



How-To-Manual

Psycho-acoustical and physiological test procedures for the
assessment of hearing impairment

Scientific background, methodology, clinical applications

Senti & Sentiero

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1 Introduction

Senti and Sentiero devices are PC-independent, portable medical equipments, designed for easy handling and detailed assessment of hearing impairment at different stages of the auditory pathway in infants, children, and adults. Various transducers for eliciting stimuli and electrodes for measuring auditory potentials from the scalp can be connected. A touch-screen allows for patient data management, parameter setting, control of the measurement procedures, and visualization of results. Data can be transferred to a PC for further analysis.

All devices are modular, so that subsets of available test methods can be combined. Some of the methods mentioned in this manual may not be included on your device. The availability of test modules depends on your device type (Senti, Senti Plus, Senti Desktop, Sentiero, Sentiero Plus, Sentiero Advanced, Sentiero Eco, and Sentiero Desktop) and on your device license. Please contact your distributor if you would like to upgrade your license to include more test modules. Screenshots are provided as examples and may deviate from the representation on your device.

The purpose of this How-to Manual is to get familiar with all the methods available on Senti and Sentiero devices. In section [2: Overview](#) all methods are quickly described together with the intended use and the device types for which the respective module is available. Information about general aspects of the method including the scientific background and its practical use are explained for all test methods in section [3: Methodology, Practical Use, Scientific Background](#).

The *How-To-Manual* provides information on Senti and Sentiero devices seen from a daily use perspective. It does not replace the *Senti and Sentiero User Manual*, which is provided together with the device and which describes the main device function in a condensed version. For general information about device handling and functions, intended use, service and maintenance, cleaning, accessories, warranty, notes on safety, technical specifications, and electromagnetic compatibility, please refer to the *Senti and Sentiero User Manual*.

The *How-To Manual* is provided as-is. PATH medical has taken care that the contents and descriptions are correct. The content was gathered and proof-read under scientific contribution of professionals and long term experts in the field. Selected literature is provided to enable the reader to read more on the scientific background of the methods implemented in Senti and Sentiero. PATH medical cannot take any liability arising from (mis-)interpretation or (mis-)application of this *How-To Manual* and the provided references therein.

Please note that this *How-To-Manual* is meant for audiologicaly qualified personnel and does not replace adequate training and qualification.

2 Overview

In *Table 1* all test methods available on Senti and Sentiero devices (including Senti [*model SIH100097*], Senti Desktop [*model SID100419, SID100433*], Sentiero [*model SOH100098, SOH100360*], and Sentiero Desktop [*model SOD100497*]) are described in short together with the intended use. Please refer to the user manual to find out about specific intended use of your platform and contraindications.

Method	Short description / Intended use	Devices
PURE-TONE AUDIOMETRY		
PTA Pure-tone audiometry	Pure-tone audiometry according to IEC 60645-1 including high-frequency audiometry up to 16 kHz and automatic threshold detection procedures.	All
	Frequency-specific determination of hearing thresholds in cooperative subjects for audiological diagnostics and occupational medicine.	
MAGIC Multiple-choice graphic interactive check	Image-based pure-tone audiometry. - <i>MAGIC Screen</i> : screening mode with fixed user-defined stimulus levels - <i>MAGIC Audio</i> : threshold mode with automatically controlled stimulus levels.	All
	Frequency-specific determination of hearing status in cooperative subjects (especially in pre-school and school children) for audiological diagnostics.	
SPEECH AUDIOMETRY		
SUN Speech Understanding In Noise	Speech audiometry with logatoms and ipsilateral noise. - <i>SUN Predefined</i> : screening mode with fixed user-defined speech level - <i>SUN Adaptive</i> : threshold mode with automatically controlled speech levels	All
	Determination of speech intelligibility in noise in cooperative subjects for audiological screening (especially in the elderly) (<i>SUN Fixed</i>) and diagnostics (<i>SUN Adaptive</i>).	
MATCH Mainzer Audiometric Test for Children	Image-based speech audiometry with realistic words. - <i>MATCH Fixed</i> : fixed user-defined speech level - <i>MATCH Adaptive</i> : threshold mode with automatically controlled speech levels	All
	Determination of speech intelligibility in quiet and in noise in cooperative subjects for audiological diagnostics. Speech material and images are optimized for 2-year-old children.	
MAUS Munich Auditory Screening Test for Processing	Speech-based test with subtests regarding sequence of syllables, words in noise, phoneme differentiation and identification.	All ¹

Method	Short description / Intended use	Devices
Disorders	Screening for auditory processing disorders (ADP) in cooperative subjects (especially in children, 6 to 11 years).	
UST Universal Speech Test e.g. Freiburger Speech Test	Speech audiometry with words (e.g. monosyllabic words, numbers) including optional ipsilateral or contralateral noise, multiple word lists.	All ¹
	Determination of speech intelligibility in quiet and in noise in cooperative subjects for audiological diagnostics. Intended age group depends on the speech material of the particular test.	
BASD Bochum Auditory Speech Discrimination Test	Auditory discrimination test with subtests regarding consonants, frequency, level, and time.	All
	Diagnostics of auditory processing and speech development disorders in cooperative subjects.	
HHIE-S Hearing Handicap Inventory for the Elderly-Screening	Questionnaire concerning activity limitations, participation restrictions, associated feelings and emotions of daily life.	All
	Determination of subjective hearing status in cooperative adult subjects for audiological screening.	
OTOACOUSTIC EMISSIONS		
TEOAE Transient Evoked Otoacoustic Emissions	Objective test for a rough non-frequency specific checking outer hair cell functionality within frequency range from ca. 0.7 to 4 kHz. - <i>TEOAE Quick</i> : fixed stop criterion - <i>TEOAE Diagnostic</i> : user-defined stop criterion in different frequency bands	Sentiero [SOH100098, SOH100360] Sentiero Desktop [SOD100497]
	Determination of outer hair cell status in subjects of all age groups (especially in newborns and infants) for screening and audiological diagnostics.	
DPOAE Distortion Product Otoacoustic Emissions	Objective test for checking outer hair cell functionality at specific frequencies. - <i>DPOAE Quick/Diagnostic</i> : one/multiple fixed user-defined stimulus level(s) - <i>DPOAE Threshold</i> : threshold estimation with automatically controlled stimulus levels Additional features: - <i>DPHIREs</i> : user-defined frequency selection (start, stop, step size), allows for assessing DPOAE fine structure - <i>FMDPOAE</i> : frequency-modulated DPOAE, allows for reducing the impact of the 2 nd DPOAE source	Sentiero [SOH100098, SOH100360] Sentiero Desktop [SOD100497]
	Determination of outer hair cell status in subjects of all age groups for audiological purposes: e.g., follow-up after newborn hearing screening, confirmation of cochlear hearing loss, topological hearing diagnostics, detection of beginning cochlear impairment during noise over-exposure or ototoxic drug administration; frequency-specific	

Method	Short description / Intended use	Devices
	determination of hearing thresholds (<i>DPOAE Threshold</i>).	
AUDITORY EVOKED POTENTIALS		
ABR Auditory Brainstem Responses	Objective test for checking cochlear and neural sound processing with statistic response detection and optional contralateral masking. Stimuli: chirp and click. - Frequency-specific (ABR-FS) : low/mid/high chirp - ABR-BIN : binaural measurement	Sentiero [SOH100360]
	Determination of hearing status along the auditory pathway up to the brainstem in subjects of all age groups for audiological purposes: e.g. follow-up diagnostics after newborn hearing screening, neurological diagnostics, topological hearing diagnostics, determination of hearing thresholds.	
ASSR Auditory Steady-State Responses	Objective test for checking cochlear and neural sound processing with frequency-specific chirp stimuli (cochlear travelling wave compensated), 40 and 80 Hz stimulus rate, statistic response detection. <i>ASSR Fixed</i> : fixed user-defined stimulus levels. <i>ASSR Threshold</i> : threshold estimation with automatically controlled stimulus levels	Sentiero [SOH100360]
	Determination of hearing status along the auditory pathway up to the brainstem (80 Hz) and subcortical regions (40 Hz) in subjects of all age groups for audiological purposes: e.g. follow-up diagnostics after newborn hearing screening, neurological diagnostics, topological hearing diagnostics, frequency-specific determination of hearing thresholds.	
MIDDLE EAR TESTS		
Tympanometry	Objective test for measuring middle ear impedance dependent on static pressure (+/-) in the outer ear canal.	Sentiero Desktop [SOD100497]
	Determination of middle ear status in subjects of all age groups for audiological purposes: e.g. detection of middle ear pathologies (e.g. otitis media, middle ear effusion, perforation of eardrum, dysfunction of auditory ossicles, Eustachian tube dysfunction, otosclerosis, tympanosclerosis) or blockage of the ear canal.	
Acoustic Reflex	Objective test for measuring ipsilateral or contralateral acoustic reflex elicited by tones with different levels and frequencies or broad-band noise.	Sentiero Desktop [SOD100497]
	Determination of acoustic reflex thresholds in subjects of all age groups for audiological purposes: e.g. topological diagnostics and detection of middle ear pathologies (e.g. otosclerosis) or neural pathologies (e.g. facial nerve dysfunction).	
¹ only available for Senti [model SIH100097] and Sentiero [model SIH100098] devices with enhanced memory (i.e. PCB rev. ≥ 67)		

Table 1: Overview of test methods available on Senti and Sentiero devices

3 Methodology, Practical Use, Scientific Background

A description of the methodology and a practical guide of the methods used in Senti and Sentiero devices are presented in the following. This includes conventional pure-tone audiometry (PTA or PT Audio), image-based pure-tone audiometry (MAGIC), speech tests (e.g. SUN, MATCH, UST), and other psycho-acoustical test methods (e.g. MAUS, BASD). Physiological test methods comprise otoacoustic emissions (OAE), auditory brainstem responses (ABR), auditory steady-state responses (ASSR), and middle ear tests (e.g. tympanometry, acoustic reflex, Eustachian tube function tests). The highly sophisticated mechanisms of OAE, ABR, and ASSR generation, recording, reproducibility, stimulus parameter settings, and clinical applications are described in detail. Especially, the relationship between these measures and behavioural pure-tone thresholds is discussed. Additional clinical case examples are given. A list of references to further reading is also included for each module.

Please note that detailed technical information as e.g. available transducers, maximum levels, and other technical details are presented for each module in a separate **Technical Specification** document available for download from www.pathme.de/support/. For more information about available test module parameters please refer to the device online help.

In general, it is recommended to conduct all tests in an acoustically shielded booth or in a separate quiet room. When using ear probes or insert earphones, the transducer must be placed with a tight fit without any leakage between ear tip and outer ear canal. Proper occlusion of the ear canal by the ear tip diminishes the influence of external sounds. For a reliable measurement an electro-magnetic shielded booth has to be used

Ear probe or insert earphone channels must not be blocked e.g. with cerumen. Ear probes or insert earphones should not be used in cases of external otitis (outer ear canal infection) or in cases where the outer ear canal is occluded with cerumen. Prior to any test, it is recommended to perform an otoscopy in order to determine if there is any blockage in the ear canal or any other visible middle ear disorder (e.g. perforated ear drum). Also a deformation of the ear canal may deteriorate sound transmission and may therefore deteriorate test performance.

It is recommended to perform as many audiological tests as possible in order to get a complete overview on the hearing status along the auditory pathway, especially if there are doubts about the true hearing status or if there are any inconsistencies or discrepancies. Qualified personnel needs to decide which tests are appropriate given the age, cooperativeness, and clinical history/anamnesis of the tested subject. Please note that interpretative hints and recommended parameter settings are provided in this *How-To-Manual* on an informative basis only. It is up to the qualified examiner to analyse results and to set parameters according to individual circumstances.

3.1 Psycho-Acoustical Test Procedures

Psycho-acoustical test procedures include pure-tone audiometry, speech audiometry and other behavioural tests which require patient feedback.

For all psycho-acoustical tests, the ability, willingness, and concentration of the subject to be tested are essential. Before performing any psycho-acoustical test procedure, the subject must be instructed about the task. The examiner must ensure that the subject has understood the task and is capable of performing the task. Always place the transducer on the subject's ears *after* instruction so that the subject's hearing ability is not reduced due to the transducer's sound attenuation.

Low ambient noise conditions are also essential for an appropriate test performance since hearing performance may be artificially reduced by too loud ambient noise.

In general, proper transducer placement and calibration is important for a reliable outcome. Incorrect placement of a transducer or usage of an incorrectly calibrated transducer may adulterate the result. A suitable transducer should be connected and properly fitted. Variation in earphone position up-down or front-back and leakage between earphone and ear may yield inappropriate results as e.g. falsely poor hearing thresholds, particularly at high frequencies.

If not specified otherwise all psycho-acoustical tests can be performed in subjects of all ages as long as appropriate participation and cooperation can be expected. This means that these tests are not expected to be suitable e.g. for very small children, mentally handicapped subjects or other non-cooperative subjects. For these subjects physiological test methods are recommended to be applied.

3.1.1 Pure-Tone Audiometry (PTA)

METHODOLOGY

PTA is the most commonly used psycho-acoustic method for testing a subject's ability to hear various sound frequencies. PTA is the key hearing test for assessing air-conduction (AC) and bone-conduction (BC) hearing thresholds enabling the determination of degree and type (conductive or sensorineural) of the hearing loss. Hearing thresholds typically indicate the softest sound audible to an individual. AC stimuli can be delivered via headphone, insert earphones or loudspeakers. BC stimuli can be delivered via an electro-mechanical bone conductor which is positioned on the forehead or mastoid of the subject to be tested. If there is better hearing for bone conduction than for air conduction (air-bone gap) a conductive hearing loss is likely. If both air and bone conduction thresholds are out of the normal range a sensorineural (cochlear or retro-cochlear impairment) is likely. PTA can be used to assess the hearing status for tonal stimuli in cooperative subjects who are able to perform the task, e.g., in clinics (conventional audiology, bed-side use, ambulances) and occupational medicine. To differentiate a detected sensorineural hearing loss, supra-threshold measurements (e.g. Fowler, Carhart, categorical loudness scaling) may be performed. Otoacoustic emissions (OAE) and auditory evoked potentials (AEP) may be used for further topological diagnostics. Please note that for subjects who are not expected to be able to perform the test or are not able to react to the sound in a proper way to get frequency-specific information of the hearing loss, DPOAE or ASSR Threshold measurement is advised.

The test procedure demands an examiner who controls the test and who evaluates the response of the tested subject. Hearing is commonly tested at octave frequencies varying from low (250 Hz) to high frequencies (8 kHz). A typical test procedure (butterfly) starts at 1 kHz, moves up to higher frequencies, goes back to 1 kHz (re-check) and moves down to lower frequencies. It should be emphasized that the audiometric frequency range is just a part of the entire human auditory range, which extends between 20 Hz and 20 kHz. The core method of PTA is to present a pure-tone close to threshold, i.e. keep dropping the sound pressure level until the person stops responding (raising a hand or pressing a button) and then increasing the sound pressure level until the person starts responding again (see ISO 8253-1).

During some conditions subjects must be tested with masking noise on the non-test ear in order to prevent that sound going from the stimulated side over to the non-stimulated side can be heard on the non-stimulated side (cross hearing). The threshold of the test ear is measured at the same time as presenting the masking noise to the non-test ear. Thresholds obtained with masking provide an accurate representation of the true hearing threshold of the test ear. The interaural attenuation can go down to 0 dB for bone conductors because the bones of the skull are very efficient at transmitting sound. Therefore, it is recommended to measure bone conduction thresholds always with masking noise. For headphones, interaural attenuation amounts to about 40 dB. Masking should be used if the difference in air conduction in one ear and bone conduction in the other ear is 40 dB or greater. For insert earphones, interaural attenuation is in the range of 55 dB so that the use of insert earphones reduces the need for masking. A masking dilemma occurs when masking from the non-test ear crosses over to the test ear and affects threshold testing for the test ear. In this case, a reliable masked threshold cannot be obtained. This phenomenon generally occurs in the presence of a substantial conductive hearing loss component.

Automatic PTA assesses hearing thresholds following Békésy or Hughson-Westlake procedures. In contrast to the method of adjustment, for which the subject can vary the stimulus level until it is just audible, the subject can only control the direction in which the stimulus level varies. The subject increases and decreases the stimulus level around hearing threshold depending on its audibility (method of tracking). The available measuring procedures correspond to the algorithms suggested by ISO 8253-1.

Screening PTA examines whether the hearing threshold levels at different frequencies are better, equal to, or worse than the specified screening level. The stimulus is delivered to the ear at specific frequencies and levels that have been chosen for the screening. The subject passes the screening test according to predefined criteria, e.g., a *pass* occurs if all stimuli are heard in each ear. Screening at certain selected levels and frequencies is typically faster than measuring hearing thresholds using common PTA procedures.

Different PTA modules are available:

- **PTA 4** for assessing AC pure-tone thresholds at frequencies from 125 Hz to 6 kHz with stimulus levels from 0 to 70 dB HL following IEC 60645-1 class 4.
- **PTA 4 Advanced** for assessing AC pure-tone thresholds at frequencies from 125 Hz to 8 kHz with stimulus levels from -10 up to 110 dB HL following IEC 60645-1 class 4 with extended frequency and level range.
- **PTA 3** for assessing AC and BC pure-tone thresholds following IEC 60645-1 class 3. Frequencies and levels are the same as for PTA 4 Advanced. Due to the limited capacity of the electro-mechanical bone-conductor, BC stimulus levels are lower. The module also provides a contralateral masking option, presentation of different stimulus types (sine, pulsed sine, warble tone), and automatic threshold detection procedures (Békésy, Hughson-Westlake).
- **PTA-HF** for assessing pure-tone thresholds at high frequencies from 9 to 16 kHz. PTA-HF is only available with specific headphones, e.g. Sennheiser HDA 300.

PRACTICAL USE

Select *PTA* from the module selection screen. The PTA user interface appears as shown in *Figure 1*. Press the settings button  (PTA3 only) in order to select the transducer and its placement (AC, BC mastoid, BC forehead), to select the stimulus type (pure-tone, pulsed pure-tone, warble tone), to turn on or off masking noise, or to activate automatic testing. For some subjects (e.g. children) a pulsed sine or a warble tone may be more interesting than a continuous pure-tone and hence may be preferred. For the Békésy procedure, pulsed stimuli are used. For subjects with a tonal tinnitus, a pulsed sine or warble tone may distinguish the stimulus from the tinnitus more efficiently. Enable masking if required (see METHODOLOGY).

Before the transducer is fitted and the test is started, the subject must be instructed about the task. The subject shall indicate if a tone is heard or not, e.g. by raising a hand or pressing the patient response button if a tone is heard or by putting down the hand or releasing the patient response button if *no* tone is heard. For pulsed tones, please make sure that the subject understands to respond to the pulsed tone once (i.e. indicate *heard* as long as the pulsed tone is audible) and not for each single stimulus pulse. The test is *not* intended to be self-controlled by the subject. Manual

tests must be fully controlled by the examiner. Automatic tests do not need level/frequency control by the examiner, but should be supervised by qualified personnel nevertheless.

Select the test ear. If loudspeakers are connected or binaural measurement is enabled on the device, also binaural stimulation can be selected. Perform either a manual test or an automatic test at the selected frequencies. For further information about a typical workflow of pure-tone audiometry see e.g. ISO 8253-1 and ASHA (2005). During manual tests, stimulus frequency (7), level and/or masking level (if activated) (6) can be selected. The selected levels can be read from the crosshairs in the audiogram (red: right ear, blue: left ear, black: binaural, green: masking) and from the values between the selector elements (stimulus level | masking level). For PTA-HF, the audiogram shifts to higher frequencies when moving the crosshairs beyond 8 kHz. When pressing the stimulus selection button (9) either the stimulus level or the masking level or both levels locked together can be controlled. The stimulus level control buttons can be configured in the device settings (up arrow: decrease level, down arrow: increase level or vice versa). The stimulus can be presented as long as the loudspeaker button (8) is pressed. If the stimulus is played, the orange status indicator (1) is on. If the masking noise is played, the green status indicator (2) is on. If the patient response button is pressed, the large green status indicator (3) is on. If a threshold is determined, set the symbol at the position of the red or blue crosshairs (5) by pressing the audiogram (4). The symbol can be toggled from *heard* to *not heard* to deleting the symbol.

Hearing thresholds are plotted across test frequencies in an audiogram form. Right ear symbols are plotted in red, left ear symbols in blue, and binaural symbols in black. The used symbols refer to ISO 8253-1, Table 1. BC symbols can be plotted as proposed by ISO 8253-1 or mirrored (usual representation e.g. in Germany). The BC symbol representation can be defined in the device settings.

The audiogram is divided into three coloured zones: green (normal hearing ≤ 20 dB HL), orange (mild hearing loss >20 to 40 dB HL), and grey (>40 dB HL: moderate to profound hearing loss).

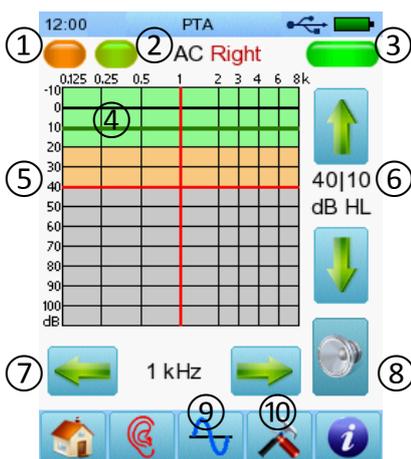


Figure 1: PTA user interface

For the interpretation of the result, the following hints may be considered (see Figure 2):

- **Conductive hearing loss:** Audiogram shows normal bone-conduction thresholds, air-conduction thresholds are poorer than normal by at least 10 dB. This air-bone gap occurs due to the damping of the air-conduction stimuli on the way through the outer and middle ear. A conductive hearing loss typically occurs due to outer or middle ear problems including

abnormalities of the tympanic membrane, occlusion of the auditory canal (e.g. by cerumen), middle ear infection or fluid (e.g. otitis media), perforation of the tympanic membrane, ossicular defects.

- **Sensorineural hearing loss:** Audiogram shows air- and bone conduction thresholds that are both within a range of about 10 dB. Thresholds are higher than 20 dB HL. A sensorineural hearing loss typically occurs due to lesions of sensory cells, auditory nerve, or central auditory pathways (presbycusis, noise-induced hearing loss, Ménière's disease, vestibular schwannoma).
- **Mixed hearing loss:** Mixture of conductive and sensorineural hearing loss.

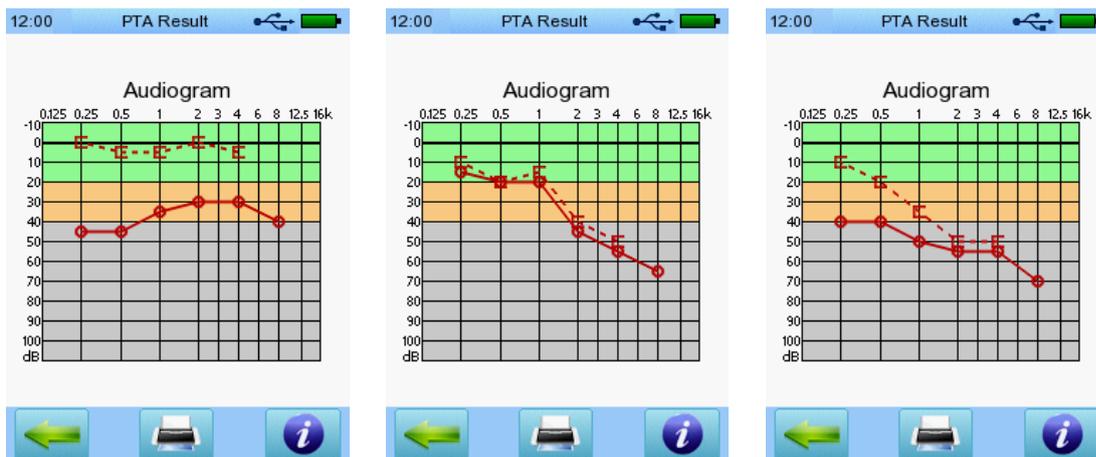


Figure 2: PTA result examples (left: conductive hearing loss; middle: sensorineural hearing loss; right: mixed hearing loss with conductive and sensorineural components)

LITERATURE

- American Speech-Language-Hearing Association (2005): Guidelines for manual pure-tone threshold audiometry, online: <http://www.asha.org/policy/GL2005-00014.htm>
- ISO 8253-1: Acoustics – Audiometric test methods – Part 1: Pure-tone air and bone conduction audiometry

3.1.2 Multiple-Choice Auditory Graphical Interactive Check (MAGIC)

METHODOLOGY

Play-audiometry is a well-established method in paediatric audiology. However, the test procedure, in which the child must be continuously observant, is exhausting, and the task (usually placing a peg in a pegboard) is varied only little. In contrast, image-based and self-paced test procedures can considerably enhance the child's attentiveness. MAGIC is an image-based, self-controlled test which provides a playful alternative to conventional pure-tone audiometry. The test is especially designed for pre-school and school children but can be used for other cooperative subjects as well. Please note that for subjects who are not expected to be able to perform the test or are not able to react to the sound in a proper way, a DPOAE or ASSR Threshold measurement is advised.

Two MAGIC workflows are available:

- **MAGIC Screen** allows quick hearing screening at user-selectable frequencies and levels. If multiple levels are selected, the algorithm starts at the lowest level and proceeds to the next higher level each time the tone is not heard.
- **MAGIC Audio** allows hearing threshold determination at user-selectable frequencies with an automatically controlled bracketing algorithm. Mute tones are included for detecting *wrong* inputs of the subject.

MAGIC can be performed at standard audiometric frequencies from 250 Hz to 8 kHz. Different animals represent different frequencies (cow = 250 Hz, bear = 500 Hz, elephant = 1 kHz, cat = 2 kHz, sheep = 3 kHz, mouse = 4 kHz, bird = 5 or 6 kHz, dolphin = 8 kHz). Each animal is presented in three variants: *neutral* to start the sound presentation, *healthy* and *sick* for indicating the two conditions *heard* and *not heard*, respectively (see *Figure 3*).

The self-controlled workflow needs extensive explanation to the subject. An introductory story is recommended for explaining the task and for motivating the subject to be tested. The subject shall take the role of a doctor who shall diagnose healthy and sick animals which will make a sound or not, respectively. This can also help to put off the pressure of the subject, because it is not him/her to be diagnosed, but he/she will diagnose the animals' ability to give sounds.

Via touch-screen the subject controls the sound presentation and the response if the sound was heard (healthy animal) or not (sick animal). The examiner explains the test procedure during the instruction phase, supervises the measurement and assists the subject if indicated. The examiner can also intervene in the measurement procedure at any time or can do a retest at any frequency if necessary (MAGIC Audio).

For general information about conventional pure-tone audiometry please refer to section [3.1.1: Pure-Tone Audiometry \(PTA\)](#).

PRACTICAL USE

Select *MAGIC* from the module selection screen. Select the preset that you would like to perform. If necessary, change the parameters (e.g. test mode, frequency, screening levels (MAGIC Screen) / test level range (MAGIC Audio), stimulus type) and preset name as required. For some subjects (e.g. children) a warble tone may be more interesting than a pure-tone and hence may be preferred. Also,

for subjects with a tonal tinnitus a warble-tone may distinguish the stimulus from the tinnitus more efficiently.

Make sure that a valid transducer is connected (e.g. headphone, insert earphones, bone conductor) and select the test ear (*Right+Left*: sequential measurement of right and left ear for each frequency). The measurement can be started with the introduction phase (if enabled in the settings) or the test phase.

It is recommended to start with the instruction phase. For instruction tell the subject that his/her task is to be a doctor now. Some animals will give a sound because they are healthy and happy (shown cheering with hands up) and some animals will not give a sound because they are sick (shown wearing a scarf). The subject in the role as a doctor shall find out which animals are healthy and which are sick. To find out whether the animal gives a tone or not the neutral animal shall be pressed (see *Figure 3* - ①). The response shall be given by pressing the respective healthy ③ or sick ② animal. A response is only accepted *after* the belly of the neutral animal has been pressed, i.e. after tone presentation. The instruction phase starts with a stimulus at a user-definable initial level (MAGIC Audio) or at a fixed level (MAGIC screen). The second stimulus is presented with a level 10 dB lower (if first response was heard). Finally, a mute tone is presented in order to accustom the subject to the situation that also no sound may occur.

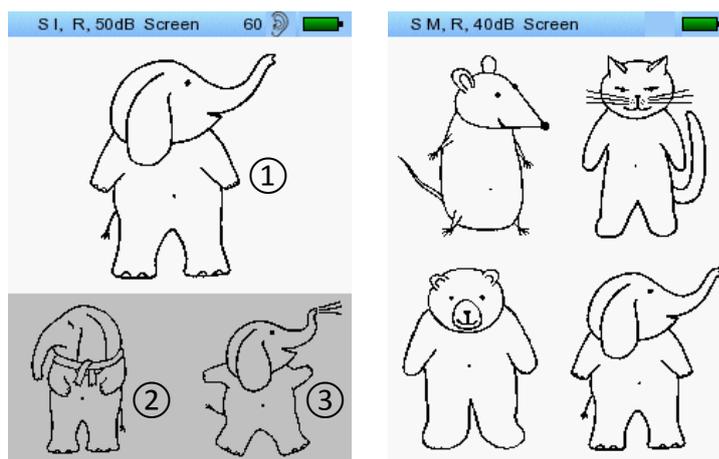


Figure 3: MAGIC user interface (left: tone presentation and response; right: animal selection)

A typical instruction may follow the workflow presented in *Table 2*. A short instruction sheet is also available for download on the PATH medical homepage.

Instruction of examiner	Task for examiner
<i>Here you see an animal. Press the belly of the animal and you can hear if the animal gives a sound or not. The first animal gives a sound.</i>	Show the subject how to press the belly of the neutral animal.
<i>Press the animal's belly. Do you hear the sound?</i>	Ask the subject to press the belly several times.
<i>Each time you press the animal's belly it gives a sound.</i>	The subject shall notify that the sound is audible. If not a higher stimulus level needs to be selected (pressing <i>not heard</i> : stimulus level increases by 20 dB automatically). Repeat the

	instruction from the first step. Show the subject how to press the healthy animal corresponding to <i>heard</i> .
<i>The next animal also gives a sound, but it is a quieter sound. Press the belly and listen.</i>	The subject shall hear this sound as well. Make sure that the subject presses the healthy animal corresponding to <i>heard</i> .
<i>The next animal does not give a sound. You won't hear anything. Press the belly and listen.</i>	The subject shall notify that no sound is audible. If not, repeat the instruction. Show the subject how to press the sick animal corresponding to <i>not heard</i> .

