PATH MEDICAL

How-To-Manual

Psycho-acoustical and physiological test procedures for the assessment of hearing impairment
Scientific background, methodology, practical use

Senti & Sentiero

Manufacturer

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Manual Information

Article number: 100893-EN
Release date: 2023-12
Revision: 06
Valid from: Firmware Rev. 2.9, Mira PC Software Rev. 2.5

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The latest revision of the How-To-Manual is available online at www.pathme.de/support/download.

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Table of Contents

1 Introduction

Senti and Sentiero devices are PC-independent, portable medical devices, 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 display allows for patient data management, parameter setting, control of 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 Desktop, Sentiero, Sentiero Advanced, 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 typical clinical applications 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***. For information on technical data and available test module parameters please refer to the ***Senti and Sentiero Technical Specifications***. For additional information on the device and its test modules please refer to the **PATH MEDICAL website's *Learning* section**, which includes scientific papers, device tutorials, quick guides, and device videos.

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 on 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 to assist audiologically qualified personnel and does not replace adequate training and qualification.

2 Overview

Table 1 describes briefly all test modules available on Senti and Sentiero devices (including Senti *[model SIH100097]*, Senti Desktop *[models SID100419, SID100433]*, Sentiero *[models SOH100098, SOH100360]*, and Sentiero Desktop *[model SOD100497]*) together with their typical clinical application. Please refer to the *Senti and Sentiero User Manual* for the device's intended use and contraindications.

Test module	Short description / Clinical application	Devices
PURE-TONE AUDIOMETRY		
PTA Pure-tone audiometry	Pure-tone audiometry according to IEC 60645-1 including screening and threshold mode, air and bone conduction stimulation, contralateral masking noise, high-frequency audiometry up to 16 kHz and automatic threshold detection procedures.	All
	Frequency-specific determination of hearing status in cooperative patients for audiological screening and diagnostics and occupational medicine.	
Tinnitus-Matcher	Pure-tone audiometry to tune stimuli to match perceived tinnitus in both frequency and level.	All
	Frequency-specific determination of perceived tinnitus in cooperative patients.	
MAGIC Multiple-choice graphic interactive check	Image-based and self-controlled pure-tone audiometry including air and bone conduction stimulation. - *MAGIC Screen*: screening mode with fixed user-defined stimulus levels - *MAGIC Audio:* threshold mode with automatically controlled stimulus levels.	All
	Frequency-specific determination of hearing status in cooperative patients (especially in pre-school and school children) for audiological screening and diagnostics.	
SPEECH AUDIOMETRY		
SUN Speech Understanding In Noise	Self-controlled speech audiometry with logatoms and ipsilateral noise. - *SUN Predefined*: screening mode with fixed user-defined speech level - *SUN Adaptive*: threshold mode with automatically controlled speech levels	All
	Determination of speech intelligibility in noise in cooperative patients for audiological screening (especially in the elderly) (*SUN Fixed*) and diagnostics (*SUN Adaptive*).	
	Image-based and self-controlled speech audiometry with realistic words and optional ipsilateral noise.	All

Test module	Short description / Clinical application	Devices
MATCH Mainzer Audiometric Test for Children	- *MATCH Fixed*: fixed user-defined speech level - *MATCH Adaptive*: threshold mode with automatically controlled speech levels	
	Determination of speech intelligibility in quiet and in noise in cooperative patients for audiological diagnostics. Words and images are optimized for two-year-old children.	
UST Universal Speech Test e.g., Freiburger (German), Dr. Tato (Spanish), NU-6 (English), CID W-22 (English), PBK-50 (English), Maryland CNC (English), Mots français CAD (French)	Speech audiometry with words (e.g., monosyllabic words, numbers) and optional ipsilateral or contralateral noise. The test module is available for different word lists. Note: there are specific workflow adaptations to fit the typical workflow of a speech test.	All [1]
	Determination of speech intelligibility in quiet and in noise in cooperative patients for audiological diagnostics. Intended age group depends on the speech material of the particular test.	
Speech CD Player e.g., NVA (Dutch)	Speech audiometry with words (e.g., monosyllabic words, numbers) played continuously as on a CD player and with optional ipsilateral or contralateral noise. Note: there are specific workflow adaptations to fit the typical workflow of a speech test.	All [1]
	Determination of speech intelligibility in quiet and in noise in cooperative patients for audiological diagnostics. Intended age group depends on the speech material of the particular test.	
Live Speech	Speech audiometry with live speech and multiple test modes including speech detection threshold, speech recognition threshold, and word recognition.	All
	Determination of speech detection thresholds and speech/ word recognition thresholds in quiet.	
OTHER SUBJECTIVE AUDIOMETRY TESTS		
MAUS Munich Auditory Screening Test for Processing Disorders	Speech-based test with subtests regarding sequence of syllables, words in noise, phoneme differentiation and identification.	All [1]
	Screening for auditory processing disorders (ADP) in co-operative patients (especially in children from 6 to 11 years).	
BASD Bochum Auditory Speech Discrimination Test	Auditory discrimination test battery with subtests regarding discrimination of consonants and high-resolution changes in frequency, level, time, and amplitude modulation and with monaural, binaural, dichotic, and interaural stimulus presentation.	All
	Diagnostics of auditory processing and speech development disorders in cooperative patients.	

Test module	Short description / Clinical application	Devices
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 patients for audiological screening.	

Test module	Short description / Clinical application	Devices
OTOACOUSTIC EMISSIONS		
SOAE Spontaneous Otoacoustic Emissions	Recording of spontaneous otoacoustic emissions of the outer hair cells within 0.4 to 9.6 kHz.	Sentiero *[SOH100098, SOH100360]* Sentiero Desktop *[SOD100497]*
	Visualization of outer hair cell status in patients of all age groups.	
TEOAE Transient Evoked Otoacoustic Emissions	Objective test for checking outer hair cell functionality within 0.7 to 4 kHz (either in entire frequency range or in five frequency bands) using a short-term broadband stimulus and statistical response detection. - *TEOAE Quick*: fixed stop criterion - *TEOAE Diagnostic*: user-defined stop criterion in different frequency bands	Sentiero *[SOH100098, SOH100360]* Sentiero Desktop *[SOD100497]*
	Determination of outer hair cell status in patients 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 using two sine stimuli overlapping on the basilar membrane and statistical response detection. - *DPOAE Quick:* one fixed user-defined stimulus level - *DPOAE Diagnostic*: multiple fixed user-defined stimulus levels (Sentiero Desktop: optionally with static pressure offset) - *DPOAE Threshold*: threshold estimation with automatically controlled stimulus levels Additional optional features: - *DPHIRES*: user-defined frequency selection (start, stop, step size): allows for assessing DPOAE fine structure; multifrequency measurement: allows for simultaneous test at multiple frequencies - *FMDPOAE*: frequency-modulated DPOAE, allows for reducing the impact of the 2nd DPOAE source	Sentiero *[SOH100098, SOH100360]* Sentiero Desktop *[SOD100497]*
	Determination of outer hair cell status in patients 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	

Test module	Short description / Clinical application	Devices
	early stage cochlear impairment during noise over-exposure or ototoxic drug administration; frequency-specific determination of hearing thresholds (*DPOAE Threshold*).	
AUDITORY EVOKED POTENTIALS		
ABR Auditory Brainstem Responses	Objective test for checking cochlear and neural sound processing using various short-term stimuli. - *Quick ABR:* one fixed user-defined stimulus level, statistical wave V evaluation - *ABR*: multiple fixed user-defined stimulus levels with multiple stimulus types (click, chirp), air and bone conduction stimulation, contralateral masking, statistical wave V detection Additional optional features: - *ABR-FS*: low/mid/high chirp, tone bursts - *ABR-BIN*: binaural measurement	Sentiero *[SOH100360]*
	Determination of hearing status along the auditory pathway up to the brainstem in patients 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.	
E-ABR Electrically Evoked Auditory Brainstem Responses	Objective test for checking cochlear and neural sound processing with statistical response detection by means of recording electrically evoked potentials externally triggered by a cochlear implant test system (provided by the cochlear implant manufacturer).	Sentiero *[SOH100360]*
	Determination of hearing status along the auditory pathway up to the brainstem in patients of all age groups with a cochlear implant for audiological purposes including cochlear implant fitting.	
ECochG Electrocochleography	Objective test for checking cochlear and neural sound processing using short-term click stimuli and statistical response detection.	Sentiero *[SOH100360]*
	Determination of hearing status along the auditory pathway including summating potential (SP), action potential (AP) and cochlear microphonic (CM) in patients of all age groups for audiological purposes.	
ASSR Auditory Steady-State Responses	Objective test for checking cochlear and neural sound processing using frequency-specific chirp stimuli (cochlear travelling wave compensated), 40/80 Hz and mixed stimulus rates, multifrequency testing, contralateral masking, and statistical response detection. - *ASSR Fixed*: fixed user-defined stimulus levels - *ASSR Threshold*: threshold estimation with automatically controlled stimulus levels	Sentiero *[SOH100360]*

Test module	Short description / Clinical application	Devices
	Determination of hearing status along the auditory pathway up to the brainstem (80 Hz) and subcortical regions (40 Hz) in patients 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.	
VESTIBULAR EVOKED MYOGENIC POTENTIALS		
VEMP Vestibular Evoked Myogenic Potentials	Objective test for checking vestibular function using acoustic stimuli with a user-defined stimulus level, multiple stimulus types (click, chirp), air and bone conduction stimulation, and myogenic activity control. Myogenic potentials can be detected from the sternocleidomastoid muscle (cervical VEMP) or ocular muscle (ocular VEMP).	Sentiero *[SOH100360]*
	Determination of vestibular status including utricle and saccule function, specifically e.g., during Meniere`s disease, vestibular neuritis, vestibular schwannoma, multiple sclerosis, otosclerosis or superior semicircular canal dehiscence.	
IMMITTANCE AUDIOMETRY		
Tympanometry	Objective test for measuring middle ear impedance dependent on static pressure (+/-) in the outer ear canal.	Sentiero Desktop *[SOD100497]* Sentiero *[SOH100360]* + TY-MA *[100947]*
	Determination of middle ear status in patients 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 Threshold	Objective test for measuring ipsilateral and contralateral acoustic reflex elicited by tones with different levels and frequencies or noise. - Automatic mode (after performing tympanometry) - Manual mode	Sentiero Desktop *[SOD100497]* Sentiero *[SOH100360]* + TY-MA *[100947]*
	Determination of acoustic reflex thresholds in patients 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).	
Acoustic Reflex Decay	Objective test for measuring the decay of ipsilateral and contralateral acoustic reflexes elicited by tones with different levels and frequencies or noise.	Sentiero Desktop *[SOD100497]* Sentiero *[SOH100360]* + TY-MA *[100947]*
	Determination of acoustic reflex decay in patients of all age groups for audiological purposes, e.g., detection of retro-cochlear pathologies.	

Test module	Short description / Clinical application	Devices
ETF Eustachian Tube Function Tests	Objective impedance audiometry tests with multiple subtests: non-perforated eardrum, perforated eardrum, patulous Eustachian tube.	Sentiero Desktop *[SOD100497]* Sentiero *[SOH100360]* + TY-MA *[100947]*
	Determination of Eustachian tube function at different test conditions (non-perforated eardrum, perforated eardrum, patulous Eustachian tube)	
[1] only available for Senti [model SIH100097] and Sentiero [model SIH100098] devices with extended 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 Audio), image-based pure-tone audiometry (MAGIC), speech tests (e.g., SUN, MATCH), and other psycho-acoustical test methods (e.g., MAUS, BASD). Physiological test methods comprise otoacoustic emissions (OAE), auditory brainstem responses (ABR), electrocochleography (ECochG), auditory steady-state responses (ASSR), vestibular evoked myogenic potentials (VEMP), 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 behavioral pure-tone thresholds is discussed. Additionally, 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 (especially when presenting low-level stimuli). 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 reliable AEP measurements an electromagnetically shielded booth should be used. A shielded electrode cable also reduces the impact of electromagnetic noise. Moreover, it is recommended to keep the electrode leads close to the patient's body and to carefully separate the electrode cable from the sound transducer cable.

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 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 patient. Please note that interpretative hints and recommended parameter settings are provided in this *How-To-Manual* on an informative basis only and do not give any hint towards diagnosis. It is up to the qualified examiner to analyze 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 behavioral tests which require patient feedback.

For all psycho-acoustical tests, the ability, willingness, and concentration of the patient to be tested are essential. Before performing any psycho-acoustical test procedure, the patient must be instructed about the task. The examiner must ensure that the patient has understood the task and is capable of performing the task. Always place the transducer on the patient's ears *after* instruction so that the patient'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 high 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 patients 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 disabled patients or other non-cooperative patients. For these patients it is recommended to apply physiological test methods.

3.1.1 Pure-Tone Audiometry (PTA)

METHODOLOGY

PTA is the most commonly used psycho-acoustic method for testing a patient'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 is delivered via an electro-mechanical bone conductor which is positioned on the forehead or mastoid of the patient 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 the bone conduction levels are within the normal range of hearing. If both air and bone conduction thresholds are out of the normal range a sensorineural (cochlear or retro-cochlear impairment) or mixed hearing loss is likely if the bone is still better than the air conduction levels. PTA can be used to assess the hearing status for tonal stimuli in cooperative patients who are able to perform the task, e.g., in clinics (conventional audiology, bed-side use, ambulances) and occupational health. In order 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 patients 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 patient. 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 patients must be tested with masking noise on the non-test ear in order to prevent sound going from the stimulated side over to the non-stimulated side and 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 contralateral 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 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 in both ears.

Automatic PTA assesses hearing thresholds following Békésy or Hughson-Westlake procedures. In contrast to the method of adjustment, for which the patient can vary the stimulus level until it is just audible, the patient can only control the direction in which the stimulus level varies. The patient 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 screening. The patient 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 but provides less information 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 -10 to 70 dB HL in compliance with 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 in compliance with IEC 60645-1 class 4 with extended frequency and level range.
- **PTA 3** for assessing AC and BC pure-tone thresholds in compliance with 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 (pure-tone, pulsed pure-tone, 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 *Audio* from the module selection screen. Select the preset that you would like to use. If necessary, change the parameters (e.g., audiometry protocol). If *Expert* mode is selected, the user interface appears as shown in *Figure 1*. Press the *settings* button ⑬ (PTA3 only) in order to select the transducer and its placement (AC, BC mastoid, BC forehead), select the stimulus type (pure-tone, pulsed pure-tone, warble tone), switch to uncomfortable loudness (UCL) mode, activate automatic testing, or activate the bilateral audiogram view (plot data from both ears in one audiogram graph). Please note that you can also switch transducers by pressing the *AC* button ③ which toggles from AC to BC (mastoid) to BC-F (forehead) if an AC and a BC transducer are connected.

For some patients (e.g., children) a pulsed pure-tone 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 patients with a tonal tinnitus, a pulsed pure-tone or warble tone may distinguish the stimulus from the tinnitus more efficiently. Enable masking mode if required by pressing the *masking* button ⑫ (see *METHODOLOGY*). Masking mode can be discontinued by pressing button ⑭.

Before the transducer is fitted and the test is started, the patient must be instructed about the task. The patient 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 patient 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 patient. 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 by pressing the *ear* button ⑪. The currently active ear is shown. 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 ⑧, level and/or masking level ⑦ (in masking mode masking level buttons are highlighted with a gray area) 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 (in *Figure 1*: stimulus level: 40 dB HL, masking level: -10 dB HL). For PTA-HF, the audiogram shifts to higher frequencies when moving the crosshairs beyond 8 kHz. In masking mode, either the stimulus level or the masking level or both levels locked together can be controlled. The locked mode can be activated by pressing the *lock* button ⑮. The stimulus level buttons can be configured in the device *Audio Preferences* (up arrow: decrease level, down arrow: increase level or vice versa). The stimulus can be presented as long as the *loudspeaker* button ⑨ 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 ⑥ by pressing the audiogram ⑤. The symbol can be toggled from *heard* to *not heard* to deleting the symbol. The test can be finished with the *stop* button ⑩.

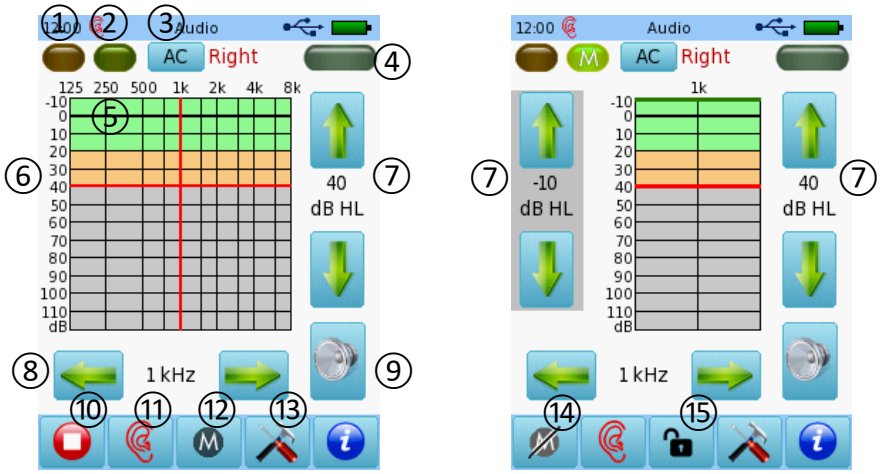

Figure 1: Audio Expert user interface (left: standard mode; right: masking mode)

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 and no response symbol representation can be configured in *Audio Preferences*.

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

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

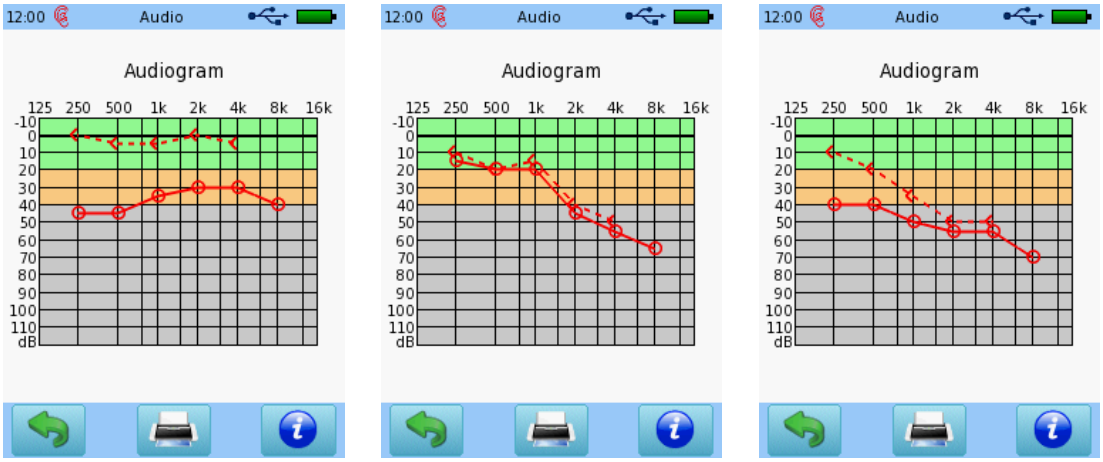

Figure 2: Audio result examples (left: conductive hearing loss; middle: sensorineural hearing loss; right: mixed hearing loss with conductive and sensorineural components)

Screen, *Diagnostic* and *Auto Audio* protocols provide adapted user interfaces as shown in *Figure 3*. The user interfaces of these protocols are in many parts similar to the *Expert* user interface. In the following the differences are explained. The *Screen* user interface provides a result table ① instead of an audiogram graph. The table contains either the tested level (heard) or *NR = no response* (not heard). The currently active frequency/level combination is highlighted in the result table. The *Auto Audio* user interface provides a *play* button ③ instead of the *loudspeaker* button, which allows starting the automatic threshold detection procedure. The patient's response, which is read from the patient response button, influences the direction of the stimulus level. If a threshold is detected by the automatic algorithm, it is automatically set in the audiogram graph. In all protocols, there is no *settings* and no *masking* button. Instead, in the footer you have direct access for changing the stimulus type (pure-tone, pulsed pure-tone, warble tone) by pressing the *stimulus type* button ②.

Figure 3: Audio user interfaces for different protocols (left: Screen; middle: Diagnostic; right: Auto Audio)

LITERATURE

- American Speech-Language-Hearing Association (2005): Guidelines for manual pure-tone threshold audiometry, online: http://www.asha.org/policy/GL2005-00014.htm
- IEC 60645-1: Electroacoustics – Audiometric equipment – Part 1: Equipment for pure-tone audiometry
- ISO 8253-1: Acoustics – Audiometric test methods – Part 1: Pure-tone air and bone conduction audiometry

3.1.2 Tinnitus-Matcher

METHODOLOGY

The American Tinnitus Association defines tinnitus as “the perception of sound when no actual external noise is present“. Tinnitus is usually subjective in that only the indiviual experiences hearing it, but can be objective in rare cases in that others can hear it as well. While it is commonly referred to as “ringing in the ears”, tinnitus can manifest many different perceptions of sound, including buzzing, hissing, whistling, swooshing, and clicking. In some rare cases, tinnitus patients report hearing music. The sound can be of high or low pitch and can be described as soft or loud. Tinnitus can be constant or intermittent. Although relatively rare, in some cases, tinnitus correlates with spontaneous otoacoustic emissions (SOAE).

While no cure for tinnitus is yet known, patients can be helped by getting the tinnitus defined more precisely than with just a standard audiometric evaluation.

Tinnitus is often caused by hearing loss or other underlying health conditions. Therefore, for those experiencing tinnitus, tinnitus matching is completed in addition to standard audiometry, which often includes pure tone and speech testing, loudness discomfort levels, acoustic immittance and otoacoustic emission evaluations. Tinnitus matching is often conducted along with tinnitus questionnaires to determine the impact that tinnitus has on the patient since tinnitus can negatively affect a person’s quality of life.

Tinnitus matching involves using different tones or noises to try to identify the patient’s specific perception of the tinnitus that they are experiencing. It involves adjusting the pitch and loudness (frequency and intensity) of a signal to allow the patient to determine as close as possible, a match to the subjective perceptions of the sound that they are hearing. Tinnitus matching is done to provide information useful for tinnitus management.

Loudness and pitch matching is conducted after the audiologic evaluation. As with standard audiometry, pitch matching is often started at 1000 Hz and the patient is asked to identify if their tinnitus is higher or lower than the signal presented. The goal is to bracket the pitch to within a half octave and finally to match the pitch of the tinnitus. At the pitch-matched frequency, hearing threshold and tinnitus loudness match are obtained in 1 dB steps. Initial loudness match is presenting the signal at 10-20 dB SL when normal hearing threshold levels are present and at 5-10 dB SL where hearing loss is present. Pure tones or narrow bands of noise can be used for the loudness and pitch matching.

The main differences of the Tinnitus Matcher to the PTA module are that the frequencies can be set with a high resolution of down to 0.1Hz with levels that can be set with a step size as small as 1 dB HL. In addition, both ears can be independently stimulated. Stimuli also include, in addition to pure tones, pulsed and warbled tones, and narrowband noise. Tinnitus Matcher supports the same range of air conduction transducers as PTA.

Another test that is often completed is the Octave Confusion Test. The goal is to confirm the octave of the patient's tinnitus. Patients with tinnitus sometime confuse the pitch of their tinnitus with a tone that is an octave above or below their tinnitus. The test is performed by presenting tones one octave above and one below the frequency that the patient selected during frequency matching.

In addition to loudness and pitch matching, the minimum masking level (MML) is found to make the tinnitus inaudible. A correlation between the MML and treatment efficancy has been identified in that when there was an improvement in the problem with their tinnitus there was a decrease in the MML (Jostreboff, Hazell & Graham, 1994). It has also been reported that when tinnitus masking is used as treatment, that if the MML is less than the loudness match, benefit is considered likely and conversely, if the MML is greater than the loudness match, the success is less likely (Vernon, Griest & Press, 1990; Vernon and Meikle, 2000).

The minimum masking level (MML) is measured by presenting a stimulus that is adjusted so that the tinnitus is not perceived anymore. The stimulus type must be selected to be able to mask the tinnitus, i.e., it must contain sufficient spectral components of the tinnitus (Vernon and Meikle,2003). Either pure-tones or noise can be used dependent on the spectral complexity of the tinnitus (AWMF guideline, 2021).

In addition to MML, residual inhibition is also measured. Residual inhibition is the temporary suppression or elimination of tinnitus that occurs following auditory stimulation (Vernon, 1982; Vernon & Meikle, 1988). Residual inhibition (RI) is measured by presenting a masking stimulus for 1 minute at a level of the MML + 10 dB HL. Different stimulus types may be used for RI including (amplitude-modulated) pure-tones or narrowband or broadband noise (e.g., white noise). The task for the patient is to indicate when the tinnitus perception is the same as before presenting the masking stimulus. The amount of time that this takes what is measured (Vernon and Meikle 2003). Complete RI describes the time period when the tinnitus perception is completely absent after the masking offset whereas partial RI describes the time period when the tinnitus is present but with reduced loudness/annoyance.

PRACTICAL USE

Select *Tinnitus-Matcher* from the module selection screen. Note that there are no presets available for this module. Make sure that a valid transducer is connected (headphone, insert earphones, or loudspeakers) and start the test by selecting the test ear (pressing LEFT or RIGHT). Before the transducer is fitted and the test is started, the patient must be instructed about the task. The patient shall identify if their tinnitus is higher or lower than the signal presented.

Select the test ear by pressing the *ear* button ①. The currently active ear is shown. During the test, stimulus frequency ②, level ③, stimulus presentation type ④ and frequency steps ⑤ can be selected. The selected levels can be read from the crosshairs in the audiogram (red: right ear, blue: left ear) and from the values between the selector elements (in Figure 4: stimulus level: 50 dB HL). The active ear can be switched, with its own stimulus parameters. To “copy” a setting to the other ear, use the swap ear function ⑥. The stimulus is presented if a *loudspeaker* button ⑦ is activated. If the stimulus is played, the corresponding test ear button is shown red or blue. This button can also be used as a tone on/off switch. Once a matching point is empirically found, set the symbol at the position of the red or blue crosshairs by pressing the audiogram. More than one point can be marked on the audiogram. The module can be finished with the *stop* button ⑧.

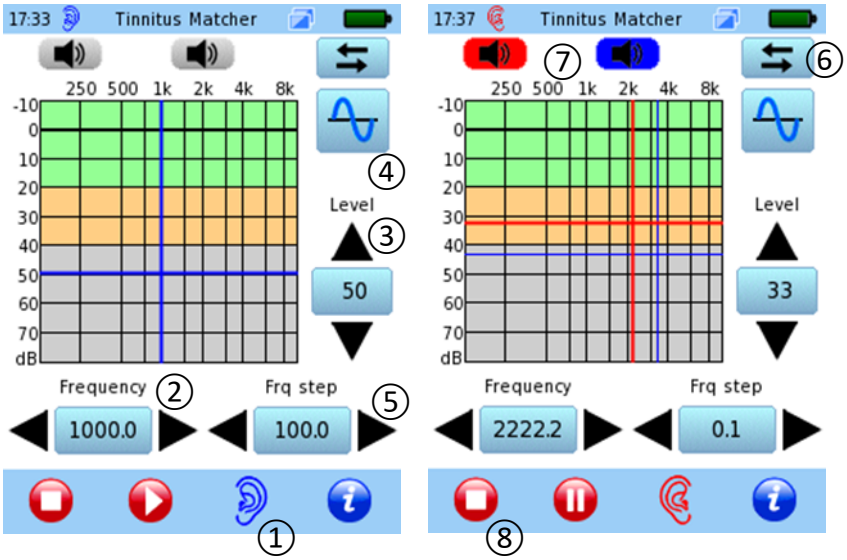

Figure 4: Tinnitus Matcher user interface (left: monaural, right:binaural)

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3.1.3 Multiple-Choice Auditory Graphical Interactive Check (MAGIC)

METHODOLOGY

Play-audiometry is a well-established method in pediatric audiology. However, the test procedure, in which the child must be continuously attentive, is exhausting, and the task (usually placing a peg in a pegboard) varies only slightly. 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 patients as well. Please note

that for patients 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 incorrect inputs of the patient.

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 – see *Figure 5*).

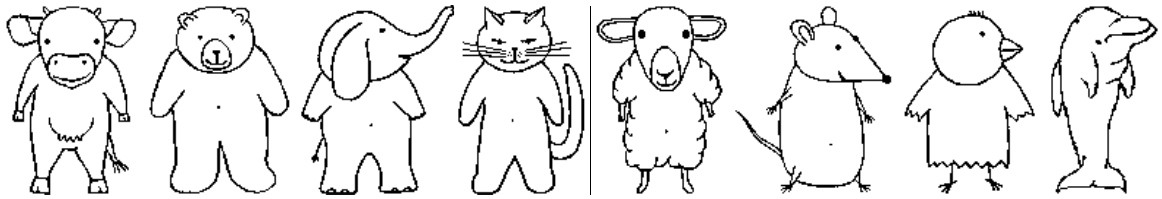

Figure 5: MAGIC animals (from left to right: cow, bear, elephant, cat, sheep, mouse, bird, and dolphin)

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 6*). The self-controlled workflow needs extensive explanation to the patient. An introductory story is recommended for explaining the task and for motivating the patient to be tested. The patient shall take the role of a doctor whose task is to diagnose healthy and sick animals based on whether or not they make a sound, respectively. This can also help to ease the pressure on the patient, because it is not him/her who is being diagnosed, but he/she will diagnose the animals' ability to produce sounds.

Via touch-screen the patient 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 patient 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 use. 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 patients (e.g., children) a warble tone may be more interesting than a pure-tone and hence may be preferred. Also, for patients 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 patient that his/her task is to be a doctor now. Some animals will produce a sound because they are healthy and happy (shown cheering with hands up) and some animals will not produce a sound because they are sick (shown wearing a scarf). The patient in the role as a doctor shall find out which animals are healthy and which are sick. To find out whether the animal produces a tone or not the neutral animal shall be pressed (see *Figure 6* - 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 determined by the device (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 patient to the situation that also no sound may occur.

Figure 6: MAGIC user interface (left: tone presentation and response; middle/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 website's *Learning* section.

Instruction of examiner	Task for examiner
Here you see an animal. Press the belly of the animal and you can hear if the animal makes a sound or not. The first animal makes a sound.	Show the patient how to press the belly of the neutral animal.
Press the animal's belly. Do you hear the sound?	Ask the patient to press the belly several times.
Each time you press the animal's belly it makes a sound.	The patient should notify that the sound is audible. If not a higher stimulus level needs to be selected (pressing *not heard*: stimulus level increases by 20 dB automatically). Repeat the instruction from the first step. Show the patient how to press the healthy animal corresponding to *heard*.

Instruction of examiner	Task for examiner
The next animal also makes a sound, but it is a quieter sound. Press the belly and listen.	The patient should hear this sound as well. Make sure that the patient presses the healthy animal corresponding to *heard*.
The next animal does not make a sound. You won't hear anything. Press the belly and listen.	The patient should notify that no sound is audible. If not, repeat the instruction. Show the patient how to press the sick animal corresponding to *not heard*.

Table 2: MAGIC instruction

After the instruction phase the test phase starts. Depending on age and physical/mental abilities, the test phase may be conducted completely self-controlled (i.e., patient 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 patient conducts the test appropriately. If there is any hint that the patient 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 (option in settings ⑤) (MAGIC Audio). Also a previous patient response can be undone when pressing the *undo* button ④ 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 patient's response is provided (see *Table 3*). For example, the header in *Figure 6* 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 patient. If you suspect that the patient might take advantage of the header information, turn off the current level information in the module settings (also possible during the test for MAGIC Audio via the *settings* button ⑤).

Stimulus	**Test phase**	**Current level**	**MAGIC mode:**	**Previous level**	**Response**
S: sine F: warble (FM tone)	I: Instruction M: Measurement	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 patient is allowed to select a new animal (see *Figure 6 - right*). The order in which the different animals are selected is up to the operator (i.e., tested patient or examiner).

After the test is finished, for MAGIC Screen the result is shown as a table (see *Figure 7*) with heard ④, not heard ⑥, and skipped/not tested ⑤ symbols. For MAGIC Audio, the result is shown as an audiogram. For MAGIC Audio it is possible to retest specific frequencies. A retest may be indicated if an incorrect response of the patient is shown. An incorrect response is represented by a "*?*" in the audiogram below the affected frequency. The number of incorrect responses is shown below the "*?*" ⑦. Another indication for retesting a frequency may be an outlier in the audiogram. In the MAGIC Audio result screen you can see test details by pressing in the audiogram the respective frequency.

The responses at the selected frequency are shown (in this case example: 25 dB HL: heard, 5 dB HL: not heard, 15 dB HL: heard, mute: not heard, 10 dB HL: heard; test run finished and threshold determined to be 10 dB HL). The gray line marks the minimum level configured in the module settings.

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

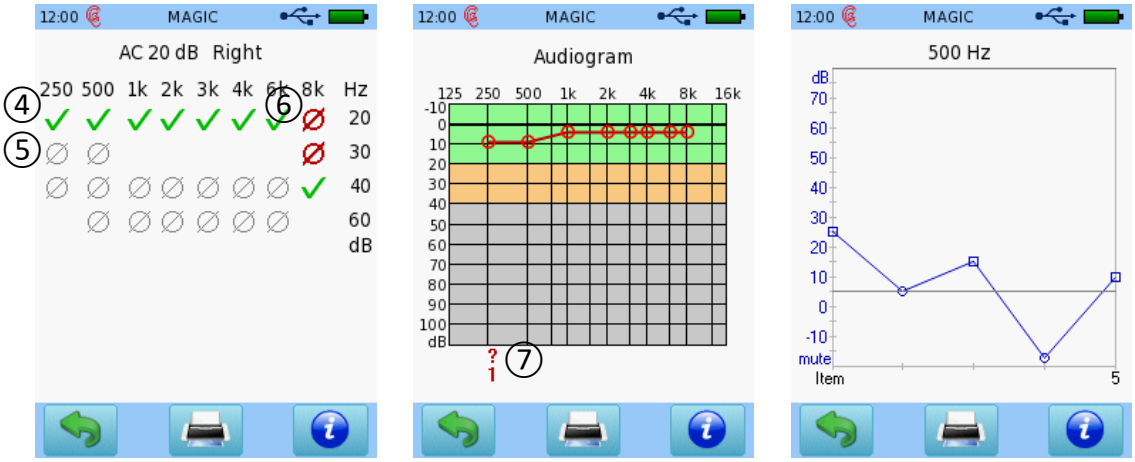

Figure 7: MAGIC result (left: MAGIC Screen; middle: MAGIC Audio; right: MAGIC Audio detail)

STUDY RESULTS

The feasibility and reliability of MAGIC was investigated in children in a multi-center 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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3.1.4 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. For example, consonants are presented within a nonsense vowel-consonant-vowel (VCV) word (e.g., SUN: aga, afa, asa) or vowels are presented in a CVC format, by using voiced plosive consonants, with the first and second consonant fixed (e.g., bid, bed, bad 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 repeated by the patient for each presented speech level, are displayed in the format of a speech audiogram. A specific value, e.g., hearing level 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 a central disorder should be considered.

Speech tests may be conducted with headphones, insert earphones, and loudspeakers. Loudspeakers are especially used when testing patients 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 patient with and without wearing the hearing aid. Compared to pure-tone audiometry, speech audiometry examines auditory processing on a higher cognitive level: not only hearing but also understanding.

Especially for speech tests with realistic words, word lists must be appropriate for the target patient and hence must consider the patient'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 in general should be provided in the patient's native language. If the above recommendations are 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 and MATCH, and the speech test platforms UST, Speech CD Player, and Live Speech which are explained in the following sections.

