handling in the ETF – Non Perforated test.





#### 2.4.8 Eustachian tube function – perforated eardrum

The default display of Eustachian tube function test for the perforated eardrum shows a graph for the selected ear. The following information and handles are available during testing:

- 1. Name of test and ear which is tested.
- 2. The pressure curve showing that the pressure drops each time the patient swallows. Automatically these pressure drops are numbered. Notice that an exponential release of pressure means that the probe sealing might not be sufficient. If you measure an exponential pressure release while the probe tip is correctly placed inside a test cavity, it means that the tubing of Titan shows a leakage. Consult the technical manual for further explanation of this matter.
- 3. The table refers to the numbered pressure drops and gives the values at which the pressure started and stopped dropping.
- 4. Before the measurement starts an instruction pops up to tell you how to instruct the patient. Press **Continue** to start the measurement.



#### Manual ETF Testing - Perforated Eardrum

Choosing to test manually gives you the option to change the starting pressure on screen. Further handling of the test is the same as in automated testing.



#### 2.4.9 Eustachian tube function – patulous eustachian tube

Basically, the Patulous Eustachian Tube test is an impedance baseline test. It monitors changes in impedance over time without applying pressure changes or acoustic stimuli. When a patulous Eustachian tube is present you would typically expect to recognize the breathing of the patient in the tympanometry curve. If the Eustachian tube is closed and the tympanic membrane is intact you expect to measure small tympanometry changes which can be caused by acoustical disturbances from around the patient, accidental displacements of the probe, or by spontaneous movements of the eardrum. Further it allows measuring movements due to the heart beat in for example a glomus tumor. Or the test can be used to measure reflexes where the stimulus is presented through an external device like a cochlear implant.

The default display of the Eustachian tube function test for the patulous Eustachian tube shows the graph for the selected ear.

The following information is available during testing:

- 1. Name of test and ear which is tested.
- 2. The tympanometry curve.
- 3. Before the measurement starts an instruction pops up to tell you how to instruct the patient. Press **Continue** to start the measurement.



Manual ETF Testing – Patulous Eustachian Tube

Choosing to test manually does not change any handling in the ETF - Patulous Eustachian Tube test.



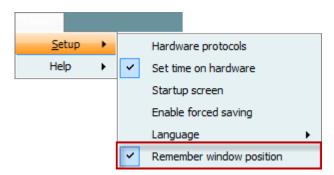


#### eSRT - electrically evoked stapedius reflex threshold

Electrical Evoked Stapedial Reflex Thresholds (eSRT) can be a very useful objective measure for the upper stimulus levels during the programming of a cochlear implant. The measure is particular useful during the fitting of cochlear implants in pediatrics, but also during the fitting on adults in particular adults unable to provide reliable behavioral measures.

When using the Titan to obtain the eSRT levels, the cochlear implant is used as the stimulus source, while the Titan is used for monitoring, if there is any change as a function of time when a stimulus is presented through the cochlear implant.

Therefore, it is useful to set the Titan suite and cochlear implant suite up side by side or in top of each other. The Titan suite can be locked in a position, so it opens in that format all the time. This is done from the main tab – Menu – Setup – Remember window position.



The following functions are available during the measurement:





1	Protocol	Select an eSRT protocol
2	Probe tone	226Hz
3	Probe status	Indicates probe status (in ear, out of ear, leaking, blocked)
4	Target pressure	Indicates how far the pressure is from target pressure
5	Tests in protocol	Lists the tests that is part of the protocol, a checkmark at the right indicates the test is included, a checkmark at the left indicates data is obtained for the test.
6	Start/Stop	Start and stop the measurement. In case of drifting, Stop and Start the measure to reset the baseline.
7	Time scale	The time scale is continuous. Use the slider to move back and forth on the time scale.
8	Time scale	Press the end of the time scale to go back to the point in time of the running measurement.
9	Threshold indication	The dashed line indicates the setting of the reflex threshold level, which is used to see when a reflex is present.
10	Marker	Use the marker (M) to indicate when a reflex is present. This is done by clicking with the mouse in top of the reflex. As default the marker will indicate Mnumber (time).
11	Marker	Edit the name of the marker to help you identify which electrode it is from.  Press the trash bin to delete a marker.  By pressing the marker in the table, the view of the graph with go to the point
		in time of the marker to see the reflex.
12	Save and review session	Press Save or Save & Exit to save the session. Review a saved session from the session list.





#### 2.5 Protocol setup & criterion

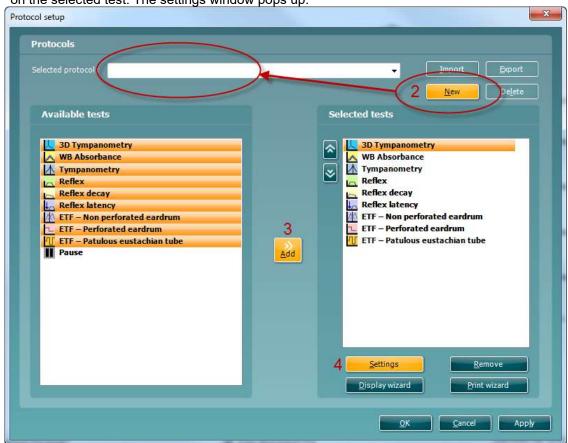
To create your own personalized protocol, I you need to enter the Titan Protocol Setup menu.

1. From the Imp tab, Select Menu | Setup | Protocol Setup.



- 2. Click on the **New** button and name your protocol.
  - a. You will be asked if you want to create a copy of the selected protocol. Select Yes, to copy the protocol settings of the selected protocol. Select No, to create the new protocol from default settings.
- 3. Select the tests you want to include in your protocol from the list on the left (using ctrl or shift key for multiple tests). And press **Add**. Or double click on the test you want to include.

Select the test on the right that you want to modify the settings for Press Settings. Or double click
on the selected test. The settings window pops up.

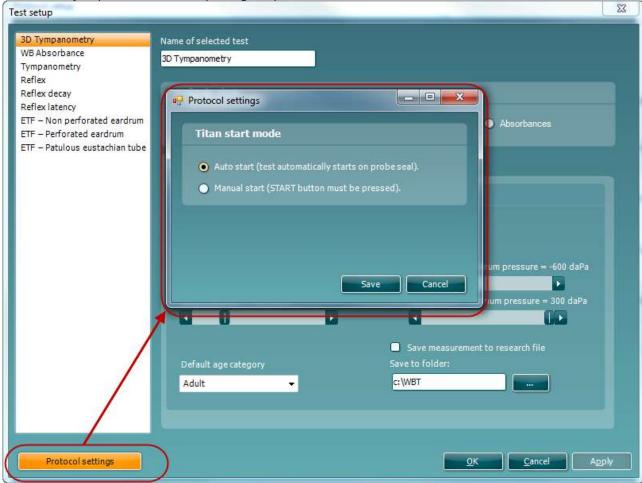




#### 2.5.1 Protocol settings

At the bottom left corner of the test setup window, you will find the **Protocol settings** button. Pressing it will pop up a window in which you can set your preferred starting mode. **Auto start** means that the test automatically runs when the probe is detected to be in the ear. **Manual start** means that you have to give the start command to run the test.

Note that this setting only affects Titan in handheld use. PC controlled mode always needs a start command. However, if you press start before placing the probe in the ear, it will act the same as with auto start mode.







#### 2.5.2 3D tympanometry

Make sure that **3D Tympanometry** is selected from the list of tests on the left of the screen.

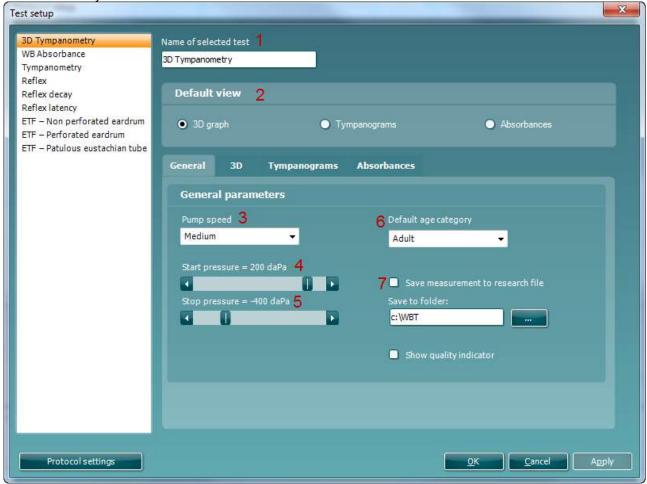
The following items can be changed in the 3D Tympanometry settings.

- Name of selected test. You can choose to have more than one of the same tests in your protocol. It
  might therefore be wise to change the name of the test, so it will be easier to recognize when
  running the complete test protocol.
- 2. **Default view** defines which tab is opened by default and thus which is default for viewing while the measurement takes place.

#### General tab

- 3. **Pump speed**. Here the pump speed for automated tympanometry is selected. The mentioned pump speeds are valid for the clinical setting which is using the shoulder box. When measuring without the shoulder box the pump speeds are about 60% faster due to the smaller volumes in the tubing of Titan. Available options are.
  - Medium, which results in a constant speed of about 200 daPa/s
  - Slow, which results in a constant speed of about 100 daPa/s
  - Very slow, which results in a constant speed of about 50 daPa/s
- 4. **Start pressure**. Here the start pressure for automated tympanometry is selected. The start pressure can vary between +300 and -600 daPa. For calculating the equivalent ear canal volume the measurement points at starting value are taken.

5. **Stop pressure**. Here the stop pressure for automated tympanometry is selected. The stop pressure can vary between +300 and -600 daPa.





- 6. Default age category sets the age group for the patient in case the birth date is unknown. Typically, the birth date will be recognized automatically in which case this setting chooses the appropriate age group. Notice that the system applies two calibration sets, one for babies up to six months of age and one for the remaining children and adults. The calibration values are only set prior to a measurement which means that in case an accidental wrong selection is discovered after the measurement, the measurement needs to be repeated with use of the correct calibration set.
- 7. Checking the option to **Save measurement to research file** results in a Matlab file being written at the location which is defined by clicking the button.

Checking the option **Show Quality indicator** enables an indication the quality of the data used for WBT2000. (license required) The indication will be shown in the upper right corner after the 3dt is completed. A checkmark will indicate the quality of research data is ok and a X will indicate the quality of the research data is insufficient.

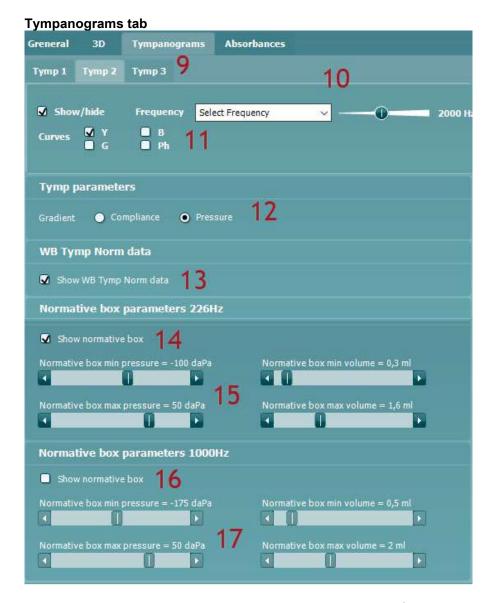
#### 3D tab

8. Setting **Multi color** result in a colorful 3D graph while not selecting this option results in, depending on ear selection, a red or blue shaded 3D graph.









- 9. The 1<sup>st</sup> tymp will always be shown. Optionally **Show 2<sup>nd</sup> tymp** and **Show 3<sup>rd</sup> tymp** can be set to show multiple tympanograms.
- 10. The dropdown boxes allow selecting which tympanograms are shown by default. Within the display of the graph these can be changed by right mouse clinking on the graph. The following choices are available.
  - 226 Hz to display the 226 Hz tympanogram from the 3D Tympanometry measure
  - 678 Hz to display the 678 Hz tympanogram from the 3D Tympanometry measure
  - 800 Hz to display the 800 Hz tympanogram from the 3D Tympanometry measure
  - 1000 Hz to display the 1000 Hz tympanogram from the 3D Tympanometry measure
  - Resonance Frequency to display the tympanogram from the 3D Tympanometry measure that is found at the lowest resonance frequency at peak pressure
  - Abs. average to display the averaged tympanogram which is defined for babies up to six months to be between 800 and 2000 Hz and for all older children and adults to be between 375 and 2000 Hz. The correct averaging range is automatically selected depending on the calibration values that are used
  - **Select frequency** (license required) allows you to set the view to the tympanogram from 200-4000 Hz in 50 Hz steps. The default frequency is set in the setup using the slider that becomes available enabling **Select frequency**
- 11. Curves allow selecting which type of tympanogram curves are displayed as default.



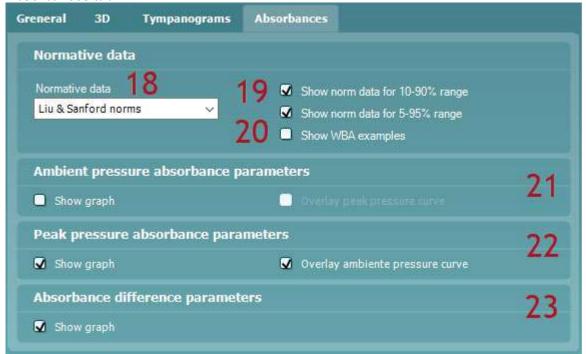


- 12. **Tymp parameters.** Gradient as either a measure of compliance (in ml) or as a measure of pressure (in daPa). Select to display the gradient.
- 13. **WB tymp norm data** allows showing or hiding the normative area for the wideband averaged tympanogram.
- 14. **Show normative box** for 226 Hz tympanograms can be selected to show a rectangle in which the compliance peak is expected under normal conditions of the middle ear.
- 15. **Normative box** minimum and maximum pressure and compliance values for 226 Hz tympanograms are defined here.
- 16. **Show normative box** for 1000 Hz tympanograms can be selected to show a rectangle in which the compliance peak is expected under normal conditions of the middle ear.
- 17. **Normative box** minimum and maximum pressure and compliance values for 1000 Hz tympanograms are defined here.





## Absorbances tab



- 18. The Normative data dropdown allows selecting from which publication normative data is shown in absorbance graphs. Currently available norms for adults are retrieved from Liu et al<sup>6</sup> and norms for other age groups are from Sanford et al<sup>7</sup> and from norm data not published at the time of writing. The norm data for the two age selections 1 month and 3 month are retrieved from the data presented in Sanford and Feeney 2008<sup>4</sup>. The system displays the same norm ranges in both the Ambient pressure mode and in Absorbance at Tympanometric Peak Pressure (TPP) mode. In software version 3.0 the norms for age selection 1 month and 3 months are TPP data, and all other age groups display norm datasets obtained under ambient pressure conditions. Available data suggests that the difference between the two conditions is relatively small, but upcoming releases might hold independent norms for the two conditions as such norms become available based on large datasets obtained with the Titan.
- 19. **Show norm data for 10-90% range** displays this range in absorbance graphs in the situation that such range is available for the combination of the patient's age and the selected normative data. **Show norm data for 5-95% range** displays this range in absorbance graphs in the situation that such range is available for the combination of the patient's age and the selected normative data.
- 20. **Show WBA examples** set the default display to include examples of normal and pathological absorbance curves. It includes also examples for a lose (leaking) and blocked probe.
- 21. At **Ambient pressure absorbance parameters**, it is indicated if the absorbance closest to ambient pressure is displayed and if it includes an overlay with the curve at peak pressure.
- 22. At **Peak pressure absorbance parameters**, it is indicated if the absorbance at peak pressure is displayed and if it includes an overlay with the curve closest to ambient pressure.
- 23. **Absorbance difference parameters** (license required) provides and additional view that that allows for calculation of the peak difference from the 50% percentile.



<sup>&</sup>lt;sup>6</sup> Wideband absorbance tympanometry using pressure sweeps: System development and results on adults with normal hearing, Liu et al., J. Acoust. Soc. Am., Vol. 124, No. 6, page 3708-3719.

<sup>&</sup>lt;sup>7</sup> Sound-Conduction Effects on Distortion-Product Otoacoustic Emission Screening Outcomes in Newborn Infants: Test Performance of Wideband Acoustic Transfer Functions and 1-kHz Tympanometry, Sandford et al., Ear & Hearing, vol. 30, no. 6, 635–652.

<sup>&</sup>lt;sup>4</sup> Effects of maturation on tympanometric wideband acoustic transfer functions in human infants, Sanford and Feeney, JASA, October 2008. 2106-2122.



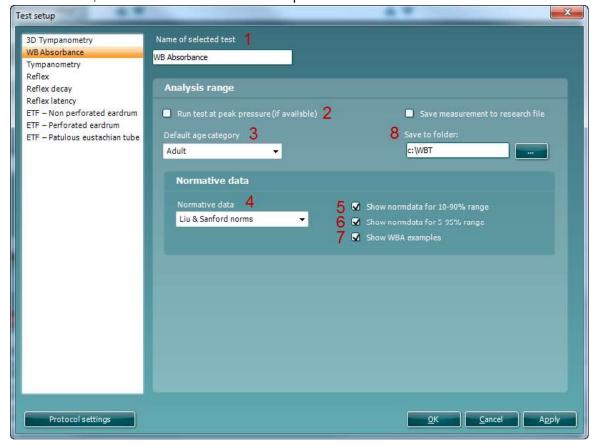
## 2.5.3 Wideband absorbance

Make sure that **WB Absorbance** is selected from the list of tests on the left of the screen.

The WB Absorbance test measures the absorbance as function of frequency at a given pressure. That pressure can be ambient pressure or the peak pressure from a previously measured tympanogram.

The following items can be changed in the WB absorbance settings:

- Name of selected test. You can choose to have more than one of the same tests in your protocol. It
  might therefore be wise to change the name of the test, so it will be easier to recognize when
  running the complete test protocol.
- 2. Run test at peak pressure (if available) will run the test at the most recent peak pressure that was retrieved. This can be the peak pressure from either traditional or wideband tympanometry tests. If set to do so but no peak pressure is available, the test will be performed at ambient pressure.
- 3. Default age category sets the age group for the patient in case the birth date is unknown. Typically, the birth date will be recognized automatically in which case this setting chooses the appropriate age group. Notice that the system applies two calibration sets, one for babies up to six months of age and one for the remaining children and adults. The calibration values are only set prior to a measurement which means that in case an accidental wrong selection is discovered after the measurement, the measurement needs to be repeated with use of the correct calibration set.







- 4. The **Normative data** dropdown allows selecting from which publication normative data is shown in absorbance graphs. Currently available norms for adults are retrieved from Liu et al<sup>8</sup> and norms for other age groups are from Sanford et al<sup>9</sup> and from norm data not published at the time of writing.
- 5. **Show norm data for 10-90% range** displays this range in absorbance graphs in the situation that such range is available for the combination of the patient's age and the selected normative data.
- 6. **Show norm data for 5-95% range** displays this range in absorbance graphs in the situation that such range is available for the combination of the patient's age and the selected normative data.
- 7. **Show WBA examples** set the default display to include examples of normal and pathological absorbance curves. It includes also examples for a lose (leaking) and blocked probe.
- 8. Checking the option to **Save measurement to research file** results in a Matlab file being written at the location which is defined by clicking the button.

<sup>&</sup>lt;sup>9</sup> Sound-Conduction Effects on Distortion-Product Otoacoustic Emission Screening Outcomes in Newborn Infants: Test Performance of Wideband Acoustic Transfer Functions and 1-kHz Tympanometry, Sandford et al., Ear & Hearing, vol. 30, no. 6, 635–652.

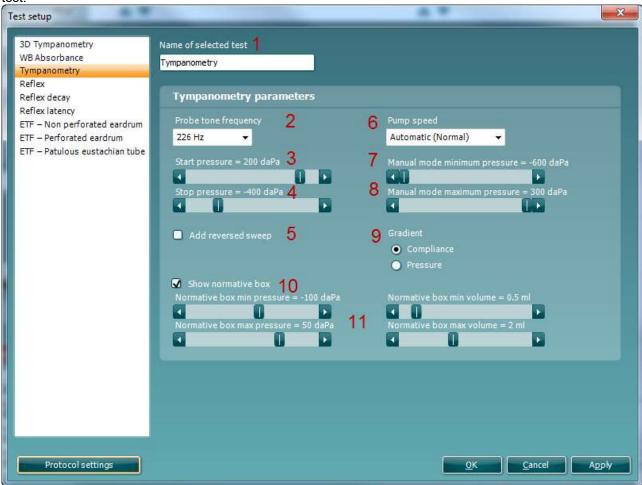


<sup>&</sup>lt;sup>8</sup> Wideband absorbance tympanometry using pressure sweeps: System development and results on adults with normal hearing, Liu et al., J. Acoust. Soc. Am., Vol. 124, No. 6, page 3708-3719.



## 2.5.4 Tympanometry settings

Make sure that **Tympanometry** is selected from the list of tests on the left of the screen, the test is selected which you want to change or view the settings for. The following items can be changed in the tympanometry test.



- 1. **Name of selected test**. You can choose to have more than one of the same tests in your protocol. You may therefore want to change the name of the test, so it will be easier to recognize when running the complete test protocol.
- 2. **Probe tone frequency**. The frequencies which can be selected are 226 Hz (recommended for normal testing), 678 Hz, 800 Hz, 1000 Hz (usually recommended for testing babies up to a half year old).
- 3. **Start pressure**. Here the start pressure for automated tympanometry is selected. The start pressure can vary between +300 and -600 daPa. For calculating the equivalent ear canal volume, the measurement points at starting value are taken.
- 4. **Stop pressure**. Here the stop pressure for automated tympanometry is selected. The stop pressure can vary between +300 and -600 daPa.
- 5. **Ad reversed sweep**. When the checkbox is marked, the automated tympanometry will add a sweep from the stop pressure back to the start pressure.
- 6. **Pump speed**. Here the pump speed for automated tympanometry is selected. The mentioned pump speeds are valid for the clinical setting which is using the shoulder box. When measuring without the shoulder box the pump speeds are about 60% faster due to the smaller volumes in the tubing of Titan. Available options are





- Automatic (normal), is the high pump speed which automatically slows down to low pump speed around the peak of the tympanogram. We recommend using this setting for screening and normal tympanometry tests
- Fast, which results in a constant speed of about 300 daPa/s
- Medium, which results in a constant speed of about 200 daPa/s
- Slow, which results in a constant speed of about 100 daPa/s
- Very slow, which results in a constant speed of about 50 daPa/s
- 7. **Manual mode minimum pressure** allows you to set the lower limit of the pressure range during manual tympanometry.
- 8. **Manual mode maximum pressure** allows you to set the upper limit of the pressure range during manual tympanometry.
- 9. **Gradient**. Gradient as either a measure of compliance (in ml) or as a measure of pressure (in daPa). Select to display the gradient.
- 10. **Show normative box** can be selected to show a rectangle in which the compliance peak is expected under normal conditions of the middle ear.
- 11. Normative box minimum and maximum pressure and compliance values are defined here.

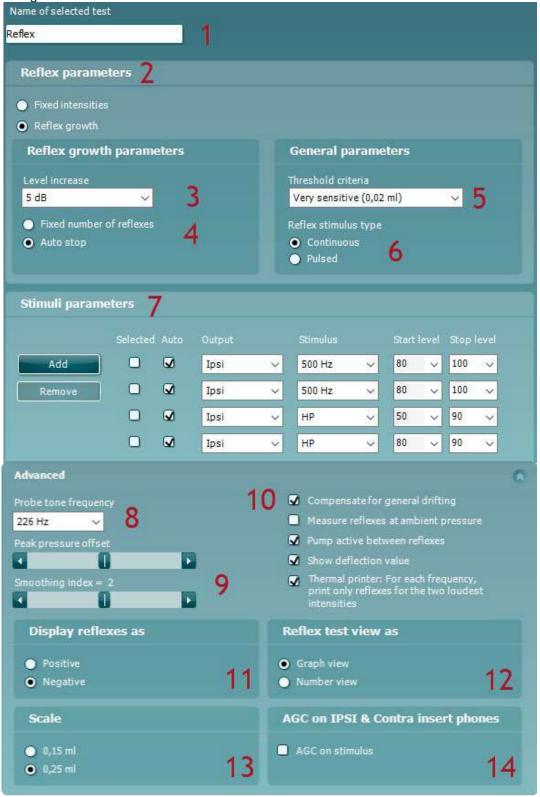




## 2.5.5 Standard reflex settings

Make sure that **Reflex** is selected at the list of tests on the left of the screen. The following items can be

changed in the standard reflex test:







- 1. **Name of selected test**. You can choose to have more than one of the same tests in your protocol. You may change the name of the test, so it will be easier to recognize when running the complete test protocol.
- 2. **Reflex parameters**. Select in which way the automated reflex measurement will perform the test. There are two options:
  - Using **Fixed intensities**, the automated reflex test will perform a single reflex measurement at the **Start level** of the measurement.
  - Using Reflex growth, the automated reflex threshold search can be set up according to personal preferences. Be aware that a reflex threshold which is found using the Reflex growth will only be used in decay and latency testing if the reflex settings match the following criteria: Level increase = 5 dB, Threshold criteria = "Sensitive (0,3 ml)"
- 3. **Level increase**. This defines the increase level of each step during the **Reflex growth**. Increase levels from 1 dB to 20 dB can be chosen.
- 4. Fixed number of reflexes or Auto stop has to be chosen. When choosing Fix number of reflexes the reflex test will complete the sequence from Start level up to Stop level, also if threshold criterion is reached before reaching Stop level. When Auto stop is chosen Titan will detect the reflex threshold according to the threshold criterion and confirm the reflex at the same intensity. Then the sequence is stopped. The stimulus level will never exceed the intensity level which is set as Stop level.
- 5. Threshold criteria let you set the sensitivity of the pass criteria. Three options are available:
  - **Very sensitive (0.02 ml)** which means a "pass" is given for a change in compliance bigger than 0.02 ml (at all probe tone frequencies)
  - **Sensitive (0.03 ml)**, which means a "pass" is given for a change in compliance bigger than 0.03 ml (at all probe tone frequencies)
  - **Normal (0.05 ml)**, which means a "pass" is given for a change in compliance bigger than 0.05 ml (at all probe tone frequencies)
  - Robust (0.08 ml), which means a "pass" is given for a change in compliance bigger than 0.08 ml (at all probe tone frequencies)
- 6. **Reflex stimulus type:** The reflex stimulus can be set to **Continuous** or **Pulsed**. Setting the probe tone to pulsed makes it possible to obtain a reflex at 1000 Hz ipsi.
- 7. Pressing the **Add reflex** button will add another reflex below the existing ones.

  The checkboxes below **Auto** mark the reflexes which are included in the automated reflex test. If not marked those reflexes are not tested until you test them manually.

Probe frequency	226 Hz		678 Hz	800 Hz	1000 Hz
Ear side	Ipsi	Contra	Contra	Contra	Contra
Stimulus type		250	250	250	250
(in Hz)	500	500	500	500	500
	1000	1000	1000	1000	1000
	2000	2000	2000	2000	2000
	3000	3000	3000	3000	3000
	4000	4000	4000	4000	4000
		6000	6000	6000	6000
		8000	8000	8000	8000
		250 NB	250 NB	250 NB	250 NB
		500 NB	500 NB	500 NB	500 NB
	1000 NB				
	2000 NB				
	3000 NB				
	4000 NB				
		6000 NB	6000 NB	6000 NB	6000 NB
		8000 NB	8000 NB	8000 NB	8000 NB
	LP	LP	LP	LP	LP
	HP	HP	HP	HP	HP
	WB	WB	WB	WB	WB



Below **Output** is chosen whether the reflexes are measured ipsilaterally or contralaterally. Below **Stimulus**, the type of reflex stimulus is chosen. The following table shows which stimuli are available depending on the probe tone frequency and which side you are measuring. **NB** stands for narrow band noise. **LP** stands for low pass filtered noise which has a spectrum from 400 Hz up to 1600 Hz. **HP** stands for high pass filtered noise which has a spectrum from 1600 Hz up to 12 kHz. **WBN** stands for wideband noise which has a spectrum from 400 Hz up to 12 kHz.

**Start level** will set the stimulus level at which each reflex sequence is started. For ipsilateral measurements at some frequencies the maximum output is limited compared to contralateral measurements.

**Stop level** defines the highest intensity possible at each reflex sequence. Pressing the **Remove reflex** button will delete the last reflex of the existing list.

- 8. **Probe tone frequency**. The frequencies which can be selected are 226 Hz (recommended for normal testing), 678 Hz, 800 Hz and 1000 Hz.
- 9. The **Peak pressure offset** defines how far from the peak pressure the reflex is measured. When multiple peaks are found, the automated test will use from the highest peak. Note that the automated reflex can only use the peak pressure when a tympanogram measured at the same frequency precedes the reflex test.
  - The **Smoothing index** allows you to choose with how much detail the reflex measurement is measured and displayed. A smoothing index of 0 equals to not applying smoothing. A smoothing index of 4 will smooth the curve most intensively.
- 10. Checking the **Compensate for general drifting** option will ensure that base of a reflex sequence will stay at zero also when the probe seal is not completely tight. The compensation takes place just after a reflex measurement is finished. The reflex graph is then refreshed.

**Measure reflexes at ambient pressure** allows you to measure reflexes while the tympanic peak pressure is being ignored. When checked measurements are performed at 0 daPa.

**Pump active between reflexes** will, when checked, make sure that before each presentation of the stimulus the pressure is restored to the peak pressure. When not activated the pump is used once for each stimulus type at the start of each reflex sequence.

Show deflection value allows you to present the numerical value of the deflection value in each graph. The number represents the average deflection over a certain width of the reflex plateau. Be aware that sometimes the deflection value might show equal or bigger than the reflex criterion without that the system indicates that a reflex is being detection. This happens when the shape of the reflex does not fulfill the requirements that are embedded in the reflex detection algorithm. Selecting Thermal printer: For each frequency, print only reflexes for the two loudest intensities only applies for direct printing from hand held use.