Table 2: MAGIC instruction

After the instruction phase the test phase starts. Dependent on age and physical/mental abilities, the test phase may be conducted completely self-controlled (i.e. subject enters response) or with assistance of the examiner. Supervision by a qualified examiner is recommended at all times.

The progress of the test procedure may be visualized by a shelf, from which the current test animal is selected (option for MAGIC Audio). During the test, please check if the subject conducts the test appropriately. If there is any hint that the subject does not understand the workflow (e.g. pressing healthy animal after mute tone presentation or pressing the screen randomly) you may restart the test or repeat the instruction phase in-between (MAGIC Audio). Also a previous patient response can be undone when pressing the undo button in the footer (press the power on/off switch to make the footer visible).

In the header, information about the current test status including stimulus levels and subject's response is provided (see Table 3). For example, the header in Figure 3 shows that the test is in the instruction phase with a tone presented at 50 dB HL when pressing the animal's belly. The previous stimulus, which was presented at 60 dB HL, was heard by the subject. If you suspect that the subject might take advantage of the header information, turn off the current level information in the settings (also possible during the test for MAGIC Audio).

Stimulus	Test phase	Current level	MAGIC mode:	Previous level	Response
S: sine F: warble (FM tone)	I: Instruction T: Test	Value [dB HL], mute	Audio, Screen	Value [dB HL], mute	 heard  not heard

Table 3: MAGIC header information

At the beginning of the test phase and after finishing a test run at a frequency, the subject is allowed to select a new animal (see Figure 3 - right). The order in which the different animals are selected is up to the operator (i.e. tested subject or examiner).

After the test is finished, for MAGIC Screen the result is shown as a table (see Figure 4) with heard ④, not heard ⑥, and skipped/not tested ⑤ symbols or for MAGIC Audio as an audiogram. For MAGIC Audio it is possible to retest specific frequencies. A retest may be indicated if a *wrong* response of the subject is shown. A *wrong* response is represented by a “?” in the audiogram below

the affected frequency. The number of *wrong* responses is shown below the “?” ⑦. Another indication for retesting a frequency may be an outlier in the audiogram.

Please note that during this test the footer is hidden. You may activate the footer by pressing the power on/off switch shortly.

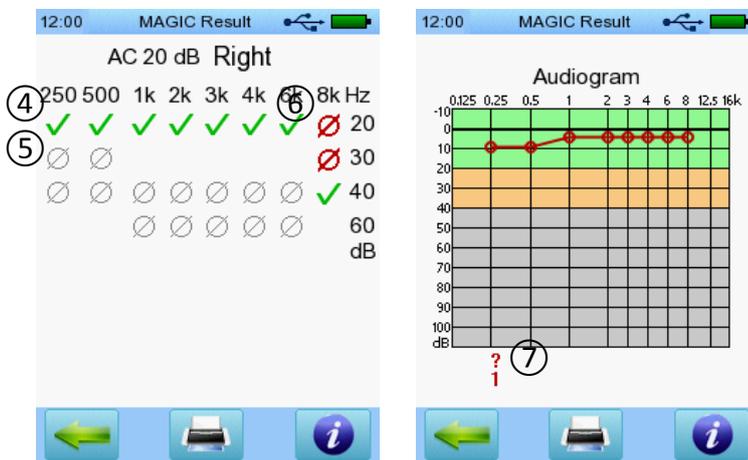


Figure 4: MAGIC result (left: MAGIC Screen; right: MAGIC Audio)

STUDY RESULTS

The feasibility and reliability of MAGIC was investigated in children in a multi-centre study conducted at the Department for Communication Disorders, ENT department of the University of Mainz Medical School’s hospital (Germany), at the ENT clinic of Klinikum rechts der Isar, Technische Universität München (Germany), and at Cyprus Audiology Centre Nicosia (Cyprus) (Schirkonyer *et al.*, 2010b, 2011). MAGIC tests were conducted in 108 children aged between 3;6 and 11;11 years at frequencies 0.5, 1, 2, 4 kHz ($n = 82$) and additionally at 0.25, 3, 6, 8 kHz ($n = 26$). Additionally, hearing threshold estimation by means of DPOAE I/O functions were performed in 36 children from the collective. DPOAE I/O functions were recorded at frequencies $f_2 = 1, 1.5, 2, 3, 4$ and 6 kHz with primary tone levels L_2 in the range from 10 to 65 dB SPL. Thresholds were estimated by linear regression analysis. Primary tone levels L_1 and L_2 were set according to the scissor paradigm. The frequency ratio f_2/f_1 was 1.2. Both MAGIC and DPOAE I/O functions were measured with Sentiero. For comparison, play-audiometry pure-tone thresholds were determined at the corresponding frequencies. There was a highly significant ($p < 0.001$) correlation between image-based (MAGIC) and play-audiometry thresholds. The correlation coefficient ($n = 1247$) was $r = 0.73$. The histogram of the difference between image-based and play-audiometry thresholds showed normal distribution. The mean difference amounted to -1.5 ± 9.6 dB. Test time per frequency (one ear) was on average about 30 s, ranging from 14 to 91 s. Test time decreased with increasing age. Also, MAGIC pure-tone thresholds and estimated DPOAE thresholds were highly significant ($p < 0.005$) with a correlation coefficient of $r = 0.60$.

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3.1.3 Overview: Speech Intelligibility Tests

Analytic speech tests assess the phonetic level of speech perception. They reflect the auditory processing of individual speech sounds. These tests aim at evaluating the perception of consonants and vowels in simple words or word-like contexts. Consonants are e.g. presented within a nonsense vowel-consonant-vowel (VCV) word (e.g. SUN: aga, afa, aša). Vowels are presented in a CVC format, e.g. by using voiced plosive consonants, with the first and second consonant fixed (e.g. bīd, bēd, bād in an English test).

Word tests determine speech recognition ability. These tests aim at assessing the maximum achievable recognition score at an optimum speech level or test the loss in recognition score at a given speech level. In this respect they determine the effective hearing impairment for realistic speech stimuli that represent commonly used speech as e.g. monosyllabic words (e.g. bed, cow, row), spondees/two-syllable words (e.g. pancake, playground), or two-digit numbers (e.g. 21, 45, 97). Individual speech recognition values, i.e. the percentage of words which are correctly heard and spoken by the subject for each presented speech level, are displayed in the format of a speech audiogram. A specific value, e.g. hearing loss at 50 % intelligibility may be provided as speech recognition threshold. Initial speech levels may be derived from the individual hearing threshold at a specific frequency (e.g. 0.5 kHz, see e.g. PTA, MAGIC) plus a fixed offset. The average across the pure-tone thresholds 0.5, 1, and 2 kHz (Fletcher index) is expected to be close to the speech recognition threshold (for spondees). If the average pure-tone threshold is significantly better than the speech recognition threshold (for spondees), the possibility of central disorder should be considered.

Speech tests may be conducted with headphones, insert earphones, and loudspeakers. Loudspeakers are especially used when testing subjects with hearing-aids or other amplifying devices which prevent the use of headphones or insert earphones.

In general, speech tests may be used to determine speech intelligibility in quiet or in noise (i.e., with ipsilateral noise) or for checking the fitting performance of hearing aids, i.e., by testing the subject with and without wearing the hearing aid. Compared to pure-tone audiometry, speech audiometry examines auditory processing on a higher intellectual level: not only hearing but also understanding.

Especially for speech tests with realistic words, word lists must be appropriate for the target subject and hence must consider the subject's age and language abilities (i.e. the expected knowledge of words). Please also consider that speech is evolving and that some previously commonly used words may get out of use (maybe dependent on age). Moreover, test results depend on the speaker (e.g. male, female voice) and the pronunciation and accentuation of words. Word tests should in general be provided in the subject's native language. If not followed, the outcome may not reflect the actual hearing status. Please note that if the examiner evaluates the correctness of the response, the examiner's hearing and language abilities also influence the outcome of the test.

Senti and Sentiero devices provide various speech tests such as SUN, MATCH, and UST, which are explained in the following sections.

3.1.4 Speech Understanding in Noise (SUN)

METHODOLOGY

SUN is a quick and self-controlled speech in noise test especially designed for screening adults and older adults for hearing disability using a set of intervocalic consonants (VCVs). Understanding speech in noise is the most common listening difficulty experienced by adults (Kramer *et al.*, 1998). However, the test can be used for other cooperative subjects as well. The test is designed in a way that it is self-convincing, fast, and of low cognitive load.

The test aims at logatom recognition in noise, specifically at the identification of consonants and hence at the early assessment of a high frequency hearing loss. The test is fully automated. Three alternative VCVs (e.g. aFa, aGa, aSa) are displayed on the touch screen. VCVs are presented via headphones, insert earphones or loudspeakers at different signal-to-noise ratios. The subject has to select the correct item from the screen. Recordings are available with speakers of different languages (e.g. Italian, German, English, French, Spanish, Russian) and with different character representations (e.g. Latin, Greek, Farsi, Hindi, Cyrillic).

Two SUN workflows are available:

- **SUN Predefined** allows for conducting the test with pre-determined signal-to-noise ratio (SNR) groups, i.e. the test starts at a certain SNR whereupon during the test the SNR is reduced after a fixed number of words. The sequence of the words is fixed and optimized with regard to the intelligibility of the VCVs. The speech level remains constant during the entire test. The test determines a score dependent on the number of correct answers (Paglialonga *et al.*, 2011a,b).
- **SUN Adaptive** allows for conducting the test with an adaptive SNR (similar to Kaernbach, 1991). The speech level is decreased after a correct answer and increased after a wrong answer. The noise level remains constant during the entire test. An additional “?” button is present which may be pressed if the subject did not understand the logatom. The test provides SNR thresholds.

PRACTICAL USE

Select *SUN* from the module selection screen. If more than one speech test is licensed, *SUN* can be found in the *Speech* section. If necessary, change the parameters (e.g. test mode, test level, masking noise type, language, character set) as required. Make sure to select a language and character set that is familiar to the tested subject.

Before starting the test, instruct the subject about the task. On the display, three different VCV options are visualized. However, a voice pronounces only one of them. The subject shall listen to a speech sample. After the speech sample is played, the subject is asked to press the button, which corresponds to the *word* that has been understood. If the word has not been understood, the subject shall guess and press any button (SUN Predefined) or for SUN Adaptive the subject may press the “?” button (see *Figure 5*). Make sure that the subject understands the task.

In order to accustom the subject to the *words* you may start with a training phase (*Training* mode needs to be enabled in settings). In the training phase, some of the logatoms from the test are played without noise. Proceed to the test phase if the subject is familiar with the task.

Before starting the training or test phase, make sure that a valid transducer is connected (headphone, insert earphones or loudspeakers) and select the test ear. The training or the test starts. Please note that during the *SUN Predefined* test, the initial responses are not counted for the final result.

Dependent on age and physical/mental abilities, the test may be conducted completely self-controlled (i.e. subject enters response) after instruction or with assistance of the examiner. Supervision by a qualified examiner is recommended at all times.

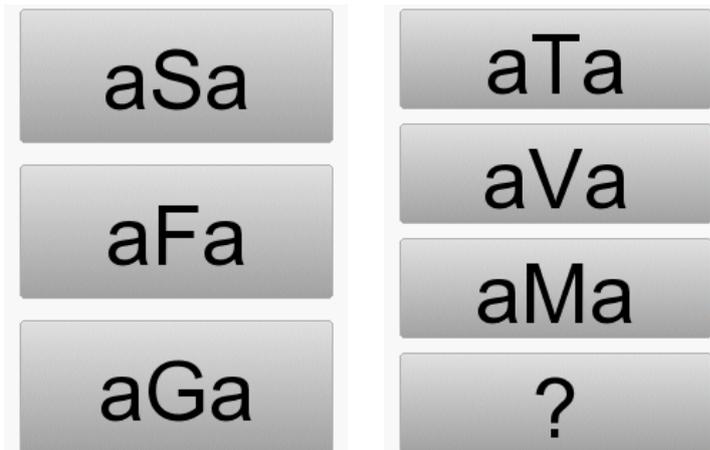


Figure 5: *SUN Predefined* (left) and *SUN Adaptive* (right) user interface

After the test is finished, for *SUN Predefined* the result is shown as a score with a traffic light status (see *Figure 6 - left*) or for *SUN Adaptive* as an SNR threshold together with a score and a traffic light status (see *Figure 6 - middle/right*). The time course of the SNR is additionally shown in a graph when pressing on the result screen. The three-stage status light refers to the following definitions: green for hearing ability within normal range, yellow for hearing ability might be below the normal range, red for hearing ability well below the normal range. The limits between hearing range groups depend on the selected language.



Figure 6: *SUN* result (left: *SUN Predefined*; middle: *SUN Adaptive* with traffic light view; right: *SUN Adaptive* with SNR time course view)

Please note that during this test the footer is hidden. You may activate the footer by pressing the power on/off switch shortly.

STUDY RESULTS

A study on the effectiveness of SUN (predefined mode) for adult hearing screening was performed at the Institute of Biomedical Engineering (IsIB), Milan, Italy (Paglialonga *et al.*, 2011a). The study was conducted on 1273 adolescents and adults (13 to 89 years) with varying degrees of audiometric thresholds including SUN (predefined mode) in Italian language and pure-tone audiometry at 1, 2, and 4 kHz as reference. Tests were performed both in an environment with low and high ambient noise. After the test, all subjects were asked to fill a questionnaire for evaluating the difficulty of the task, the test duration and the overall rating. The main outcome of the study was that SUN is suited for adult hearing screening because of the following detailed findings: The overall SUN result was in line with pure-tone audiometry with a good correlation between the three SUN categories (traffic light status) and three specifically defined PTA classes. The test performance was similar across all subjects independent of age. The test performance was also not influenced by ambient noise levels up to 65 dB(A) so that the test may also be performed in a non-clinical setting, where ambient noise is not typically controlled (e.g. hearing aid providers). The test time was very short with 2 minutes on average for both ears. Even older adults typically managed to conduct the test within 1 minute per ear. This is deemed as an important factor for a hearing screening test since inattentiveness and fatigue are likely to increase with increasing test time. The cognitive load was low and the acceptance of the test was very high. About 85 % of the subjects considered the test to be easy or slightly difficult. 95 % of the subjects judged the test duration to be short or fair. More than 90 % of the subjects rated SUN pleasant or neutral.

A further study (Paglialonga *et al.*, 2013) extended the above data by testing SUN (predefined mode) in more than 6000 subjects. SUN was found to be very reliable with a good agreement to pure-tone audiometry and self-reported hearing handicap. The test's sensitivity and specificity to identify disabling hearing impairment were 84 % and 75%, respectively. Test time was on average lower than 1 minute per ear.

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3.1.5 Mainzer Audiometric Test for Children (MATCH)

METHODOLOGY

MATCH is an interactive, image-based speech-intelligibility test, which can be performed in quiet and in noise. The test is based on the Mainzer Kindersprachtest I (German speech test for children), which is using one- and two syllable words presented on image cards. Disadvantages of the Mainzer Kindersprachtest were that the number of words was too low, words and images were not up to date, and words did not match the typical vocabulary of a two-year-old child.

MATCH consists of 26 words corresponding to the typical vocabulary of a two-year-old child (see *Figure 7*). Although the test is especially designed for children, it can be used for other cooperative subjects as well. The words are selected from recent studies on the vocabulary of young children (Suchodoletz and Sachse, 2008). The phoneme distribution of the German test shows a good accordance with conversational German (Schiel, 2010; Schirkonyer *et al.*, 2014). The test items are figuratively presentable and not gender-specific. Simple pictures appropriate for children represent the words (e.g. duck, milk, car, etc.) so that the subject does not need reading skills. The subject just needs to point at the suspected correct image. The test is designed as closed-set test (i.e., limited number of alternatives available for selection) because an open-set test is expected to be too difficult for smaller children. Four pictures are presented simultaneously on the touch-screen together. One of them belongs to the spoken word. If the word has not been understood, the subject does not need to guess but may press the “?” button. The sound presentation is started by pressing on a “magic box”. After the subject has given the response the test continues until all items have been presented. The test is completely randomized, i.e., the sequence of words and the alternatives are randomized so that the test can be repeated with the same subject. It is possible to conduct the test with a subset of the complete word list. For example, if the child does not know some words, these words can be removed from the test.



Figure 7: MATCH images (from left to right: 1) monkey, apple, eye, car, bear, ball, tree, 2) bed, boat, butter, eggs, duck, cucumber, hair, 3) bunny, trousers, light, milk, mouth, nose, ear, 4) grandpa, horse, door, clock, water)

In a preliminary version, MATCH is also available with additional ipsilateral noise. This mode assesses speech intelligibility in noise following the same procedure as without noise. It was shown that the threshold of speech intelligibility in noise is more sensitive for assessing a hearing loss (Leensen *et al.*, 2011). The test with ipsilateral noise is suitable for older children and adults.

Two MATCH workflows are available:

- **MATCH Fixed** allows for conducting the test with a fixed speech level. The test determines a score dependent on the number of correct answers.
- **MATCH Adaptive** allows for conducting the test with an adaptive speech level presentation. The speech level is decreased after a correct answer and increased after a wrong answer. The test determines a 71.4 % speech recognition threshold in quiet (without ipsilateral noise) or in noise (with ipsilateral noise).

Normative data for children has been collected and presented by Bohnert *et al.* (2013), Zoth *et al.* (2013) and Schirkonyer *et al.* (2014).

PRACTICAL USE

Select *MATCH* from the module selection screen. If more than one speech test is licensed, *MATCH* can be found in the *Speech* section. If necessary, change the parameters (e.g. test mode, test level (MATCH Fixed) / test level range (MATCH Adaptive), masking noise, language, items) as required. Make sure to select a language that is familiar to the tested subject. Select or deselect masking noise if you prefer to test speech intelligibility in noise or in quiet, respectively.

Make sure that a valid transducer is connected (headphone, insert earphones, or loudspeakers) and start the test by selecting the test ear. When starting the test, instruct the subject about the task. Tell the child that there is a magic box on the screen of the device and that the task is to find out what is inside the box. A typical instruction may follow the workflow presented in *Table 4*. The instruction is also explained in the online help of the device.

Instruction of examiner	Task for examiner
<i>The magic box may contain different things.</i>	Show the subject how to press the box with the green question marks (see <i>Figure 8 - ①</i>).
<i>Press the magic box and listen carefully what is inside the box this time.</i>	Ask the subject to press the magic box. Afterwards, the response alternatives appear. (see <i>Figure 8 - ③</i>)
<i>Did you hear what is inside the box? If you do not hear what is inside the box press the green question mark at the bottom of the screen. If you hear it, show me what is inside the box.</i>	The subject shall notify if the word has been understood or not. Show the subject the green question mark button and show how to press the correct response image.

Table 4: MATCH instruction

Please note that the response input is only possible after the word has been played. During the word presentation the question mark button ② is greyed out and no response at all is possible.



Figure 8: MATCH user interfaces (left: elicit stimulus; right: response alternatives)

In the header, information about the current test status including stimulus levels and subject's response is provided (see Table 5). For example, the header in Figure 8 (right image) shows that the word is presented at 50 dB HL. The correct answer is at the top left image (monkey). One item has already been tested. The previous word has been understood by the subject.

Speech level	Correct word	Current level	Response
Value [dB HL]	Image position index: 0 2 1 3	Value [dB HL], mute	<div style="display: inline-block; width: 15px; height: 15px; background-color: green; margin-right: 5px;"></div> heard <div style="display: inline-block; width: 15px; height: 15px; background-color: red; margin-right: 5px; margin-top: 5px;"></div> not heard

Table 5: MATCH header information

If you suspect that the subject might take advantage of the header information, turn off the header information in the settings before starting the test.

Depending on age and physical/mental abilities, the test may be conducted completely self-controlled (i.e. subject elicits stimulus and enters response) after instruction or with assistance of the examiner. Supervision by a qualified examiner is recommended at all times.

During the test, there are some specific features available when connecting the patient response button. The patient response button shall in this case be operated by the examiner. A speech sample may be repeated by the examiner by pressing the button briefly and a previous response can be undone (e.g. if the subjects would like to correct the response after response input) when pressing the button for about 2 s.

After the test is finished, for MATCH Fixed the result is shown as a score and for MATCH Adaptive the result is shown as a speech audiogram (estimated discrimination function) with a speech recognition threshold (see Figure 9). Additionally, time course of speech level and reaction time as well as a measurement protocol are shown when pressing on the result screen. The measurement protocol shows a list of all presented words, the presented alternatives, and the subject's response.

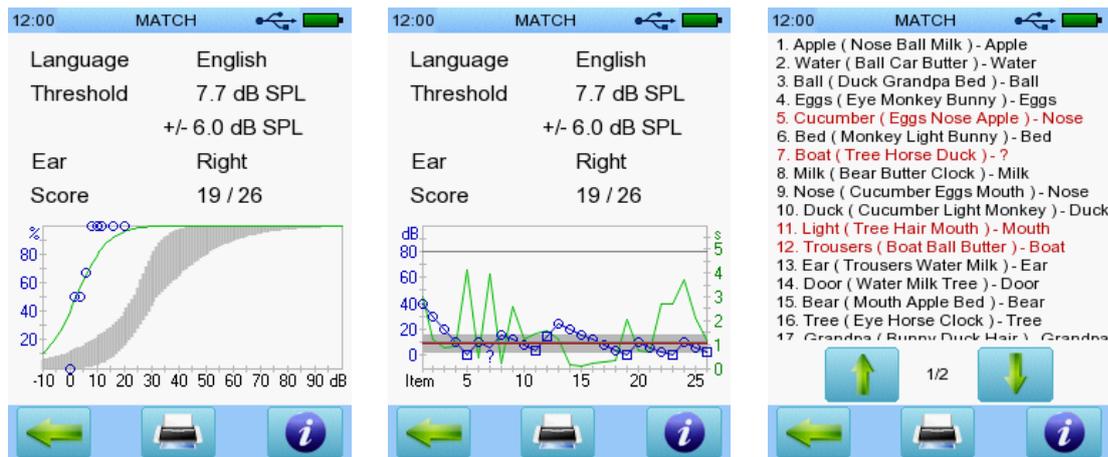


Figure 9: MATCH Adaptive result (left: speech audiogram and discrimination function; middle: time course of speech level (blue symbols) and reaction time (green symbols); right: measurement protocol)

STUDY RESULTS

A study (Bohnert *et al.*, 2013; Schirkonyer, 2013; Schirkonyer *et al.*, 2014) for evaluating the test performance of MATCH with children was conducted at the Department for Communication Disorders, ENT-department of the University of Mainz Medical School's hospital (Germany). In the study, pure-tone audiometry and MATCH was performed with Senti Desktop in 111 children (213 ears) from 2;6 to 6;9 years. Thereof, 157 ears exhibited normal hearing, whereas 56 ears were hearing-impaired. Some children exhibited a unilateral hearing impairment. Normal hearing was defined in the study as screening pass at 30 dB HL at 0.5, 1, 2, 4, and 6 kHz. If a fail occurred, hearing thresholds were determined by extrapolated DPOAE I/O-functions. All tests were performed in a quiet room with ambient noise < 50 dB(A) or in a booth. Data from all subjects were split up into three age groups (AG1: 2;6-4;3 years, AG2: 4;3-5;6 years, AG3: 5;5-6;9 years). Speech recognition thresholds at 50 % were 29.4 ± 1.2 (AG1), 27.8 ± 0.9 (AG2) and 25.4 ± 0.8 dB HL (AG3), whereas speech recognition thresholds at 71.4 % were 38.2 ± 1.0 (AG1), 34.9 ± 0.7 (AG2) and 31.1 ± 1.0 dB HL (AG3), i.e. the speech recognition thresholds slightly decreased with increasing age. The median of the test duration amounted to 4.0 (AG1), 3.4 (AG2), and 3.1 minutes per ear (AG3), i.e., test duration decreased with increasing age. Test-retest stability ($n = 79$) was good with a correlation of $r = 0.89$. When comparing average pure-tone thresholds at 0.5, 1, and 2 kHz to MATCH 71.4 % speech recognition thresholds ($n = 55$) there was a good correlation of $r = 0.81$.

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3.1.6 Universal Speech Test (UST)

METHODOLOGY

The Universal Speech Test (UST) provides a platform for speech tests which follow a typical workflow of presenting words (organized in word lists) at different speech levels with the aim of determining a 50 % speech recognition threshold and optionally a maximum discrimination level, which amounts at the best to 100 %. The UST offers three test phases: (1) voice hearing phase (optional) for determining the level at which a word or in general human voice can be heard but not understood (2) word understanding phase (optional) for determining a level at which the subject begins to understand a word and (3) the test phase which allows for determining speech recognition scores at different speech levels. The optional pre-test phases can be used for determining a starting level for the test phase. Alternatively, audiometric threshold data (e.g. average hearing threshold across 0.5, 1 and 2 kHz) may be used. UST is available with optional ipsilateral noise for assessing speech intelligibility in noise. Contralateral noise is available for masking purposes, e.g. for patients with unilateral hearing loss or distinct difference in hearing threshold between left and right ear. The intended use and the targeted patient group depend on the speech material used.

As an example the 'Freiburger speech test' (Halbrock, 1953), a well-established German speech test for adults, is explained in the following. Please note that other speech tests may use different word types and may aim at different target speech recognition values. The 'Freiburger speech test' uses monosyllabic nouns that represent commonly used speech (e.g. Ring, Spott, Farm, Hang, ...) and two-digit numbers with mainly four-syllables (e.g. 98, 22, 54, ...). Word lists are based on the most commonly used words at the time at they were recorded. Lists were prepared such that the words exhibit a similar phonetic distribution. The test comprises 20 word lists with 20 monosyllabic nouns each and 10 word lists with 10 two-digit numbers each (see DIN 45621-1). The 'Freiburger speech test' can be split up in two separate sub-tests. Both are typically conducted without ipsilateral noise in order to determine speech understanding in quiet. The monosyllabic word test is intended for determining individual speech recognition values, i.e., the percentage of words which are correctly heard and spoken by the test person for multiple speech levels (65, 80, 95, 110 dB SPL), which are displayed in the format of a speech audiogram. The intended use of the two-digit number test is to determine a hearing loss for numbers at 50 % intelligibility. Numbers are presented at two speech levels. The lower one corresponds to the hearing loss of the subject at 4 kHz determined by pure-tone audiometry plus 20 dB. The higher one has to be set to a level that is 5 dB higher than the initial level. The initial speech level corresponds to the individual hearing loss at 500 Hz from the pure-tone audiogram plus 20 dB.

For normal-hearing subjects, monosyllabic nouns usually require 10 to 20 dB higher levels to achieve the same speech recognition score as for two-digit numbers (Brinkmann and Richter, 1997). Hearing-impaired subjects may not reach a 100 % speech recognition score even at high speech levels. Normative data for monosyllabic words and two-digit numbers is presented in DIN 45626-1.

PRACTICAL USE

Select the *UST subtest* (e.g. *Freiburger*) from the module selection screen. If more than one UST subtest is licensed, the respective *UST subtest* can be found in the *Speech / UST* section. If necessary, change the parameters (e.g. ipsilateral noise or contralateral masking noise, noise level, voice

hearing / word understanding phase) as required. Make sure to select a UST sub-test with language and word lists that are matching the tested subject's language abilities.

Make sure that a valid transducer is connected (headphone, insert earphones, or loudspeakers) and start the test by selecting the test ear. Before the test, the subject must be instructed about the task. During the voice hearing phase the subject shall respond if a voice is heard or not. During the word understanding phase the subject shall respond if a word has been understood or not. The determined word understanding level is marked in the speech audiogram as lowest speech level with a score of zero. During the test phase, the subject shall repeat the word. The examiner needs to evaluate if the word was understood correctly or not. Please note that the test must be conducted by a qualified and normal-hearing examiner. The examiner needs to elicit the stimulus and enter the response. The test is *not* intended to be self-controlled by the subject.

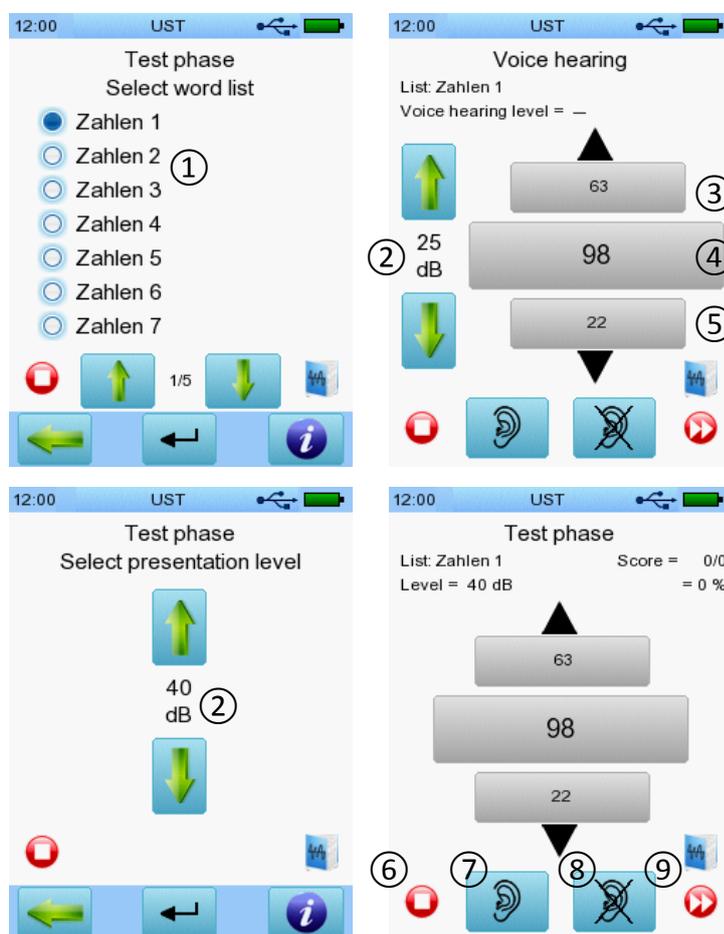


Figure 10: UST user interface (top left: word list selection; top right: main user interface during voice hearing phase; bottom left: level selection during test phase; bottom right: main user interface during test phase)

For each pre-test phase and during the test for each tested speech level, a word list needs to be selected (see Figure 10 - ①). Already selected word lists are greyed out but can be selected again. Make sure that previously presented words are not already known to the subject. Therefore, during the test phase, select for each tested speech level a new word list. After selecting the word list, adjust the speech level to your needs by pressing the up/down buttons ②. In most tests, typically

multiple levels are selected for determining speech recognition scores from very low (around 0 %) to very high (around 100 %).