3.1.5 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 patients 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 patient has to select the correct item from the screen. Recordings are available with speakers of different languages (e.g., Italian, German, English[1]) and with different character representations (e.g., Latin, Greek, Farsi, Hindi, and 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 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 an incorrect answer. The noise level remains constant during the entire test. An additional question mark button is present which may be pressed if the patient did not understand the logatom. The test provides an SNR threshold as result.

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 patient.

Before starting the test, instruct the patient about the task. On the display, three different VCV options are visualized. However, a voice pronounces only one of them. The patient shall listen to a speech sample. After the speech sample is played, the patient is asked to press the button, which corresponds to the *word* that has been understood. If the word has not been understood the patient shall guess and press any button (SUN Predefined) or the patient may press the *question mark* button (SUN Adaptive) (see *Figure 8*). Make sure that the patient understands the task.

In order to accustom the patient 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 patient is familiar with the task.

[1] Please ask PATH MEDICAL for further information on available languages.

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., patient enters response) after instruction or with assistance of the examiner. Supervision by a qualified examiner is recommended at all times.

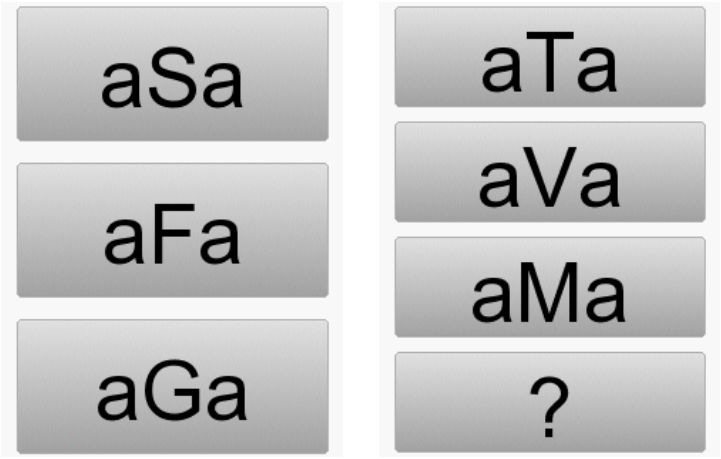

Figure 8: User interfaces for different SUN test modes (left: SUN Predefined; right: SUN Adaptive)

After the test is finished, for SUN Predefined the result is shown as a score with a traffic light status (see *Figure 9 - left*) or for SUN Adaptive as an SNR threshold together with a score and a traffic light status (see *Figure 9 - middle/right*).

Figure 9: SUN result (left: SUN Predefined; middle: SUN Adaptive with traffic light view; right: SUN Adaptive with SNR time course view)

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 which might be below normal range, red for hearing ability well below normal range. The limits between hearing range groups depend on the selected language.

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

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 patients 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 patients 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 two minutes on average for both ears. Even older adults typically managed to conduct the test within one minute per ear. This is deemed as an important factor for a hearing screening test because 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 patients considered the test to be easy or slightly difficult. 95 % of the patients judged the test duration to be short or fair. More than 90 % of the patients 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 patients. SUN was found to be very reliable with a good correlation 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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3.1.6 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 uses one- and two syllable words presented on image cards. Disadvantages of the Mainzer Kindersprachtest I 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 10*). Although the test is especially designed for children, it can be used for other cooperative patients 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 correspondence 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 patient does not need reading skills. The patient 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 patient does not need to guess but may press the "*?*" button. The sound presentation is started by pressing on a "magic box". After the patient 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 patient. 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 10: 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)

MATCH is also available with additional ipsilateral noise with a fixed noise level of 65 dB. 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 an incorrect 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 have been collected and presented by Bohnert *et al.* (2013), Zoth *et al.* (2013) and Schirkonyer *et al.* (2014). A more detailed explanation is available in the MATCH Quick Guide (100800-24).

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 patient[2]. 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 patient 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
The magic box may contain different things.	Show the patient how to press the box with the green question marks (see *Figure 11* - ①).
Press the magic box and listen carefully what is inside the box this time.	Ask the patient to press the magic box. Afterwards, the response alternatives appear (see *Figure 11* - ③).
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.	The patient shall notify if the word has been understood or not. Show the patient the green question mark button and show how to press the correct response image.

Table 4: MATCH instruction

[2] Please ask PATH MEDICAL for further information on available languages.

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 grayed out and no response is possible.

Figure 11: MATCH user interfaces (left: elicit stimulus; right: response alternatives)

In the header, information about the current test status including stimulus levels and patient's response is provided (see *Table 5*). For example, the header in *Figure 11* (right image) shows that the word is presented at 40 dB HL. The correct answer is at the bottom right image (door). One item has already been tested. The previous word has been correctly selected by the patient.

Speech level	Correct word	Number of items	Response
Value [dB HL] ④	Image position index ⑤: 0 2 1 3	Number of tested items ⑥	correct item selected incorrect item selected ⑦

Table 5: MATCH header information

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

Dependent on age and physical/mental abilities, the test may be conducted completely self-controlled (i.e., patient 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 patients 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 (see *Figure 12*) and for MATCH Adaptive the result is shown as a speech audiogram (estimated discrimination function) with a speech recognition threshold (see *Figure 13*). Additionally, the time course of speech level and reaction time as well as the test protocol are shown when pressing on the result screen. The test protocol shows a list of all presented words, the presented alternatives, and the patient's response. The time course

graph can help to evaluate the reliability of the test, whereas the test protocol may provide information on problems e.g., with discrimination of specific phonemes.

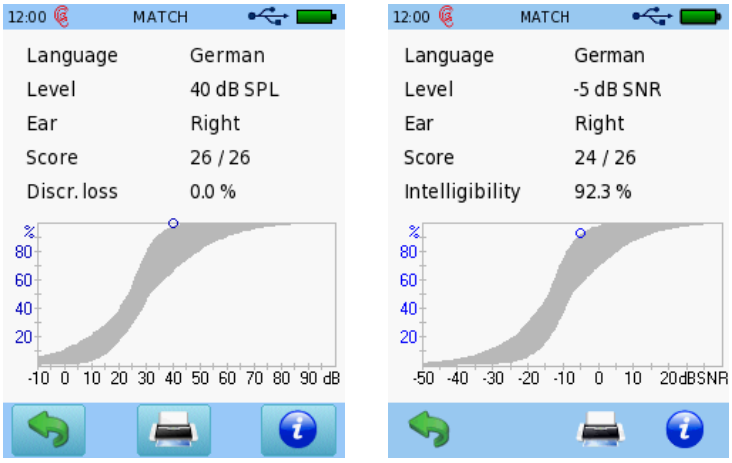

Figure 12: MATCH Fixed result (left: score in quiet; right: score in noise)

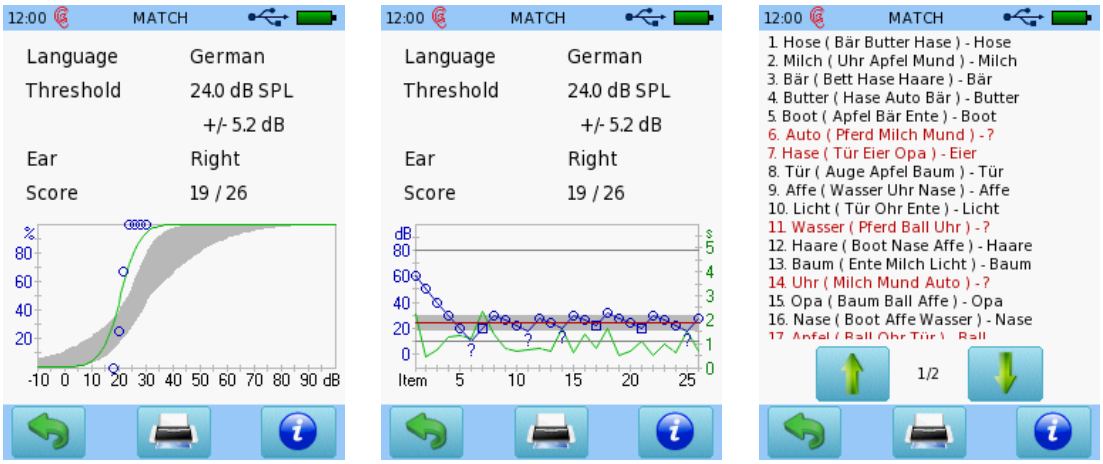

Figure 13: MATCH Adaptive in quiet result (left: speech audiogram and discrimination function; middle: time course of speech level (blue symbols) and reaction time (green line); right: test protocol with word selections)

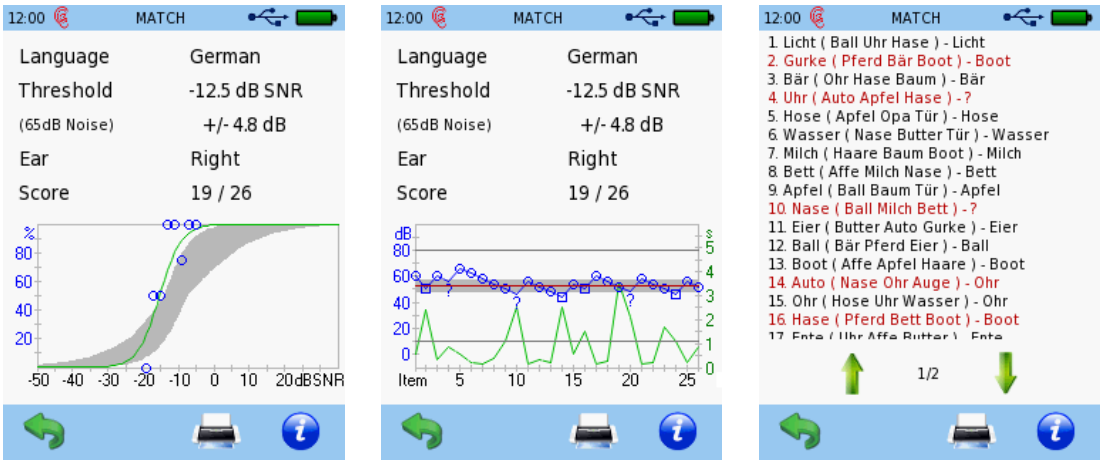

Figure 14: MATCH Adaptive in noise result (left: speech audiogram and discrimination function; middle: time course of speech level (blue symbols) and reaction time (green line); right: test protocol with word selections)

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 patients 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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3.1.7 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 patient 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 clinical application and target patient group depend on the speech material used. Typical speech material includes single syllable words, two syllable words/spondees, and two-digit numbers[3].

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 in such a way 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 subtests. 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 repeated 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 patient 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 patients, 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 patients 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 speech test is licensed, the respective UST subtest can be found in the *Speech* section. If necessary, change

[3] Please contact PATH MEDICAL for an overview of available speech tests under the UST framework.

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 subtest with language and word lists that are matching the tested patient'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 patient must be instructed about the task. During the voice hearing phase, the patient shall respond if a voice is heard or not. During the word understanding phase the patient 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 patient 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 patient.

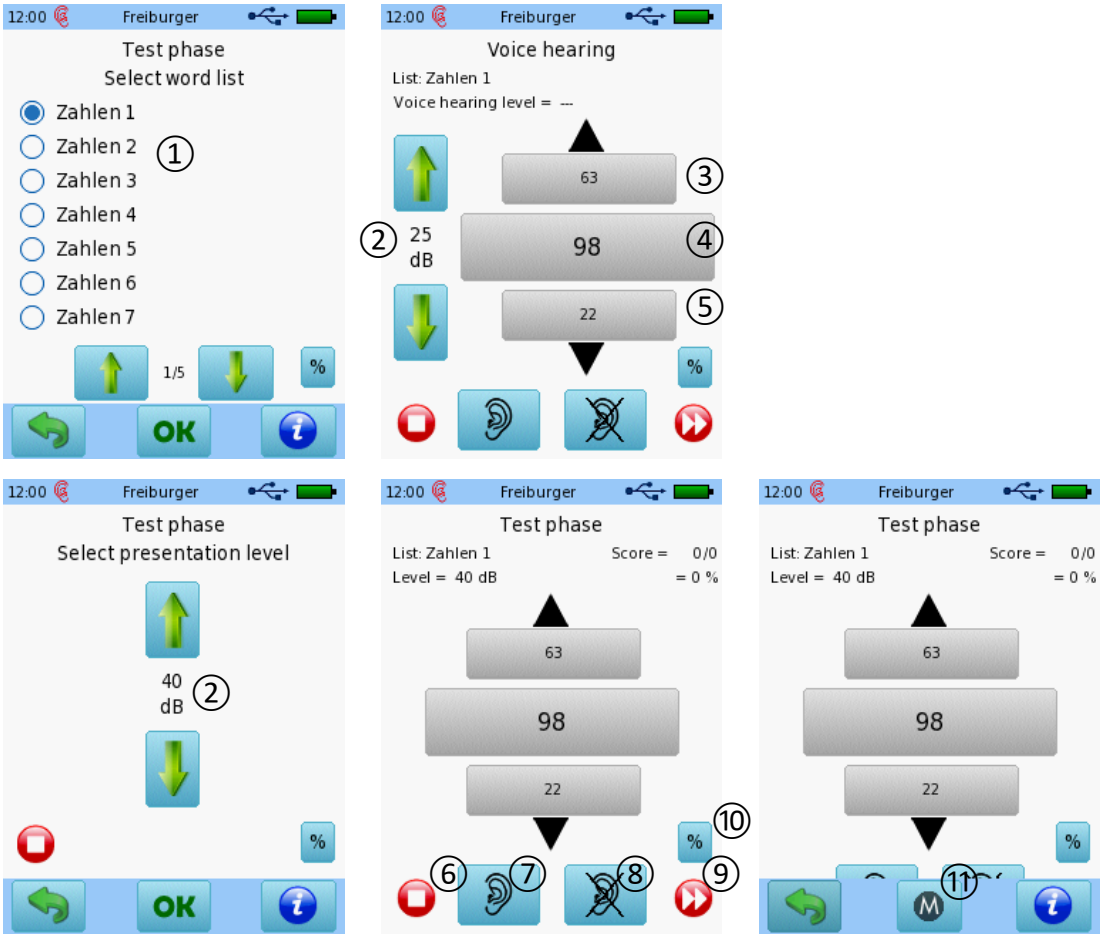

Figure 15: UST user interface (top left: word list selection; top right: main user interface during voice hearing phase; bottom left: level selection during test phase; bottom middle: main user interface during test phase; bottom right: main user interface with visible footer)

For each pre-test phase and during the test for each test run (i.e., for each tested speech level), a word list needs to be selected (see *Figure 15* - ①). Already selected word lists are grayed out but can be selected again. Make sure that previously presented words are not already known to the patient. Therefore, during the test phase, select for each test run (i.e., 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 large *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 patient has answered, enter the patient response (correctly repeated: ⑦, incorrectly repeated: ⑧). Already tested words are colored green (correctly repeated) or red (incorrectly repeated). 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. The current result screen can be displayed by pressing the *score* button ⑩. During the test masking can be turned on or off by pressing the *masking* button ⑪ in the footer.

After the test is finished, the result (see *Figure 16*) is shown as a graphical and tabular speech audiogram together with a 50 % speech recognition threshold. Toggle the views by pressing the result screen. There are specific result adaptations for specific tests (e.g., *Freiburger*: see *Figure 17*).

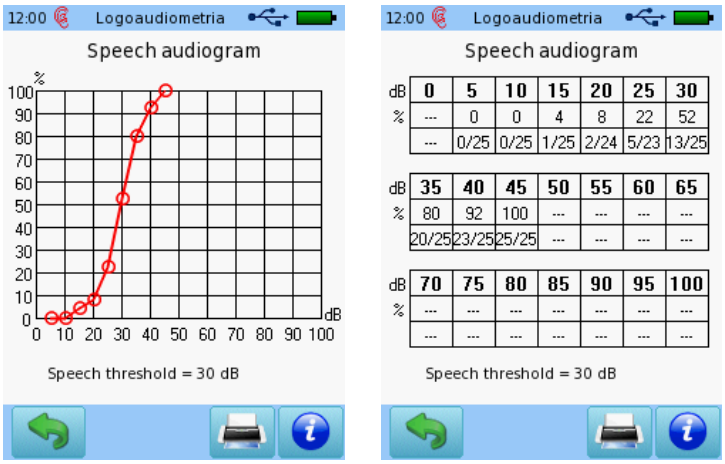

Figure 16: Typical UST result (left: speech audiogram graph; right: speech audiogram table)

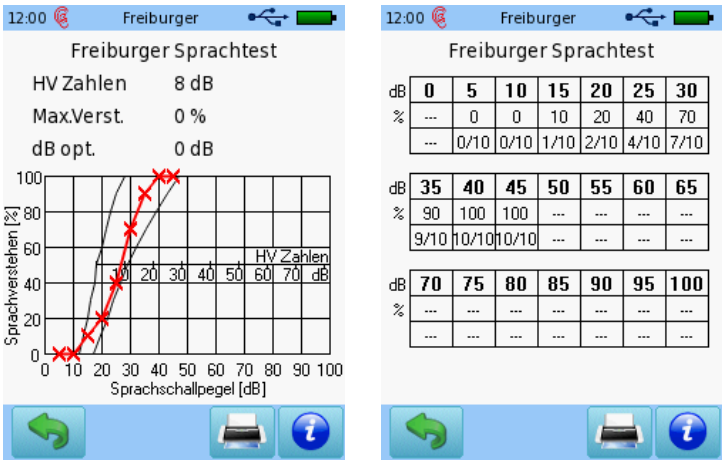

Figure 17: Specific Freiburger result (left: speech audiogram graph; right: speech audiogram table)

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

There are two adaptations of the basic UST procedure as described above for performing specific speech tests.

The first adaptation offers a user interface which allows presenting words from one or multiple word lists at different speech levels (see *Figure 18*) for a simplified determination of a speech threshold. This workflow is available e.g., for the *Spondees Children* or *Spondees Adult* speech tests. After selecting the word list ①, the user changes the speech level until a speech threshold is obtained. The determined speech threshold ③ is the level which is set by the examiner when finishing the test with the *stop* button ②.

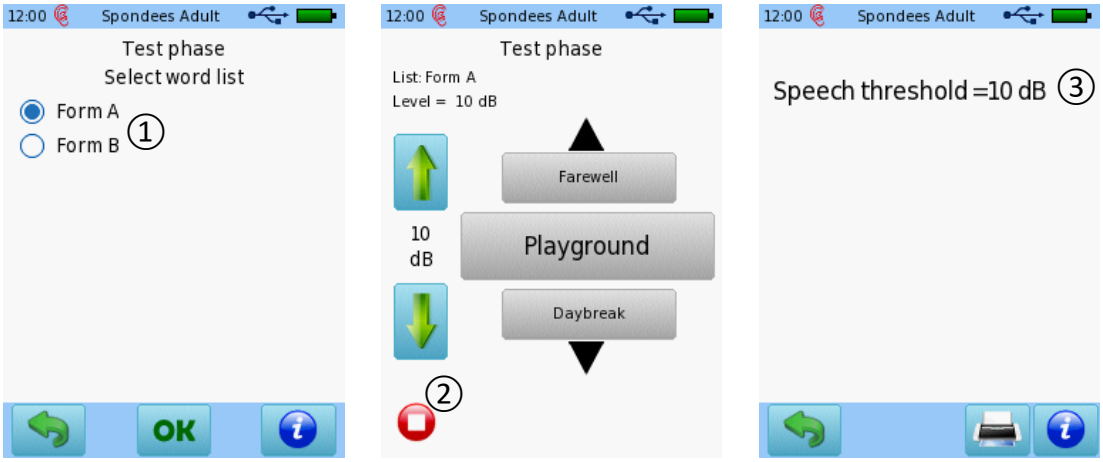

Figure 18: UST user interface adaptation for simplified determination of speech thresholds (left: list selection; middle: test with level selection for determination of the speech threshold; right: result view)

The second adaptation is similar to the standard UST procedure but provides level selection within the main test screen (and not between word list selection and test screen as for the standard UST procedure) so that the level can be changed while going through a single word list (see *Figure 19*). This workflow is available e.g., for the *NU-6*, *CID W-22*, *PBK-50*, *Maryland CNC*, and *Mots français CAD* speech tests. The test result is initially presented as a table but can be switched to a graph by pressing the result screen.

Figure 19: UST user interface adaptation for determination of speech thresholds with level control during testing a single list (left: list selection; middle: test with level selection and scoring; right: initial result view as table)

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3.1.8 Speech CD Player

METHODOLOGY

The Speech CD Player provides an alternative platform for speech tests which follow a typical workflow of presenting words organized in word lists that are grouped in a CD track at one or multiple speech levels. The test can be performed in quiet or in noise. Contralateral masking noise can be applied optionally. The Speech CD Player provides the ability to select a CD track and play the words from this track with start, stop, and pause functions. Scoring can be performed for each presented word. The clinical application and target patient group depend on the speech material used[4].

PRACTICAL USE

Select the Speech CD Player subtest from the module selection screen. If more than one speech test is licensed, the respective subtest can be found in the *Speech* section. Make sure to select a subtest with language and word lists that are matching the tested patient's language abilities. In the following the workflow is explained as an example for the Dutch NVA speech test (see *Figure 20*).

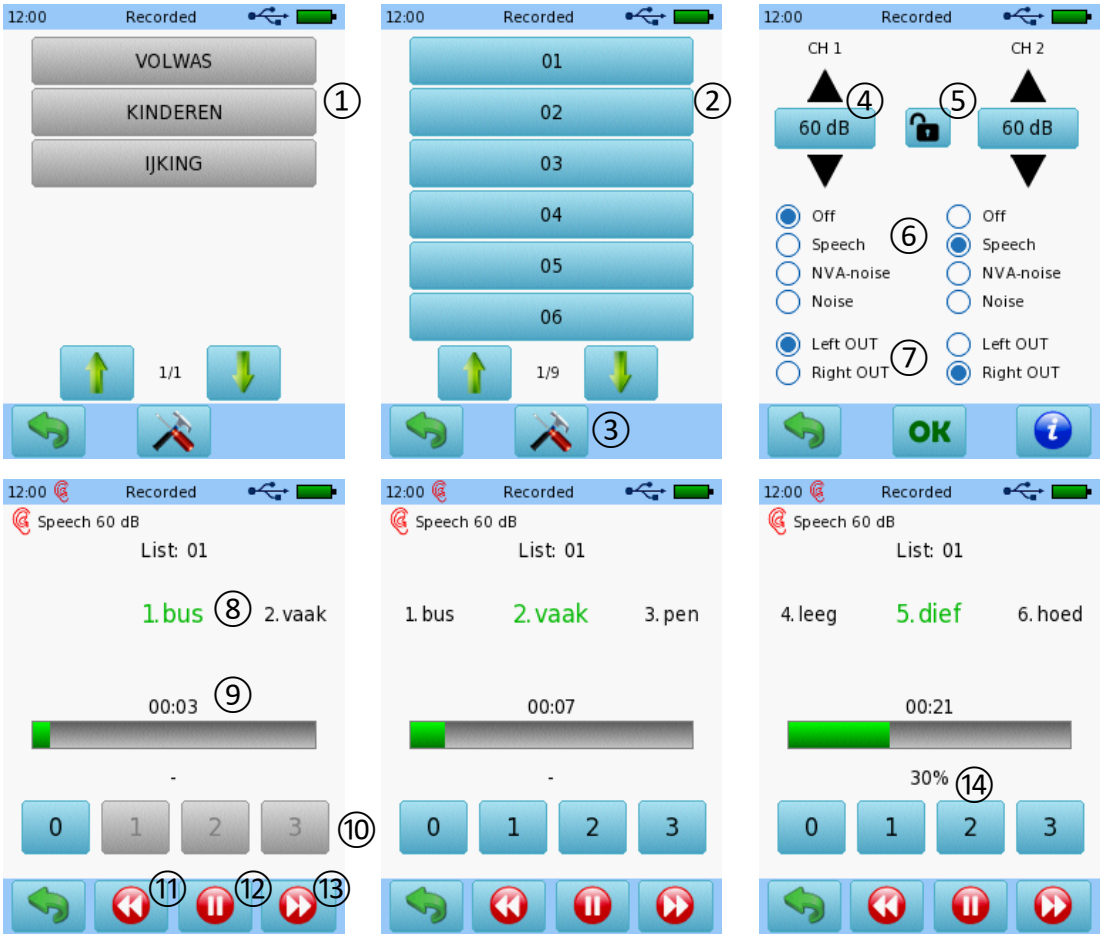

Figure 20: NVA user interface (top left: list selection; top middle: track selection; top right: stimulus output configuration; bottom left to right: test user interface at different times within a track)

[4] Please contact PATH MEDICAL for an overview of available speech tests under the Speech CD Player framework.

Make sure that a valid transducer is connected (headphone, insert earphones, or loudspeakers). Before starting the test, the patient must be instructed about the task. During the test, the patient shall repeat the word. The examiner needs to evaluate if the word has been understood correctly or not. Please note that the test must be conducted by a qualified and normal-hearing examiner. The examiner needs to control the stimulus playback if required and enter the response. The test is *not* intended to be self-controlled by the patient.

Initially, the appropriate speech material needs to be selected by the examiner. Each button ① selects a group of tracks from the CD (e.g., with words for different age groups). Afterwards, the respective track ② from the track group can be selected. In order to set up the stimulus output configuration, press the *settings* ③ button. In the settings menu, the user can configure the output for the two stimulus channels. For each channel, the speech level can be set by pressing the up/down buttons ④. If you wish to change both levels simultaneously you can lock the speech levels of channel 1 and 2 by pressing the *lock* button ⑤. For each channel, the stimulus type ⑥ and the ear side ⑦ can be configured. After the track selection, the test starts automatically by playing the words from the chosen track as the CD is running. During the test, the currently played word ⑧ and the elapsed time are displayed. As soon as activated, at any time the *scoring* buttons ⑩ may be pressed (for NVA to score the number of correct phonemes). The presentation can be interrupted by pressing the *pause* button ⑫. If you wish to repeat the current word or proceed to the next word press the *back* ⑪ or *forward* ⑬ buttons. By pressing the *back* button twice you can rewind to the previous word. The score ⑭ is displayed according to the user input. At the end of a track, a single data point for the speech audiogram is stored. When leaving the test the result screen is shown as a graphical and tabular speech audiogram together with a 50 % speech recognition threshold and a maximum score (see *Figure 21*). Toggle between the views by pressing the graph / table.

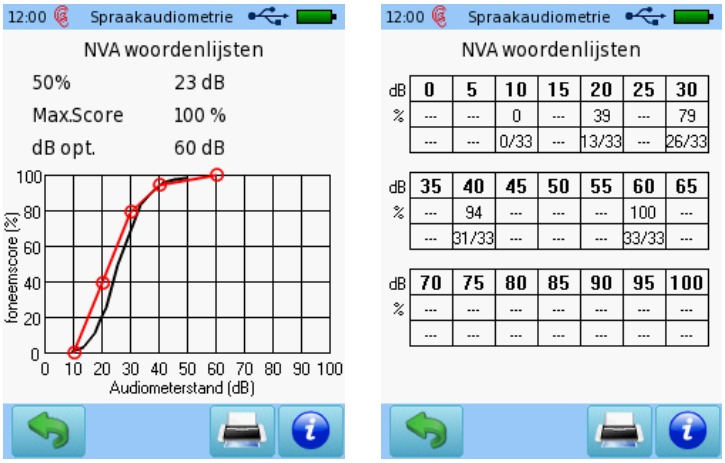

Figure 21: NVA result (left: speech audiogram graph; right: speech audiogram table)

3.1.9 Live Speech

METHODOLOGY

The Live Speech module provides a basic platform for speech tests with live speech presented by the examiner via microphone. The output level can be balanced by means of a volume unit (VU) meter. The user is responsible for the correct selection, pronunciation and balancing of the words as well as for the result evaluation. In general, there are known deficits of this method related to reproducibility across presentations (e.g., due to varying pitch, voice quality, speed of production of words by the examiner). The Live Speech module offers three modes: Speech Detection Threshold (SDT), Speech Recognition Threshold (SRT), and Word Recognition (WR).

The speech recognition threshold or speech reception threshold is the minimum speech level at which the patient recognizes 50 % of the speech material. Recognition means that the patient can reproduce the presented speech material correctly (either by repeating the presented speech material or by selecting the test item from a closed set of choices). The speech detection threshold or speech awareness threshold is the minimum speech level at which the patient is able to notice the presence of speech 50 % of the time. The patient does not need to identify the presented material as speech but must indicate awareness of the presence of sound. Word recognition threshold is determined by setting presentation at a fixed level above the speech detection threshold (can be altered to obtain the best score possible) and obtaining a percentage correct score.

The clinical application of Live Speech is the determination of speech recognition or detection thresholds in quiet in cooperative patients for audiological diagnostics. The clinical application and intended patient target group depend on the applied speech material.

PRACTICAL USE

Select the *Live* speech module from the module selection screen. If more than one speech test is licensed, the respective speech module can be found in the *Speech* section.

Make sure that a valid transducer is connected (headphone or insert earphones). Before starting the test, the patient must be instructed about the task. During the test, the patient shall repeat the presented test item (SRT, WR) or indicate that a sound has been detected (SDT). The examiner needs to evaluate if the presented test item has been understood correctly (SRT, WR). Please note that the test must be conducted by a qualified and normal-hearing examiner. The examiner needs to produce live speech and enter the response. The test is *not* intended to be self-controlled by the patient.

The *Live* speech module provides several options for configuring the test (see *Figure 22*). First, please select the test mode (SDT: Speech Detection Threshold, SRT: Speech Recognition Threshold, WR: Word Recognition) by pressing the *test mode* button ② until the favored test mode appears. The test ear (right, left, both) can be selected by pressing the respective *ear* checkboxes ①.

Before starting the live speech presentation, the microphone input level may need to be adjusted: make sure that the *input/output* button ⑧ shows *MIC*. If necessary, turn on the microphone by pressing the *microphone on/off* button ⑦ and speak into the microphone with a speech intensity that you will use for the live speech presentation. Adjust the microphone input with the *level* buttons ④ so that the VU meter indicator ③ settles close to 0 and does not continuously reach the red area. Press the *level up* button to increase and the *level down* button to decrease the sensitivity of the

microphone. You may skip the microphone level adjustment procedure if your speech intensity is appropriate for the given microphone level setting. If the microphone level is correct you can proceed with setting the speech level: press the *input/output* button ⑧ to show the headphone icon and use the *level* buttons ④ to change the speech level as needed.

Figure 22: Live Speech user interface (left: SDT user interface with microphone turned off; middle: SDT user interface with microphone turned on and microphone level adjustment; right: WR user interface after accepting the determined threshold)

During the test, make sure that when you speak into the microphone the VU meter indicator mainly remains in the blue area close to zero. If the indicator continuously reaches the red area during the presentation of live speech, please adjust the microphone level as described above. During SDT or SRT mode the speech level needs to be adjusted by the examiner until the respective threshold is determined. In WR mode, correct and incorrect answers can be additionally counted by pressing the *OK* ⑨ or *not OK* button ⑪, respectively. The score and percentage are displayed ⑩. Please note that these values are not remembered when changing the speech level. If the speech threshold has been determined, press the *accept threshold* button ⑤. The currently selected speech level and for WR also the score are taken over and displayed in the *test mode* button ②. Press the stop button ⑥ to finish the test. Results of all three modes are saved. The result screen shows a speech audiogram including the word recognition score and the determined speech detection and recognition threshold (see Figure 23).

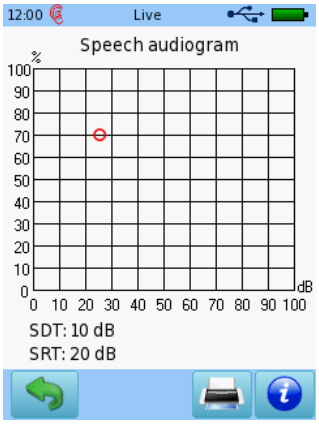

Figure 23: Live Speech result (with word recognition score in speech audiogram, speech detection threshold and speech recognition threshold)

3.1.10 Munich Auditory Screening Test for Processing Disorders (MAUS)

METHODOLOGY

MAUS is a German screening test for identifying patients with 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 patients 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 subtests: sequence of syllables, words in noise, and phoneme differentiation and identification. These subtests allow for maximum sensitivity for detecting APD (see section *STUDY RESULTS*). The sequence of syllables subtest includes 18 items with six three-syllable-words (e.g., muwage = mu-wa-ge), six four-syllable-words and six five-syllable-words. All items are meaningless words. The occurrence of vowels and consonants noticeable for patients with ADP is balanced. The word in noise test includes 12 items per ear with speech-simulating ipsilateral noise. In contrast to the other subtests, 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.*, 2004).

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 subtest and proceeds to the subtests words in noise and phoneme differentiation and identification (see *Figure 24*). For each subtest, instruct the patient about the tasks as described in *Table 6*. The instructions are also displayed on the device screen before the subtest starts.

Instruction of examiner	**Task for examiner**
Subtest 1: Sequence of syllables	
You will hear magic words. Listen carefully and repeat what you heard.	
Subtest 2: Words in noise	
Now you will hear words while there is noise. Listen carefully and repeat what you heard.	
Subtest 3: Phoneme differentiation and identification	
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? *[if correct:] Great.*	Wait for patient's response and check if the patient understands the task for similar syllables.

[if wrong:] Listen carefully again, I will tell you the words once more… [repeat instruction]	
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? *[if correct:] Great.* *[if wrong:] Listen carefully again… [repeat instruction]*	Wait for patient's response and check if the patient understands the task for different syllables.

Table 6: MAUS instruction

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

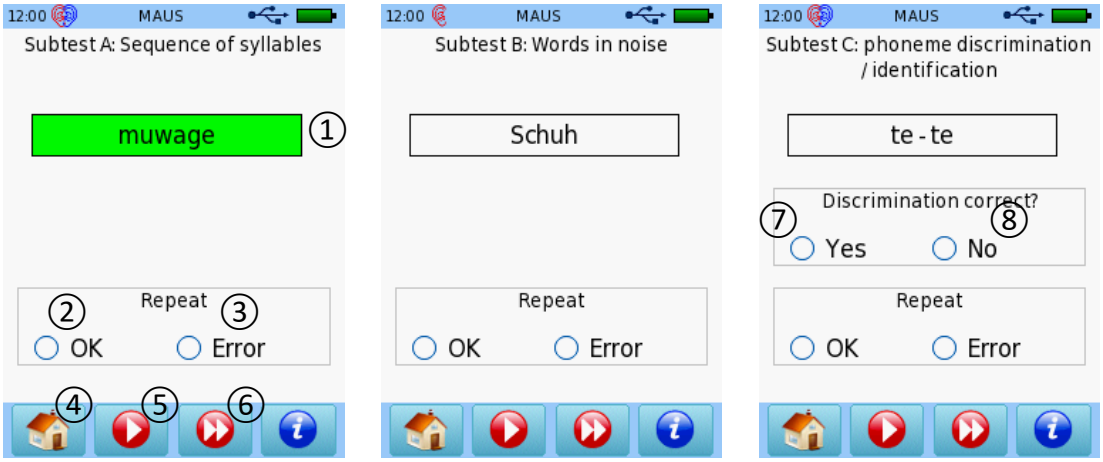

Figure 24: MAUS user interface for the different subtests (left: sequence of syllables; middle: words in noise; right: phoneme discrimination and identification)

The current test item is displayed in a box on the screen ①. The box containing the test item is highlighted green as long as the test item is presented. The response status can be entered by selecting the *OK* (correctly repeated) ② or the *Error* (incorrectly repeated) ③ radio button. For subtest phoneme discrimination and identification additionally the correctness of the discrimination must be entered (Yes: correctly discriminated ⑦; No: incorrectly discriminated ⑧). The initial test item for each subtest is played automatically. After the response status is entered, the next test item can be started by pressing the *play* ⑤ button. You can cancel the current subtest and proceed with the next subtest by pressing the *forward* button ⑥. The test can be stopped by pressing the *home* button ④.