- 11. **Display reflexes as** either **Positive** or **Negative** makes the reflex curve flip over the x-axis. When chosen **Positive** you will normally expect the deflection to go in positive direction. At probe tone frequencies other than 226 Hz the compliance is less stiffness controlled and when measuring an acoustic reflex it is then not uncommon to measure a negative deflection in adults. Therefore, the display of reflexes at those probe tone frequencies is showing both positive and negative scale of the y-axis. Changing this option into **Negative** will still mirror the graph over its x-axis.
- 12. When **Reflex test view** is set as **Number**, the stimulus level is shown. When **Reflex test view** is set as **Graph**, the measurement can be visually interpreted by the clinician. In both cases after a reflex test is performed it will show if the result passed or failed the reflex threshold criteria. And by clicking the right mouse button on a reflex you can choose to see the enlarged graph presentation.
- 13. At **Scale** you choose the maximum values of the y-axis of the reflex graph. Note that for probe tone frequencies other than 226 Hz the scaling is in mmho instead of ml.
- 14. When the AGC (Automatic Gain Control) checkbox is marked, the size of the ear canal is taken into account for adjusting the stimulus level. Without compensation the intensity level will increase as the sizes of the ear canal decreases. Note that current tympanometry standards do not yet describe how AGC should be applied. We recommend that AGC is used in when testing infant ears as theoretically in ear canal volumes smaller than 0,2 ml the stimulus level can be increased by 20 dB and more. The AGC is applied for both the ipsilateral and contralateral insert.



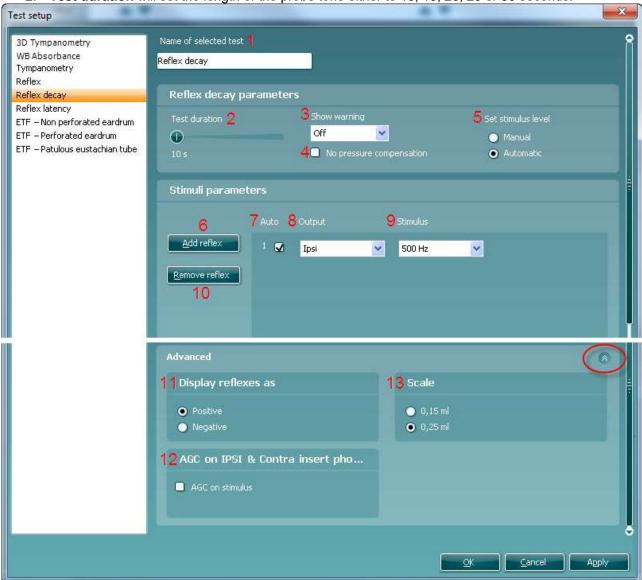


## 2.5.6 Reflex decay

Make sure that **Reflex decay** is selected from the list of tests on the left of the screen. The following items can be changed in the reflex decay setting:

Name of selected test. You can choose to have more than one of the same tests in your protocol.
You may change the name of the test, so it will be easier to recognize when running the complete
test protocol.

2. Test duration will set the length of the probe tone either to 10, 15, 20, 25 or 30 seconds.



- 3. **Show warning** gives you the opportunity to set a level at which Titan gives a warning. For further explanation see item 5.
- 4. Checking the **No pressure compensation** options results in decay measurements without compensation for the peak pressure of the tympanogram. In other words, measurements are performed at 0 daPa.
- 5. Set stimulus level allows you to choose if the stimulus level is set Manual or Automatic. Manual means that prior to the test, a pop up window asks you to set the stimulus level. When choosing Manual it is recommended to have Show warning off. Otherwise Titan will ask you twice to set the stimulus level when it exceeds the warning level. Automatic means that Titan sets the stimulus level 10 dB above reflex threshold level. If that stimulus level exceeds the warning level or cannot be obtained you are still asked to set the stimulus level manually.





- 6. Pressing the Add reflex button will add another reflex below the existing ones.
- 7. The checkboxes below **Auto** mark the reflexes which are included in the automated reflex test. If not marked those reflexes are not tested until you test them manually.
- 8. Below **Output** is chosen whether the reflexes are measured ipsilaterally or contralaterally.
- 9. Below **Stimulus**, the type of reflex stimulus is chosen. All decay testing is performed with a 226 Hz probe tone. The available stimuli for that frequency are the same as for reflexes.
- 10. Pressing the **Remove reflex** button will delete the last reflex of the existing list.
- 11. **Display reflexes as** either **Positive** or **Negative** makes the reflex curve flip over the x-axis. When chosen **Positive** you will normally expect the deflection to go in positive direction.
- 12. When the AGC (Automatic Gain Control) checkbox is marked, the size of the ear canal is taken into account for adjusting the stimulus level. Without compensation the intensity level will increase as the sizes of the ear canal decreases. Note that current tympanometry standards do not yet describe how AGC should be applied. We recommend that AGC is used in when testing infant ears, as theoretically in ear canal volumes smaller than 0.2 ml the stimulus level can be increased by 20 dB and more. The AGC is applied for both the ipsilateral and contralateral insert.
- 13. At **Scale** you choose the maximum values of the y-axis of the reflex graph.

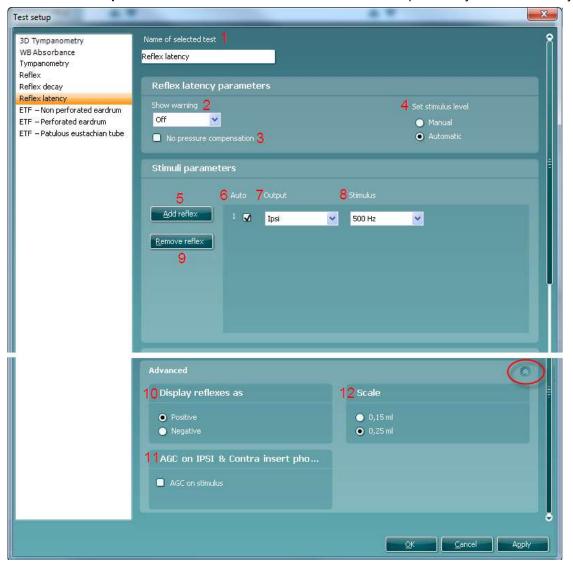




## 2.5.7 Reflex latency

Make sure that **Reflex latency** is selected from the list of tests on the left of the screen. The following items can be changed in the reflex latency setting:

- Name of selected test. You can choose to have more than one of the same tests in your protocol.
  You may change the name of the test, so it will be easier to recognize when running the complete
  test protocol.
- 2. **Show warning** gives you the opportunity to set a level at which Titan gives a warning. For further explanation see item 4.
- 3. Checking the **No pressure compensation** options results in latency measurements without compensation for the peak pressure of the tympanogram. In other words, measurements are performed at 0 daPa.
- 4. Set stimulus level allows you to choose if the stimulus level is set Manual or Automatic. Manual means that prior to the test, a pop up window asks you to set the stimulus level. When choosing Manual it is recommended to have Show warning off. Otherwise, Titan will ask you twice to set the stimulus level when it exceeds the warning level. Automatic means that Titan sets the stimulus level 10 dB above reflex threshold level. If that stimulus level exceeds the warning level or cannot be obtained you are still asked to set the stimulus level manually.
- 5. Pressing the Add reflex button will add another reflex below the existing ones.
- 6. The checkboxes below **Auto** mark the reflexes which are included in the automated reflex test. If not marked those reflexes are not tested until you test them manually.
- 7. Below **Output** is chosen whether the reflexes are measured ipsilaterally or contralaterally.







- 8. Below **Stimulus**, the type of reflex stimulus is chosen. All decay testing is performed with a 226 Hz probe tone. The available stimuli for that frequency are the same as for reflexes).
- 9. Pressing the **Remove reflex** button will delete the last reflex of the existing list.
- 10. Display reflexes as either Positive or Negative makes the reflex curve flip over the x-axis.
- 11. When the AGC (Automatic Gain Control) checkbox is marked, the size of the ear canal is taken into account for adjusting the stimulus level. Without compensation the intensity level will increase as the sizes of the ear canal decreases. Note that current tympanometry standards do not yet describe how AGC should be applied. We recommend that AGC is used in when testing infant ears as theoretically in ear canal volumes smaller than 0.2 ml the stimulus level can be increased by 20 dB and more. The AGC is applied for both the ipsilateral and contralateral insert.
- 12. At **Scale** you choose the maximum values of the y-axis of the reflex graph. Note that for other probe tone frequencies than 226 Hz the scaling is in mmho instead of ml.





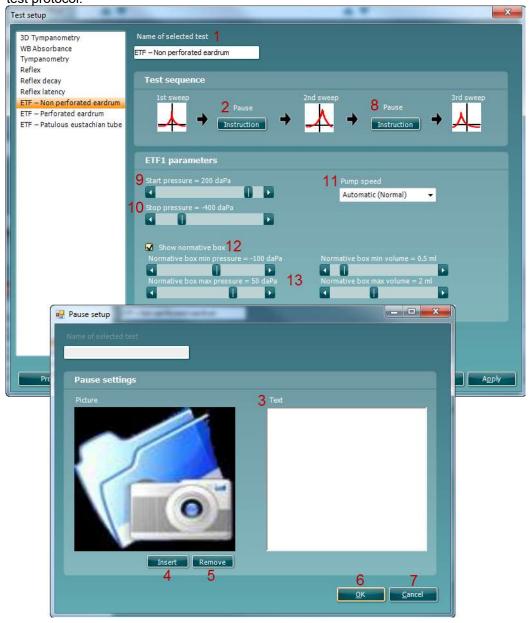
## 2.5.8 Eustachian tube function – non perforated eardrum

Make sure that **ETF – Non perforated** eardrum is selected from the list of tests on the left of the screen.

The Eustachian tube function test for the non perforated eardrum, or ETF 1, or Williams's procedure is setup to measure three tympanograms. It keeps the pressure in between the first and second tympanogram at **Stop pressure** and between the second and third tympanogram at the **Start pressure**. After testing the pressure is brought back to 0 daPa. In between all tympanograms, a message tells you which instruction should be given to the patient. The original Williams procedure is to make the patient swallow in between the different tympanograms. We advise to ask the patient to perform Valsalva's maneuver after the first tympanogram and to swallow after the second tympanogram because the expected deviations of the peak pressure will then be larger.

The following items can be changed in the ETF1 settings:

1. **Name of selected test**. You can choose to have more than one of the same tests in your protocol. You may change the name of the test, so it will be easier to recognize when running the complete test protocol.





- 2. Pressing **Instruction** here will pop up a window in which you can set the instruction which is shown in between the first and second tympanometry sweeps.
- 3. Type your instruction in the area labeled with **Text**.
- 4. Pressing **Insert** gives the option to show a picture with your instruction. You will be prompted to browse to your picture and to open it.
- 5. Pressing **Remove** will remove the picture from the instruction.
- 6. Pressing **OK** brings you back to the **Test setup** and saves the instruction.
- 7. Pressing Cancel brings you back to the Test setup discarding all changes you made.
- 8. Pressing **Instruction** here will pop up a window in which you can set the instruction which is shown in between the second and third tympanometry sweeps.
- 9. **Start pressure**. Here the start pressure for the three automated tympanograms is set. The start pressure can vary between +300 and -600 daPa.
- 10. **Stop pressure**. Here the stop pressure for automated the three automated tympanograms is selected. The stop pressure can vary between +300 and -600 daPa. The Non Perforated Eardrum test is performed.
- 12. **Pump speed**. Here the pump speed for automated tympanometry is selected. The mentioned pump speeds are valid for the clinical setting which is using the shoulder box. When measuring without shoulder box the pump speeds are up to ...% faster due to the smaller volumes in the tubing of Titan. Available options are
  - Automatic (normal), high pump speed which automatically slows down to low pump speed around the peak of the tympanogram. We recommend using this setting for screening and normal tympanometry tests
  - Fast, which results in a constant speed of about 300 daPa/s
  - Medium, which results in a constant speed of about 200 daPa/s
  - Slow, which results in a constant speed of about 100 daPa/s
  - Very slow, which results in a constant speed of about 50 daPa/s
- 13. **Show normative box** can be selected to show a rectangle in which the compliance peak is expected under normal conditions of the middle ear.
- 14. Normative box minimum and maximum pressure and compliance values are defined here.



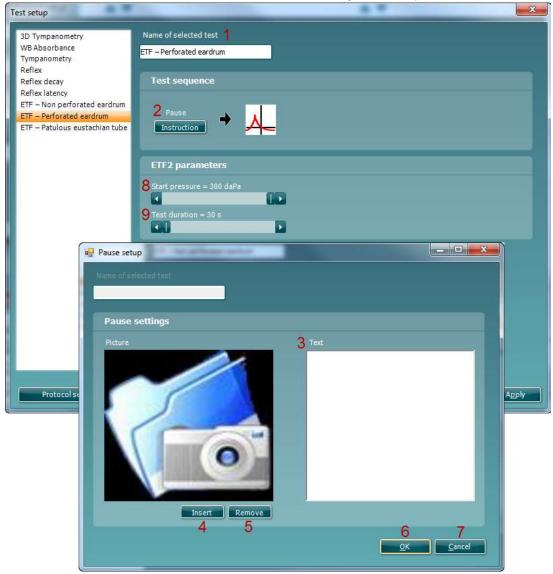


## 2.5.9 Eustachian tube function – perforated eardrum

Make sure that **ETF – Perforated eardrum** is selected from the list of tests on the left of the screen. The Eustachian tube function test for the perforated ear drum, or Toynbee test, or ETF 2 will put the middle ear under a certain **Start pressure**. Then the pump is stopped and over time is measured if the patient can release pressure by opening the Eustachian tube. The patient is usually asked to swallow several times during the test.

The following items can be changed in the Eustachian tube function – Perforated Eardrum setting:

- Name of selected test. You can choose to have more than one of the same tests in your protocol. It
  might therefore be wise to change the name of the test, so it will be easier to recognize when
  running the complete test protocol.
- 2. Pressing **Instruction** here will pop up a window in which you can set the instruction which is shown in between the first and second tympanometry sweeps.
- 3. Type your instruction in the area labeled with **Text**.
- 4. Pressing **Insert** gives the option to show a picture with your instruction. You will be prompted to browse to your picture and to open it.
- 5. Pressing **Remove** will remove the picture from the instruction.
- 6. Pressing **OK** brings you back to the **Test setup** and saves the instruction.
- 7. Pressing Cancel brings you back to the Test setup discarding all changes you made.
- 8. Start pressure. Here the start pressure is set and can vary between +300 and -600 daPa.
- 9. Test Duration. Here the test duration is set and it can vary from 30 up to 150 seconds.





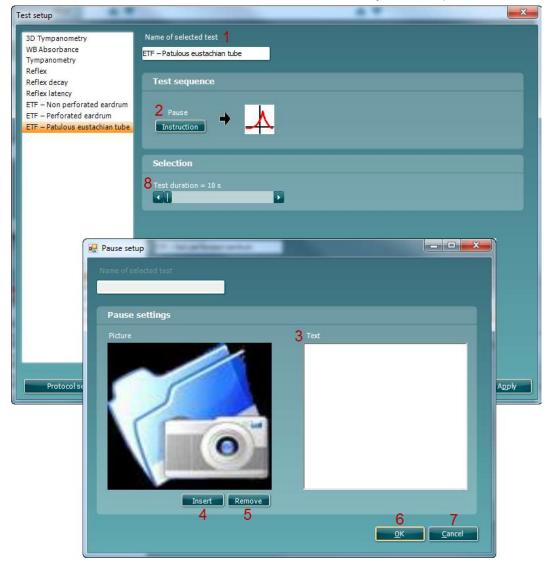


## 2.5.10 Eustachian tube function – patulous eustachian tube

Make sure that ETF - Patulous Eustachian tube is selected from the list of tests on the left of the screen.

The Eustachian tube function test for a patulous Eustachian tube or ETF 3 monitors the compliance of the eardrum over a certain period of time. If the Eustachian is spontaneously open, you expect to measure compliance changes due to movements of the eardrum. Typically, you expect to recognize the rhythm of breathing. Measuring the ETF 3 in a healthy subject only shows spontaneous disturbances in the compliance due to probe movement, acoustical disturbances in the surrounding of the patient or spontaneous movements of the ear drum. With Titan's precision it is not uncommon to measure a patient's heart beat.

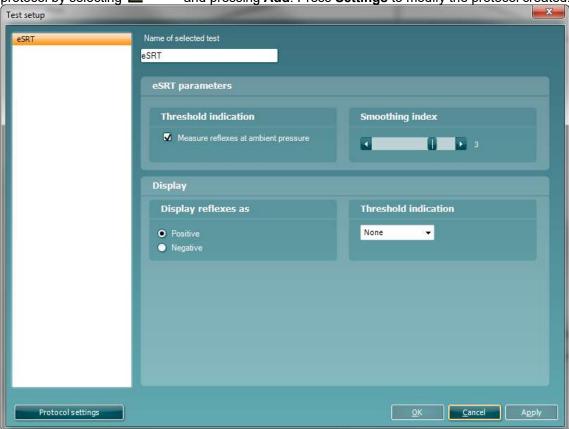
- 1. **Name of selected test**. You can choose to have more than one of the same tests in your protocol. It might therefore be wise to change the name of the test, so it will be easier to recognize when running the complete test protocol.
- 2. Pressing **Instruction** will pop up a window in which you can set the instruction which is shown before the measurement starts.
- Type your instruction in the area labeled with Text.
- 4. Pressing **Insert** gives the option to put in a picture with the instruction. You will be prompted to browse to the picture you want to include and open it.
- Pressing Remove will remove the picture of the instruction.
- 6. Pressing **OK** brings you back to the **Test setup** and saves the instruction.
- 7. Pressing Cancel brings you back to the Test setup discarding all changes you made.
- 8. **Test Duration**. Here the test duration is set and it can vary from 10 up to 60 seconds.





## eSRT - Electrically Evoked Stapedial Reflex Thresholds

Enter Menu – Seup – Protocol Setup and create a protocol pressing New. Add the eSRT test est a protocol by selecting esrt and pressing Add. Press Settings to modify the protocol created.



## eSRT parameters



Check the box to obtain an eSRT at the ambient pressure. If unchecked the pressure will be obtained at peak pressure, if a peak pressure is present.

The more smoothing that is applied the less noisy/detailed the trace will be. The smoothing level can be set from 0-4, with 0 being no smoothing applied and 4 being maximum smoothing applied.

Display



Set the display of the reflexes to positive to have a positive deflection and negative to have a negative deflection of the reflexes.

This setting adds a threshold line to the graph, so it is possible to see when a threshold is present, e.g. by setting it for 0.05 ml.

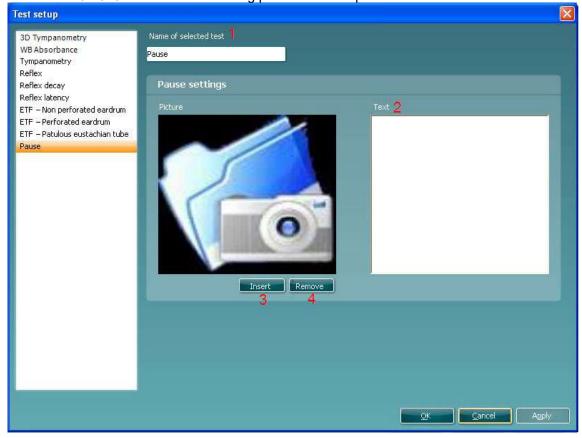
Once the protocol is modified press ok to save the changes to the protocol.



## 2.5.11 Pause

Within a protocol it is possible to use **Pause**. It can be used as a break in between tests or to give an instruction to the clinician before continuing or ending a protocol. The following items can be changed in the **Pause** element:

- 1. **Name of selected test**. You can choose to have more than one of the same tests in your protocol. You may change the name of the test, so it will be easier to recognize when running the complete test protocol.
- 2. Click with the mouse in the white area labeled **Text** and type your instruction.
- 3. Press Insert to open a browser window to find a picture to include with the pause text.
- 4. Press Remove to remove the existing picture from the pause element.







## 2.6 The display wizard

The way you view your measurement during testing is part of the **Protocol setup**. The **Display wizard** is meant to personalize your way of viewing the test during testing and also after testing. It is also possible to view different subtests of a protocol within one screen. In addition, the display can be setup to show an overview after the measurements is done, called the **Combined view**.

Note that when you enter the **Display wizard** for a protocol which already contained a personalized display you will receive a warning "This will delete the old view in the Display wizard, continue?" When entering the Display wizard, you will always start with a blank view. In other words, before you finish personalizing, check carefully if every setting of every display is according, your preferences.

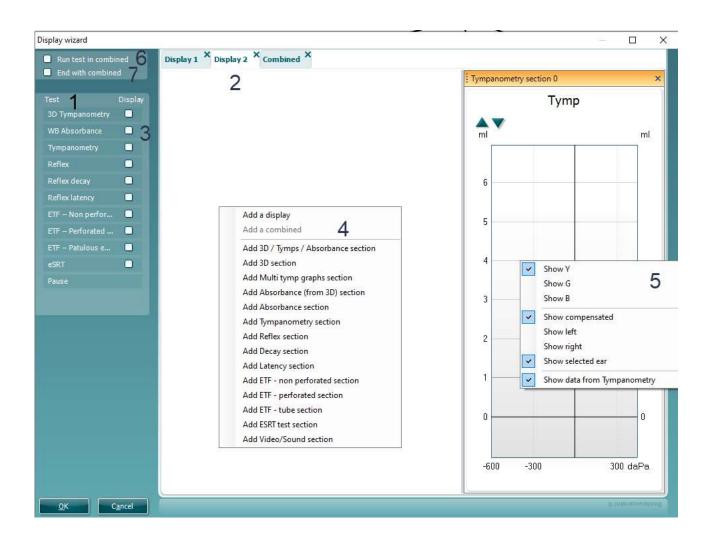
This chapter will describe the handling and possibilities of the Display Wizard. To open the Display Wizard for a specific protocol, go to the **Imp** tab, and select **Menu | Titan Setup**. The **Test Protocol** window opens. Now select the protocol you want to adapt the view and select **Display Wizard** at the bottom of this window.

Now the **Display Wizard** opens and shows the following information and controls:

- 1. The list of **Tests** shows which tests are included in the current selected protocol.
- 2. Each tab contains a display which is defined to be used somewhere during testing with this protocol.
- 3. The checkboxes below **Display** show during which tests the current display is used.
- 4. Clicking the right mouse button on a empty space of the selected display gives you the following options:
  - Add display, which adds a display which is used during testing
  - Add combined, which adds a display which is mostly used to view an overview of different tests after all measurements are finished
  - Add tymp section, to add tympanogram graphs
  - Add reflex section, to add reflex graphs
  - Add decay section, to add a reflex decay graph
  - Add latency section, to add a reflex latency graph
  - Add etf none perforated section, to add a Eustachian tube function none perforated eardrum graph
  - Add etf non perforated section, to add a Eustachian tube function perforated eardrum graph
  - Add etf tube section, to add a Eustachian tube function patulous tube function graph
  - Add video/sound section, to add a picture, movie or sounds sample to the Display. The
    idea is either to give extra information to the patient or clinician or to provide distractions for
    patients who have difficulties to remain calm during the measurements
- 5. Clicking the right mouse button on a inserted element gives the following options:
  - Show Y, to show to the acoustic admittance curve (only available for tympanometry element)
  - **Show G**, to show the acoustic conductance curve of the tympanogram (only available for tympanometry element)
  - Show B, to show the acoustic susceptance curve of the tympanogram (only available for tympanometry element)
  - **Show compensated**, to show the tympanogram compensated for the equivalent ear canal value (only available for tympanometry element)
  - Show left, Show right or Show selected ear to choose which ear should be shown.
- 6. Selecting **Show in combined** means that during the measurement of the protocol the **Combined display** is shown.
- 7. Selecting **End with combined** will show the **Combined display** after the last test is performed or when the protocol is manually stopped. This gives the opportunity to end with an overview of for example tympanometry and reflexes of both ears.



# MMMM

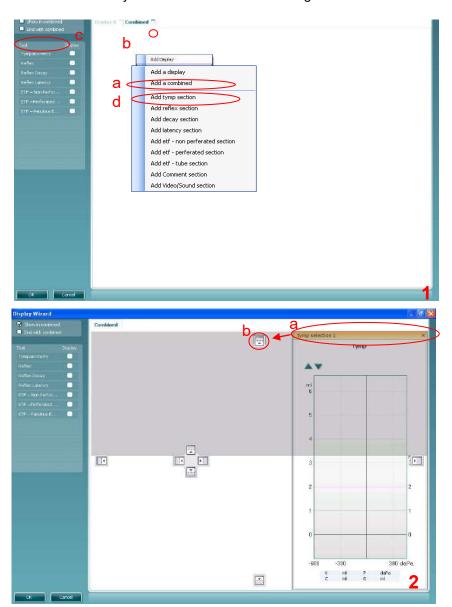




## 2.6.1 Example of use of the display wizard

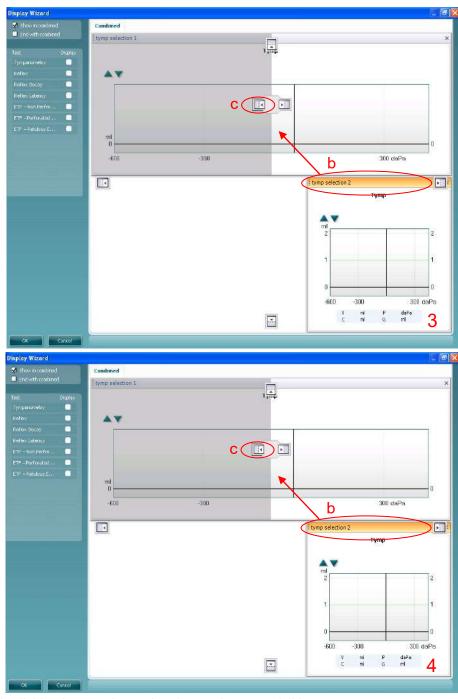
The Display wizard is set up to automatically fill up all empty space in the screen. Manually scaling elements in the Display Wizard is *not* recommended. This Combined View will show tympanograms and reflexes of both ears.

- 1. To open the Display Wizard for a specific protocol, go to the **Imp** tab, and select **Menu | Protocol Setup**. The **Protocol setup** window opens. Select **Display wizard** at the bottom of this window. The Display Wizard opens with only the empty **Display 0**.
  - a. Use right mouse click in the screen and select Add a combined.
  - b. Since we do not need **Display 0** in this example, we close it by pressing the cross next to its name.
  - c. Check the box **End with combined** to ensure that the protocol will show the Combined View when Titan is done measuring.
  - d. Again, use right mouse click in the screen select **Add tymp section** to add a tympanogram graph in the screen.
- 2. Now one **Tymp section** is in the screen.
  - Take the element with your left mouse button and drag it over the screen.





# MMMMM



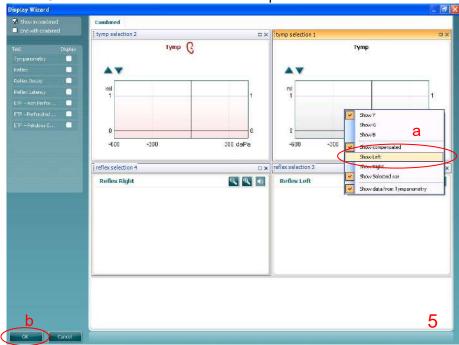
Available places to leave the element become visible.

- b. Drag the mouse to the icon marking the top half of the display.
- 3. Now the tymp element fills up the top half of the display.
  - a. Use right mouse click on an empty place and select **Add tymp section** to add another tympanogram.
  - b. Take the new element with your left mouse button and drag it over the screen. Available places to leave the element become visible.
  - c. Drag the mouse to the icon which marks the left side of the top half of the display.
- 4. The two tympanograms we needed are now in the display and placed at the top half.
  - a. Use right mouse click on the empty place and select **Add reflex section** to add one of the reflex graphs.
  - Again, use right mouse click on the empty place and select Add reflex section to add the second reflex graph.





- c. Take the newest element with your left mouse button and drag it over the screen. Available places to leave the element become visible.
- d. Drag the mouse to the icon which marks the left side of the bottom half of the display.
- 5. Now all graphs are placed correctly. Only thing remaining is to assign which ear is shown in which graph.
  - a. Use right mouse click on every element to assign which ear should be shown in the display.
  - b. Press **OK** to save this combined view to the protocol.







## 2.7 General setup

The **General setup** can be opened by clicking **Menu | Setup | General setup...** and offers the following options:



- 1. **Startup ear** allows you to select which ear the program will always start on as default. The selected startup ear applies to all modules.
- The Print button can be set up to automatically print to PDF.
  - a. Check the PDF print enabled box to set the print icon to print to PDF functionality.
  - b. Check the **Open after print** box to open the PDF document after printing.
  - c. Select the File location to where the PDF document should be saved.
  - d. Select PDF timename configuration to define the name of the file. Selecting the button will open another window to set the fields defining the name of the PDF file. A field called "ID Number" must be added to the PDF file. Use the arrow keys to add fields to the file name. The adjustable delimiter will separate the different fields from one another.







## 2.8 Temporary setup

The **Temporary setup** can be accessed in two ways and allows you to make temporary changes to the protocol currently shown in the protocol drop down list.

1. Go to Menu | Setup | Temporary setup...

2. Click on the Temporary setup icon on the control panel

When a temporary change has been made to a protocol, the protocol name will then appear with an asterisk next to it. If data is measured before you enter temporary setup you are prompted to save or discard the data. In temporary setup the same options are available as in the normal protocol settings.