A word is played by pressing the big word button (4). If you would like to select another word from the list, you can browse through the word list via the triangular up/down buttons above/below the list. The smaller word buttons show the previous (3) and next (5) word in the list. After the word has been played and the subject has answered, enter the patient response (heard/understood: (7), not heard/not understood: (8)). Already tested words are coloured green (understood) or red (not understood). The test can be stopped by pressing the stop button (6). Any pre-test phase or test run at the current speech level can be cancelled by pressing the forward button (9).

After the test is finished, for UST the result (see Figure 11) is shown as a graphical and tabular speech audiogram together with a 50 % speech recognition threshold. Toggle the views by pressing the graph / table.

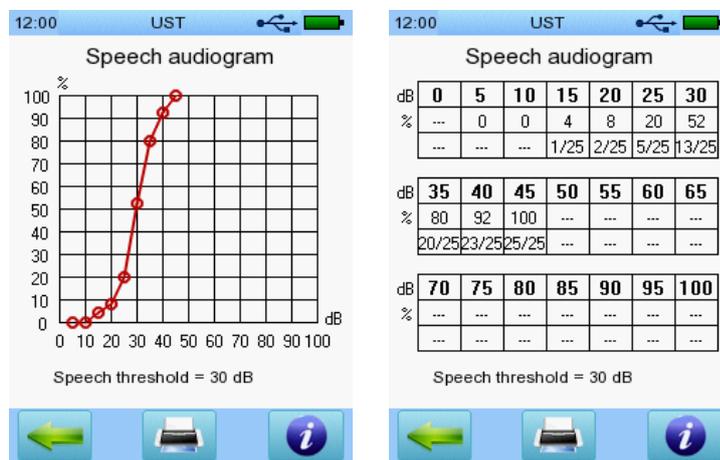


Figure 11: UST result (left: speech audiogram graph; right: speech audiogram table)

Please note that during this test the footer is hidden. You may activate the footer by pressing the power on/off switch shortly.

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3.1.7 Munich Auditory Screening Test for Processing Disorders (MAUS)

METHODOLOGY

MAUS is a German screening test for identifying subjects with a central auditory processing disorder (APD). The test was especially designed and validated for children from 6 to 11 years but may be used for other cooperative subjects as well. The test is supposed to be conducted after exclusion or treatment (e.g. hearing aid, surgery) of a peripheral hearing disorder. In case of a positive result regarding APD, further diagnostics may be advised for the differentiation to other dysfunctions, such as cognitive dysfunctions, attention deficit disorders, general dysfunctions of short-term memory. MAUS is only available in German language (recordings: © Westra Elektroakustik GmbH 2003/2004). MAUS includes three sub-tests: sequence of syllables, words in noise, and phoneme differentiation and identification. These sub-tests allow for maximum sensitivity for detecting APD (see section *STUDY RESULTS*). The sequence of syllables sub-test includes 18 items with 6 three-syllable-words (e.g. muwage = mu-wa-ge), 6 four-syllable-words and 6 five-syllable-words. All items are meaningless words. The occurrence of vowels and consonants noticeable for subjects with ADP is balanced. The word in noise test includes 12 items per ear with speech-simulating ipsilateral noise. In contrast to the other sub-tests, for which items are presented binaurally, all word in noise items are presented monaurally. The phoneme differentiation and identification test includes 13 consonant-vocal and 10 consonant-consonant-vocal pairs of meaningless syllables. The entire speech material is presented at a fixed level of 65 dB HL. The test duration is about 15 minutes. For further details please refer to the section *STUDY RESULTS* and to the MAUS manual (Nickisch *et al.*, 2004a).

PRACTICAL USE

Select *MAUS* from the module selection screen. If more than one speech test is licensed, *MAUS* can be found in the *Speech* section. Make sure that a valid transducer is connected (e.g. headphone, insert earphones). The test starts with the sequence of syllables sub-test and proceeds to the sub-tests words in noise and phoneme differentiation and identification. For each sub-test, instruct the subject about the tasks as described in *Table 6*. The instructions are also displayed on the device screen before the sub-test starts.

Instruction of examiner	Task for examiner
Sub-test 1: Sequence of syllables	
<i>You will hear magic words. Listen carefully and repeat what you heard.</i>	
Sub-test 2: Words in noise	
<i>Now you will hear words while there is noise. Listen carefully and repeat what you heard.</i>	
Sub-test 3: Phoneme differentiation and identification	
<i>Now I will say two meaningless words. Listen carefully and tell me if these words are exactly the same or not! Both cases may occur. After that, please repeat the words in the correct order. Let's give it a try. Mi-Mi, these words are exactly the same. Which words did I say?</i>	Wait for subject's response and check if the subject understands the task for similar syllables.

<p>[if correct:] Great.</p> <p>[if wrong:] Listen carefully again, I will tell you the words once more... [repeat instruction]</p>	
<p>Now listen again: Bo-Sa, these words sound different. Can you hear that? Which words did I say? Try it yourself now: Li-Pa. Is that similar or different?</p> <p>[if correct:] Great.</p> <p>[if wrong:] Listen carefully again... [repeat instruction]</p>	<p>Wait for subject's response and check if the subject understands the task for different syllables.</p>

Table 6: MAUS instruction

Please note that for the first sub-test (sequence of syllables) the subject has two tries, i.e. if the sequence of syllables was not repeated correctly the first time, the item is automatically replayed and the subject may repeat the word a second time. For the other sub-tests, all test items are played only once. For further qualitative analysis, it is recommended to write down wrong responses on a separate protocol sheet. The test is *not* intended to be self-controlled by the subject.

The result shows a list of scores with colour-code (see Figure 12). The scores are calculated automatically from the input of the examiner. The maximum scores are for sequence of syllables 36 points, for 'words in noise' 12 points per ear, and for 'phoneme discrimination and identification' 22 points each. The score is mapped to an age-dependent T-value range which is represented by coloured areas (<30: extreme substandard, 30-40: substandard, 41-60: normal, 61-70: surpassing, >70 extreme surpassing). Please note that even if all responses were correct, for some age groups, the score is not mapped to the best T-value range. If all results are normal or better, the probability for an APD is very low. If at least one result is substandard or worse, an APD may possibly be present. Please note that the test is a screening test, which may deliver false positive results. So, if MAUS delivers a conspicuous result, further diagnostics (e.g. intelligence diagnostics, neuro-paedaudiologic diagnostics, objective audiometric diagnostics as e.g. ABR) is advised.

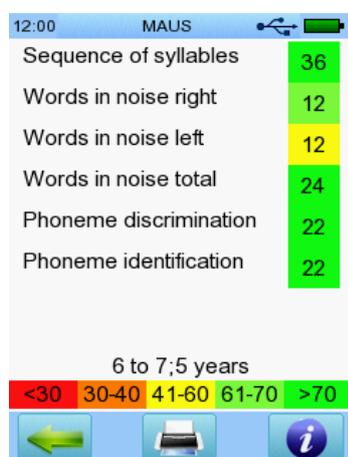


Figure 12: MAUS result

STUDY RESULTS

In a pre-study by Nickisch and Oberle (2002), 79 children from 6 to 12 years (average: 8,8 years) with normal peripheral hearing (pure-tone thresholds ≤ 20 dB HL) and clinical indication for APD including two or more APD-positive results with the following psycho-acoustic tests: Mottier test from Zurich reading test, Heidelberg sound differentiation test (HLAD) test with sound differentiation, analysis and identification, speech audiometry in noise, number sequences, dichotic listening test, directional hearing, time-compressed speech, binaural fusion, Patsy test, gap detection, and joining phonemes. The incidence rate of results atypical for normal-hearing subjects was analysed. A combination of tests was investigated with the aim of getting maximum sensitivity regarding APD detection. A combination of three tests was found to deliver maximum sensitivity: speech audiogram in noise, Mottier test, and phoneme differentiation from HLAD. Normative data (Nickisch *et al.*, 2004b) was derived from 356 school children (189 male, 167 female) with an average age of 8.76 years and with normal peripheral hearing.

A clinical study (Nickisch *et al.*, 2004a) with 52 children (36 with APD, 16 without APD) from 6 to 12 years (average age of 9.5 years) with normal peripheral hearing was performed. All children exhibited normal peripheral hearing. APD was diagnosed if at least two of the other tests mentioned above exhibited an APD-positive result. MAUS was conducted for comparison. The correlation between the MAUS sub-tests and the other test methods was examined and amounted to $r = 0.78$ (MAUS: sequence of syllables \leftrightarrow Mottier test), $r = 0.51$ (MAUS: words in noise \leftrightarrow speech audiometry in noise), $r = 0.76$ (MAUS: phoneme differentiation \leftrightarrow HLAD: sound differentiation) and $r = 0.81$ (MAUS: phoneme identification \leftrightarrow HLAD: sound identification). All correlations were highly significant. The agreement rate of APD screening results was compared between the MAUS sub-tests and the other test methods and amounted to 71 % (MAUS: sequence of syllables \leftrightarrow Mottier test), 75 % (MAUS: words in noise \leftrightarrow speech audiometry in noise), 73 % (MAUS: phoneme differentiation \leftrightarrow HLAD: sound differentiation), and 87 % (MAUS: phoneme identification \leftrightarrow HLAD: sound identification). The sensitivity of MAUS amounted to 97 %. In an extended study (Heuckmann *et al.*, 2006) the sensitivity was validated with 132 school children (80 with APD, 52 without APD) from 6 to 12 years (average age: 9,5 years) and amounted to 96 %.

Retest reliability of MAUS was investigated in a study (Heuckmann *et al.*, 2005) with 62 school children from 8 to 10 years. Therefore, MAUS was conducted twice with a time lag of two to six weeks from the first to the second test. The overall retest reliability for MAUS was $r = 0.75$ with the sub-tests ranging from $r = 0.64$ (sequence of syllables) to $r = 0.75$ (phoneme differentiation).

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3.1.8 Bochum Auditory Speech Discrimination Test (BASD)

METHODOLOGY

The Bochumer Auditory Speech Discrimination Test (BASD) provides an audiometric test battery for detecting speech development deficits and related auditory processing disorders (APD), i.e., functional deficits that are *not* caused by peripheral hearing disorders or attention deficit disorders. BASD examines auditory processing of speech and non-speech stimuli by measuring just noticeable differences (JND) in frequency, level and duration of a presented sinusoidal signal. The non-speech-based part of BASD is based on the Leipzig inventory for assessing central-auditory processing disorders during child development (LIPP, see Ludwig, 2008). Additional test items are speech stimuli for testing the discrimination between different consonants ba/ga (contrast in voicing) and ga/ka (contrast in place of articulation). The test is designed as a playful task, i.e. a memory game, and is especially intended for children from 4 years on. However, the test may also be used for other cooperative subjects. The test is conducted as a three alternatives forced choice procedure. The task is to find two similar items (i.e. with same consonant, frequency, level, duration) from three alternatives. The two similar items are randomly spread across the three memory cards. When pressing the cards images appear as in a memory game. If the two selected cards show the same image the response was correct. This provides an immediate feedback to the tested subject and hence increases motivation.

Start parameters are set as follows: stimulus level differences from 5 to 20 dB (5 dB steps), differences in duration from 100 to 300 ms (50 ms steps), and difference in frequency are set to 0.05, 0.1, 0.2, 0.4, 0.8, and 1.6 octaves. Basic frequencies are 500 Hz und 1 kHz. Stimulation modes are: monaural (left or right ear), dichotic (signal ipsilateral, broadband noise contralateral), binaural (same signal in both ears), as well as inter-aural (same stimulus on contralateral ear, different stimulus on test ear).

For determining the JND an adaptive algorithm is performed by changing the step size dependent on the duration of the measuring time, i.e. in the beginning steps are larger compared to those at the end of the procedure. For level, frequency and duration tests, in the beginning, the target property (i.e. level difference, frequency difference, duration difference) is increased/decreased after each trial, later it is increased/decreased after two trials (decreased if both trials were correct, increased if at least one trial was incorrect). JNDs are calculated on the basis of the reversal points.

PRACTICAL USE

Select *BASD* from the module selection screen. If more than one speech test is licensed, the test can be found in the *Speech* section. If necessary, change the parameters (e.g. presentation level, presentation mode, frequency for tonal sub-tests, initial difference for level, frequency, and duration, number of trials and reversals) as required. Select the sub-test.

Make sure that a valid transducer is connected (e.g. headphone, insert earphones) and start the test by selecting the test ear. The available test ear configurations depend on the selection of the presentation mode (monaural, binaural, dichotic, interaural) in the module settings. If *monaural*, *dichotic* or *interaural* is selected you may test either the right or left ear. If *dichotic* is selected, all test stimuli are presented together with contralateral noise. If *interaural* is selected, all test stimuli are presented with three identical contralateral stimuli (e.g. right ear selected for sub-test ba/ga – right ear: ga – ba – ga, left ear: ga – ga – ga). If *binaural* is selected, both ears are tested together.

Before starting the test, the subject must be instructed about the task. The task is to listen to three stimuli represented by three memory cards. Two of these three stimuli are identical, i.e. they feature the same consonant, level, frequency or duration. The two identical stimuli shall be indicated by the subject by uncovering the corresponding two cards.

Dependent on age and physical/mental abilities, the test may be conducted completely self-controlled (i.e. subject elicits stimulus and enters response) after instruction or with assistance of the examiner. Supervision by a qualified examiner is recommended at all times.

When starting the test, the main user interface is shown (see *Figure 13*). The stimulus can be elicited by pressing the play button ②. The stimulus presentation can be repeated by pressing the play button again. The subject responds by pressing two out of three memory cards ④ corresponding to the stimuli that are considered similar regarding the target property (consonant, level, frequency, duration). If the selected cards are correct, the test proceeds to the next trial. If the selected cards are not correct, the third card is automatically uncovered in order to provide feedback which combination would have been correct. The blue bars on the left ① and right ③ of the play button represent card decks showing the test progress, i.e. the left bar decreases with each trial and the right bar increases with each correct response.

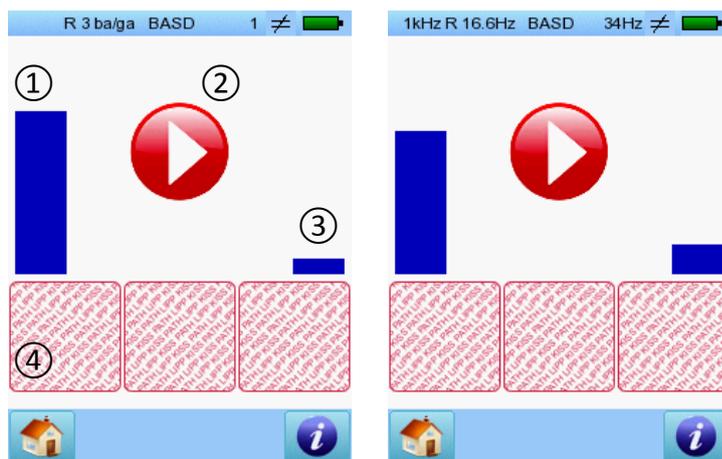


Figure 13: BASD user interface (left: ba/ga differentiation; right: frequency differentiation)

The header provides various information as explained in *Table 7*.

Frequency	Ear	Current differ. / Current position of different item	Test type	Previous differ. / Previous not-pressed item	
500 Hz, 1 kHz for tonal tests	R (right), L (left), B (binaural)	Difference value for tonal tests, else position of different item	ba/ga or ga/ka not available for tonal tests	Difference value for tonal tests, else position of not pressed item	≠ correct (difference could be detected) = incorrect

Table 7: BASD header information

For example, the left screenshot from *Figure 13* provides the following information: test performed on right ear, current item that is different to the other two items is the third item (i.e. item to the right of the screen), the performed sub-test is ba/ga, the previously not pressed button is the button

on the left of the screen (i.e., the middle and right button were pressed), the response was correct. The right screenshot from *Figure 13* provides the following information: the test is performed with a 1 kHz tone at the right ear, the current frequency difference is 16.6 Hz, the previous frequency difference was 34 Hz, the response was correct.

The BASD result is shown as a score for consonant tests and as a discrimination threshold for tonal tests. Preliminary normative data is available (see *STUDY RESULTS*).

STUDY RESULTS

In a study performed at the University of Leipzig (Freigang *et al.*, 2011), the LIPP test (similar to non-speech-based part of BASD) was performed in 59 adults from 65 to 89 years. Tests were performed at a stimulus level of 35 dB SL with monaural, dichotic, and interaural presentation. The measurements yielded significant age-dependent deteriorations in the ability to discriminate acoustic properties. Most prominent, interaural frequency and duration discrimination at low test frequencies was elevated which could be explained by a deterioration of time- and phase-dependent processing at brain stem and cortical levels.

In a project supported by the German Federal Ministry for Education and Research (BMBF) a speech screening program for pre-school children was developed (Neumann, 2012). The screening program should allow to differentiate between normal speech development (group A), conspicuous speech development with need for educational speech training (group B), and speech development disorders with need for therapy (group C). Moreover, cases of APD within each group should be detected. A previously developed speech screening test for children called KiSS (Euler *et al.*, 2010) was found to exhibit good sensitivity and specificity for identifying conspicuous speech development, but insufficient discrimination between groups B and C. The task of the project was to develop an enhanced psycho-acoustical test battery for examining auditory processing (with differentiation between groups A to C) in children from 4 to 5 years. Moreover, the electrophysiological correlates of processing the same stimuli with measuring event-related potentials, i.e. mismatch negativity (MMN), was investigated.

In 189 pre-school children from 4 to 4;5 years BASD was tested along several reference tests. Peripheral hearing was tested by means of pure-tone audiometry, tympanometry, stapedius reflex threshold, and Göttinger speech intelligibility test (in quiet) for children. Speech development was tested by means of AWST-R vocabulary test for children, SET-K 3-5 speech development test for children (with sub-tests morphological rule construction, speech understanding, phonological commemoration of non-words, sentence commemoration), PLAKSS articulation test, and KiSS.2 speech test for children. Auditory processing was tested by means of Göttinger speech intelligibility test (in quiet/in noise) for children, Uttenweiler dichotic test, Mottier test, parental questionnaire. Cognitive abilities were tested by means of Coloured Progressive Matrices (CPM) language-free intelligence test, and a phoniatric/audiological examination. Based on these tests, experts classified general speech development and suspicion of APD for each child. From the 189 children, 120 (63.5 %) were classified to group A, 37 (19.6 %) to group B, and 32 (16.9 %) to group C. From 188 children, 13 (6.9 %) were suspected of APD. From the APD-positive children, 2 (1.7 %) were from group A, 4 (10.8 %) from group B, and 7 (22.6 %) from group C. The sensitivity of KiSS.2 for detecting a conspicuous speech development (including group B and C) amounted to 89.7 %, the specificity to 89.1%. In 71 of the 189 children (with similar shares of each group A to C) MMN was applied. There were no significant differences between the test groups.

Normative BASD data were established in a study with 293 children from 4;0 to 5;11 years. An age-dependent development effect could be observed. Medians of discrimination thresholds are presented in *Table 8* for the different age groups. For frequency differentiation age-dependent dropouts occurred. When considering a frequency discrimination exceeding 500 Hz as invalid, 35 % of all data from age group 4;0 to 4;5 years had to be removed. This share decreased with increasing age to 9 % for age group 5;6 to 5;11 years. This means that the frequency discrimination sub-test may not be suited for very young children.

Age (years)	4;0-4;5	4;6-4;11	5;0-5;5	5;6-5;11
Level [dB]	8.7 [n=143]	8.6 [77]	7.6 [50]	6.0 [23]
Frequency [Hz]	67.8 [103]	69.0 [59]	62.3 [41]	40.0 [21]
Duration [ms]	146.0 [143]	146.7 [77]	113.4 [50]	65.3 [23]
Ga-Ka [score/12]	6 [122]	5 [73]	6 [50]	10 [23]
Ba-Ga [score/12]	6 [125]	8 [74]	9 [50]	11 [23]

Table 8: BASD discrimination threshold medians for different age groups

Normative data for the 90 % percentile is shown for different age groups in *Table 9*. The correlation between BASD sub-tests and expert classification was significant for the sub-tests frequency (if invalid results mainly from young children were removed), place of articulation, and voicing. Also, the differentiation of APD was investigated. Significant correlations could be found between voicing and expert decision as well as between duration and suspicion of parents or of child care workers.

Age (years)	4;0-4;5	4;6-4;11	5;0-5;5	5;6-5;11
Level [dB]	13.4	13.4	12.7	12.7
Frequency [Hz]	296	344	223	70
Duration [ms]	249	254	158	157
Ga-Ka [score/12]	2	2	2	4
Ba-Ga [score/12]	2	3	5	6

Table 9: BASD 90 % percentile for different age groups

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3.1.9 Hearing Handicap Inventory for the Elderly (HHIE-S)

METHODOLOGY

In screening questionnaires, subjects are asked to rate their hearing status by answering one or more specific questions. The HHIE questionnaire was developed and standardised by Ventry and Weinstein (1982) and included 25 questions. The abbreviated screening version HHIE-S (Weinstein, 1986) includes 10 questions which concern activity limitations, participation restrictions and associated feelings and emotions of daily life. For example, one of the questions of the emotional category is: *Does a hearing problem cause you to feel embarrassed when meeting new people?* For example, one of the questions of the participation restriction category is: *Do you have difficulty hearing when someone speaks in a whisper?* The answer can be *Yes*, *Sometimes*, or *No*. The answers are matched to a multiple-point response scale: *Yes* = 4 points, *Sometimes* = 2 points, and *No* = 0 points. The total score is calculated by adding the points and is then subsequently compared to the defined cut-off to decide whether there is a pass or a fail response. Normally, the questionnaire is performed in a face-to-face administration format. The interviewer subsequently reads each question and possible response categories out loud, awaits the subject's response and fills out the corresponding answer on the form.

The questionnaire is especially designed for hearing screening in the elderly, however, may be used for other cooperative subjects as well. Please note that the test is a self-assessment test and therefore depends on the subject's cooperation and ability to respond honestly and realistically and may hence exhibit a result that is deviating from the real hearing status. Further audiologic diagnostics is advised, especially if the HHIE-S screening result suggests hearing problems.

PRACTICAL USE

Select *HHIE-S* from the module selection screen. Select the language in which you would like to perform the questionnaire. Inform the subject about the task: a number of questions from daily life situations are posed. The subject shall respond with *Yes*, *Sometimes*, or *No* dependent on which answer seems most appropriate. Dependent on age and physical/mental abilities, the test can be performed completely self-controlled after instruction or with assistance of the examiner (i.e. examiner reads questions and/or enters responses).

Please note that during this test the footer is hidden. You may activate the footer by pressing the power on/off switch shortly.

STUDY RESULTS

Jupiter and DiStasio (1998) investigated the performance of HHIE-S in 50 elderly subjects from 65 to 85 years with no history of otologic disease, high-level noise exposure or ototoxicity. In the study, the HHIE-S questionnaire was performed together with determination of a three-frequency (0.5, 1, 2 kHz) pure-tone threshold average (Fletcher index) in the better ear. The average HHIE-S score amounted to 9.8 whereas the average pure-tone threshold amounted to 36.8 dB HL. The correlation between the HHIE-S score and the pure-tone threshold average amounted to $r = 0.67$ for the situational questions, to $r = 0.52$ for the emotional questions and to $r = 0.63$ for all questions.

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3.2 Physiological Test Procedures

Physiological test procedures include otoacoustic emissions (OAE), auditory evoked potentials (AEP), acoustic immittance tests (tympanometry), and other tests that rely on the measurement of physiological properties.

Physiological test procedures do not require active participation of the tested subject during the test. In contrast to psycho-acoustical tests, the ability and willingness of the subject to cooperate only play a subordinate role. Nevertheless, some cooperation is necessary. This may include (dependent on the test procedure) that the subject keeps calm, does not swallow, does not move, or does not remove the transducer or any other relevant test equipment from its required position during the test. In contrast to psycho-acoustical test procedures, physiological test procedures may be conducted in subjects that are not able or not willing to perform a psycho-acoustical task, i.e., subjects who are too young or otherwise incapable of responding behaviourally. This may be neonates and small children, mentally or physically handicapped subjects, or people simulating a hearing loss. The examiner must ensure that the subject is capable of fulfilling the respective prerequisites (e.g. being quiet during the test). Also, older subjects should be informed about the test procedure, so that they know what to expect during the test. This may positively contribute to patient relaxation.

Dependent on the test procedure, the test environment must be appropriate. This may include low ambient noise conditions (OAE) and low electro-magnetic radiation (AEP). Non-compliance may deteriorate the result.

Physiological test procedures rely on specific physiological processes that are active at different stages of the auditory pathway and hence reflect the mechanical or the neurological functioning of the auditory system. Therefore, physiological tests (single test or combination of tests) can be used for topological hearing diagnostics, i.e., for detecting the site of impairment along the auditory pathway. Tympanometry, OAE and AEP are supposed to be able to differentiate between middle-ear, cochlear, and neural disorders. This is important since an adequate therapy for a hearing disorder can only be developed if it is known which stage of the auditory pathway is impaired. With psycho-acoustical tests, a differentiation between sound-conductive and sensorineural hearing loss is possible by evaluating the difference between air- and bone-conductive pure-tone thresholds. However, the discrimination of a sensorineural hearing loss, i.e., the differentiation between a sensory (cochlear) and a neural disorder with subjective testing may be not reliable, because the validity of relevant tests (e.g. Short Increment Sensitivity Index (SISI), Fowler, Carhart) is limited. Moreover, in infants and other non-cooperative patients psycho-acoustical tests cannot reliably be performed.

As for psycho-acoustical tests, proper transducer placement and calibration is important for a reliable outcome. Incorrect placement of a transducer or usage of an incorrectly calibrated transducer may adulterate the result. A suitable transducer should be connected and properly fitted.

If not specified otherwise all physiological tests can be performed in subjects of all ages as long as appropriate participation and cooperation can be expected.

3.2.1 Overview: Otoacoustic Emissions

The discovery of otoacoustic emissions (OAE) (Kemp, 1978) has produced a fast, powerful, and versatile tool for diagnosing cochlear integrity. OAE measurements are today a standard part of the audiometric test battery. OAEs are measured by means of a highly sensitive low-noise microphone within an ear probe that is placed in the outer ear canal. There are spontaneous and evoked OAEs. OAEs are the by-product of the non-linear sound amplification process in the cochlea (Davis, 1983; Dallos, 1992). OAEs are low-level sound emissions generated by the outer hair cells (OHCs) of the inner ear. OAE levels depend on the number of functioning outer hair cells given a normal middle-ear function. Also, OAE levels depend on the ear canal volume. Because of the smaller ear canal volume, OAE amplitude in newborns is higher compared to that in adults (Norton, 1992; Lasky, 1998a,b; Abdala, 2000). As a consequence, OAEs in newborns are easier to measure. OAEs are measured by means of a highly sensitive low-noise microphone within an ear probe placed in the outer ear canal. There are spontaneous and evoked OAEs.

Spontaneous otoacoustic emissions (SOAE) are sinusoidal signals and appear without any sound stimulation in a healthy cochlea and seem to be a direct consequence of the cellular force generation of OHCs (Zwicker and Schloth, 1984; Burns *et al.*, 1998; Jülicher *et al.*, 2003). SOAEs do not appear in all normal hearing subjects and are present in about a half of the normal hearing population, with a distinctly higher prevalence in women than in men (Bilger *et al.*, 1990; Penner *et al.*, 1993; Penner and Zhang, 1997). SOAEs are therefore not suited for audiological diagnostics.

Evoked OAEs are triggered by external sounds, either by transient (clicks and tone bursts) or stationary stimuli (tones) delivered via loudspeakers within the ear probe. Commonly used types of evoked OAEs are:

Stimulus frequency otoacoustic emissions (SFOAE) are elicited by one continuous, low-level sinusoidal signal. Recording of SFOAEs is difficult because stimulus and response superimpose. SFOAEs are typically derived as the difference in sound pressure in the ear canal with and without a suppressor tone added to the probe tone (Kalluri and Shera, 2001; Neely *et al.*, 2005).

Transient evoked otoacoustic emissions (TEOAE) are elicited by clicks or tone bursts (see *Figure 14*). TEOAEs represent the sum of the pulse responses of OHCs along the cochlea. They already disappear at mild hearing losses and are therefore commonly used in hearing screening programs. For more information on TEOAEs, please refer to section [3.2.2: Transient Evoked Otoacoustic Emissions \(TEOAEs\)](#).

Distortion product otoacoustic emissions (DPOAEs) are elicited by two sine tones with a specific frequency and level ratio (see *Figure 14*). DPOAEs represent cubic distortions of OHCs and arise directly from the frequency-selective compressive non-linearity of OHCs. DPOAEs can be applied as a test for a frequency-specific assessment of cochlear dysfunction. DPOAEs are reported to be measurable at a cochlear hearing loss of up to 40 to 50 dB HL, corresponding to the range of amplification of OHCs. For more information on DPOAE, please refer to section [3.2.3: Distortion Product Otoacoustic Emissions \(DPOAEs\)](#).

Sentiero devices provide both TEOAE and DPOAE test procedures. TEOAEs and DPOAEs are present in essentially every normal-hearing subject. TEOAEs give a rapid overview of cochlear function, whereas DPOAEs provide more quantitative information about sound processing at distinct cochlear sites.

OHCs are reported to be impaired by sound overexposure, ototoxic drugs (e.g. therapeutic antibiotics), infections (e.g. meningitis, mumps, materno-fetal infection), and anoxia (e.g. birth trauma), or to be partly missing in genetic hearing loss. OHC impairment results in a loss of sensitivity and frequency selectivity of the hearing organ (Liberman and Dodds, 1984). OAEs, as a by-product of cochlear non-linear sound amplification, then appear with reduced amplitude or disappear (Mills and Rubel, 1994).

Since OAEs are a by-product of the non-linear sound amplification process of OHCs in the cochlea they can only serve as a measure for evaluating OHC integrity, i.e., lesions of inner hair cells or retro-cochlear defects (e.g. neural defects, auditory processing disorders) are not detectable by means of OAE. In sound-conductive hearing-loss, both the stimulus and the response amplitude are reduced, so that OAEs are not present, even with a mild sound-conductive hearing-loss (Margolis, 2002), as e.g. due to Eustachian tube dysfunction or amniotic fluid in the tympanic cavity. So, if there is no OAE response detectable the following pathologies are possible: sound conductive hearing loss, cochlear hearing loss exceeding 20-30 dB HL (TEOAE) or 40-50 dB HL (DPOAE), or retro-cochlear hearing loss. In these cases, tympanometry, auditory brain-stem responses (ABR), and auditory steady-state responses (ASSR) should be performed to determine type and degree of the hearing loss.