The result shows a list of scores with color code (see *Figure 25*). 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 colored areas (<30: extremely substandard, 30-40: substandard, 41-60: normal, 61-70: surpassing, >70 extremely 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-pedaudiologic diagnostics, objective audiometric diagnostics as e.g., ABR) is advised.

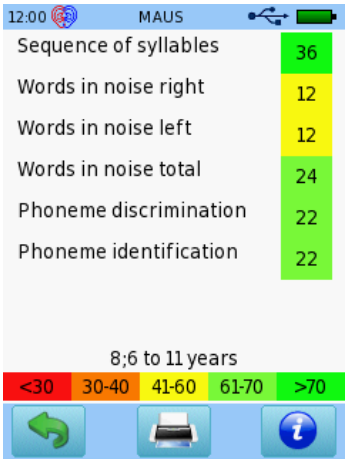

Figure 25: MAUS result

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 patients was analyzed. 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 subtests and the other test methods was examined and amounted to r = 0.78 (MAUS: sequence of syllables ↔ Mottier test), r = 0.51 (MAUS: words in noise ↔ speech audiometry in noise), r = 0.76 (MAUS: phoneme differentiation ↔ HLAD: sound differentiation) and r = 0.81 (MAUS: phoneme identification ↔ HLAD: sound identification). All correlations were highly significant. The agreement rate of APD screening results was compared between the MAUS subtests and the other test methods and amounted to 71 % (MAUS: sequence of syllables ↔ Mottier test), 75 % (MAUS: words in noise ↔ speech audiometry in noise), 73 % (MAUS: phoneme differentiation ↔ HLAD: sound differentiation), and 87 % (MAUS: phoneme identification ↔ 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 subtests ranging from r = 0.64 (sequence of syllables) to r = 0.75 (phoneme differentiation).

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3.1.11 Bochum Auditory Speech Discrimination Test (BASD)

METHODOLOGY

The Bochum 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, duration, and amplitude modulation 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 patients. 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 immediate feedback to the tested patient 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 differences 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. For the amplitude modulation subtest the reference modulation frequency is 20 Hz. The deviating tone has a modulation frequency of 20 Hz + x Hz with x varying from 0 to 80. 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 subtests, initial difference for level, frequency, and duration, number of trials and reversals) as required. Select the subtest.

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 subtest 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 patient 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, duration or amplitude modulation. The two identical stimuli shall be indicated by the patient by uncovering the corresponding two cards.

Depending on age and physical/mental abilities, the test may be conducted completely self-controlled (i.e., patient 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 26*). The stimulus can be elicited by pressing the *play* button ②. The stimulus presentation can be repeated by pressing the *play* button again. The patient 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, amplitude modulation). 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 regarding 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.

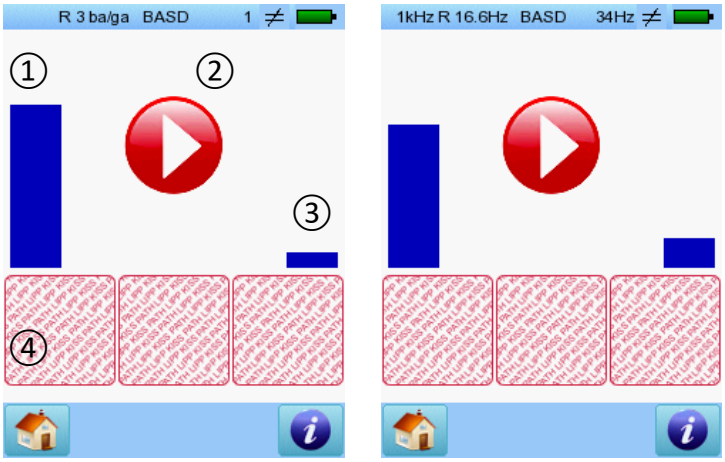

Figure 26: BASD user interface (left: ba/ga differentiation; right: frequency differentiation)

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, otherwise position of different item	ba/ga or ga/ka not available for tonal tests	Difference value for tonal tests, otherwise position of not pressed item	≠ correct (difference could be detected) = incorrect

Table 7: BASD header information

For example, the left screenshot from *Figure 26* 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 subtest 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 26* 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.

BASD results are shown as a score for consonant tests and as a discrimination threshold for tonal tests (see *Figure 27*). For tonal tests, the time course of the responses can be displayed by pressing the result screen. Preliminary normative data is available (see *STUDY RESULTS*).

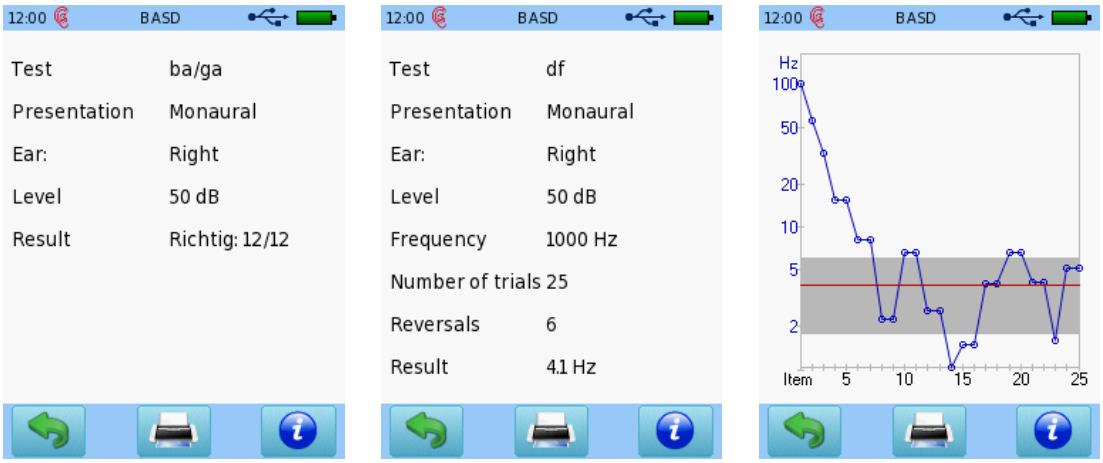

Figure 27: BASD result (left: ba/ga differentiation; middle, right: frequency differentiation result data and time course)

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 prominently, 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 subtests 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 Colored 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 subtest 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 subtests and expert classification was significant for the subtests 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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3.1.12 Hearing Handicap Inventory for the Elderly (HHIE-S)

METHODOLOGY

In screening questionnaires, patients are asked to rate their hearing status by answering one or more specific questions. The HHIE questionnaire was developed and standardized 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. 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 patient'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 patients as well. Please note that the test is a self-assessment test and therefore depends on the patient's cooperation and ability to responds 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 patient about the task: a number of questions from daily life situations are posed (see *Figure 28* left). The patient 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). The result is shown as score with a traffic light status (see *Figure 28* right).

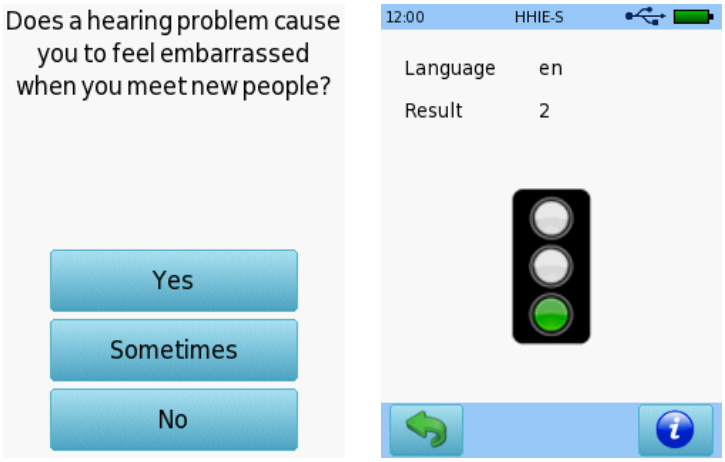

Figure 28: HHIE-S user interface (left) and result (right)

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

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), vestibular evoked myogenic potentials (VEMP), acoustic immittance tests (tympanometry), and other tests that rely on the measurement of physiological properties.

Physiological test procedures (except VEMP) do not require active participation of the tested patient during the test. In contrast to psycho-acoustical tests, the ability and willingness of the patient to cooperate only play a subordinate role. Nevertheless, some cooperation is necessary. This may include (depending on the test procedure) that the patient 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 patients that are not able or not willing to perform a psycho-acoustical task, i.e., patients who are too young or otherwise incapable of responding behaviorally. This may be neonates and small children, mentally or physically disabled patients, or people simulating a hearing loss. The examiner must ensure that the patient is capable of fulfilling the respective prerequisites (e.g., being quiet during the test). Also, older patients should be informed about the test procedure, so that they know what to expect during the test. This may positively contribute to patient relaxation. VEMP requires active patient participation as the tested patient must perform a specific muscle contraction (head movement, gaze in specific direction) and is therefore only applicable in patients who are able and willing to perform the required task.

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

Physiological test procedures (except VEMP) 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 reportedly 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 conduction 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. In addition, VEMP can be used to assess the status of the vestibular system.

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 patients 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 usually higher compared to that in adults (Norton, 1992; Lasky, 1998a,b; Abdala, 2000). As a consequence, OAEs in newborns are easier to measure.

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 patients 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. For more information on SOAEs, please refer to section *3.2.2: Spontaneous Otoacoustic Emissions (SOAEs).*

Evoked OAEs are triggered by external sounds, either by transient (clicks or tone bursts) or stationary stimuli (sine 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 29*). 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 *3.2.3: Transient Evoked Otoacoustic Emissions (TEOAEs).*

Distortion product otoacoustic emissions (DPOAE) are elicited by two sine tones with a specific frequency and level ratio (see *Figure 29*). 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 DPOAEs, please refer to section *3.2.4: Distortion Product Otoacoustic Emissions (DPOAEs)*.

Sentiero devices provide SOAE, TEOAE and DPOAE test procedures. TEOAEs and DPOAEs are present in essentially every normal-hearing patient. 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 OAEs. 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), 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 brainstem 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. The test method 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 or 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 patients 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 proceeding with 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, OAE measurements are also limited towards higher frequencies with increasing variability of OAE levels (Dreisbach *et al.*, 2006). 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 patient 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 as 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 allow 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., quantization 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 29*). For DPOAE recording, separate loudspeakers are commonly used for each primary tone in order to exclude technically generated distortion components.

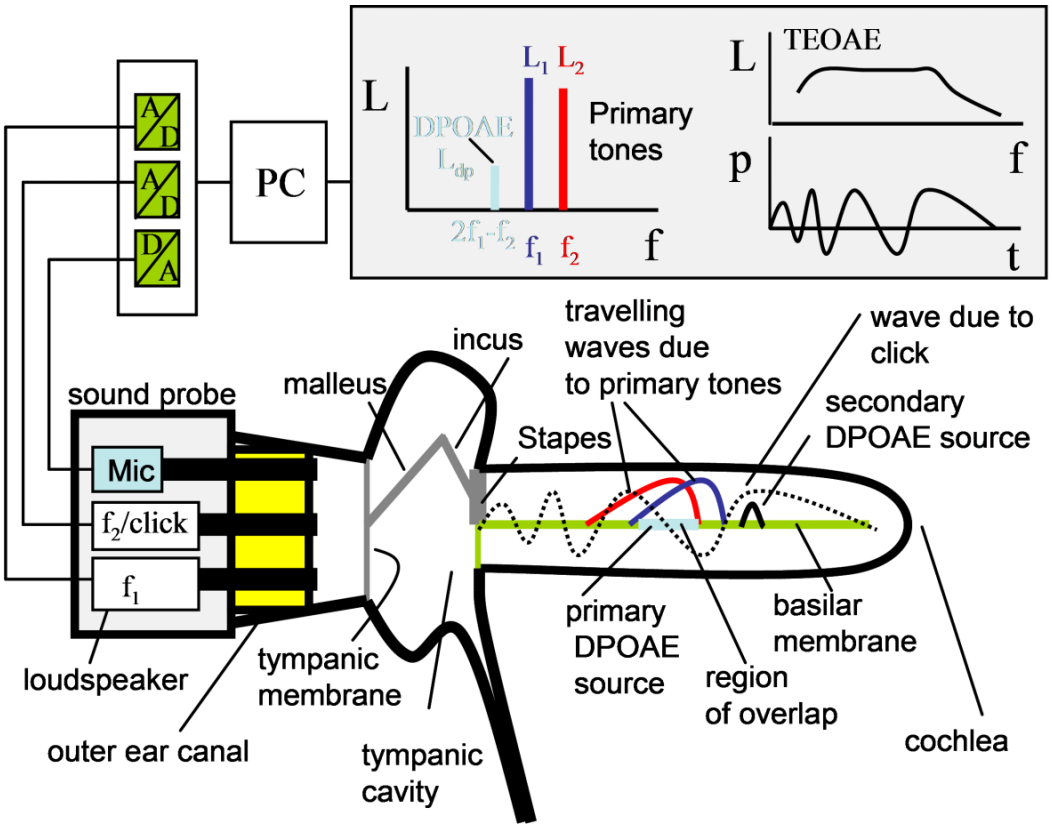

Figure 29: Schematic overview of TEOAE and DPOAE measurement (A/D = Analog-Digital-Converter, D/A = Digital-Analog-Converter, PC = Personal Computer, L = sound pressure level, p = sound pressure, f = frequency, t = time)

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 for example 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 (e.g., if the ear probe is frequently used: once a day before starting to test patients or if any failure of the ear probe is suspected). 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 PT-S fits into blue test cavity, large probe tip PT-A fits into red test cavity). Start the probe test (see *Figure 30*) 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 or probe tip and/or contact your distributor.

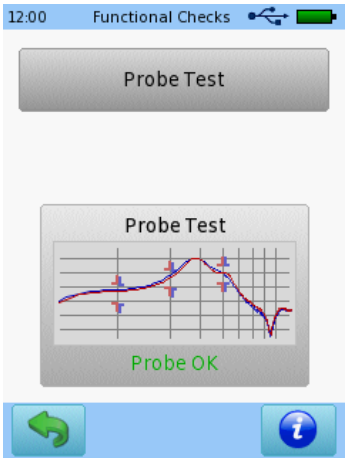

Figure 30: Probe test

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3.2.2 Spontaneous Otoacoustic Emissions (SOAEs)

METHODOLOGY

Spontaneous Otoacoustic emissions (SOAE) are sounds that can be recorded in the ear canal, using a probe microphone, in the absence of acoustic stimulation. Like all OAEs, SOAE are thought to be generated by the outer hair cells of the cochlea and can be seen as a side effect of the cochlear amplifier.

SOAEs are reportedly present from approximately 40% to upwards of 80% patients depending on age, presence or absence of hearing loss and measurement system used (Dhar & Hall, 2012). They are very stable pure tones-like signals, typically in a range from 500 Hz to 4 kHz, and more rarely up to 8 kHz. They are more commonly found in the right ear and in females. There is some evidence that infants have a higher prevalence of SOAEs than children and young adults (Prieve & Hula, 1999). In addition, to prevalence, there is also evidence that adult and infant SOAEs are found at different frequencies (Bright, 1997; Prieve & Hula, 1999)

Clinical use of SOAE is more limited than evoked otoacoustic emissions because they are not present in all ears, and there is variability in the frequency and amplitude of the recorded SOAE between individuals, although they are stable in frequency within an individual. When present, they are thought to support normal hearing levels in the frequency region of the SOAE frequency with no more than 25 dB HL hearing levels. In addition, in some ears SOAE correlates to tinnitus and may be used to augment tinnitus matching procedure.

PRACTICAL USE

Select OAE, then SOAE from the module selection screen. Note that no presets are available for this module. The patient should be calm and sitting comfortably in a chair or lying on a bed. For babies, try to test the patient during sleep. Make sure that a valid ear probe (e.g., EP-TE, EP-DP or EP-LT) 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 patient'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 when two ear probes are connected). After the selection the test will start running and performing the statistics over the spectrum. A dB(A) indication of the current overall sound level, as recorded by the probe microphones, is shown on top of the display. Values below 30 dB(A) are desirable.

The implementation of the SOAE applies a phase locked loop (PLL) to each SOAE candidate to achieve a precise frequency reading, allowing a 0.1 Hz resolution.

The use of ear muffs over the probes when recording SOAE is strongly suggested, since the method is very sensitive to external noise. Not only will external noise hinder recording of SOAE, but tonal components in the external noise will also be recorded as SOAE. Moreover, SOAE themselves are suppressed by noise. It is recommended to record SOAE binaurally, since a detection that appears on both ears is a strong indication that it is not a SOAE signal but a tonal ambient noise component.

If SOAE are present, a detection shall not take longer than about 5 minutes.

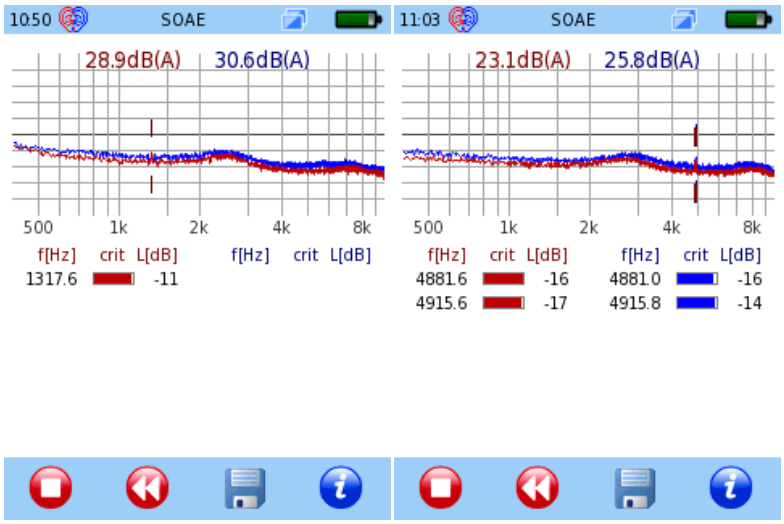

Figure 31: SOAE interface (left: SOAE detected at 1317 Hz and -11 dB(SPL); right: false SOAE detection from tonal ambient noise components - matching frequencies from both ears)

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3.2.3 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 29*). 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 overlooked 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 and at different stimulus levels. User-definable criteria can be set, i.e., SNR criteria (6 or 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 that you would like to perform from the module selection screen, 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 the selection of SNR and pass criteria influence the overall test result, i.e., different settings may result in different overall results. The stricter the selected criteria, the more prominent the TEOAE response must be yielding a valid result. The criteria are saved together with the result data and cannot be changed afterwards.

The patient should be calm and sitting comfortably in a chair or lying on a bed. For babies, try to test the patient during sleep. Make sure that a valid ear probe (e.g., EP-TE, EP-DP or EP-LT) 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 patient'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 when two ear probes are connected). Before the measurement starts, the calibration screen is shown (see

Figure 32). In *expert* calibration view mode (configuration in *TEOAE Preferences*), during calibration the parameters stimulus level, symmetry between both channels (not for one channel ear probe EP-TE), and leakage are checked (green check mark: ok, gray Ø: not ok) ①. If the stimulus and symmetry criteria pass but the leak check does not pass, after a while the calibration can be skipped with the *forward* button ②. If all three criteria are met, the calibration graph turns green. In *simple* calibration view mode (configuration in *TEOAE Preferences*), during calibration a traffic light status is shown. As long as not all calibration criteria are met, the traffic light remains red or yellow. If all criteria are met, the traffic light turns green. After successful ear probe calibration, the measurement starts automatically.

Figure 32: TEOAE ear probe calibration (top left: expert mode monaural; top middle: expert mode monaural with skip option; top right: expert mode binaural; bottom left/middle: simple mode monaural; bottom right: simple mode binaural)

A non-linear broadband click stimulus sequence is presented for TEOAE Quick at a fixed level (85 dB peSPL) and for TEOAE Diagnostic at a user-defined level. The response is detected via the ear probe microphone.

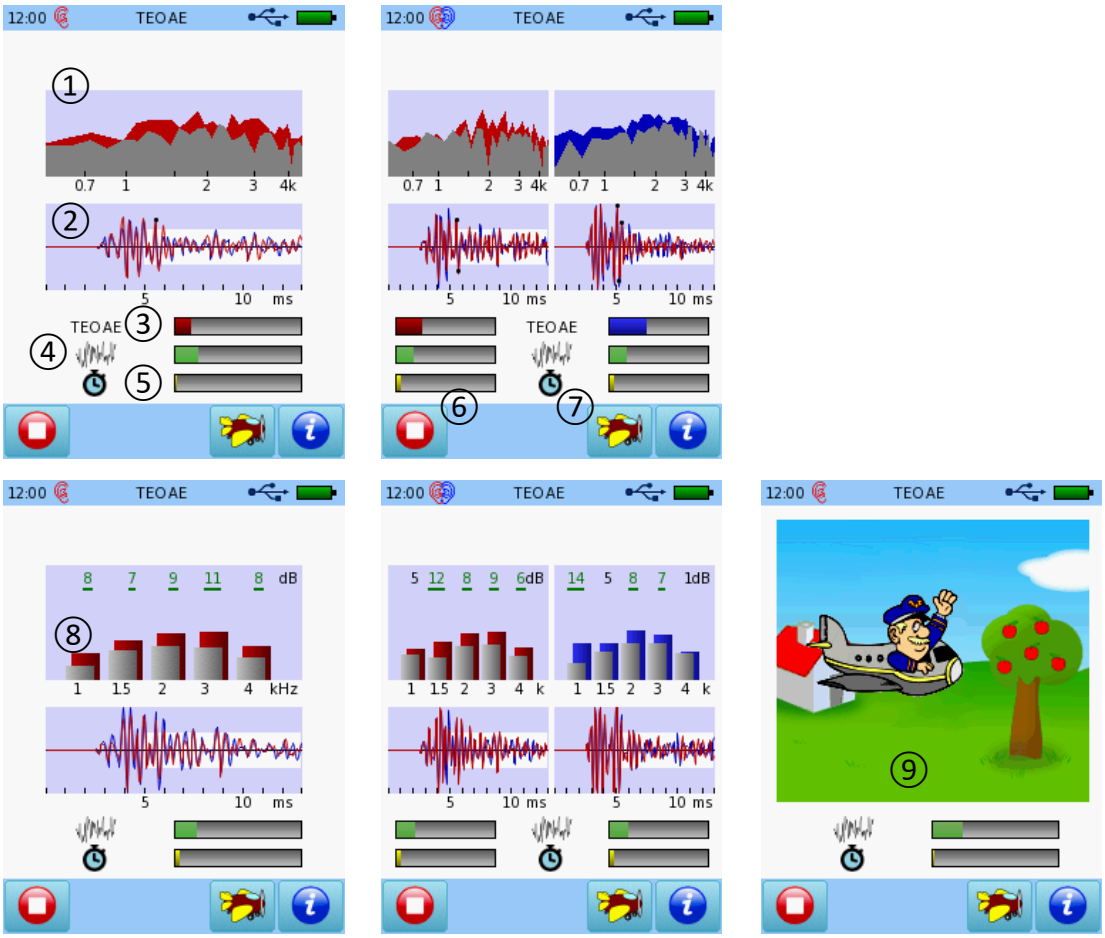

Figure 33: TEOAE measurement (top: TEOAE Quick; bottom: TEOAE Diagnostic; left: monaural; right: binaural; bottom far right: cartoon mode)

During the measurement (see Figure 33) the overall measurement progress ⑤ and the noise floor ④ are displayed. 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 (e.g., swallowing, moving), or the ear probe cable may rub e.g., on clothes. If the leak check is enabled in *TEOAE Preferences* and the criterion fails during the test (e.g., when the probe slips out of the ear canal) at the place of the green noise bar the warning information "*unstable*" is shown. The overall measurement time depends on test conditions, i.e., the higher the noise floor the lower the progress bar speed.

The time-domain response (averaged into two buffers, time window from 5 to 13 ms) ② and the frequency spectrum (signal: red area (right ear), blue area (left ear), noise: gray area) are shown during the measurement. For *TEOAE Quick* a continuous spectrum ① and a TEOAE validity bar ③ are shown. For *TEOAE Diagnostic*, the spectrum is shown separated for the different frequency bands together with the current SNR values ⑧. A cartoon mode (plane or other object flying through a comic style landscape ⑨) can be activated by pressing the *plane* button ⑦. The cartoon mode is especially meant for focusing a child's interest and hence improving noise conditions during a test. The test can be aborted by the examiner with the *stop* button ⑥.

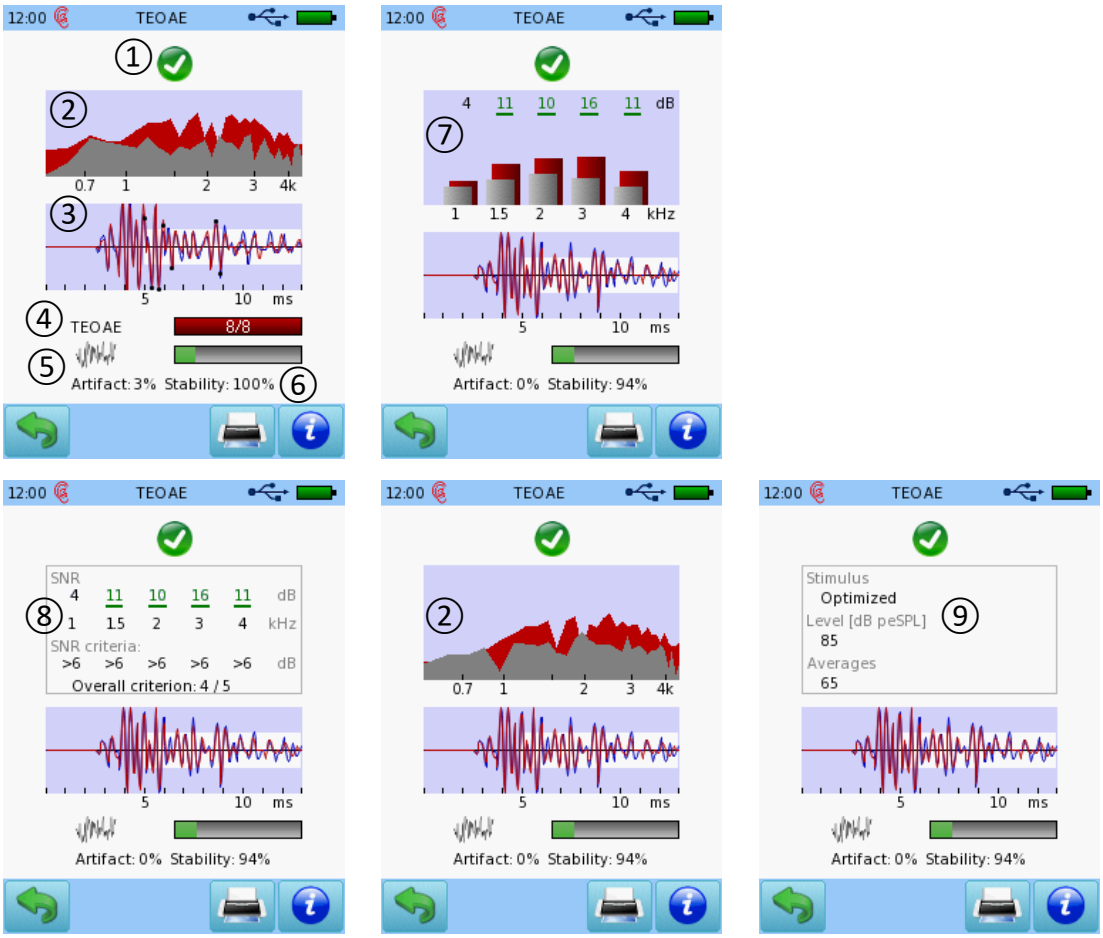

Figure 34: TEOAE result (top left: TEOAE Quick; top right: TEOAE Diagnostic frequency band view; bottom left: SNR view, bottom middle: spectrum view, bottom right: parameter view)

After the test is finished, the result screen (see *Figure 34*) shows the overall result status ① (green symbol if the test criterion is reached or red symbol if not; termination of the measurement by the user is indicated by a yellow question mark symbol). For further analysis, the spectrum of the response signal and noise (TEOAE Quick: continuous spectrum ②; TEOAE Diagnostic: frequency bands ⑦) and the time signal ③ are shown together with quality data, i.e., noise level ⑤, artefact rate, and stimulus stability ⑥. For TEOAE Quick the statistical validity can be read from the TEOAE validity bar ④. For TEOAE Diagnostic additional result views can be displayed by pressing the result screen, i.e., SNR and overall pass criteria ⑧, continuous spectrum ②, and test parameters (stimulus type, level, and averaged) ⑨.

In cases when no valid result is detected and the artefact rate exceeds about 20 % or the stimulus stability is below about 80 %, please try to eliminate possible causes (e.g., ambient noise, inappropriate ear probe placement) and restart the measurement.

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3.2.4 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 29*). 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 for frequency-specific assessment of cochlear dysfunction at the f_2 place. In humans, both quadratic (e.g., f_2-f_1) and cubic distortion products (e.g., $2f_1$-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 *Figure 35*) 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 was 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 35*).

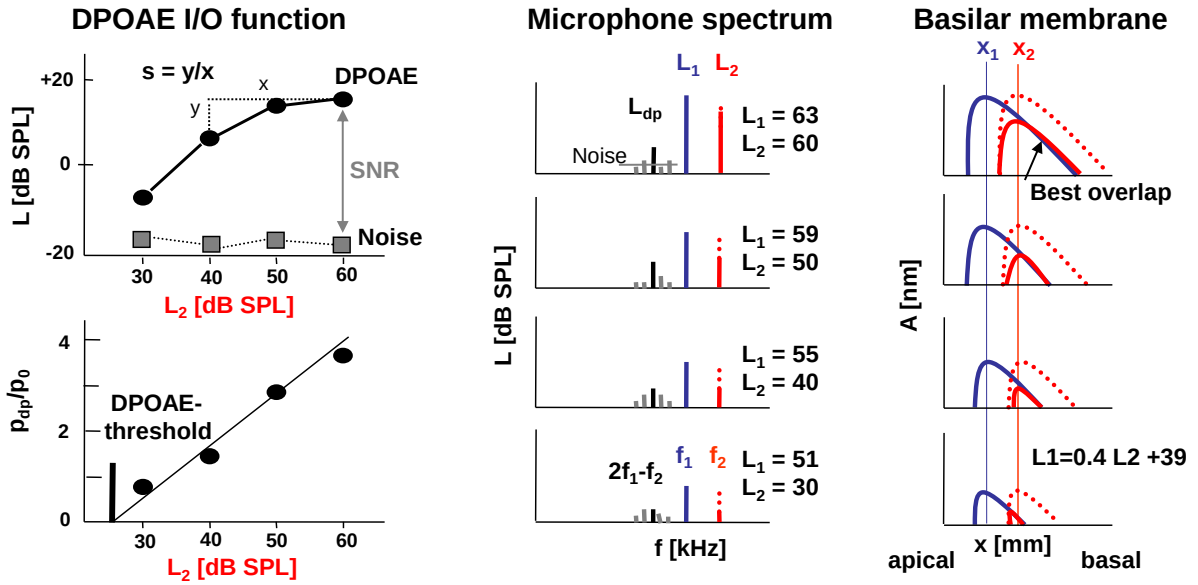

Figure 35: Schematic overview of DPOAE generation with different primary tone level settings: scissor paradigm (solid lines), $L_1 = L_2$ (dotted lines)

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 an SNR of 10 dB, the standard deviation amounts to 1.8 dB, at an SNR of 20 dB to 0.7 dB, and at an 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 36*; 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 large 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 shorter ear canal length (Keefe *et al.*, 1993). The relation between OAE level and auditory threshold – or rather the lack of it – is strongly debated. Formerly, 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 equaled 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 behavioral 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 behavioral threshold than the DPOAE detection threshold (Boege and Janssen, 2002; Gorga *et al.*, 2003; Janssen *et al.*, 2006).

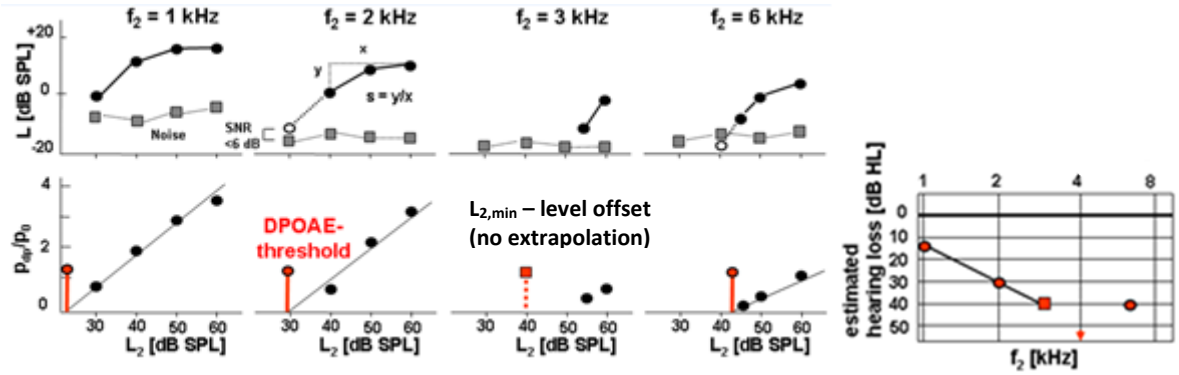

Figure 36: Schematic overview of a DPOAE audiogram derived from DPOAE threshold estimation

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 36*). 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 behavioral audiometry or frequency-specific evoked response audiometry [auditory brainstem responses (ABR) with narrowband 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 behavioral 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 pediatric 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 patients 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 behavioral 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 reportedly able to reveal OHC impairment in the very early stage, i.e., early stage hearing loss for example 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 early stage 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 with a frequency close to $2f_1$-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 neighborhood 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 has only been applied in normal-hearing patients and in a limited frequency range (1.4 to 2.6 kHz) so far.

The **FMDPOAE**™ measurement technique was developed by PATH MEDICAL (Lodwig, 2012, 2013 a,b, 2014 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 ±50 Hz at 1 kHz and ±100Hz at 4 kHz with a modulation rate of 1.4 to 1.6 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, the following are the 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 early stage 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 response detection status (valid/invalid response) 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. User-definable criteria can be set, i.e., SNR criteria (6, 9 or 12 dB) and for *DPOAE Quick* an overall pass criterion (number of valid responses: x out y).
- **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 f_2 from 1 to 8 kHz (for DPOAE Diagnostic with *DPHIRES* the frequency range is extended).

For Sentiero Desktop devices pressurized DPOAEs are available. This feature allows measuring DPOAEs with static pressure offset in order to compensate for a shift in maximum middle ear compliance. The

use of pressurized DPOAEs may improve DPOAE detectability in patients with abnormal tympanogram (see e.g., Zebian *et al.*, 2013; Beck *et al.*, 2016).