## 2.9 PC shortcuts

For quick operation from the keyboard the following hotkeys are available:

L - switch to left ear R - switch to right ear

Space - during automated testing: start or stop

Space - during manual testing in tympanometry: start or stop recording Space - during manual testing in reflexes: start or stop speaker icon

A - select or deselect all tests of a protocol

M - switch on or off manual testing

P - pressure release during manual tympanometry

T - go into temporary settings

Ctrl S - save and new

Ctrl P - print

Ctrl R - add a row while in manual reflex testing
Ctrl C - add a column while in manual reflex testing

Page up - go one up in saved sessions
Page down - go one down in saved sessions
Arrow up - go one test up within the protocol
Arrow down - go one test down within the protocol
Arrow left - During manual testing decrease pressure
Arrow right - During manual testing increase pressure





# **3 ABRIS440**

## 3.1 About ABRIS440 module

The Titan with ABRIS440 is intended for use in the audiologic evaluation and documentation of ear and nerve disorders using auditory evoked potentials from the inner ear, the auditory nerve and the brainstem. The target population for Titan with ABRIS440 is newborns.

The Titan with ABRIS440 does not require that the user has special technical skills or the ability to interpret the results as these are provided as a PASS or REFER.

# 3.2 Automated Auditory Brainstem Response (Automated ABR) testing

Automated ABR testing is commonly used for infant hearing screenings as it tests the entire auditory system up to the brainstem.

Automated ABR technology uses a broadband stimulus such as a click or CE-Chirp® to stimulate the ear using a fast stimulus rate. Electrodes are placed on the baby and record the brain activity (EEG) that is evoked during presentation of the stimulus. Advanced algorithms are used to determine if there is a response to the stimulus in the recorded EEG.

It is ideal for testing newborns and infants as the patient does not need to be awake or respond in any way to the test stimulus. Responses from the brainstem are detected from electrodes that are attached to the head of the neonatal patient. Results are automatically analyzed and displayed as either PASS or REFER.

#### 3.2.1 Automated ABR with Titan

The Titan ABRIS440 module performs Automated ABR by stimulating the ear with a click or CE-Chirp® at a fast stimulus rate (90Hz).

The algorithm is a multiple q-sample test with a critical test value set to a sensitivity of 99.9% and was developed by Stürzebecher et al. (1999¹0) and later improved by Mario Cebulla and colleagues (2006¹¹). The algorithm assesses the incoming EEG in the frequency domain assessing amplitude and phase at a range of harmonics of the response to the periodic stimulus. By measuring a large number of EEG-responses, and performing a frequency analysis on the data, it is possible to calculate a test value, which gives an indication of the phase stability for the frequencies equal to the stimulus rate and the first 8 harmonics. Comparing the phase stability with a mathematically found critical test value, it is possible to determine if there is a response to the stimulus in the EEGs. The calculation is performed everyone and a half seconds, and if the test value is greater than or equal to the critical test value the algorithm returns a "PASS". If the test value has not reached the critical test value before the maximum test time (180 seconds), the algorithm returns a "REFER".

The critical test value for PASS/REFER cannot be modified.

<sup>&</sup>lt;sup>11</sup> Cebulla, M., Stürzebecher, E., Elberling, C. (2006). Objective detection of auditory steady-state responses: Comparison of one-sample and q-sample tests. J Am Acad Audiol, 17(2), 93-103.



<sup>&</sup>lt;sup>10</sup> Stürzebecher, E., Cebulla, M., & Wernecke, K.D. (1999). Objective response detection in the frequency domain: Comparison of several q-sample tests. Audiol Neurootol, 4, 2-11.



## 3.2.2 Sensitivity and specificity

Sensitivity and specificity are common words used when discussing newborn hearing screening given the importance of detecting those children with a potential hearing loss who require further diagnostic assessment and treatment.

Within a universal newborn hearing screening (UNHS) program, it is important to have a high rate of detection of infants with severe hearing losses (sensitivity) and a low referral rate of infants who have normal hearing (specificity).

In a medical diagnosis:

**Sensitivity** refers to the probability that a test will be positive when the disease is present (true positive). **Specificity** refers to the probability that a test will be negative when the disease is not present (true negative).

These terms can often be confusing in the field of hearing screening. This may be due to the fact that hearing screening instruments label the outcome of a test where "normal" hearing was detected as a "pass" whereas the definition above refers to labelling a test that detects a disease as "positive" and non-diseased or normal as "negative".

Essentially, hearing screening products should have a high sensitivity, meaning they should be good in detecting patients with a disease (a potential hearing loss) and labelling the result as a REFER. They also need to have a high specificity, ensuring patients without the disease (normal hearing) are not unnecessarily sent on for further diagnostic testing when it was not required.

Sensitivity is principally determined by the instrument implementation (algorithms and hardware). Poor sensitivity leads to unwanted false passes and can have very serious consequences for the child, as they would not receive timely and adequate treatment or amplification, leading to potential language development and social issues.

Specificity is also a measure of instrument implementation, however it also heavily influenced by the test environment, the tester and the test procedure. Therefore, the specificity quoted by one screening program with highly trained screeners who screen babies in a quiet room 12-24 hours after the child's birth, may differ from another screening program where staff have limited training, babies are tested in noisy test environments or within hours of being born. Poor specificity (or false refers) can lead to an increased cost to screening programs requiring babies to be rescreened numerous times or being sent for unnecessary costly diagnostic assessments. It also leads to increased anxiety for parents or caregivers.

The values for sensitivity and specificity using the default CE-Chirp® 35dB nHL protocol are:

Algorithmic Sensitivity: 99.9% Specificity: better than 96%

The sensitivity value is the percentage of newborns with a severe hearing loss that are correctly identified (REFERED) by the algorithm. The sensitivity is found by performing a Monte Carlo simulation, where the algorithm is supplied with random numbers, which have the same frequency components as normal human EEGs

The specificity is the percentage of normal hearing newborns found by the algorithm. The specificity value is determined by clinical testing of newborns with normal hearing.





## 3.3 Preparing for the test

## 3.3.1 ABRIS patient preparation

The Titan with ABRIS440 collects electrical signals from the brain via electrodes which are placed on the baby. As these signals are very small, it is recommended that the baby be asleep or in a very calm state for testing. The baby can stay in its crib, be placed on an examination table or be held by the parent.

Ideally, show the electrodes and transducer to be used to the parent before testing and explain the following:

- The aim of the test is to test screen the hearing organ for its functionality
- The skin will be prepared before placing three electrodes
- A transducer (probe, insert headphones etc) will be used to deliver the sound to the ear
- A soft clicking sound will be heard during the test
- The baby is not required to do anything during the test as it is automated
- Crying, sucking and movement may result in a longer test time

## 3.3.2 ABRIS preparation of the skin

The skin should be clean and free of lotions or oils. If any greasy skin care products have been used where the electrodes are to be placed, the lotion/oil should be carefully removed prior to placing the electrodes. This removal procedure should be discussed with a qualified nurse or doctor.

The electrode sites can be prepared and cleaned in order to obtain lower skin impedances. For this purpose a large variety of skin preparation pastes/gels can be purchased. Please note that two different types of electrode pastes/gels exist: One which is an abrasive gel to prepare the skin and another which is an electrically conductive paste used with reusable electrodes. Only the first type can be used for skin preparation (you can feel the abrasive nature of this type of paste when rubbing it between your fingers). The paste supplied with the unit is this type of skin preparation paste/gel (NuPrep).

Typically, if the baby's skin is clean and free of lotions/oils, you will not need to perform any skin preparation. However, to lower the skin impedances, follow these instructions:

- Clean the skin where the electrodes will be placed with an alcohol wipe.
- Put some of the skin preparation gel (NuPrep) onto a piece of gauze and rub the skin gently several times. A good and thorough job of rubbing the skin with the gel might turn the skin a little red but will ensure good electrode impedance. Neonates generally do not require excessive abrasion.
- Remove excessive abrasive gel before placing the electrodes. Some clinicians prefer to clean off the gel with alcohol wipes of a piece of gauze. This will also ensure a very clean and dry area, well suited for the adhesive part of the electrode.
- If the baby's skin is dry or you are obtaining high impedances, applying a small amount of conductive gel/paste to the baby's skin prior to connecting the surface electrode will help to rehydrate the skin and to lower impedances.

# 3.3.3 Electrode placement and cable connection

After having prepared the skin, place the three electrodes as follows for the desired montage.

#### Electrodes

The disposable electrodes supplied with the unit are single use only. For further information, refer to the "Tips for use of the Sanibel Disposable Tab and Snap Electrodes in ABR Infant Screening" Quick Guide document.

If reusable electrodes are to be used, cleaning and disinfecting procedures should be clarified with your hospital's infection control department.





## Mastoid montage

The mastoid montage allows you to test monaurally only (one ear at a time). If you wish to test both ears at the same time (binaural testing), you must use the nape montage.

Place one electrode on the vertex and one on each mastoid (hard boney area behind the ear).

Connect the cables from the PreAmp as follows: White cable: Vertex (hairline on the forehead)

Red cable: Right mastoid Blue cable: Left mastoid

Remember, that all three electrodes must be positioned in order to perform testing.

#### Nape montage

By using the nape montage, you can test both ears at the same time (binaural testing).

Place one electrode on the vertex, one on the cheek and one on the nape (back of the neck just below the hairline).

Connect the cables from the PreAmp as follows:

White cable: Vertex (hairline on the forehead)

Red cable: Cheek Blue cable: Nape

The red cable electrode can also be placed on the side of the side of the forehead or on the shoulder.

Remember, that all three electrodes must be positioned in order to perform testing.

## 3.4 Electrode impedances

## **Electrode Impedances Measurement Techniques**

When measuring electrode impedances, the numerical value that describes the impedance of each electrode depends on the application of the surface electrode and the method of impedance measurement. Application factors include the size of the electrode preparation of the skin prior to electrode adhesion, application of pressure of the electrode and the electrode placement site.

The frequency used to measure the impedance also significantly affects the value. As a general rule, electrode impedances are low when measured using a high frequency and high when measured using a low frequency (Rosell et al., 1988).

Typically, a test stimulus of a 33Hz square wave is used for determining electrode impedances in clinical ABR systems and therefore will produce higher impedance readings than if a 1000Hz frequency is used (as is often the case in ABR screening equipment).

The Titan preamplifier, like most clinical devices uses a 33Hz square wave frequency for determining electrode impedances. Therefore, electrode impedances seen with the Titan will be higher than those seen on many other newborn hearing screening instruments (that are using a 1000Hz frequency for measurement). While the numerical value may differ (between equipment) due to the measurement technique used, the actual impedance (the resistance of the skin between two electrodes) is actually the same.

For example, on other newborn hearing screening devices (using a 1000Hz measurement frequency), you will typically see electrode impedance values between  $0\text{-}5k\Omega$  whereas typical impedance values for the Titan are between  $15\text{-}25k\Omega$ . These value differences do not affect the test.





## **Electrode impedance check**

After attaching the electrodes and cables to the baby, it is essential to check if the impedances are acceptable for testing. Typically, the impedance of each electrode site should be as low as possible, however testing is still possible with high impedances.

The system will automatically detect the electrode impedance and an indication of the impedance acceptability will be displayed on the infant picture in either green or amber.

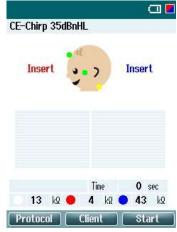
In the PC software, only the color indications on the infant picture are displayed. However, the start and end impedances can be viewed on the print report.

On the hand held unit, the numerical values as well as the color indicators are displayed. The start impedance value is recorded and displayed on the print report

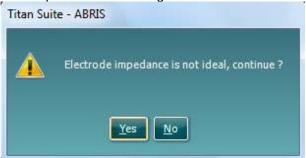


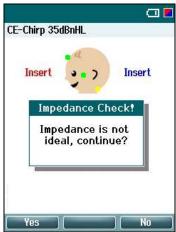
Green = Acceptable (Impedance is between  $0 - 40k\Omega$ )

Amber = Poor (Impedance >  $40k\Omega$ )



If any of the electrode impedance indicators are amber, the user will be asked to confirm whether or not they wish to proceed with testing.







## 3.4.1 ABRIS default protocols

The software contains three factory default ABRIS protocols.

#### 1. CE-Chirp® 35dB nHL

This is the only factory default protocol that will display a PASS or REFER result when the test finishes.

The values for sensitivity and specificity using this protocol are:

Algorithmic Sensitivity: 99.9% Specificity: better than 96%

These values are based on the following test parameters:

Stimulus type: CE-Chirp® Stimulus intensity: 35dB nHL

Test time: 3 minutes Residual noise limit: Off

#### 2. Click 35 dB nHL

This factory default protocol will not display a PASS or REFER result when the test finishes by default. To use the settings of this protocol and display PASS/REFER labels, copy the protocol, and enable pass/refer in the setup.

When enable pass/refer is checked, you will be prompted to accept a disclaimer before proceeding.



# 3. HiLo CE-Chirp® 35dB nHL

This factory default protocol will not display a PASS or REFER result when the test finishes by default. To use the settings of this protocol and display PASS/REFER labels, copy the protocol, and enable pass/refer in the setup.

When enable pass/refer is checked, you will be prompted to accept a disclaimer before proceeding.







## 3.5 ABRIS440 menu items

From the main menu, the following options are available - **Setup**, **Print**, **Edit** or **Help**. The menu has the following structure:

**Menu** to go to **Setup**, **Print**, **Edit** or **Help**. The menu has the following structure:

**Menu | Setup | Protocol setup...** to enter the Titan Setup where the settings of ABRIS protocols can be viewed and changed. If data is measured before you enter the protocol setup, you are prompted to save or discard that data.

**Menu | Setup | Show/hide protocols...** to enter the setup to choose which protocols are available during the PC controlled measurements.

Menu | Setup | General setup... to enter the setup where PDF printing options are defined.

Menu | Setup | User guide setup... to edit the pictures and instructions displayed in the user guide.

**Menu | Setup | Password protection...** to change and/or activate password protection for the complete Titan Suite. When activated users cannot enter the **Protocol setup** or **User guide.** 

Menu | Setup | Unlock protection... to temporarily disable password protection.

Menu | Setup | Language... to change the language used in the software.

Menu | Setup | Simulation mode... to activate simulated testing with simulated hardware.

**Menu | Print | Print...** to print the current measurement using the print template that is linked to the current protocol. You will enter the print window from where you can select your printer and change settings before printing. Note that you are prompted to select a template if the protocol did not include a template.

**Menu | Print | Print preview...** to see a print preview of the current measurement using the print template that is linked to the current protocol. Note that you are prompted to select a template if the protocol did not include a template.

**Menu | Print | Print wizard...** to open the print wizard window from where you can select a template to print the current measurement.

**Menu | Edit | Export...** to export the current measurement to an XML file.

Menu | Help | About... brings you to an information window which displays the following:

- Titan Suite version
- Hardware version
- Firmware version
- Copyright Interacoustics 2009

Further, you can reach the Interacoustics website by pressing the link to <a href="www.interacoustics.com">www.interacoustics.com</a>.

By pressing the License button, you are able to change the license keys of the Titan Suite. The license keys for the Titan 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 | Instructions for use... to open the digital version of the Instructions for Use manual

Menu | Help | Additional information... to open the digital version of the Additional Information manual.



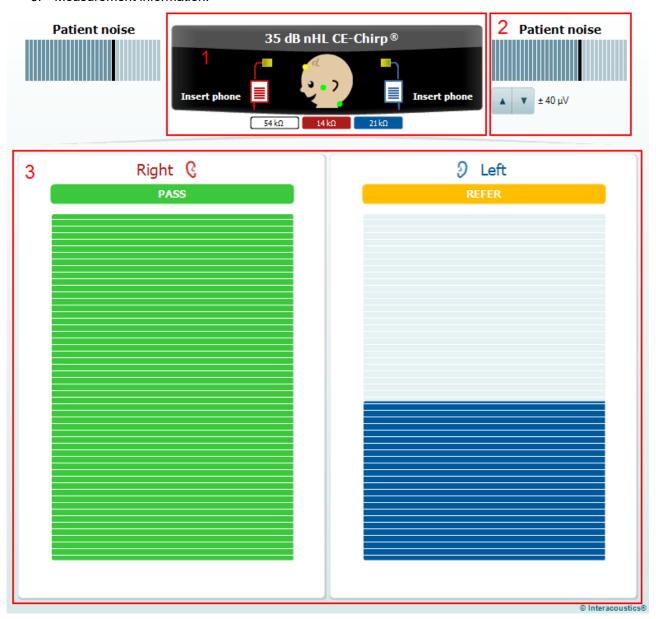


# 3.6 General operation of ABRIS440

## 3.6.1 Main display structure

As indicated in the picture below, the main display of the ABRIS module shows three types of information:

- 1. Stimulus type and level, transducer information, surface electrode positions and impedances.
  - A green dot indicates an impedance between 0 and 40kΩ (ACCEPTABLE)
  - An amber dot indicates the impedance is above 40kΩ (POOR)
- 2. EEG information (Patient noise).
- 3. Measurement information.

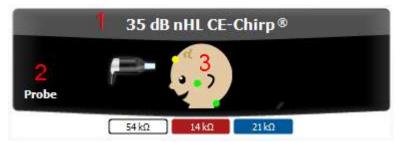


The following paragraphs will describe each area in more detail.



### 3.6.2 Transducer information area

The following information and controls are found in the transducer information area:



- 1. The **label** shows the stimulus intensity in dB nHL and the stimulus type (CE-Chirp®, Click, HiLo CE-Chirp® or NB CE-Chirp®) used by the current protocol.
- 2. For both ears the **type of transducer** is indicated by a picture and a label. The transducers are automatically detected when connected to the PreAmp. Because the transducer contains its own calibration data it can be freely connected to any Titan. The following transducers can be used for ABRIS:
  - Headphones (TDH39) or (DD45)
  - Insert phones (EARTone ABR)
  - Probe (IOW probe)
  - Earcups (EARTone ABR with EarCups)



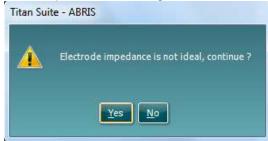
In cases where the probe and other transducers are connected at the same time you are asked before testing is started to choose which transducer will be used. After having made your choice, the other transducer is ignored as if it was not connected.

Note that a monaural insert or headphone is available for connection to the ABRIS PreAmp. These transducers are only compatible for contralateral reflex measurements within the impedance module. Within the ABRIS module the monaural headphone and insert are ignored.

On the **infant picture** the impedance status of the three electrodes are shown. The impedance value for each individual electrode is also indicated below the infant picture in  $k\Omega s$ .

3. Note that the indications can only be accurate while all three electrodes are connected to the PreAmp via the supplied electrode cables. A green dot indicates an acceptable electrode impedance (between 0 and  $40k\Omega$ ). An amber indication means that the electrode impedance is higher than advisable (above  $40k\Omega$ ). In such a case it is recommended to redo the skin preparation of the baby for this electrode.

When it is not possible to get low enough impedances, the software will allow you to start a measurement. In such situations the following pop-up will appear asking you to confirm that the non-ideal impedance can be ignored.



Press **Yes** if you wish to continue testing. Press **No** if you want to re-prepare the skin and replace the high impedance electrode.

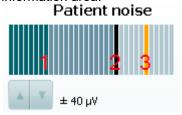


Electrode impedance is monitored only before and after testing. During testing the indications are therefore shown in grey. Just before a recording stops the electrode impedance is measured and saved with the session. Historic sessions show these saved electrode impedances. If an electrode falls off or becomes disconnected during testing, the PreAmp will detect an abnormal input and a pop-up will ask the user to "Reconnect electrode".



### 3.6.3 Patient noise & EEG information area

The patient noise & EEG information area displays either the EEG peak values in a bar view (below on the left) or the raw EEG in a graph view (below on the right). The following information and controls are found in the EEG information area:





- 1. The number of darker bars indicate the peak level of the EEG signal.
- 2. The black bar represents the EEG peak level above which a measurement will be rejected.
- 3. EEG peak levels above the rejection level are displayed in amber. The highest EEG peak level disappears after a short delay in order to see the highest peak levels when the EEG is quickly fluctuating.
- 4. In graphical view the raw EEG is shown on a 23 ms time line. The curve remains green while the EEG peak level is below the rejection level. The curve turns red when the measurement is rejected due to high EEG peak levels.
- 5. The arrow buttons allow modification of the EEG rejection level. Within the protocol setup there is an option to hide these controls and keep to a fixed rejection level. The rejection level chosen is the same for both ears.





### 3.6.4 Measurement information area

The measurement can be viewed in either bar or graph view. For explanatory reasons below both views are merged in one picture although normally you cannot combine different views in the same screen.



The following information and controls are found in the measurement information area:

- 1. Screening results can be PASS, REFER or INCOMPLETE and are indicated above the measurement as soon as the result is available. A measurement that is performed with a broadband Click or broadband CE-Chirp® gives a single result per ear that is colored green for a PASS and amber for a REFER. When the measurement is performed with the HiLo CE-Chirp® or NB CE-Chirp® then a PASS in only one of the two bands is colored gray until both bands reach a PASS. In the case where a measurement is manually stopped, results are labeled as INCOMPLETE. Note that the Enable Pass/Refer option must be checked for the test protocol for a PASS, REFER or INCOMPLETE label to be displayed when the test ends.
- 2. **Graph presentation** of the measurement shows which percentage of the pass criterion is reached as a function of time. Thus reaching 100% equals to reaching the pass criterion. The graph presentation allows a more detailed view of how the measurement over time progresses. However, the trajectory of the measurement or steepness of the curve depends on many independent factors and does not add any value to the screening result.
- 3. **Bar presentation** shows how the measurement is progressing over time as the bar fills from the bottom to the top. When the bar is completely full, this equates to reaching the pass criterion.
- 4. **Warning information** is shown when applicable. The following warnings may be displayed before or during testing:
  - EEG is too high , means that the EEG peak level causes rejection of the measurement.
  - Reconnect eletrode, means that the impedance of one of the electrodes is so high that either the electrode has lost contact with the skin or the electrode cable is disconnected or broken. All measurements are rejected while this message is displayed on screen.





- Leg is too low, means that the impedance between electrodes is so low that it is likely that two or more electrodes have short circuited. All measurements are rejected while this message is displayed on screen.
- Connect transducer, means that there is no transducer connected the PreAmp.
- Connect PreAmp, means that the PreAmp is not connected to the Titan.



- appears when more than one transducer, for example the Probe and Insert phones (or Headphones or EarCups) are connected to the PreAmp at the same time. You are required to select which transducer will be used prior to starting a test. After selection the required transducer, the other will be ignored as if it was not connected.
- 5. The **residual noise** level is only shown underneath the graph view when residual noise as a stop criterion has been selected in the protocol setup. 20-40nV is a typical residual noise range level at which you can conclude that there is such a limited amount of noise that if a hearing response could be measured, it should have become significant already. For example, if the residual noise limit was set to 30nV and during testing it reaches 30nV it will automatically stop the test and the result will be displayed as a REFER (if Pass/Refer labeling has been enabled for the selected protocol).
- 6. **Stop testing at ...** shows at which residual noise level the test will automatically stop and indicate a REFER (if Pass/Refer labeling has been enabled for the selected protocol)..

### NOTICE

The EEG level can be affected if the Titan is charging in the cradle during testing. It is advised not to charge the Titan during ABRIS testing.





## 3.7 Protocol setup and criterion

### 3.7.1 ABRIS protocol setup

To create or adapt your own personalized protocol you need to enter the Titan **Protocol Setup** menu.

1. From the ABRIS tab, Select Menu | Setup | Protocol Setup



- 2. Click on the **New** button and name your protocol.
  - a. You will be asked if you want to create a copy of the selected protocol. Select Yes, to copy the protocol settings of the selected protocol. Select No, to create the new protocol from default settings.

### 3.7.2 ABRIS settings

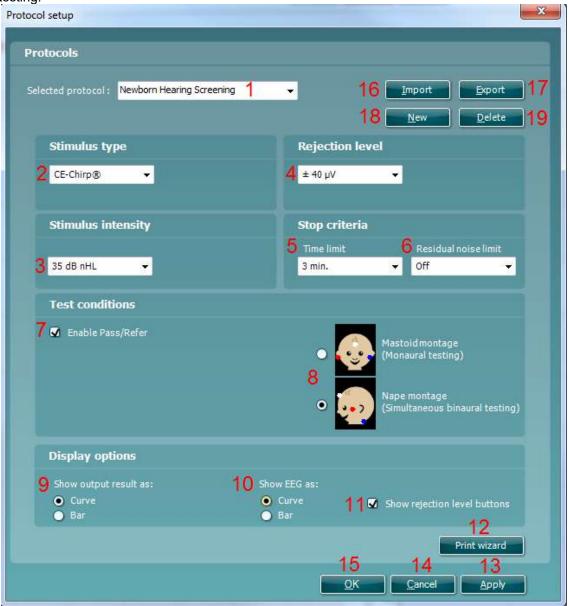
The following options are available in the **Protocol setup** window:

- 1. The **Selected protocol** shows the protocol name of which you are currently viewing/changing the settings. When creating a new protocol, you are requested to type the new protocol name in this field after pressing the **New** button (item 18).
- 2. **Stimulus type**. ABRIS allows testing with three different stimulus types:
  - Click which represents a traditional broadband click
  - CE-Chirp® which represents a broad band signal that compensates for travel time in the cochlea. The CE-Chirp® uses the same frequency characteristics as a traditional click, however by sending the lower frequencies a little earlier and the highest frequencies a little later into the cochlea, all frequencies activate their corresponding positions on the basilar membrane at the same time. As a result the ABR response of a CE-Chirp® is bigger and is much easier to detect compared to traditional click measurements. Screening with the CE-Chirp® will in general take less time and have a higher chance of reaching a pass in difficult testing circumstances
  - **HiLo CE-Chirp®** is using two CE-Chirp® stimuli. The lower stimulus covers the frequency up to 1.5kHz. The higher stimulus covers the frequency range above 1.5kHz. Using the HiLo CE-Chirp® therefore allows more frequency specific testing. Screening of the lower frequencies typically takes longer than the higher frequencies because it is more vulnerable to ambient noise
- 3. **Stimulus intensity**. Three different stimulus levels are available: 30, 35 or 40 dB nHL. When the HiLo CE-Chirp® is selected, there is an option to select a different intensity for the high and low portion of the stimulus.
- 4. The **Rejection level** dropdown menu allows you to set the EEG artifact rejection level that will be used by the preamplifier. Rejected measurements will make the EEG curve turn red when displayed in graph view and amber when displayed in bar view. When the **Show rejection level button** is checked under the display options (item 11), the amplifier gain button will appear on the test screen and can be modified from there.
- 5. The **Time limit** dropdown allows you to set how long the test will continue before it automatically stops testing. Test time refers to the total time used for testing. In other words, time used when measurements are being rejected is not taken into account.



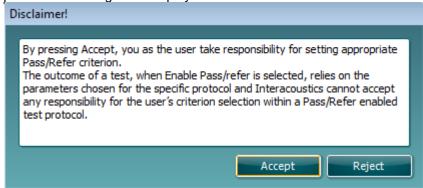


6. The **Residual noise limit** can be set as a stop criterion. When the residual noise reaches a low level (typically lower than 40 nV) the recording is so clean that a hearing response would have been detected if it was present. It may then be concluded that it is unlikely that a PASS will be reached by testing longer. To save time the test will be stopped if the residual noise limit is reached during testing.





7. **Enable Pass/Refer** should be checked when a pass/refer label is to be displayed based on the result outcome. When selected, the following disclaimer will appear and must be accepted for pass/refer labeling to be displayed.



If the enable pass/refer box is left unchecked, no pass/refer label will appear on the test screen when the test ends.

- 8. By selecting your **Electrode montage**, you set which picture is used for indicating electrode impedances. The montage selected also tells the system which is the active, reference and ground electrode. Note that binaural testing is only possible when the **Nape montage** is selected.
- 9. Show output result as: curve/bar allows you to set how the test results will be displayed. Bar view shows how the measurement is progressing over time as the bar fills from the bottom to the top. When the bar is completely full, this equates to reaching the pass criterion. Graph view of the measurement shows which percentage of the pass criterion is reached as a function of time. Thus reaching 100% equals to reaching the pass criterion. The graph presentation allows a more detailed view of how the measurement over time progresses. However, the trajectory of the measurement or steepness of the curve depends on many independent factors and does not add any value to the screening result.
- 10. Show EEG as: curve/bar allows you to set the default display of the patient noise and EEG information. Bar view will display the patient noise as EEG peak levels. Levels that exceed the rejection level turn amber. Graph view shows the raw EEG on a 10 ms time line. The EEG curve turns red when measurements are being rejected.
- 11. When **Show rejection level buttons** is selected, you are allowed you to change the rejection level from the test screen.
- 12. Pressing the **Print wizard** button opens the Print wizard window from where you can select which print template is used as a default for the current protocol.
- 13. Pressing **Apply** will apply any new settings made or changed within a protocol.
- 14. Pressing **Cancel** will close the protocol setup window and return you to the testing screen without saving any changes.
- 15. Pressing **OK** closes the protocol settings window after automatically saving all changes.
- 16. Pressing the **Import** button opens a dialog window that allows you to import ABRIS protocols.
- 17. Pressing the **Export** buttons opens a dialog window that allows you to export an ABRIS protocol to file that can be read by the Titan Suite.
- 18. Pressing **New** creates a new protocol. You have to start by entering a unique protocol name.
- 19. Pressing **Delete** deletes the selected protocol following on-screen confirmation. .





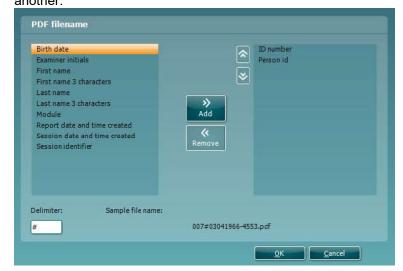
## 3.8 General setup

The **General setup** can be opened by clicking **Menu | Setup | General setup...** and offers the following options:



The **Print button** can be set up to automatically print to PDF.