As a general rule, if there is a suspicion of a hearing disorder, OAEs should be used first. It is fast and helps to confirm normal middle-ear and cochlear function. This is the case if OAEs are present over a wide frequency range. If OAEs are absent, the presence of a middle-ear or cochlear (OHC) pathology is likely. OAEs then should be followed by tympanometry. If the tympanogram is normal and OAEs are absent, then a cochlear disorder is likely. If the tympanogram is abnormal, a sound-conductive hearing-loss is likely. If there is an indication for a hearing disorder and both the tympanogram and OAEs are normal, ABR/ASSR may reveal if there is a cochlear (inner hair cell) or neural pathology. For example, in auditory neuropathy, where synchronization of neural activity is malfunctioning (either due to inner hair cell synaptic or neural dysfunction), normal OAEs and abnormal ABRs occur (Doyle *et al.*, 1998; Starr *et al.*, 1996).

Typical clinical applications of OAEs are: hearing screening, follow-up diagnostics after newborn hearing screening, confirmation of cochlear hearing loss (together with tympanometry and ABR), quantitative evaluation of hearing loss and recruitment for providing hearing aid fitting parameters, early detection and monitoring of OHC impairment after noise over-exposure or ototoxic drug administration, topological diagnostics, as well as identifying subjects simulating a hearing loss.

Hearing screening is a selection procedure used to decide whether further diagnostics is advised or not. Consequently, a screening decision is binary, i.e. *pass* (negative finding, no diagnostics necessary) or *refer* (positive finding, follow-up diagnostics advised). The requirements for screening are different from those for diagnostics. Because screening is performed in large populations, the typically used devices provide automatic evaluation rather than rely on an expert's judgement. A screening test should be performed as quickly as possible. Therefore, the respective methods must avoid long preparation times and the test should stop automatically if the desired quality of the result is achieved. OAEs (especially TEOAEs) are widely regarded as being suitable for screening in newborns and infants, as they are quickly measured and not present in the case of OHC dysfunction (e.g. Kemp and Ryan, 1991; Norton *et al.*, 2000a,b). The premise for this approach is that cochlear hearing loss always includes OHC damage or malfunction. It should be emphasized that a sound conductive loss due to Eustachian tube dysfunction and/or amniotic fluid in the tympanic cavity also

cause *refer* results under screening conditions mainly due to the attenuation of an existing OAE signal.

A disadvantage of using OAEs in screening protocols is a lower validity as compared to ABR methods (Barker *et al.*, 2000; Norton *et al.*, 2000a). This is especially true in populations with a high prevalence of minor threshold elevation due to a temporary conductive hearing loss, as it is found in term neonates in the first 36 hours of life due to Eustachian tube dysfunction or amniotic fluid in the tympanic cavity or due to a persisting sensory hearing loss in premature and neonatal intensive care unit infants. In order to maintain a high sensitivity, the specificity may be reduced dramatically, making a screening procedure inefficient. To avoid high referral rates, OAE referrals should be followed up with an ABR screening before further diagnostics, i.e., two-stage screening (Rhodes *et al.*, 1999; Norton *et al.*, 2000b). DPOAE audiograms may provide an alternative means for revealing a temporary hearing loss. When applying DPOAE audiograms before ABR screening, time and costs can be saved in those babies where DPOAEs are measurable and thus no additional ABR is needed. DPOAE audiograms have an advantage over TEOAEs or click-evoked ABRs because they can quantitatively assess cochlear hearing thresholds at distinct test frequencies.

Especially for hearing-aid adjustment in infants, a quantitative evaluation of the hearing loss and recruitment is necessary. When elicited at high stimulus levels (which is common in clinical practice), TEOAEs are absent at a cochlear hearing loss exceeding 20-30 dB HL, whereas DPOAEs are absent at a cochlear hearing loss exceeding 40-50 dB HL. Thus, when applying both TEOAEs and DPOAEs, a rough estimate of the hearing loss is possible.

OAE measures are stable through time and hence are capable of monitoring recovery from OHC impairment. Therapeutic drugs such as antibiotics (e.g. aminoglycosides) and anti-tumor chemotherapeutic agents (e.g. cisplatin) are reported to induce an irreversible hearing-loss, that typically affects the highest frequencies first, with hearing loss systematically progressing to the lower frequencies (e.g. Kopelman *et al.*, 1988; Fausti *et al.*, 1994; Berg *et al.*, 1999; Stavroulaki *et al.*, 2001). Early detection of ototoxicity is important for providing effective management options such as substitution of medications, change of dosage, and mode of administration (Lonsbury-Martin and Martin, 2001). Because TEOAEs are less effective above 4 kHz, DPOAEs are the test of first choice for detecting and monitoring OHC dysfunction due to ototoxic drugs. Moreover, DPOAEs have an additional advantage over TEOAEs, in that they can give information about compression of the OHC amplifiers. If OHC function is disturbed during the toxic process then not only DPOAE level, but also DPOAE growth should be altered. Like antibiotic and chemotherapeutic drugs, salicylate is also known to affect hearing sensitivity and to induce tinnitus (Myers and Bernstein, 1965; McFadden and Plattsmier, 1984; Wier *et al.*, 1988; Long and Tubis, 1988; Boettcher and Salvi, 1991; Brown *et al.*, 1993; McFadden and Pasanen, 1994). However, most importantly, impairment due to salicylate toxicity is reversible. Assuming that a loss of OHC stiffness is responsible for distortions within cochlear micromechanics, the corresponding change in inner hair cell activity may be one potential correlate of tinnitus (Janssen *et al.*, 2000).

Microphone noise, physiological noise (breathing, blood flow), and ambient noise do not allow proper OAE measurements at very low stimulus levels. At low frequencies, OAE measurements are not reliable even at high stimulus levels mainly due to technical noise. Because of the limited frequency range of the ear probe's electro-acoustic transducers, high-frequency OAE measurements are limited. To achieve low noise floor levels, OAE measurements have to be done in a sound-attenuating

booth or any other quiet environment especially when close-to threshold stimulus levels are used. Alternatively, a sound insulation headphone, that is covering the ear probe, may be used. Moreover, the subject needs to be calm, i.e. not heavily moving, breathing, or swallowing. The ear probe cable needs to hang loosely, so that it does not touch any material, e.g. clothes. Touching or rubbing the cable may add noise.

Automated measuring and evaluation procedures guarantee test consistency and simplify the interpretation of OAE recordings. Fourier transformation computations from the time domain signal allows for automatic evaluation of OAE signals. To minimize the influence of unwanted external signals, algorithms for noise reduction and artefact rejection are applied. The noise floor level is usually higher at low frequencies due to microphone properties and low-frequency body sounds such as breathing. Artefact rejection can be performed by elimination of high noise level buffers or by weighting each buffer dependent on its noise content. In addition, the noise floor level is reduced by time domain averaging of the recorded signal. The idea of averaging is that the signal is constant and hence the same in each buffer whereas the noise is random and hence changes in each buffer. Adding all the buffers increases the signal and reduces the noise. Theoretically, the improvement in SNR is proportional to the square root of the number of samples that are averaged, limited by technical properties (e.g. quantisation noise).

OAEs can only be tested with a special ear probe that typically contains one (for TEOAE) or two (for TEOAE or DPOAE) loudspeakers and a microphone (see Figure 14). For DPOAE recording, separate loudspeakers are commonly used for each primary tone in order to exclude technically generated distortion components.

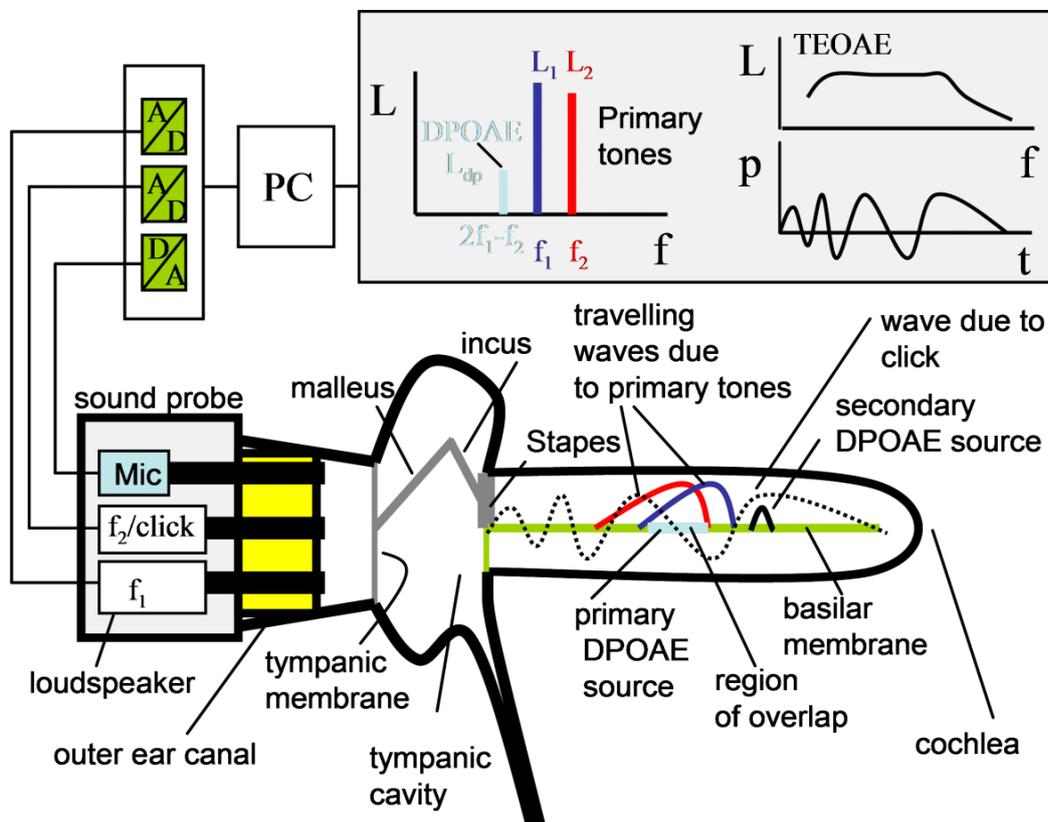


Figure 14: Schematic overview of TEOAE and DPOAE measurement (A/D = Analog-Digital-Converter, D/A = Digital-Analog-Converter, PC = Personal Computer, L = sound pressure level, p = sound pressure, f = frequency, t = time)

Before each OAE measurement, a calibration of the ear probe is automatically performed in order to adapt the stimulus output to the ear canal volume. However, due to standing wave effects, the estimated ear canal volume may not exactly reflect the real ear canal volume in all cases (Siegel, 1994; Whitehead *et al.*, 1995). The ear probe needs to be inserted properly with a tight fit and without any leakage between ear probe and ear canal. If there is leakage, low frequency sound components cannot be delivered to the cochlea properly and hence no apical and medial OHCs will contribute to the OAE response. Furthermore, proper occlusion of the ear canal by the ear tip diminishes the influence of external sounds. Ear probe channels must not be blocked by e.g. cerumen.

For a review of methodology, technical and clinical aspects of OAEs see Janssen and Müller (2008).

PRACTICAL USE

In general, it is recommended to check the functionality of the ear probe regularly. The ear probe can be tested by placing the ear probe together with an adequate probe tip in the correct test cavity (small probe tip fits into blue test cavity, large probe tip fits into red test cavity). Start the probe test (see *Figure 15*) and check if the probe test passes. If not check the ear probe cable, the probe tip placement on the ear probe, and the ear probe and probe tip channels e.g. regarding contamination). If applicable, clean the probe tip. Do not use sharp items with the ear probe. If the probe test does not pass or if you suspect any dysfunction, please retry with another ear probe and/or contact your distributor.

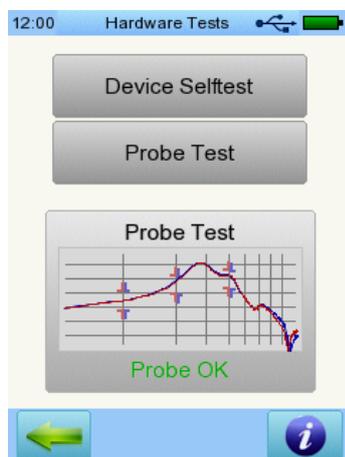


Figure 15: Probe test

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3.2.2 Transient Evoked Otoacoustic Emissions (TEOAEs)

METHODOLOGY

Transient otoacoustic emissions (TEOAEs) elicited by clicks represent the sum of the pulse responses of OHCs along the cochlea (see *Figure 14*). Almost all OHCs along the cochlear partition or a part of them (the site in the cochlea depending on the carrier frequency of the tone burst) are excited. Due to frequency dispersion in the cochlea, a specific component of the TEOAE response can be directly traced to a specific frequency component of the transient signal. As the basilar membrane at basal sites moves faster than at more apical sites, high-frequency TEOAE components stem from basal cochlear sites, whereas low-frequency TEOAE components come from more apical ones. Also, basal responses appear at the beginning and apical responses at the end of the TEOAE time function.

TEOAE responses are typically evoked by one of the following stimulus trains: (i) four clicks of equal magnitude (linear protocol), (ii) three clicks of positive polarity followed by a fourth click of inverse polarity with a relative magnitude of 9.5 dB higher than the corresponding positive clicks (non-linear protocol) (Kemp *et al.*, 1986; Bray, 1989). Under the hypothesis that the TEOAE recordings originate from saturated cochlear generators, it is assumed that the non-linear protocol removes stimulus artefacts of a linear nature (i.e. the stimulus itself), because stimulus signals increase linearly with the stimulus level, while response signals (i.e. emission emerging from the non-linear operation of OHCs) increase non-linearly with the stimulus level. It is generally accepted that the non-linear protocol is a practical compromise to maximize the reliability of a TEOAE recording (Kemp *et al.*, 1990a,b; Grandori and Ravazzani, 1993; von Specht *et al.*, 2001; Hatzopoulos *et al.*, 2003).

TEOAE signals are recorded between the short pauses between the stimuli within the stimulus trains. There are several objective methods for separating the TEOAE signal from the background noise and for automatically evaluating the validity of a recorded emission. The first method is based on the calculation of the buffer correlation of the time domain averaged signals between two separate signal buffers (Kemp *et al.*, 1990a). If the two buffers are completely identical, the correlation coefficient is 1 and thus the reproducibility 100%. A signal is commonly accepted as valid for a reproducibility exceeding a minimum of 60%. The second method relies on the computation of the spectral power ratio of the sum and the difference of the two signal buffers, denoted as the signal-to-noise ratio (SNR). The pass criterion for a valid signal is typically set to an SNR of 6 dB. The third signal validation procedure is based on a binomial statistical test, which determines the statistical probability that an emission has been recorded. Binomial statistics reduces the recorded signal to binary events, and uses knowledge on the expected distribution of these events (binomial distribution) (Giebel, 2001).

The inter-individual variance of the TEOAE level is high with a standard deviation exceeding 10 dB (Kemp *et al.*, 1986; Probst *et al.*, 1987; Bonfils and Uziel, 1989; Smurzynski and Kim, 1992). However, the intra-individual variance is quite low with a standard deviation around 1 dB (Harris *et al.*, 1991).

When recording TEOAEs, stimulus artefacts may generate signals being in phase in two averaging buffers resulting in a pseudo response of high reproducibility. By means of windowing functions, the stimulus artefact can be excluded so that the reproducibility of the overall signal is restricted to the signal section of interest (Kemp *et al.*, 1990a, Kemp *et al.*, 1990b). It should be emphasized that since the stimulus artefact always appears in the early recording period, the high frequency TEOAE components from the basal site of the cochlea get lost as a result of the windowing procedure. Due

to the fact that the stimulus and the high-frequency TEOAE components superimpose and therefore have to be cancelled during TEOAE recording, TEOAEs fail to measure OHC functionality in the basal region of the cochlea, i.e. above 4 kHz. Therefore, a high-frequency hearing loss cannot be detected by means of TEOAEs. Also, valid TEOAE responses can be present in ears with a mid-frequency hearing loss (e.g. congenital hearing loss). The problem with TEOAEs here is that infants with congenital hearing loss may be overseen and the hearing loss is detected later in life.

The wide-band TEOAE stimulus calibration is not influenced as much as DPOAEs by standing wave problems. Moreover, TEOAEs are usually stimulated with a relatively high click level, i.e. where cochlear compression already saturates basilar membrane displacement. As opposed to DPOAEs, no level ratio between primary tones needs to be fulfilled. This results in TEOAEs being less susceptible to stimulus calibration errors.

TEOAEs already disappear at low conductive hearing losses (> 10-15 dB HL) or mild cochlear hearing losses (> 20-30 dB HL) and are therefore a suitable tool for (newborn) hearing screening (Robinette and Glattke, 2002; Janssen, 2009; Janssen and Müller (2009).

In order to get more frequency-specific and quantitative information on hearing loss DPOAE or ASSR threshold measurements are advised.

Two TEOAE workflows are available:

- **TEOAE Quick** allows for simple TEOAE testing with an automated, statistical algorithm for response detection with fixed detection criteria. TEOAE Quick assesses cochlear outer hair cell function more qualitatively. The test can be performed binaurally if two ear probes are connected. In doing this test time is reduced by a factor of two.
- **TEOAE Diagnostic** allows for a more profound testing for assessing responses in five half-octave frequency bands around 1, 1.5, 2, 3, and 4 kHz. User-definable criteria can be set, i.e. SNR pass criteria (3, 6, 9 dB) for each frequency band and an overall pass criterion (number of passed frequency bands for overall pass: 3/5, 4/5, 5/5).

PRACTICAL USE

Select the TEOAE test from the module selection screen. that you would like to perform, i.e. *TEOAE Quick* or *TEOAE Diagnostic*. If more than one OAE test is licensed, *TEOAE Quick* and *TEOAE Diagnostic* can be found in the *OAE* section. For TEOAE Diagnostic: If necessary, change the parameters (e.g. single band SNR criterion, overall pass criterion) as required. Please note that selection of pass criteria influences the overall test result, i.e., different settings may result in different overall results. The stricter the selected criteria, the more prominent is the TEOAE response leading to a valid result. The criteria are saved together with the result data and cannot be changed afterwards.

The subject should be calm and sitting comfortably in a chair or lying on a bed. For babies, try to test the subject during sleep. Make sure that a valid ear probe (e.g. EP-TE or EP-DP) is connected and that the cable of the ear probe does not rub against any material as e.g. clothes. Select an ear tip with appropriate size matching the probe tip size and the subject's ear canal size. Make sure that the ear probe is inserted without any leakage between ear probe and ear canal. In cases where the ear probe is not inserted properly or ear probe channels are blocked a warning will appear.

Select the test ear (*Right+Left*: simultaneous measurement of right and left ear – only available for TEOAE Quick when two ear probes are connected). After successful ear probe calibration, the measurement starts. A non-linear broadband click stimulus sequence is presented at a fixed level (80 dB SPL) and the response is detected via the ear probe microphone.

During the measurement (see *Figure 16*) the overall measurement progress ⑦, the noise floor ⑧, the stimulus stability ②, and the ratio of rejected frames (artefacts) ① are indicated. The noise floor and the artefact rate are both indicators for the adequacy of measurement conditions. With good measurement conditions, the noise floor bar should remain in the lower quarter and the artefact rate should be lower than 20 %. If the noise floor bar is higher or the artefact rate substantially increases, ambient noise levels may be too high, the patient may be not calm enough (e.g. swallowing, moving), or the ear probe cable may rub e.g. at clothes. The overall measurement time depends on test conditions, i.e. the higher the artefact ratio the lower the progress bar speed. The stimulus stability decreases as the stimulus level changes e.g. due to movement of the ear probe. The stimulus stability should be higher than 80 %. In case the ear probe slips out of the ear canal, the stimulus stability decreases.

Time course (averaged into two buffers, time window from 5 to 13 ms) ⑥ and frequency spectrum (signal: green area, noise: yellow area; 0.7 to 4 kHz) ③ are shown on the screen. For *TEOAE Quick* a continuous spectrum ③ and TEOAE validity bar ④ are shown. For *TEOAE Diagnostic*, additionally the spectrum can be shown separated for the different frequency bands together with the current SNR values ⑤. Also the SNR criterion for each frequency band and the overall criterion can be displayed. You can toggle between the different view modes by pressing the graph area on the screen. The test can be aborted by the examiner with the stop button ⑨.



Figure 16: TEOAE measurement (left: TEOAE Quick; right: TEOAE Diagnostic)

After the test is finished, the result screen (see *Figure 17*) shows *Valid response* if the test criterion is reached or *No valid response* if not. Termination of the measurement by the user is indicated by *Incomplete test*. For further analysis, the spectrum of the response signal and noise, and the time signal is shown together with quality data, i.e. artefact rate and stimulus stability. For TEOAE Diagnostic the test criteria can be displayed (see *Figure 17* - right). In case no valid result is detected and the artefact rate exceeds about 20 % or the stimulus stability undercuts about 80 %, please try to eliminate possible causes (e.g. ambient noise, inappropriate ear probe placement) and restart the measurement.



Figure 17: TEOAE result (left: TEOAE Quick; middle: TEOAE Diagnostic with spectrum separated in frequency bands; right: TEOAE Diagnostic with pass criteria)

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3.2.3 Distortion Product Otoacoustic Emissions (DPOAEs)

METHODOLOGY

Distortion product otoacoustic emissions (DPOAEs) represent cubic distortions of outer hair cells (OHC) when stimulated simultaneously by two tones f_1 (lower frequency) and f_2 (higher frequency) (see *Figure 14*). DPOAEs arise directly from the frequency-selective compressive nonlinearity of OHCs (Brownell *et al.*, 1985; Kemp *et al.*, 1986). The two primary tones interact in the cochlea within the region of overlap of the traveling waves of the two primary tones close to the characteristic place of f_2 . Thus, DPOAEs can be applied as a probe for frequency-specific assessment of cochlear dysfunction at the f_2 place. In humans, both quadratic (f_2-f_1) and cubic distortion products ($2f_1-f_2$) can be detected. The cubic distortion component $2f_1-f_2$ yields the highest amplitude and is therefore primarily used in audiological diagnostics (Gorga *et al.*, 2000). DPOAE amplitudes typically range from about 20 dB SPL down to the limiting noise floor level, i.e. about -20 dB SPL. DPOAEs provide quantitative and frequency-specific information about the range and operational characteristics of the cochlear amplifier, i.e., sensitivity, compression, and frequency selectivity of the hearing organ. Especially, extrapolated DPOAE I/O functions (see below) allow for assessing loss of cochlear sensitivity and compression (Janssen and Müller, 2008). The number of OHCs contributing to DPOAE generation depends on the size of the overlapping region, which is determined by the primary tone levels L_1 and L_2 , and the frequency ratio f_2/f_1 . A frequency ratio of about 1.2 has been found to be optimal. Different primary tone level ratios have been suggested. A primary tone level setting, which accounts for the different compression of the primary tone traveling waves at the f_2 place, is the scissor paradigm (Whitehead *et al.*, 1995; Kummer *et al.*, 2000; Boege and Janssen, 2002). Due to the steep slope of the traveling wave towards the cochlear apex, the maximum interaction site is close to the f_2 place in the cochlea. To preserve optimum overlap of the primary tone traveling waves at a constant frequency ratio, the primary tone level difference has to be increased with decreasing stimulus level. This results in a decrease in L_1 being lower than the decrease in L_2 (see *Figure 18*).

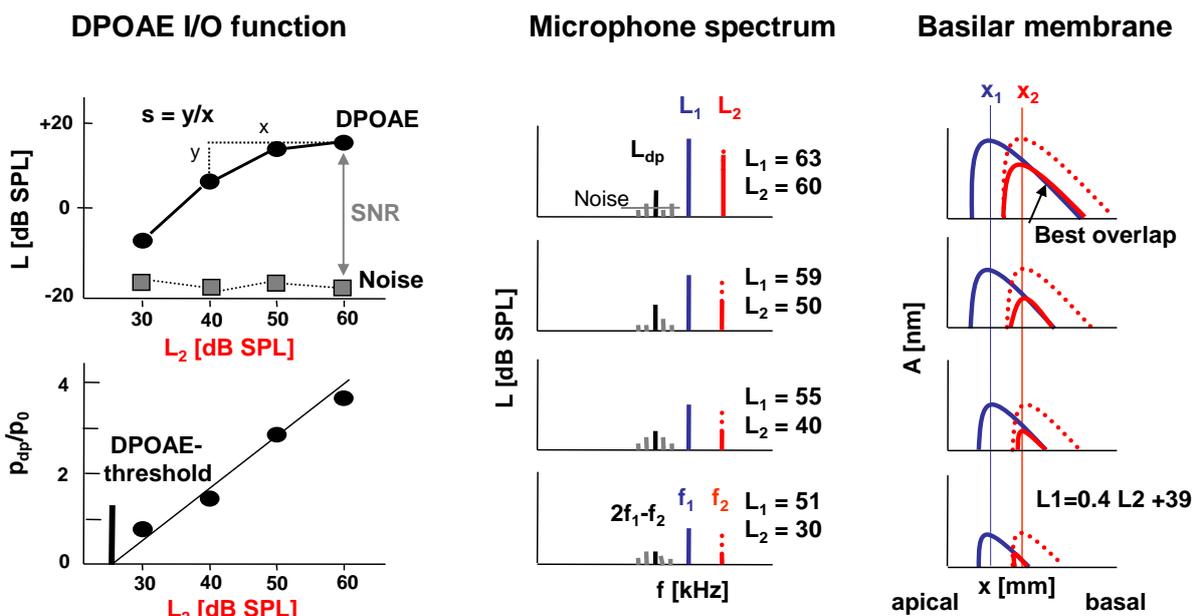


Figure 18: Schematic overview of DPOAE generation with different primary tone level settings: scissor paradigm (solid lines), $L_1 = L_2$ (dotted lines)

Despite the fact that DPOAEs are supposed to primarily reflect OHC activity at the f_2 place, there is evidence that DPOAEs are generated by two distinct cochlear sources (Whitehead *et al.*, 1992; Brown *et al.*, 1996; Shera and Guinan, 1999). As already mentioned, the first source, the effect of which is actually intended to be measured, is located at the region of overlap of the traveling waves of the two primary-tones near the f_2 place and is due to intermodulation distortion. The second source, which is unintentionally adding constructively or destructively to the first source emission, is located at the characteristic frequency place of the emission at $2f_1-f_2$ and is due to reflection of energy that has travelled apically from the overlap region near f_2 . Thus, energy from both interacting sources yields the composite DPOAE signal which is actually recorded in the outer ear canal. The influence of the second DPOAE source may be observed when monitoring the DPOAE level across frequency with narrow frequency spacing of f_2 (DPOAE fine-structure).

There are several objective methods for separating the DPOAE signal from the background noise and for automatically evaluating the validity of a recorded emission. The first method is based on the calculation of the noise floor level by averaging the levels of several adjoining frequency components around the DPOAE frequency component, with the SNR being indicated by the difference between the emission level and the noise floor level. The SNR criterion is usually set to 6 dB. The second data validation procedure is based on phase statistics, which checks the coupling of the DPOAE component phase to the phase of the primary tones. The phase statistics average normalized phase vectors of the signal received at the known DPOAE frequency. Like the binomial statistics, the vector sum can be scaled in probability terms, providing defined and very high sensitivities. A typical level of significance exceeds 99% per single frequency test.

The intra-individual variance of the DPOAE level is quite low with a standard deviation below 2 dB (Johnsen and Elberling, 1982a,b). Repetitive DPOAE measurements with unchanged sound probe position exhibited an exponentially increasing standard deviation of DPOAE level with increasing SNR (Janssen *et al.*, 2005a). For example, at a SNR of 10 dB, the standard deviation amounts to 1.8 dB, at an SNR of 20 dB to 0.7 dB, and at a SNR of 40 dB to 0.1 dB. This means that the higher the SNR, the higher the reliability of the DPOAE measurement. This finding is important with respect to the evaluation of small DPOAE changes. For clinical practice, repetitive DPOAE measurements with changed sound probe position are relevant. The standard deviation of DPOAE level amounted to about 1.6 dB (Müller *et al.*, 2005) when changing sound probe position between measurements.

DPOAE grams plot the DPOAE level L_{dp} as a function of f_2 (the main DPOAE generation site) for a selected combination of primary-tone levels L_1 and L_2 . It should be emphasized that DPOAE grams reflect the sensitivity of the cochlear amplifier (CA) best when recorded at close-to-threshold stimulus levels (Janssen *et al.*, 1998; Kummer *et al.*, 1998; Dorn *et al.*, 2001). In normal hearing (normal CA), DPOAE grams are close to each other at high and more separated at low stimulus levels reflecting cochlear non-linear sound processing. In cochlear hearing loss ears (impaired CA), DPOAE grams are more separated even at high stimulus levels, revealing loss of CA compression (Janssen *et al.*, 1998, Kummer *et al.*, 1998, Neely *et al.*, 2003).

DPOAE level I/O-functions plot the DPOAE level L_{dp} as a function of primary-tone level L_2 for a selected f_2 and thus reflect CA dynamics at the f_2 place in the cochlea (Dorn *et al.*, 2001). In normal hearing, in response to low-level stimuli, DPOAE level I/O-functions exhibit steep slopes, while at high stimulus levels slopes decrease, thus mirroring the strong amplification at low and decreasing amplification (saturation) at moderate sound levels. However, this is only true when a specific

stimulus level setting is used which accounts for the different compression of the primary-tones at the f_2 place (scissor paradigm: Kummer *et al.*, 2000).

DPOAE pressure I/O-functions plot the DPOAE pressure p_{dp} (instead of the DPOAE level L_{dp}) as a function of the primary-tone level L_2 . Due to the logarithmic dependency of the DPOAE level on the primary tone level there is a linear dependency between DPOAE pressure p_{dp} and primary tone level L_2 (Boege and Janssen, 2002). Thus, DPOAE data can easily be fitted by linear regression analysis.