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

- **Multifrequency 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} should have a distinct distance of at least one octave. Frequency distance of the primary tones is controlled automatically.
- **FMDPOAE**™ allows measurement of DPOAEs 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 Diagnostic* only:

- **DPOAE High Resolution** allows DPOAE measurement at user-definable start and stop frequencies from 0.8 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*, *DPOAE Diagnostic* or *DPOAE Threshold*. If more than one OAE test is licensed, *DPOAE Quick*, *DPOAE 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 (e.g., f_2 frequency; for *DPOAE Quick/Diagnostic*: L_2 level, SNR criterion; for *DPOAE Quick*: overall pass criterion; for *DPOAE Diagnostic*: L_2/L_1 setup, minimum L_{dp}, 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 *Mutichannel DPOAE* mode may be activated in order to improve DPOAE reliability and measurement time, respectively. For *DPOAE 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 patient should be calm and sitting comfortably in a chair or lying on a bed. For babies, try to test the patient during sleep. Make sure that a valid ear probe (e.g., EP-DP, EP-VIP) 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 patient'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 (see *Figure 32*), the measurement starts. For further information on ear probe calibration please refer to section *3.2.3: Transient Evoked Otoacoustic Emissions (TEOAEs)*. The ear

probe calibration view mode can be configured in *DPOAE Preferences*. The DPOAE stimuli are presented according to the parameter settings and the response is detected via the ear probe microphone. During the *DPOAE Quick/Diagnostic* measurement, the following screen items are displayed:

DPOAE Quick (see *Figure 37, top*)*:*

- DPOAE validity bar ① for all selected f_2 at the currently tested L_2 (the bar color corresponds to the ear: red: right ear, blue: left ear)

DPOAE Diagnostic (see *Figure 37, bottom*):

- DPOAE validity ① and timeout bar ④ for currently tested f_2/L_2 combinations
- Response status matrix ⑤ (displayed for right or left ear when pressing the screen on the left or right screen side, respectively): indicates for each f_2/L_2 if a DPOAE is valid (green check mark), invalid (red Ø) or skipped (gray Ø).
- DPOAE gram ⑩ (DPOAE high resolution only – see *Figure 38*) (displayed for right or left ear when pressing the screen on the left or right screen side, respectively)

DPOAE Quick/Diagnostic

- Overall progress bar ②
- Noise bar ③

DPOAE Threshold (see *Figure 39*):

- DPOAE validity ① and timeout bar ② for currently tested f_2/L_2 combinations
- Noise bar ③
- Test status level-frequency-matrix ⑪: 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
- DPOAE audiogram ⑫ (displayed for right or left ear when pressing the screen on the lower or upper screen side, respectively)

Please note that the *FMDPOAE* option does not influence the measurement screen. For binaural and multifrequency 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 test conditions. With good test conditions, the noise floor bar should remain in the lower quarter. If the noise floor bar is higher (the noise bar gradually turns red), ambient noise levels are too high, the patient may be not calm enough (swallowing, moving), or the ear probe cable may rub e.g., against 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.

Tests can be paused and continued after a pause ⑦ or stopped ⑥. Also, current f_2/L_2 measurements can be skipped ⑧. For *DPOAE Quick*, all currently ongoing f_2/L_2 measurements are skipped. If a binaural measurement is performed, the user can decide at which ear to skip the currently ongoing f_2/L_2 measurements. For *DPOAE Diagnostic*, a single running f_2/L_2 measurement can be selected. A cartoon mode (see *Figure 33*) is available by pressing the *plane* button ⑨. The cartoon mode is especially meant for focusing a child's interest and hence improving noise conditions during a test.

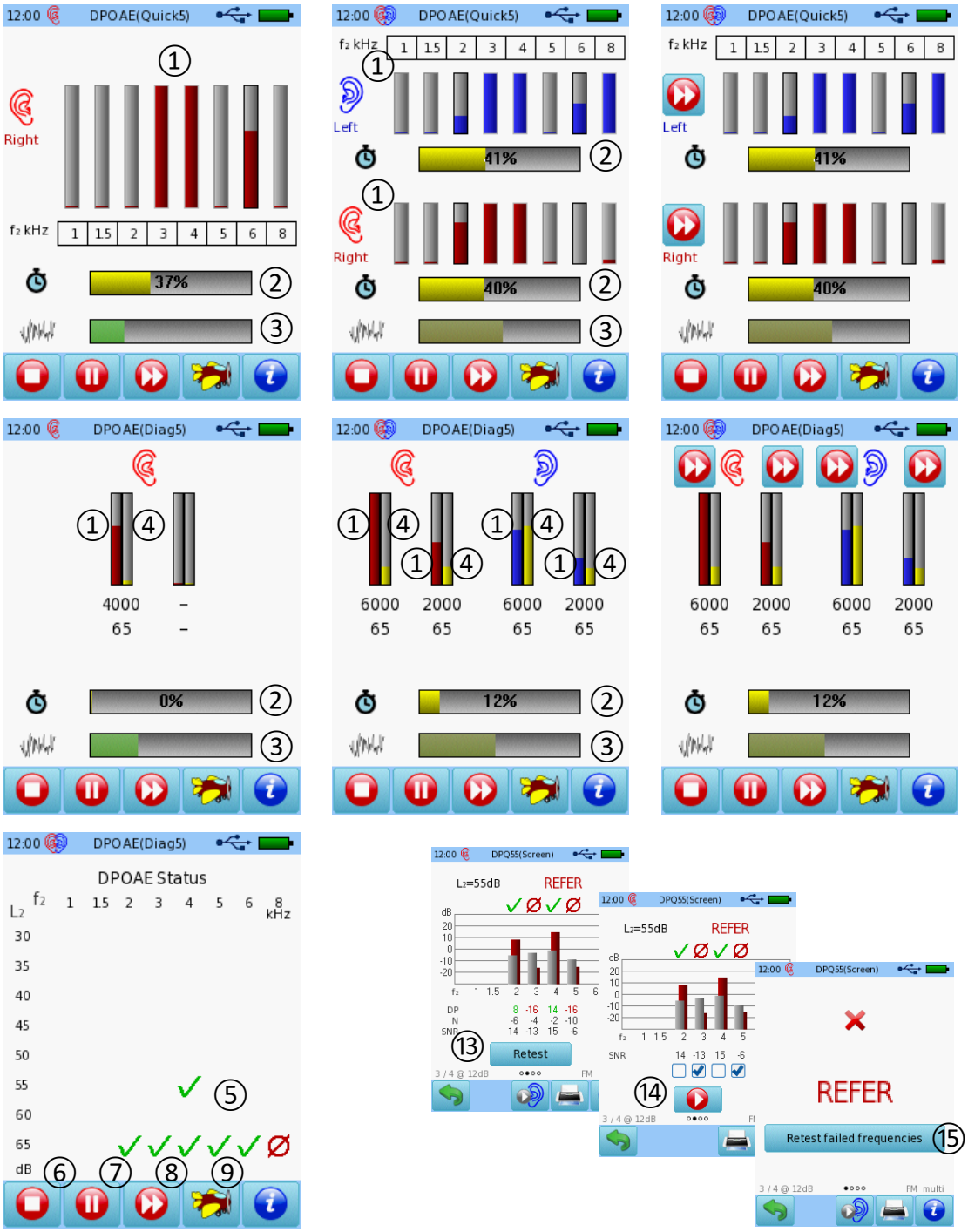

Figure 37: DPOAE Quick/Diagnostic measurement (top: DPOAE Quick, middle row: DPOAE Diagnostic; left: monaural test, middle: binaural test, right: binaural, skip current f_2/L_2 measurement; bottom left: DPOAE Diagnostic with current response status matrix; bottom right: DPOAE Quick retest views)

After the *DPOAE Quick* test is finished, DPOAE measurements at specified frequencies can be repeated by pressing the *retest* button ⑬ in the bar graph view. By default the frequencies with invalid responses are marked for retest but any frequency can be selected. The retest is started by pressing the *play* button ⑭. If the *retest failed frequency* button ⑮ is pressed in the overall result view, DPOAEs are immediately retested at the frequencies with invalid responses. *DPOAE Diagnostic* can be

configured to automatically repeat f_2/L_2 combinations with invalid responses after the *DPOAE Diagnostic* test is finished.

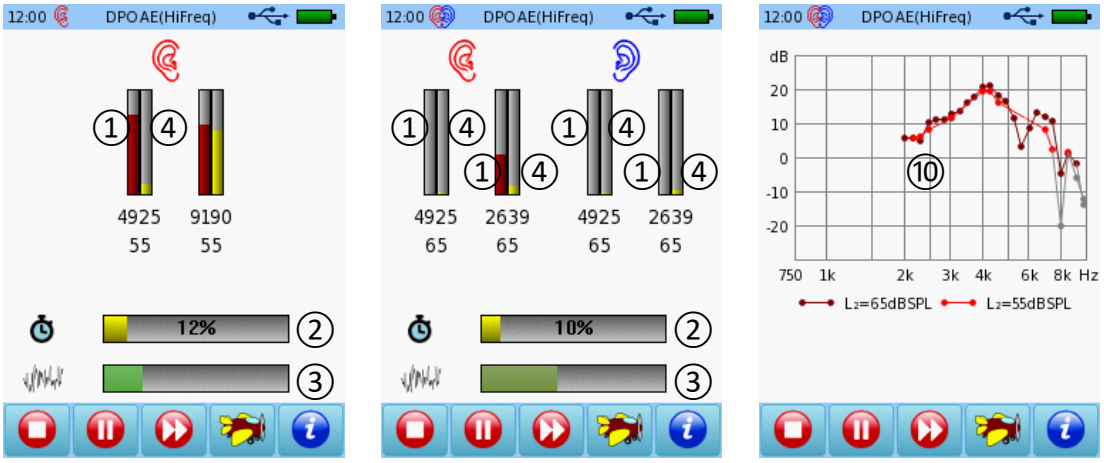

Figure 38: DPOAE High Resolution measurement (left: monaural; middle: binaural; right: DPOAE gram)

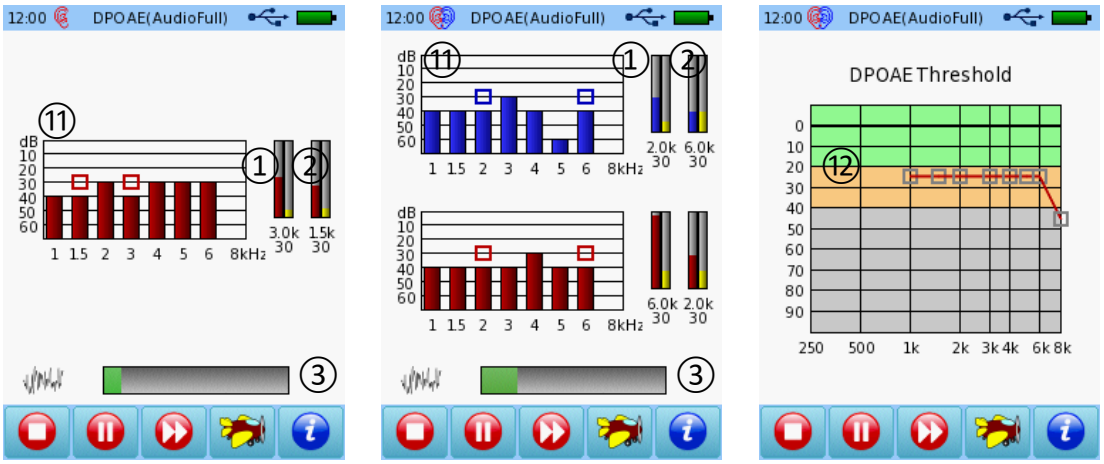

Figure 39: DPOAE Threshold measurement (left: monaural; middle: binaural; right: audiogram)

The following screen items are displayed on the result screen for the respective modules:

<u>*DPOAE Quick*</u> (see *Figure 40*):

- Overall result (dependent on selected x out of y overall result criterion)
- DPOAE and noise level bars for each tested f_2 for the given L_2
- DPOAE gram: plots DPOAE and noise levels for all f_2 at the given L_2
- Result data table (including L_2, f_2, DPOAE level L_{dp}, noise floor level L_{nf}, and SNR)

Please note that the different result views can be switched by sliding a finger on the screen horizontally. Relevant test parameters (SNR criterion, FMDPOAE, multifrequency) are shown in gray at the bottom of the result screen together with the currently selected result view index (filled circle in row of circles: •○○○ = first page of four pages). The preferred initial result screen can be selected in the *DPOAE Preferences* section in the device settings.

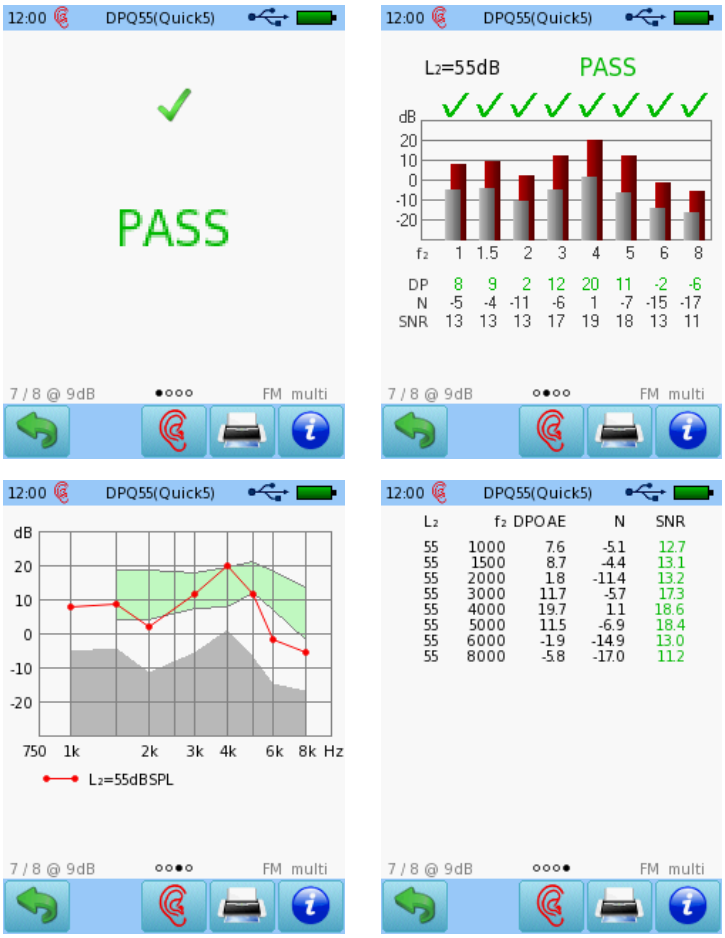

Figure 40: DPOAE Quick result (top left: overall result; top right: DPOAE and noise level bars for each tested f_2; bottom left: DPOAE gram; bottom right: data table)

<u>*DPOAE Diagnostic*</u> (see *Figure 41*):

- DPOAE validity matrix: indicates for each f_2/L_2 if a DPOAE is valid (green check mark), invalid (red Ø) or skipped (gray Ø)
- DPOAE gram bar graph: plots DPOAE and noise levels as vertical bars and shows their numeric values together with the resulting SNR for each f_2 at the selected L_2. The DPOAE gram bar graph can be run through all L_2 by pressing the result screen.
- DPOAE gram: plots DPOAE levels for all f_2 at all L_2 (different color for each L_2). The DPOAE gram can be run through all L_2 by pressing the result screen. For a single L_2, the DPOAE and noise levels for all f_2 at the selected L_2 are plotted.
- Result data table (including L_2, f_2, DPOAE level L_{dp}, noise floor level L_{nf}, and SNR)

Figure 41: DPOAE Diagnostic result (top left: DPOAE validity matrix; top middle: DPOAE and noise level bars for each tested f_2; top right, bottom left, bottom middle: DPOAE gram; bottom right: data table)

<u>*DPOAE High Resolution*</u> (see *Figure 42*):

- DPOAE gram: plots DPOAE levels for all f_2 at all L_2 (different color for each L_2). The DPOAE gram can be run through all L_2 by pressing the result screen. For a single L_2, the DPOAE and noise levels for all f_2 at the selected L_2 are plotted.
- Result data table (including L_2, f_2, DPOAE level L_{dp}, noise floor level L_{nf}, and SNR)

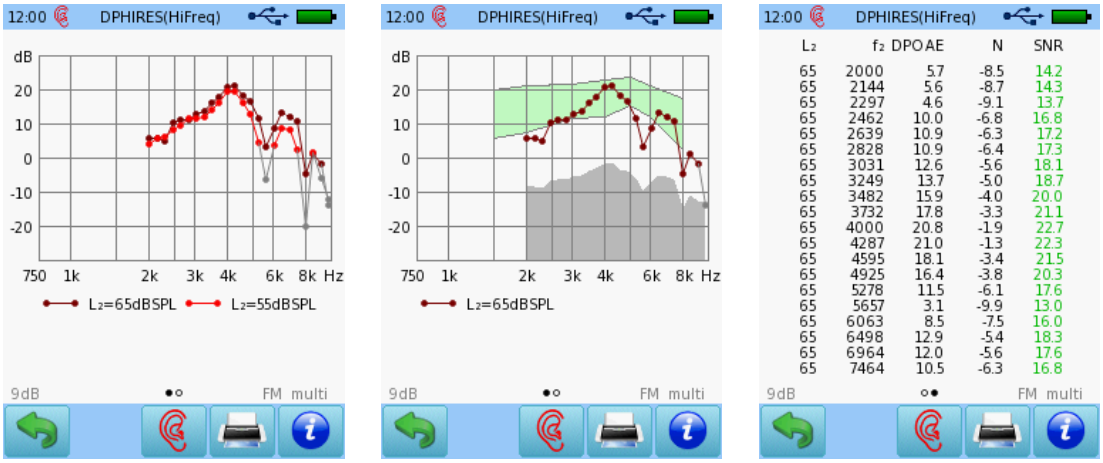

Figure 42: DPOAE High Resolution result (left, middle: DPOAE gram; right: data table)

<u>*DPOAE Threshold*</u> (see *Figure 43*):

- DPOAE audiogram, i.e., estimated DPOAE thresholds L_{dpth} plotted across f_2. 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 36*). When pressing the result screen, also the valid DPOAE f_2/L_2 combinations are shown in the audiogram graph as red (right ear) or blue (left ear) dots.
- DPOAE gram: plots DPOAE levels for all f_2 at all L_2 (different color for each L_2). The DPOAE gram can be run through all L_2 by pressing the result screen. For a single L_2, the DPOAE and noise levels for all f_2 at the selected L_2 are plotted.
- DPOAE I/O function: plots DPOAE levels for all L_2 at a selected f_2. The DPOAE I/O function can be run through all f_2 by pressing the result screen.
- DPOAE threshold table (including DPOAE threshold L_{dpth} and minimum L_2)
- Result data table (including L_2, f_2, DPOAE level L_{dp}, noise floor level L_{nf}, and SNR)

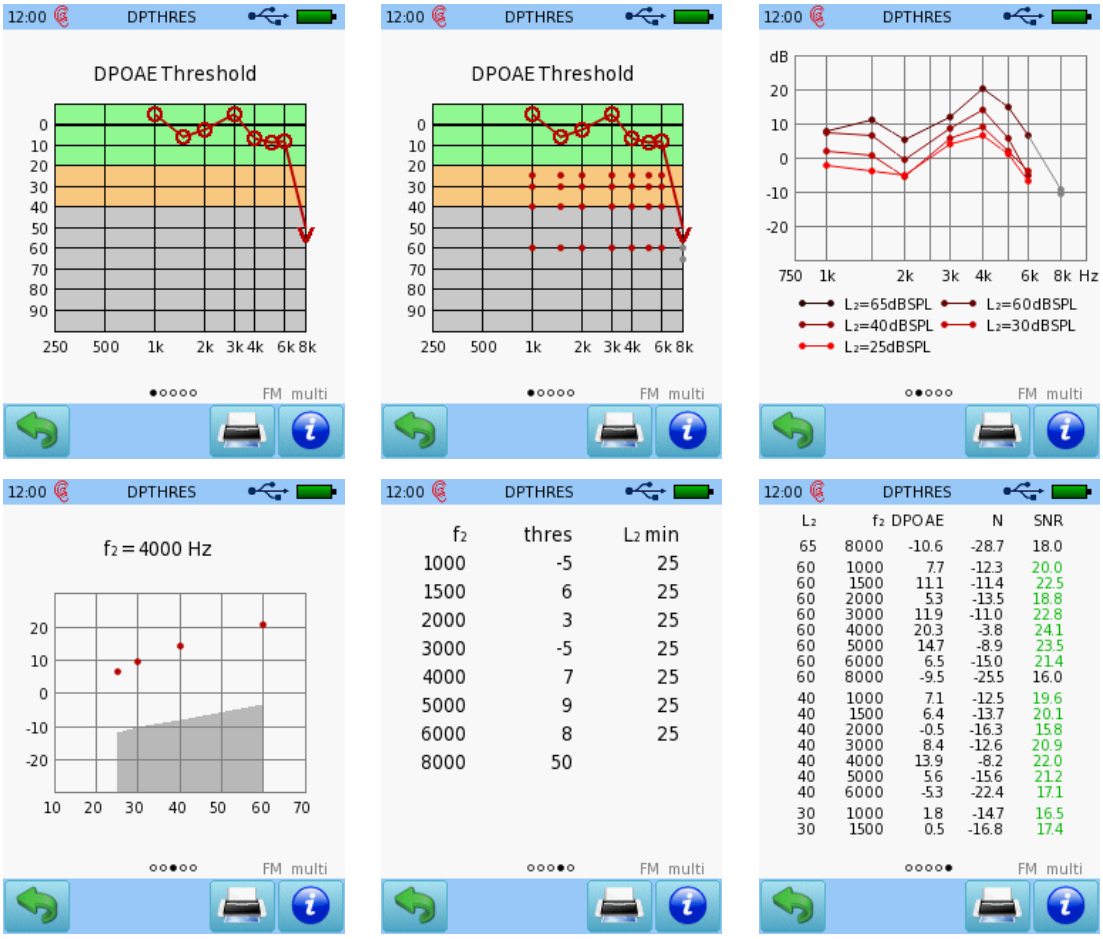

Figure 43: DPOAE Threshold result (top left/middle: DPOAE thresholds; top right: DPOAE gram; bottom left: DPOAE I/O function; bottom middle: threshold table; bottom right: data table)

Please note that the *FMDPOAE* and *Multifrequency DPOAE* options do not influence the layout of the result screen.

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3.2.5 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 to 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., quantization 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 response (see *Figure 44*). 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, and inferior colliculus). Typical clinical application areas are: (newborn) hearing screening, topological diagnostics (together with tympanometry and otoacoustic emissions), neuro-monitoring, and determination of hearing

thresholds especially in small children and other non-cooperative patients. The following test methods are commonly used for clinical applications:

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 patient's age and hearing status. The recorded potentials contain five to seven waves roughly associated with specific sites along the auditory pathway. ABRs are not affected by sleep. For more information on ABR, please refer to section *3.2.6: Auditory Brainstem Reponses (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. Depending 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 *3.2.7: Auditory Steady-State Responses (ASSR)*.

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). The response latency amounts to about 1 to 3 ms. For more information on ECochG, please refer to section *3.2.8: Electrocochleography (ECochG)*.

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 patient's vigilance and attention.

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 patient needs to attend to the stimulus difference (e.g., P300). For more complex stimulus differences as e.g., semantic incongruities in speech samples, the patient's language processing skills are required (e.g., N400).

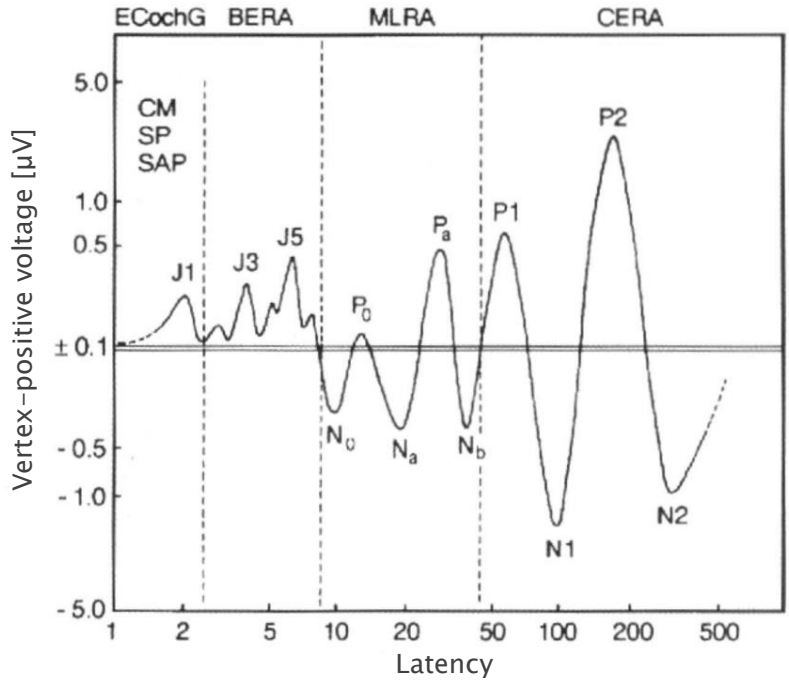

Figure 44: Overview of short, middle and late latency AEP waves

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 an AEP test (e.g., ABR or ASSR), the impedance should be 0 kΩ for both the red and white electrode.

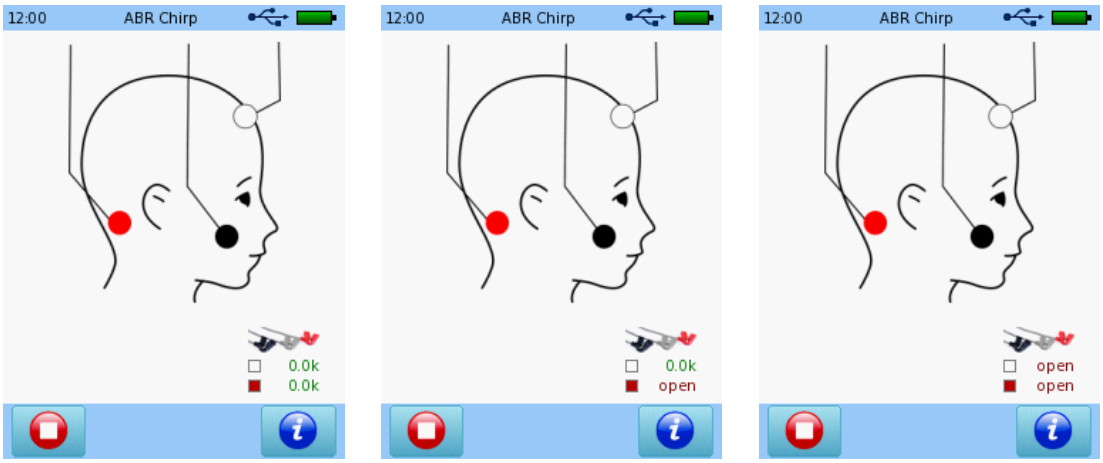

Figure 45: AEP electrode cable check with electrode testing device (left: all clips connected; middle: red clip removed; right: black clip removed or red and white clip removed)

When detaching either the red or white electrode clip 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 clip, both impedances are *open*. If there is any deviation from this behavior or if you suspect any dysfunction, please retry with another electrode cable and/or contact your distributor.

LITERATURE

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3.2.6 Auditory Brainstem Reponses (ABRs)

Auditory brainstem responses (ABRs) recorded from electrodes placed on the scalp represent far field potentials generated by the fiber 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. The waves are commonly referred to as Jewett/wave I to VII. In clinical diagnostics mainly waves I, III, and V are analyzed. Wave I and II stem from the auditory nerve, and while it was assumed for many years that wave III arose from the cochlear nucleus, wave IV and V from the lateral lemniscus and inferior colliculus (lower brainstem), and wave VI and VII from sub-cortical regions, there is more recent data suggesting that multiple sites along the auditory pathway may contribute to the later waves and that each anatomical site may contribute to more than one wave (Hall, 2007). 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 a patient's vigilance (i.e., sleep, attentiveness) (Picton and Hillyard, 1974) and can therefore be performed during sedation or anaesthetization.

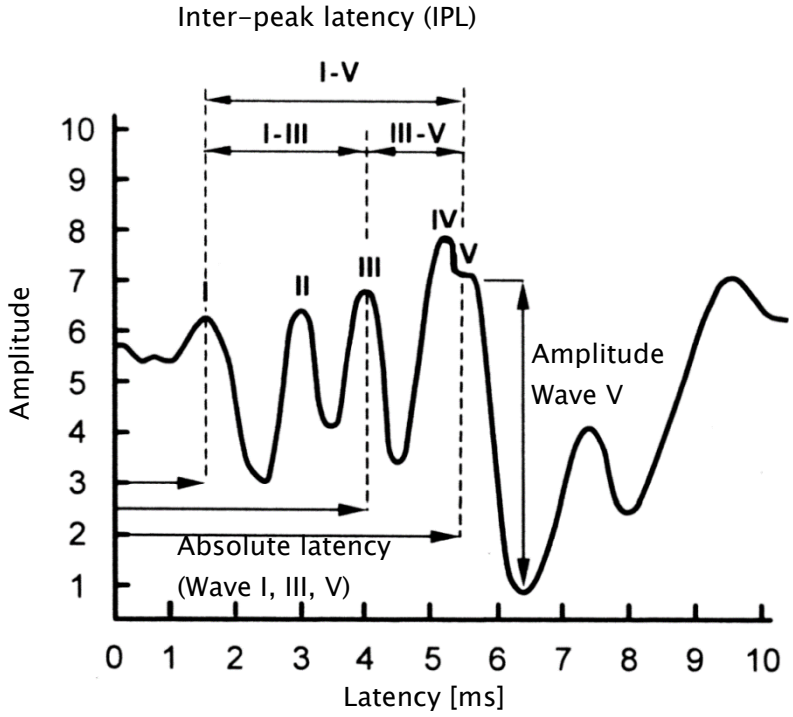


Figure 46: Overview of ABR waves

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) can be detected, especially in children with doubtful behavioral pure-tone audiograms (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 disabled 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 pathologies 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 fibers. However, temporal specificity of the stimulus is achieved at the expense of frequency specificity. In contrast, narrowband 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.

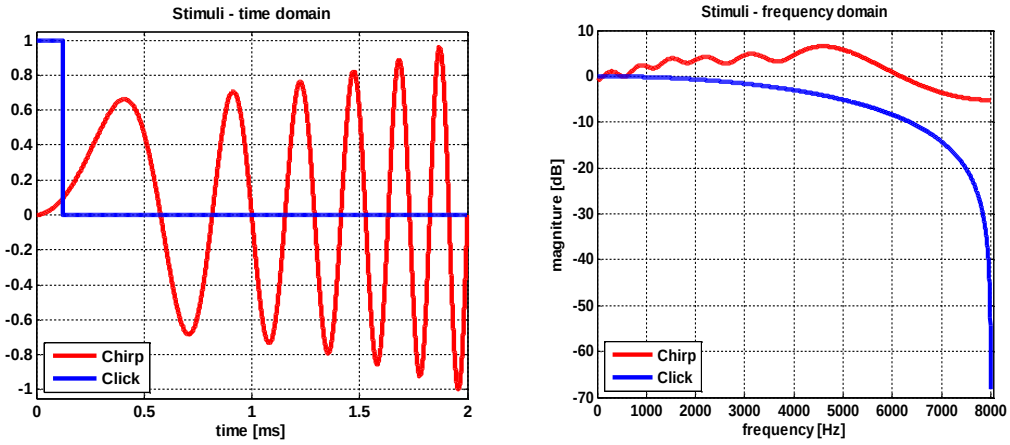


Figure 47: ABR stimuli: click and chirp (left: time domain; right: frequency domain)

A **click** (see *Figure 47* – 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 47* – 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 can be compensated resulting in an increase of the synchronization of action potentials and with that in higher ABR amplitudes (Dau *et al.*, 2000, Elberling *et al.*, 2007). The advantage of a chirp stimulus over the commonly used click stimulus is that it yields a higher synchronization of action potentials on the nerve fibers, 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 µs) sinusoidal stimulus pulse which is 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 synchronization 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 at frequencies below 1000 Hz. ABRs with a broad-band stimulus (click, broadband chirp) do not allow direct frequency-specific assessment of hearing loss and exhibit nearly normal patterns in patients with low- to mid-frequency hearing loss. An ABR threshold is detected at stimulus levels corresponding to the hearing loss at medium to high frequencies. Frequency-specificity is generally improved when using ABR with narrowband stimuli (narrowband chirps, tone burst). However, low-frequency stimulation at high stimulus levels also stimulates basal sensory cells. Thus, the assessment of low-frequency functionality is only possible at low stimulus levels. Ipsilateral masking noise may be used to reduce response contributions from mid- to high-frequency cochlear regions. For getting even more frequency-specific information DPOAEs (at a hearing loss up to 50 dB HL) or ASSRs should to be used.

In patients with hearing loss wave I may be missing. In these patients, the 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 electromagnetic 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 patient.

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, identification of neural disorders on the auditory pathway (vestibulocochlear nerve and lower brainstem lesions: e.g., acoustic neuroma, neural disorder), 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, contralateral masking noise, stimulus level, stimulus

rate, number of averages, noise stop criterion, Spread Spectrum, 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 only wave V is evaluated.
- Narrowband (low-, mid-, high-) chirps provide latency information and are more frequency-specific than broadband stimuli (click, broadband 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. Please note that for low- and mid-chirps ipsilateral masking noise is presented in order to reduce response contributions from more basal cochlear regions.
- Tone bursts are more frequency-specific than narrow-band chirps but yield lower amplitudes (especially at lower levels).

Stimulus polarity:

- Alternating polarity helps reduce the stimulus artefact that is generated by the transducer itself (especially recommended for bone conduction measurements). Alternating polarity provides a broader, rounded wave V peak.
- Rarefaction and condensation provides 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.

Rate Mode:

- If activated, the test can be performed for a fixed stimulus level at multiple stimulus rates.

Masking noise:

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

Stimulus level:

Up to eight stimulus levels (including repetitions) can be pre-configured. Stimulus levels are given in dB nHL, i.e., relative to the hearing threshold of a collective of normal hearing patients, which is defined as 0 dB nHL. A stimulus level can be repeated up to three times. A mute stimulus is available for comparative measurements. Measurements start at the highest level. The 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 wave III (at about 30 dB nHL) disappear. In rate mode only one stimulus level can be set.

Stimulus rate:

The higher the stimulus rate, the smaller the response amplitude (notably for I to IV and for high levels) and the longer the latency. The latency shift due to stimulus rate is compensated on the device and hence not visible in the result graph. 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 because these are typical power system frequencies. By pressing the stimulus rate box, a user-defined stimulus rate can be entered. The resulting inter-stimulus interval is displayed on the *settings* screen. In rate mode up to eight stimulus rates (including repetitions) can be selected.

Number of averages:

At fixed measurement conditions, with increasing number of averages, the noise floor decreases (number of averages increased by factor four reduces noise by half), but the measurement time increases. The time per trace and the total measurement time are shown on the *settings* screen.

Spread Spectrum:

If activated, the stimulus rate is slightly varied in order to reduce the influence of electrical interference synchronized to the stimulus rate. Also, ABR amplitude is known to decrease at a constant stimulus rate due to adaptation. Activation of this option is always recommended. Please note that the Spread Spectrum option is always active for stimulus rates exceeding 70 Hz and during binaural stimulation for decoupling the responses from the two channels.

Automated Wave V detection:

If activated, the occurrence of a statistically valid wave V is automatically detected.

Minimum Wave V amplitude:

If *Automated Wave V detection* is activated, the minimum wave V amplitude, which must be available to mark a recognized wave V as valid, can be selected.

Auto Proceed:

If activated, the recording of a trace is stopped as soon as a statistically valid wave V is detected for the given trace. The test then proceeds with the recording of the next trace. Please note that this option is only available if the *automated wave V detection* option is activated.

Auto Stop:

If activated, the test stops if for two consecutive traces no statistically valid wave V could be detected. Please note that this option is only available if the *automated wave V detection* option is activated.