- a. Check the PDF print enabled box to set the print icon to print to PDF functionality.
- b. Check the Open after print box to open the PDF document after printing.
- c. Select the File location to where the PDF document should be saved.
- d. Select File name to define the name of the file. Selecting the button will open another window to set the fields defining the name of the PDF file.
  A field called "ID Number" must be added to the PDF file. Use the arrow keys to add fields to the file name. The adjustable delimiter will separate the different fields from one another.







## 3.9 User guide

The User Guide can be displayed on startup of the ABRIS440 module to assist the user with patient preparation or test procedures.

The setup is accessed by going to Menu | Setup | User guide setup...

The default setup for the User Guide has preselected guidance pictures and text. All four guide pictures and test instructions are selected and **Show user guide when module starts** is checked.

User guide setup

Clean the skin where the electrodes will be placed using alcohol wipes and/or altrasive preparation gel.

Show

Sh

The following options are available:

- 1. Right clicking on the **Picture** allows you to add a new picture to assist with guidance. A Microsoft window will open allowing you to select pictures stored elsewhere on your PC. Navigate to and select the desired image and then click Open. The picture will be replaced with your chosen one.
- The **Text** can be edited the text in the text box by simply placing the cursor in the white box with your mouse.
- 3. There are four available guidance pictures with text. Uncheck **Show** on the ones you do not want shown when the User guide is displayed.
- 4. Uncheck **Show user guide when module starts** if you do not want the User Guide to appear on the screen each time the module starts.
- 5. **Reset guide** allows you to reset the guide pictures and text to the default settings (English language) as when the software was installed.
- 6. Pressing **OK** will accept any changes made and will close down the User Guide setup
- 7. Cancel will close down the User Guide setup without saving any changes made.

## 3.10 PC shortcuts

For quick operation from the keyboard the following shortcuts are available:

L - switch to left ear
R - switch to right ear
B - switch to both ears

Space - start or stop the measurement

Ctrl S - save and new

Ctrl P - print

Page up - go one up in saved sessions
Page down - go one down in saved sessions

Arrow up - increase rejection level (only while rejection level controls are visible)
Arrow down - decrease rejection level (only while rejection level controls are visible)

Home - takes you back to current session from a saved session

End - takes you to the last saved session in the list



# $\mathcal{M}$





## **4 DPOAE440**

### 4.1 About DPOAE440 module

The Titan with DPOAE440 is intended for use in the diagnostic audiologic evaluation and documentation of ear disorders using Distortion Product Otoacoustic Emissions. The target population for Titan with DPOAE440 includes all ages.

The Titan with DPOAE440 is designed to be used only by skilled personnel 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.

The DPOAE440 contains the following tests:

- DP-Gram
- ▶ DP-I/O Test

Availability of these tests or specific settings within these tests on the hardware or in the software depend on the license purchased.

## 4.2 Preparing for the test

### **DPOAE** patient Instruction

Place the patient on a 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, talking and swallowing will disturb 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.

### 4.3 The DPOAE440 menu items

From the main menu, the following options are available - **Setup**, **Print**, **Edit** or **Help**. The menu has the following structure:

**Menu | Setup | Protocol setup...** to enter the Titan Setup where the settings of DPOAE protocols can be viewed and changed. If data is measured before you enter the protocol setup, you are prompted to save or discard the data.

**Menu | Setup | Temporary setup...** to enter the protocol settings and make changes which are only valid during the current session. If temporary changes are made to a protocol, its name appears ending with an asterisk. If data is measured before you enter temporary setup you are prompted to save or discard the data. In temporary setup the same options are available as in the normal protocol settings.

**Menu | Setup | Show/hide protocols...** to enter the setup to choose which protocols are available during the PC controlled measurements.





**Menu | Setup | General setup....** to enter the DPOAE general setup where you can set norm data preferences, icons to be shown on the graphs, the default Suite startup ear and PDF printing options.

Menu | Setup | User guide setup... to edit the pictures and instructions displayed in the user guide.

**Menu | Setup | Norm data setup...** to enter the setup where norm data can be entered. The norm data range can be displayed on the DP-Gram as an indication at which levels OAEs are normally expected.

**Menu | Setup | Password protection...** to change and/or activate password protection for the complete Titan Suite. When activated users cannot enter the **Protocol setup** or **User guide setup**.

Menu | Setup | Unlock protection... to temporarily disable password protection.

Menu | Setup | Language to change the language used in the software.

Menu | Setup | Simulation mode... to activate simulated testing with simulated hardware.

**Menu | Print | Print...** to print the current measurement using the print template that is linked to the current protocol. You will enter the print window from where you can select your printer and change settings before printing. Note that you are prompted to select a template if the protocol did not include a template.

**Menu | Print | Print preview...** to see a print preview of the current measurement using the print template that is linked to the current protocol. Note that you are prompted to select a template if the protocol did not include a template.

**Menu | Print | Print wizard...** to open the print wizard window from where you can select a template to print the current measurement.

Menu | Edit | Export... to export the current measurement to an XML file.

Menu | Help | About... brings you to an information window which displays the following:

- Titan Suite version
- Hardware version
- Firmware version
- Copyright Interacoustics 2009

Further, you can reach the Interacoustics website by pressing the link to <a href="www.interacoustics.com">www.interacoustics.com</a>
By pressing the License button, you are able to change the license keys of the Titan Suite. The license keys for the Titan 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 | Instructions for use... to open the digital version of the Instructions for Use manual.

Menu | Help | Additional information... to open the digital version of the Additional Information manual.



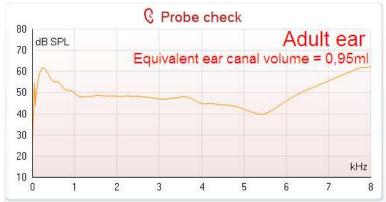


## 4.4 General operation of DPOAE440

### 4.4.1 Probe check

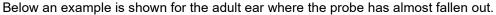
Interpreting probe check information from a graph is not always easy. Therefore, the quality control that is required to perform a proper DPOAE measurement is fully automated. In other words, with the Titan, it is not necessary to monitor probe check information yourself, but you are of course welcome to do so. The following paragraphs give a few ideas about the information that can be gained from the probe check graph.

The stimulus that is used for the probe check is a broad band click. It is calibrated to give a reasonably flat response between 200Hz and 8000Hz when measured by calibration equipment. When presented in the ear and recorded by the probe microphone it typically results in a graphic like the one shown below.



It is generally said that when the best probe placement is achieved, the probe check will show a flat response over a wide frequency area. However, because the probe microphone is used for this monitoring, the intensities at the eardrum will be slightly different from those displayed on the graph. Therefore, a dip, like in this example, around 5 kHz is normal and represents the situation measured at the end of the probe whereas at the eardrum the intensities are approximately the same as for the other frequencies.

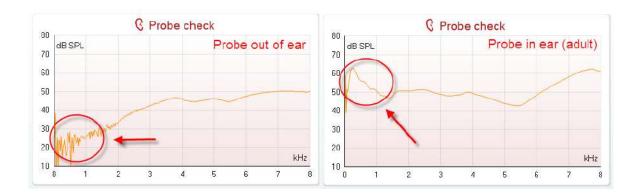
When monitoring the probe check graph, you will normally also see noise that is being picked up by the system. A probe that is slowly moving out of the ear can be recognized by the typical frequency dip moving to a lower frequency range.





Looking at the low frequency area of the graph will also give you information about whether or not the probe is in the ear.





### 4.4.2 DP-Gram bar view

The DP-Gram can be shown in bar view or graph view. Your preference for these views is defined in the protocol setup and can also temporarily be changed in the temporary settings.

The following information can be found in the DP-Gram bar view:



- 1. The result can be labeled with **Pass** or **Refer** and is indicated above the measurement as soon as the result is available. A user defined Pass/Refer criterium can be enabled within the protocol setup. When **Enable Pass/refer** is used, if the measurement is stopped before completion of the test, **Incomplete** will appear in the label.
- 2. The **Bar representation** shows the progress over time for each frequency measured in a bar graph format. When a bar becomes completely filled and changes to green, it has reached the stop criterion set in the protocol. Those bars that do not meet the stop criterion will remain in the color of the selected ear (red or blue).
- 3. In addition, **check marks** above the green bars indicate that those frequencies have reached their stop criterion. When a user defined Pass/refer protocol has been created, although several bars might turn green it does not necessarily mean that it will result in a pass. For example, within the protocol setup it can specified that particular frequencies are mandatory for reaching an overall pass.

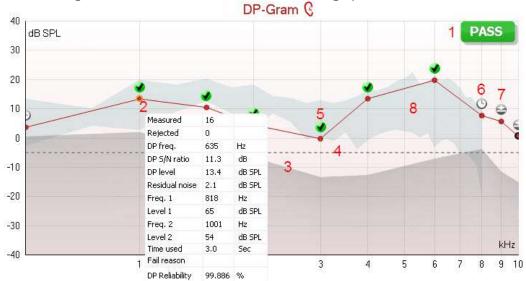




## 4.4.3 DP-Gram graph view

The DP-Gram can be shown in bar view or graph view. Your preference for these views is defined in the protocol setup and can also temporarily be changed in the temporary settings.

The following information can be found in the DP-Gram graph view:



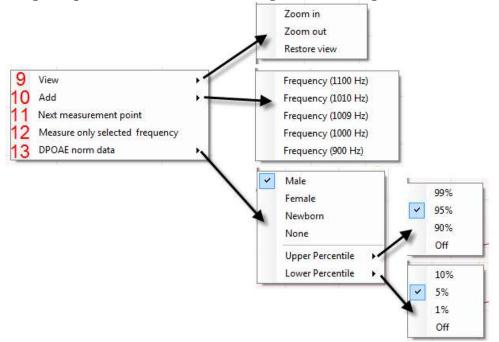
- The result can be labeled with Pass or Refer and is indicated above the measurement as soon as
  the result is available. A user defined Pass/Refer criterium can be enabled within the protocol setup.
  When Enable Pass/refer is used, if the measurement is stopped before completion of the test,
  Incomplete will appear in the label.
- Each Measurement point shows the absolute DPOAE level in dB SPL as a function of frequency. Selecting a measurement point by a left mouse click will show its details in the Response & Zoom graph. Hovering the mouse over a measurement point allows you to see the following details for that point:
  - Measured indicates how many measurement samples were taken to get to the current result
  - **Rejected** indicates how many samples were rejected due to too much noise
  - **DP freq.** refers to the frequency (in Hz) where the main DPOAE can be expected. That is the 2f<sub>1</sub>-f<sub>2</sub>
  - **DP S/N ratio** indicates the difference between the absolute value of the DPOAE and the noise floor around the **DP freq**. This difference is the signal to noise ratio. Note that calculations are done with raw numbers after which rounding off takes place. Therefore, the mathematical difference between the presented DP level and Residual noise level might differ slightly from the given number
  - DP level indicates the absolute value of the DPOAE in dB SPL
  - Residual noise indicates the average noise level (in dB) around the DP freq.
  - Freq.1 refers to the frequency of the first stimulus in Hz
  - Level 1 refers to the intensity of the first stimulus in dB SPL
  - Freq. 2 refers to the frequency of the second stimulus in Hz.
  - Level 2 refers to the intensity of the second stimulus in dB SPL
  - Time used displays the number of seconds that was spent measuring this frequency
  - **Fail reason** indicates why the individual measurement did not meet the specified criterion as set in the protocol. Reasons displayed include:
    - S/N meaning that the specified signal to noise ratio was not reached
    - **DP tol.** meaning that the **DP level** fluctuated too much over time
    - Min IvI meaning that the DP level did not reach the minimum required level
  - DP relia. meaning that the DP reliability is not sufficient
  - **DP Reliability** indicates the certainty that the measured OAE is not part of the noise within the same frequency area





- 3. The **noise floor** is indicated by the upper limit of the gray area. The distance between the noise floor and the measurement point defines the DP signal to noise ratio.
- 4. The **minimum required DP level** is shown as a dotted line across the graph. DPOAEs detected below the dotted line are considered to be insignificant.
- 5. The **DP found checkmark symbol**, a black checkmark in a green circle, indicates that this individual measurement met its specified criterion.
- 6. 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. It is displayed during testing when "Include DP criteria as stop criteria" is deselected in the protocol setup. To hide this indicator from the test screen, de-select it in the General setup.
- 7. 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.
- 8. Optionally, **DP norm data** can be imported or added to the software and is shown as a shaded area in the graph. The norm data can be used to indicate where DPOAEs might be expected for a normal population. Within the general setup you can set whether or not the norm data area is to be displayed. When norm data is displayed on the test screen, it will also appear on the print report.

Using the right mouse click on the DP-Gram gives the following additional functions:



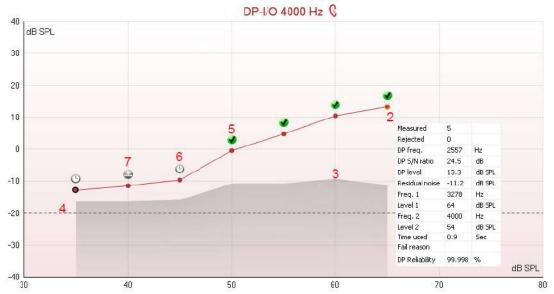
- 9. The **scroll wheel** of your mouse allows zooming in and out with respect to the frequency axis. Additionally, you can **Zoom in**, **Zoom out** or **Restore view** by selecting the appropriate item from the right mouse click menu.
- 10. Add an additional frequency after testing of the original 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.
- 11. **Next measurement point** interrupts the automatic test procedure and forces the Titan to start testing the next frequency immediately. This function is available when max test point has been selected in the protocol.
- 12. **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.
- 13. **DPOAE norm data** allows you to change which DP norm data is shown in the DP-Gram.





## 4.4.4 DP-I/O (DP-input/output)

The following information can be found in the DP-I/O graph:



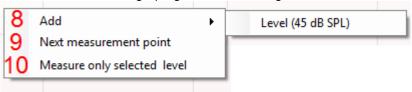
- 1. The results of the test are shown in the DP-I/O graph.
- 2. Each **Measurement point** shows the absolute DPOAE level in dB SPL as function the stimulus level for the tested frequency. Selecting a measurement point by a left mouse click will show its details in the **Response & Zoom graph**. Hovering the mouse over a measurement point allows you to see the following details for that point:
  - Measured indicates how many measurement samples were taken to get to the current result
  - Rejected indicates how many samples were rejected due to too much noise
  - **DP freq.** refers to the frequency (in Hz) where the main DPOAE can be expected. That is the 2f<sub>1</sub>-f<sub>2</sub>
  - **DP S/N ratio** indicates the difference between the absolute value of the DPOAE and the noise floor around the **DP freq**. This difference is the signal to noise ratio. Note that calculations are done with raw numbers after which rounding off takes place. Therefore, the mathematical difference between the presented DP level and Residual noise level might differ slightly from the given number
  - DP level indicates the absolute value of the DPOAE in dB SPL
  - Residual noise indicates the average noise level (in dB) around the DP freq.
  - Freq.1 refers to the frequency of the first stimulus in Hz
  - Level 1 refers to the intensity of the first stimulus in dB SPL
  - Freq. 2 refers to the frequency of the second stimulus in Hz
  - Level 2 refers to the intensity of the second stimulus in dB SPL
  - Time used displays the number of seconds that was spent measuring this frequency
  - **Fail reason** indicates why the individual measurement did not meet the specified criterion as set in the protocol. Reasons displayed include:
    - S/N meaning that the specified signal to noise ratio was not reached
    - DP tol. meaning that the DP level fluctuated too much over time
    - Min IvI meaning that the DP level did not reach the minimum required level
  - **DP relia.** meaning that the **DP reliability** is not sufficient
  - **DP Reliability** indicates the certainty that the measured OAE is not part of the noise within the same frequency area
- 3. The **noise floor** is indicated by the upper limit of the gray area. The distance between the noise floor and the measurement point defines the DP signal to noise ratio.
- 4. The **minimum required DP level** is shown as a dotted line across the graph. DPOAEs detected below the dotted line are considered to be insignificant.
- 5. The **DP found checkmark symbol**, a black checkmark in a green circle, indicates that this individual measurement met its specified criterion.





- 6. 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.
- 7. 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.

Using the right mouse click on the DP-I/O graph gives the following additional functions:

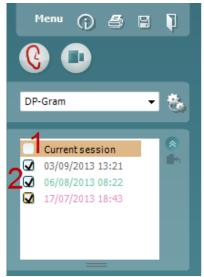


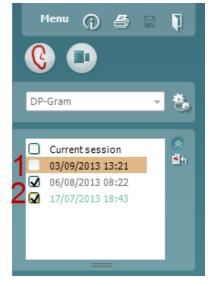
- 8. Add an additional level after testing of the original protocol has finished. Point and right click your mouse at the frequency that you would like to test. Click on Add then select an available level to additionally measure. After adding one or more levels you will notice that the Start button changes to say Continue. Clicking Continue will measure all inserted levels without a time limit. Press Stop when the additional points are sufficiently tested.
- 9. **Next measurement point** interrupts the automatic test procedure and forces the Titan to start testing at the next intensity immediately. This function is available when max test point has been selected in the protocol.
- 10. **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.

## 4.4.5 Comparing DPOAE data (historic overlay)

Multiple DPOAE sessions can be compared using the overlay function. This can be either the current session and multiple historic session or two or more historic sessions.

- 1. Highlight the first session for comparison by clicking on the date or Current session text. This will display the DPOAE results for the selected session.
- Select the session/s for comparison by checking the box beside the session date/time. The
  overlayed session/s will appear on the DP-Gram graph in various colors corresponding to the colors
  of the session date/time. The dotted line of an overlayed session indicates the noise floor for the
  specific session.

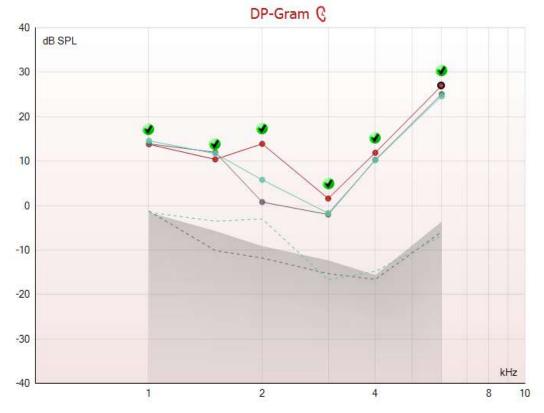








Note, when the first session for comparison is selected, only comparable sessions show an active checkbox.



Sessions that are not compatible for comparison cannot be selected. This includes:

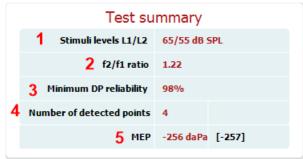
- 1. Sessions where a Pass/Refer label is given (as enabled in the protocol setup),
- 2. DP-Gram test results cannot be compared with DPO I/O tests results.

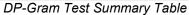
## 4.4.6 Printing the overlaid sessions

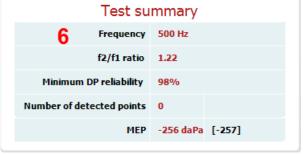
When the historic overlay function is used on the test screen, the overlaid graph will automatically appear on the print template. The DP point summary and DP test summary table information on the printout reflects the session that was selected first.

## 4.4.7 Test summary table

The **test summary table** is updated during testing and displays information about the DPOAE measurement recorded.







DP I/O Test Summary Table



The following information is displayed in the **test summary table**:

- 1. Stimulus levels L1/L2 displays the L1 and L2 stimulus levels in dB SPL
- 2. **f2/f1 ratio** displays the ratio between the f1 and f2 frequencies.
- 3. **Min. DP reliability** displays the min DP reliability percentage required for detection of a DPOAE as selected in the protocol setup.
- 4. No. of detected points indicates the number of DP points detected during testing.
- 5. **MEP** indicates the actual pressure (left) and target pressure from tympanogram (Square brackets). Only when a pressurized test is performed.
- 6. Frequency displays the DP I/O test frequency in Hz.

## 4.4.8 Point summary table

The **point summary table** is updated during testing and displays information for each DPOAE measurement recorded.

The following information is displayed in the **point summary table**:

Point summary									
	1 f2 (Hz)	DP level (dB SPL)	Noise (dB SPL)	5NR	Reliab.	Detected			
	1000	12.2	-5.4	17.6	100.0	4			
	1500	11.3	-12.0	23.3	100.0	4			
	2000	7.2	-11.9	19.1	100.0	4			
	3000	-0.1	-15.3	15.2	99.5	4			
	4000	9.6	-17.2	26.8	100.0	4			
	6000	24.3	-5.1	29.4	100.0	•			

7	Point summary							
Level (dB SPL)	DP level (dB SPL)		SNR	Reliab. (%)	Detected			
45	5.1	-13.2	18.3	100.0	*			
50	6.9	-15.9	22.8	100.0	*			
55	4.6	-13.2	17.8	100.0	*			
60	-2.5	-8.5	6.0	98.4	4			
65	-5.3	-14.2	8.9	99.3	4			
70	10.2	-11.6	21.8	100.0	•			

DP-Gram Point Summary Table

DP I/O Point Summary Table

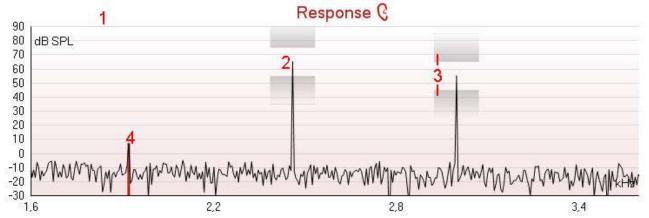
- 1. **Frequency** displays the f2 frequency in Hz.
- 2. **DP level** displays the DP level measured in dB SPL for the specific frequency.
- 3. Noise displays the noise for the specific frequency in dB SPL
- 4. **SNR** displays the signal to noise ratio.
- 5. **Reliab** displays the reliability percentage for the specific frequency.
- 6. **Detected** displays a **check mark** when the specified DP point has met the criteria for a present DPOAE.
- 7. Level displays the stimulus level in dB SPL.





### 4.4.9 Response and zoom graph

The following information can be found in the response & zoom graphs. Zooming in and out is possible by using the scroll wheel of your mouse.



- 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.
- 2. The two test stimuli are easily recognized as the two peaks in the response graph.
- 3. The **stimulus tolerance** is indicated by two shaded areas above and below the peak of the stimulus. As long as the peak stays in between the shaded areas the stimulus intensity is acceptable. The system automatically generates a warning when one of the stimuli is outside its tolerance.
- 4. The **DPOAE frequency** at which the main distortion product is expected, at 2f<sub>1</sub>-f<sub>2</sub>, is indicated as a colored bar (red or blue depending on the selected ear). Within the example above it is easy to identify that the DPOAE peak is significantly above the noise floor. When zooming in on this peak the residual noise floor can be seen on the graph and is indicated by gray shading behind the curve.

### 4.4.10 Probe status and stimuli tolerance

Before testing, the probe status is monitored and the probe status bar will change color and indicate whether the probe is in ear, out of ear or blocked. On pressing the START button, the probe status becomes inactive (grey) as it is no longer being monitored.

During testing, the stimuli tolerance is constantly being monitored for each frequency. The probe microphone monitors the output from the two speakers, ensuring that the intensity output by the two speakers remains within a specified range (stimuli tolerance). When the stimulus intensity cannot be kept within the specified range, a pop-up will appear.



Typically, this indicates that a seal has been lost between the probe ear tip and the ear canal or has moved within the ear canal. Check the probe to ensure it is not blocked and/or replace the probe in the patient's ear if it has come lose.

When the probe is reinserted, the dialog box will automatically disappear once the stimuli tolerance has been reached and testing will continue.

If the stimuli tolerance cannot be reached after replacing the probe in the patient's ear, the user can press **Skip**. This will skip the testing the current test frequency.



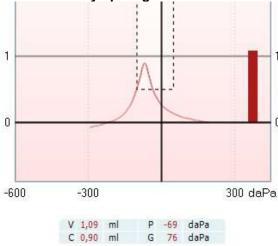


### 4.4.11 Pressurized DPOAE testing

The pressurization function within the DPOAE440 module allows for testing at the tympanometric peak pressure recorded in the IMP440 module. Research (Sun & Shaver, 2009) indicates that negative middle ear pressure has the effect of decreasing DPOAE amplitudes, particularly at frequencies ≤ 1 kHz. Compensation of the negative middle ear pressure, by equalizing the pressure on both sides of the tympanic membrane, has the effect of increasing the DPOAE amplitudes (at the lower frequencies) and detection is improved. This may be clinically useful when trying to determine cochlear hair cell function in the presence of negative middle ear pressure.

In order to perform a pressurized measurement, a **tympanogram** must first be measured in the **IMP440** module.

1. Record the **tympanogram/s** in the IMP440 module (do not save the results).



- 2. Go to the **DPOAE440** module and select a protocol using pressurization or change the protocol to run at **Peak pressure**.
- 3. The **peak pressure**, as detected in the **IMP440** module will appear on the screen.



4. Press **START** to measure.

Sun, X., & Shaver, M.D. (2009). Effects of negative middle ear pressure on distortion product otoacoustic emissions and applications of a compensation procedure in humans. *Ear & Hearing*, *30*(2), 191-202.



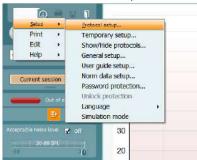


## 4.5 Protocol setup and criterion

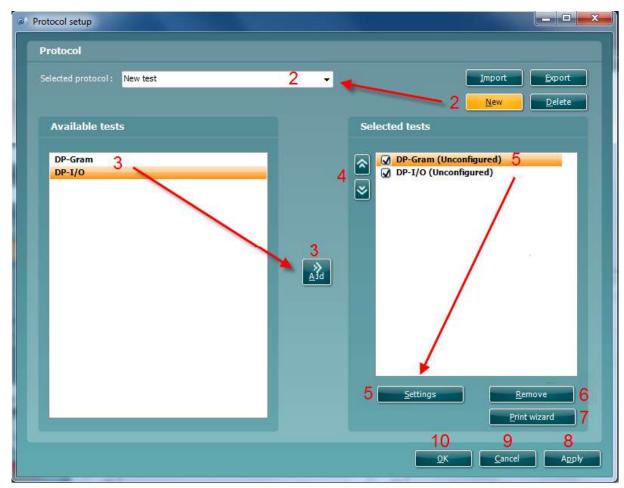
## 4.5.1 DPOAE protocol setup

To create or adapt your own personalized protocol you need to enter the Titan Protocol Setup menu.

1. From the **DPOAE** tab, Select **Menu | Setup | Protocol Setup...** 



- 2. Click on the **New** button and name your protocol.
  - a. You will be asked if you want to create a copy of the selected protocol. Select Yes, to copy the protocol settings of the selected protocol. Select No, to create the new protocol from default settings.
- 3. Select the test you want to include in your protocol from the list on the left and press **Add**. Alternatively, double click on the test you want to include.



4. The **arrow** buttons allow you to modify the order of the tests.



- 5. Select the test on the right that you want to modify the settings for and click on **Settings**. Alternatively, double click on the selected test. The **Test setup** window will open where the test settings are specified. Note that a test will show "(unconfigured)" beside it if it does not contain any settings. You must configure a test before you can save and exit the protocol setup.
- 6. The Remove test button is used to remove a test from the Selected tests list.
- 7. The **Print wizard** button takes you to the area where a print layout can be created and/or linked to the selected protocol.
- 8. Pressing Apply will apply any new settings made or changed within a protocol.
- 9. Pressing **Cancel** will close the protocol setup window and return you to the testing screen without saving any changes.
- 10. Pressing **OK** closes the protocol settings window after automatically saving all changes.

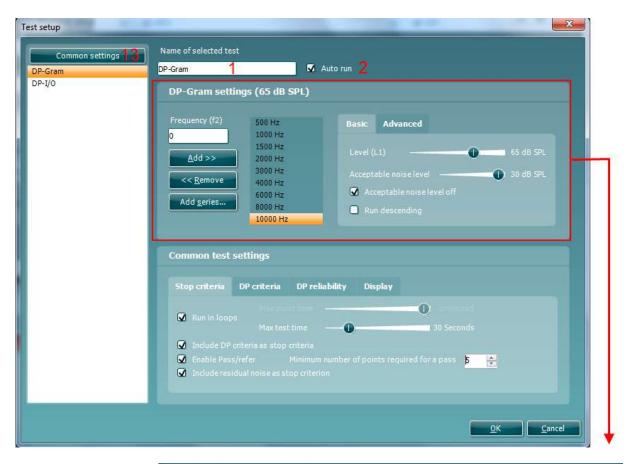
### 4.5.2 DP-Gram test settings

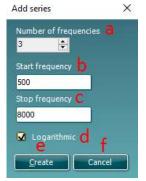
The following options are available in the **DP-Gram** test:

- 1. **Name of selected test**. You can choose to have more than one of the same type of tests in your protocol. You may therefore want to give each test an individual name, so it will be easier to recognize when running the complete test protocol.
- 2. The **Auto run** checkbox defines which tests will run automatically, one after the other, when START is pressed. Note that when a protocol is used on the hand held unit, all tests will always be executed in the order they are in the protocol setup.
- 3. The **f**<sub>2</sub> **frequencies** to be used in the DP-gram are added to the frequency listing after typing them in and pressing **Add**.
- 4. Pressing **Add series...** opens the **Add series** window in which a series of frequencies can be added in the following way:
  - At Number of frequencies type in the number of frequencies that you would like to be part
    of the series.
  - b. Define the Start frequency.
  - c. Define the Stop frequency.
  - d. Indicate if the series should spread the frequency evenly according to a logarithmic scale. If unchecked a linear scale distribution will be used.
  - e. Press Create to add the series to the frequency listing.
  - f. Press Cancel to cancel out of the Add series window.
- 5. Press **Remove** to delete a selected frequency from the list.
- 6. At **Level (L<sub>1</sub>)** (under the **Basic** tab) the intensity at which the first stimulus f<sub>1</sub> is presented is defined. The intensity of f<sub>1</sub> is often referred to as the 'stimulus level'.
- 7. At **Acceptable noise level**, set the initial acceptable noise level limit between -30 and +30 dB SPL above which recordings are considered to be too noisy. During testing the acceptable noise level can be changed using the slider bar on the control panel.
- 8. Checking the **Acceptable noise level off** box will disable the rejection of any recordings even when there is too much noise in the recording.
- 9. Activating **Run descending** makes the testing run from the highest down to lowest frequency. By default this option is disabled and the testing starts from the lowest to highest frequency.