The intersection point of the linear regression line with the L_2 -axis at $p_{dp} = 0$ Pa can then serve as an estimate of the stimulus level at the **DPOAE threshold** (see *Figure 19*; Boege and Janssen, 2002; Gorga *et al.*, 2003). The estimated threshold level L_{dpth} when plotted across frequency f_2 provides a measure for estimating CA threshold at the f_2 place. Due to standing waves in the outer ear canal, stimulus and response cannot always be reliably determined and thus DPOAE thresholds do not always match pure-tone thresholds. This is true especially for huge ear canal volumes. If this is the case a discrepancy between DPOAE thresholds and PTA thresholds mainly occurs for adults (dependent on ear canal size) in the mid-frequency region around 3 kHz and at the higher test frequencies (> 6 kHz). Standing wave effects are less important in newborns and infants due to the smaller ear canal length (Keefe *et al.*, 1993). The relation between OAE level and auditory threshold – or rather the lack of it – is strongly debated. Earlier, it was common to define confidence limits to determine the degree of certainty with which any measured response could be assigned to either normal or impaired hearing (Gorga *et al.*, 1996; Gorga *et al.*, 2000), or to define a DPOAE detection threshold as the stimulus level at which the response equalled the noise present in the instrument (Dorn *et al.*, 2001). However, since the noise is of technical origin (e.g. microphone noise) the threshold evaluated in this way does not match the behavioural threshold. A more relevant measure is the intersection point between the extrapolated DPOAE I/O-function and the primary tone level axis at which the response's sound pressure is zero and hence at which OHCs are inactive. A linear dependency between DPOAE sound pressure and primary tone sound pressure level is present when using the scissor paradigm for eliciting DPOAEs. The estimated DPOAE threshold L_{dpth} is independent of noise and seems to be more closely related to behavioural threshold than the DPOAE detection threshold (Boege and Janssen, 2002; Gorga *et al.*, 2003; Janssen *et al.*, 2006).

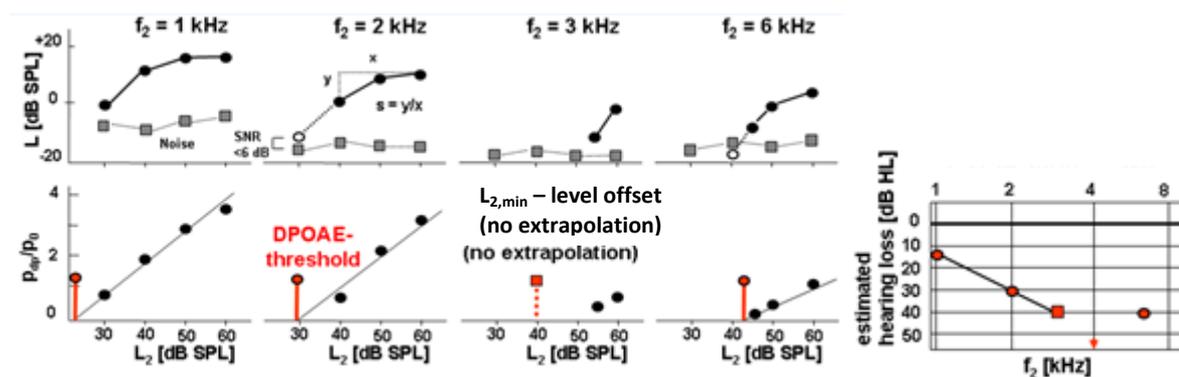


Figure 19: Schematic overview of a DPOAE audiogram derived from DPOAE threshold estimation

When plotting the DPOAE threshold in dB hearing level (HL), the estimated DPOAE thresholds can be plotted in an audiogram form (**DPOAE audiogram**) (see *Figure 19*). DPOAE audiograms can be applied in babies with a refer result in newborn hearing screening to reveal a transitory conductive hearing loss due to Eustachian tube dysfunction and/or amniotic fluid in the tympanic cavity or to confirm a

persisting cochlear hearing loss in follow-up diagnostics. In case of mild and moderate hearing loss DPOAE audiograms are an alternative method to behavioural audiometry or frequency-specific evoked response audiometry (auditory brainstem responses (ABR) with narrow-band stimuli, auditory steady state responses (ASSR)). Especially in infants where the conditioned free-field audiogram does not reflect the real threshold, DPOAE audiograms may assess cochlear hearing loss more precisely than behavioural tests. Moreover, unilateral hearing loss can be detected. DPOAE audiograms are able to quantitatively assess the hearing loss at distinct frequencies in a couple of minutes. Predicting hearing loss at five frequencies by tone burst ABR or ASSR may take half an hour and more. This is an essential advantage of DPOAE over tone burst ABR or ASSR. Thus, DPOAE audiograms can serve as an advanced tool for bridging the gap between screening and audiological testing in paediatric audiology.

DPOAE slope, calculated from DPOAE level I/O-functions (e.g. between stimulus levels L_2 of 40 and 60 dB SPL), indicates CA compression. When plotted across frequency, a slope profile can be established. In ears with cochlear hearing loss, the slope s of the DPOAE level I/O-function increases with increasing hearing loss indicating loss of CA compression (Janssen *et al.*, 1998; Kummer *et al.*, 1998; Müller and Janssen, 2004; Neely *et al.*, 2003). DPOAE slope differs significantly between hearing-loss classes (Janssen *et al.*, 2005b). DPOAE slope is reported to be related to the slope of the loudness functions (Neely *et al.*, 2003, Müller and Janssen, 2004). Thus, the slope of DPOAE I/O-functions is suggested to allow a quantitative assessment of CA compression and hence provide an objective recruitment test. Especially for hearing aid adjustment in children, a quantitative evaluation of hearing loss and recruitment is necessary. With the help of DPOAE audiograms and DPOAE growth characteristics of the cochlear impaired ear, additional parameters for a non-cooperative hearing aid adjustment can be provided (Müller and Janssen, 2004).

The influence of the second DPOAE source may be observed when plotting the DPOAE level across frequency with narrow frequency spacing, i.e. ≤ 100 Hz (**DPOAE fine-structure**). Due to either destructive or constructive superposition of the second source across frequency, a pattern of dips and peaks in the DPOAE fine-structure can be observed in subjects with normal or near-normal hearing (He and Schmiedt, 1993, 1996, 1997; Talmadge *et al.*, 1999; Mauermann *et al.*, 1999a,b). DPOAE fine-structure may give information about the fine-structure of behavioural pure-tone thresholds. However, due to the superposition of the second source, the correlation between the two measures is not clear. Moreover, DPOAE fine-structure is supposed to be able to reveal OHC impairment in the very early stage, i.e. beginning hearing loss e.g. due to noise over-exposure or ototoxic drug administration. Peaks and dips of the DPOAE fine-structure and with that apparently the impact of the second source are reported to disappear in patients with increasing hearing loss (Mauermann *et al.*, 1999b). In ears with a beginning hearing loss the second source is active at least at some cochlear places. For clinical evaluation of DPOAE I/O functions, the interference of the second DPOAE source deteriorates the interpretability and the accuracy of deduced measures such as DPOAE threshold and compression, so that an elimination of the second source is expected to improve their reliability. This can be done to a certain extent by suppressing the second DPOAE source by stimulating the ear simultaneously with a supra-threshold level tone its frequency being near $2f_1-f_2$ (Heitmann *et al.*, 1998), by applying a windowing technique (Mauermann and Kollmeier, 2004), by an onset decomposition technique (Dalhoff *et al.*, 2013), or as proposed by PATH medical by frequency-modulated primary tones (Lodwig, 2012, 2013 a,b). When applying a DPOAE suppression technique high suppressor tone levels have to be used to reduce the impact of the second source. As a consequence, OHCs in the neighbourhood of the $2f_1-f_2$ place are affected that

lead to a less frequency-specific evaluation of the hearing loss. The disadvantage of the windowing technique is that this method is very time consuming. The onset decomposition technique seems to be able to predict cochlear hearing threshold with high accuracy in a short time. However, this technique was applied only in normal-hearing subjects and in a limited frequency range (1.4 to 2.6 kHz) so far.

The **FMDPOAE**TM measurement technique was developed by PATH medical (Lodwig, 2012, 2013 a,b) as a means of suppressing the impact of the second DPOAE source. Primary tone frequencies are varied over time, following $f_1(t) = f_{1norm} + d_1(t)$ and $f_2(t) = f_{2norm} + d_2(t)$ resulting in $f_{dp}(t) = 2*f_1(t) + f_2(t)$. Primary tone frequencies are shifted between ± 100 Hz with a modulation rate of about 1.5 Hz. Because of the associated phase shift the impact of the second source, which may deteriorate DPOAE detection and with that also DPOAE threshold estimation especially at fine structure minima, is reduced. Moreover, due to frequency modulation the number of stimulated OHCs is increased resulting in a higher DPOAE level. Thus, FMDPOAE does not need any additional stimuli and does not extend test time. FMDPOAE seems to have the potential to improve both screening and diagnostic DPOAE testing performance significantly.

DPOAEs are reported to be measurable at a conductive hearing loss up to 20 to 25 dB HL and a cochlear hearing loss of up to 40 to 50 dB HL, representing approximately the range of the cochlear amplifier (Davis, 1983; Ruggero *et al.*, 1997).

In general, there are the following main clinical applications with DPOAE: follow-up diagnostics after (newborn) hearing screening, assessment of loss of sensitivity (cochlear threshold) and compression (recruitment) of OHC amplifiers, and detection of beginning cochlear impairment during noise over-exposure or ototoxic drug administration, and hearing aid fitting especially in young children.

DPOAE newborn hearing screening is usually performed in the mid-frequency region (e.g. between 1.5 and 4 kHz). High-frequency testing is less reliable due to the standing-wave problem and limitations of the electro-acoustic transducer. Below 1 kHz, the SNR is insufficient. The objective of hearing screening in childhood is to identify hearing impairments which are not apparent and may cause significant handicap for the child concerned. Preschool hearing screening tests should provide more frequency-specific and quantitative information on the hearing loss as available in a DPOAE audiogram.

Two DPOAE workflows are available:

- **DPOAE Quick/Diagnostic** allows for a frequency-specific measurement of DPOAEs at one or multiple stimulus levels. A pass/fail result is delivered for each selected frequency/stimulus level combination. DPOAE Quick refers to a measurement at one screening level, whereas DPOAE Diagnostic refers to a measurement at multiple levels.
- **DPOAE Threshold** allows for a frequency-specific determination of cochlear hearing thresholds by measuring DPOAEs with adaptive level setting. Estimating cochlear hearing loss by means of extrapolated DPOAE I/O-functions provides a quantitative assessment of outer hair cell function/dysfunction. An automatic frequency and level optimization procedure is conducted before each measurement at a specific frequency.

DPOAE tests can be performed binaurally if two ear probes are connected. In doing this test time is reduced by a factor of two. With the above standard modules, DPOAEs can be measured at frequencies from 1.5 to 8 kHz (f_2).

Several module extensions are available, which provide specific additional features:

- **Multichannel DPOAE** allows for a simultaneous measurement of DPOAEs at multiple primary tone pairs (Zurek and Rabinowitz, 1993; Lodwig, 2013b). In order to avoid overlap of the traveling waves of the tone pairs ($f_{11}:f_{21}$, $f_{12}:f_{22}$, $f_{13}:f_{23}$, ...) on the basilar membrane, tone pair frequencies $f_{1i}:f_{2i}$ have to have a distinct distance of at least one octave. Frequency distance of the primary tones is controlled automatically.
- **FMDPOAETM** allows measurement of DPOAE with frequency-modulated primary tones, which is meant to reduce the influence of the second DPOAE source and therefore is expected to improve reliability of DPOAE detection and hence hearing threshold estimates.

Extension to *DPOAE Quick/Diagnostic* only:

- **DPOAE High Resolution** allows DPOAE measurement at user-definable start and stop frequencies from 1.0 to 10 kHz and user-definable linear or logarithmic step size. This allows on the one hand to measure DPOAE grams in a user-definable frequency range and on the other hand to measure DPOAE fine structure with narrow frequency spacing.

PRACTICAL USE

Select the DPOAE test that you would like to perform from the module selection screen, i.e. *DPOAE Quick/Diagnostic* or *DPOAE Threshold*. If more than one OAE test is licensed, *DPOAE Quick/Diagnostic* and *DPOAE Threshold* can be found in the *OAE* section. Select the preset that you would like to perform. If necessary, change the parameters (f_2 frequency; for *DPOAE Quick/Diagnostic*: L_2 level, L_2/L_1 setup, timeout) and the preset name as required. For L_2/L_1 level setup, PATH medical recommends to use the *Auto* setting which provides optimized primary tone levels similar to the scissor paradigm by Kummer *et al.* (2000). You can either select adaptive timeout (timing is controlled by the device) or manual timeout with a minimum and maximum measurement time. Please consider that a doubling of measurement time corresponds to an increase in SNR of up to 3 dB.

If licensed, *FMDPOAE* and *Multichannel DPOAE* mode may be activated in order to improve DPOAE reliability and measurement time, respectively. For *DPOAE Quick/Diagnostic*, the *DPOAE High Resolution* option can be used with linear or logarithmic step size for measuring DPOAE grams in a user-definable frequency range or for measuring DPOAE fine structure. If fine structure properties are meant to be investigated, *FMDPOAE* should be deactivated. In all other cases, it is recommended to activate *FMDPOAE*.

The subject should be calm and sitting comfortably in a chair or lying on a bed. For babies, try to test the subject during sleep. Make sure that a valid ear probe (e.g. EP-DP) is connected and that the cable of the ear probe does not rub against any material as e.g. clothes. Select an ear tip with appropriate size matching the probe tip size and the subject's ear canal size. Make sure that the ear probe is inserted without any leakage between ear probe and ear canal. In cases where the ear probe is not inserted properly or ear probe channels are blocked a warning will appear.

Select the test ear (*Right+Left*: simultaneous measurement of right and left ear). After successful ear probe calibration, the measurement starts. The DPOAE stimuli are presented according to an optimized frequency-specific scissor paradigm and the response is detected via the ear probe microphone. During the measurement, the following screen items are displayed for the respective modules:

DPOAE Quick/Diagnostic (see Figure 20 – left):

- DPOAE validity ① and timeout bar ② for all selected f_2 at the currently tested L_2 (the bar colour corresponds to the ear: red: right ear, blue: left ear)
- Noise bar ③
- Result matrix shows up when pressing the screen: indicates for each f_2/L_2 if a DPOAE is valid (green symbol), invalid (red symbol) or skipped (grey symbol) ⑤

DPOAE Quick/Diagnostic Binaural (+ Multichannel) (see Figure 20 – middle):

- DPOAE validity ① and timeout bar ② for currently tested f_2/L_2 combinations
- Overall progress bar ④
- Noise bar ③
- Result matrix ⑤

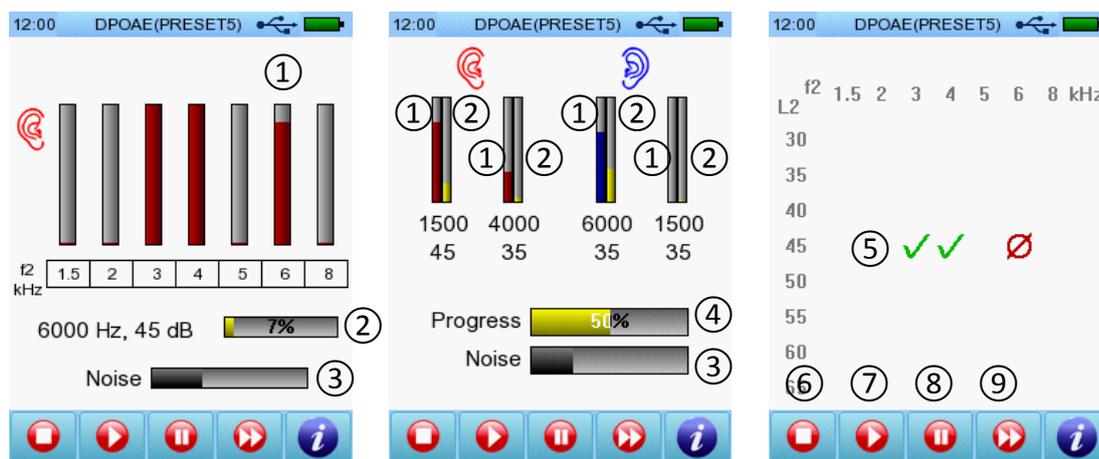


Figure 20: DPOAE Quick/Diagnostic measurement (left: monaural; middle: binaural + multichannel; right: result matrix)

DPOAE Quick/Diagnostic + High Resolution (see Figure 21):

- DPOAE validity ① and timeout bar ② for currently tested f_2/L_2 combinations
- Overall progress bar ③
- Noise bar ④
- DPOAE gram (L_{dp} plotted across f_2 with different colours for different L_2) shows up when pressing the screen ⑤

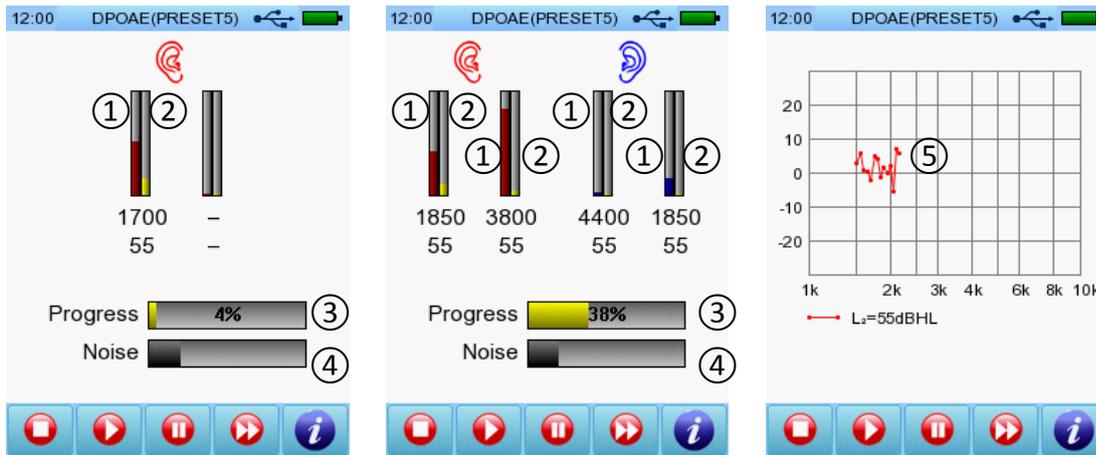


Figure 21: DPOAE High Resolution measurement (left: monaural; middle: binaural + multichannel; right: DPOAE gram)

DPOAE Threshold (+ Binaural, + Multichannel) (see Figure 22):

- DPOAE validity ① and timeout bar ② for currently tested f_2/L_2 combinations
- Noise bar ④
- Test status level-frequency-matrix ③: filled vertical bars indicate at which minimum level a valid DPOAE was detected, open box symbols indicate at which f_2/L_2 a DPOAE measurement is currently running
- Game-like distraction screen for children shows up when pressing the car race button ⑤.

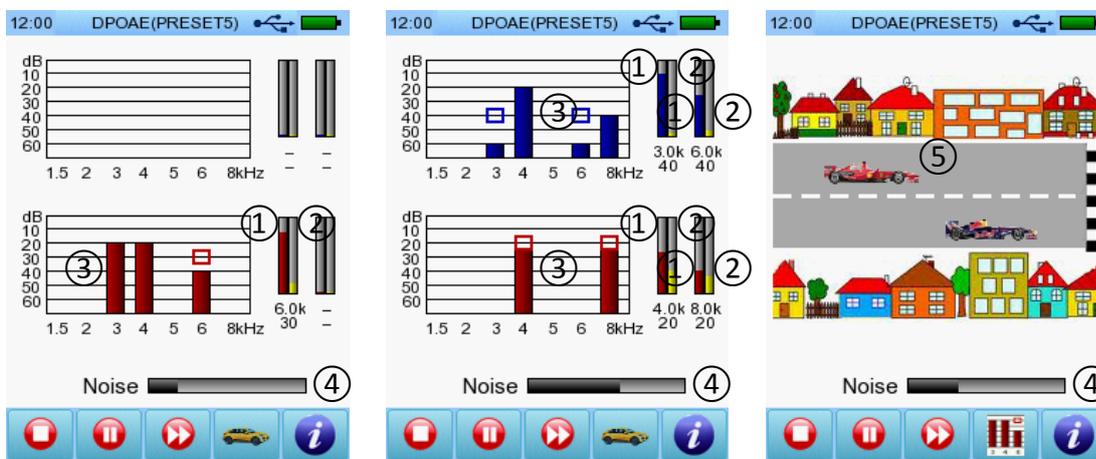


Figure 22: DPOAE Threshold measurement (left: monaural; middle: binaural + multichannel; right: distraction game)

Please note that the *FMDPOAE* option does not influence the measurement screen. For binaural and multichannel measurements, the user interface is adapted so that all data recorded simultaneously can be seen on a single screen.

If the DPOAE validity bar achieves full amplitude, a valid DPOAE is detected. If the progress bar achieves full amplitude, the measurement timeout is reached. The noise floor is an indicator for the adequacy of measurement conditions. With good measurement conditions, the noise floor bar should remain in the lower quarter. If the noise floor bar is higher, ambient noise levels may be too high, the patient may be not calm enough (swallowing, moving), or the ear probe cable may rub e.g. at clothes.

During the measurement the stimulus stability is observed by means of a low frequency probe tone. If the stimulus stability deteriorates, e.g. due to movement of the ear probe, the ear probe calibration procedure restarts. After successful re-calibration, the measurement continues.

During the measurement DPOAEs are measured automatically at the selected f_2/L_2 combinations. The test can be paused (see Figure 20 - ⑧), continued ⑦ after a pause, or stopped ⑥. Also, a current measurement can be skipped ⑨.

After the test is finished, the following screen items are displayed for the respective modules:

DPOAE Quick/Diagnostic (see Figure 23):

- Result matrix: indicates for each f_2/L_2 if a DPOAE is valid, invalid or skipped
- DPOAE gram bar graph shows up when pressing the screen: plots DPOAE and noise levels as vertical bars and shows their numeric values together with the resulting SNR for each f_2 at a selected L_2 . The DPOAE gram bar graph can be run through all L_2 .



Figure 23: DPOAE Quick/Diagnostic result (left: result matrix; right: DPOAE gram bar graph)

DPOAE Quick/Diagnostic + High Resolution (see Figure 24):

- DPOAE gram/DPOAE fine structure (L_{dp} plotted across f_2 with different colour for each L_2)

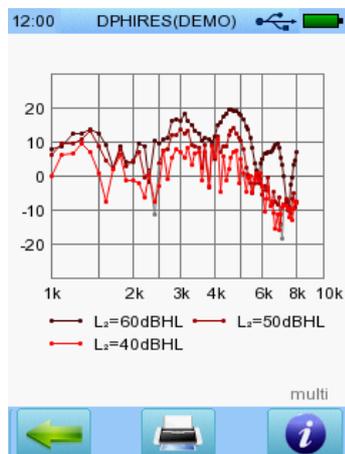


Figure 24: DPOAE High Resolution result

DPOAE Threshold (see Figure 25):

- DPOAE audiogram, i.e. estimated DPOAE thresholds L_{dpth} plotted across f_2

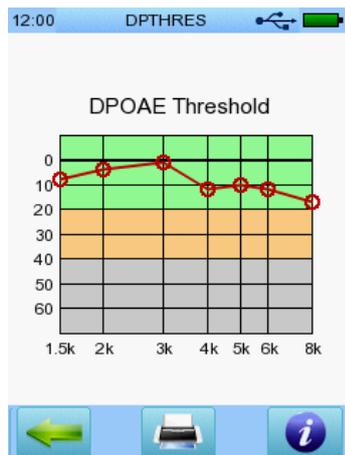


Figure 25: DPOAE Threshold result

The type of DPOAE threshold estimation is indicated by means of different symbols. Estimated thresholds are limited to 50 dB HL. If one or two valid points are available, thresholds are estimated by subtracting an experimental offset. If more than two valid points are available, thresholds are estimated by means of linear regression analysis (see Figure 19).

Please note that the *FMDPOAE* and *Multichannel DPOAE* options do not influence the result screen.

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3.2.4 Overview: Auditory Evoked Potentials

Auditory evoked potentials (AEP) are a tool for diagnosing auditory processing along the ascending pathway from the outer ear up to the auditory cortex including the diagnosis of neural disorders. AEPs are generated in the cochlea, pass on the cochlear nerve, through the cochlear nucleus, superior olivary complex, lateral lemniscus, to the inferior colliculus in the midbrain, on to the auditory cortex. AEPs are very small event-related electrical voltage potentials that are triggered by an acoustic stimulus and that are recorded as far field potentials via electrodes from the scalp or as near field potentials e.g. with an electrode close to the eardrum. Far field potentials are recorded with some distance from their source, whereas near field potentials are recorded close to their source. A recording channel requires one electrode as ground and two electrodes to measure the desired potential.

AEP recording is a derivative of electroencephalography (EEG). EEG recordings include various wave patterns: *delta* (4 Hz, seen in babies and in adults during slow wave sleep), *theta* (4-7 Hz, seen in young children and in adults e.g. during relaxation and wake-up), *alpha* (7-14 Hz, seen during relaxation and while closing the eyes), *beta* (15-30 Hz, seen during active movements and concentration), and *gamma* (30-100 Hz, seen during movements and cognitive processes).

AEP recordings deviate from standard EEG recordings in the fact that a response signal is averaged time-locked to an acoustic stimulus. The acoustically triggered firing of neurons results in very low electrical potentials. The small amplitudes require signal amplification and cancelling of unwanted external signals (e.g. via differential amplification, i.e. common mode rejection (CMR); filtering). In order to further minimize the influence of unwanted external signals, algorithms for artefact rejection are applied. Artefact rejection can be performed by elimination of high noise level buffers or by weighting each buffer dependent on its noise content. In addition, with enough repetitions of an acoustic stimulus, signal averaging allows the AEP response to emerge from the superimposing background noise, i.e. spontaneous neural firing and other interferences as biological artefacts (e.g. due to eye blinks and movements, swallowing, and other cardiac, muscle, and brain activity; see also EEG wave patterns), and environmental artefacts (e.g. due to electromagnetic radiation of 50/60 Hz depending on the local power system's frequency). The idea of averaging is that the signal is constant and hence the same in each buffer whereas the noise is random and hence changes in each buffer. Adding all the buffers increases the signal and reduces the noise. Theoretically, the improvement in SNR is proportional to the square root of the number of samples that are averaged, limited by technical properties (e.g. quantisation noise). Besides environmental conditions, the response detection is dependent on electrode placement, electrode type (surface electrode, needle electrode), electrode cable shielding, and technical aspects such as the amount of amplification and filter properties.

AEPs can be differentiated according to the response latency, i.e. the time gap between stimulus onset and the response (see *Figure 26*). With increasing latency the neural generator moves to more central areas.

Early latency responses (= Brainstem Evoked Response Audiometry, BERA) include potentials that can be recorded in a time frame of about 0 to 10 ms after stimulus onset. The physiological source of these potentials is located between the cochlea, the auditory nerve, and various regions of the auditory brainstem (superior olivary complex, lateral lemniscus, inferior colliculus). Typical clinical application areas are: (newborn) hearing screening, topological diagnostics (together with

typanometry and otoacoustic emissions), neuro-monitoring, and determination of hearing thresholds especially in paedaudiology and other non-cooperative subjects. The following test methods are commonly used for clinical applications:

Electrocochleography (ECochG) is a procedure where neural activity is recorded by placing a near-field electrode in the ear canal close to the eardrum (extratympanic recording) or with a needle electrode that is perforating the eardrum to rest on the cochlear promontory (transtympanic recording). Due to the invasive nature of transtympanic recording, this measurement technique has only limited applications. As stimulus a click or tone burst is typically used. The response latency amounts to about 1 to 3 ms. The following potentials can be recorded and can be roughly allocated to the following generation places: (1) cochlear microphonic (CM): outer hair cells (waveform similar to stimulus), (2) summing potential (SP): basilar membrane, and (3) compound action potential (CAP): vestibulocochlear nerve. Potential clinical applications are determination of hearing thresholds and identification and monitoring of Morbus Meniere's disease or endolymphatic hydrops.

Auditory Brainstem Responses (ABR) are recorded with surface electrodes on the scalp. Clicks, chirps or tone bursts are typically used. The response latency depends on the stimulus type and level, technical conditions (e.g. transducer type), and the subject's age and hearing status. The recorded potentials contain 5 to 7 waves roughly associated with specific sites along the auditory pathway (see section 3.25. ABRs are not affected by sleep. For more information on ABR, please refer to section [3.2.5: Auditory Brainstem Responses \(ABRs\)](#).

Auditory Steady-State Responses (ASSR) are recorded with surface electrodes on the scalp. As stimulus an amplitude-modulated signal (tone burst, chirp) is typically used. The repetition rate of the stimulus (e.g. 40 Hz, 80 Hz) is selected in such a way that the transient responses overlap in the brainstem, hence delivering a steady-state response. A response is detected according to statistical properties so that no visual analysis is required by the examiner. Dependent on the repetition rate ASSRs may be affected by sleep (40 Hz) or not (80 Hz). For more information on ASSR, please refer to section [3.2.6: Auditory Steady-State Responses \(ASSR\)](#).

Currently, ABR and ASSR modules are available with different options and for various transducers on Sentiero Advanced.

Middle latency responses (MLR) are potentials that can be recorded from the scalp in a time frame of about 10 to 50 ms after stimulus onset. The physiological source of these potentials is located at the thalamus and the primary auditory cortex. The signal is comprised of multiple maxima with positive (P) and negative (N) polarity called P0, Na, Pa, Nb, and P1.

Late latency responses (= Cortical Evoked Response Audiometry, CERA) are potentials that can be recorded in a time frame exceeding 50 ms after stimulus onset. The physiological source of these potentials is the auditory cortex. The signal is typically much larger than for early and middle latency responses and comprises waves P1, N1, P2, and N2.

Middle and late latency responses are highly susceptible to the subject's vigilance.

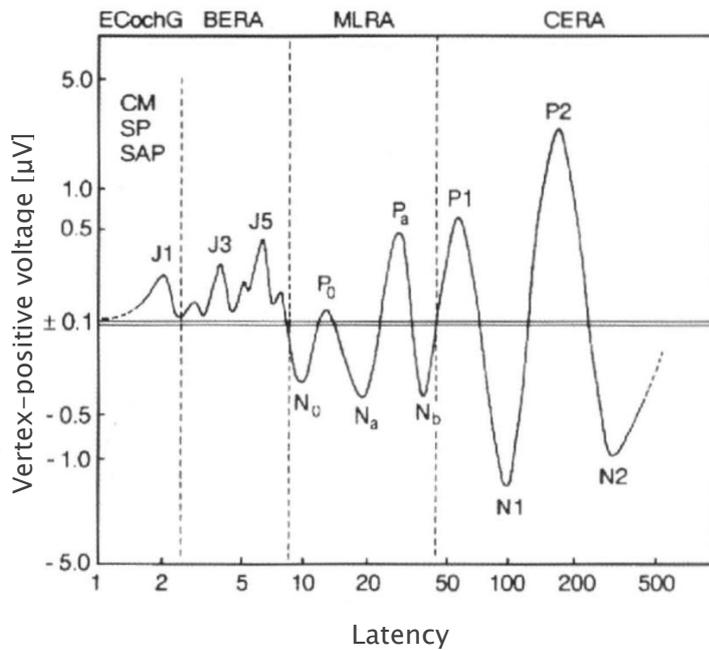


Figure 26: Overview of short, middle and late latency AEP waves

Other AEP methods include mismatch negativity (MMN), which is a procedure detecting potentials elicited by regular acoustic changes (e.g. in level or frequency) evoked by a sequence of identical sounds that is occasionally interrupted by a differing sound. MMN procedures may be independent of cognitive processing or not, i.e., the subject needs to attend to the stimulus difference (e.g. P300). For more complex stimulus differences as e.g. semantic incongruities in speech samples, the subject's language processing skills are required (e.g. N400).