Noise stop criterion:

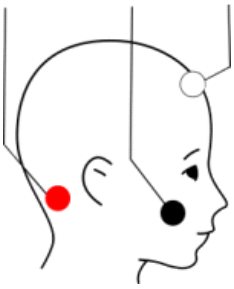
If activated (i.e., noise stop criterion >0 nV), the recording of a trace is stopped as soon as the residual noise drops below the defined noise threshold and no response is detected. Hence, if activated this option speeds up the recording in case no response is present.

Age group (for normative latencies):

Select the appropriate age group corresponding to the age of the tested patient.

Before the test is started the patient should be instructed about the test procedure. In order to reduce muscle artefacts, the patient should be calm and fully relaxed lying comfortably on a recliner or bed. It is also recommended that patients keep their eyes closed during the measurement for reducing artefacts e.g., due to eye blinks. For babies, try to test the patient 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 are 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 48* (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 on the mastoid)

Black electrode (ground):
- e.g. cheek

Figure 48: ABR electrode positioning with vertical montage

Alternatively to the vertex position, the high forehead position is possible for the white electrode. However, in this case the ABR amplitude slightly decreases. Despite this fact, the forehead is preferred in practice, especially in patients where vertex electrode placement is inconvenient because of hair. 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 – please note that in this case a symmetric electrode montage is recommended and that no contralateral masking noise is available). The electrode impedance measurement starts (see *Figure 49*). 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 ①. The ABR test can be started by pressing the *play* button ② if the impedances are below 6 kΩ and the difference between red and white electrode impedance is below 3 kΩ. If you do not press the *play* button for a while, a message appears in order to remind you to start the measurement by pressing the *play* button. It is possible to configure an automatic start of the ABR test after adequate impedances are available

in the *AEP Preferences*. The measurement is then automatically started if the impedances are below 4 kΩ and the impedance difference is below 2 kΩ. However, in some cases these impedances may not be obtained (e.g., in small children cleaning of the skin may not be possible as the child would wake up when rubbing the skin) and an ABR test shall be performed despite the not ideal test conditions. For these cases, a *forward* button ③ appears if the impedances are below 12 kΩ and the impedance difference is below 6 kΩ. If impedances are worse no ABR test is possible. 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 *3.2.5: Overview: Auditory Evoked Potentials*) and clean the skin, use conductive gel and wait a couple of minutes until the gel is infiltrated into the skin.

Figure 49: ABR impedance measurement (left: good impedances with play button; middle: good impedances with play button and reminder to start test by pressing the play button; right: poor impedances with forward button)

When performing an ABR test with an ear probe, information about ear probe calibration ① and impedance measurement ② are shown on screen (see *Figure 50*). You can configure the ear probe calibration view mode in *AEP Preferences* to *Simple* or *Expert* mode. If the results from impedance measurement or ear probe calibration are not fully valid, a *forward* button may occur in order to proceed to the ABR test. For further information on ear probe calibration, skip criteria and differences in calibration view mode please refer to *PRACTICAL USE* in section *3.2.3: Transient Evoked Otoacoustic Emissions (TEOAEs)*.

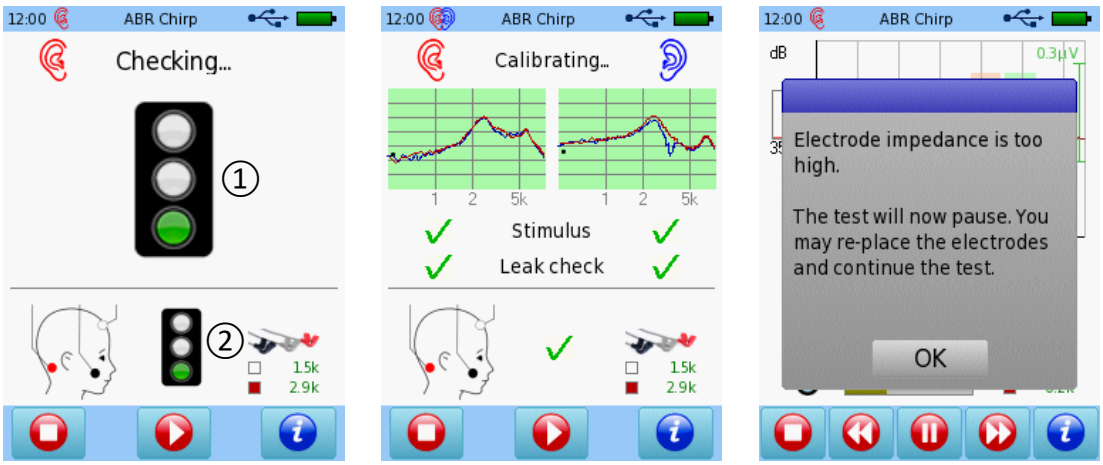


Figure 50: ABR impedance measurement and ear probe calibration (left: good impedances and ear probe fit (simple mode); middle: good impedances and ear probe fit (binaural test, expert mode; right: bad impedance during measurement)

After successful electrode impedance measurement, you can start the test by pressing the *play* (or *forward*) 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 impedances get too high (e.g., an electrode has fallen off), the test is automatically interrupted (see *Figure 50*). The test can only be continued if the electrode impedances get back to tolerable values.

During the ABR measurement the following information is provided on the screen (see *Figure 51*):

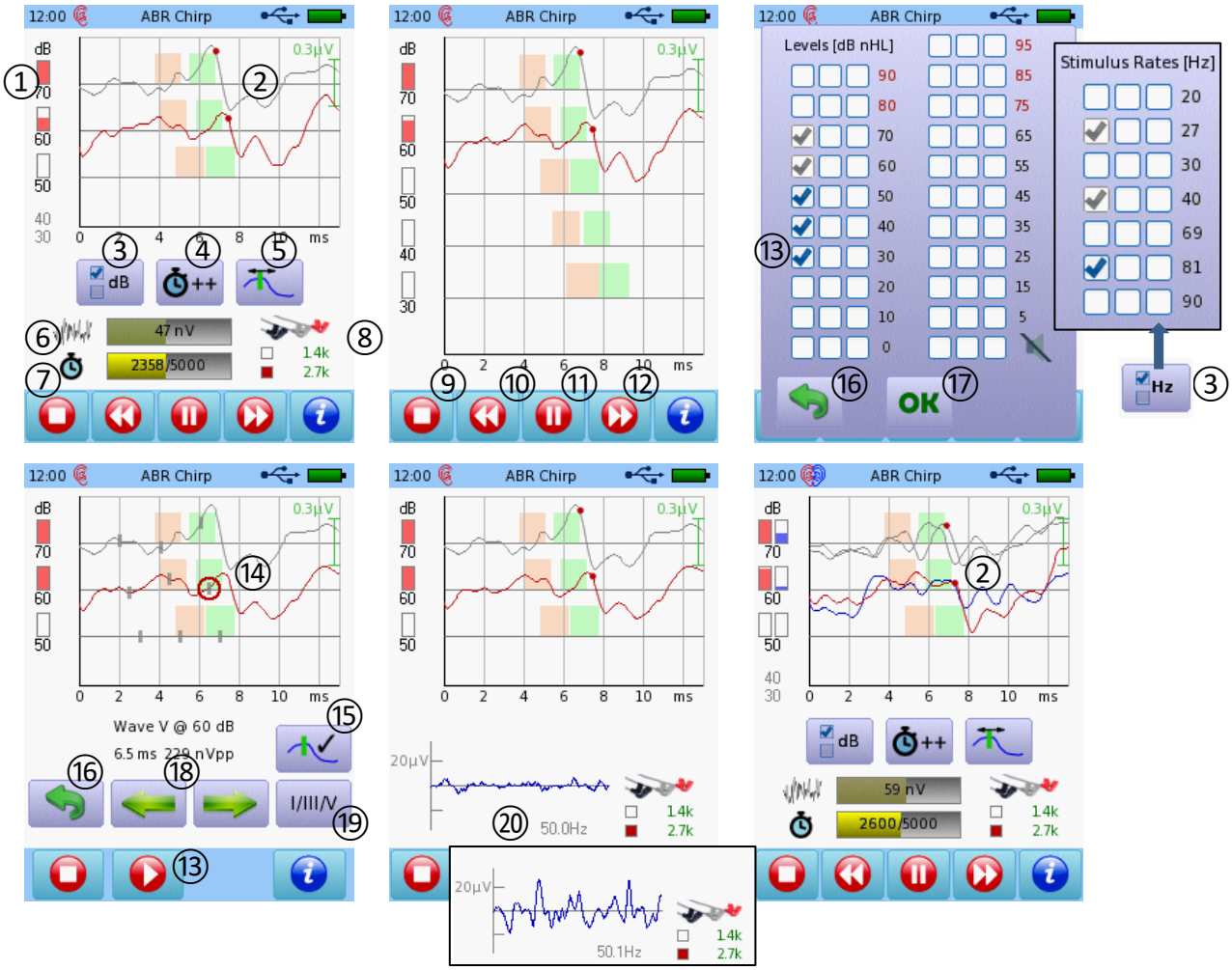


Figure 51: ABR measurement (top left: standard measurement screen; top middle: extended measurement screen; top right: level selection (for rate mode: stimulus rate selection); bottom left: Jewett marker setting; bottom middle: standard measurement screen with EEG noise graph for low and high noise conditions; bottom right: standard measurement screen for binaural measurement)

ABR traces are shown for each selected stimulus level (for rate mode: for each selected stimulus rate). In the standard measurement screen a maximum of three traces is shown at the same time. The currently tested trace is shown in red (right ear) and/or blue (left ear) ②. Already finished traces are grayed out. Normative data for wave III (red area) and V (green area) is shown if configured in the settings. When pressing the graph area an extended view of up to eight traces is shown. Pressing the graph again will switch back to the standard measurement screen with three traces. By sliding a finger

horizontally over the time axis of the ABR traces graph area, the time scale can be adapted. By sliding a finger vertically over the graph area, the amplitude scale can be adapted. If the automatic wave V detection is activated, the wave V status indicator ① reflects the statistically computed probability that a wave V is present in the recorded signal. For binaural measurements, the red bar refers to the right ear, the blue bar to the left ear. If a statistically significant wave V is detected a red or blue dot is displayed at the trace for the right or left ear, respectively. Please note that the wave V status indicator only represents the statistical detectability of a wave V signal and does not consider normal amplitude or latency.

During an ABR measurement, the pre-configured level selection can be adapted by pressing the *level setup* button ③ (for rate mode the pre-configured stimulus rates can be adapted instead). A level matrix opens and the selected levels are shown. Already tested levels are grayed out. The level setup screen can be left with the *back* ⑯ (without saving the changes) or *OK* button ⑰ (saving the changes). Also, the pre-configured number of averages can be increased by 1000 for the current trace by pressing the *increase averages* button ④. Jewett markers can be set for the currently active trace by pressing the *Jewett marker mode* button ⑤. Initially all markers are shown in gray. The active marker is shown with a circle ⑭. The active marker can be moved by pressing the *right/left arrow* buttons ⑱ and can be set by pressing the *set marker* button ⑮. The marker is then shown red or blue (for the right or left ear, respectively). When moving the marker, it turns gray again. You can choose which Jewett marker (V, III, and I) should be set by pressing the *Jewett marker selection* button ⑲. The Jewett marker mode can be left by pressing the *back* button ⑯.

The EEG noise bar ⑥ represents biological and external noise which is an indicator for the adequacy of measurement conditions. With good measurement conditions, the EEG noise bar should remain green. With increasing noise, the EEG noise bar gradually turns yellow and red, which indicates that 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. When pressing the EEG noise bar, an EEG noise graph ⑳ is shown. You can return to the EEG noise bar view by pressing the EEG noise graph. The progress bar ⑦ shows the progress of the measurement at the currently active trace. If the bar is full, the measurement for the current trace is finished, i.e., the number of averages that has been defined by the user is reached. Depending on the settings, a measurement 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 ⑧ is regularly updated during the measurement and the measurement is paused if impedance gets too high. The test can be manually paused ⑪, continued after a pause ⑬, or stopped ⑨. Also, a current measurement can be restarted ⑩ or skipped ⑫.

After the test is finished, the ABR result is shown (see *Figure 52*). The recorded ABR traces ② are displayed for each stimulus level together with normative areas if a normative data age group has been configured. If automated wave V detection has been activated the estimated wave V is shown as a dot on the trace. Also the statistical validity of the wave V is shown in the wave V status indicator ①. After setting the Jewett markers, the wave name (I, III, and V) is displayed at the respective markers ③. The resolution of the amplitude axis can be changed by sliding a finger up (zoom in) or down (zoom out) on the result graph screen. The resolution of the time axis can be changed by sliding a finger right (zoom in) or left (zoom out) on the time axis of the result graph screen. Please note that signal delays for insert earphones and for different stimulus rates are compensated.

The latencies for wave I, III, and V can be adjusted by the user on the Jewett marker screen ④. The currently active marker is indicated by a circle. The trace can be selected with the *up/down* buttons ⑤. The active marker can be moved along the selected trace with the *right/left arrow* buttons ⑥ and can be set by pressing the *set marker* button ⑦. While moving the marker it is gray. When setting the marker it turns red or blue (for the right or left ear, respectively). 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 latency corresponding to the active marker and the resulting amplitude is shown as a numeric value below the ABR traces graph. You can choose which Jewett marker (I, III, or V) you wish to change by pressing the *Jewett marker selection* button ⑧. If any marker has been changed an *OK* button ⑬ appears in the footer. When leaving the result view, any changes can be accepted by pressing the *OK* button ⑬ or discarded by pressing the *back* button ⑫.

By sliding a finger from right to left on the result screen you can move forward to other result views. The three screens present a level-latency-diagram (wave V: circles, wave III: triangles, wave I: squares) ⑨, numeric values of amplitudes, latencies and inter-peak latencies together with other test-related information (such as impedances, number of averages, and noise for each trace) ⑩, and general information about the used transducer and settings (as averages, stimulus rate, stimulus type, test options, normative area age group, and total time) ⑪. 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).

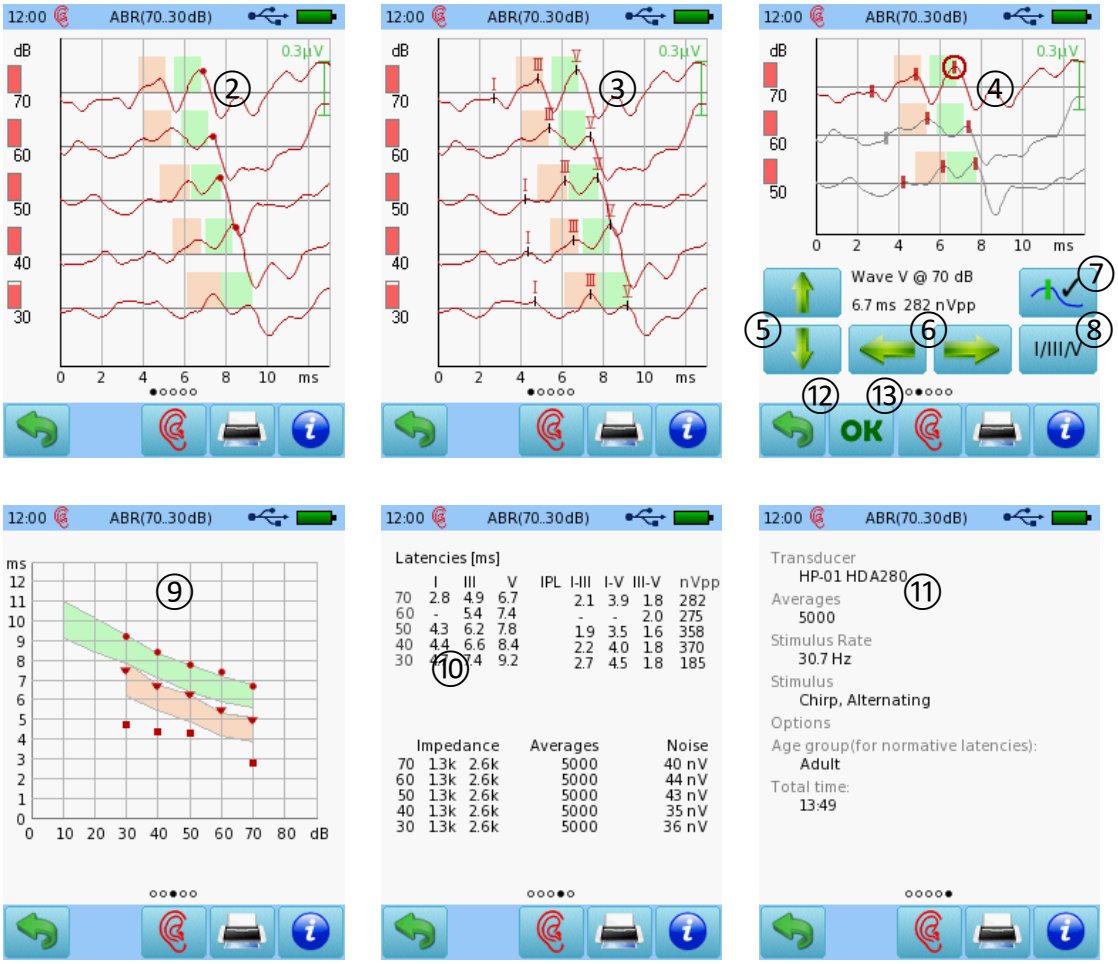


Figure 52: ABR result (top left: traces with estimated wave V; top middle: traces with confirmed waves I, III, and V; top right: Jewett marker setting; bottom left: level-latency diagram; bottom middle: measurement data; bottom right: general test information)

For level repetitions, there are additional options for presenting ABR traces. They can be shown sorted by time (test order) or by level and ABR traces of the same level can be displayed summarized or can be plotted on top of each other in order to evaluate the repeatability of an ABR response for a given level. The available options are shown in *Figure 53*:

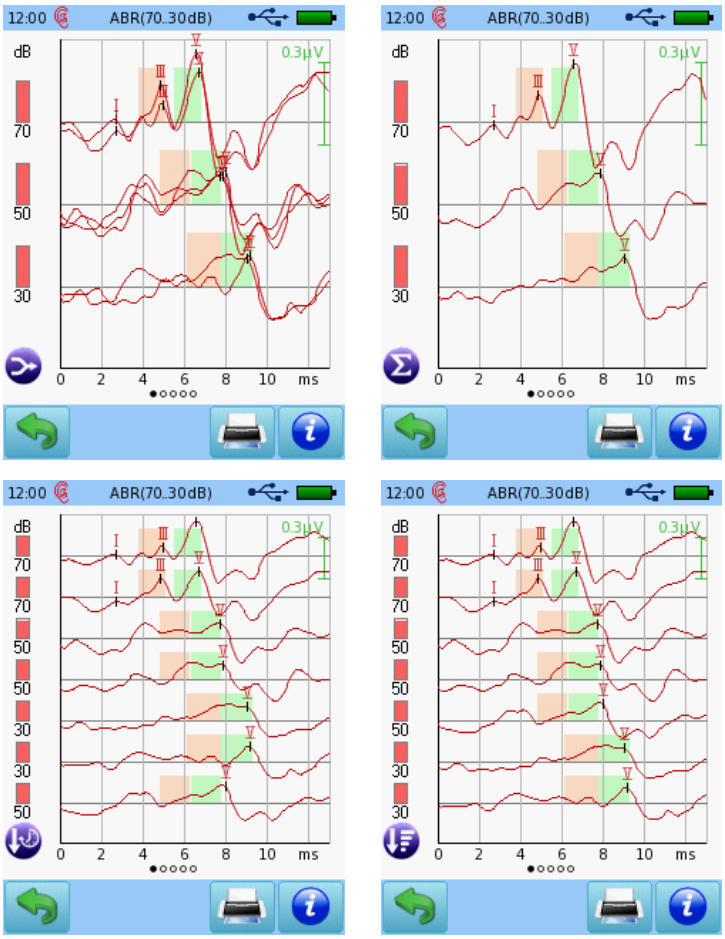


Figure 53: ABR result options for repeated levels (top left: overlay traces of same levels; top right: show summed traces for same levels; bottom left: show traces in test order; bottom right: show traces sorted by level)

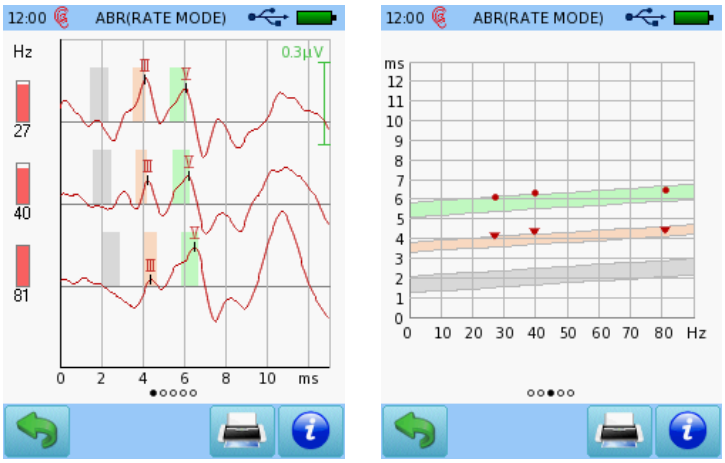


Figure 54: ABR result for rate mode (left: traces with confirmed waves III and V; right: stimulus rate vs. latency diagram)

If rate mode has been selected, traces are displayed for each tested stimulus rate (instead of stimulus level as in standard mode) and a stimulus rate vs. latency diagram is available (instead of a level-latency-diagram) (see *Figure 54*). The basic layout of result views in rate mode is similar to the result views in standard mode.

For the interpretation of ABR results, the following case examples may be considered (see *Figure 55* to *Figure 58*):

- **Normal hearing patient** (see *Figure 55*): ABRs with broadband stimuli are typically measurable down to about 10 dB nHL in a normal hearing patient. Wave V latency increases and wave V amplitude decreases with decreasing stimulus level. Wave V latencies are within normal range when an appropriate age group has been selected.

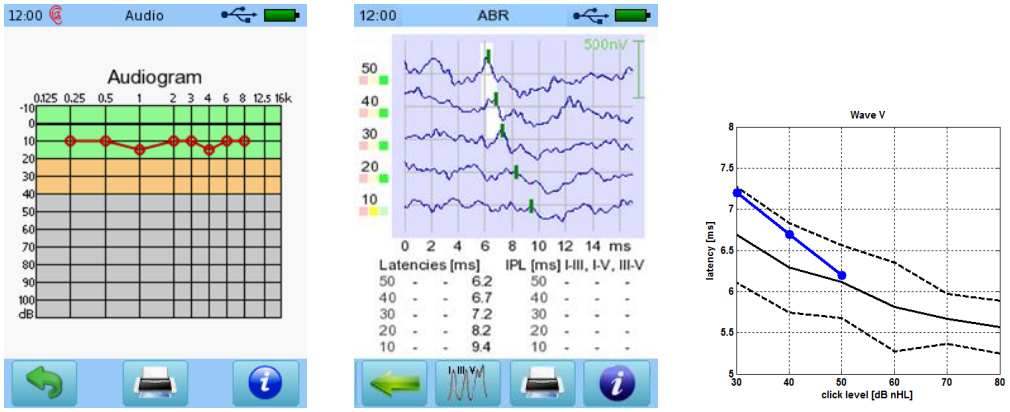


Figure 55: ABR result example for normal hearing patient (left: audiogram; middle: ABR traces; right: latency-level function)

- **Conductive hearing loss** (see *Figure 56*): In a patient suffering from conductive hearing loss, the effective stimulus level decreases. As a consequence, latencies and amplitudes of all waves are changed. This includes that wave V latency typically increases 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 a flat audiogram the level-latency 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.

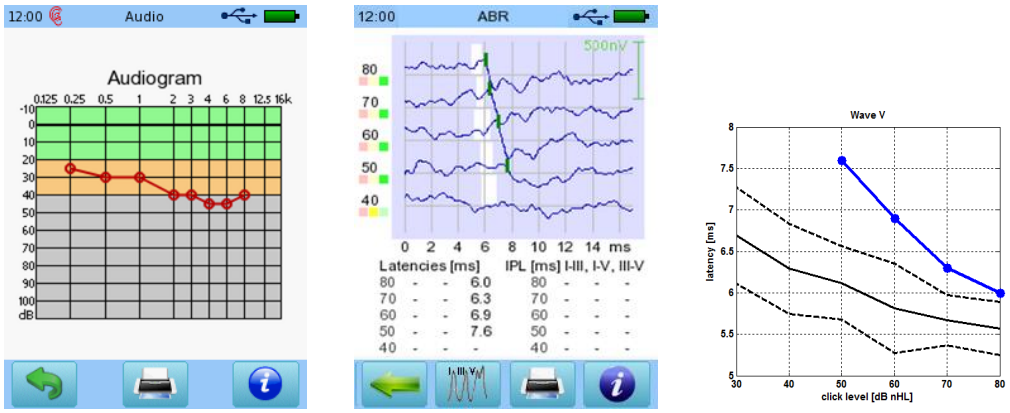
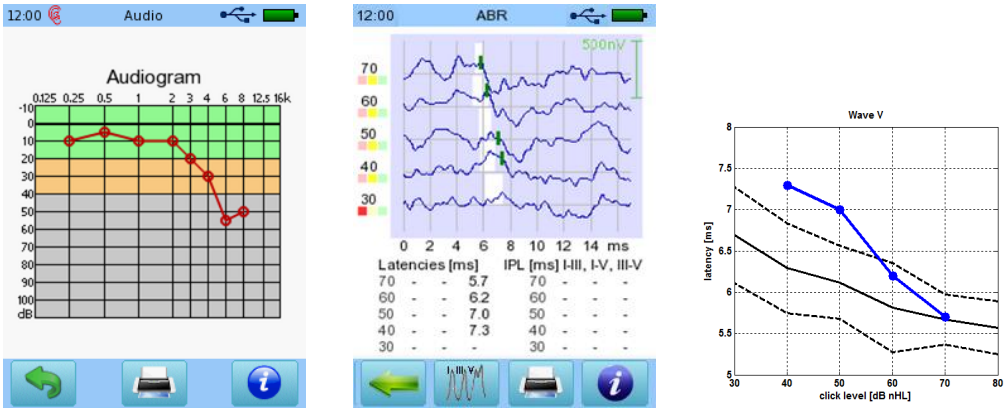


Figure 56: ABR result example for patient with conductive hearing loss (left: audiogram; middle: ABR traces; right: latency-level function)

- **Cochlear hearing loss** (see *Figure 57*): 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 patients 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. Level-latency functions for these patients converge on those of normal hearing patients at high stimulus levels.

  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 patient, ABRs appear with lower amplitude and slightly increased wave 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.

  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 synchronization of nerve fiber activity in the apical region of the cochlea.



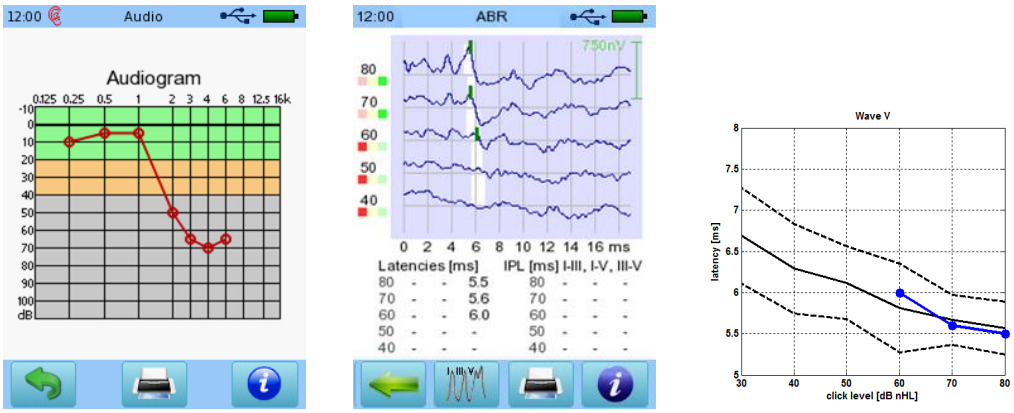


Figure 57: ABR result examples for patients with cochlear hearing loss (top: case example 1; bottom: case example 2) (left: audiogram; middle: ABR traces; right: latency-level function)

- **Retro-cochlear hearing loss** (see *Figure 58*): ABRs in a patient with neural disorders (click, stimulus rate: 10 Hz): The ABR wave pattern is different compared to normal hearing patients 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 the 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.

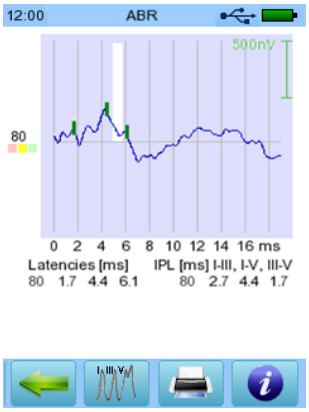


Figure 58: ABR result example for patient with retro-cochlear hearing loss

Quick ABR

An alternative to the standard ABR module is provided on Sentiero Advanced mainly for screening purposes. Select *QuickABR* from the module selection screen. If more than one AEP test is licensed, *QuickABR* can be found in the *AEP* section. If required, change the parameters. The parameter options are reduced compared to the standard ABR module and only provide a selection of stimulus level and normative latency age group. Stimulus levels are given in dB eHL, which represents an *estimated hearing level* with dB eHL = dB nHL + 10 dB. The offset was selected based on the experience that ABR can typically be recorded only down to 10 dB above hearing threshold. Hence, by introducing the additional offset, the typical ABR detection threshold for normal hearing patients is considered to be reached at 0 dB eHL. A fixed stimulus setup (stimulus rate, stimulus polarity, number of averages) is applied. In the *QuickABR* module the statistical detection algorithm checks for wave V in the normal

latency area only, which is different to the standard ABR module, which checks for a wave V in a broader time frame also including late latencies.

For preparation of the patient (instruction, skin preparation, and electrode montage) please refer to the explanations for the standard ABR module. Make sure that a valid transducer (e.g., headphone, insert earphone, ear probe, ear couplers) and electrode cable are connected. Select the test ear (*Right+Left*: simultaneous measurement of right and left ear). The electrode impedance measurement starts. If the test is performed with one or two ear probes also the ear probe calibration starts. For more information on impedance measurement and ear probe calibration please refer to the explanations for the standard ABR module. After successful electrode impedance measurement, you can start the test by pressing the *play* (or *forward*) button. During the *QuickABR* measurement the following information is provided on the screen (see *Figure 59*):

The recorded ABR trace is plotted for the selected stimulus level ①. The stimulus level is displayed below the ABR trace graph. Normative data for wave III (red area) and V (green area) is shown if configured in the settings. By sliding a finger vertically over the graph area, the amplitude scale can be adapted. The wave V validity indicator ② reflects the statistically computed probability that a wave V with normal latency is present in the recorded signal. For binaural measurements, the red bar refers to the right ear, the blue bar to the left ear. If a valid wave V is detected for one ear side, a green check mark is shown instead of the wave V validity indicator.

The EEG noise bar ③ represents biological and external noise which is an indicator for the adequacy of measurement conditions. With good measurement conditions, the EEG noise bar should remain green. With increasing noise, the EEG noise bar gradually turns yellow and red, which indicates that 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 ④ shows the progress of the measurement relative to the maximum number of averages. If the bar is full, the measurement is finished. The measurement may finish earlier if a valid response is detected before reaching the maximum number of averages. The electrode impedance ⑤ is regularly updated during the measurement and the measurement is paused if impedance gets too high. The test can be manually paused ⑦, continued after a pause (*pause* button turns to *play* button – not shown in *Figure 59*), or stopped ⑥.

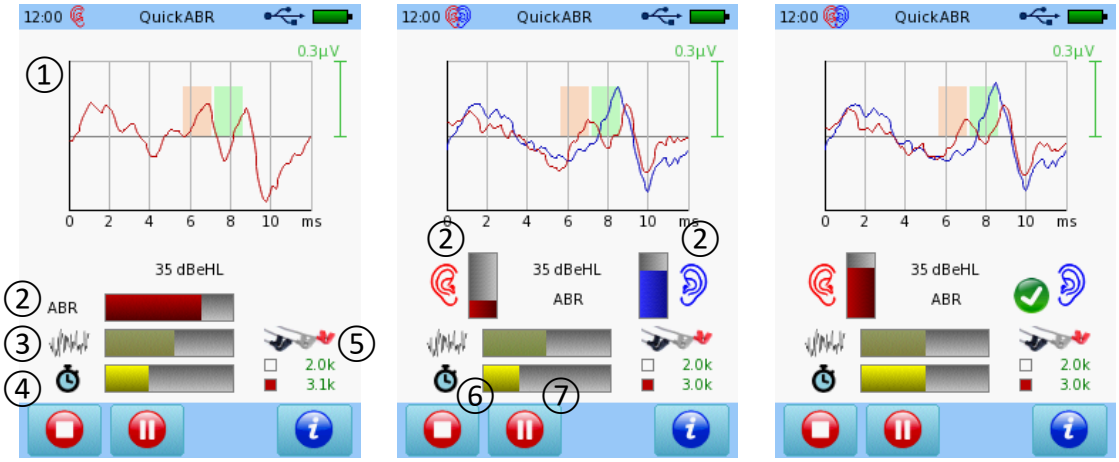


Figure 59: QuickABR measurement (left: monaural; middle/right: binaural)

After the test is finished, the *QuickABR* result is shown (see *Figure 60*). The recorded ABR trace ① is displayed for the selected stimulus level together with normative areas if a normative data age group is configured. The overall result is shown as a green check mark ② (valid response) or a red symbol ③ (invalid response). The resolution of the amplitude axis can be changed by sliding a finger up (zoom in) or down (zoom out) on the result graph screen. Please note that signal delays for insert earphones are compensated. Additional information on the applied stimulus type and level, number of averages, EEG amplitude, and impedance is shown at the bottom of the result view ④.

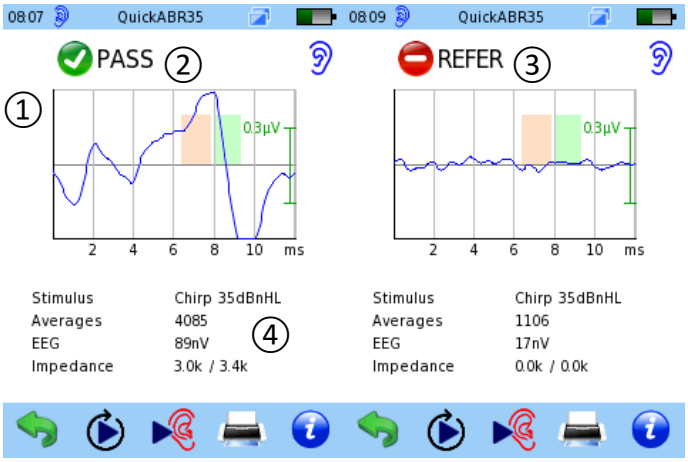


Figure 60: QuickABR result (left: valid response; right: no valid response)

E-ABR

Another version of the standard ABR module is the E-ABR module, which allows recording electrically evoked auditory brainstem responses in order to determine if the auditory nerve adequately responds to electrical stimulation.

The E-ABR module provides the capability to measure ABR responses at patients with a cochlear implant. The electrical stimulus is applied from an external stimulator, usually a cochlear implant fitting system (which is provided by the cochlear implant manufacturer). The electrical stimulus is transmitted directly to the cochlear implant coil where it is forwarded to the cochlear implant electrode and converted to a stimulation of the auditory nerve. The ABR responses are recorded from the patient's scalp via surface electrodes attached to the patient (as for normal ABR). The surface electrodes are attached to an electrode cable, which is connected to the Sentiero Advanced. In order to synchronize the responses correctly, the time sequence of the stimuli needs to be known on the device side. For that reason stimulus trigger impulses are transferred from the cochlear implant fitting system to the measurement device.