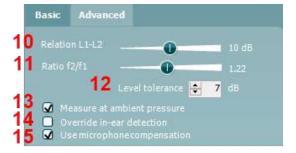


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- 10. The **Relation L**<sub>1</sub> **L**<sub>2</sub> (under the **Advanced** tab) sets the difference in intensity level between the two stimuli (in dB).
- 11. The Ratio f2/ f1 sets the ratio relationship between the two stimulus frequencies.





- 12. The **Level tolerance** defines the range within which the presented intensity of the stimuli is still acceptable. The number indicates the allowed difference in both a positive and negative direction from the intensity settings. More information about this can be viewed in the **Response & zoom graph.**
- 13. When **Measure at ambient pressure** is checked, the test will run at ambient pressure (0 daPa). When unchecked, the module will use the peak pressure measured in the IMP module.
- 14. When **Override in-ear detection** is checked, ear canal volume is not considered for the stimulus. Instead, the protocol will use a 711 coupler calibration as reference for the stimulus level. This functionality can be useful when in-ear detection is not possible to achieve because of a perforated eardrum or a PE-tube.
- 15. When the checkmark **Use microphone compensation** is checked, a method of stimulus control is activated to ensure accurate stimulus levels for small as well as large ear canals. For technical purposes, e.g. when testing the equipment against IEC 60645-6, the method can be deactivated.

### 4.5.3 Common test settings for a DP-gram test

The common test settings area is divided into four tabs – **Stop criteria**, **DP criteria**, **DP reliability**, and **Display**. The following options within each tab are described below.

### Stop criteria

- 1. When **Run in loops** is selected, the **Max test time** option is available. Here you define how long the total DP-Gram test may take until it stops automatically by using the slider. Each test point (frequency) will be measured for a short period of time (approx 3 seconds) before continuing to the next one. After reaching the last test point in the series, it loops back to the first test point and will continue testing for all points that have not yet met the stop criterion until the maximum test time has been reached.
- 2. A **Maximum point time** can be set when **Run in loops** in unchecked/disabled. In this instance, each test point (frequency) will only be tested once for the set point time before it times out, unless it meets the stop criterion prior.
- 3. Selecting **Include DP criteria as stop criteria** results in the system measuring a specific point for no longer than needed to meet the DP criteria as setup on the next tab.
- 4. Checking **Enable pass/refer** results in the system labeling an overall test as either a **Pass** or **Refer** based on user defined **DP criteria**. If the measurement is stopped before completion of the test, **Incomplete** will appear on the label. When **Enable pass/refer** is checked the following disclaimer window will appear. You must press Accept to continue creating a pass/refer protocol.

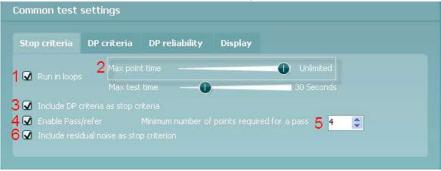


5. The **Minimum number of points required for a pass** must also be set. The overall Pass or refer result will depend on whether the minimum number of individual frequencies reached the DP criteria. The overall result may also depend on whether all mandatory test points have reached the DP criteria as well (see item 12 below for more information).





6. Selecting Include residual noise as stop criterion causes the system stop testing at a frequency for which the residual noise has reached its indicated residual noise floor. The measurement at the specific frequency is considered to be so silent that a DPOAE would have been detected, if it were present. Measurements that reach the noise floor will stop testing and the result will indicate that the DP criteria was not met for the individual point.



### DP criteria

Under the **DP criteria tab** both pass and stop criteria are defined for each individual added frequency point. **Include DP criteria as stop criteria** and **Enable Pass/refer** from the **Stop criteria tab** use the settings here to determine whether a measured point meets the stop criteria, passes or refers. Note that all criterion in the row for the selected frequency must be met in order for it stop, pass or refer. Each individual criterium on its own is not sufficient.

- 7. To change more than one frequency's settings at the same time, use the **check boxes** beside the required frequencies. Check the box next to **f2** to select or de-select all frequencies in the list.
- 8. **Min. DP IvI.** Is the minimum level (in dB SPL) that an OAE must be measured at for it to meet the stop criterium.
- 9. **SNR** is the minimum signal to noise ratio that must be reached to meet the stop criteria. The signal to noise ratio (in dB) is the difference between the DPOAE level and the residual noise level.
- 10. **DP tolerance** defines how stable the OAE level must be over time in order for it to meet the stop criteria. The **DP tolerance** can be set to off, ±2 dB or ±4 dB.
- 11. **Residual noise** allows you to define at which level the residual noise is considered to be so silent that a DPOAE would have been detected, if it were present. When the measured residual noise reaches the defined level, the measurement is stopped. Therefore, test time can be saved by enabling this feature.
- 12. **Required for pass** is where you define which measurement points are mandatory to reach a pass when **Enable Pass/refer** is checked for an overall result.



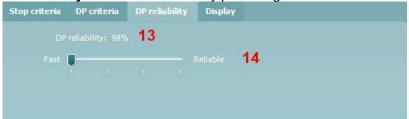




## **DP** reliability

The **DP reliability tab** indicates and allows you to set how reliable the DPOAE measurement must be in order to allow the system to accept the measurement as a true DPOAE. Basically, the OAE is compared to the noise surrounding it and then the reliability represents the chance that the OAE is indeed not part of the noise. For this comparison, it is assumed that the noise is normally distributed.

13. **DP reliability** indicates the reliability percentage that has been set.



- 14. The **slider** allows you to set the reliability percentage. The lower the percentage, the faster testing can occur, however the reliability of the measurement will be less. The options available are:
  - a. 98%
  - b. 99%
  - c. 99.9%
  - d. 99.99% (Reliable)

By default, the DP reliability is set to 98%. For diagnostic testing we recommend using a reliability of at least 99.9% because that allows making conclusions for individual measurement points.

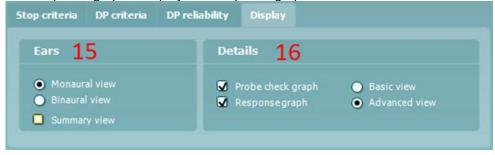
### **Display**

Under the **Display tab**, options are available for setting how the results will be displayed on the test screen.

- 15. Under **Ears**, you can select:
  - a. **Monaural view** displays one ear at a time on the test screen
  - b. Binaural view displays both ears on the test screen
  - c. **Summary view** displays the test summary and point summary tables on the test screen. This option is only available when **monaural view** is selected.

These views can also be toggled temporarily on the test screen using the **monaural/binaural view** and/or **summary view** icons.

- 16. Under **Details**, you can select:
  - a. Basic view displays a simple bar view of the result.
  - b. Advanced view displays a detailed view of noise and OAE response points on the graph.
  - c. Probe check graph displays the probe check graph on the test screen.
  - d. Response graph displays the response graph on the test screen.







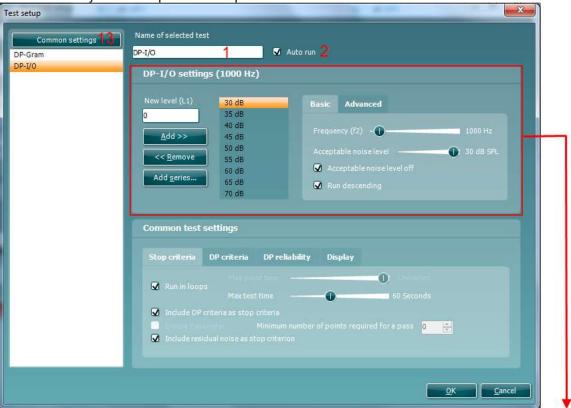
## 4.5.4 DP-I/O settings

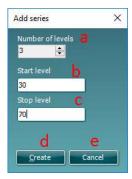
The following options are available in the **DP-I/O** test:

1. **Name of selected test**. You can choose to have more than one of the same type of tests in your protocol. You may therefore want to give each test an individual name, so it will be easier to recognize when running the complete test protocol.

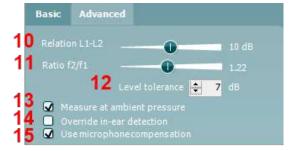
The Auto run checkbox defines which tests will run automatically, one after the other, when START is pressed. Note that when a protocol is used on the hand held unit, all tests will always be executed

in the order they are in the protocol setup.













- 3. The L<sub>1</sub> levels to be used in the DP-I/O test are added to the intensity levels listing after typing them in and pressing **Add**.
- 4. Pressing **Add series...** opens the **Add series** window in which a series of intensity levels can be added in the following way:
  - a. At **Number of levels** type in the number of intensities that you like to be part of the series.
  - b. Define the **Start level**.
  - c. Define the Stop level
  - d. Press Create to add the series to the intensity level listing.
  - e. Press Cancel to cancel out of the Add series window.
- 5. Press **Remove** to delete a selected intensity from the list.
- 6. **Frequency (f2)**, (under the **Basic** tab) defines the frequency to be used in the Input/Output test. User the slider and the right and left arrow keys on your keyboard to set the **f2 frequency**.
- 7. At **Acceptable noise level** set the initial acceptable noise level limit between -30 and +30 dB SPL above which recordings are considered to be too noisy. During testing the Acceptable noise level can be changed using the slider bar on the control panel.
- 8. Checking the **Acceptable noise level off** box will disable the rejection of any recordings even when there is too much noise in the recording.
- 9. Activating **Run descending** makes the testing run from the highest down to lowest intensity. By default, this option is enabled, and the testing starts from the highest to the lowest intensity.
- The Relation L1 L2 (under the Advanced tab) sets the difference in intensity level between the two stimuli (in dB).
- 11. The Ratio f2/ f1 sets the ratio relationship between the frequencies of the two intensities. .
- 12. The **Level tolerance** defines the range in within the presented intensity of the stimuli are still acceptable. The number indicates the allowed difference in both positive and negative direction from the intensity settings. More information about this can be viewed in the **Response & zoom graph.**
- 13. When **Measure at ambient pressure** is checked, the test will run at ambient pressure (0 daPa). When unchecked, the module will use the peak pressure measured in the IMP module.
- 14. When **Override in-ear detection** is checked, ear canal volume is not considered for the stimulus. Instead, the protocol will use a 711 coupler calibration as reference for the stimulus level. This functionality can be useful when in-ear detection is not possible to achieve because of a perforated eardrum or a PE-tube.
- 15. When the checkmark **Use microphone compensation** is checked, a method of stimulus control is activated to ensure accurate stimulus levels for small as well as large ear canals. For technical purposes, e.g. when testing the equipment against IEC 60645-6, the method can be deactivated.





## 4.5.5 Common test settings for a DP-I/O test

The common test settings area is divided into four tabs – **Stop criteria**, **DP criteria**, **DP reliability**, and **Display**. The following options within each tab are described below.

### Stop criteria



- 1. When Run in loops is selected, the Max test time option is available. Here you define how long the total DP-I/O test may take until it stops automatically by using the slider. Each test point (intensity) will be measured for a short period of time (approx. 3 seconds) before continuing to the next one. After reaching the last test point in the series, it loops back to the first test point and will continue testing for all points that have not yet met the stop criterion until the maximum test time has been reached.
- 2. A **Maximum point time** can be set when **Run in loops** in unchecked/disabled. In this instance, each test point (intensity) will only be tested once for the set point time before it times out, unless it meets the stop criteria prior. The user can manually force the test to continue to the next point by right clicking on the graph and clicking on **Next measurement point** in the drop down list.
- 3. Selecting **Include DP criteria as stop criteria** results in the system measuring a specific point for no longer than needed to meet the DP criteria as set on the next tab.
- 4. Selecting Include residual noise as stop criterion causes the system stop testing at a intensity for which the residual noise has reached its indicated residual noise floor. The measurement at the specific intensity is considered to be so silent that a DPOAE would have been detected, if it were present. Measurements that reach the noise floor will stop testing and the result will indicate that the DP criteria were not met for the individual point.

## DP criteria

Under the **DP criteria tab** both pass and stop criteria are defined for each individual added frequency point. **Include DP criteria as stop criteria** and **Enable Pass/refer** from the **Stop criteria tab** use the settings here to determine whether a measured point meets the stop criteria, passes or refers. Note that all criterions in the row for the selected frequency must be met in order for it stop, pass or refer. Each individual criterion on its own is not sufficient.

- 5. The **f2** column displays the test frequency for the DP-I/O test.
- 6. **Min. DP IvI.** Is the minimum level (in dB SPL) that an OAE must be measured at for it to meet the stop criterium.
- 7. **SNR** is the minimum signal to noise ratio that must be reached to meet the stop criteria. The signal to noise ratio (in dB) is the difference between the DPOAE level and the residual noise level.
- 8. **DP tolerance** defines how stable the OAE level must be over time in order for it to meet the stop criteria. The **DP tolerance** can be set to off, ±2% or ±4%.
- 9. **Residual noise** allows you to define at which level the residual noise is considered to be so silent that a DPOAE would have been detected, if it were present. When the measured residual noise reaches the defined level, the measurement is stopped. Therefore, test time can be saved by enabling this feature.
- 10. **Required for pass** is disabled and cannot be selected for this test type.





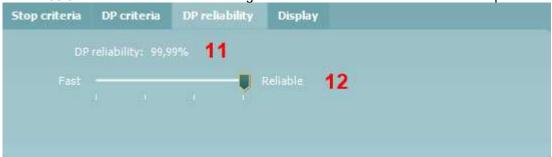


### **DP** reliability

The **DP reliability tab** indicates and allows you to set how reliable the DPOAE measurement must be in order to allow the system to accept the measurement as a true DPOAE. Basically, the OAE is compared to the noise surrounding it and then the reliability represents the chance that the OAE is indeed not part of the noise. For this comparison, it is assumed that the noise is normally distributed.

- 11. **DP reliability** indicates the reliability percentage that has been set.
- 12. The **slider** allows you to set the reliability percentage. The lower the percentage, the faster testing can occur, however the reliability of the measurement will be less. The options available are:
  - a. 95%
  - b. 98%
  - c. 99%
  - d. 99.9%
  - e. 99.99% (Reliable)

By default, the DP reliability is set to 98%. For diagnostic testing we recommend using a reliability of at least 99.9% because that allows making conclusions for individual measurement points.



### Display

Under the Display tab, options are available for setting how the results will be displayed on the test screen.

- 13. Under **Ears**, you can select:
  - e. Monaural view displays one ear at a time on the test screen
  - f. **Binaural view** displays both ears on the test screen
  - g. **Summary view** displays the test summary and point summary tables on the test screen. This option is only available when **monaural view** is selected.

These views can also be toggled temporarily on the test screen using the **monaural/binaural view** and/or **summary view** icons.

- 14. Under **Details**, you can select:
  - h. Probe check graph displays the probe check graph on the test screen.
  - i. Response graph displays the response graph on the test screen.











## 4.6 Creating a pass-refer DPOAE protocol

It is possible to create a screening protocol in the DPOAE module that provides a test outcome labelled as PASS, REFER or INCOMPLETE.

The application of DPOAEs in screening is very different to that when used for diagnostic purposes. It is therefore extremely important to select the correct test settings or protocol, depending on the patient or expected use of the test results. As a screening protocol is typically used for the purpose of differentiating patients with likely normal hearing from those with a peripheral dysfunction, it is important to create a protocol that has only a small probability of providing a pass on a test, for patients with a moderate or greater hearing impairment.

In newborn hearing screening, test protocols typically require that 3 out of 4 bands (in the speech frequency range) are detected for a PASS result. When the newborn passes the hearing screening test, it indicates that there is a significantly low chance that they have a significant auditory disorder requiring amplification (e.g., a hearing aid or cochlear implant).

A REFER result only indicates that the detection criteria of the test protocol was not met. This could be due to test conditions (i.e., too noisy), a hearing loss (conductive or sensorineural) or poor testing techniques. Infants that REFER on a screening test may be rescreened before being referred to a diagnostic audiology department for more thorough testing to rule out a permanent hearing loss.

Ensure that the pass-refer protocol that you create is valid for the test population and for the expected clinical outcome. For more comprehensive information about outer hair cell function and for clinical based treatment and rehabilitation decisions, a diagnostic OAE protocol should be used in conjunction with other diagnostic audiological tests.

A protocol used for screening purposes has the purpose of differentiating patients with likely normal hearing from those with a peripheral dysfunction. Therefore, it is important to create a protocol that has only a small probability of providing a pass on a test, on patients with a moderate or greater hearing impairment.

The following test parameters should be carefully defined to create a highly sensitive pass-refer protocol:

### 1. Test frequencies

Select or create an appropriate test protocol that includes the cochlear region of interest. For DPOAEs, the test frequency is denoted by f2 and usually includes frequencies in the range of 1000 – 6000 Hz. The number of DP test frequencies included in the protocol should also be considered, usually 4 or 5 frequencies are tested. In newborn screening, 1000 Hz is typically omitted due to ambient and physiological noise affecting test outcomes.

## 2. Stimulus levels (L1/L2)

Two different stimulus levels, labeled as L1 and L2, need to be defined when performing DPOAE assessments. The L1 is the stimulus level of the first primary tone (f1), while L2 defines the stimulus level of the second primary tone (f2). Selecting the most appropriate stimulus levels for each primary is critical to recording a valid DPOAE.

The possible intensity relationship between L1 and L2 are: L1 < L2, L1 = L2 and L1 > L2. The L1 > L2 stimulus intensity relationship consistently produces robust DPOAEs and is widely used for diagnostic and screening applications. A typically recommended screening protocol uses a 65/55 dB SPL relationship.

### 3. Stimulus f2/f1 ratio

The ratio of f2/f1 sets the ratio relationship between the two stimulus frequencies. The frequency relationship is critical to evoking a DPOAE response. If the two tones are spaced too far apart or too close together, a DPOAE will not be recorded. Evidence suggests that the most clinically effective f2/f1 ratio for testing patients across all age groups is between 1.20 and 1.23. The DPOAE is largest when the ratio of f1 to f2 is 1.22.





### 4. Stimulus tolerance level

Accurate presentation of the stimulus to the ear is important to produce valid OAEs. A stimulus tolerance value (dB) defines the allowed difference of the stimulus presentation level in both a positive and negative direction. Setting an appropriate stimulus tolerance level will ensure that a warning is provided to the tester when unwanted stimulus level changes occur that could affect test outcomes.

Changes in stimulus levels during testing usually occur due to probe movement in the ear canal. Probe movement can be reduced by ensuring a secure probe fit before testing and instructing the patient to remain still during testing.

### 5. Noise rejection level

As ambient and physiologic (patient) noise levels have a huge effect on OAE recordings, assessing the noise levels in the test environment before and during testing is extremely important, especially in non-ideal test environments such as in a newborn nursery.

In DPOAE testing, a typical noise rejection setting is 30 dB SPL. This ensures that data recorded in conditions where the background noise is high are rejected and not included in the averaging of the response. While it lengthens the test time, it is not recommended to turn the acceptable noise level off. Data recorded with high levels of noise can reduce the integrity of the data being analyzed.

#### 6 Test time

A suitable test time should be selected to ensure that enough time can be spent to extract the DPOAE response from the surrounding noise in the recording. This can usually be set as either an absolute test time (e.g., 1-6 minutes) or as a maximum test time per DP point (e.g., 2 or 4 seconds). Testing normally continues until the maximum test time is reached or the required number of DP points are detected, whichever happens sooner.

## 7. Residual noise as a stop criterium

Residual noise is the remaining or left over noise in the recording after continued averaging (data collection). Using a residual noise value as a stopping criterion instead of absolute test time can save unnecessary test time in cases where OAEs are absent.

For example, each specific OAE device has a hardware noise floor that averaged noise will never fall below. Let's say this value was –20 dB SPL. The protocol could be set to stop testing at each frequency if the noise floor dropped below this value (as an OAE would have already been detected if it was present). The device's hardware noise floor can be determined by placing the probe in a test cavity and running a protocol lasting a few minutes.

## 8. Number of DP points for a pass

Screening protocols typically use criteria of 3 out of 4 or 3 out of 5 DP points for a PASS result. Setting the required numbered of bands too loosely (e.g., 1 out of 4 for a PASS) would increase the chances of passing an ear with a hearing loss, whereas setting it too stringently (e.g., 4 out of 4 for a PASS) would increase the number of REFER outcomes.

### 9. Mandatory DP points

A mandatory DP frequency can be defined for inclusion in screening protocols. For example, if a 3 out of 4 bands for a pass protocol was used, the 2000 Hz band could be set as a mandatory DP point for inclusion. This means that if during testing, 3000 and 4000 Hz were detected, testing would continue until 2000 Hz was detected or the test timed out.

### 10. Min DP level

OAE amplitudes are generally in the range of -10 dB SPL to +30 dB SPL in healthy functioning ears. Therefore, setting a minimum OAE level ensures that low-level artifact responses are not accepted as a true OAE response, even when the required SNR is met. Minimum OAE levels should not be set lower than device specific system distortion levels.

### 11. DP tolerance

A DP tolerance level may be set to define how stable the OAE level must remain over time in order for it to meet the detection criteria of a true response. A strict DP tolerance value of ±2 dB will increase test times for each test frequency, but will provide further certainty that it is a valid OAE response.





### 12. DP reliability

DP reliability is another criterion that can be used in conjunction with the SNR and DP tolerance setting to ensure certainty of the DP frequency response.

DPOAEs are traditionally interpreted as present when the difference between the OAE and the noise level is significant, i.e., a SNR of 6 dB is obtained. This can be problematic as the noise level used to calculate the SNR is an average level and while the OAE level is relatively stable, noise fluctuates. If fluctuations around the measured frequency are large, then a signal to noise ratio of 6 dB does not imply that the OAE appears significantly outside the noise spectrum. The OAE can actually be an accidental peak of the noise.

Using the reliability instead of (or in addition to) the signal to noise ratio gives more confidence in the OAE result.

### 13. Selecting an appropriate Signal-to-Noise Ratio (SNR)

The signal-to-noise ratio (SNR) refers to the difference in dB, between the level of the OAE response and the background noise. The SNR can be thought of as an estimate of the reliability with which the OAE response level has been estimated. When SNRs are high, the contribution of the noise in the recording is low and there is more certainty that the displayed OAE response is true. The SNR is calculated from two variables – the OAE response (or signal) generated by the cochlea and the noise, a random variable unrelated to cochlear status. The signal (OAE response) should remain constant during averaging, while the noise level should decrease as test time increases. Most literature recommends a minimum SNR of 6 dB in addition to other criteria to determine the presence of a valid OAE response.

The following literature provide examples of DPOAE screening protocol settings and recommendations.

American Academy of Audiology Childhood Hearing Screening Guidelines. (2011). (http://www.cdc.gov/ncbddd/hearingloss/documents/AAA Childhood%20Hearing%20Guidelines 2011.pdf) p. 39.

Iowa's Early Hearing Detection & Intervention Program, Newborn Hearing Screening Protocol. (2008). <a href="https://www.infanthearing.org/statequidelines/lowa/lowa-Screening.pdf">https://www.infanthearing.org/statequidelines/lowa/lowa-Screening.pdf</a> p.2.

Universal Newborn Hearing Screening and Early Intervention Program, Diagnostic and amplification protocols. (2016). <a href="https://www.nsu.govt.nz/system/files/resources/unhseip-policy-quality-standards-diagnostic-amplification-protocols-jan16.pdf">https://www.nsu.govt.nz/system/files/resources/unhseip-policy-quality-standards-diagnostic-amplification-protocols-jan16.pdf</a> p. 56.

### Determining a screening protocol's sensitivity

To avoid undertaking unfeasibly large clinical trials involving say 10,000 infants, some countries that administer UNHS programs stipulate test criteria for a sensitivity assessment.

The following is an extract from the United Kingdom Newborn Hearing Screening (NHS) program tender document:

Evidence of cavity trials at volumes close to 0.05; 0.1; and 0.2ml; showing a maximum of 1 pass on 120 repetitions. To be conducted with normal stimulus levels present in (a) quiet conditions and (b) with wide band-noise applied externally to such a level that the reject system is activated between 30% and 70% of the time. Such noise may be generated by the wide band masking of a clinical audiometer. For condition (b) if a method of data rejection is employed that does not enable this test to be performed, provide evidence of an equivalent test in noisy conditions.

Based on the above information, a user defined screening protocol's sensitivity could be assessed by the following method:

- 1. Create a user-defined pass/refer protocol in the DPOAE module.
- 2. Place the probe in a cavity with similar impedance to an ear matching the test population that the protocol will be used for (e.g., if the screening protocol is to be used on children, a small cavity volume of 0.2 cc could be used).
- 3. Run a minimum of 120 full tests in quiet. DO NOT stop any of the tests manually. Repeat step 3 applying external wide band noise as described above.





4. Calculate the sensitivity using the following mathematical equation:

$$Sensitivity \geq \frac{Number\ of\ true\ refers}{Number\ of\ tests + 1|}$$

The final sensitivity estimate is calculated by expressing the number of 'true refers' as a percentage of the total number of tests. When tests are performed in a standard test cavity, we would hope that all test outcomes were a 'refer' and therefore the test sensitivity would be measured at 100%. However, statistically it is not safe to use this value unless the number of tests is very large. Instead, the sensitivity is assessed assuming a worst case scenario such that if 'n' tests are performed, if there was an 'n+1' test it would produce a 'false pass'.





## 4.7 General setup

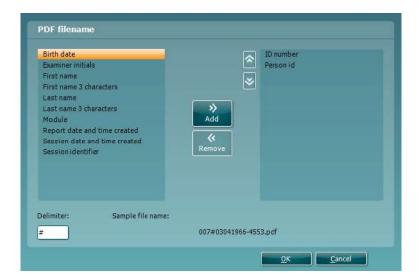
The General setup is accessed by going to Menu | Setup | General setup...



Here, the following options are available to setup:

- Selected DPOAE norm data allows you to select the norm data category you wish to display on the screen (Newborn, Male, Female, None). The Lower limit and Upper limit of the norm data can also be selected.
- 2. **Icons on graph** allow you to select whether or not to show the **timeout symbol**, the **noise floor symbol** (**min. level reached**) or the **DP found checkmark symbol** on the advanced DP-Gram graph or DP-I/O graph..
- 3. **Startup ear** allows you to select which ear the program will always start on as default. The selected startup ear applies to all modules.
- 4. The **Print button** can be set up to automatically print to PDF.
  - a. Check the **PDF print enabled** box to set the print icon to print to PDF functionality.
  - b. Check the Open after print box to open the PDF document after printing.
  - c. Select the **File location** to where the PDF document should be saved.
  - d. Select PDF filename configuration to define the name of the file. Selecting the button will open another window to set the fields defining the name of the PDF file. A field called "ID Number" must be added to the PDF file. Use the arrow keys to add fields to the file name. The adjustable delimiter will separate the different fields from one another.





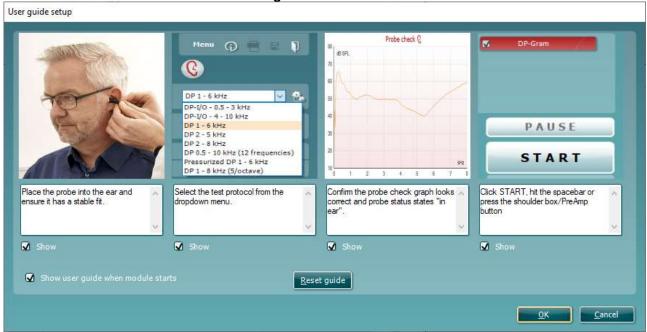




## 4.8 User guide

The User Guide setup is accessed by going to Menu | Setup | User guide setup

The default setup for the User Guide has preselected guidance pictures and text. All four guide pictures and test instructions are selected and **Show user guide when module starts** is checked.



The following options are available:

- 1. Right clicking on the **Picture** allows you to add a new picture to assist with guidance. A Microsoft window will open allowing you to select pictures stored elsewhere on your PC. Navigate to and select the desired image and then click Open. The picture will be replaced with your chosen one.
- The **Text** can be edited the text in the text box by simply placing the cursor in the white box with your mouse.
- 3. There are four available guidance pictures with text. Uncheck **Show** on the ones you do not want shown when the User guide is displayed.
- 4. Uncheck **Show user guide when module starts** if you do not want the User Guide to appear on the screen each time the module starts.
- 5. **Reset guide** allows you to reset the guide pictures and text to the default settings as when the software was installed
- 6. Pressing **OK** will accept any changes made and will close down the User Guide setup
- 7. Cancel will close down the User Guide setup without saving any changes made.



## 4.9 Temporary setup

The **Temporary setup** can be accessed in two ways and allows you to make temporary changes to the protocol currently shown in the protocol drop down list.