PRACTICAL USE

In general, it is recommended to check the functionality of the electrode cable regularly. The electrode cable can be tested by attaching all electrode clips at the electrode testing device or any available conducting metal bolt. When starting the ABR or ASSR test, the impedance should be 0 kΩ for both the red and white electrode. When detaching either the red or white electrode from the electrode testing device, the impedance of the red or white electrode, respectively, changes to *open*, i.e., there is no conducting connection between the red or white electrode, respectively, against the black electrode. When detaching the black electrode, both impedances are *open*. If there is any deviation from this behaviour or if you suspect any dysfunction, please retry with another electrode cable and/or contact your distributor.

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3.2.5 Auditory Brainstem Responses (ABRs)

Auditory brainstem potentials (ABRs) recorded from electrodes placed on the scalp represent far field potentials generated by the fibre tracts and nuclei of the ascending auditory pathway between the cochlea and the brainstem. The ABR latency epoch consists of up to seven prominent wave peaks which typically appear within the first 10 ms (Jewett and Williston, 1971). Commonly ABRs are elicited by transient stimuli (click, chirp, tone burst). ABRs represent the sum of synchronized neural activity of the ascending auditory pathway. Wave I and II stem from auditory nerve, wave III from cochlear nucleus, wave IV and V from lateral lemniscus and inferior colliculus (lower brainstem), and wave VI and VII from sub-cortical regions. The waves are commonly referred to as Jewett I to VII. In clinical diagnostics mainly waves I, III, and V are analysed. Due to the fact that the velocity of the traveling wave running into the cochlea is highest in the basal region, click-evoked ABRs mirror mainly the activity of basal (high-frequency) cochlear regions. This is also true for low frequency tone bursts and chirps when high stimulus levels are applied. Typical properties are wave amplitude and latency. Wave amplitudes represent the amplitude difference between a positive peak and a following negative peak typically amounting to less than 2 μV (Picton *et al.*, 1981). Absolute wave latencies represent the time from stimulus onset until the wave peak occurs. Inter-peak latencies (IPL) describe the time between the wave peaks. Wave V has the highest, wave I the lowest amplitude. Amplitudes also decrease with decreasing stimulus level. Wave latencies are shorter at higher stimulus levels due to an increasing basalward spread of excitation (Folsom, 1984). ABRs are quite independent of subject's vigilance (i.e. sleep, attentiveness) (Picton and Hillyard, 1974) and can therefore be performed during sedation or anaesthetization.

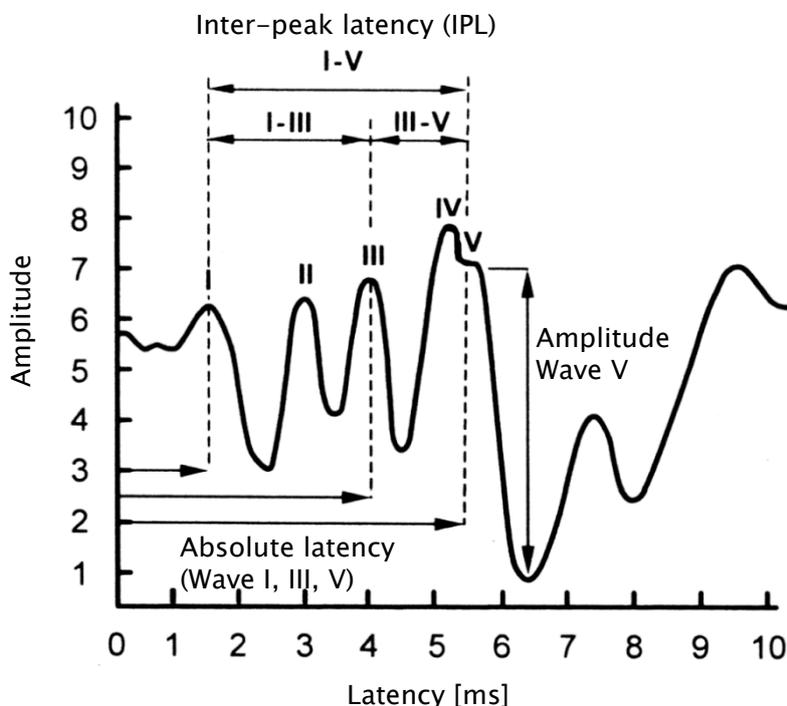


Figure 27: Overview of ABR waves

Commonly, ABRs are elicited by stimulating the hearing organ via air conduction (AC) using headphones, insert earphones or loudspeakers. However, ABRs can also be elicited by stimulating the cochlea directly by bypassing the middle ear via bone conduction (BC). In this case, a bone-

conductor is placed on the mastoid (or forehead) for stimulating the sensory cells in the cochlea. A hearing loss caused by middle-ear pathologies (middle ear effusion, Eustachian tube dysfunction, otosclerosis), especially in children with doubtful behavioural pure-tone audiograms, can be detected (Mauldin and Jerger, 1979). Conductive and cochlear hearing loss exhibit different wave amplitude and latency patterns. Especially, wave V latency and threshold are used for audiological diagnostics in children or handicapped persons who are not able to reliably report on their hearing disability. The IPL between wave I and V represent the neural transmission time between cochlea and lower brainstem. IPL is therefore used for assessing retro-cochlear pathology between cochlea and lower brainstem.

ABR can be elicited with several stimuli as e.g. clicks, chirps or tone bursts. Broadband stimuli as click and broadband chirp are temporally concise stimuli which result in synchronized neural discharges and robust potentials. They are used to stimulate as many as possible sensory cells along the cochlea for getting highest neural activity on the nerve fibres. However, temporal specificity of the stimulus is achieved at the expense of frequency specificity. In contrast, narrow-band stimuli as frequency-specific chirp or tone burst comprise limited frequency components. Sensory cells are stimulated at the site within the cochlea corresponding to the stimulus frequency components. Due to the travelling time along the basilar membrane latency varies, i.e., it increases with decreasing frequency. Typically, with decreasing frequency also the amplitude decreases and the waveform gets less sharply defined. With increasing stimulus level the frequency specificity decreases due to an increasing spread of excitation.

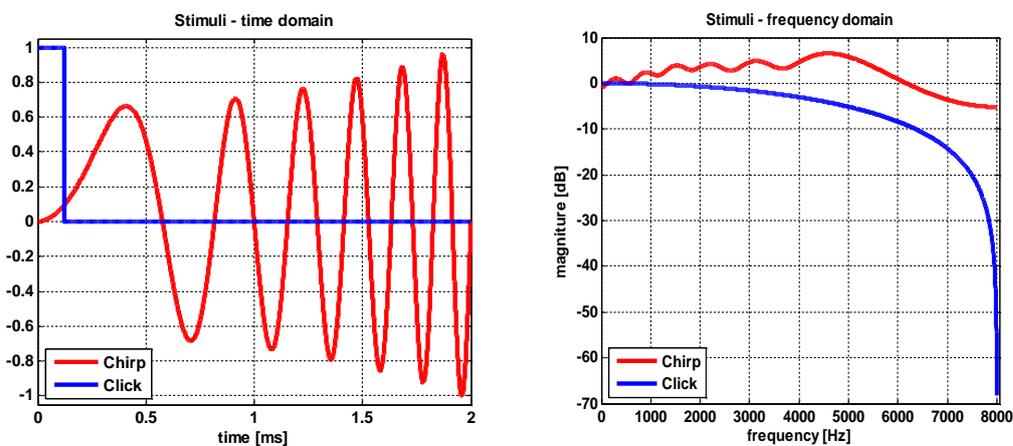


Figure 28: ABR stimuli: click and chirp (left: time domain; right: frequency domain)

A **click** (see Figure 28 – blue curves) is a sound obtained by applying a DC pulse. Its abrupt onset and brief duration lead to a high synchronization of neural activity. However, earphones alter the spectrum of a DC pulse. The auditory system itself also filters the stimulus. Thus, frequency limits are always imposed on click-evoked potentials (Durrant, 1983). A **chirp** (see Figure 28 – red curves) is a frequency-modulated sinusoidal signal with low frequencies at the beginning and high frequencies at the end of the stimulus or reversed. Due to the frequency modulation, the place-specific travelling time on the basilar membrane is compensated resulting in an increase of the synchronization of action potentials and with that in higher ABR amplitudes (Elberling *et al.*, 2007). The advantage of a chirp stimulus over the commonly used click stimulus is that a higher synchronization of action potentials on the nerve fibres is yielded, which is especially true at stimulus levels close to threshold. Chirps may contain frequency components covering a major range of the basilar membrane

(broadband chirp) or only a rather limited range (narrowband chirp). This may include low chirp (e.g. 100 to 850 Hz), mid chirp (e.g. 850 Hz to 3 kHz), and high chirp (3 to 10 kHz). A **tone burst** is a short (about 50 to 200 μ s) sinusoidal stimulus pulse with characterized by carrier frequency, plateau duration, rise and fall time, and the windowing function, which allows fading in and out the stimulus. The windowing of the stimulus results in additional frequency components besides the carrier frequency.

It is important to note, that due to the maturation of the neural pathway absolute latencies and IPL vary during the first year of life (Starr *et al.*, 1977). Adult latencies are reached for wave I at about 6 to 24 weeks, and for wave V at about 18 months. IPL I-V decreases during the first 18 months of life. For preterm infants, latencies of all components are typically prolonged compared to term infants. The influence of age on ABRs in the elderly is a matter of controversy. While some authors reported a change in IPL, others claim that there is no delay in neural transmission time with ageing. Also, no significant correlation was observed between the score of speech discrimination tests and IPL.

Since synchronisation of neural activity is low in the more apical regions of the cochlea due to the decrease of the travelling wave velocity (Mrowinski, 2009), sensitivity of ABRs is quite low below 1000 Hz. Click-evoked ABR does not allow direct frequency-specific assessment of hearing loss and exhibits nearly normal patterns in patients with low- and/or mid-frequency hearing loss. Low-frequency stimulation at high stimulus levels also stimulates basal sensory cells. Thus, assessment of low-frequency functionality is only possible at low stimulus levels. For getting more frequency-specific information DPOAE (at a hearing loss up to 50 dB HL) or frequency-specific stimuli have to be used. However, when applying low-frequency stimulation at high stimulus levels the basal region of the cochlea is also stimulated. Thus, frequency specificity of ABRs is restricted. ABR threshold is reached at stimulus levels corresponding to the hearing loss at medium to high frequencies. Compared to ABRs, auditory steady-state responses (ASSRs) provide better frequency specificity.

In patients with hearing loss wave I may be missing. In these patients, determination of IPL is not possible and thus neural disorders cannot reliably be assessed. Correct placement of electrodes is crucial in order to yield optimal ABR patterns. Due to the fact that electro-magnetic fields have impact on ABRs proper measuring conditions are essential. Proper measuring conditions are present if ABRs are measurable down to 10 dB nHL in a young normal hearing subject.

Intended clinical applications of ABRs are topological diagnostics, i.e. assessment of peripheral and central sound processing on the auditory pathway up to the lower brainstem (along with other audiological tests), identification of neural disorders (vestibulocochlear nerve and lower brainstem lesions: e.g. acoustic neuroma, neural disorder) on the auditory pathway, non-frequency-specific determination of hearing loss within mid-frequency region when using broadband stimuli (Gorga *et al.*, 1985), and rough determination of hearing loss within different frequency regions when using frequency-specific stimuli. Despite low frequency specificity ABR may provide a tool for fitting hearing aids in children.

PRACTICAL USE

Select *ABR* from the module selection screen. If more than one AEP test is licensed, *ABR* can be found in the *AEP* section. Select the preset that you would like to perform. If necessary, change the parameters (e.g. stimulus type, stimulus polarity, masking noise, stimulus level, stimulus rate,

number of averages, noise stop criterion, Jitter, Auto Proceed, Auto Stop, age group for normative latency areas) and the preset name as required.

The different parameter options and possible applications are explained in the following:

Stimulus type:

- Click at low stimulus rates (≤ 20 Hz) evokes clear waves I, III, and V and can be used to obtain information on amplitude and latency. Use click for neurological issues, where the evaluation of inter-peak latency is required. Due to poor frequency specificity thresholds can be assessed only qualitatively. For hearing screening click-ABR measurements are conducted by using a fixed screening level (e.g. 35 dB nHL).
- Chirp evokes higher response amplitudes than click for wave III and V. In contrast, wave I is typically hard to identify. Use chirps for hearing threshold determination, because wave V is evaluated only.
- Narrow-band chirps provide latency information and are more frequency-specific than broadband stimuli (click, chirp). Hence, they may be used for a more frequency-specific hearing threshold determination. However, the response amplitude is typically lower than for broadband stimuli, so that the response is harder to detect in the time domain.

Stimulus polarity:

- Alternating polarity helps reducing the stimulus artefact that is generated by the transducer itself (especially recommended for bone conduction measurements). Alternating polarity gives you a broader, rounded wave V peak.
- Rarefaction and condensation gives you a more peaked response and may yield higher amplitude for wave I. Latency difference between condensation and rarefaction is nearly identical in normal hearing adults. However, responses to condensation and rarefaction clicks may considerably differ in patients with cochlear hearing loss.

Stimulus level:

1 to 5 stimulus levels (including mute stimulus for comparative measurements) can be selected. They are given in dB nHL, i.e. relative to the hearing threshold of a collective of normal hearing subjects, which is defined as 0 dB nHL. A stimulus level can be repeated by selecting it twice. Measurements will start at the highest level. Standard deviation of latency is typically lower and wave amplitude is higher at higher stimulus levels. At lower stimulus levels wave I (at about 60 dB nHL) and then wave III (at about 30 dB nHL) disappear.

Masking noise:

Contralateral masking is recommended to be used if there is significant asymmetry in hearing loss between ears, i.e., if there is a difference of about 30 to 40 dB (headphones) or about 50 to 60 dB (insert earphones). If a bone conductor is used, application of contralateral noise is essential.

Stimulus rate:

The higher the stimulus rate, the smaller the response amplitude and the longer the latency. The latency shift due to stimulus rate is compensated on the device and hence not visible. Higher rates improve efficiency of data collection by reducing measurement time at a fixed number of averages, but jeopardize the identification of a response, particularly in some pathological cases. Wave I and III may disappear at stimulus rates above 50 Hz. If all waves are intended to be evaluated (e.g. for neurological diagnostics) low stimulus rates should be

used. For ABR threshold determination also higher stimulus rates may be used. 50 and 60 Hz are not available stimulus rates since these are typical power system frequencies.

Number of averages:

At fixed measurement conditions, with increasing number of averages, the noise floor decreases (number of averages increased by factor 4 reduces noise by half), but the measurement time increases. The overall measurement time is shown in the settings.

Noise stop criterion:

If activated, the recording of a trace is stopped as soon as the residual noise drops below the defined noise threshold and response is not detected. Hence, if activated this option speeds up the recording in case no response is present.

Jitter:

If activated, the stimulus rate is slightly varied in order to reduce the influence of electrical interference that is synchronized to the stimulus rate. Also, ABR amplitude is known to be decreased at a constant stimulus rate due to adaptation. Therefore, the activation of this option is always recommended. Please note that the Jitter option is always active during binaural stimulation.

Auto Proceed:

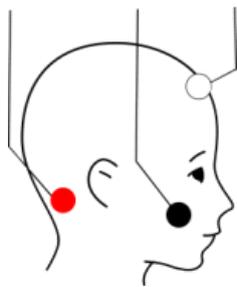
If activated, the recording of a trace is stopped as soon as the trace is considered valid by the automatic validity detector. The test then proceeds with the recording of the next trace.

Auto Stop:

If activated, the test stops if two consecutive traces are considered invalid by the automatic validity detector.

Before the test is started the subject should be instructed about the test procedure. In order to reduce muscle artefacts, the subject should be calm and fully relaxed lying comfortably on a recliner or bed. It is also recommended that subjects keep their eyes closed during the measurement for reducing artefacts e.g. due to eye blinks. For babies, try to test the subject during sleep. In order to reduce environmental artefacts, conduct the measurement in a room with low electromagnetic radiation, i.e. in an electrically shielded metal booth or any other room without powered-on electric devices (e.g. computer, light, telephone, cell phone, power transformer) in close range to the measurement equipment. An acoustically shielded booth or a quiet room is recommended if ABR is applied for threshold determination at low sound pressure levels.

Make sure that a valid transducer (e.g. headphone, insert earphone, ear probe, bone conductor) and electrode cable is connected. Make sure that the skin is clean at the intended positions of the electrodes. If applicable, thoroughly clean the skin (e.g. using skin prepping gel) in order to remove dirt, oil, and superficial dead skin. Select appropriate electrodes and attach them on the skin of the patient. An electrolyte gel may be put on the electrode contact in order to improve the conductivity of the skin layer, which effectively increases the electrode surface area. Attach the electrode clips of the electrode cable at the correct electrode. The white and red electrode are the recording electrodes, the black electrode is the ground electrode. Do not place the ground electrode near the heart to avoid inducing electrocardiography (ECG) waves. There are several possibilities to place the electrodes. The position of the electrodes affects waveform morphology and latency. Best electrode position for yielding maximum wave amplitudes is vertex (white electrode) and ipsilateral mastoid (red electrode) as shown in *Figure 29* (vertical montage).



- White electrode:
- Vertex or high forehead
- Red electrode:
- Ipsilateral mastoid (for monaural recording)
 - Nape of the neck (for binaural recording sequentially or concurrently, for bone conduction recording if bone conductor is placed at the mastoid)
- Black electrode:
- e.g. cheek

Figure 29: ABR electrode positioning with vertical montage

Alternatively to the vertex position, high forehead position is possible for the white electrode. However, in this case ABR amplitude is slightly decreased. Despite this fact forehead is preferred in practice, especially in patients where vertex electrode placement is inconvenient because of hairs. Wave I amplitude may be larger in a horizontal montage (white electrode: ipsilateral mastoid; red electrode: contralateral mastoid) than in the standard vertical montage.

Select the test ear (*Right+Left*: simultaneous measurement of right and left ear). The electrode impedance measurement starts (see Figure 30). Electrode impedance is dependent on the electrode material and the surface area to which it contacts. The impedance is shown for the red and white electrode, respectively, against the black electrode. Both impedances must be $<12\text{ k}\Omega$ in order to be able to start the measurement. It is recommended that impedances are $<5\text{ k}\Omega$ and that the difference between the red and white electrode impedance is $<2\text{ k}\Omega$. Please note that in neonates the impedance may be higher due to tenderness of the skin. If impedances are too high, check the electrode cable (see PRACTICAL USE in section 3.2.4: *Overview: Auditory Evoked Potentials*) and clean the skin, use gel and wait a couple of minutes until the gel is infiltrated into the skin.

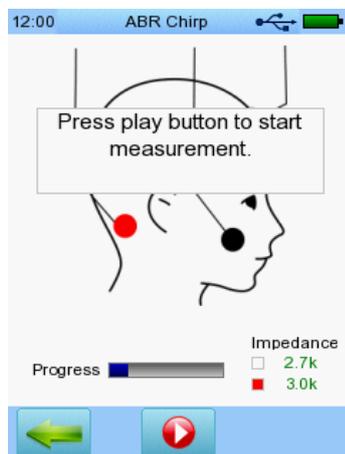


Figure 30: ABR impedance measurement

After successful electrode impedance measurement, you can start the test by pressing the play button. The ABR stimulus is presented via the transducer and the response is detected via the electrode cable. During the measurement the electrode impedance is monitored. In case that at least one of the impedances gets too high (e.g. an electrode has fallen off), the test is automatically interrupted. The test can only be continued if the electrode impedances get back to tolerable values.

During the measurement the following information is provided on the screen (see Figure 31): ABR traces are shown for each selected stimulus level. The currently tested trace is shown in red (right

ear) and/or blue (left ear) ②. Already finished traces are greyed out. If selected, respective normative data for wave V is shown as white areas. The validity status indicator ① reflects the statistically computed probability that a wave V is present in the recorded signal. It is represented by an indicator light at each trace (green: wave V detected; yellow: maybe detected; red: not detected). For binaural measurement the upper indicator refers to the left ear, the lower indicator to the right ear. Please note that the indicator light only represents the statistical detectability of a wave V signal and does not consider normal amplitude or latency. If the validity indicator is yellow or green, the estimated latency of the wave V is shown as a small red or blue vertical bar ③ at the trace. The EEG bar ④ represents biological and external noise which is an indicator for the adequacy of measurement conditions. With good measurement conditions, the EEG bar should remain in the lower third. If the EEG bar is higher, biological and external artefacts may be too high, i.e. the patient may be not calm and relaxed enough (e.g. swallowing, moving, clenched jaw/teeth), or the electromagnetic radiation may be too prominent. The progress bar ⑤ shows the progress of the measurement at the current level. If the bar is full, the measurement at the current level is finished, i.e., the number of averages that has been defined by the user is reached. Dependent on the settings, a measurement at a level may be finished before the number of averages has been reached (e.g. if *Auto Proceed* or *Noise Stop Criterion* is active). The electrode impedance ⑥ is regularly updated during the measurement and the measurement is paused if impedance gets too high. The test can be manually paused ⑨, continued ⑨ after a pause, or stopped ⑦. Also, a current measurement can be skipped ⑧.

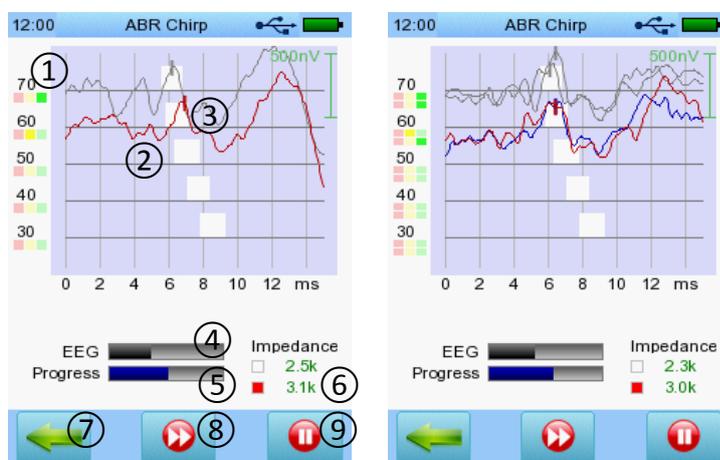


Figure 31: ABR measurement (left: monaural; right: binaural)

After the test is finished, the ABR result is shown (see Figure 32). The recorded ABR traces ① are shown for each stimulus level in the upper part of the screen. The resolution of the amplitude axis can be changed by sliding with the finger up (zoom in) or down (zoom out) on the result graph screen. Please note that signal delays for insert earphones and for different stimulus rates are compensated. If applicable, estimated latencies for wave V are shown as small black vertical bars (Jewett markers). The latencies for wave I, III, and V can be adjusted manually (see below). Jewett markers that have been confirmed or set by the user are shown in green (see Figure 33).

There are three different information screens available in the lower part of the screen, which can be accessed by pressing the lower part of the screen. The three screens present information about latency and inter-peak latency ②, general information about the used transducer and settings

③, and information about impedance, averages and noise ④). In order to ensure adequate measurement conditions noise should be <100 nV after 2000 averages. With increasing averages, noise decreases (e.g. < 70 nV after 4000 averages, < 50 nV after 8000 averages).

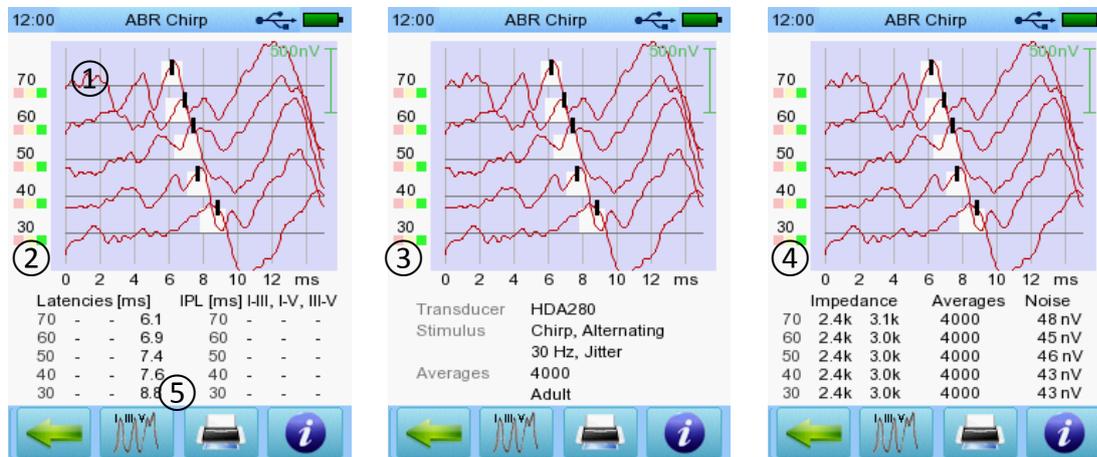


Figure 32: ABR result with estimated Jewett markers (left: latencies and inter-peak latencies; middle: general information; right: impedance, averages and noise)

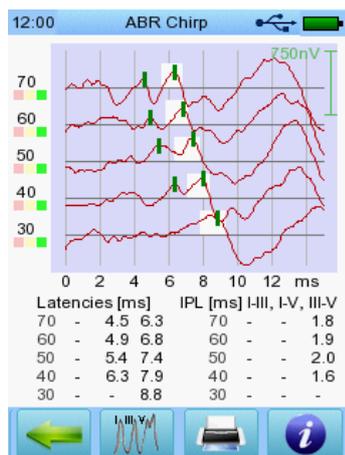


Figure 33: ABR result with confirmed Jewett markers

Jewett markers can be set, changed or discarded by the user via the Jewett marker button (see Figure 33 - ⑤). When pressing the button the Jewett marker selection setting screen appears (see Figure 34). The trace for which any Jewett marker should be set can be selected by pressing the respective trace button ①. You can choose which Jewett marker (I, III, or V) you wish to change by pressing the Jewett I/III/V selection button ⑤. The Jewett marker you are currently changing is shown by a red dot above the vertical bar ②. The selected Jewett marker can be moved by pressing on the upper part of the screen or by using the up/down arrow buttons ③. Please note that the order of the markers is always preserved with a minimum distance of 0.5 ms (e.g. when moving the Jewett I marker to the right the Jewett III marker will be moved too as soon as the Jewett I marker reaches the Jewett III marker). The currently selected latency is shown as a value between the up/down arrow buttons. You can set or reset the latency by pressing button ④. If the selected value is set, the Jewett marker turns green. If it is reset, the Jewett marker turns grey. If you are finished with setting the Jewett marker you can either confirm ⑦ or dismiss ⑥ your changes.

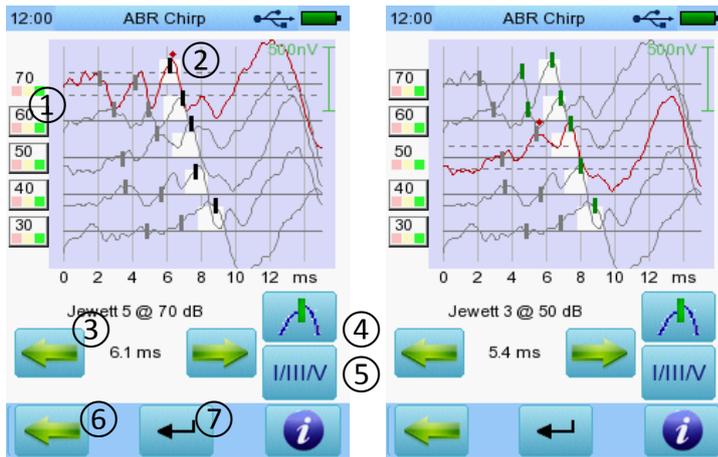


Figure 34: ABR Jewett marker setting (left: set Jewett V marker at 70 dB nHL; right: set Jewett III marker at 50 dB nHL)

For the interpretation of the result, the following case examples may be considered (see Figure 35 to Figure 38):

- **Normal hearing subject** (see Figure 35): ABRs with broadband stimuli are typically measurable down to about 10 dB nHL in a normal hearing subject. Jewett V latency increases and Jewett V amplitude decreases with decreasing stimulus level. Jewett V latencies are within normal range when an appropriate age group has been selected.

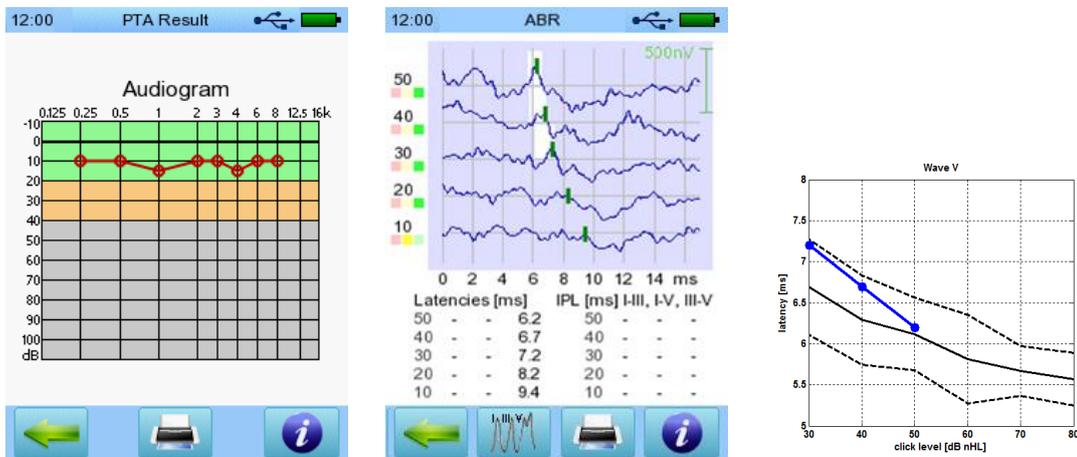


Figure 35: ABR result example for normal hearing subject (left: audiogram; middle: ABR traces; right: latency-level function)

- **Conductive hearing loss** (see Figure 36): In a patient suffering from a conductive hearing loss, the effective stimulus level is decreased. As a consequence, latencies and amplitudes of all waves are changed. This includes that wave V latency is typically increased, i.e. out of normal latency range. The waves prior to wave V are often not detectable. The inter-peak latency is not affected. In a conductive hearing loss with an flat audiogram the latency-level function is shifted along the level axis by the amount of the conductive hearing loss. ABR threshold is reached at stimulus levels corresponding to the hearing loss at medium to high frequencies.