The E-ABR module on Sentiero Advanced allows measuring up to 15 traces in one test run and provides automated response detection and Jewett V marking. The basic ABR operation principles are the same as for the standard ABR module.

Select *E-ABR* from the module selection screen. If more than one AEP test is licensed, *E-ABR* can be found in the *AEP* section. Select the preset that you would like to perform. If necessary, change the recording parameters (e.g., automated wave V detection, deactivation of impedance check during the measurement, trigger options) and the preset name as required. Stimulus parameters must be

configured at the cochlear implant fitting system. For further information on the cochlear implant fitting system please refer to the respective operation manual or contact the cochlear implant manufacturer.

Before the test is started the patient should be instructed about the test procedure. Make sure that the test conditions (patient position and relaxation, electrode montage, environmental conditions) are appropriate and a valid electrode cable is connected to the Sentiero Advanced. For further information please refer to the explanations for the standard ABR module. Please also make sure that the stimulus configuration on the cochlear implant fitting system is appropriate and an adequate transducer is connected to the cochlear implant fitting system.

Select the test ear. The electrode impedance measurement starts (see explanations for standard ABR module). The ABR test can be started by pressing the *play* button if impedances are appropriate. When starting the play button, the device checks for a valid trigger input. As soon as a trigger signal is recognized the measurement starts synchronized to the trigger signal. 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 E-ABR measurement the information provided on the screen (see *Figure 61*) is similar as for standard ABR, i.e., the screen shows E-ABR traces (view of all traces appears when clicking the traces graph; the traces are consecutively numbered), noise, the recording progress for the currently measured trace, and electrode impedances. The trace starts 1 ms before stimulus onset in order to show the electrical artefact of the external stimulator. A trace is finished as soon as the progress bar is full, i.e., the pre-configured number of averages is reached. The measurement is then paused. After setting up the next test configuration on the cochlear implant fitting system, the recording can be started again on Sentiero Advanced by pressing the *play* button. If configured, a trigger pause automatically results in switching to a new trace. The recording of a trace can be skipped or restarted by pressing the *forward* or *back* button. The pre-configured number of averages can be increased by pressing the *increase averages* button. An EEG noise graph can be displayed when pressing the EEG bar. After the test is finished, an E-ABR result is shown comparably to the standard ABR result.

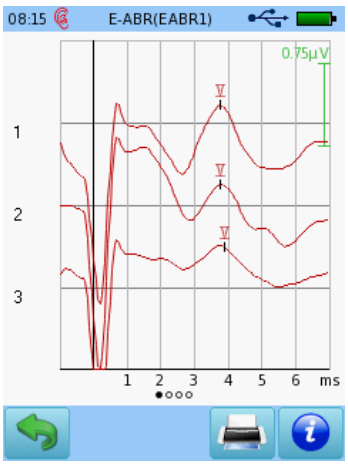


Figure 61: E-ABR measurement

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3.2.7 Auditory Steady-State Responses (ASSR)

Auditory Steady-State Responses (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., 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 stimulus rate is used) onset neurons are activated in different regions along the auditory pathway. The stimulus rate is selected in such a way that the transient responses overlap at the place of generation, hence delivering a steady-state response. Typical stimulus rates are 40 and 80 Hz. 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 include both early and middle latency response components, whereas 80 Hz ASSR consist of early latency responses (Mäkelä and Hari, 1987). 40 Hz ASSR are affected by vigilance and are hence suitable for awake and alert patients (Galambos *et al.*, 1981), whereas 80 Hz ASSR are not affected by vigilance and are hence suitable for babies and in general for sleeping patients (including sedated and anaesthetized patients) (Levi *et al.*, 1983). In newborns, middle latency responses are usually not available, so that the amplitude of 40 Hz ASSR is generally reduced. Moreover, the optimal stimulus rate also depends on the carrier frequency. 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). For frequencies from 6 kHz onwards, even higher stimulus rates up to 160 Hz can be used (Lodwig and Rosner, 2016). With increasing stimulus rate the background noise during recording of the response decreases. The response can be detected via far-field electrodes within the EEG as a sine signal with a frequency following the stimulus rate. The response can be statistically analyzed in the frequency domain (Stapells *et al.*, 1987; Dobie and Wilson, 1989; Picton *et al.*, 2001).

When using different stimulus 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 one 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 patients. Moreover, the stimulus 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 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 ASSRs at frequencies where no DPOAE response could be detected. Average test time for eight test frequencies is about 15 minutes for patients with normal hearing and for patients who are hearing impaired about 25 minutes (Rosner, 2013b).

Two ASSR workflows are available:

- **ASSR Fixed** allows frequency-specific measurement of ASSR at one or multiple levels. A response detection status (valid/invalid response) is delivered for each frequency/level combination.
- **ASSR Threshold** allows frequency-specific determination of hearing thresholds within a configurable 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 at a frequency if two consecutive responses at a frequency are not valid.

ASSR tests can be performed binaurally if an adequate transducer is connected (e.g., headphone, two ear probes), which may reduce test time by a factor of two. ASSR can be measured at frequencies from 250 Hz to 8 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, stimulus bandwidth, averaging time) and the preset name as required.

Stimulus rate:

It is generally recommended to use 40 Hz ASSR in awake and alert patients (e.g., children and adults) and to use 80 Hz ASSR in sleeping patients (e.g., babies, sedated patients, during anesthesia). The auto mode provides a performance-optimized stimulus rate paradigm that increases the stimulus rate with increasing frequency taking into account the dependency of stimulus rates on carrier frequencies and the dependency of noise floor levels on stimulus rates. The auto mode can be used for awake or sleeping patients. Please note that stimulus rates are jittered for improving resistance to interfering noise.

Stimulus bandwidth:

With increasing stimulus bandwidth the response amplitude increases but frequency specificity decreases. The stimulus bandwidth selection impacts the frequency selection.

Masking noise

Contralateral masking is recommended if there is significant asymmetry in hearing loss between ears, i.e., differences 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.

Averages:

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

Noise stop criterion:

> If activated (i.e., noise stop criterion >0 nV), the recording of a trace is stopped as soon as the residual noise drops below the defined noise threshold and no response is detected. Hence, if activated this option speeds up the recording in case no response is present.

Before the test is started the patient should be instructed about the test procedure. In order to reduce muscle artefacts, the patient should be calm and fully relaxed lying comfortably on a recliner or bed. For 40 Hz ASSR patients should stay awake, whereas for 80 Hz ASSR patients may sleep. For babies, try to test the patient 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. A shielded electrode cable may also help in reducing electromagnetic noise. 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, bone conductor) 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 *3.2.6: Auditory Brainstem Reponses (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 proceed with the measurement. It is recommended that impedances are <6 kΩ and that the difference between red and white electrode impedance is <3 kΩ. After successful electrode impedance measurement, you can start the test by pressing the *play* button. The ASSR stimuli 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. For further information about impedance measurement see *PRACTICAL USE* in section *3.2.6: Auditory Brainstem Reponses (ABRs)*.

During the measurement the following information is provided on the screen (see *Figure 62*):

The statistical validity of an ASSR is shown for each currently tested frequency/level combination ①. The traces are shown in red (right ear) and/or blue (left ear). For 40-Hz ASSR up to two and for 80-Hz ASSR and for automatic stimulus rate mode up to four frequency/level combinations are measured simultaneously. A trace is finished if it hits the top of the box (valid response), if it hits the gray triangular area within the box (invalid response) or if the configured maximum averaging time is reached (invalid response). The EEG noise bar ② represents biological and external noise which is an indicator for the adequacy of measurement conditions. With good measurement conditions, the EEG noise bar should remain green. With increasing noise, the EEG noise bar gradually turns yellow and red, which indicates that 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. When pressing the EEG noise bar, an EEG noise graph ⑤ is shown. You can return to the EEG noise bar view by pressing the EEG noise graph. The overall progress bar ③

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.

The test can be manually paused ⑦, continued after a pause (*pause* button turns to *play* button – not shown in *Figure 62*), or stopped ⑥. Also, a current measurement can be skipped ⑧. If multiple measurements are running the frequency/level combination can be selected (skip ⑨: skip level at frequency, stop ⑩: skip all levels at frequency) after pressing the main *forward* button ⑧. The *forward* ⑨ and *stop* buttons ⑩ at the frequency/level combinations can be removed by pressing the main *forward* button ⑧ again. The current measurement status for the right or left ear can be displayed when pressing the left or right graph area, respectively. The screen is colored red for the right ear and blue for the left ear. Currently tested frequency/level combinations are shown with the *clock* symbol ⑪, already tested frequency/level combinations feature a green check mark ⑫ (valid response), a red Ø ⑬ (invalid response), or a gray Ø (incomplete response because measurement was stopped for this frequency/level combination).

Figure 62: ASSR measurement (top: monaural 40 Hz ASSR measurement; top left: standard measurement screen; top right: measurement screen with EEG noise graph; bottom: binaural 80 Hz ASSR measurement; bottom left: standard measurement screen; bottom middle: skip/stop selection; bottom right: measurement status and result matrix)

The statistical response algorithm is based on the magnitude squared coherence test (Dobie and Wilson, 1989) 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 four times higher than the power added up of the single sweeps.

After the test is finished, the ASSR result is shown (see *Figure 63* for general ASSR result views and *Figure 64* for audiogram result view specific for ASSR Threshold). For all ASSR measurements, three screens are available. The response status matrix ① shows the response status for each tested frequency/level combination, i.e., if the response is valid (green check mark), invalid (red Ø) or undefined/not finished (gray Ø). When pressing any of the response status symbols, the related detailed response information ② is shown including information on frequency, level, stimulus rate and response status at the top of the screen. Below, the statistical validity trace is shown in red (right ear) or blue (left ear), respectively. In *Figure 63* you can see three typical response examples (bottom left: valid response – the validity trace hits the top of the box before the maximum measurement time is reached; bottom middle: invalid response – the validity trace hits the gray triangle within the box; bottom right: invalid response – the timeout is reached without getting a valid response). At the bottom, the response amplitude, noise amplitude, and electrode impedances are displayed. You can return to the response status matrix by pressing the screen or the *back* button. The general information screen ③ shows the applied transducer, the test configuration (test mode, stimulus bandwidth, stimulus rate), and the total measurement time.

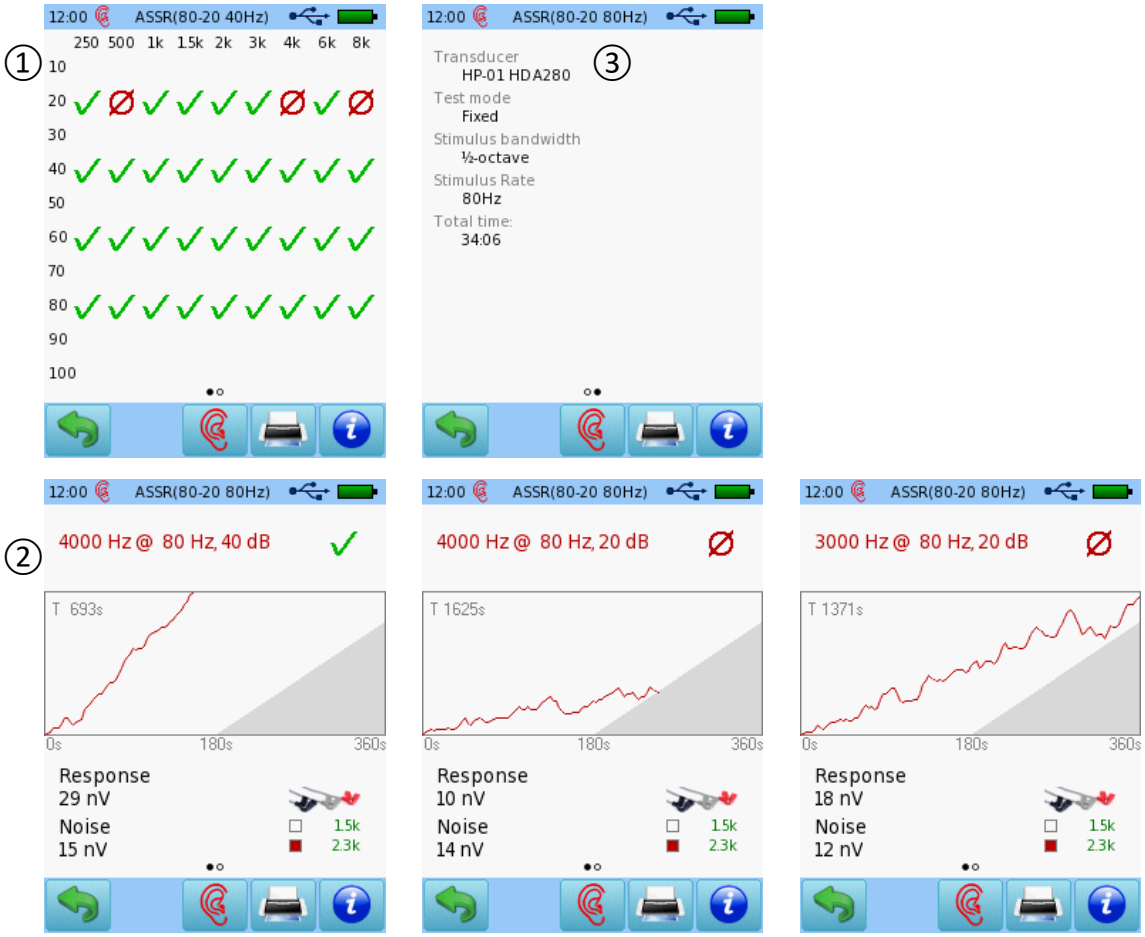

Figure 63: ASSR result (top left: response status matrix; top right: general test information; bottom: detailed response information for valid and invalid responses)

In order to ensure adequate measurement conditions noise should be below 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.

For ASSR Threshold an additional ASSR audiogram is available (see *Figure 64*). The audiogram shows estimated ASSR thresholds, which are derived by subtracting an empirically determined offset from the lowest stimulus level at which a valid ASSR response has been detected (Rosner, 2013a). Thresholds are shown in red (right ear) or blue color (left ear). The width of the threshold symbol corresponds to the configured stimulus bandwidth. An *arrow up* symbol at the threshold symbol means that the threshold is equal or better to the shown threshold. An *arrow down* symbol means that the threshold exceeds the level at which this symbol is shown. By sliding a finger from right to left on the audiogram screen, the response matrix is shown (see *Figure 63*).

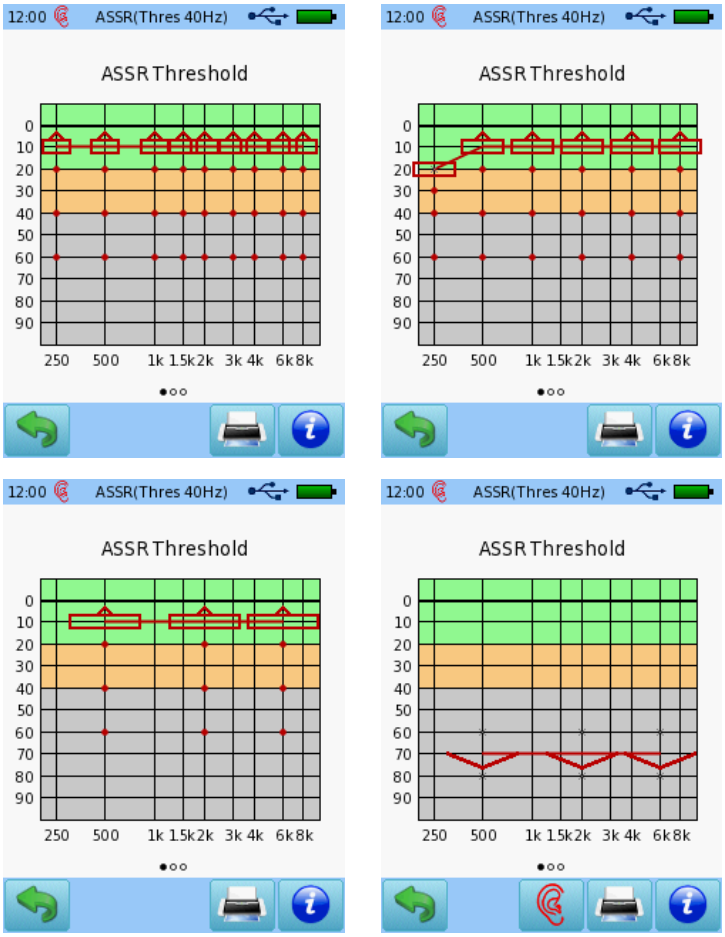

Figure 64: ASSR Threshold result (top left: ½ octave stimulus bandwidth; top right: octave stimulus bandwidth; bottom: two octaves stimulus bandwidth).

The following case examples (see *Figure 65*) show that ASSRs are capable of appropriately estimating behavioral thresholds. The relationship between hearing thresholds estimated from ASSR measurements and behavioral hearing threshold has been investigated by various study groups (e.g., Dimitrijevic *et al.*, 2002, Ahn *et al.*, 2007).

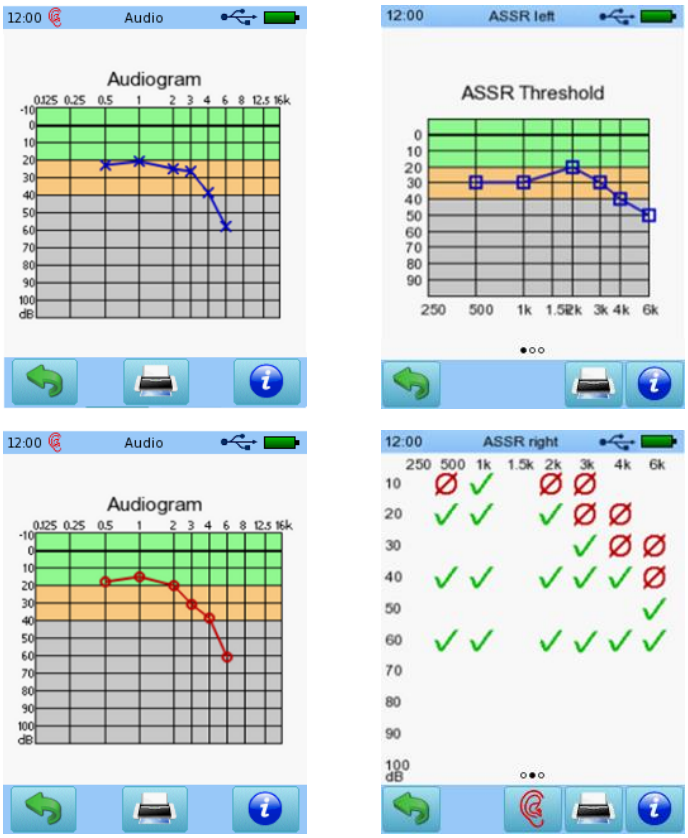

Figure 65: ASSR case examples (left top/bottom: behavioral pure-tone thresholds; right top: ASSR thresholds; right bottom: ASSR response status matrix)

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3.2.8 Electrocochleography (ECochG)

Electrocochleography (ECochG) records neural activity from the cochlea and vestibulocochlear nerve by means of a near-field electrode positioned in the ear canal or resting on the surface of 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 and extratympanic recording is usually favored. A typical electrode montage includes an ear canal electrode deeply inserted into the ear canal (or a tympanic membrane electrode resting on the eardrum) (recording electrode), a surface electrode attached to the contralateral earlobe or mastoid (reference electrode), and a surface electrode attached to the cheek (ground electrode). Impedances may be relatively high for ear canal electrodes which may also result in a poor balancing of electrode impedances and hence may yield less efficient common mode rejection and noise suppression. Moreover, the amplitude and the signal-to-noise ratio (SNR) of the recorded potentials depend on the insertion depth of the ear canal electrode, i.e., the deeper the insertion the higher the amplitudes and the lower the SNR. It is also possible to use a surface electrode attached to the ipsilateral earlobe or mastoid as recording electrode. However, this electrode montage usually suffers from highly reduced amplitudes and is therefore not recommended. In general, when using an extratympanic recording electrode, extended signal averaging is needed in order to yield adequate responses.

The following potentials can be recorded and can be roughly allocated to the following generation places: (1) cochlear microphonic (CM): outer hair cells, (2) summating potential (SP): basilar membrane, and (3) action potential (AP): vestibulocochlear nerve. The action potential including its main component N1 is commonly the most prominent peak in the recorded response and is usually dominated by activity of basal nerve fibers. N1 virtually corresponds to wave I from an ABR measurement. The summating potential and the action potential can be enhanced by summing up rarefaction and condensation responses. The cochlear microphonic resembles the waveform of the stimulus especially at low to medium stimulus levels and therefore can be easily confused with stimulus artefacts. Moreover, the cochlear microphonic can be covered by the stimulus artefact when using extratympanic electrodes. The cochlear microphonic is suppressed by stimulation with alternating polarity. The visibility of cochlear microphonic is improved by subtracting condensation from rarefaction responses.

As stimulus a click or tone burst is typically used. The response latency amounts to about 1 to 3 ms. Action potential latencies increase with decreasing stimulus level reflecting the decreasing contribution of basal cochlear regions. In contrast, cochlear microphonic and summating potential latencies are rather independent of stimulus level. The amplitudes of all components increase with increasing stimulus level. The summating potential exhibits a distinct saturation at high stimulus levels. The action potential amplitude also decreases with increasing stimulus rate. Masking is usually not applied for ECochG measurements as the recorded potentials are near-field potentials, which are largest close to the recording electrode.

Potential clinical applications include the determination of hearing thresholds, identification and monitoring of Menière's disease or endolymphatic hydrops, and intraoperative monitoring. However, please note that hearing threshold determination by means of ECochG (especially when recorded with an extratympanic electrode) is not as reliable as hearing threshold determination by means of ABR.

PRACTICAL USE

Select *ECochG* from the module selection screen. If more than one AEP test is licensed, *ECochG* can be found in the *AEP* section. Select the preset that you would like to perform. If necessary, change the parameters (e.g., stimulus level, stimulus rate) and the preset name as required.

Before the test is started the patient should be instructed about the test procedure. In order to reduce muscle artefacts, the patient should be calm and fully relaxed lying comfortably on a recliner or bed. For babies, try to test the patient 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. A shielded electrode cable may also help in reducing electromagnetic noise. An acoustically shielded booth or a quiet room is recommended if ECochG 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 and that both cables are separated from each other in order to reduce crosstalk from the transducer. Make sure that the skin is clean at the intended positions of the surface electrodes (reference, ground). For further instructions about skin preparation, electrode placement and impedance please refer to *PRACTICAL USE* in section *3.2.6: Auditory Brainstem Reponses (ABRs)*. Select a suitable recording electrode and position the recording electrode in the ear canal. For further information on electrode montage and aspects regarding electrode selection please refer to the initial paragraph of the ECochG section.

Select the test ear. The electrode impedance measurement starts. Both impedances must be suitable for performing a measurement. For further information about impedance measurement see *PRACTICAL USE* in section *3.2.6: Auditory Brainstem Reponses (ABRs)*. After successful electrode impedance measurement, you can start the test by pressing the *play* button. The ECochG 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 66*):

ECochG traces are shown for the configured stimulus level and rate in three graphs: responses from rarefaction and condensation stimuli shown together in one plot ①, rarefaction and condensation responses added to yield a single trace ②, and rarefaction and condensation responses subtracted to yield a single trace ③. The tested trace is shown in red (right ear) or blue (left ear).

During an ECochG measurement, the EEG noise bar ④ represents biological and external noise which is an indicator for the adequacy of measurement conditions. With good measurement conditions, the EEG noise bar should remain green. With increasing noise, the EEG noise bar gradually turns yellow and red, which indicates that 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. When pressing the EEG noise bar, an EEG noise graph is shown. You can return to the EEG noise bar view by pressing the EEG noise graph. The progress bar ⑤ shows the progress of the measurement. If the bar is full, the measurement is finished, i.e., the

number of averages that has been defined by the user is reached. 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 ⑦ or stopped ⑧.

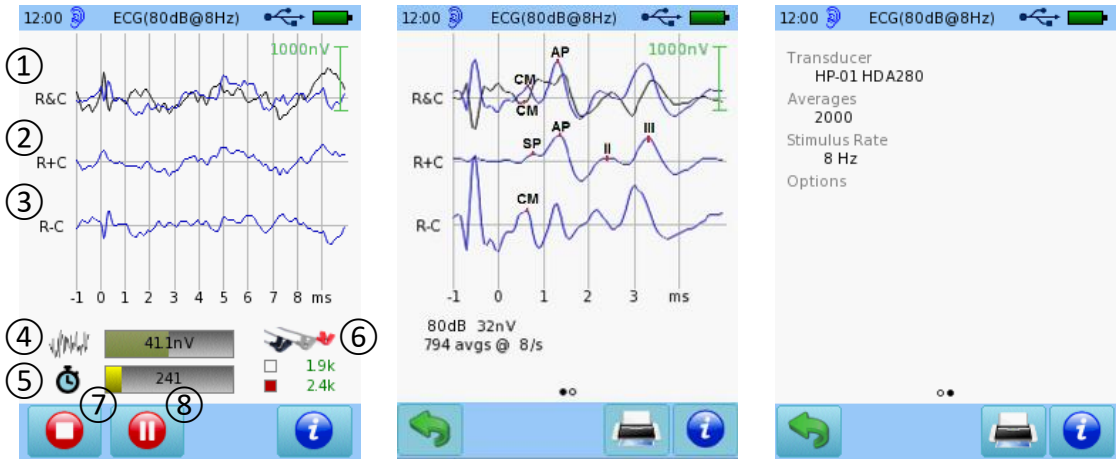

Figure 66: ECochG measurement (left) and result (middle, right)

After the test is finished, the ECochG result is shown (see *Figure 66*). The recorded ECochG traces are displayed again in three graphs (rarefaction and condensation, rarefaction plus condensation, rarefaction minus condensation) as explained above. Below the graph additional test information is displayed as e.g., the stimulus level, noise, number of averages, and stimulus rate. By swiping over the time axis you can adjust the resolution of the time axis. By sliding a finger from right to left on the result screen you can move forward to the general information result screen, which presents information about the used transducer and settings (averages, stimulus rate, and other test options). In order to ensure adequate measurement conditions noise should be <100 nV after 2000 averages. With increasing averages, noise decreases.

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3.2.9 Vestibular Evoked Myogenic Potential (VEMP)

METHODOLOGY

Vestibular evoked myogenic potential (VEMP) is a short latency muscle reflex driven by otolithic organs that play a major role for detecting the orientation, static balance and linear acceleration of the head. Two otolithic organs, utricle and saccule, lie within the vestibule of the inner ear. These contain a three-layered structure; a sensory epithelium called the macula that is formed by a series of hair cells with supporting cells, gelatinous layer and crystal-embedded otolithic membrane. The crystals in the otolithic membrane, called otoconia, are much heavier than the gelatinous layer and cause the membrane shifting relative to the sensory epithelium by gravity or linear acceleration. This shearing motion displaces the hair bundles and evokes receptor potentials in the embedded hair cells. The orientation of hair bundles therefore corresponds to the orientation of acceleration to be detected. The utricle is oriented relatively horizontally and mainly detects movements of the head in the horizontal plane. The saccule is oriented relatively vertically and mainly detects vertical movement.

The vestibular dysfunctions arise from various different regions along the vestibular pathway. Vestibular neuritis, vestibular schwannoma, multiple sclerosis, otosclerosis or Meniere's disease will be indicated by the decrease or absence of VEMP responses. Superior semicircular canal dehiscence (SSCD) or third-window disorder is a disorder with an abnormal opening into the anterior semicircular canal of the vestibular system. This dehiscent bone adjacent to the semicircular canal creates another pathway for auditory stimulation to the vestibular system, resulting in the increase of intra-labyrinthine pressure indicated by hyper sensitive vestibular responses and lower threshold (Welgampola et al., 2003).

Although VEMP is a vestibular reflex, it can be evoked by auditory stimuli (Rosengren and Colebatch, 2018; Rosengren *et al.*, 2019). The inion response originated from neck muscle contraction was observed in those with hearing loss but was absent in those with vestibular dysfunction (Bickford *et al.*, 1964). A particular type of vestibular neurons called "irregular neurons" were activated by low frequency acoustic stimulation (McCue and Guinan, 1994). Otolith afferents sensitive to air conducted (AC) sound could arise from either the saccule or the utricle (Curthoys *et al.*, 2012), tuning to AC sound with frequencies between 500 and 3000 Hz (Curthoys *et al.*, 2016). In addition to the AC sound stimulation, bone conducted (BC) vibration is also used for VEMP recording (Sheykholeslami *et al.*, 2000; Welgampola *et al.*, 2003; McNerney and Burkard, 2011) especially for yielding more robust responses of ocular VEMP than those evoked by AC stimuli (Rosengren *et al.*, 2011).

Neural projections of otolith organs to a number of muscle groups have been determined. For clinical evaluation, two major otolith projections, to sternocleidomastoid (SCM) muscle and extraocular muscle, are especially of interest. Each of these myogenic potentials predominantly reflects either of two distinct otolith organs, the saccule and utricle (Curthoys *et al.*, 2018). Measurements of the myogenic potentials of SCM muscle and ocular muscle are called cervical VEMP (cVEMP) and ocular VEMP (oVEMP), respectively, and supply useful information for clinical diagnostics as described below.

cVEMP assesses the function of the saccule and inferior vestibular nerves by observing the myogenic potentials of the ipsilateral SCM muscle (Curthoys, 2010). Acoustic stimulus is commonly used for the measurement (e.g., tone burst of rise-plateau-fall period of 2-1-2 or 2-2-2 at 95 dB nHL; Rosengren *et al.*, 2009; Curthoys *et al.*, 2016). Normal saccular response shows frequency tuning, with increased peak amplitude at 500 Hz to 1k Hz (Young *et al.*, 1977), and hence 500 Hz tone burst is often used as a

standard stimulus (Dlugaiczyk, 2020). Frequency tuning, however, can be changed in inner ear diseases such as Meniere's disease where the tuning is shifted to 1 kHz or above (Rauch *et al.*, 2004; Sandhu *et al.*, 2012; Taylor *et al.*, 2012; Winters *et al.*, 2012). Since SCM reflexes are inhibitory responses, the SCM muscle should be contracted while recording their myogenic potentials commonly by lifting and turning the patient's head away from the stimulated ear. The typical montages of the electrodes are the ipsilateral SCM muscle, sternoclavicular joint, and chin or sternum. cVEMP typically shows a biphasic waveform response, a positive peak at around 13 ms (termed p1 or p13) and a negative peak at around 23 ms (termed n1 or n23) after the stimulus onset.

oVEMP observes the myogenic potentials of the inferior oblique muscle which is connected to the bottom of the eyeball to assess the utricular functions (Rosengren *et al.*, 2005). Utricular activated superior vestibular nerves are projected to the contralateral oblique muscle that evoke excitatory vestibular reflex. For clinical oVEMP test, acoustic stimuli (e.g., 500 Hz tone burst at 95 dB nHL, Kantner and Gürkov, 2014) or BC vibration stimuli (Rosengren *et al.*, 2011) are used. The recording electrode is mounted on the skin covering the contralateral oblique muscle and the reference electrode is commonly placed further below (1-2 cm) the recording electrode (Todd *et al.*, 2007; Iwasaki *et al.*, 2007). The ground electrode can be placed on the chin or sternum. For maximum response yield, the patient is instructed to keep an upward gaze of about 35 degrees during the measurement (Kantner and Gürkov, 2014). oVEMP elicits a biphasic response, where a negative peak at around 10 ms (termed n1 or n10) and subsequent positive peak at around 15 ms (termed p1 or p15) are typically observed. The interpeak amplitude is usually smaller than that observed in cVEMP.

In both types of VEMP tests, the amplitude between the peaks, the latencies of each peak and the threshold of the peak response are mainly evaluated for clinical assessment. In addition, the difference of the peak amplitudes between left and right is evaluated as an important VEMP parameter. Vestibular dysfunctions can be indicated by the binaural amplitude mismatch of greater than 36% in cVEMP (Young *et al.*, 2002) or 33% in oVEMP (Piker *et al.*, 2011). For cVEMP test where the inhibitory responses are measured, the magnitude of the peak-to-peak amplitude is proportional to the background electromyographic (EMG) activities of recorded muscles (Colebatch *et al.*, 1994; Rosengren, 2015) and hence performing normalization with EMG activity is crucial for the bilateral comparison. This can be achieved by recording pre-stimulus background EMG activity in each stimulation period and scaling each response trace relative to the corresponding EMG response (McCaslin and Jacobson, 2014).

PRACTICAL USE

Conductive hearing loss can make the VEMP peaks undetectable. Therefore, operating audiometric test and middle ear tests prior to the VEMP test is highly recommended.

Select VEMP from the module selection screen. If more than one AEP test is licensed, VEMP 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, in-test frequency change, stimulus polarity, initial stimulus level, stimulus frequency, burst style, stimulus rate, number of averages, range of response plot, Spread Spectrum, Auto Proceed, invert right ear trace polarity, range of myogenic potentials and the protocol of the VEMP test) and the preset name as required.

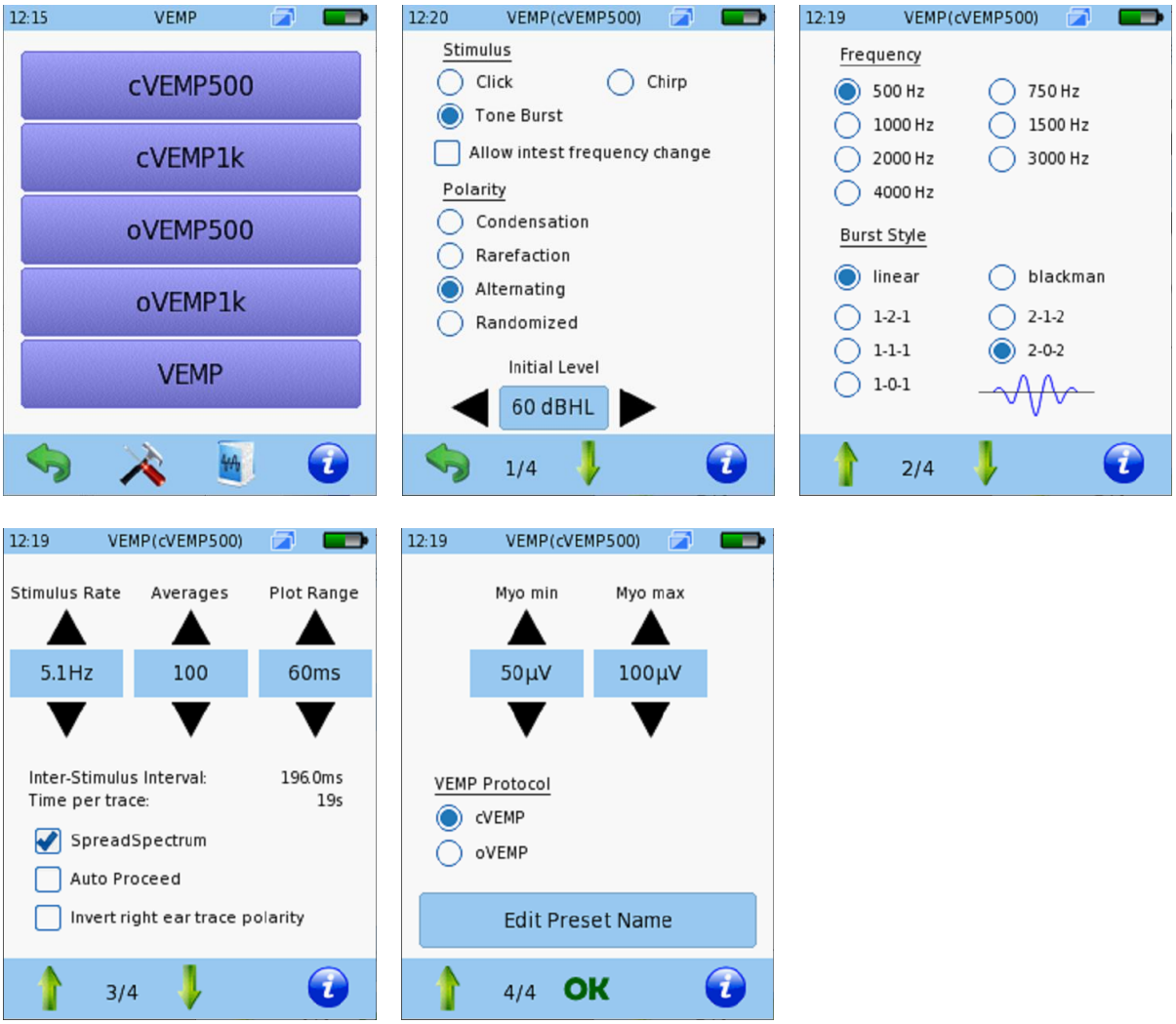

Figure 67: VEMP test settings (top left: preset selection screen; top middle: stimulus type, in-test frequency change switch and stimulus polarity; top right: tone burst frequency and stimulus burst style; bottom left: stimulus rate, number of averages, plot range, switches for Spread Spectrum, auto proceed and right trace polarity inversion; bottom middle: EMG range and VEMP test type)

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

Stimulus type:

- Tone burst stimulus is most commonly used for cVEMP and oVEMP tests. Healthy vestibular afferents show frequency tuning, evoking the largest responses at approximately 500 Hz to 1 kHz. The peak of the tuning tends to shift toward higher frequency with age. Different VEMP protocols also show different preferred frequencies, whereby frequency higher than 500 Hz provides larger responses in oVEMP. In addition, some inner ear diseases such as Meniere's disease often result in the largest responses at 1 kHz or higher.
- Click sound has a fast onset, stimulates a wide range of frequencies and were believed to evoke larger responses than tone bursts. Hence, click had been used as a conventional stimulus in initial cVEMP test for screening purpose. Recent investigations, however, suggest that 500 Hz tone burst evoke larger responses. Also due to the lack of frequency specificity some vestibular dysfunctions that affect frequency tuning of VEMP responses such as Meniere's disease cannot be assessed with click sound.