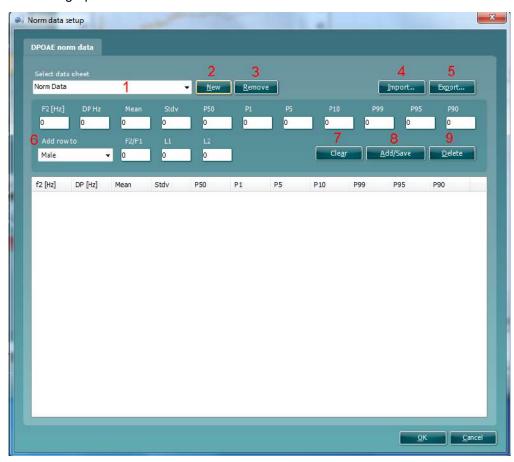
- 1. Go to Menu | Setup | Temporary setup
- 2. Click on the Temporary setup icon on the control panel

When a temporary change has been made to a protocol, the protocol name will then appear with an asterisk next to it. If data is measured before you enter temporary setup you are prompted to save or discard the data. In temporary setup the same options are available as in the normal protocol settings.

## 4.10 Norm data setup

The Norm data setup is accessed by going to **Menu | Setup | Norm data setup...** 

By default, there is no norm data stored in the module. For research purposes, you may wish to collect data on certain patients and create a norm data table that can be used to display a shaded norm data area on the DP-Gram graph.



The following explains the various options in the Norm data setup window:

- 1. **Select data sheet** allows you to select the data sheet to be used by the DPOAE module for displaying a shaded norm data area on the DP-Gram graph.
- 2. **New** allows you to create a new norm data sheet.
- 3. **Remove** allows you to delete a created norm data sheet.
- 4. Import allows you to import norm data from an excel spreadsheet





- 5. **Export** allows you to export a norm data sheet to an excel spreadsheet.
- 6. This section is where you enter the test parameters and result information. You can specify that the data relates to Males, Females or Newborns under the **Add row to** drop down box.
- 7. Clear removes all data entered into the fields in item 6.
- 8. Add/Save adds the entered information into a row in the data sheet.
- 9. **Delete** allows you to delete a selected row from the data sheet.
- 10. **OK** saves any changes to the data sheet and returns you to the test screen.
- 11. **Cancel** closes the Norm data setup window and returns you to the test screen without saving and changes.

#### 4.11 PC shortcuts

For quick operation from the keyboard the following hotkeys are available:

L - switch to left ear
R - switch to right ear
Space - start or stop

A - select or deselect all tests of a protocol

T - go into temporary settings

Ctrl S - save and new

Ctrl P - print

Ctrl N - delete all data and start new measurement

Page up - go one up in saved sessions
Page down - go one down in saved sessions
Arrow up - go one test up within the protocol
Arrow down - go one test down within the protocol

Arrow right - select next measurement point/jump to next point while testing select next measurement point/jump to previous point while testing

Ctrl Shift L - saves probe check information in an xml file to the desktop





## **5 TEOAE440**

#### 5.1 About TEOAE440 module

The Titan with TEOAE440 is intended for use in the audiologic evaluation and documentation of ear disorders using Transient Evoked Otoacoustic Emissions. The target population for Titan with TEOAE440 includes all ages.

The Titan with TEOAE440 is designed to be used only by skilled personnel 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.

The TEOAE440 contains the following tests:

➤ TEOAE

Availability of these tests or specific settings within these tests on the hardware or in the software depend on the license purchased.

## 5.2 Preparing for the test

#### 5.2.1 Probe test

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.

Refer to the Instructions for Use manual for further information about how to perform this daily probe test.

## 5.2.2 TEOAE patient instruction

Place the patient on a 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, talking and swallowing will disturb test results

#### 5.2.3 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.





#### 5.3 The TEOAE440 menu items

From the main menu, the following options are available - **Setup**, **Print**, **Edit** or **Help**. The menu has the following structure:

**Menu | Setup | Protocol setup...** to enter the Titan Setup where the settings of DPOAE protocols can be viewed and changed. If data is measured before you enter the protocol setup, you are prompted to save or discard the data.

**Menu | Setup | Temporary setup...** to enter the protocol settings and make changes which are only valid during the current session. If temporary changes are made to a protocol, its name appears ending with an asterisk. If data is measured before you enter temporary setup you are prompted to save or discard the data. In temporary setup the same options are available as in the normal protocol settings.

**Menu | Setup | Show/hide protocols...** to enter the setup to choose which protocols are available during the PC controlled measurements.

**Menu | Setup | General setup....** to enter the DPOAE general setup where you can set norm data preferences, the default Suite startup ear and PDF printing options.

Menu | Setup | User guide setup... to edit the pictures and instructions displayed in the user guide.

**Menu | Setup | Norm data setup...** to enter the setup where norm data can be entered. The norm data range can be displayed on the TE response graph as an indication at which levels OAEs are normally expected.

**Menu | Setup | Password protection...** to change and/or activate password protection for the complete Titan Suite. When activated users cannot enter the **Protocol setup** or **User guide setup**.

Menu | Setup | Unlock protection... to temporarily disable password protection.

Menu | Setup | Language to change the language used in the software.

Menu | Setup | Simulation mode... to activate simulated testing with simulated hardware.

**Menu | Print | Print...** to print the current measurement using the print template that is linked to the current protocol. You will enter the print window from where you can select your printer and change settings before printing. Note that you are prompted to select a template if the protocol did not include a template.

**Menu | Print | Print preview...** to see a print preview of the current measurement using the print template that is linked to the current protocol. Note that you are prompted to select a template if the protocol did not include a template.

**Menu | Print | Print wizard...** to open the print wizard window from where you can select a template to print the current measurement.

Menu | Edit | Export... to export the current measurement to an XML file.

Menu | Help | About... brings you to an information window which displays the following:

- Titan Suite version
- Hardware version
- Firmware version
- Copyright Interacoustics 2009





Further, you can reach the Interacoustics website by pressing the link to <a href="www.interacoustics.com">www.interacoustics.com</a>
By pressing the License button, you are able to change the license keys of the Titan Suite. The license keys for the Titan 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** | **Instructions for use...** to open the digital version of the Instructions for Use manual. **Menu** | **Help** | **Additional information...** to open the digital version of the Additional Information manual.

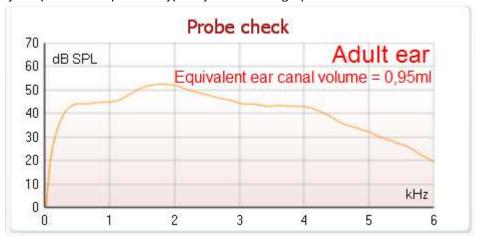
## 5.4 General operation of TEOAE440

#### 5.4.1 Probe check

Interpreting probe check information from a graph is not always easy. Therefore, the quality control that is required to perform a proper TEOAE measurement is fully automated. In other words, with the Titan, it is not necessary to monitor probe check information yourself, but you are of course welcome to do so. The following paragraphs give a few ideas about the information that can be gained from the **probe check graph**.

The probe check graph will appear on the display if it has been selected in the protocol setup.

The stimulus that is used for the probe check is a broad band click. It is calibrated to give a reasonably flat response between 200Hz and 8000Hz when measured by calibration equipment. When presented in the ear and recorded by the probe microphone it typically results in a graphic like the one shown below.



It is generally said that when the best probe placement is achieved, the probe check will show a flat response over a wide frequency area. However, because the probe microphone is used for this monitoring, the intensities at the eardrum will be slightly different from those displayed on the graph. A relatively flat spectrum from 500Hz to 4000Hz indicates a good probe fit.

Looking at the low frequency area of the graph will also give you information about whether or not the probe is in the ear.







### 5.4.2 TE response graph basic view

The TEOAE response graph can be shown in **basic view** or **advanced view**. Your preference for these views is defined in the protocol setup and can also temporarily be changed in the temporary settings. The following information can be found in the **basic view**:



- The result can be labeled with Pass or Refer and is indicated above the measurement as soon as
  the result is available. A user defined Pass/Refer criterium can be enabled within the protocol setup.
  When Enable Pass/refer is used, if the measurement is stopped before completion of the test,
  Incomplete will appear in the label.
- The Bar representation shows the progress over time for each frequency measured in a bar graph format. When a bar becomes completely filled and changes to green, it has reached the stop criterion set in the protocol. Those bars that do not meet the stop criterion will remain in the color of the selected ear (red or blue).
- 3. In addition, check marks above the green bars indicate that those frequencies have reached their stop criterion. When a user defined Pass/refer protocol has been created, although several bars might turn green it does not necessarily mean that it will result in a pass. For example, within the protocol setup it can specified that particular frequencies are mandatory for reaching an overall pass or other settings may determine that the test does not pass (e.g., Total OAE, waveform reproducibility).





#### 5.4.3 TE response graph advanced view

The TE response graph can be shown in **basic view** or **advanced view**. Your preference for these views is defined in the protocol setup and can also temporarily be changed in the temporary settings.

The following information can be found in the TEOAE advanced view:



- The result can be labeled with Pass or Refer and is indicated above the measurement as soon as
  the result is available. A user defined Pass/Refer criterium can be enabled within the protocol setup.
  When Enable Pass/refer is used, if the measurement is stopped before completion of the test,
  Incomplete will appear in the label.
- Each bar indicates the frequency band width, the level of signal (OAE) and the level of noise in dB SPL. The signal (OAE) in each frequency band is displayed in either red or blue depending on the ear (right/left) selected. The noise in each frequency band is displayed in gray.
- 3. Hovering the mouse over a bar allows you to see the following details for that point:
  - Measured indicates the number of sweeps that were measured to get to the current result
  - Rejected indicates the number of sweeps that were rejected due to too much noise
  - Band center refers to the center frequency (in kHz) for the selected bar
  - Band start refers to the starting band frequency (in kHz) for the selected bar
  - Band end refers to the stopping band frequency (in kHz) for the selected bar
  - TE SNR indicates the difference between the absolute value of the TEOAE and the noise floor for the specific band. This difference is called the signal to noise ratio. Note that calculations are done with raw numbers after which rounding off takes place. Therefore, the mathematical difference between the presented TE level and Noise level might differ slightly from the given number
  - TE level indicates the absolute value of the TEOAE in dB SPL
  - Noise level indicates the average noise level (in dB SPL) for the selected band
  - Time used displays the number of seconds that was spent measuring the selected band
  - **Fail reason** indicates why the entire measurement did not meet the specified criterion as set in the protocol. Reasons displayed include:
    - Min. bands meaning that the specified minimum no. of bands for a pass was not reached
    - Min. sweeps meaning that the specified minimum no. of sweeps was not reached
    - Total OAE meaning that the minimum total OAE value was not reached
    - Repro meaning that the minimum wave reproducibility % was not reached
- 4. The **noise** is indicated in each bar in gray. The distance between the noise floor and the top of the bar defines the TE signal to noise ratio.

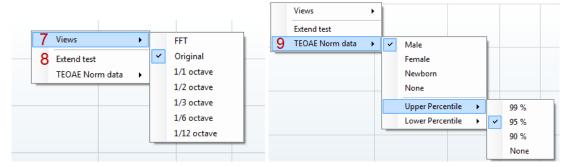




- 5. The **TE found checkmark symbol**, a black checkmark, indicates that this individual bar met its specified criterion.
- 6. Optionally, **TE norm data** can be imported or added to the software and is shown by two solid lines. The top line is the upper percentile, and the bottom line is the lower percentile as selected in the **General setup**. The norm data can be used to indicate where TEOAEs might be expected for a normal population. Within the **General setup** you can define whether or not to display the norm data area.

Using the right mouse click on the TE response graph gives the following additional functions:

- 7. Views allows toggling from the Original view to FFT view, 1/1, 1/2, 1/3, 1/6 or 1/12 octave band view.
- 8. **Extend test** allows continued testing after the test has ended on its own or been manually stopped. The counter will count up in time from the already elapsed testing time without a time limitation. Press **Stop** to stop testing. Extend test is only available when the protocol is <u>not</u> enabled for PASS/REFER.



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

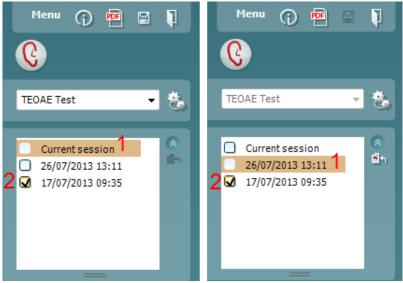




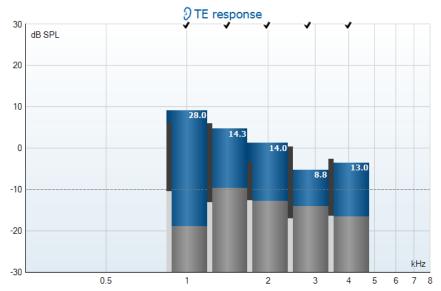
## 5.4.4 Comparing TEOAE data (historic overlay)

Two TEOAE sessions can be compared using the overlay function. This can be either the current session and a historic session or two historic sessions.

- 1. Highlight the first session for comparison by clicking on the date or Current session text. This will display the TEOAE bands for the selected session.
- 2. Select the session for comparison by checking the box beside the session date/time. The overlayed session appears as a thin bar in grey and black. The lighter grey color indicates the noise, while the black indicates the OAE.



Note, when the first session for comparison is selected, only comparable sessions show an active checkbox.



Sessions that are not compatible for comparison cannot be selected. This includes:

- 1. Sessions where a Pass/Refer label is given (as enabled in the protocol setup)
- 2. Sessions testing differing frequency bands (e.g., Custom vs Center)



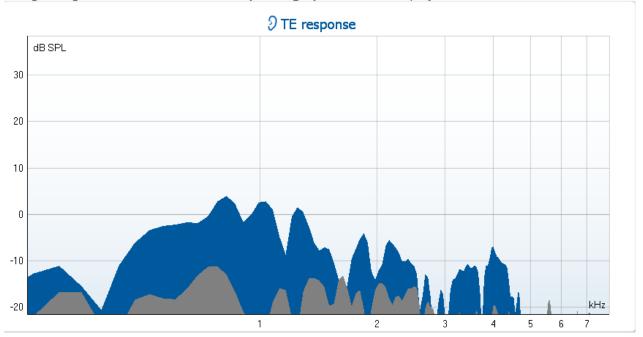


## 5.4.5 Printing the overlaid sessions

When the historic overlay function is used on the test screen, the overlaid graph will automatically appear on the print template. The TE band summary and TE test summary table information on the printout reflects the session that was selected first.

## 5.4.6 TE response graph FFT view

Using the right mouse click on the TE response graph allows for display of the FFT view.



## 5.4.7 Stimulus graph

The **stimulus** graph displays the click stimulus being presented to the ear as a function of magnitude (Pa) over time (ms).

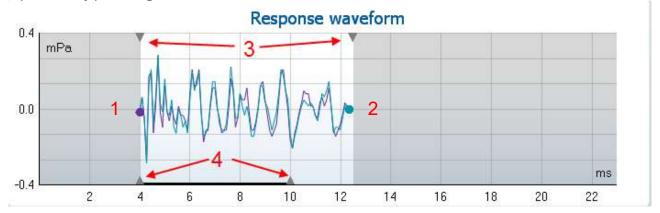
The **scroll wheel** of your mouse allows for **zooming in and out** with respect to the magnitude (y) axis.





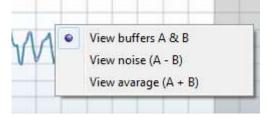
#### 5.4.8 Response waveform graph

The **TE response waveform graph** shows the two superimposed averaged OAE waveforms (in aqua and purple). The waveforms are displayed as a function of magnitude (mPa) over time (ms). The waveform reproducibility percentage is derived from the correlation between these two overlaid waveforms.



- 1. **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.
- 2. The **scroll wheel** of your mouse allows for **zooming in and out** with respect to the magnitude (y) axis.
- 3. The arrows at the top of the graph 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 in the protocol setup,
- 4. 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**.

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



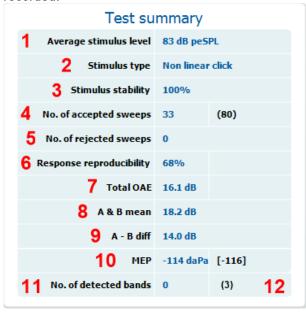
- 5. View buffers A & B is the default view showing the two superimposed averaged OAE waveforms.
- 6. View noise (A B) displays the noise in the waveform (Noise = A buffer B buffer).
- 7. View average (A + B) displays the mean of the A and B waveforms.





#### 5.4.9 Test summary table

The test summary table is updated during testing and displays information about the TEOAE measurement recorded.



The following information is displayed in the **test summary table**:

- 1. Stimulus level displays the average stimulus level in dB peSPL during and after testing.
- 2. Stimulus type displays the click stimulus used for testing Linear or Non-linear click.
- 3. **Stimulus stability** is displayed as a percentage and indicates the change between the stimulus level at the beginning of the measurement period and the subsequent level at a set point in time during the measurement. A stimulus stability of 90% or greater indicates a change in stimulus level of less than 1 dB throughout testing. A stimulus stability of 79% indicates a change of approximately 2 dB in stimulus level and a stimulus stability of 59% indicates a change of approximately 3 dB in stimulus level during testing.
- 4. **No. of accepted sweeps** displays the number of sweeps accepted and processed. Sweeps are only accepted if they are below the **acceptable noise level** (if set).
- 5. **No. of rejected sweeps** displays the number of sweeps rejected. Sweeps are rejected if recorded above the **acceptable noise level** (if set).
- 6. **Response reproducibility** is displayed as a percentage and indicates the correlation between the averaged responses in the A and B buffer waveforms within the **waveform reproducibility window**.
- 7. **Total OAE** value is the total (energy) level of the correlated portions of A and B response waveforms after removing the uncorrelated portions, calculated from the entire recording window.
- 8. A & B mean is the sound pressure level of the average of the A and B waveforms.
- 9. **A B diff** is the average difference between the A and B waveforms and gives an indication of the residual noise in the recording.
- 10. MEP indicates the middle ear pressure at which the measurement has taken place. Value in square brackets is the target value from the tympanogram. Only displayed when running a pressurized test.
- 11. **No. of detected bands** indicates the number of bands detected as meeting the criteria for an OAE based on the criterion set in the protocol setup.
- 12. The **minimum test requirements** as defined in the protocol are displayed beside some of the items in the table. These **numbers in parentheses** change to a **check mark** when the minimum requirement has been met during testing.





#### 5.4.10 Band summary table

The **band summary table** is updated during testing and displays **band** information about the TEOAE measurement recorded.

The following information is displayed in the **band summary table**:



- 1. **Frequency** displays the center frequency for each band in the test in kHz.
- 2. **TE level** displays the overall TE level measured in dB SPL.
- 3. Noise displays the noise for the specific band in dB SPL
- 4. **SNR** displays the signal to noise ratio.
- 5. **Detected** displays a **check mark** when the specified band has met the criteria for a present TEOAE.

#### 5.4.11 Probe status and stimuli tolerance

During testing, the probe status is monitored, and the probe status bar will change color and indicate whether the probe is in ear, out of ear, blocked, leaking or too noisy.

During testing, the stimulus stability is constantly being monitored. The probe microphone monitors the output from the speaker, ensuring that the intensity output remains within a specified range (stimuli tolerance). When the stimulus intensity cannot be kept within the specified range, a pop-up will appear (below).



Typically, this indicates that a seal has been lost between the probe ear tip and the ear canal or has moved within the ear canal. Check the probe to ensure it is not blocked and/or replace the probe in the patient's ear if it has come lose.

When the probe is reinserted, the dialog box will automatically disappear once the stimuli tolerance has been reached and testing will continue.

If the stimuli tolerance cannot be reached after replacing the probe in the patient's ear, the user can press Continue. This will continue the testing overruling the stimuli tolerance level settings for the current test. To stop testing, press Stop.

It is important to check the probe status and replace it in the patient's ear before pressing Continue. If Continue is pressed first, the probe may output a loud noise while trying to recalibrate the output signal.



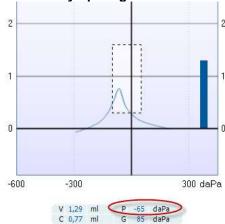


## 5.4.12 Pressurized TEOAE testing

The pressurization function within the TEOAE440 module allows for testing at the tympanometric peak pressure recorded in the IMP440 module. Research (Hof et al., 2005) indicates that negative middle ear pressure has the effect of decreasing TEOAE amplitudes, particularly at frequencies ≤ 2 kHz. Compensation of the negative middle ear pressure, by equalizing the pressure on both sides of the tympanic membrane, has the effect of increasing the TEOAE amplitudes (at the lower frequencies) and detection is improved. This may be clinically useful when trying to determine cochlear hair cell function in the presence of negative middle ear pressure.

In order to perform a pressurized measurement, a **tympanogram** must first be measured in the **IMP440** module.

1. Record the **tympanogram/s** in the IMP440 module (do not save the results).



- 2. Go to the **TEOAE440** module and select a protocol using pressurization or change the protocol to run at **Peak pressure**.
- 3. The peak pressure, as detected in the IMP440 module will appear on the screen.



4. Press START to measure.

Hof, J.R., Anteunis, L.J.C., Chenault, M. N., & van Dijk, P. (2005). Otoacoustic emissions at compensated middle ear pressure in children. *Int J of Aud, 44*, 317-320.





## 5.5 Protocol setup and criterion

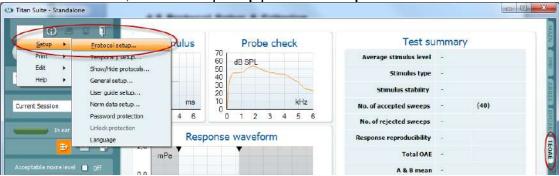
Ensure that the protocol that you select or create is valid for the test population and for the expected clinical outcome. Protocols generally differ between those used for Newborn Hearing Screening where a clinical outcome is based on a single test versus those used in a diagnostic follow up situation where the OAE result forms part of an overall test battery approach where many tests are analyzed to form a conclusion.

The following section describes how to create a protocol in the protocol setup and provides some information about things to consider when setting various parameters.

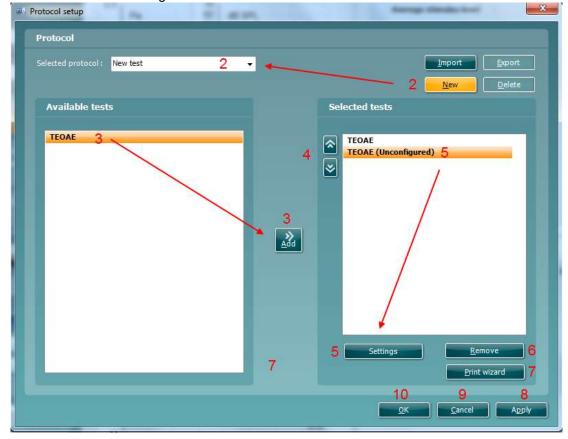
## 5.5.1 TEOAE protocol setup

To create or adapt your own personalized protocol you need to enter the Titan **Protocol Setup** menu.

1. From the **TEOAE** tab, Select **Menu | Setup | Protocol Setup...** 



- 2. Click on the **New** button and name your protocol.
  - a. You will be asked if you want to create a copy of the selected protocol. Select Yes, to copy the protocol settings of the selected protocol. Select No, to create the new protocol from default settings.







- 3. Select the test you want to include in your protocol from the list on the left and press **Add**. Alternatively, double click on the test you want to include. More than one TEOAE test can be included in a protocol.
- 4. The **arrow** buttons allow you to modify the order of the tests.
- 5. Select the test on the right that you want to modify the settings for and click on **Settings.**Alternatively, double click on the selected test. The **Test setup** window will open where the test settings are specified. Note that a test will show "(unconfigured)" beside it if it does not contain any settings. You must configure a test before you can save and exit the protocol setup.
- 6. The Remove test button is used to remove a test from the Selected tests list.
- 7. The **Print wizard** button takes you to the area where a print layout can be created and/or linked to the selected protocol.
- 8. Pressing **Apply** will apply any new settings made or changed within a protocol.
- 9. Pressing **Cancel** will close the protocol setup window and return you to the testing screen without saving any changes.
- 10. Pressing **OK** closes the protocol settings window after automatically saving all changes.

#### 5.5.2 TEOAE test settings

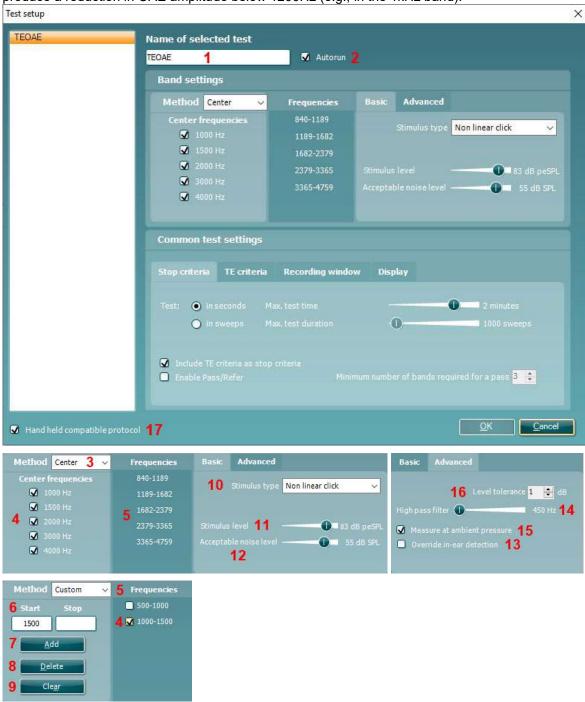
The following options are available in the **TEOAE** test:

- 1. **Name of selected test**. You can choose to have more than one of the same type of tests in your protocol. You may therefore want to give each test an individual name, so it will be easier to recognize when running the complete test protocol.
- 2. The **Auto run** checkbox defines which tests will run automatically, one after the other, when START is pressed. Note that when a protocol is used on the hand held unit, all tests will always be executed in the order they are in the protocol setup.
- 3. **Method** offers two frequency band creation options: **Center** and **Custom**.
  - a. **Center** allows for selecting the center frequency for testing. This test method is the most popular method used for TEOAE testing as each band stimulates approximately the same number of hair cells on the basilar membrane.
  - b. **Custom** allows the ability to choose the start and stop frequency for each custom band (clinical version only). The custom method would typically be used by researchers.
- 4. **Check boxes** allow you to select or deselect the frequency bands for testing when using the **Center** frequency band method.
- 5. The **Frequencies** column displays the selected frequency bands for testing.
- 6. The **Start** and **Stop** fields allow the free text entry of the start and stop frequency when using **Custom** bands.
- 7. Press the **Add** button after entering the **Start** and **Stop** frequency or press enter on the keyboard.
- 8. Press the **Delete** button to remove individual frequency bands selected with a checkmark.
- 9. Press the Clear button to clear all frequency bands from the frequencies list.
- 10. Select the preferred Stimulus type (under the Basic tab) from the dropdown list. Non linear or Linear click are available. A non-linear click stimulus is typically used in both screening and diagnostic OAE testing. Caution should be used when testing with a linear stimulus as it has more chance of producing artifact responses. If using a linear stimulus, the stimulus level for testing does not usually exceed 70-75dB SPL.
  - Please note that the linear click is licensed and might not be available in case the license was not purchased.
- 11. The **Stimulus level** slider bar allows selection of stimulus level for testing between 30-90 dB peSPL (clinical version) and 60-84 dB pe SPL (screener version). When a stimulus level below 50 dB peSPL is selected, the probe check is disabled during testing.
- 12. Typical stimulus levels usual range from 80-84 dB SPL. If using a linear stimulus, the stimulus level for testing does not usually exceed 70-75dB SPL.
  - At **Acceptable noise level**, sets the initial acceptable noise level limit between +30 and +60 dB SPL above which recordings are considered to be too noisy. During testing the acceptable noise level can be changed using the slider bar on the control panel.





- 13. When Override in-ear detection is checked, ear canal volume is not considered for the stimulus. Instead the protocol will use a 711 coupler calibration as reference for the stimulus level. This functionality can be useful when in-ear detection is not possible to achieve because of a perforated eardrum or a PE-tube.
- 14. The default **High pass filter** is set at 450 Hz. Increasing the **high pass filter** will assist in the collection of data during noisy conditions, helping to remove low frequency noise. Setting the filter to 1200Hz will attenuate not only the noise below this frequency, but also the OAE response. This may produce a reduction in OAE amplitude below 1200Hz (e.g., in the 1kHz band).



15. When **Measure at ambient pressure** is checked, the test will run at ambient pressure (0 daPa). When unchecked, the module will use the peak pressure measured in the IMP module.





- 16. **Level tolerance** defines the range in which the presented stimulus is still acceptable. The number (in dB) indicates the allowed difference in both a positive and negative direction from the stimulus level. When the level tolerance exceeds the limit set, a warning is given on screen.
- 17. **Hand held compatible protocol** ensures that the protocol created is compatible for transfer to the Titan handheld device. TEOAE tests that contain more than 12 brands are not compatible for use on the handheld device and will not be displayed in the Hardware protocols menu.

## 5.5.3 Common test settings for a TEOAE test

The common test settings area is divided into four tabs – **Stop criteria**, **TE criteria**, **Recording window**, and **Display**. The following options within each tab are described below.

#### Stop criteria

- Test: in seconds allows defining the maximum test time from 5 seconds to 30 minutes (Screener version: 5 seconds to 6 minutes). The maximum test time is how long the take may take until it stops automatically. Testing continues until the maximum test time has been reached unless the stop criterion for the test has been met.
- 2. Test: in sweeps allows defining the maximum number of sweeps from 50 to 5000 (Screener version: 30 to 4500 sweeps). The maximum number of sweeps is how many sweeps may be collected until the test stops automatically. Testing continues until the maximum number of sweeps has been collected unless the stop criterion for the test has been met.



- 3. Selecting **Include TE criteria as stop criteria** results in the system measuring the frequency range for no longer than needed to meet the TE criteria as setup on the next tab.
- 4. Checking Enable Pass/Refer results in the system labeling an overall test as either a Pass or Refer based on user defined TE criteria. If the measurement is stopped before completion of the test, Incomplete will appear on the label. When Enable Pass/Refer is checked, the following disclaimer window will appear. You must press Accept to continue creating a pass/refer protocol. Ensure that the screening protocol is valid for the test population and meets the desired sensitivity and specificity.