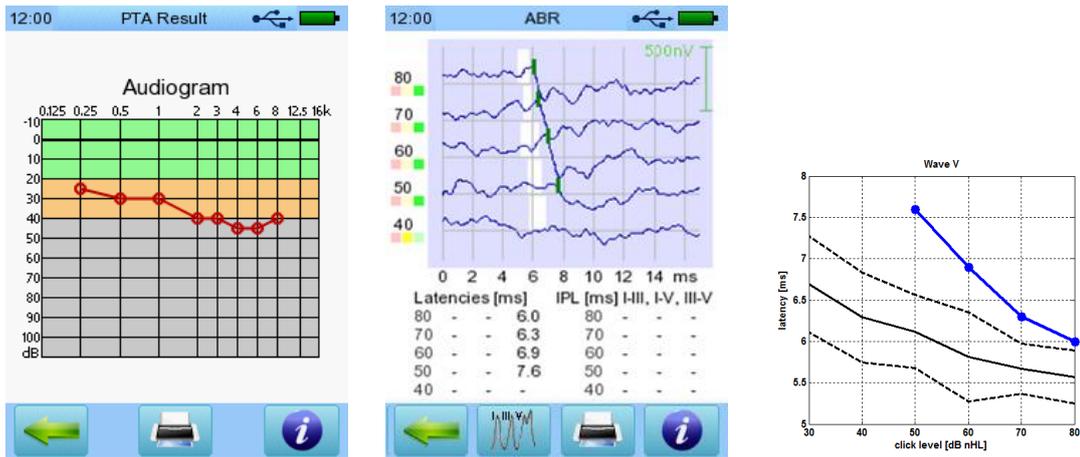
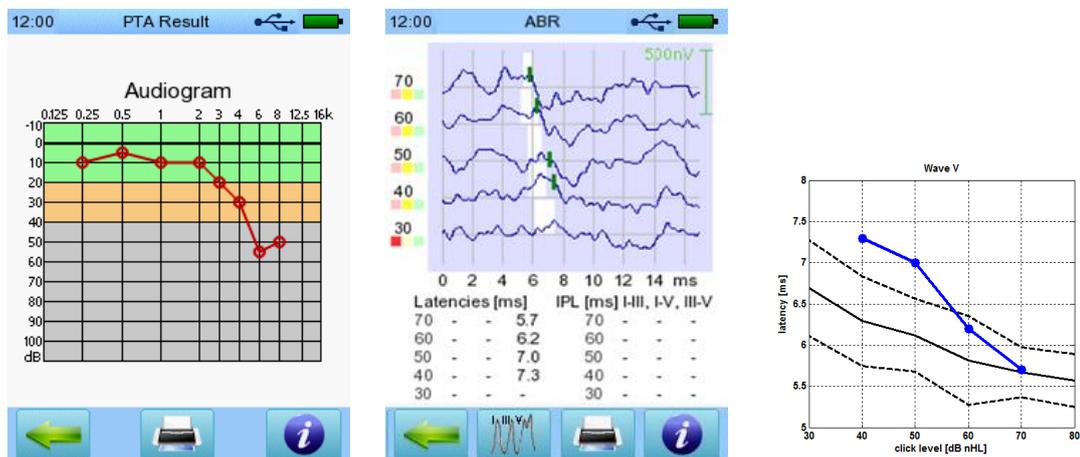


Figure 36: ABR result example for subject with conductive hearing loss (left: audiogram; middle: ABR traces; right: latency-level function)

- **Cochlear hearing loss** (see Figure 37):

The overall effect is dependent on the severity and configuration of the hearing loss, and also on the frequency composition of the stimulus. Wave V latencies are essentially equivalent to those collected in normal hearing subjects as long as the stimuli are at least 20 dB above the threshold at 4 kHz, the configuration of the hearing loss is not steeply sloping and of mild to moderate in severity. Inter-peak latency I-V is normal. Latency-level functions for these subjects converge on those of normal hearing subjects at high stimulus levels.

- o **Case example 1:** ABRs in a patient suffering from a moderate high frequency cochlear hearing loss (click, stimulus rate: 20 Hz): In comparison to a normal hearing subject, ABRs appear with lower amplitude and slightly increased Jewett V latency. The ABR threshold is reached at stimulus levels corresponding to the hearing loss at medium to high frequencies. The prolongation of latency at low stimulus levels corresponds to the propagation time of the travelling wave along the non-functioning basal part of the cochlea at these levels.
- o **Case example 2:** ABRs in a patient suffering from a severe high frequency cochlear hearing loss (click, stimulus rate: 20 Hz): ABR threshold is reached at stimulus levels corresponding to the hearing loss at high frequencies. Low-frequency thresholds cannot be assessed due to low synchronisation of nerve fibre activity in the apical region of the cochlea.



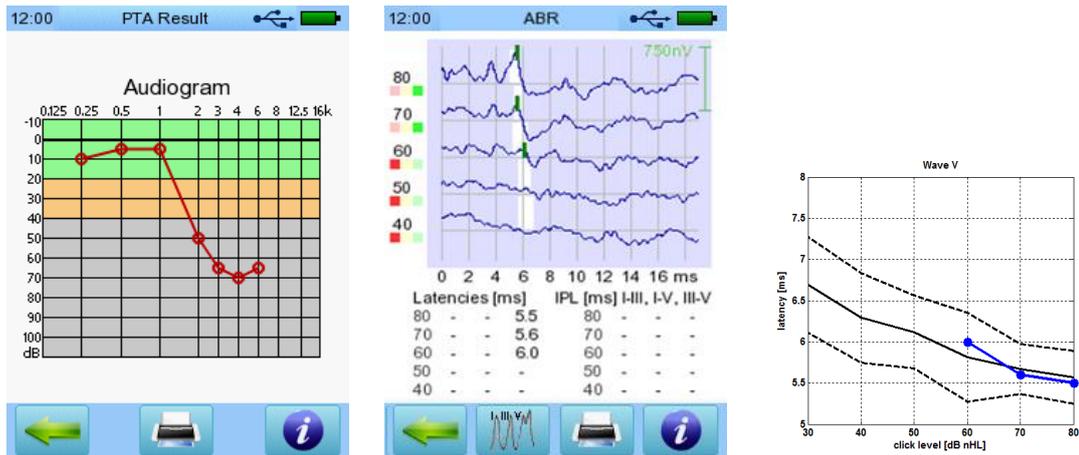


Figure 37: ABR result examples for subjects with cochlear hearing loss (top: case example 1; bottom: case example 2) (left: audiogram; middle: ABR traces; right: latency-level function)

- **Retro-cochlear hearing loss** (see Figure 38): ABRs in a patient with neural disorders (click, stimulus rate: 10 Hz): The ABR wave pattern is different compared to normal hearing subjects and patients with cochlear or conductive hearing loss with respect to I-V inter-peak latency (IPL). I-V IPL is prolonged (4.4 ms) due to reduced neural transmission time between cochlea and brainstem exceeding normal I-V interval (female: 3.8 ± 0.2 ms; male: 4.0 ± 0.2 ms). If data from both ears are available, interaural wave V latency differences can be evaluated (not shown). Differences in wave V latency should not amount to more than 0.3 to 0.4 ms between ears if there is no distinct interaural asymmetry in hearing loss.

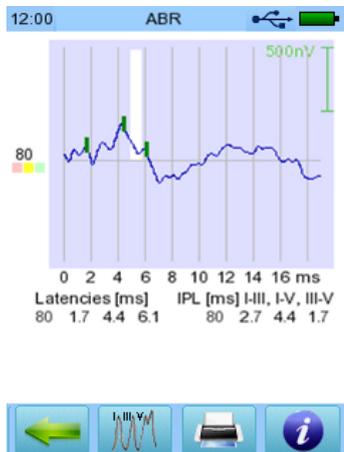


Figure 38: ABR result example for subject with retro-cochlear hearing loss

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3.2.6 Auditory Steady-State Responses (ASSR)

ASSRs provide frequency-specific and quantitative information on sound processing within the brainstem and sub-cortical regions (Picton *et al.* 2003; Herdman and Stapells 2003). ASSRs are elicited by means of narrowband stimuli, i.e. either an amplitude- (and frequency-) modulated sine or a narrowband chirp, which compensates for the time delay on the basilar membrane. Compared to a modulated sine, the use of a narrowband chirp reduces frequency specificity but increases response amplitudes. Depending on the frequency components of the stimulus different sensory cell regions within the cochlea are stimulated. Depending on the modulation frequency (i.e. for sine: amplitude modulation rate, for chirp: repetition rate – in the following only the term repetition rate is used) onset neurons are activated in different regions along the auditory pathway. The repetition rate of the stimulus is selected in such a way that the transient responses overlap at the place of generation, hence delivering a steady-state response. Typical repetition rates are 40 and 80 Hz. Other repetition rates yield lower response amplitudes or signal-to-noise ratios (SNRs). 40 Hz ASSR are generated mainly in the auditory sub-cortex (Mäkelä and Hari, 1987; Pantev *et al.*, 1996; Ross *et al.*, 2003), whereas 80 Hz ASSR are generated in the brainstem (Herdman *et al.*, 2002). Compared to transient AEPs, 40 Hz ASSR can be referred to as middle latency responses, whereas 80 Hz ASSR can be referred to as early latency responses (Mäkelä and Hari, 1987). 40 Hz ASSR are affected by vigilance and are hence only suitable for awake and alert subjects (Galambos *et al.*, 1981), whereas 80 Hz ASSR are not affected by vigilance and are hence suitable for babies and in general for sleeping subjects (including sedated and anaesthetized subjects) (Levi *et al.*, 1983). The response can be detected via far-field electrodes within the EEG as a sine signal with a frequency following the repetition rate of the stimulus. The response can be statistically analysed in the frequency domain (Stapells *et al.*, 1987; Dobie and Wilson, 1989; Picton *et al.*, 2001).

When using different repetition rates for different carrier frequencies, a simultaneous measurement at multiple frequencies is possible (Lins and Picton, 1995). The suppression effect for simultaneous multiple-frequency measurements with a minimum distance of 1 octave between simultaneously tested frequencies is significantly lower for 80 Hz ASSR compared to 40 Hz ASSR (John *et al.*, 1998; Ross *et al.*, 2003). For 40 Hz ASSR, the amplitude may decrease by 50 %, whereas for 80 Hz ASSR, the amplitude may decrease by about 15 %. The suppression effect may vary distinctly between subjects.

Moreover, the repetition rate may be slightly changed during the test in order to reduce artefacts due to electromagnetic radiation.

In contrast to DPOAEs, ASSRs give information on the degree of the hearing loss within the entire dynamic range of hearing. Therefore, ASSRs are a suited means for a frequency-specific and quantitative evaluation of hearing status especially in children and may contribute to improve hearing aid fitting. Intended use of ASSR is follow-up diagnostics after newborn hearing screening, topological diagnostics (together with tympanometry, OAE), neurological diagnostics, and frequency-specific determination of hearing thresholds.

ASSRs are especially useful for objective hearing threshold determination at low frequencies, where DPOAEs are not available. For objective determination of hearing thresholds it is recommended to measure at a first stage DPOAE Threshold at the required frequencies and to measure at a second stage ASSR at frequencies where no DPOAE response could be detected.

Average test time for eight test frequencies is for normal hearing subjects about 15 minutes and for hearing impaired subjects about 25 minutes (Rosner, 2013b).

Two ASSR workflows are available:

- **ASSR Fixed** allows frequency-specific measurement of ASSR at one or multiple levels. A pass/fail result is delivered for each frequency/level combination.
- **ASSR Threshold** allows frequency-specific determination of hearing thresholds within a definable level range by measurement of ASSR with adaptive level setting (bracketing algorithm). Hearing loss is estimated by means of fixed offset values. Threshold detection is stopped if two consecutive responses are not valid.

ASSR tests can be performed binaurally if an adequate transducer is connected (e.g. headphone, two ear probes), which reduces test time by a factor of two. ASSR can be measured at frequencies from 250 Hz to 6 kHz with multi-frequency stimulus presentation.

PRACTICAL USE

Select ASSR from the module selection screen. If more than one AEP test is licensed, ASSR can be found in the AEP section. Select the preset that you would like to perform. If necessary, change the parameters (e.g. test mode, stimulus frequencies, stimulus levels (ASSR Fixed) or level range (ASSR Threshold), stimulus rate, number of averages) and the preset name as required.

Stimulus rate:

It is recommended to use 40 Hz ASSR in awake and alert subjects (e.g. children and adults) and to use 80 Hz ASSR in sleeping subjects (e.g. babies, sedated subjects, during anesthesia). Also, 40 Hz ASSR response amplitudes increase with decreasing carrier frequency (Rodriguez *et al.*, 1986, Picton *et al.*, 1987), whereas 80 Hz ASSR response amplitudes are maximal at medium carrier frequencies between 1 and 2 kHz (John *et al.*, 2001, Dimitrijevic *et al.*, 2002).

4 frequencies per ear:

For 40 Hz ASSR threshold determination it is recommended to disable the “4 frequencies per ear” option. Then, the measurement is conducted with measurement at two simultaneous frequencies only. For some patients, with “4 frequencies per ear” enabled, the test time may be reduced. For 80 Hz ASSR always 4 frequencies are tested simultaneously.

Averages:

At fixed measurement conditions, with increasing averaging time, the noise floor decreases and the quality of threshold determination increases.

Before the test is started the subject should be instructed about the test procedure. In order to reduce muscle artefacts, the subject should be calm and fully relaxed lying comfortably on a recliner or bed. For 40 Hz ASSR subjects should stay awake, whereas for 80 Hz ASSR subjects may sleep. For babies, try to test the subject during spontaneous sleep or sedation if medically approved. In order to reduce environmental artefacts, conduct the measurement in a room with low electromagnetic radiation, i.e. in an electrically shielded metal booth or any other room without powered-on electric devices (e.g. computer, light, telephone, cell phone, power transformer) in close range to the measurement equipment. An acoustically shielded booth or a quiet room is recommended if ASSR is applied for threshold determination at low sound pressure levels.

Make sure that a valid transducer (e.g. headphone, insert earphone, ear probe) and electrode cable are connected. Make sure that the skin is clean at the intended positions of the electrodes. For further instructions about skin preparation, electrode placement and impedance please refer to *PRACTICAL USE* in section [3.2.5: Auditory Brainstem Responses \(ABRs\)](#).

Select the test ear (*Right+Left*: simultaneous measurement of right and left ear – please note that in this case a symmetric electrode montage is recommended). The electrode impedance measurement starts. Both impedances must be <12 kΩ in order to be able to start the measurement. It is recommended that impedances are <5 kΩ and that the difference between the red and white electrode impedance is <2 kΩ. For further information about impedance measurement see *PRACTICAL USE* in section [3.2.5: Auditory Brainstem Responses \(ABRs\)](#).

After successful electrode impedance measurement, you can start the test by pressing the play button. The ASSR stimuli (chirps with half-octave bandwidth) are presented via the transducer and the response is detected via the electrode cable. During the measurement the electrode impedance is monitored. In case that at least one of the impedances gets too high (e.g. an electrode has fallen off), the test is automatically interrupted. The test can only be continued if the electrode impedances get back to tolerable values.

During the measurement the following information is provided on the screen (see *Figure 39*): statistical ASSR traces ① are shown for each currently tested frequency/level combination. The traces are shown in red (right ear) and/or blue (left ear). A trace is finished if the curve reaches the top of the trace after the minimum averaging time (end of grey area) or if it reaches the defined maximum averaging time. The EEG bar ③ represents biological and external noise which is an indicator for the adequacy of measurement conditions. With good measurement conditions, the EEG bar should remain in the lower third. If the EEG bar is higher, biological and external artefacts may be too high, i.e. the patient may be not in the required state of vigilance (i.e. awake or sleeping), or the electromagnetic radiation may be too prominent. The overall progress bar ② shows the progress of the measurement. If the bar is full, the complete test sequence is finished. The electrode impedance ④ is regularly updated during the measurement and the measurement is paused if impedance gets too high.

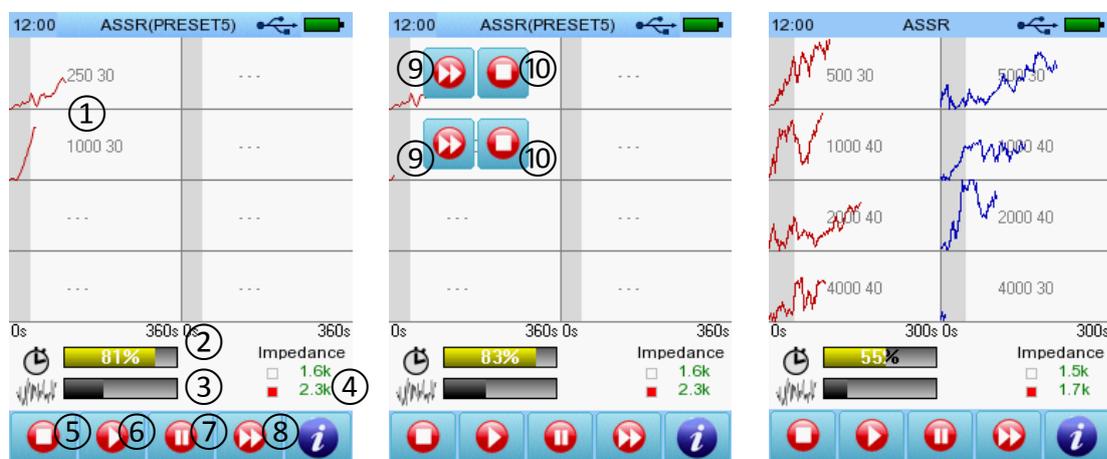


Figure 39: ASSR measurement (left: monaural with 2 frequencies per ear; middle: monaural with skip/stop frequency selection; right: binaural with 4 frequencies per ear)

The test can be manually paused (7), continued after a pause (6), or stopped (5). Also, a current measurement at a frequency can be skipped or stopped (8). If multiple measurements are running the frequency can be selected (skip (9): skip level at frequency, stop (10): stop frequency) after pressing the skip button (8).

The statistical response algorithm is based on the magnitude squared coherence (Dobie and Wilson, 1989) test and determines whether a response is present or absent. The response detection algorithm compares the mean square (= power) of the averaged waveform to the sum of mean squares of the single sweeps and calculates a score. A valid response is detected if the detection score of 4 (which is equivalent to a significance level of 5%) is achieved after a minimum of 45 seconds has been averaged. This means the power of the grand average must be 4 times higher than the power added up of the single sweeps.



Figure 40: ASSR result (top: ASSR Fixed – left: validity matrix, right: single measuring point information; bottom: ASSR Threshold – left: audiogram, middle: validity matrix, right: single measuring point information).

After the test is finished, the ASSR result is shown (see Figure 40). For ASSR Fixed two main screens are available (validity matrix (2) and single measuring point information (3)), whereas for ASSR Threshold an additional ASSR audiogram (1) is available. The audiogram shows estimated ASSR thresholds (4), which are derived by subtracting an empirical offset from the lowest stimulus level at which a valid ASSR response has been detected (Rosner, 2013a). By pressing on the audiogram the validity matrix (2) is shown, which displays for all measuring points if a response was detected (5) or

not ⑥. By pressing on a specific validity icon, the measuring point information for the selected frequency/level combination is shown, which displays general parameter informations ⑦ (including frequency and level), the statistical ASSR trace ⑧, impedance ⑩, and response and noise amplitude ⑨. In order to ensure adequate measurement conditions noise should be <20 nV after 360 s averaging time. With increasing averaging time, noise decreases and vice versa, i.e. if a valid ASSR response is detected quickly, a higher noise is expected to be shown.

The following case examples (see *Figure 41*) show that ASSRs are capable of appropriately estimating behavioural thresholds.

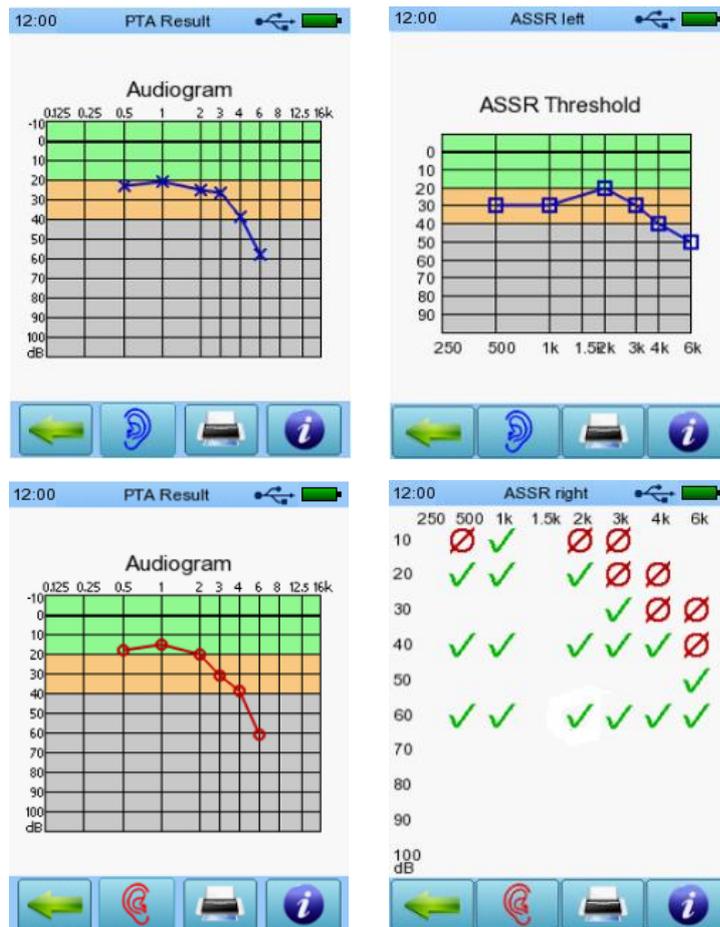


Figure 41: ASSR case examples (left top/bottom: behavioural pure-tone thresholds; right top: ASSR thresholds; right bottom: ASSR validity matrix)

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3.2.7 Overview: Tympanometry

The function of the middle ear is to minimize the loss of acoustic energy that appears when sound is transferred from air in the outer ear canal (low density) to fluid in the inner ear (high density). Without the specific middle ear features, approximately 99.9 % of the sound energy would be reflected at the fluid due to the different densities. The middle ear helps to improve the energy balance by increasing sound pressure and force (see *Figure 42*). The increase of sound pressure is simply due to the fact that the tympanic membrane area is seventeen times larger than the area of the footplate of the stapes which is the connecting link between middle and inner ear. The increase of sound pressure becomes clear when looking at the physical equation, which defines pressure as force divided by area ($p = F / A$). So, with reduced area and same force the pressure increases. The increase of force is due to the different length of the malleus and the incus providing a lever action of the ossicular chain (malleus, incus, stapes). Both mechanisms yield an impedance matching which allows for a transmission of 60% of the sound energy to the inner ear.

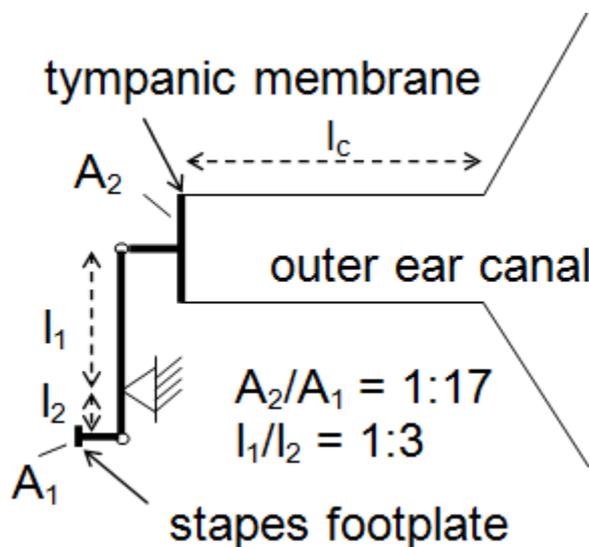


Figure 42: Schematic drawing of the middle ear. A_1 and A_2 = areas of stapes footplate and tympanic membrane, l_1 and l_2 = lever arm length (malleus and incus)

The middle ear is able to increase the impedance if necessary for providing protection against loud sounds. In the case of a sound higher than about 80 dB HL, the middle ear muscles (stapedius muscle and tensor tympani muscle) are activated resulting in an increased stiffness of the middle ear. As a consequence, the energy transmitted to the inner ear is lower.

The term immittance comprises impedance Z (unit: acoustic ohm) or admittance Y ($= 1/\text{impedance}$, unit: acoustic mho) and their complex components. Regarding the middle ear, the impedance defines the opposition of the middle ear to the flow of acoustic energy, whereas the admittance defines the amount of energy that flows into the middle ear. In middle ear diagnostics, typically the admittance is evaluated. Admittance is determined by compliance ($= 1/\text{stiffness}$, spring load), mass, and friction or resistance. Mathematically, the admittance Y is a complex value consisting of conductance G (real part) and susceptance B (imaginary part), i.e. $Y = G + jB$. Friction influences conductance, whereas compliance and mass influence susceptance. Conductance (friction) is independent of frequency, whereas susceptance (compliance, mass) is dependent on frequency with compliant susceptance

being inversely proportional to frequency and mass susceptance being directly proportional to frequency. With increasing frequency, the total susceptance progresses from positive values (stiffness controlled) towards 0 mmho (resonance) to negative values (mass controlled). The resonance frequency is directly proportional to the stiffness of the middle ear, i.e. with increasing stiffness the resonance frequency increases (e.g. with otosclerosis), and inversely proportional to the mass of the middle ear, i.e., with increasing mass the resonance frequency decreases.

The typical measurement setup consists of an ear probe which is sealed in the ear canal and contains a loudspeaker that produces the stimulus signal, a microphone that monitors the response (i.e. the portion of the stimulus reflected from the tympanic membrane), and a pneumatic port for applying air pressure via an air tube. The device to which the ear probe is connected provides the pump for generating varying air pressure. The impedance calibration is typically done with several test cavities of different volume. The test cavities have a defined volume of air so that their admittance is known. This allows calibrating the device for the typical range of acoustic admittances.

Immittance audiometry determines the reflectance of sound at the ear drum and is hence able to give information on middle ear dysfunction caused by different middle ear pathologies including otosclerosis (increase of stiffness), otitis media (increase of mass), and Eustachian tube dysfunction (decrease of static pressure in the tympanic cavity). Different pathologies may result in similar tympanograms (e.g. flat tympanogram may occur due to malleus fixation or middle ear effusion) and the same pathology in different subjects or with different characteristics may not result in identical tympanogram shapes (e.g. tympanogram in middle ear effusion is dependent on the amount of fluid in the tympanic cavity) so that additional diagnostics may be necessary. Tympanometry and acoustic reflex tests cannot be reasonably performed if the ear drum is perforated (e.g. if a tympanostomy tube is in place).

PRACTICAL USE

It is recommended to check the functionality of the pneumatic system (i.e. air tube and pump unit) regularly. This can be done via the pump unit test (see *Figure 43* - left), which checks correct pressure generation and retention. Connect the tympanometry ear probe to the device and make sure that also the air tube is properly attached to the device. Place the probe tip in an appropriate test cavity and make sure that the probe tip is deeply inserted into the test cavity so that there is no leakage between probe tip and test cavity. First, pressure generation is tested. The static air pressure starts at 0 daPa and continuously increases until +200 daPa, i.e. a continuously increasing curve shall be displayed. Second, pressure retention is tested. The initial static air pressure of +200 daPa shall be kept without major reduction of air pressure during the test time, i.e. a rather flat line shall be displayed. If the pneumatic system functions appropriately, the test passes (i.e. a green icon is shown). Please note that if the second subtest (pressure retention) fails it may be due to a leaky connection, which primarily may occur between the ear probe and the test cavity. In this case try another test cavity or try to seal the ear probe by detaching the probe tip and placing a finger on top of the output channels. Alternatively, conduct the test for the pump unit only as follows: The pump unit test can be conducted by detaching the tympanometry ear probe and by sealing the air pressure socket at the device e.g. with the finger. In this setup only the pump unit of the device is tested.

It is recommended to readjust the admittance calibration on the device regularly via the tympanometry calibration procedure (see *Figure 43* - right), which sets the correct admittance reference values for the three test cavities of known volume (0.5, 2.0, and 5.0 ml). For this test, use

the provided test cavity box. Place the correct probe tip in the first test cavity (e.g. 0.5 ml) and make sure that the probe tip is deeply inserted into the test cavity so that there is no leakage between probe tip and test cavity. Wait until the admittance value settles and press the button representing the selected test cavity volume (e.g. 0.5 ml). The respective admittance is adjusted accordingly. Continue the same procedure with the other two test cavities. If all three test volumes have been calibrated successfully a message box will appear.

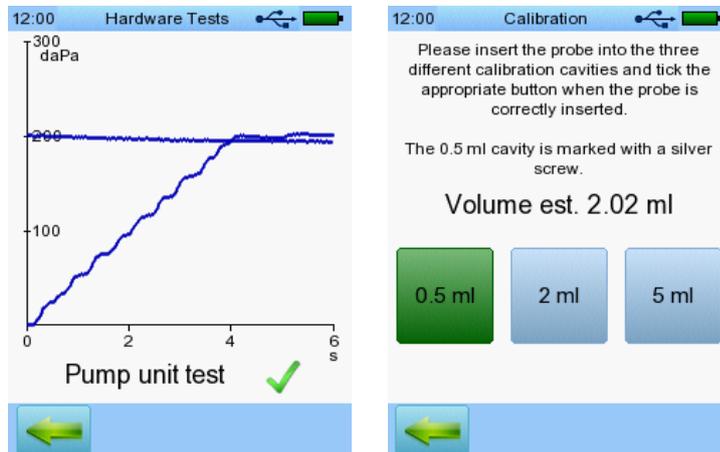


Figure 43: pump unit test (left) and admittance calibration (right)

If there is any deviation from the behaviour described above or if you suspect any dysfunction, please retry with another tympanometry ear probe and/or contact your distributor.