- Chirp (i.e., rising frequency sweep) theoretically compensates the time difference of tonotopic auditory responses and evokes larger response amplitude than click. However, it is still unclear whether chirp also evokes larger responses in vestibular organs since there is no clear evidence that otoliths are aligned in tonotopic manner. Little data exists for narrow band chirp stimuli but do suggest that these may be a viable alternative to tone-burst, but more data is needed.

Allow in-test frequency change:

- This option is only available for tone burst stimulus. If activated, tone burst frequency as well as stimulus level of each measurement within a test can be configured.

Stimulus polarity:

- Alternating polarity helps reduce the stimulus artefact that is generated by the transducer itself.
- Rarefaction and condensation provide a more peaked response and may yield higher peak amplitudes. Condensation evokes larger response amplitude than rarefaction in oVEMP. Using single polarity is recommended for normal testing condition.

Initial level:

Initial level can be configured. The maximum initial level depends on the specification of the connected transducer. Stimulus levels are given in dB nHL, i.e., relative to the hearing threshold of a collective of normal hearing patients, which is defined as 0 dB nHL. The stimulus level of within-test measurements can be configured before each measurement starts. Multiple measurements of the same stimulus level are also possible.

Frequency:

- If tone burst is selected as the test stimulus, tone burst frequency can be configured. If “Allow in-test frequency change” option is activated, stimulus frequency can be also configured at the beginning of each measurement within a test. Patients with normal vestibular functions typically show the largest response to 500 Hz tone burst and hence 500 Hz is usually an initial choice. The preferred frequency, however, may vary depending on patient’s age and test protocol. Use also higher frequencies if 500 Hz tone burst provides poor response.

Burst style:

- Stimulus filter can be configured to either linear or Blackman filter.
- Stimulus rise-plateau-fall cycles can be configured. As the number of each period increases, the total stimulus duration also increases. Abrupt stimulation such as 1-1-1 configuration will evoke more synchronous neural activities and hence will provide larger responses whereas larger cycles such as 2-1-2 configuration gives more frequency specificity. Since frequency tuning in VEMPs supplies useful information for diagnosing inner ear diseases (e.g., Meniere’s disease), 2-1-2 configuration is recommended. oVEMP gives shorter peak latencies compared to those observed in cVEMP and those peaks might be contaminated by the stimulus artefact when a large cycle stimulus is used. In such case, reduce the cycle number.

Stimulus rate:

- Robust VEMP responses can be yielded at 5 stimuli per second and the peak amplitude decreases as stimulus rate increases. The rate of 10 stimuli per second still evokes distinct peaks. Although the shift of peak latency with increasing stimulus rate is still debatable, some reports show that a rate of 10 stimuli per second provides no significant peak shift compared to that of 5 stimuli per second. To obtain the best performance select 5 stimuli per second. To reduce the test duration and hence patient’s discomfort select 10 stimuli per second. By

pressing the stimulus rate box, a use-defined stimulus rate can be entered. The resulting inter-stimulus interval is displayed on the settings screen.

Averages:

- This configures the number of responses to be measured and averaged for one VEMP trace. The corresponding measurement time per trace is displayed on the settings screen. As the number increases, the test duration also increases. Since both cVEMP and oVEMP require patient's muscle contraction during measurement (i.e., lifting and turning the neck and gazing upward, respectively), shorter test duration is desirable to avoid myogenic artifacts. Commonly used number of averages are between 100 to 200, based on the VEMP characteristics that responses are robust and peak positions and amplitudes are rapidly stabilized.

Plot Range:

- The average traces of recorded potentials are displayed as a function of time. This configures the maximum time value of the trace plot.

Spread Spectrum:

- If activated, the stimulus rate is slightly varied in order to reduce the influence of electrical interference synchronized to the stimulus rate. This also reduces the risk of decreased responses due to adaptation, if any. Activation of this option is always recommended.

Auto Proceed:

- If activated, the recording of a trace automatically proceeds with the recording of the next trace without prompting for the next stimulus configuration.

Invert right ear trace polarity:

- If activated, the polarity of the right ear responses is reversed relative to the left ear responses. It should be activated if the red and white electrodes are placed symmetrically for consecutive bilateral tests.

Myogenic Min/Max:

- The range of EMG activity during the measurement can be configured. Background EMG activities are required in cVEMP where the vestibular reflex is an inhibitory evoked potential. The default ranges are 50 – 100 µV for cVEMP and 2 – 10 µV for oVEMP. The test is paused when the myogenic activity is outside the configured range and is automatically resumed when the myogenic activity returns to the configured range.

VEMP protocol:

- There are two VEMP protocols available: cVEMP and oVEMP. By selecting one of them, a corresponding electrode montage image is shown prior to the test.

Before the test is started the patient should be instructed about the test procedure. If cVEMP test is to be operated, patient's SCM contraction and cervical spine problems must be assessed. In order to reduce muscle artefacts, the patient should be calm and fully relaxed lying comfortably on a recliner or bed. 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 or power transformer) in close range to the measurement equipment.

Since high level acoustic transient stimuli are required to elicit the VEMP responses, users must ensure that the stimulus is correctly calibrated prior to the test. In addition, stimulus level should be carefully chosen so that the patient does not get any subjective loudness discomfort and physical damage. If a

bone conductor is used, the stimulus level should be lower compared to that for air conducted stimulus.

Make sure that a valid transducer (e.g., headphone, insert earphone or bone conductor) and electrode cable are 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 to the correct electrode. The white and red electrodes 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, peak amplitude and latency.

Select the test ear. An illustration of the electrode montage according to the test type (i.e., cVEMP ① or oVEMP ②) is displayed. The test ear is indicated by a red (right) or blue (left) icon ③.

- cVEMP electrode montage

  The white electrode is positioned at the upper one-third of the SCM muscle on the test side, the red electrode is positioned on the sternoclavicular junction and the black electrode is mounted on the forehead. Alternatively, the white and red electrodes can be attached at the upper one-third of the left and right SCM muscle, respectively (symmetric montage for bilateral tests).
- oVEMP electrode montage

  The white electrode is mounted laterally to the midline (i.e., slightly outside relative to the pupil) of the lower eyelid of the opposite side to the test side. The red electrode is attached 1-2 cm beneath the white electrode on the midline (i.e., directly under the pupil) and the black electrode is mounted on the forehead. Alternatively, the white and red electrodes can be attached under the right and left eyes, respectively (symmetric montage for bilateral tests).

Electrodes must be carefully positioned since a slight shift of the electrode position will result in a dramatic change of the structure of the recorded potentials in both types of VEMP test. The black electrode (ground) can also be mounted on the chin, nose or cheek. For bilateral tests, it is important to place the electrodes symmetrically to get comparable results. Symmetric montage does not require relocating the electrodes during consecutive bilateral tests and hence saves the test time and reduces patient's discomfort, although it might have smaller peak amplitudes than the standard montage.

The electrode impedance measurement starts (see *Figure 68*). 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 ④. The VEMP test can be started by pressing the play button ⑤ if the impedances are below 6 kΩ and the difference between red and white electrode impedance is below 3 kΩ. If you do not press the play button for a while, a message appears in order to remind you to start the measurement by pressing the play button. It is possible to configure an automatic start of the VEMP test after adequate impedances are available in the AEP Preferences. The ready-to-test screen is then automatically displayed if the impedances are below 4 kΩ and the impedance difference is below 2 kΩ. However, in some cases these impedances may not be obtained (e.g., in small children cleaning of the skin may not be possible as the child would wake

up when rubbing the skin) and a VEMP test shall be performed despite the not ideal test conditions. For these cases, a forward button appears if the impedances are below 12 kΩ and the impedance difference is below 6 kΩ. If impedances are worse no VEMP test is possible. If impedances are too high, check the electrode cable (see PRACTICAL USE in section *3.2.5 Overview: Auditory Evoked Potentials*) and clean the skin, use conductive gel and wait a couple of minutes until the gel is infiltrated into the skin.

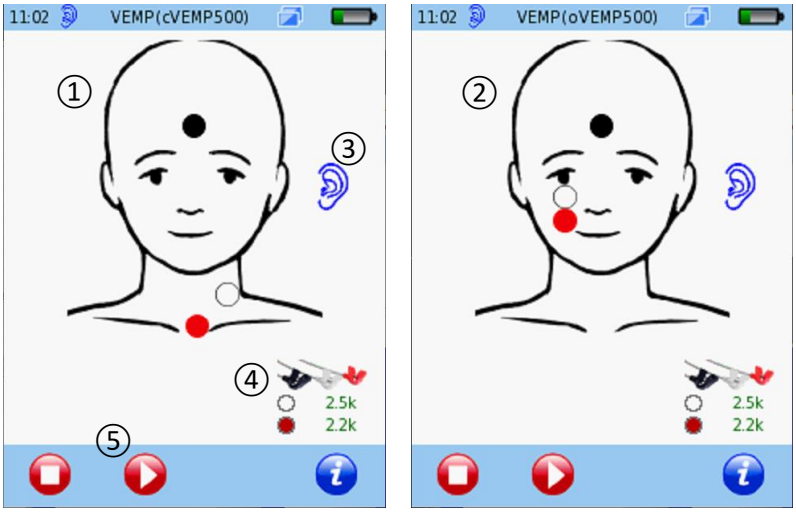

Figure 68: VEMP impedance measurement with electrode montage image corresponding to selected test type (left: cVEMP; right: oVEMP; both testing left ear). Examples show good impedances with play button

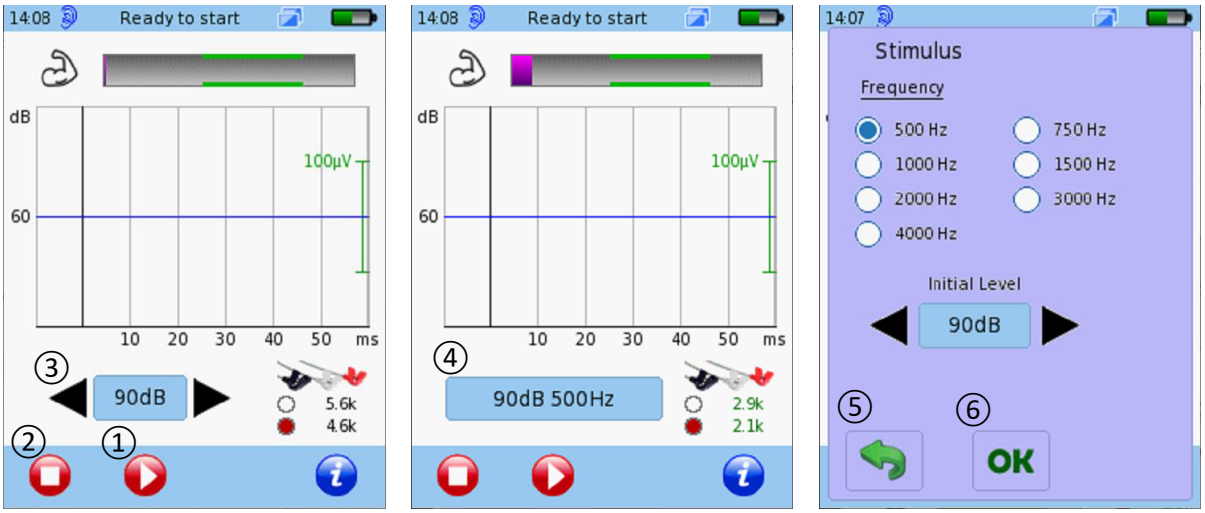

Figure 69: VEMP ready-to-start screen (left: in-test frequency change deactivated; middle: in-test frequency change activated; right: level and frequency setting screen)

After successful electrode impedance measurement, you can move to the ready-to-test screen (*Figure 69*) by pressing the play (or forward) button. You can start VEMP measurement by pressing the play button ① or terminate the test by pressing the stop button ②. In the ready-to-test screen the stimulus level can be varied by pressing the level change arrows ③. If in-test frequency change option is activated, a level-frequency setup button ④ is displayed instead. If the setup button is pressed a level-frequency setup screen opens. The setup screen can be left with the back ⑤ (without saving the changes) or OK button ⑥ (saving the changes).

Prior to the measurement, ask the patient to pose at the following test position.

- cVEMP

  Check patient's cervical spine condition to ensure that the patient can maintain adequate SCM muscle contraction without causing any pain or discomfort. Ask patient to lift head slightly from the resting position and then turn it away from the stimulating ear side at ≥45° (i.e., neck torsion) to contract SCM muscle. The patient should be instructed to maintain the head position during the test.

- oVEMP

  Ask patient to perform ~35° upward gaze keeping head at the resting position. The patient should be instructed to maintain the up-gaze during the test.

The VEMP stimulus is presented via the transducer and the response is detected via the electrode cable. During the measurement the electrode impedance and EMG potentials are monitored. In case that impedances get too high (e.g., an electrode has fallen off), the test is automatically interrupted. The measurement is also automatically interrupted if the observed EMG activity is outside the user specified range (e.g., patient's head position or gaze direction is incorrectly changed). The test can only be continued if the electrode impedances get back to tolerable values and the myogenic activity fits within the specified range.

During the VEMP measurement the following information is provided on the screen (see *Figure 70*):

VEMP traces are shown for each selected stimulus level and frequency. In the standard measurement screen a maximum of eight traces are shown at the same time. The currently tested trace is shown in red (right ear) or blue (left ear). The green trace indicates the stimulus waveform. By sliding a finger horizontally over the time axis of the VEMP traces graph area, the time scale can be adapted. By sliding a finger vertically over the graph area, the amplitude scale can be adapted. By pressing the VEMP traces peak marker screen (described later, see *Figure 71*) is displayed. You can return to the standard measurement screen by pressing the back button on the peak marker screen.

The EMG bar ① represents myogenic activity which is an indicator for the patient's muscle contraction. The configured valid EMG range is indicated as green lines in the bar. With good measurement conditions, the EMG bar should remain within the green range. The EMG outside the green range indicates that the muscle contraction may be too low (e.g., not enough neck torsion) or too high (e.g., moving, clenched jaw/teeth, squinting eyes). The stimulation and measurement are paused if EMG value gets outside the green range. The progress bar ② shows the progress of the measurement at the currently active trace. If the bar is full, the measurement for the current trace is finished, i.e., the number of averages that has been defined by the user is reached. The electrode impedance ③ is regularly updated during the measurement and the measurement is paused if impedance gets too high. The test can be manually paused ④, continued after a pause, or stopped ⑤. Also, a current measurement can be skipped ⑥. Test is paused (i.e., returns to ready-to-start mode) after each trace recording is completed (Figure 70 right). The level (and frequency, if in-test frequency change is activated) can be adjusted by pressing level/frequency button ⑦ for a new trace recording. You can start a new trace recording with newly configured level and/or frequency by pressing the play button ⑧. A maximum of eight traces can be recorded in one VEMP test. Test is finished when the stop button ⑤ is pressed.

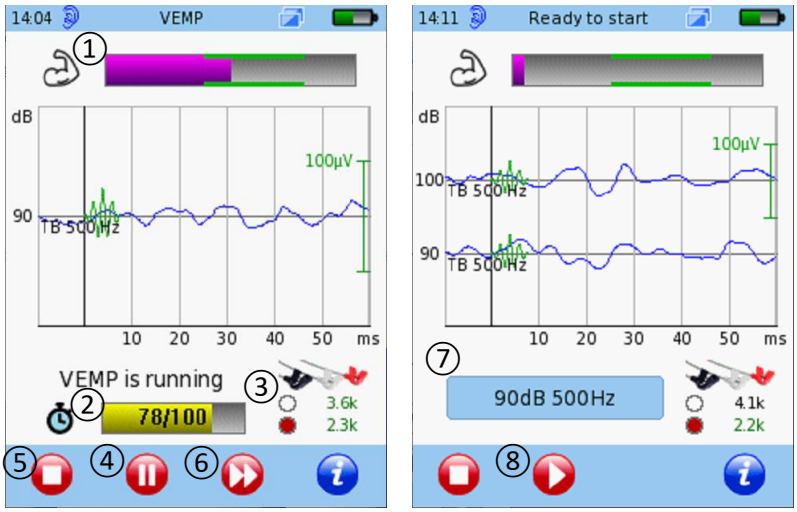

Figure 70: VEMP measurement (left: standard measurement screen; right: in-test ready-to-start screen)

After the test is finished, the VEMP result is shown (see *Figure 71*). The recorded VEMP traces ① are displayed for each stimulus level and frequency. A bar graph ② on the left of each trace represents overall EMG activity for the trace. The resolution of the amplitude axis can be changed by sliding a finger up (zoom in) or down (zoom out) on the result graph screen. Traces can be shown sorted by time (test order) or by level and VEMP traces of the same level can be displayed summarized or can be plotted on top of each other in order to evaluate the repeatability of an VEMP response for a given level. If in-test frequency change option has been selected, traces are displayed for each tested frequency-level pair and can be sorted by frequency. If the other side has not been tested, the ear button with a play icon ③ is shown. The same conditions can be tested on the other ear by pressing this button. If both sides have been tested, the ear button without a play icon ④ that represents currently selected ear is shown instead. You can switch left-right result display by pressing this button. The resolution of the time axis can be changed by sliding a finger right (zoom in) or left (zoom out) on the time axis of the result graph screen. The latencies for P1 and N1 can be adjusted by the user on the peak marker screen ⑤. The currently active marker is indicated by a circle. This screen shows the maximum of three traces that are sorted by stimulus level (or frequency if in-test frequency change has been activated). To scroll the trace display upward or downward, select any marker of top or bottom trace, respectively. The active marker can be moved along the selected trace with the right/left arrow buttons ⑥ and can be set by pressing the set marker button ⑦. While moving the marker it is gray. When setting the marker it turns red or blue (for the right or left ear, respectively). The latency corresponding to the active marker and the resulting peak-to-peak amplitude is shown as a numeric value below the VEMP traces graph. You can choose which marker (P1 or N1) you wish to change by pressing the peak marker selection button ⑧. If any marker has been changed an OK button ⑨ appears in the footer. When leaving the result view, any changes can be accepted by pressing the OK button ⑨ or discarded by pressing the back button ⑩.

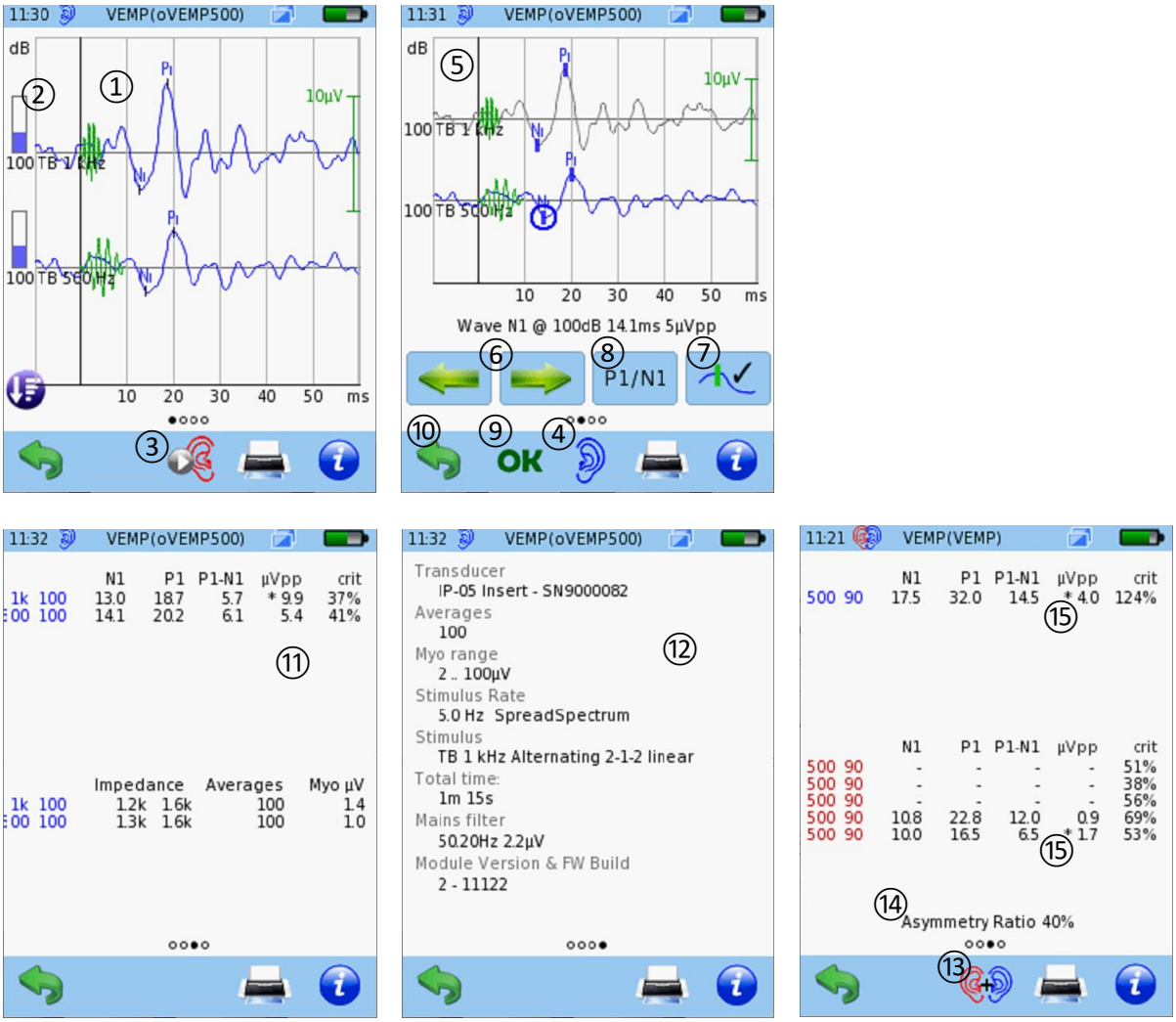

Figure 71: VEMP result (top left: traces with confirmed peak P1/N1; top right: peak marker settings; bottom left: measurement data; bottom middle: general test information; bottom right: bilateral measurement data)

By sliding a finger from right to left on the result screen you can move forward to other result views. The two screens present numeric values of latencies, inter-peak latencies and peak-to-peak amplitudes together with other test-related information (such as impedances, number of averages, and pre-stimulus myogenic potential for each trace) ⑪, and general information about the used transducer and settings (such as averages, EMG range, stimulus rate, stimulus type, test options, total time, mains filter information and module and firmware versions) ⑫.

If both sides have been tested consecutively with using the other ear play button ③, the results of those tests can be displayed in the same display by pressing the ear icon ④ multiple times until the both-ear icon ⑬ appears. If the same stimulus conditions (stimulus type, stimulus frequency and level) were used for both ears and peak markers have been set for any of stored traces in the both results, asymmetry ratio ⑭ is automatically calculated and displayed. This indicates the magnitude of difference of the peak-to-peak amplitudes between both ears. If multiple peak-to-peak amplitudes are available in a test (i.e., multiple traces with defined peaks have been stored in the test), the highest peak-to-peak amplitude value for a given stimulus condition, indicated by a star ⑮, is used for calculating asymmetry ratio.

For the interpretation of VEMP results, the following case examples may be considered:

- Normal patient: VEMPs with tone burst stimuli typically show peaks above 80 dB HL and the peaks quickly fade as the stimulus level decreases. The stimulus frequency of 500 Hz usually evokes the largest P1 and N1 amplitudes. VEMP amplitudes generally decrease with age.
- Meniere's disease: the stimulus frequency that evokes maximum peak-to-peak amplitude is shifted to higher than 500 Hz. Elevated asymmetry ratio in cVEMP is also observed, typically larger than 35%.
- Third window syndrome (superior canal dehiscence syndrome): the peak threshold decreases to ≥ 10 dB below normal threshold for given stimulus.
- Vestibular schwannoma: tumors arising from the inferior vestibular nerve are associated with absent VEMP responses. Patients with vestibular schwannoma have small or absent cVEMP responses and/or show high asymmetry ratio. The peak latencies usually remain in normal range, but some patients with large tumors show prolonged latencies.
- Vestibular neuritis: about a half of the patients show abnormal VEMP responses. Some patients with abnormal VEMP responses have normal caloric responses.
- Multiple sclerosis: P1-N1 latencies are prolonged. VEMP responses are absent in patients with brainstem legions such as Wallenberg syndrome.

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3.2.10 Overview: Immittance Audiometry

The function of the middle ear is to minimize the loss of acoustic energy that occurs 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 of the inner ear due to the different densities. The middle ear helps to improve the energy transmission to the inner ear by increasing sound pressure and force (see *Figure 72*). 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 at the oval window. 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, and stapes). Both mechanisms yield an impedance matching which allows for a transmission of up to 60 % of the sound energy to the inner ear at about 1 to 3 kHz.

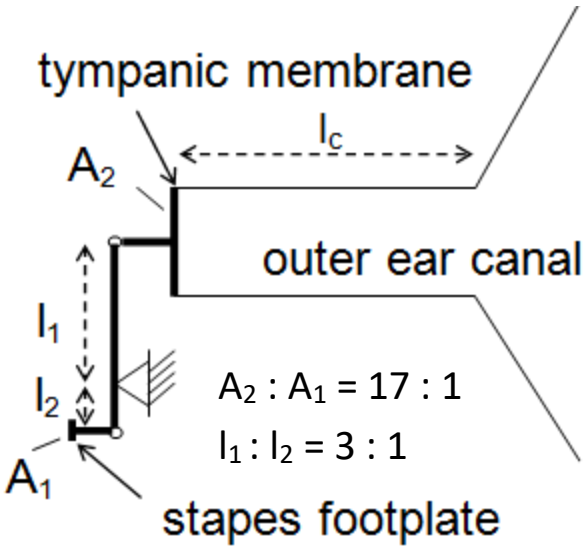

Figure 72: Schematic drawing of the middle ear. A_1 and A_2 are the areas of the stapes footplate and tympanic membrane, l_1 und l_2 are the lever arm lengths of malleus and incus

The middle ear is able to increase the impedance if necessary for providing protection against loud sounds. In case of a sound exceeding about 80 dB HL, the stapedius muscle is activated resulting in an increased stiffness of the middle ear. As a consequence, the energy transmitted to the inner ear decreases. The stapedius reflex is active both on the ipsilateral and contralateral ear.

The term immittance comprises impedance Z (unit: acoustic ohm) or admittance Y (= 1/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/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 volumes. 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 provide 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 patients 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). For more information on tympanometry, acoustic reflex tests, and Eustachian tube function tests please refer to sections *3.2.11: Tympanometry*, *3.2.12: Acoustic Reflex Test*, and *3.2.13: Eustachian Tube Function Tests*, respectively.

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 73*), 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 should 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 should 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: detach the tympanometry ear probe from the device and seal the air pressure socket at the device e.g., with a finger or by screwing the cap on the pressure outlet socket. In this setup only the pump unit of the device is tested.

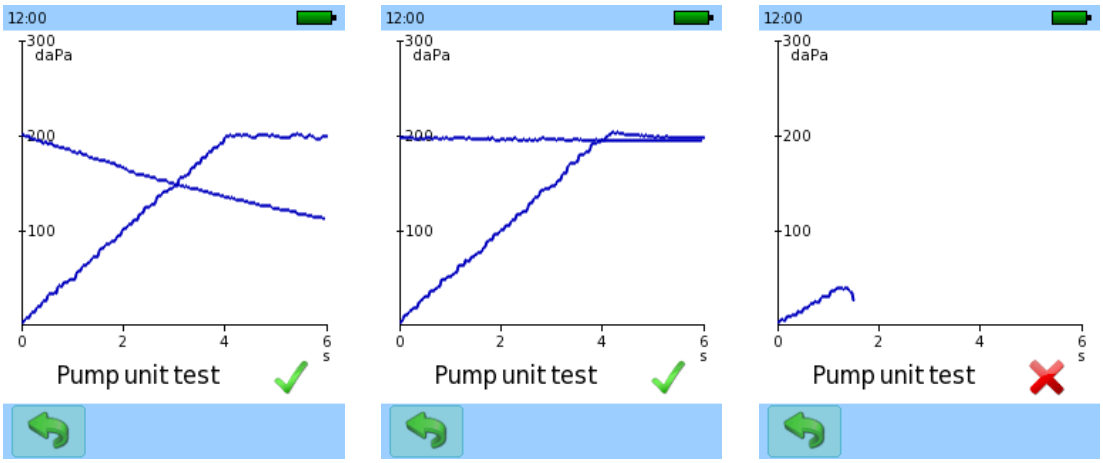

Figure 73: Pump unit test (left: test with slightly leaky probe tip seal; middle: test with closed pressure outlet socket; right: failed test with leaky seal when probe tip is not inserted into the test cavity)

It is recommended to readjust the admittance calibration on the device regularly via the tympanometry calibration procedure (see *Figure 74*), which sets the correct admittance reference values for the three test cavities of known volume (0.5, 2.0, and 5.0 ml).

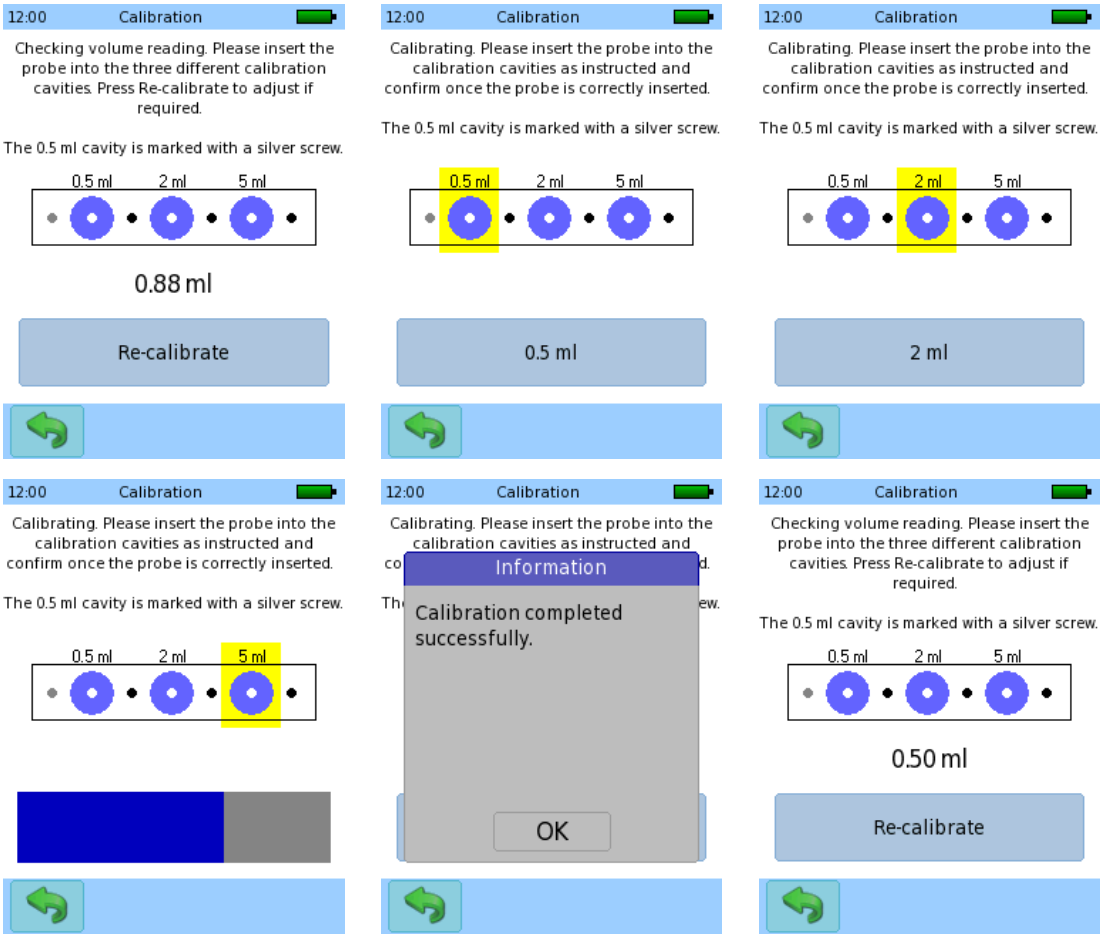

Figure 74: Admittance calibration at three different volumes

For this test, use the provided test cavity box. Place the correct probe tip (PT-S) 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 volume value settles. If the displayed value

differs from the nominal value press the *re-calibrate* button. Press the *volume (0.5 ml)* button to start the calibration for the 0.5 ml volume. The respective admittance is adjusted accordingly. Proceed with the two other volumes as indicated on the screen. During calibration for a volume a progress bar is shown. If all three test volumes have been calibrated a message box will appear indicating either successful or failed calibration. If calibration failed please repeat the procedure and make sure that you use the correct volumes as indicated on the screen. Please remember that the volume of the cavity next to the silver screw represents the 0.5 ml volume. After successful calibration you can verify the admittance calibration by re-entering the tympanometry calibration. Check that the displayed value corresponds to the respective nominal value.

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

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3.2.11 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 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 admittance 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 the 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 (Djupesland and Zwislocki, 1972), which means that the admittances are summed up ($Y_{total} = Y_{ear\ canal} + Y_{middle\ ear}$). 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 with a low frequency stimulus at 226 Hz (or 220 Hz). At low frequencies, the normal middle ear system is stiffness-controlled and susceptance (stiffness element) contributes more to overall admittance than conductance (frictional element). Other typical probe tone frequencies include 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 graph called a tympanogram which plots middle ear admittance as a function of static air pressure in the outer ear canal (see *Figure 75*). Different middle ear pathologies exhibit different tympanogram shapes. The following rough description refers to low frequency (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 ear 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 (gray solid curve). An activated stapedius muscle yields reduced compliance as well.