5. The **Minimum number of bands required for a pass** must also be set. The overall Pass or Refer result will depend on whether the minimum number of individual frequency bands reached the TE criteria. The overall result may also depend on whether all mandatory bands have reached the TE criteria as well.

#### TE criteria

Under the **TE criteria tab** both pass and stop criteria are defined for each individual added frequency band. **Include TE criteria as stop criteria** and **Enable Pass/Refer** from the **Stop criteria tab** use the settings here to determine whether a frequency band meets the stop criteria, passes or refers. Note that all criterion in the row for the selected frequency band must be met in order for it stop, pass or refer. Each individual criterium on its own is not sufficient.

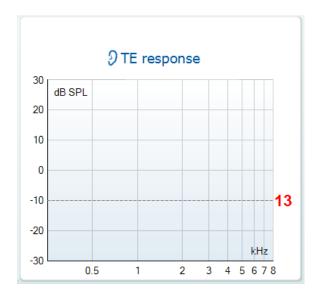
- 6. To change more than one frequency band's settings at the same time, use the **checkboxes** beside the required frequencies. Check the **select all** box next to **Frequency** to select or de-select all frequency bands in the list.
- 7. The **Frequency** column displays the frequency bands included for testing.
- 8. **Min SNR** is the minimum signal to noise ratio that must be reached to meet the stop criteria. The signal to noise ratio (in dB) is the difference between the TEOAE level and the noise level.
- Mandatory defines which frequency bands are mandatory for the test to stop/pass.



- 10. At **Min. sweeps**, the minimum number of sweeps to be recorded during the test is defined. This can be set between 50 and 5000. It is recommended to collect a minimum of 80 sweeps to ensure enough good data can be analyzed to form a conclusion.
- 11. At **Min. total OAE**, the minimum total OAE to be recorded during the test can be defined. This can be set between Off, 0 and +30.
- 12. The **Min. reproducibility** can be set between Off, 50% and 100% and represents the minimum correlation required between the A and B waveforms.
- 13. **Min. TE level** is the minimum level (in dB SPL) that an OAE must be measured at for it to meet the stop criteria. The min. TE level is displayed on the advanced graph by way of a dotted line. Setting a valid min. TE level ensures that low level artifact responses are not accepted as being an OAE response.



MMMMM



#### Recording window

The **Recording window tab** indicates and allows you to set the recording window and waveform reproducibility window.



- 14. The **recording window** range defines the area from which the OAE is analyzed following the presentation of each click stimulus.
  - a. 4 12.5 ms, short recording window (default).
  - b. 4 23 ms, long recording window.
     The starting time for the recording window is 4 ms to ensure that analysis of the OAE is not done during presentation of the stimulus or the artifact that follows.
- 15. The **stimulus rate** used for testing is updated automatically based on the length of the recording window used.





#### **Display**

Under the **Display tab**, options are available for setting how the results will be displayed on the test screen.



- 16. Under **Ears**, you can select:
  - a. **Monaural view** displays one ear at a time on the test screen
  - b. Binaural view displays both ears on the test screen
  - c. **Summary view** displays the test summary and point summary tables on the test screen. This option is only available when **monaural view** is selected.
- 17. Under **View TE**, it is possible to select how the test results are displayed in the TE response graph.
  - a. **Basic view** displays the progress over time for each frequency band measured. When a frequency band becomes completely filled and changes to green, it has reached the stop criterion set in the protocol. Those bars that do not meet the stop criterion will remain in the color of the selected ear (red or blue).
  - b. **Advanced view** displays the noise and OAE for each frequency band. Noise is displayed in gray and the OAE is displayed in the color of the selected ear (red/blue).
  - c. **Show SNR labels** option is available when **Advanced view** is selected. **SNR labels** are displayed in the top right-hand portion of the frequency band.
- 18. Additional views allows for displaying the stimuli & probe check and/or the response waveform on the test screen. Note that these options are only available when Advanced view is selected.





## 5.6 Creating a pass-refer TEOAE protocol

It is possible to create a screening protocol in the TEOAE module that provides a test outcome labelled as PASS, REFER or INCOMPLETE.

The application of TEOAEs in screening is very different to that when used for diagnostic purposes. It is therefore extremely important to select the correct test settings or protocol, depending on the patient or expected use of the test results. As a screening protocol is typically used for the purpose of differentiating patients with likely normal hearing from those with a peripheral dysfunction, it is important to create a protocol that has only a small probability of providing a pass on a test, for patients with a moderate or greater hearing impairment.

In newborn hearing screening, test protocols typically require that 3 out of 4 bands (in the speech frequency range) are detected for a PASS result. When the newborn passes the hearing screening test, it indicates that there is a significantly low chance that they have a significant auditory disorder requiring amplification (e.g., a hearing aid or cochlear implant).

A REFER result only indicates that the detection criteria of the test protocol was not met. This could be due to test conditions (i.e., too noisy), a hearing loss (conductive or sensorineural) or poor testing techniques. Infants that REFER on a screening test may be rescreened before being referred to a diagnostic audiology department for more thorough testing to rule out a permanent hearing loss.

Ensure that the pass-refer protocol that you create is valid for the test population and for the expected clinical outcome. For more comprehensive information about outer hair cell function and for clinical based treatment and rehabilitation decisions, a diagnostic OAE protocol should be used in conjunction with other diagnostic audiological tests.

A protocol used for screening purposes has the purpose of differentiating patients with likely normal hearing from those with a peripheral dysfunction. Therefore, it is important to create a protocol that has only a small probability of providing a pass on a test, on patients with a moderate or greater hearing impairment.

The following test parameters should be carefully defined to create a highly sensitive pass-refer protocol:

#### 1. Test frequency bands

Select or create an appropriate test protocol that includes the cochlear region of interest. For TEOAEs, half octave bands centered around the major audiometric test frequencies are typically used (1000, 1500, 2000, 3000, and 4000 Hz). The number of bands included in the protocol should also be considered. In newborn screening, the 1000 Hz center frequency band is typically omitted due to ambient and physiological noise affecting test outcomes.

#### 2. Stimulus type

A non-linear click stimulus is typically used in both screening and diagnostic OAE testing. For screening it is strongly advised to use the non-linear click stimulus since it is optimized for maximized sensitivity.

## 3. Stimulus level

Typical TEOAE screening and diagnostic test protocols use stimulus levels between 80 – 84 dB SPL. Stimulus levels lower than this are likely to produce more REFER outcomes on ears with normal hearing sensitivity and stimulus levels higher than 84 dB SPL should be avoided to reduce the chance of giving a PASS ears with a mild-moderate hearing impairment.

#### 4. Stimulus tolerance level

Accurate presentation of the stimulus to the ear is important to produce valid OAEs. A stimulus tolerance value (dB) defines the allowed difference of the stimulus presentation level in both a positive and negative direction. Setting an appropriate stimulus tolerance level will ensure that a warning is provided to the tester when unwanted stimulus level changes occur that could affect test outcomes.

Changes in stimulus levels during testing usually occur due to probe movement in the ear canal. Probe movement can be reduced by ensuring a secure probe fit before testing and instructing the patient to remain still during testing.





#### 5. Filtering

Applying a high pass filter assists in the collection of data during noisy conditions, helping to remove low frequency noise. Filtering should be used carefully as it not only filters out the noise, but the OAE response.

Example: Setting the high pass filter to 1200 Hz will attenuate not only the noise below this frequency, but also the OAE response. This may produce a reduction in OAE amplitude below 1200Hz (e.g., in the 1000 Hz band).

#### 6. Noise rejection level

As ambient and physiologic (patient) noise levels have a huge effect on OAE recordings, assessing the noise levels in the test environment before and during testing is extremely important, especially in non-ideal test environments such as in a newborn nursery.

In TEOAE testing, a typical noise rejection setting is between 47 - 55 dB SPL. This ensures that sweeps recorded in conditions where the background noise is high are rejected and not included in the averaging of the response. While it lengthens the test time, it is not recommended to turn the acceptable noise level off. Sweeps recorded with high levels of noise can reduce the integrity of the data being analyzed.

#### 7. Test time / number of sweeps

A suitable test time should be selected to ensure that enough time can be spent to extract the TEOAE response from the surrounding noise in the recording. This can usually be set as either an absolute test time (e.g., 1-6 minutes) or as a maximum number of sweeps (e.g., 2000 sweeps). Testing normally continues until the maximum test time is reached or the required number of TEOAE bands are detected, whichever happens sooner.

#### 8. Number of bands for a pass

Screening protocols typically use criteria of 2 or 3 out of 4 bands for a PASS result. Setting the required numbered of bands too loosely (e.g., 1 out of 4 for a PASS) would increase the chances of passing an ear with a hearing loss, whereas setting it too stringently (e.g., 4 out of 4 for a PASS) would increase the number of REFER outcomes.

#### 9. Mandatory bands

A mandatory band can be set for inclusion in screening protocols. For example, if a 2 out of 4 bands for a pass protocol was used, the 1000 Hz band could be set as a mandatory band for inclusion. This means that if during testing, 2000 and 4000 Hz were detected, testing would continue until 1000 Hz was detected or the test timed out.

#### 10. Min number of sweeps

This setting defines the minimum number of sweeps that must be recorded before the test meets the detection criteria. It is usually recommended to collect a minimum of 80 sweeps to ensure enough good data can be analyzed to form a conclusion.

#### 11. Min TE level

OAE amplitudes are generally in the range of -10 dB SPL to +30 dB SPL in healthy functioning ears. Therefore, setting a minimum OAE level ensures that low-level artifact responses are not accepted as a true OAE response, even when the required SNR is met. Minimum OAE levels should not be set lower than device specific system distortion levels.

#### 12. Minimum total OAE

The total OAE value is the total energy level of the correlated A and B response waveforms. It is obtained from the overall FFT response, not just the half octave frequency bands of interest. In other words, it gives an indication of the amplitude of the total obtained OAE response. Some newborn hearing screening protocols stipulate a minimum total OAE of 0 dB as part of the stop criteria.

#### 13. Recording window

The recording window range defines the time range from which the OAE is analyzed following the presentation of each click stimulus.

The TEOAE440 uses a minimum start time of 4 ms to ensures that any analysis of the OAE is not performed during presentation of the stimulus or the potential artifact that follows.

A short recording window of approximately 8 - 12 ms allows for more rapid presentation of the click stimulus meaning faster acquisition of OAE data.

The benefits of a short recording window are:

- a faster reduction of the noise in the final averaged response
- a shorter test time to achieve the required signal to noise
- a greater signal to noise ratio in the same amount of time as a test using a longer recording window





Using a shorter recording window results in a reduction of the lower frequency portion of the response and should not be used when trying to record TEOAEs below 1000 Hz. A longer recording window of approximately 20 ms should be used when trying to assess the broadest range of cochlear hair cell function. Stimulus presentation becomes slower meaning slightly longer test times to collect the same amount of sweeps when compared to using a short recording window. A long window should always be selected when wanting to assess TEOAEs below 1000 Hz.

#### 14. Selecting an appropriate Signal-to-Noise Ratio (SNR)

The signal-to-noise ratio (SNR) refers to the difference in dB, between the level of the OAE response and the background noise. The SNR can be thought of as an estimate of the reliability with which the OAE response level has been estimated. When SNRs are high, the contribution of the noise in the recording is low and there is more certainty that the displayed OAE response is true. The SNR is calculated from two variables – the OAE response (or signal) generated by the cochlea and the noise, a random variable unrelated to cochlear status. The signal (OAE response) should remain constant during averaging, while the noise level should decrease as test time increases. Most literature recommends a minimum SNR of 6 dB in addition to other criteria to determine the presence of a valid OAE response.

The following literature provide examples of TEOAE screening protocol settings and recommendations.

American Academy of Audiology Childhood Hearing Screening Guidelines. (2011). (http://www.cdc.gov/ncbddd/hearingloss/documents/AAA Childhood%20Hearing%20Guidelines 2011.pdf) p. 35

Healthy Hearing Program, Universal Newborn Hearing Screening. (2016). Audiology Diagnostic Assessment Protocol. https://www.childrens.health.gld.gov.au/wp-content/uploads/PDF/healthy-hearing/hh-audiology-protocol.pdf p. 114.

Neonatal Hearing Screening and Assessment (2002). Transient Evoked Oto-Acoustic Emission (TEOAE) Testing in Babies. Recommended Test Protocol, http://abrpeerreview.co.uk/onewebmedia/NHSP%20TEOAE protocol.pdf

#### Determining a screening protocol's sensitivity

To avoid undertaking unfeasibly large clinical trials involving say 10,000 infants, some countries that administer UNHS programs stipulate test criteria for a sensitivity assessment.

The following is an extract from the United Kingdom Newborn Hearing Screening (NHS) program tender document:

Evidence of cavity trials at volumes close to 0.05; 0.1; and 0.2ml; showing a maximum of 1 pass on 120 repetitions. To be conducted with normal stimulus levels present in (a) quiet conditions and (b) with wide band-noise applied externally to such a level that the reject system is activated between 30% and 70% of the time. Such noise may be generated by the wide band masking of a clinical audiometer. For condition (b) if a method of data rejection is employed that does not enable this test to be performed, provide evidence of an equivalent test in noisy conditions.

Based on the above information, a user defined screening protocol's sensitivity could be assessed by the following method:

- a. Create a user-defined pass/refer protocol in the TEOAE module.
- b. Place the probe in a cavity with similar impedance to an ear matching the test population that the protocol will be used for (e.g., if the screening protocol is to be used on children, a small cavity volume of 0.5 cc could be used).
- c. Run a minimum of 120 full tests in quiet. DO NOT stop any of the tests manually. Repeat step 3 applying external wide band noise as described above.
- d. Calculate the sensitivity using the following mathematical equation:

$$Sensitivity \ge \frac{Number\ of\ true\ refers}{Number\ of\ tests + 1|}$$

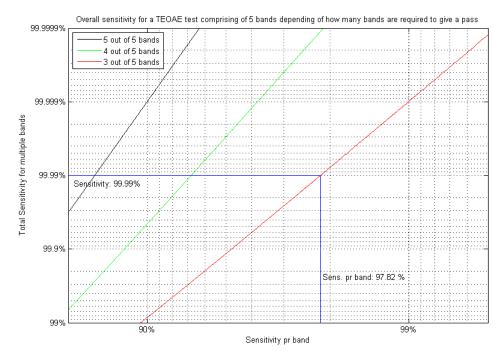




The final sensitivity estimate is calculated by expressing the number of 'true refers' as a percentage of the total number of tests. When tests are performed in a standard test cavity, we would hope that all test outcomes were a 'refer' and therefore the test sensitivity would be measured at 100%. However, statistically it is not safe to use this value unless the number of tests is very large. Instead, the sensitivity is assessed assuming a worst case scenario such that if 'n' tests are performed, if there was an 'n+1' test it would produce a 'false pass'.

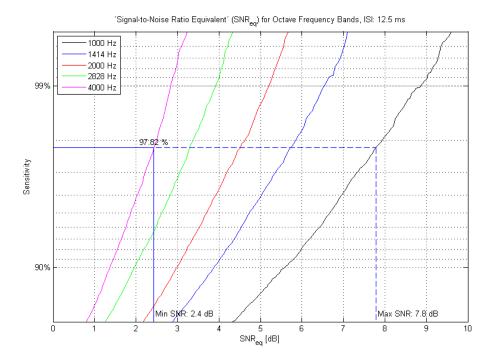
The following graphs show and describe the selection of an appropriate SNR using the Titan with TEOAE440. These values are based on simulations using a minimum of 40 sweeps, 2 minutes test time and a start recording window of 4 ms. Changes to these parameters will affect the SNReq (statistical value related to the SNR called the SNR equivalent) described below.

When creating a protocol, the SNR values will default to the recommended values for the center band method, as described below in the graphs.



**Figure 1:** The graph shows the total algorithmic sensitivity as a function of the sensitivity for each frequency band. The blue lines indicate the required sensitivity per frequency band if it is required to have 3 out of 5 bands to give a "Pass" result and the total algorithmic sensitivity to be 99.99 %. If it is required to have minimum 4 out of 5 bands to pass, the sensitivity per frequency band decreases from 97.82 % to 93.2 % in order to remain an overall sensitivity of 99.99%. If all 5 out of 5 bands are required to pass, the sensitivity per band decreases to 84%.



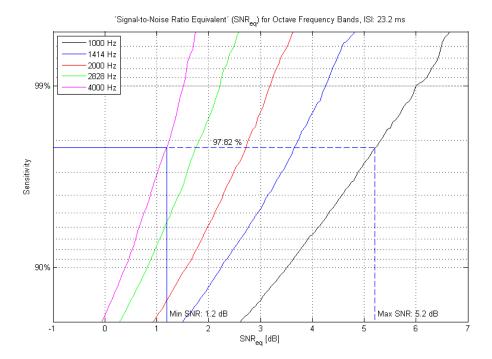


**Figure 2:** The graph shows the algorithmic sensitivity per frequency band as a function of the SNR<sub>eq</sub> per band with half octave frequency bands (center frequency band method). The click repetition interval is 12.5 ms.

In the example from figure 1 the sensitivity per frequency band is set to 97.82 % resulting in a  $SNR_{eq}$  ranging from 2.4 to 7.8 dB depending on the OAE band. Choosing the highest  $SNR_{eq}$  of 7.8 dB as the threshold to accept a response for all bands, increases the total sensitivity (decreases the number of false passes), while choosing the lowest  $SNR_{eq}$  as the threshold at which to accept a response for all bands, decreases the total sensitivity. The reason for a significantly higher  $SNR_{eq}$  in the 1 kHz band is due to noise artifacts in low frequency components, caused by movements and noise in the surroundings. To summarize: Each band could be set using the relevant SNR from the graph above or use of a typical  $SNR_{eq}$  of 6 dB for all frequency bands except the 1 kHz band (use 8 dB) and requiring at least 3 bands to exceed that threshold gives a sensitivity of at least 99.99 %. In other words no more than 1 out of 10000 patients with hearing loss will get a pass in the Titan TEOAE test.





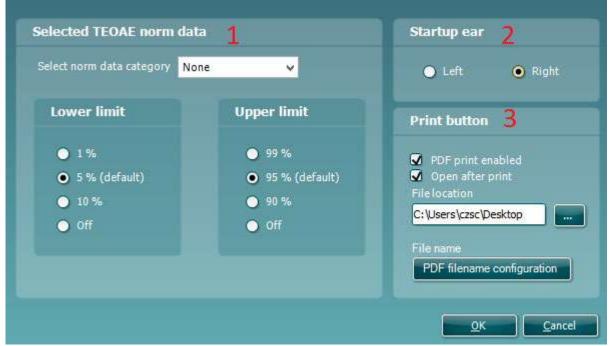


**Figure 3:** The graph shows the algorithmic sensitivity per frequency band as a function of the  $SNR_{eq}$  per band with half octave frequency bands (center frequency band method). The click repetition interval is 23.2 ms. The graphs show significant differences in  $SNR_{eq}$  depending on the half octave band. For the low frequency bands, the  $SNR_{eq}$  is high because the bandwidth of the half octave filter is narrower compared to the high frequency bands. This results in higher  $SNR_{eq}$  values.



## 5.7 General setup

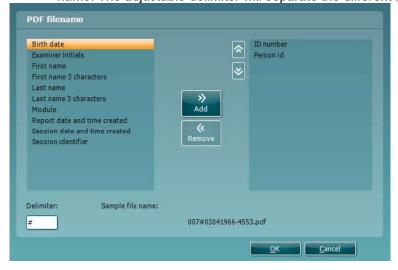
The General setup is accessed by going to Menu | Setup | General setup...



Here, the following options are available to setup:

- Selected TEOAE norm data allows you to select the norm data category you wish to display on the screen (Newborn, Male, Female, None). The Lower limit and Upper limit of the norm data can also be selected.
- 2. **Startup ear** allows you to select which ear the program will always start on as default. The selected startup ear applies to all modules.
- 3. The **Print button** can be set up to automatically print to PDF.
  - a. Check the PDF print enabled box to set the print icon to print to PDF functionality.
  - b. Check the **Open after print** box to open the PDF document after printing.
  - c. Select the **File location** to where the PDF document should be saved.
- 4. Select PDF **filename configuration** to define the name of the file. Selecting the button will open another window to set the fields defining the name of the PDF file.

A field called "ID Number" must be added to the PDF file. Use the arrow keys to add fields to the file name. The adjustable delimiter will separate the different fields from one another.





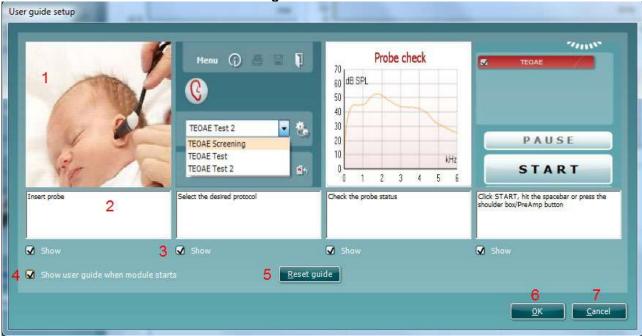


## 5.8 User guide

The User Guide setup is accessed by going to Menu | Setup | User guide setup

The default setup for the User Guide has preselected guidance pictures and text. All four guide pictures and

test instructions are selected and Show user guide when module starts is checked.



The following options are available:

- 1. Right clicking on the Picture allows you to add a new picture to assist with guidance. A Microsoft window will open allowing you to select pictures stored elsewhere on your PC. Navigate to and select the desired image and then click Open. The picture will be replaced with your chosen one.
- The **Text** can be edited the text in the text box by simply placing the cursor in the white box with your mouse.
- There are four available guidance pictures with text. Uncheck **Show** on the ones you do not want shown when the User guide is displayed.
- 4. Uncheck Show user guide when module starts if you do not want the User Guide to appear on the screen each time the module starts.
- 5. Reset guide allows you to reset the guide pictures and text to the default settings as when the software was installed
- 6. Pressing **OK** will accept any changes made and will close down the User Guide setup
- 7. Cancel will close down the User Guide setup without saving any changes made.

#### 5.9 Temporary setup

The Temporary setup can be accessed in two ways and allows you to make temporary changes to the protocol currently shown in the protocol drop down list.

- 1. Go to Menu | Setup | Temporary setup
- 2. Click on the Temporary setup icon on the control panel

When a temporary change has been made to a protocol, the protocol name will then appear with an asterisk next to it. If data is measured before you enter temporary setup you are prompted to save or discard the data. In temporary setup the same options are available as in the normal protocol settings.





## 5.10 PC shortcuts

For quick operation from the keyboard the following hotkeys are available:

L - switch to left ear R - switch to right ear Space - start or stop

A - select or deselect all tests of a protocol

T - go into temporary settings

Ctrl S - save and new

Ctrl P - print

Ctrl N - delete all data and start new measurement

Page up - go one up in saved sessions
Page down - go one down in saved sessions
Arrow up - go one test up within the protocol
Arrow down - go one test down within the protocol





# 6 Protocol management

## 6.1 Renaming a protocol

To rename a protocol you need to enter the **Protocol setup** menu.

- 1. Select Menu | Setup | Protocol setup...
- Select the protocol that you want to rename from the Selected protocol drop down menu.
   Type in the new name.
- 4. Press OK.
- 5. Press Yes in the dialog box to confirm you want to rename the protocol. If you chose a new name that already existed in the protocol list, you will be asked to go through step 2 to 5 again in order to rename your protocol.

Note: You cannot rename factory protocols.

## 6.2 Deleting a protocol

To delete a protocol, you need to enter the Titan **Protocol setup** menu.

- 1. Select Menu | Setup | Protocol setup...
- 2. Select the protocol to delete from the **Selected protocol** drop down menu.
- 3. Press Delete.
- 4. Press **Yes** in the dialog box to confirm you want to delete the protocol.

## 6.3 Exporting a protocol

To export a protocol you need to enter the Titan **Protocol Setup** menu.

- 1. Select Menu | Setup | Protocol setup...
- 2. Select the protocol to export from **Selected protocol** drop down menu.
- 3. Press Export.
- 4. When prompted, select Yes or No for saving the file as read-only? Exporting a protocol as readonly results in the protocol being protected against any setting changes when imported back into the Titan Suite.
- 5. Browse to the location where you want to store your protocol. Name the file and press **Save**.

#### 6.4 Importing a protocol

To import a protocol, I you need to enter the Titan Protocol Setup menu.

- 1. Select Menu | Setup | Protocol setup...
- 2. Press Import.
- 3. Browse to the location where you stored your protocol files. Select the protocol you want to import.
- 4. Press Open.

Note: If the imported protocol was originally saved as a read-only file, you will not be able to change any of the protocol settings.

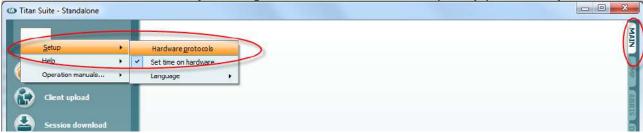




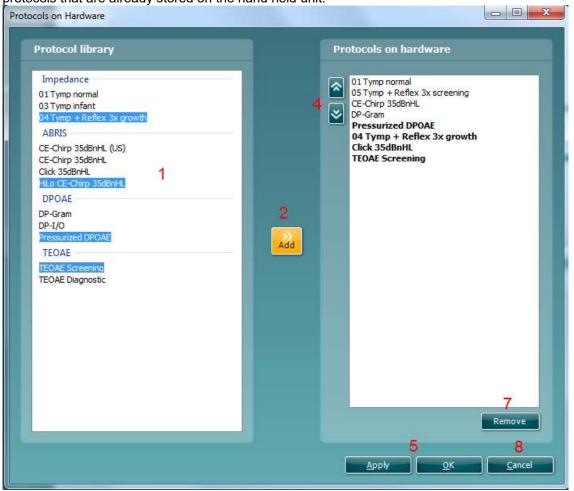
## 6.5 Transferring protocols to Titan

Protocols that have been created in the Titan Suite can be transferred to the hand held unit for use. In order to perform a transfer, connect the Titan to the PC via the cradle or USB cable, switch it on and open the Titan Suite. You cannot transfer protocols if the Suite is running in simulation mode.

Transferring protocols to the Titan hand held unit is done from the **Protocols on Hardware** window. You reach this window by selecting the **Main** tab and then **Menu | Setup | Hardware protocols**.



The **Protocols on Hardware** window displays two columns. The **Protocol Library** column lists the protocols available for transfer to the hand held unit are listed. The **Protocols on Hardware** column shows the protocols that are already stored on the hand held unit.





Follow the next steps to transfer protocols to the Titan hand held unit:

- 1. Select the protocols you want to transfer from the **Protocol Library** column. Hold down Shift or Ctrl and use the mouse to select the protocols to transfer.
- 2. Press Add.
- 3. If a protocol is chosen that was already stored on the hardware, you will be asked if you want to replace the old protocol with the new one. Choose **Yes** or **No**.



- 4. The newly transferred protocols to the hardware will now appear in bold in the **Protocols on Hardware** column. To change the order of the protocols on the Titan, select a protocol and move it up or down by pressing the arrow buttons.
- 5. To finish the transfer press either **OK** (which closes the **Protocol on Hardware** window) or **Apply** (which keeps the **Protocol on Hardware** window open).
- 6. A notification that the transfer process succeeded will appear. Press **OK** to continue.



To remove single or multiple protocols from the Titan hand held unit:

7. Select the protocol/s you want to remove from the **Protocols on Hardware** column and press **Remove**.

To undo changes made in the **Protocols on Hardware** window:

8. Press **Cancel**. You will then be asked to confirm your cancelation. Be aware that the transfer of protocols to the Titan cannot be cancelled after pressing the **Apply** button.

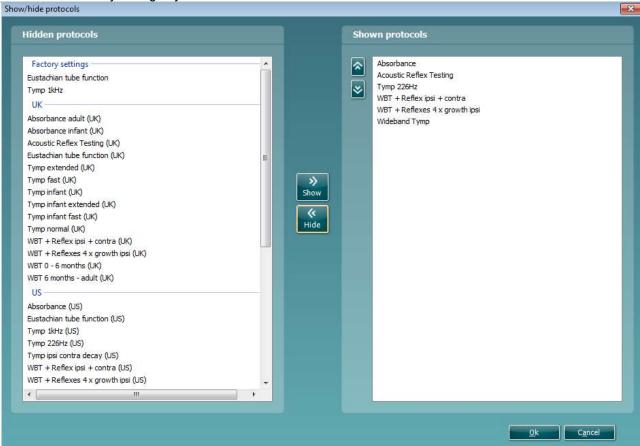




# 6.6 Show/hide and reorder protocols in Titan Suite

In any Titan Suite module, show/hide protocols work as follows:

- 1. Select Menu | Setup | Show/hide protocols...
- 2. Select protocols from the **Hidden protocols** window press the **Show** button to move them to the **Shown protocols** window.
- Select a protocol in the **Shown protocols** window Use the arrow keys to rearrange the order of the
  protocols. This is the order in which they will be displayed in the protocol selection dropdown menu
  on the test screen.
- 4. To hide protocols, select the protocols to be hidden from the **Shown protocols** window and press the **Hide** button. The selected protocols are moved back to the **Hidden protocols** window.
- Press **OK** to save your selection and close the window. Press **Cancel** to close the window and discard any changes you made.







# 6.7 Password protection

Activating the password restricts users from entering the protocol setup and user guide setup throughout the entire Titan Suite.

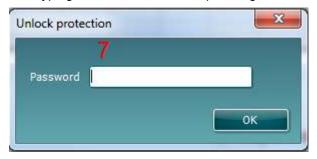
To activate password protection for the first time:

- 1. Go to and select Menu | Setup | Password protection.
- 2. Leave the current password blank. The default password is empty.
- 3. Type in your **New password**.
- 4. Retype your password as confirmation.
- 5. Press OK.