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3.2.8 Impedance Audiometry (Tympanometry)

METHODOLOGY

Sound conduction through the middle ear (from tympanic membrane via ossicles to footplate of stapes) can be tested by measuring the acoustic admittance (= 1/impedance) of the tympanic membrane while varying the static pressure in the outer ear canal using an air pump. The function of the tympanic membrane is best if the pressure is equal on both sides, i.e. in the tympanic cavity and in the outer ear canal. In this state, the vibration of the tympanic membrane is maximal and the largest part of a sound signal is transmitted to the inner ear and only a small part is reflected. In case of differing pressure on both sides of the tympanic membrane, more energy is reflected. This situation may occur e.g. due to a ventilation disorder of the tympanic cavity, fluid in the tympanic cavity or perforation of the tympanic membrane. In general, it must be taken into account that impedance tests only refer to the acoustic energy that flows into the middle ear but not how much energy is transmitted through the system. There are specific pathologies (e.g. tympanosclerotic plaques) that may result in an abnormal tympanogram but are not associated with a distinct hearing loss. In contrast, otosclerosis may produce a relatively normal tympanogram with a marked hearing loss.

Due to a measurement position, which is remote to the tympanic membrane, the admittance measurement is influenced by the middle ear *and* outer ear canal properties and hence also by the insertion depth of the ear probe. In order to derive a measure of middle ear admittance alone, the ear canal admittance must be removed from the overall admittance. Under sufficient tension of the tympanic membrane by a high positive or negative pressure, the middle ear admittance is driven towards zero, i.e., the admittance at these conditions provides an estimate for ear canal admittance. The ear canal admittance can be subtracted from the overall admittance due to the assumption that the impedances of the ear canal and middle ear are configured in parallel (Djupestrand and Zwislocki, 1972), which means that the admittances are summed up ($Y_{\text{total}} = Y_{\text{ear canal}} + Y_{\text{middle ear}}$). However, this assumption is only an approximation, so that the ear canal admittance derived from tympanometric measurements is an estimate. In general, this procedure is considered adequate for clinical use.

Standard clinical tympanometry is usually performed using a low frequency stimulus (220 or 226 Hz) for measuring the admittance of the middle ear and the outer ear canal. At low frequencies, the normal middle ear system is stiffness-controlled and susceptance (stiffness element) contributes more to overall admittance than conductance (frictional element). Higher probe tone frequencies may be e.g. 678 Hz (or 630, 660 Hz), 800 Hz, and 1000 Hz.

Typically static air pressure is varied from +300 daPa to -300 daPa. The direction of pressure change (i.e. from positive to negative pressure or vice versa) may influence static admittance (Wilson *et al.*, 1984). At higher frequency probe tones (e.g. 678 Hz) notched tympanograms are more frequent with increasing pressure change (Wilson *et al.*, 1984). Also, the rate of pressure change can have an effect on tympanograms. Single-peaked tympanograms typically increase in amplitude with increasing rates of pressure change, but also the incidence of multiple-peaked tympanograms increases (Creten and van Camp, 1974). Moreover, the incidence of notches increases with successive runs of tympanometry measurements maybe due to the viscoelasticity of the tympanic membrane.

The result of the admittance measurement is a graphic display called a tympanogram which plots middle ear admittance depending on static air pressure in the outer ear canal (see *Figure 44*).

Different middle ear pathologies exhibit different tympanogram shapes (see *Figure 44*). The following rough description refers to low frequency (220/226 Hz) tympanograms. In case of normal middle ear function the tympanogram shape corresponds to a Gaussian bell curve with its maximum being around zero static pressure (black solid line), i.e., maximum energy is transferred into the middle air at atmospheric pressure without any static pressure offset. If there is a Eustachian tube dysfunction the peak of the Gaussian bell curve is shifted in the direction of negative pressure values (red dashed line). This is due to the fact that the tympanic membrane moves best in its normal position, i.e., when the static pressure in the ear canal and the static pressure in the tympanic cavity are the same. If the static pressure in the tympanic cavity is negative then the static pressure in the outer ear canal has to be negative with the same value. As a result, the peak of the Gaussian bell curve is present exactly at the static pressure which is obtained in the tympanic cavity. In case of middle ear effusion, middle ear mass is increased. In this case middle ear movement is considerably reduced resulting in a lower compliance (light blue dotted line), which is nearly independent of static pressure. Also, in case of otosclerosis middle ear movement is reduced. As a consequence, the peak of the Gaussian bell curve is small, however located within the zero static pressure range (grey solid curve). An activated stapedius muscle yields reduced compliance as well.

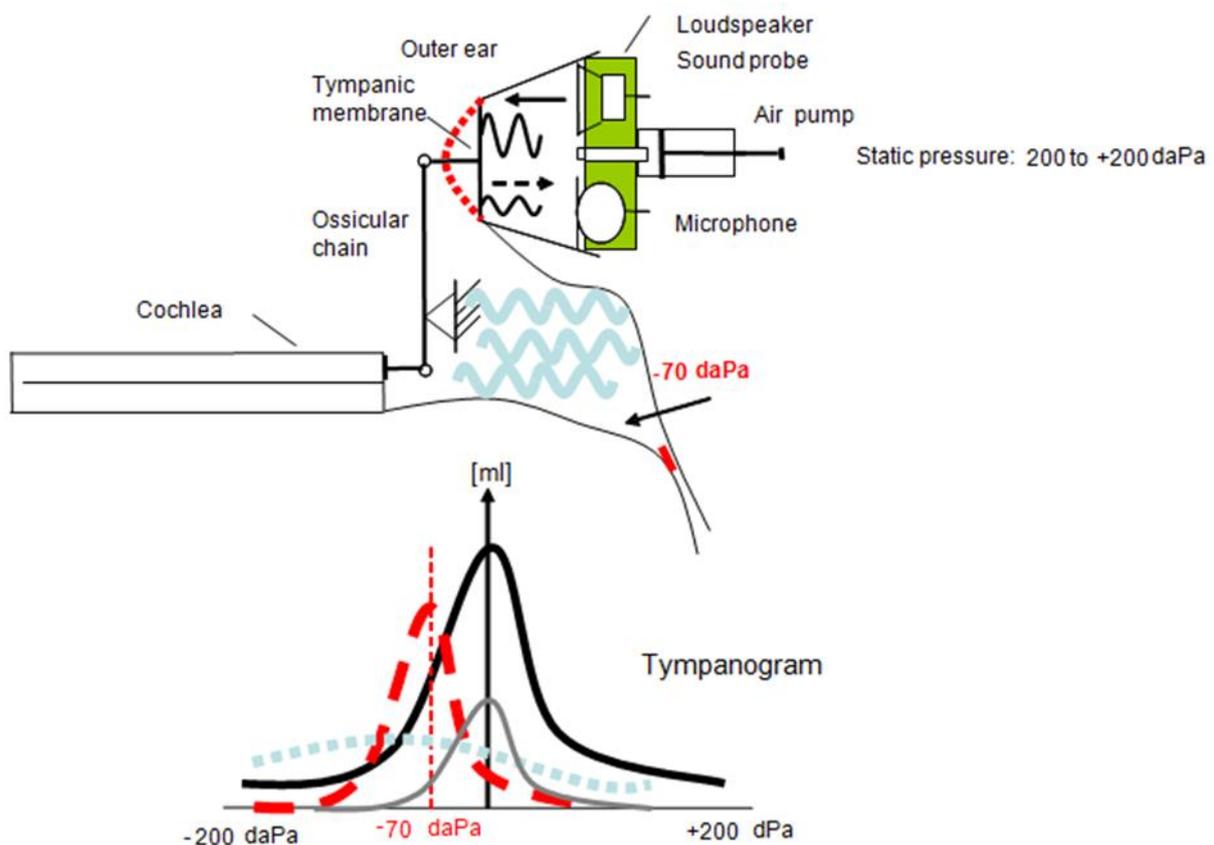


Figure 44: Schematic overview of tympanometry (top) with tympanogram examples (bottom: black solid line: normal, gray solid line: otosclerosis, red dashed line: Eustachian tube dysfunction, light blue dotted line: effusion)

Typical parameters from a tympanogram are the tympanometric shape, ear canal volume, static admittance, tympanometric peak pressure, and tympanometric width.

Jerger and Northern (1980) introduced three types of tympanogram shapes, which refer to low frequency (220/226 Hz) tympanograms. Type A represents a normal tympanogram with a pronounced peak around 0 daPa, Type B shows a flat tympanogram without pronounced peak, and Type C refers to tympanograms with the peak shifted to negative static pressure. For low probe tone frequencies commonly a single-peaked tympanogram occurs. However, in neonates and for higher probe tone frequencies tympanograms often exhibit multiple peaks and notches (dependent on which immittance component is measured).

Ear canal volume is typically estimated as the admittance at the negative or positive maximum pressure (e.g. at +200 daPa). For low frequency probe tones only a small error occurs due to a phase difference between the admittance vector of middle ear and ear canal. At higher frequencies, this error becomes more prominent. For a 226 Hz probe tone, the ear canal volume is commonly given in ml (which is similar to mmho at this frequency and at specific environmental conditions). For higher frequency probe tones, the ear canal volume is given in mmho.

The tympanogram can be normalized by subtracting the ear canal volume from the curve yielding the compensated static acoustic admittance Y_{tm} , which is an estimate of the acoustic admittance at the lateral surface of the tympanic membrane. It is typically higher when maximum negative (rather than maximum positive) pressure is used to estimate ear canal admittance (Margolis and Smith, 1977).

The tympanometric peak pressure is the pressure at which the maximum admittance occurs. The tympanometric width is the pressure difference at one half of the compensated static acoustic admittance. It quantifies the relative sharpness of the peak.

PRACTICAL USE

Select *Impedance+Reflex* from the module selection screen. Impedance can be found in the *Middle Ear* section. If licensed as class 1 tympanometer, different presets are available, otherwise there is just one preset.

If required, the following parameters can be configured for the impedance test:

Probe tone frequency: The default value is 226 Hz. Class 1 offers 678, 800, and 1000 Hz probe tones in addition.

Pressure setup: Configures pressure range and pump speed. Pressure range is up to -600 to +400 daPa for the class 1 device, and -300 to +300 for class 2. Pump unit speed can be set in increments of 50 daPa/s to values of 50 to 200 daPa/s. Additionally, "afap" is available, which means as fast as possible.

Auto Stop: The tympanogram recording can be stopped as soon as the tympanometric peak is detected, which means that the pressure will not be decreased any further than necessary if the auto stop option is enabled.

The *Impedance* test can also be performed with an option to consecutively measure impedance and automated acoustic reflex (see 3.2.9 for description of Acoustic Reflex Test). To do so, select the respective option (always or only if peak is within norm area) and the frequencies to perform reflex measurements at.

Make sure that a valid transducer (tympometry probe EP-TY) is connected. You may use a clamp to fixate the probe cable to the subject's clothes. Select an ear tip with appropriate size matching the probe tip size and the subject's ear canal size. Make sure that the ear probe is inserted without any leakage between ear probe and ear canal. Foam tips are not suitable for performing tympometry because they are not air tight.



Figure 45: Tympometry probe status light (top left), fixation clamp (bottom left) and connection to the device (right). The pressure outlet is a Luer Lock style connector.

After selecting the test ear, the measurement is ready to be started. The probe status light indicates the current measurement condition:

Steady light: Ready for testing – please place the probe in the ear

Slowly blinking (heartbeat): Measurement in progress

Fast blinking: Leakage, unable to generate the required pressure in the ear canal

The device monitors the acoustical volume seen at the probe. The impedance measurement automatically starts once the probe is positioned in the ear and the acoustical volume has stabilized. The probe status light indicator will change from steady to heartbeat mode while the admittance curve is being recorded.

In case of leakage during the test, the device will attempt to retry the measurement automatically. The probe status light will change to fast blinking, and instructions will appear on the device display.

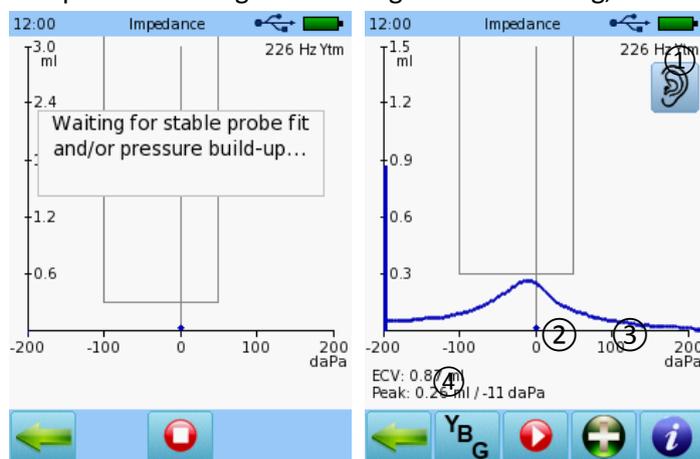


Figure 46: Impedance test while waiting for stable probe fit (left) and after completion of the test (right)

Once the test is finished, there are several options:

- ① Repeat the test with the same settings on the other ear. This is the quickest way of recording tympanograms for both ears. Since the impedance test starts automatically once the probe fit is stable, remove the probe from the current test ear before pressing the button, to prevent the same ear being measured twice (once as left and once as right ear).
- ② In case of artefacts or unclear results, the measurement can be repeated by pressing the play button. This will discard the trace currently on screen and record a new tympanogram.
- ③ The class 1 tympanometer allows to record up to three curves within one measurement. An additional tympanogram, which will be displayed on top of the existing one(s), can be added by pressing the play button. This can be useful if tympanograms are to be compared under different conditions, e.g. before and after performing a Valsalva manoeuvre.
- ④ Switch between admittance (Y), susceptance (B), and conductance (G) graphs if the device is equipped with a class 1 license.

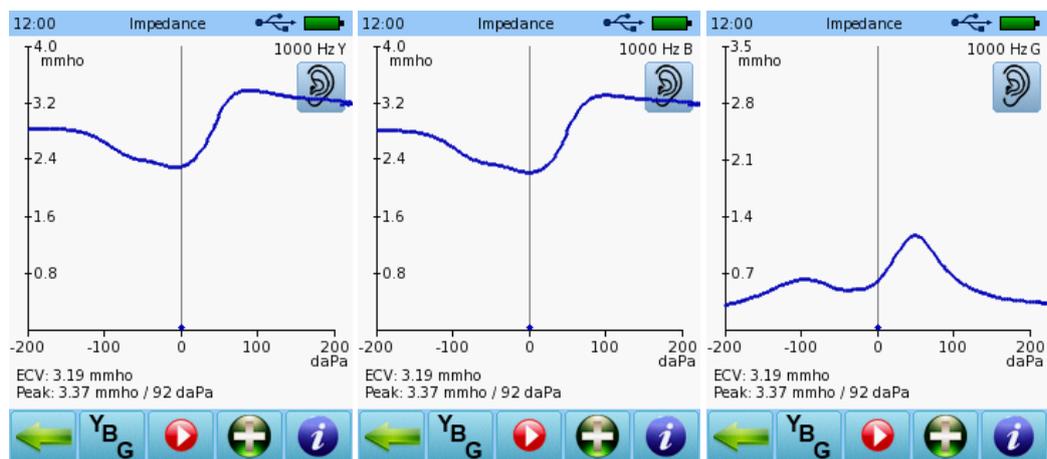


Figure 47: Admittance magnitude, susceptance and conductance graphs can be toggled via the YBG button on a class 1 device. Probe tone frequency and view mode are indicated in the upper right corner

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3.2.9 Acoustic Reflex Test

The acoustic reflex (or stapedius reflex, attenuation reflex, auditory reflex) is an involuntary muscle contraction that occurs in the middle ear in response to high-level sound stimuli (above about 80 dB HL). This includes contraction of the stapedius and tensor tympani muscle. The stapedius muscle stiffens the ossicular chain by pulling the stapes away from the oval window of the cochlea and the tensor tympani muscle stiffens the ossicular chain by loading the eardrum when it pulls the malleus in toward the middle ear. As a consequence the transmission of vibrational energy to the cochlea is decreased and the impedance is increased. The pathway involved in the acoustic reflex is complex and can involve the ossicular chain itself, the cochlea, the auditory nerve and the brainstem.

The stapedius reflex is considered to be a protective procedure. In cases where this protective procedure of the middle ear muscles is disabled (dysfunction of the efferent hearing system, otosclerosis) cochlear micromechanics (especially hair cell stereocilia) may be more easily damaged.

The acoustic reflex can be elicited ipsilaterally or contralaterally with short tone pulses (e.g. sine at 0.5, 1, 2, 4 kHz) of about 1 to 2 s. When elicited ipsilaterally, impedance measurement and acoustic reflex stimulation are done in the same ear. When elicited contralaterally, impedance measurement and acoustic reflex stimulation are done in opposite ears. Commonly, the threshold at which the stapedius muscle begins to change middle ear impedance is tested. The test is conducted at maximum compliance, i.e., at the static pressure, which yields a maximum during tympanometry. Therefore, it is recommended to conduct tympanometry before acoustic reflex testing. The result is a graphic display which plots middle ear admittance depending on time for a selected stimulus level. If the stimulus level is high enough to elicit the acoustic reflex, a distinct change in admittance can be observed.

Acoustic reflex measurements are done to identify otosclerosis, cochlear recruitment and neural disorders. Otosclerosis means fixation of the footplate within the oval window of the inner ear due to sclerotic lesions. In case of a fixation of the stapes footplate no change in impedance is measurable when delivering a loud sound to the ear. Recruitment is characterized by normal cochlear hearing at high and limited cochlear hearing at low sound levels. In hearing-impaired ears (e.g. revealed by pure-tone audiometry) having normal acoustic reflex thresholds at about 80 dB HL cochlear recruitment is most likely. Reflex threshold increases in case of middle ear dysfunction.

PRACTICAL USE

Automatic reflex threshold determination:

In advance of performing acoustic reflex testing, an Impedance test should be performed in order to determine the tympanometric peak pressure at which reflex testing should ideally be performed. This sequence is run automatically by selecting *Impedance + Reflex* in the *Middle Ear* modules section.

Make sure that a valid transducer (tympanometry probe EP-TY) is connected. You may use a clamp to fixate the probe cable to the subject's clothes. Select an ear tip with appropriate size matching the probe tip size and the subject's ear canal size. Make sure that the ear probe is inserted without any leakage between ear probe and ear canal. Foam tips are not suitable for performing tympanometry or acoustic reflex testing because they are not air tight.

Contralateral reflexes can be measured if a suitable transducer is connected in addition to the tympanometry probe. The transducer must be connected prior to selecting the reflex module in order to be recognized by the device. Suitable contralateral transducers are: Any headphone (HP-xx), the EP-DPVIP probe, insert ear phones (IP-xx) and the monaural ear phone (IP-M).

In automatic mode, the pressure to perform reflex testing is taken over from the latest tympanometry result of the same ear. Reflex testing will start automatically without further user interaction required. Reflex thresholds can be determined for 0.5, 1, 2, and 4 kHz and broadband noise (BB). The stimulus signals can be enabled and disabled in the preset, so it is possible to just determine e.g. the 1 kHz threshold if desired.

The acoustic reflex measurement is relatively sensitive to movement of the probe. This is because the change in admittance which is caused by the acoustic reflex is quite small. Movements of the probe can influence the insertion depth and with it, the admittance that is seen by the probe. These changes are in the same order as that of the reflexes. It is therefore preferred that the probe is not being held by the examiner during reflex testing. An adequate ear tip is necessary that allows a stable probe fit. The use of the fixation clamp can also be helpful to keep the probe in place.

If a stable airtight seal cannot be achieved, even with an ear tip of suitable size, the measurement can be continued at ambient pressure (i.e. 0 daPa). Although it is recommended to perform reflex testing at the peak tympanometric pressure, the test at ambient pressure may provide useful information - especially if the tympanometric peak pressure is close to zero anyways, i.e., when the middle ear function is normal.

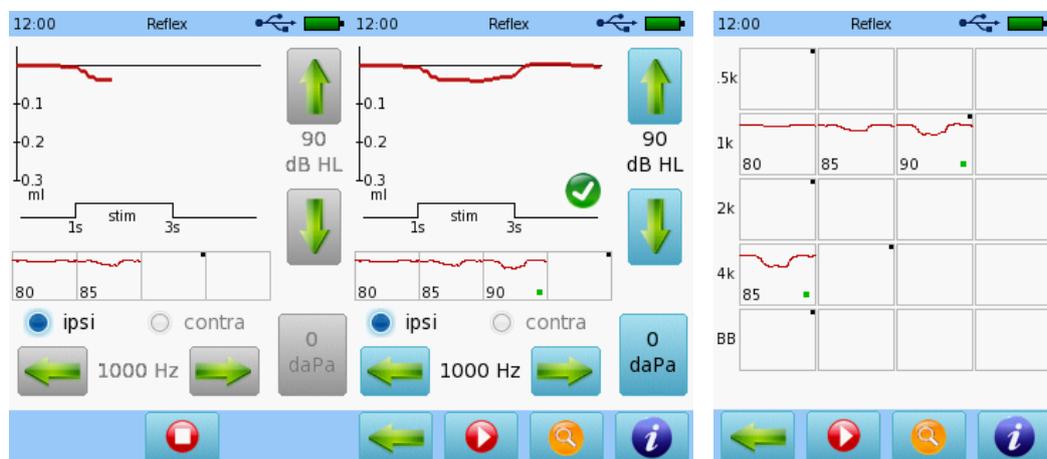


Figure 48: Acoustic Reflex measurement workflow: controls are greyed out while measurement is ongoing (left). Measurements finish when reflex thresholds are determined. Controls are enabled so that additional measurements can be performed manually (middle). An overview can be displayed that shows all measurements (right).

Reflex growth of the frequency under test can be seen directly from the measurement view. In addition, after the measurements are finished, an overview is available that displays all reflexes on one single page, or on two pages if measuring both ipsilateral and contralateral reflexes.

The buttons are disabled (greyed out) during automated tests. After determining the reflex threshold for the selected stimuli, or if thresholds cannot be determined below or at 95 dB HL, the stimulus

level and pressure controls become available so that additional measurements can be performed on a manual basis. This may be required if the subject's reflex thresholds are elevated to above 95 dB HL, because the automatic mode does not apply stimuli of 100 dB HL or above due to safety reasons. The automated test can be interrupted at any time by pressing the stop button. Frequency, level and pressure controls will then be available for manually performing measurements, e.g. if a certain recording has to be repeated because of artefacts or unclear results.

Manual reflex measurements:

If licensed as class 1 device, *Manual Reflex* is available in the *Middle Ear* section as a separate measurement mode. For all devices, the manual mode is available after finishing or interrupting an automated reflex test.

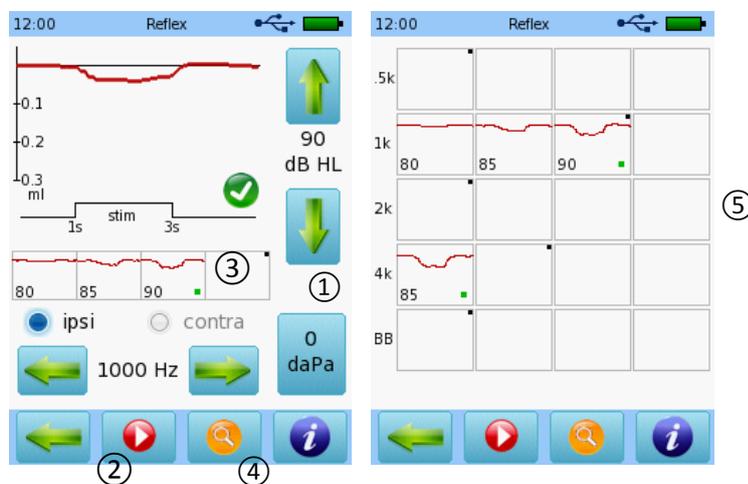


Figure 49: Manual acoustic Reflex controls in measurement perspective (left) and overview (right)

The manual mode allows full control of measurement parameters and measurement order.

① Measurement parameters can be setup for each individual reflex measurement. The parameters are the reflex stimulus frequency (or noise), the stimulus presentation level, and the presentation side (ipsilateral or contralateral). Pressure can be setup by pressing the 'daPa' button.

The contra option is only available if a suitable transducer was connected prior to starting the test (see practical use of automatic reflex threshold determination).

② Once all parameters are set, press play to perform the test.

③ The device offers four storage slots per stimulus frequency and presentation modality (ipsi/contra). The slots are depicted as miniature traces and are annotated with the presentation level. Detected reflexes are indicated by a green checkmark. A small black marker at the graph corner indicates the storage slot of the next measurement to be performed. Clicking on any of the slots' graphs will make the corresponding curve appear in the main graph and will select that slot to be overwritten with the next measurement.

④ Show an overview of all reflex measurements (⑤). The overview shows miniature graphs for all stimulus frequencies, whereas in the main view, only the reflex growth of the currently selected

stimulus frequency is visible. Apart from that, the description of ③ applies regarding meaning and usage of the graphs and their annotation.

Advanced acoustic reflex measurement modes:

If licensed as class 1 device, additional reflex testing is offered.

Manual reflex measurements (see above) are available as separate module, so that there is no need to go through a sequence of impedance and automatic reflex threshold in advance.

Reflex decay testing is possible. Practical use of the reflex decay module is the same as for the manual reflex module, as the test only differs with regard to the stimulus duration. Reflex decay testing is usually performed at stimulus levels 10 dB above reflex threshold. Therefore, a reflex threshold determination, either manually or automatic, should be performed in advance. The pressure should be set to the tympanometric peak pressure, as with normal reflex testing. Good clinical judgement should be used before reflex stimuli at high intensities, especially during reflex decay testing, where the actual duration of the presentation is greater than 10 seconds.

Admittance monitor offers a simple test where the admittance change is recorded and plotted for 20 seconds. It can be used to monitor admittance changes caused by acoustic reflexes that were elicited by external stimulation, like free field sound sources, or hearing aid / cochlear implant based stimulation. It is up to the user to interpret the recorded curves, since the device has no knowledge about the external stimulation.

Note: the admittance monitor test routine is also available as *ETF Patulous Eustachian Tube*.

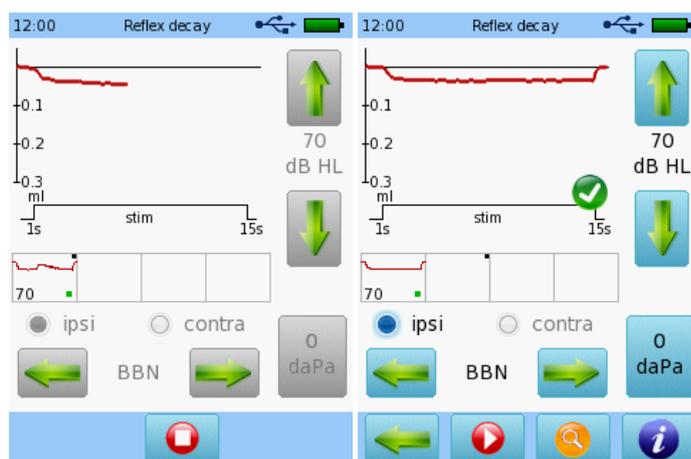


Figure 50: Reflex decay testing presents stimuli of long duration

3.2.10 Eustachian Tube Function Tests

Apart from performing impedance and acoustic reflex testing, additional functionality is available to assess the Eustachian tube function on the class 1 tympanometer.

Select *ETF* and the desired sub test from the *Middle Ear* section of the measurement module selection menu. All ETF tests require the tympanometry probe EP-TY. The handling of the tympanometry probe is described in chapter 3.2.8.

Non Perforated Eardrum: The Eustachian tube function test records three tympanograms. In between the recordings, the patient is instructed to swallow with nose and mouth closed (Toynbee maneuver) and to perform Valsalva's maneuver. Given a normal Eustachian tube function, the tympanogram peaks are expected to shift between the recordings as a result of the middle ear pressure change caused by performing the Toynbee and Valsalva maneuver. Information on how to instruct the patient will be displayed on screen during the progress of the measurement.

Perforated Eardrum: This test pressurizes the ear canal (and middle ear when the eardrum is perforated). To test the Eustachian tube function, the patient should be instructed to swallow multiple times during the test. If the Eustachian tube opens, pressure will drop.

Special care must be taken to ensure an airtight fit of the probe during testing, to make sure the observed pressure drop is through the Eustachian tube and not caused by leakage.

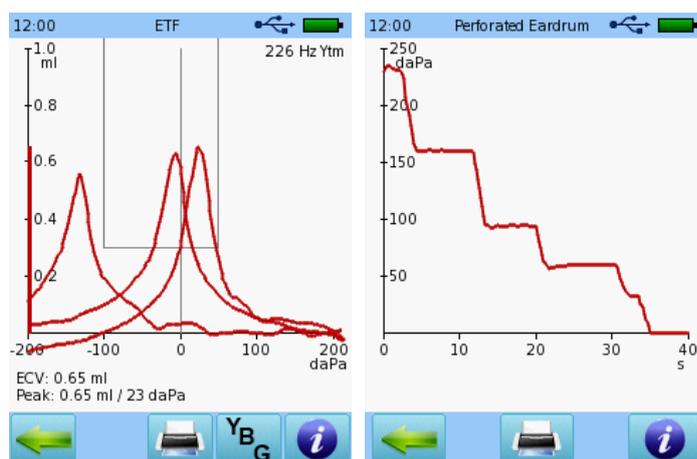


Figure 51: Normal Eustachian tube function test results in case of intact eardrum (left) where the tympanometric peak pressure can be shifted by the subject, and in case of a perforated eardrum, where the middle ear is ventilated (and pressure drops) during swallowing as the Eustachian tube briefly opens.

Patulous Eustachian Tube: This test performs a high resolution admittance measurement, similar to a reflex measurement, but without stimulus. It can be used to monitor admittance changes caused by Eustachian tube opening during breathing, chewing, or swallowing. If the Eustachian tube is permanently open, a higher fluctuation of admittance is expected compared to normal middle ear status. It is common that the rhythms of heartbeat or breathing can be identified in the admittance curve in that case.

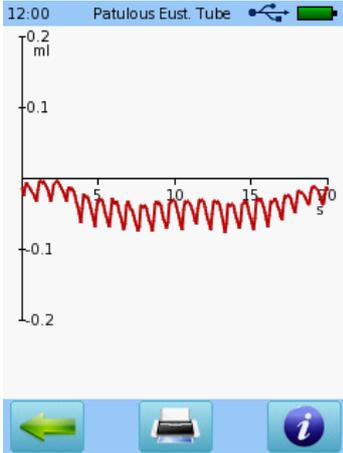


Figure 52: ETF Patulous Eustachian Tube test with the heartbeat rhythm of a subject visible in the admittance curve

Space for your annotations:

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