Deactivating the password protection temporarily (until the Suite is closed or the password is changed) is done by

- 6. Going to and selecting Menu | Setup | Unlock protection
- 7. Typing in the **Password** and pressing **OK**.



To permanently disable the Password Protection:

- 1. Go to and select Menu | Setup | Password protection.
- 2. Type in your password in the Current password field.
- 3. Leave the **New password** and **Confirm password** fields blank.
- 4. Password protection is now turned off.









# 7 Printing and making reports

# 7.1 Using the thermal printer

If you give the print command from the hand held unit it will automatically send the print job to the thermal printer when it is connected. See the Instructions for Use document for more information about setup.

#### 7.2 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 Titan Suite tabs (IMP, DPOAE, ABRIS)
- b. If you want to make a template or select an existing one to link to a specific protocol: Go to Module tab (IMP, DPOAE, ABRIS) 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: Print wizard Categories Templates ── ➤ Templates ETF - Perforated Reflex Factory defaults User defined Hidden My favorites Tymps and Reflexes DP-I/O Report DP-Gram Report Report Click on categories above to view templates. Use top Ε right corner icons for sorting & creating templates. Right-click on template to display options. Double-click on template to preview. TE Report ABRIS Report Print Cancel Preview

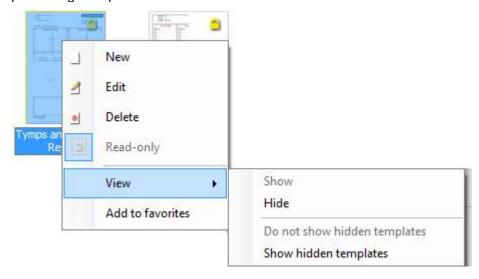
- 1. Underneath Categories you can select
  - Templates to show all available templates
  - Factory defaults to show only standard templates
  - User defined to show only custom templates
  - Hidden to show hidden templates
  - My favorites to show only templates marked as a favorite
- 2. Available templates 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 **Protocol setup** 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
  - 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:



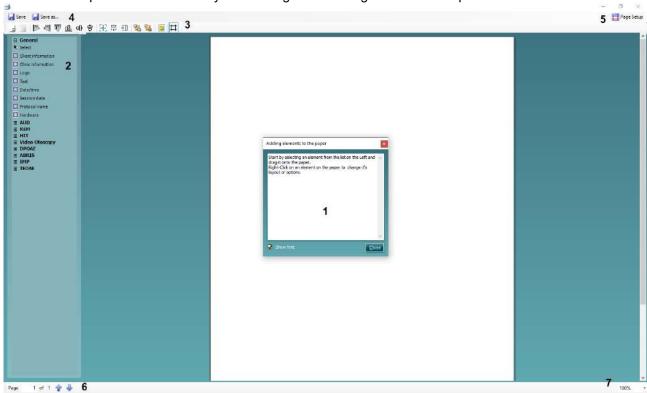




# 7.2.1 Designing a customized print template

After clicking on the **New Template** (or **Edit Template**) button the design window shows as below.

- 1. Upon opening, a short description about how to create a template will show on the screen. Press **Close** to close the message box. Uncheck the **Show hints** checkbox, if you do not want it to appear next time.
- 2. This list shows the elements which can be dragged onto the paper. When **General** is selected, the general elements are listed. Template elements for each module will be listed when selecting the relevant module name, for example **IMP**, **ABRIS**, **DPOAE** or **TEOAE**The handling and options for all elements are discussed in a separate section below.
- 3. The **taskbar** includes numerous icons for customizing the elements that are dragged onto the blank template page. These are described below in a separate section.
- 4. Press **Save** to save the print template and go back to the **Print wizard** window. If you have created a new template, you are prompted to give it a name. Press **Save As...** if you have modified an existing template and want to save under a different name.
- 5. Pressing the **Page Setup** button opens the **Page Setup** window where you can choose the paper size, source, margins and setup the paper orientation.
- 6. If the template has more than one page, use the up and down arrows, 🛣 🔩, to scroll through the different pages. You can also type in the page number that you would like to view and/or edit.
- 7. The **Zoom** drop down menu allows you to change the viewing size of the template on screen.







# 7.3 Design elements

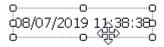
The following section describes the available elements and their respective options for the **IMP**, **DPOAE**, **TEOAE** and **ABRIS** modules.

# 7.3.1 Adding elements to the template

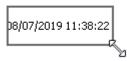
Template elements are added to the report page using the select, drag and drop function. Click on the desired element from the menu and drag it onto the template page. The element will appear as a small box in the upper left hand corner.

# 7.3.2 Moving and resizing elements

To move an element, click on the center of the element and drag it with the mouse to the desired location.

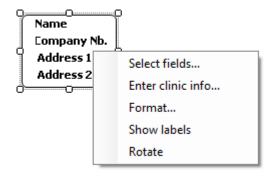


To resize an element, click on one of the corners of the element and drag it to the desired size.



# 7.3.3 Customizing an element

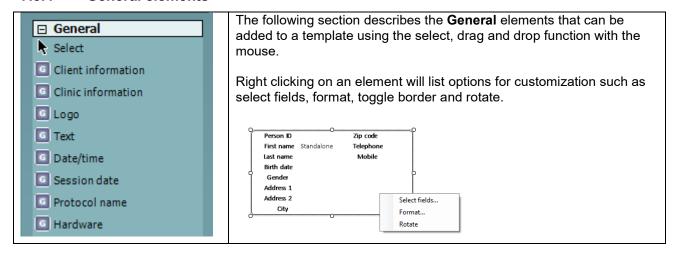
Right clicking on any element will list its options for customization.







# 7.3.4 General elements



#### 1. Client information

- Select fields opens the Select fields window where you select which items are to be shown in the client information element. You can change the order of the items by selecting one and pressing the up or down arrows. Pressing will create a new empty field that can be named and shown in the template. Change a field's name by selecting it, waiting for 1 sec and then left clicking on the name. Pressing will remove user created fields when selected
- Press to restore the manufacturer's default fields
- The Create date item cannot be changed as it will always shows the date and time that the
  patient was created in the database
- **Format...** opens the **Format Client** window. Here you can change the the font, font size and formatting, and the appearance (borders) of the **Client information** area
- Selecting Rotate makes the element rotate 90

#### 2. Clinic information.

- Select fields pops up the Select fields window where you select which items are to be shown in the clinic information element. You can change the order of the items by selecting one and pressing the up or down arrows. Pressing will create a new empty field that can be named and shown in the template. Change a field's name by selecting it, waiting for 1 sec and then left clicking on the name. Pressing will remove user created fields when selected
- Press to restore the manufacturers' default fields
- Enter clinic info... opens the Clinic info editor window (Noah only). Here you can type and save the clinic information specifically for the selected print template. The Create date item cannot be changed as it will always show the current date and time. When using in conjunction with the OtoAccess® database, you will be advised to define the clinic information via the database
- **Format...** Here you can change the the font, font size and formatting, and the appearance (borders) of the **Clinic information** area
- By selecting Show labels, the Clinic information fields can be toggled on and off
- Selecting Rotate makes the element rotate 90 degrees clockwise

### 3. Logo

- **Select image** opens a window from where you can browse to find the image stored on your PC that you want to include in the template
- Selecting Rotate makes the element rotate 90 degrees clockwise





- 4. Text. This element allows you to add additional text, e.g. footnotes on your template.
  - Enter text opens the Enter Text window. Here you can type in freetext and choose the font type, size and formatting
  - Selecting Rotate makes the element rotate 90 degrees clockwise
- 5. **Date/time**. This element allows you to put in a stamp on the template showing date and/or time of printing.
  - Enter setup...opens the Date Time setup window. Here you choose the format in which the date and/or time appears in the template. You can also choose the font type, size and formatting
  - Selecting Rotate makes the element rotate 90 degrees clockwise
- 6. **Session date**. This element allows you to put in a stamp on the template showing date and/or time that the measurements were recorded.
  - Enter setup... opens the Date Time setup window, exactly as in 5a. Here you choose the format in which the date and/or time appears in the template. You can also choose the font type, size and formatting
  - **Select modules** gives the opportunity to define which modules' session dates will be shown. On the print out you can combine measurements from the Titan Suite and other Interacoustics Suites (Callisto, Affinity, Equinox, Diagnostic)
  - Toggle border allows you to disable or enable the border around the Session date element.
  - Selecting Rotate makes the element rotate 90 degrees clockwise
- 7. **Protocol name.** This element allows you to display the protocol name/s on the template for the recorded measurement/s.
  - Select modules gives the opportunity to define which modules' protocol names will be shown. On the print out you can combine measurements from Titan Suite and other Interacoustics Suites (Callisto, Affinity, Equinox, Diagnostic)
  - Toggle border allows you to disable or enable the border around the Session date element
  - Selecting Rotate makes the element rotate 90 degrees clockwise
- 8. Hardware. This element allows you to display the hardware used for conducting the measurement.
  - Format allows you to change the font, font size and formatting, and the appearance (borders) Select modules allows you to define which modules' hardware names will be shown.
  - Select **Rotate** to rotate the element rotate 90 degrees clockwise



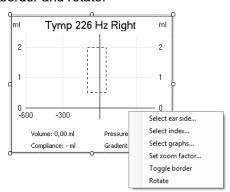


#### 7.3.5 IMP elements



The following section describes the **IMP** elements that can be added to a template using the select, drag and drop function with the mouse.

Right clicking on an element will list options for customization such as select ear side, select index, select graph, set zoom factor, toggle border and rotate.



- 1. **Tymp**. This element contains a single tympanogram.
  - Select ear side... opens a window in which you choose if the graph shows the right or left ear
  - **Select index...** opens a window in which you choose which dataset should be displayed. If a protocol exists with more than one tympanometry test, the first one contains dataset 1, the second dataset 2, etc.
  - Select graphs...allows you to choose to plot the Y, G and/or B tympanometry curves
  - Set zoom factor allows for defining the scale of the y axis
  - Toggle border allows you to disable or enable the border around the element
  - Selecting Rotate makes the element rotate 90 degrees clockwise
- 2. **Reflex**. This element contains the reflexes. If a reflex test contains many rows and columns they will automatically be scaled in order to fit in the space available.
  - Select ear side... opens a window in which you choose if the graph shows the right or left ear
  - **Select index...** opens a window in which you choose which dataset should be displayed. If a protocol exists with more than one tympanometry test, the first one contains dataset 1, the second dataset 2, etc.
  - Toggle border allows you to disable or enable the border around the element
  - Selecting Rotate makes the element rotate 90 degrees clockwise
- 3. **Decay**. This element contains the decay reflexes. If a decay reflex test contains more measurements, they will automatically be scaled in order to fit in the space available.
  - Select ear side... opens a window in which you choose if the graph shows the right or left ear
  - **Select index...** opens a window in which you choose which dataset should be displayed. If a protocol exists with more than one tympanometry test, the first one contains dataset 1, the second dataset 2, etc.
  - Toggle border allows you to disable or enable the border around the element
  - Selecting Rotate makes the element rotate 90 degrees clockwise
- 4. **Latency**. This element contains the latency reflexes. If a latency reflex test contains more measurements, they will automatically be scaled in order to fit in the space available.
  - Select ear side... opens a window in which you choose if the graph shows the right or left ear
  - **Select index...** opens a window in which you choose which dataset should be displayed. If a protocol exists with more than one tympanometry test, the first one contains dataset 1, the second dataset 2, etc.
  - Toggle border allows you to disable or enable the border around the element
  - Selecting Rotate makes the element rotate 90 degrees clockwise





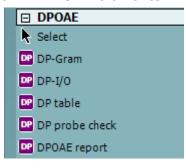
- 5. **ETF non-perforated**. This element contains the Eustachian Tube Function Non-perforated eardrum measurements.
  - Select ear side... opens a window in which you choose if the graph shows the right or left ear
  - **Select index...** opens a window in which you choose which dataset should be displayed. If a protocol exists with more than one tympanometry test, the first one contains dataset 1, the second dataset 2, etc.
  - Toggle border allows you to disable or enable the border around the element
  - Selecting Rotate makes the element rotate 90 degrees clockwise
  - Set zoom factor allows for defining the scale of the y axis
- 6. **ETF perforated**. This element contains the Eustachian Tube Function Perforated eardrum measurement.
  - Select ear side... opens a window in which you choose if the graph shows the right or left ear
  - **Select index...** opens a window in which you choose which dataset should be displayed. If a protocol exists with more than one tympanometry test, the first one contains dataset 1, the second dataset 2, etc.
  - Toggle border allows you to disable or enable the border around the element
  - Selecting Rotate makes the element rotate 90 degrees clockwise
- 7. **ETF patulous**. This element contains the Eustachian Tube Function Patulous Eustachian tube measurement.
  - Select ear side... opens a window in which you choose if the graph shows the right or left ear
  - **Select index...** opens a window in which you choose which dataset should be displayed. If a protocol exists with more than one tympanometry test, the first one contains dataset 1, the second dataset 2, etc.
  - Toggle border allows you to disable or enable the border around the element
  - Selecting Rotate makes the element rotate 90 degrees clockwise
- 8. **Imp report**. This element contains the report which is created in the report editor.
  - Toggle border allows you to disable or enable the border around the element
  - Selecting Rotate makes the element rotate 90 degrees clockwise
- 9. WB absorbance. This element contains the Wideband absorbance measurement.
  - Select ear side... opens a window in which you choose if the graph shows the right or left ear
  - **Select index...** opens a window in which you choose which dataset should be displayed. If a protocol exists with more than one tympanometry test, the first one contains dataset 1, the second dataset 2, etc.
  - Toggle border allows you to disable or enable the border around the element
  - Selecting Rotate makes the element rotate 90 degrees clockwise
- 10. **WBA examples.** This element contains various Wideband Absorbance measurement examples obtained in ears with pathologies and with a poor probe status.
  - Toggle border allows you to disable or enable the border around the element
  - Selecting Rotate makes the element rotate 90 degrees clockwise
- 11. **3DT 3D graph.** This element displays the 3D tympanometry measurement.
  - Select ear side... opens a window in which you choose if the graph shows the right or left ear
  - **Select index...** opens a window in which you choose which dataset should be displayed. If a protocol exists with more than one tympanometry test, the first one contains dataset 1, the second dataset 2, etc.
  - Select view angle... allow you to display the graph as isometric or as on screen
  - Toggle border allows you to disable or enable the border around the element
  - Selecting Rotate makes the element rotate 90 degrees clockwise





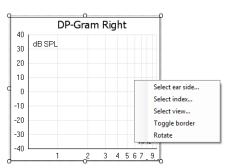
- 3DT tymps. This element displays the tympanograms measured during the 3DT test.
  - Select ear side... opens a window in which you choose if the graph shows the right or left ear
  - **Select index...** opens a window in which you choose which dataset should be displayed. If a protocol exists with more than one tympanometry test, the first one contains dataset 1, the second dataset 2, etc.
  - Select graphs...allows you to choose to plot the Y, G and/or B tympanometry curves
  - Set **zoom factor** allows for defining the scale of the y axis
  - Toggle border allows you to disable or enable the border around the element
  - Selecting Rotate makes the element rotate 90 degrees clockwise
- 13. 3DT abs. This element displays the absorbance measurements at 0daP and peak pressure.
  - Select ear side... opens a window in which you choose if the graph shows the right or left ear
  - **Select index...** opens a window in which you choose which dataset should be displayed. If a protocol exists with more than one tympanometry test, the first one contains dataset 1, the second dataset 2, etc.
  - Toggle border allows you to disable or enable the border around the element
  - Selecting Rotate makes the element rotate 90 degrees clockwise

#### 7.3.6 DPOAE elements



The following section describes the **DPOAE** elements that can be added to a template using the select, drag and drop function with the mouse.

Right clicking on an element will list options for customization such as select ear side, select index, select view, toggle border and rotate.



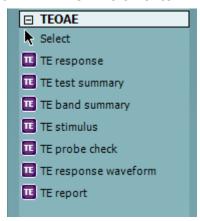
- 1. **DP-Gram**. This element contains the DP-Gram measurement.
  - Select ear side... opens a window in which you choose if the graph shows the right or left ear
  - **Select index...** opens a window in which you choose which dataset should be displayed. If a protocol exists with more than one DP-gram test, the first one contains dataset 1, the second dataset 2. etc.
  - **Select view...** opens a window in which you can choose which graph type will be displayed bar view or graph view
  - Toggle borders allow you to disable or enable the border around the element
  - Selecting Rotate makes the element rotate 90 degrees clockwise
- 2. **DP-I/O**. This element contains the DP-I/O measurement.
  - Select ear side... opens a window in which you choose if the graph shows the right or left ear
  - **Select index...** opens a window in which you choose which dataset should be displayed. If a protocol exists with more than one DP-gram test, the first one contains dataset 1, the second dataset 2, etc.
  - Toggle borders allow you to disable or enable the border around the element
  - Selecting Rotate makes the element rotate 90 degrees clockwise





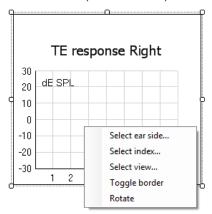
- 3. **DP table**. This element contains details about each data point of the DPOAE measurements.
  - Select ear side... opens a window in which you choose if the graph shows the right or left ear
  - **Select index...** opens a window in which you choose which dataset should be displayed. If a protocol exists with more than one DP-gram test, the first one contains dataset 1, the second dataset 2, etc.
  - **Select session...** lets you display table results from different sessions on the same printout, provided that historic session overlays have been selected in the test screen (See more about historic overlay in the section 'Comparing DPOAE data (historic overlay)'). 1 Being the session in focus; 2,3, being the historical overlays selected in the session list in the test screen.
  - Toggle borders allows you to disable or enable the border around the element
  - Rotate makes the element rotate 90 degrees clockwise
- 4. **DP probe check.** This element contains the DP probe check graph
  - Select ear side... opens a window in which you choose if the graph shows the right or left ear
- 5. **DPOAE report**. This element contains the report which is created in the report editor.
  - Toggle borders allows you to disable or enable the border around the element
  - Rotate makes the element rotate 90 degrees clockwise

#### 7.3.7 TEOAE elements



The following section describes the **TEOAE** elements that can be added to a template using the select, drag and drop function with the mouse.

Right clicking on an element will list options for customization such as select ear side, select index, select view, toggle border and rotate.



- 1. **TE response.** This element contains the TE response graph.
  - Select ear side... opens a window in which you choose if the graph shows the right or left ear
  - **Select index...** opens a window in which you choose which dataset should be displayed. If a protocol exists with more than one DP-gram test, the first one contains dataset 1, the second dataset 2, etc.
  - Select view...opens a window in which you can choose which graph type will be displayed basic, advanced or FFT
  - Toggle border allows you to disable or enable the border around the element
  - Selecting Rotate makes the element rotate 90 degrees clockwise



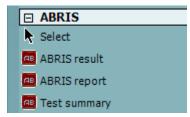


- 2. **TE test summary**. This element displays the TE test summary table.
  - Select ear side... opens a window in which you choose if the graph shows the right or left ear
  - Select results... opens a window in which can choose which result items should be displayed in the table
  - **Select index...** opens a window in which you choose which dataset should be displayed. If a protocol exists with more than one DP-gram test, the first one contains dataset 1, the second dataset 2, etc.
  - Toggle border allows you to disable or enable the border around the element
  - Selecting Rotate makes the element rotate 90 degrees clockwise
- 3. **TE band summary**. This element displays the TE band summary table.
  - Select ear side... opens a window in which you choose if the graph shows the right or left ear
  - **Select index...** opens a window in which you choose which dataset should be displayed. If a protocol exists with more than one tympanometry test, the first one contains dataset 1, the second dataset 2, etc.
  - Toggle border allows you to disable or enable the border around the element
    - Selecting Rotate makes the element rotate 90 degrees clockwise
- 4. **TE stimulus.** This element displays the TE stimulus graph.
  - Select ear side... opens a window in which you choose if the graph shows the right or left ear
  - **Select index...** opens a window in which you choose which dataset should be displayed. If a protocol exists with more than one tympanometry test, the first one contains dataset 1, the second dataset 2, etc.
  - Toggle border allows you to disable or enable the border around the element
  - Selecting Rotate makes the element rotate 90 degrees clockwise
- 5. **TE probe check**. This element displays the probe check graph
  - Select ear side... opens a window in which you choose if the graph shows the right or left ear
  - **Select index...** opens a window in which you choose which dataset should be displayed. If a protocol exists with more than one tympanometry test, the first one contains dataset 1, the second dataset 2, etc.
  - Toggle border allows you to disable or enable the border around the element
  - Selecting Rotate makes the element rotate 90 degrees clockwise
- 6. **TE response waveform.** This element displays the TE response waveform.
  - Select ear side... opens a window in which you choose if the graph shows the right or left ear
  - **Select index...** opens a window in which you choose which dataset should be displayed. If a protocol exists with more than one tympanometry test, the first one contains dataset 1, the second dataset 2, etc.
  - Toggle border allows you to disable or enable the border around the element
  - Selecting Rotate makes the element rotate 90 degrees clockwise
- 7. **TE report.** This element contains the report which is created in the report editor.
  - Toggle borders allows you to disable or enable the border around the element
  - Rotate makes the element rotate 90 degrees clockwise



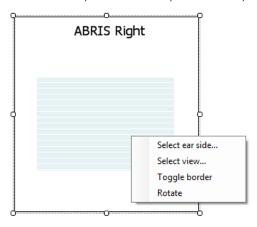


#### 7.3.8 ABRIS elements



The following section describes the **ABRIS** elements that can be added to a template using the select, drag and drop function with the mouse.

Right clicking on an element will list options for customization such as select ear side, select results, select view, toggle border and rotate.

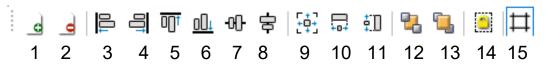


- 1. **ABRIS result**. This element contains the ABRIS result in graphic format.
  - Select ear side... opens a window in which you choose if the graph shows the right or left ear
  - Select view...opens a window in which you can choose which graph type will be displayed –
    graph or bar view
  - Toggle border allows you to disable or enable the border around the element
  - Selecting Rotate makes the element rotate 90 degrees clockwise
- 2. **ABRIS report**. This element contains the report which is created in the report editor.
  - Toggle border allows you to disable or enable the border around the element
  - Selecting **Rotate** makes the element rotate 90 degrees clockwise
- 3. **Test summary.** This element displays the ABRIS test summary table.
  - Select ear side... opens a window in which you choose if the graph shows the right or left ear
  - Select results... opens a window in which can choose which result items should be displayed in the table
  - Toggle border allows you to disable or enable the border around the element
  - Selecting Rotate makes the element rotate 90 degrees clockwise





## 7.3.9 Taskbar



- 1. Add page. Allows you to add an extra page to an existing template.
- 2. **Remove page**. Allows you to remove an extra page that has been added to the template. You will be prompted to confirm removal before it takes effect.
- 3. **Align left**. If you select two or more elements (by holding down the shift button on the keyboard) this button will align the selected elements on their left borders.
- 4. **Align right**. If you select two or more elements (by holding down the shift button on the keyboard) this button will align the selected elements on their right borders.
- 5. **Align top**. If you select two or more elements (by holding down the shift button on the keyboard) this button will align the selected elements on their top borders.
- 6. **Align bottom**. If you select two or more elements (by holding down the shift button on the keyboard) this button will align the selected elements on their bottom borders.
- 7. **Align horizontal**. If you select two or more elements (by holding down the shift button on the keyboard) this button will align the selected elements on their horizontal central axis.
- 8. **Align vertical**. If you select two or more elements (by holding down the shift button on the keyboard) this button will align the selected elements on their vertical central axis.
- 9. **Make equal size**. If you select two or more elements (by holding down the shift button on the keyboard) this button will make all element sizes equal to the element that was placed on the page first.
- 10. **Same width**. If you select two or more elements (by holding down the shift button on the keyboard) this button will make all element widths equal to the width of the element that was placed on the page first.
- 11. **Same height**. If you select two or more elements (by holding down the shift button on the keyboard) this button will make all element heights equal to the height of the element that was placed on the page first.
- 12. **Send to back**. This button sends the selected element(s) to the back.
- 13. **Send to front**. This button sends the selected element(s) to the front.
- 14. **Lock element** locks (or unlocks) the selected element(s). This means that the position and size of the element is locked. When one of the other taskbar functions is used on a locked element it will automatically unlock.
- 15. Display margins toggles between showing/hiding the print margins as a broken line.





# 7.4 Creating reports

The Titan Suite allows electronically generated reporting through the **Report editor**. This allows reports to be saved in the specific module for each test session and they can be retrieved at any time. The contents of the report can also be added to the print template, which gives you the opportunity to have all the relevant test information in one customized printout. The report function also includes the possibility to make **Report templates** which gives you the option to have different templates e.g. for different client groups or for use by different clinicians.

To open the **Report editor** in order to write a report for the current patient where measurements have been





# 7.4.1 Using the report editor with saved sessions

#### Noah

When a session is saved into Noah, there is a limited time window where reports can be added or edited. Changes or edits can only be made on the same date as the session was saved.

When a session is imported into Noah from the hand held unit, the report can only be changed on the same date as the test was imported.

#### **OtoAccess®**

Reports for historic sessions saved in OtoAccess® can be edited at any time and the updated information entered into the report will be saved.

# 7.4.2 Operation of the report editor

The follow information and operations are found in the **Report editor**:

- 1. When **Report editor** is displayed in the top bar, new reports or templates can be made. When viewing a historic saved report, (Read only) will also be visible.
- 2. **Grow font** allows you to increase the font size in steps.
- 3. Shrink font allows you to decrease the font size in steps.
- 4. Change the currently selected Font size.
- 5. Change the currently selected **Font type**.
- 6. **Template** allows you to select a saved template and insert it into the current report.
- 7. **Template editor** allows you to access a screen for creating, saving, editing, deleting, importing and exporting templates
- 8. Change the currently selected font to **Bold**.
- 9. Change the currently selected font to **Italic**.
- 10. Add an **Underline** to the currently selected font.
- 11. Change the alignment of the selection to **Align left**.
- 12. Change the alignment of the selection to Center.
- 13. Change the alignment of the selection to **Align right**.
- 14. Change the alignment of the selection to Justify.
- 15. Insert Numbering
- 16. Insert Bullets.
- 17. Import image allows you to insert an image or picture saved on your PC.
- 18. Indicates the area in which the **report** can be written.

On selecting template editor, a new screen will appear to allow for template editing. The toolbar options are described below:





- 19. Type the **template name** here.
- 20. Add new template after the template name has been entered.
- 21. **Edit template** displays a list of saved templates for editing. Select the desired template from the list to make edits.
- 22. **Delete template** displays a list of saved templates for deleting. Select the desired template from the list to delete it.





- 23. **Set as default template** will set the open template on screen as the default template to display when the report editor is opened for the first time during a session.
- 24. **Import/Export template** allows templates to be imported from a location on your PC or exported for use on another PC.
- 25. The **Save** icon becomes visible once a template has been added.
- 26. The **template name** is displayed. If it has not been saved, **(Template not saved!)** will appear beside the template name.





# 8 FAQ/troubleshooting

Problem	Explanation	Solution
The probe light stays white.	The probe has probably just been connected to Titan.	<ul> <li>Switch ear side or start a measurement.</li> <li>If the probe light still does not change to the color of the probe status, switch Titan off and back on.</li> <li>If the problem remains, request help from an authorized technician or call Interacoustics Hotline support for help.</li> </ul>
Wrong probe light and or probe status indication with shoulder box	Check whether the problem also occurs when using the short extension cord.	<ul> <li>Switch Titan off and back on.</li> <li>If the problem still exists but not when using the short extension cord, your shoulder box needs to be checked by an authorized technician.</li> </ul>
USB connection with Titan fails	- USB connection incorrect to the PC or to the cradle Titan can have powered down Titan can be placed incorrectly in the cradle Titan allows only connection to one instance of Titan Suite.	- Check USB connection Check if Titan is switched on Check if the left cradle light is solid or flashing green, indicating that Titan is placed correctly Check if Titan says "PC controlled" and if yes, close multiple instances of Titan Suite If problem still occurs: switch off Titan, restart Titan Suite and the database you are using and switch on Titan again If the problem remains, request help from an authorized technician or call Hotline support or help.
Titan will not switch on when placed in cradle.	- Empty battery but the cradle is not charging Empty battery and cradle is charging correctly: Theoretically a battery can run so empty that just after starting recharging its power is still not sufficient to support the tasks needed in Titan. Titan does in that case not yet allow itself to start up.	- Check power supply to the cradle Check if the left cradle light is solid or flashing green, indicating that Titan is placed correctly Replace Titan's batteries or wait two minutes before restarting Titan.
Software states that no probe is connected while there is a probe attached	- When the battery in Titan is nearly empty it shuts off power to the probe	- Change Titan's batteries
No printer found when printing from Titan with wireless printer	- After the wireless printer is switched on it typically takes 10 to 30 seconds to restore the wireless connection	- Wait until connection is restored or - Switch the wireless printer on before starting the measurement so connection is available when measurement has been completed.

# MMMM

Unhandled exception during Titan Suite.	Although Titan is thoroughly tested, you could have encountered an unknown software problem.	- After an unhandled exception it is advised to switch off Titan, restart Titan Suite and the database you are using and switch on Titan again.
		- If your problem occurs more often Interacoustics would very much appreciate if you report the problem and the situation from which it occurs.
Titan shows error code on screen.	Although Titan is thoroughly tested, you could have encountered an unknown firmware problem.	After a firmware error code, it is advised to switch off Titan and switch on Titan again.     If your problem occurs more often Interacoustics would very much appreciate if you report the problem and the situation from which it occurs.
Other		- Please contact an authorized technician or Interacoustics Hotline support or help.