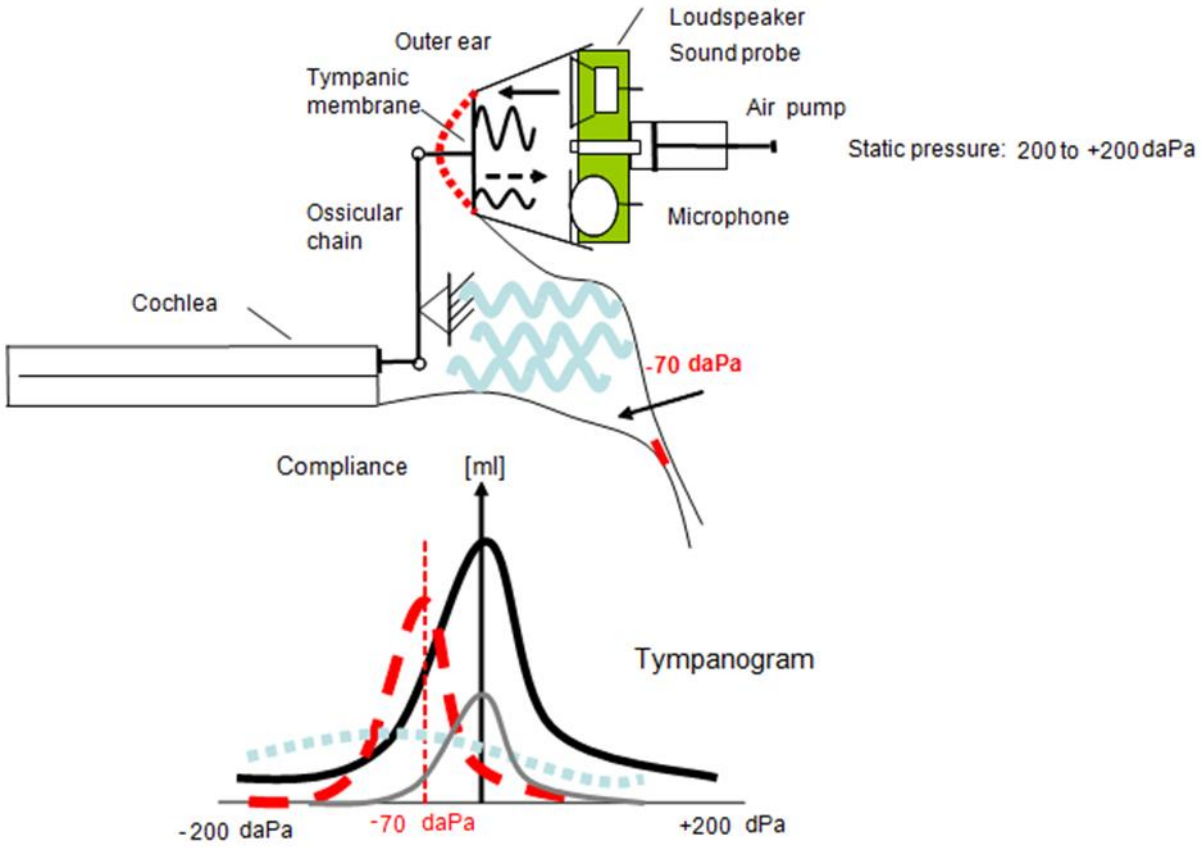

Figure 75: Schematic overview of tympanometry (top) with tympanogram examples (bottom: black solid line: normal; gray solid line: otosclerosis; red dashed line: Eustachian tube dysfunction; light blue dotted line: effusion)

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 (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 *Tymp* from the module selection screen. The *Tymp* module can be found in the *Immittance* section. Select the preset that you would like to perform. If necessary, change the parameters (e.g., minimum/maximum pressure, speed of pressure change, probe tone frequency, auto start, auto stop, reflex options) and the preset name as required. The different parameter options and possible applications are explained in the following:

Pressure setup:

Configures pressure range and pump speed. Pressure range is up to -600 to +400 daPa for class 1, 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. The “afap” option changes pressure as fast as possible with 600 daPa/s at maximum reducing the speed to 200 daPa/s as soon as a steep rise of the tympanometric curve is reached.

Probe tone frequency:

The default value is 226 Hz. Class 1 offers 678, 800, and 1000 Hz probe tones in addition. 226 Hz is commonly used as the tympanogram shows the distinct patterns which allow a classification of tympanograms (type A, B, C). 1000 Hz is frequently used for small children. Please note that the multi-frequency (MF) option allows testing of all four frequencies simultaneously without influencing test results or increasing test time.

Auto Start:

The tympanogram recording is started as soon as an appropriate ear probe fit is detected. If the option is disabled, the test must be started manually by pressing the *play* button.

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.

Manual pressure control:

The tympanogram can be recorded manually, i.e., the pressure can be set by the examiner.

The tympanometry test can optionally be performed with consecutive automated acoustic reflex testing. If you wish to perform an acoustic reflex test immediately after tympanometry select reflex options in the tympanometry settings accordingly (see *3.2.12: Acoustic Reflex Test*).

Make sure that a valid transducer (tympanometry ear probe EP-TY) is connected to the device and check that the air tube connector is tightly screwed on the pressure outlet socket of the device (see *Figure 76*). You may use a clip to fix the ear probe cable to the patient's clothes. Select an ear tip with appropriate size matching the probe tip size and the patient's ear canal size. Make sure that the ear probe is inserted without any leakage between ear probe and ear canal. Foam tips are usually not suitable for performing tympanometry because they are not airtight.

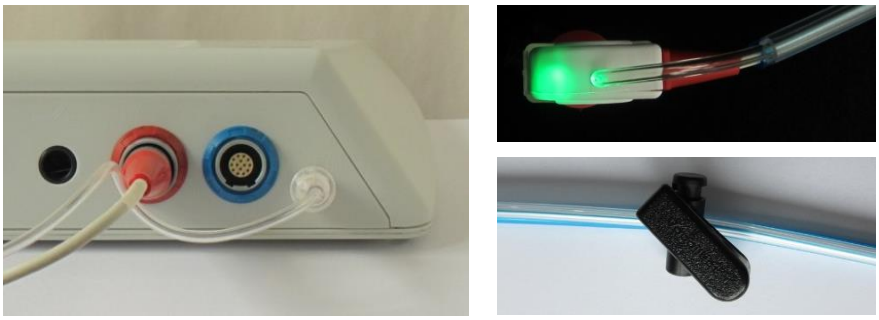

Figure 76: Tympanometry setup (left: attaching the tympanometry ear probe EP-TY to a Sentiero Desktop device; top right: EP-TY status light, bottom right: fixation clip)

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

- Steady light: Ready for testing – please place the ear 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 continuously monitors the probe fit, i.e., the acoustical volume seen at the ear probe (see *Figure 77*).

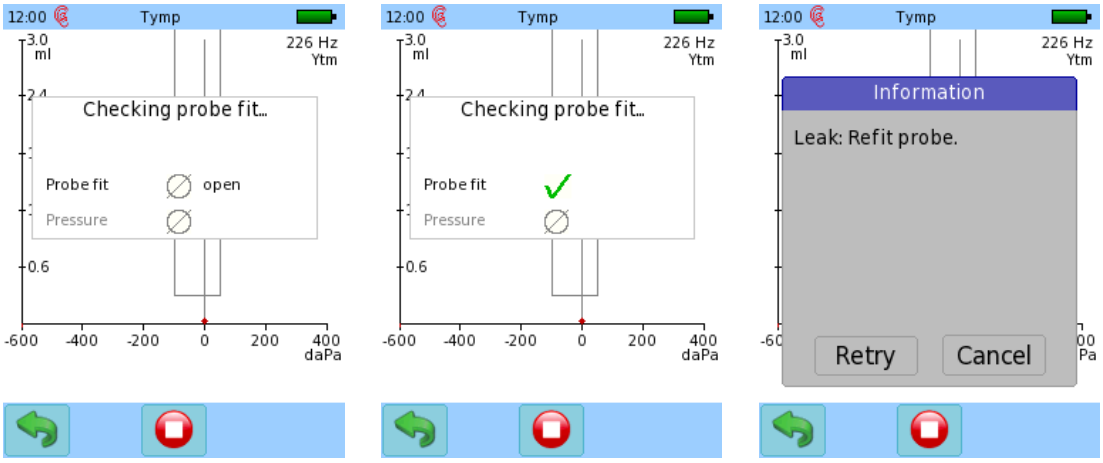

Figure 77: Monitoring of probe fit for tympanometry (left: invalid probe fit when starting the test; middle: valid probe fit when starting the test; right: invalid probe fit during test)

The tympanometry measurement starts automatically (if configured) once the ear probe is appropriately positioned in the ear canal and the acoustical volume has stabilized. The ear probe status light indicator will change from steady to heartbeat mode while the admittance curve is recorded. In case of leakage during the test, a message box appears asking the user to commence or cancel the test. The ear probe status light will change to fast blinking, and instructions will appear on the device display. The device will periodically retry to continue the measurement automatically.

During the tympanometry measurement the following information is provided on the screen (see *Figure 78*):

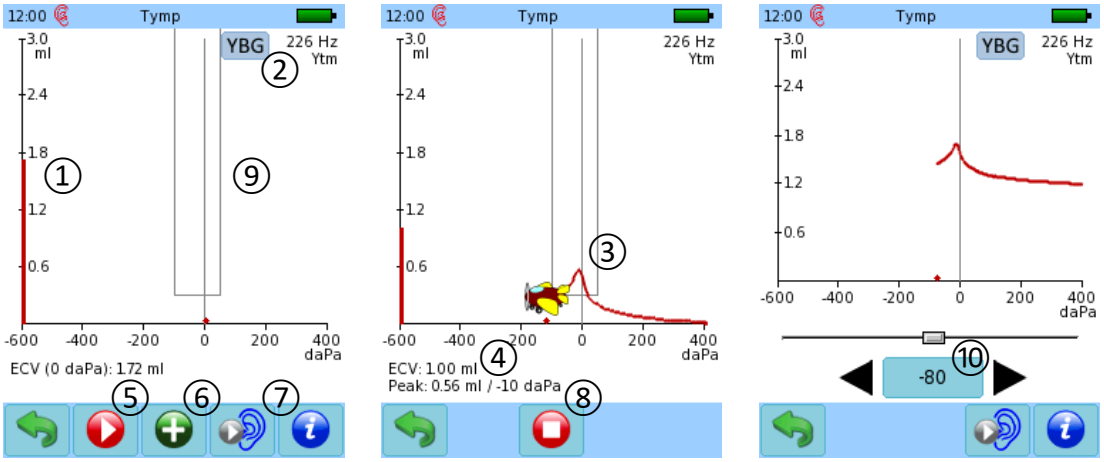

Figure 78: Tympanometry measurement (left: before measurement; middle: during measurement with cartoon mode enabled; right: manual measurement)

Before a test is started manually (if auto start option is disabled), the estimated ear canal volume (ECV) is continuously displayed as bar on the left side of the tympanogram graph ①. The numeric ECV value ④ is additionally shown below the tympanogram graph. For class 1 tympanometers, the tympanogram view mode (admittance Y, conductance G, and susceptance B) can be switched by pressing the *YBG* button ②. As soon as the tympanometry measurement starts (either automatically if the auto start option is enabled or after pressing the *play* button ⑤), the admittance as a function of the applied static pressure offset range is plotted as tympanogram ③. If the cartoon mode is enabled, a plane moves along the tympanogram trace. The cartoon mode is especially meant for focusing a child's interest and hence improving noise conditions during a test. If a peak is detected, the peak amplitude and static pressure offset is displayed below the ECV estimate ④. A gray box in the middle of the tympanogram graph represents the normal area ⑨. If the tympanogram peak is located within this area, the tympanogram can be expected to be normal. An ongoing measurement can be stopped by pressing the *stop* button ⑧.

After a tympanometry measurement is finished, there are several options: In case of artefacts or unclear results, the measurement can be restarted by pressing the *play* button ⑤, i.e., the current trace is discarded and replaced by a newly recorded trace. For class 1 tympanometers, up to three tympanometry traces can be recorded in a single measurement session. An additional tympanogram, which will be displayed on top of the existing one(s), can be added by pressing the *plus* button ⑥. This may be useful if tympanograms are to be compared under different conditions, e.g., before and after performing a Valsalva maneuver. The other ear can be tested with the same parameter settings by pressing the *ear* button ⑦. This is the quickest way of recording tympanograms for both ears. Since the tympanometry measurement starts automatically once the probe fit is stable (if auto start is

activated), remove the ear probe from the current test ear before pressing the *ear* button, to prevent the same ear being measured twice (once as left and once as right ear).

A tympanogram can also be recorded manually if configured in the parameter settings. The static pressure offset can be set by pressing the *left* or *right arrow* buttons or by using the slider ⑩.

Please note that if you have configured the tympanometry to be followed by an automatic acoustic reflex measurement, the acoustic reflex test starts after a valid tympanogram has been recorded. For more information on the acoustic reflex test please refer to section *3.2.12: Acoustic Reflex Test*.

After the test is finished, the tympanometry result is shown (see *Figure 79*).

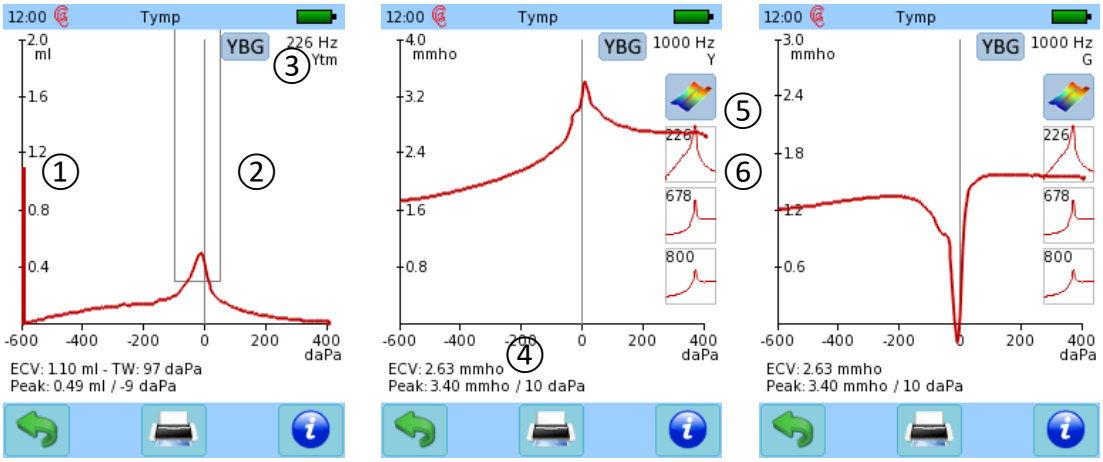

Figure 79: Tympanometry result (left: Admittance with subtracted ear canal volume; middle, right: admittance and conductance for 1000 Hz probe tone)

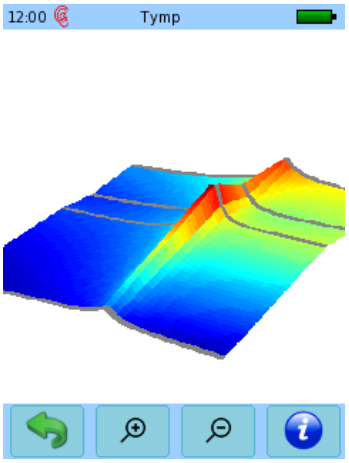

Figure 80: Tympanometry 3D result view

The tympanogram is shown as red (right ear) or blue trace (left ear). The resolution of the ml/mmho axis can be adjusted by swiping a finger up or down the screen. A vertical bar at the left side of the tympanogram graph represents the ear canal volume (ECV) ①. The numeric value of the ECV is shown below the tympanogram graph together with the tympanometric width (TW, for 226 Hz probe tones only), and the peak amplitude and static pressure offset ④. The normative area is shown as gray box ②. For class 1 tympanometers, admittance, susceptance and conductance graphs can be toggled via the *YBG* button ③. For 226 Hz probe tones, the tympanogram can be shown normalized by subtracting

the estimated ear canal volume from the trace yielding the compensated static acoustic admittance Y_{tm} (= admittance of the tympanic membrane alone). The probe tone frequency and view mode are indicated in the upper right corner. For multi-frequency measurements you can chose to plot the tympanogram for each probe tone frequency by pressing the respective small admittance graph ⑥. When pressing the 3D tympanogram graph ⑤ a 3D plot calculated from the traces at the four probe tone frequencies is shown (see *Figure 80*). You can rotate the 3D plot by sliding a finger horizontally or vertically over the screen. By pressing the *magnifying glass* buttons you can zoom in or out of the graph.

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3.2.12 Acoustic Reflex Test

METHODOLOGY

The acoustic reflex (or stapedius reflex, attenuation reflex, auditory reflex) is an involuntary contraction of the stapedius muscle in response to high-level sound stimuli (above about 80 dB HL). The stapedius muscle stiffens the ossicular chain by pulling the stapes away from the oval window of the cochlea. 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. 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 determined. The test is conducted at maximum compliance, i.e., at the static pressure offset, which yields a peak during tympanometry. Therefore, it is recommended to conduct tympanometry before acoustic reflex testing. The result is a graph which plots middle ear admittance as a function of time for a defined stimulus level. The duration of the stimulus may vary from 2 s (determination of acoustic reflex) to about 10 s (determination of decay of acoustic reflex over time). If the stimulus level is high enough to elicit an 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. The acoustic reflex threshold increases in case of middle ear dysfunction.

PRACTICAL USE

Automatic acoustic reflex

Before performing acoustic reflex testing, a tympanometry test should be performed in order to determine the tympanometric peak pressure at which reflex testing should be conducted. This sequence can be run automatically by selecting or setting up an appropriate preset in the *Tymp* module in the *Immittance* modules section. The following options referring to automatic acoustic reflex testing are available in the tympanometry settings:

Acoustic reflex mode:

> Select “always” if you would like to start automated acoustic reflex testing irrespective of the tympanometry result or select “if peak within norm (226 Hz only)” if you would like to start acoustic reflex testing only if the tympanogram peak is within the normal area. If you do not require acoustic reflex testing select “never”.

Acoustic reflex frequencies and start/stop level:

Select the frequencies at which you would like to perform acoustic reflex testing. If you wish to perform a screening test at a specific level, set the start and stop level to the same value. If you wish to determine an acoustic reflex threshold, select the start and stop level for the level range to be checked. The maximum level during automatic mode is limited to 100 dB HL.

Acoustic reflex validity criterion and repeat to confirm:

Select the criterion for a change in admittance which is considered a valid acoustic reflex. If a valid acoustic reflex is determined you can chose to repeat the test at the respective stimulus configuration for confirmation.

Acoustic reflex pressure setup:

Select the static pressure offset at which the acoustic reflex testing shall be performed. You can either use the pressure at the peak of the previously measured tympanogram or you can specify a fixed static pressure offset. If a stable airtight seal cannot be achieved even with an ear tip of suitable size, the measurement can be performed at ambient pressure (i.e., 0 daPa). Although it is recommended to perform acoustic 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.

Make sure that a valid transducer (tympanometry ear probe EP-TY) is connected. The acoustic reflex measurement is quite 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 ear 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 recommended not to hold the ear probe during acoustic reflex testing. You may use a clip to fix the ear probe cable to the patient's clothes. Select an ear tip with appropriate size matching the probe tip size and the patient'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 airtight. An adequate ear tip is necessary that allows a stable probe fit.

Contralateral acoustic reflexes can be measured if a suitable transducer for contralateral stimulation is connected in addition to the tympanometry ear probe. The transducer should be connected prior to selecting the acoustic reflex module in order for it to be recognized by the device. Suitable contralateral transducers include any headphones (HP-xx), insert earphones (IP-xx), or the EP-VIP ear probe. Please note that there are monaural transducers which are specifically meant to be applied for contralateral acoustic reflex testing.

In automatic mode, the static pressure offset for performing acoustic reflex testing is taken over from the latest tympanometry result of the same ear (or depending on the parameter configuration a fixed static pressure offset is used). Acoustic reflex testing will start automatically without further user interaction required. Acoustic reflexes can be determined at various sine frequencies between 0.5 and 4 kHz and with noise (broadband, high-pass, low-pass). Please note that the deflection of the acoustic reflex traces (positive or negative) can be configured in *Tymp Preferences*.

During the automatic acoustic reflex measurement the following information is provided on the screen (see *Figure 81*):

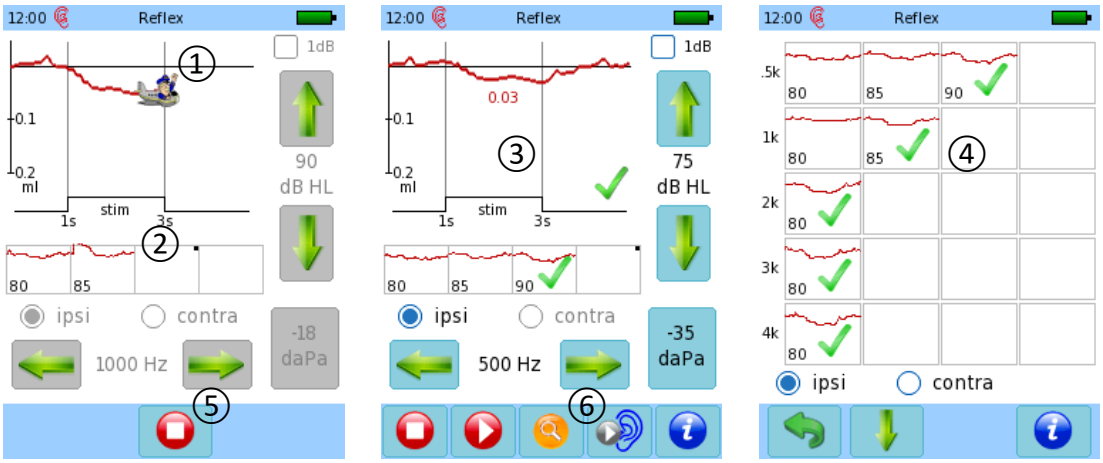

Figure 81: Automatic acoustic reflex measurement (left: threshold determination with enabled cartoon mode; middle: manual mode after test is finished; right: current result overview)

The currently measured acoustic reflex trace is shown in the main graph area ①. Previously measured reflex traces for the same stimulus frequency are displayed in the miniature graph areas ② below the main graph area. The reflex growth at the stimulus frequency under test can be deduced from the traces in the miniature graph areas if multiple levels are tested. A black marker indicates the miniature graph area in which the currently active trace will be plotted. If the cartoon mode is enabled, a flying object (e.g., a plane) is moving along the trace. The type of flying object changes from trace to trace. The cartoon mode is especially meant for focusing a child's interest and hence improving noise conditions during a test. Controls are grayed out and disabled while the automatic measurement is ongoing. The automatic measurement at a stimulus frequency is finished if the highest configured level is reached or a valid acoustic reflex is determined. The automated test can also be interrupted by the user at any time by pressing the *stop* button while the test is running ⑤. As soon as the automatic test is stopped by the user or finished at all selected stimulus frequencies the controls are enabled again and the user can replace or add additional traces in manual mode. 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. For further information on the practical use of the manual mode please refer to the section on manual acoustic reflex below.

An overview that shows all current measurements with the respective status (green check mark in case of a valid reflex) ④ can be displayed by pressing the *magnifying glass* button ⑥. If you wish to trigger the test sequence including tympanometry and automatic acoustic reflex testing on the other ear, please press the *ear* button ⑩. This is the quickest way of recording tympanograms and acoustic reflexes for both ears. Since the tympanometry measurement starts automatically once the probe fit is stable (if auto start is activated), remove the ear probe from the current test ear before pressing the *ear* button, to prevent the same ear being measured twice (once as left and once as right ear).

The acoustic reflex result view (see *Figure 82*) shows an overview of all ipsilateral or contralateral acoustic reflex traces. By selecting any of the miniature graphs the respective detailed view is opened. If the trace is valid a green check mark is shown together with the trace. The change in admittance due to the activation of the acoustic reflex is shown at a valid trace. Below the graph the stimulus time frame (stimulus turned on from 1 to 3 s after the start of the measurement) is plotted.

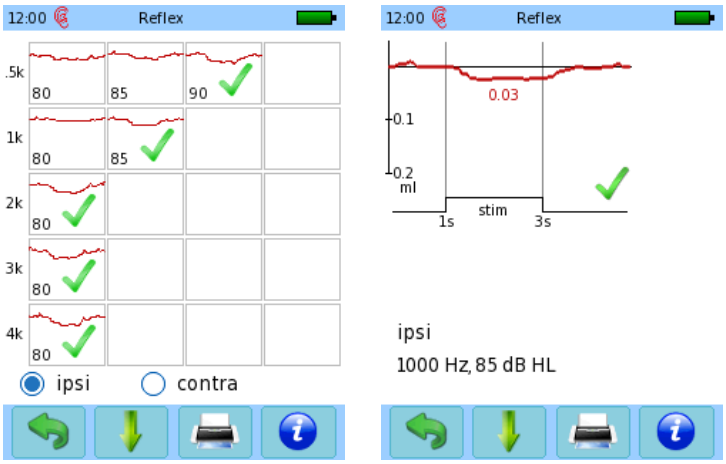

Figure 82: Acoustic reflex result (left: result overview; right: detailed information)

Manual acoustic reflex

If licensed as class 1 tympanometer, *Manual Reflex* is available in the *Immittance* section as a separate measurement mode, so that there is no need to go through a sequence of tympanometry and automatic reflex threshold in advance. For all devices, the manual mode is available after finishing or interrupting an automated acoustic reflex test. Please note that this section focuses on the specific options available for manual testing. The general workflow and user interface is similar to automatic acoustic reflex testing explained above.

During the manual acoustic reflex measurement the following information is provided on the screen (see *Figure 83*).

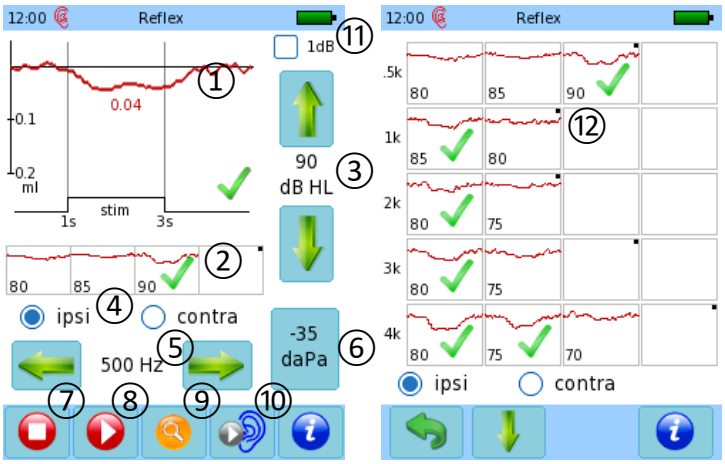

Figure 83: Manual acoustic reflex measurement (left: measurement; right: current result overview)

As for automatic acoustic reflex testing, the current acoustic reflex trace ① and previously recorded traces for the same stimulus type ② are shown. Valid traces are marked with a green check mark. The manual mode allows full control of measurement parameters and measurement order. Measurement parameters can be setup for each individual reflex measurement. The parameters are the stimulus frequency or noise (including additional high-pass or low-pass noise) ⑤, the stimulus level ③ (stimulus levels exceeding 100 dB HL are available depending on frequency), and the presentation ear side (ipsilateral or contralateral if contralateral transducer is connected) ④. The stimulus level step size can be scaled down to 1 dB by activating the respective checkbox ⑪. The static pressure offset

can be adjusted by pressing the *static pressure offset* button ⑥. Once all parameters are set as requested, press the *play* button ⑧ in order to perform the test. If you wish to continue testing on the other ear press the *ear* ⑩ button. The acoustic reflex testing can be finished by pressing the *stop* button ⑦.

The device offers four storage slots per stimulus frequency and presentation modality (ipsilateral/contralateral). The slots are depicted as miniature traces and are annotated with the presentation level. 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' graph will make the corresponding curve appear in the main graph and will select that slot to be overwritten with the next measurement. An overview of all recorded traces can be shown by pressing the *magnifying glass* button ⑨. The overview ⑫ shows miniature graphs for all stimulus frequencies, whereas in the main view, only the reflex growth of the currently selected stimulus frequency is visible. Please note that stimulus levels are shown for each stimulus frequency in the sequence chosen by the examiner.

Acoustic reflex decay

If licensed as class 1 tympanometer, acoustic reflex decay testing is possible. An acoustic reflex decay test examines if the change in admittance due to the acoustic reflex can be maintained during continuous ipsilateral or contralateral stimulation. The acoustic reflex decay is often determined with contralateral stimulation in order to reduce the impact of potential stimulus artefacts on the ipsilateral recording. An acoustic reflex decay test is considered positive if the amplitude of the acoustic reflex decreases to 50 % within a given time period (usually around 10 seconds). Lower frequencies (500 Hz or 1000 Hz) are most commonly used for this test because also normal ears may exhibit an acoustic reflex decay at higher frequencies.

The operation of the acoustic reflex decay module is principally the same as for the manual acoustic reflex module, as the test only differs with regard to the stimulus duration and evaluation of recorded traces (see *Figure 84*).

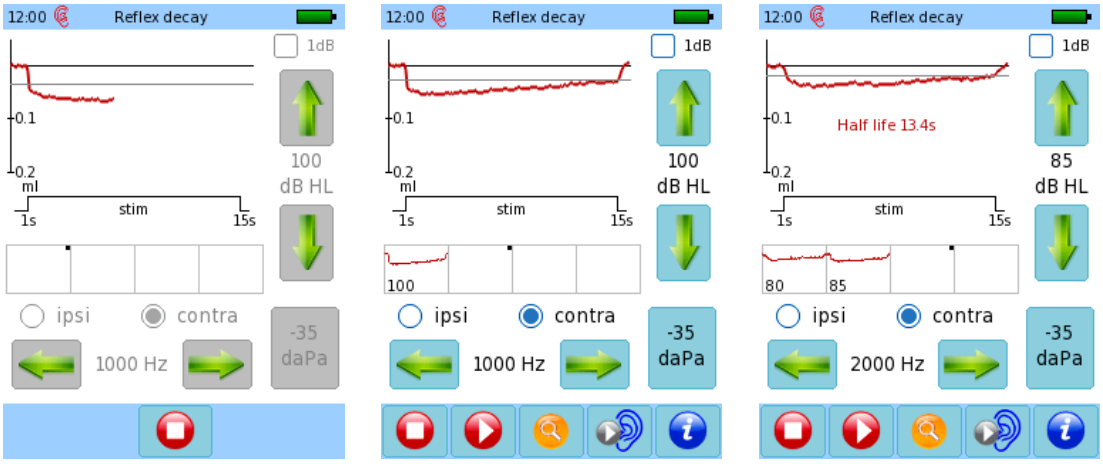

Figure 84: Acoustic reflex decay measurement (left: during a measurement; middle: after a measurement with negative decay; right: after a measurement with positive decay)

Acoustic reflex decay testing is usually performed at stimulus levels 10 dB above the acoustic reflex threshold. Therefore, an acoustic reflex threshold determination, either manually or automatically, should be performed in advance. The static pressure offset should be set to the tympanometric peak

pressure, as with normal acoustic reflex testing. Please be aware that intense stimulus levels may be uncomfortable or even painful to the patient. Good clinical judgement should be used before applying stimuli at high intensities, especially during acoustic reflex decay testing, where the actual duration of the stimulus presentation amounts to 14 seconds.

If an acoustic reflex decay test is positive, i.e., the trace reaches half the amplitude of the initial acoustic reflex amplitude before the end of the measurement, the time at which this amplitude is reached is shown as *half life* at the trace. The gray line at the trace represents 50 % amplitude of the acoustic reflex.

The acoustic reflex decay result view (see *Figure 85*) is similar to the acoustic reflex module and shows an overview of all ipsilateral or contralateral acoustic reflex decay traces. By selecting any of the miniature graphs the respective detailed view is opened. Below the graph the stimulus time frame (stimulus turned on from 1 to 15 s after the start of the measurement) is plotted.

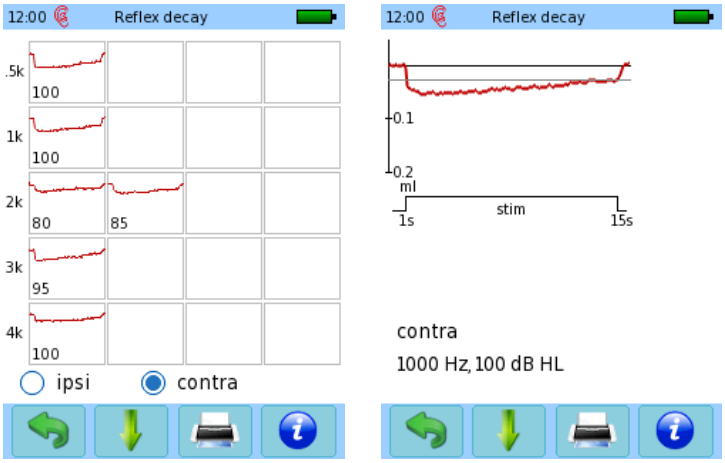

Figure 85: Acoustic reflex decay result (left: result overview; right: detailed information)

Please note that admittance changes can be monitored using the patulous Eustachian tube subtest (see *3.2.13: Eustachian Tube Function Tests*). Admittance changes caused by acoustic reflexes that were elicited by external stimulation, like free field sound sources, or hearing aid / cochlear implant based stimulation, can be recorded. It is up to the user to interpret the recorded curves, since the device has no knowledge about the external stimulation.

LITERATURE

- American Speech-Language-Hearing Association (1988): Tympanometry, online: http://www.asha.org/policy/RP1988-00027.htm
- Chermak GD, Dengerink JE, Dengerink HA (1983): Test-retest reliability of the acoustic stapedius reflex, Audiology 22, p. 136-143
- Deutsch LJ (1972): The Threshold of the Stapedius Reflex for Pure-Tone and Noise Stimuli, Acta Otolaryngology 74

3.2.13 Eustachian Tube Function Tests

METHODOLOGY

In addition to performing tympanometry and acoustic reflex testing, workflows are available to assess the Eustachian tube function (ETF) on a class 1 tympanometer. ETF test are used to check the operability of the Eustachian tube under different conditions. The Eustachian tube provides pressure equalization between the middle ear and the nasopharynx and with that to the external air pressure. The pressure equalization can be triggered by swallowing or yawning. Pressure differences cause a temporary conductive hearing loss due to reduced flexibility of the tympanic membrane and the ossicles. Certain middle ear diseases as e.g., otitis media may affect Eustachian tube function.

PRACTICAL USE

Select *ETF* and the desired subtest from the *Immittance* section of the measurement module selection menu. All ETF tests require the tympanometry ear probe EP-TY. The handling of the tympanometry ear probe is described in section *3.2.11: Tympanometry*. In the following the practical use of the different ETF subtests is explained.

Non-Perforated Eardrum

This Eustachian tube function test can be used if the tympanic membrane is not perforated. During the test three tympanograms are recorded. In between the recordings, the patient is instructed to swallow with nose and mouth closed (Toynbee maneuver) and to breathe out of the nose with nose and mouth closed (Valsalva 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. Please note that the difference in static pressure offset between the three tympanogram peaks also depends on the ability of the patient to perform the maneuvers. Information on how to instruct the patient will be displayed on screen during the progress of the measurement (see *Figure 86*).

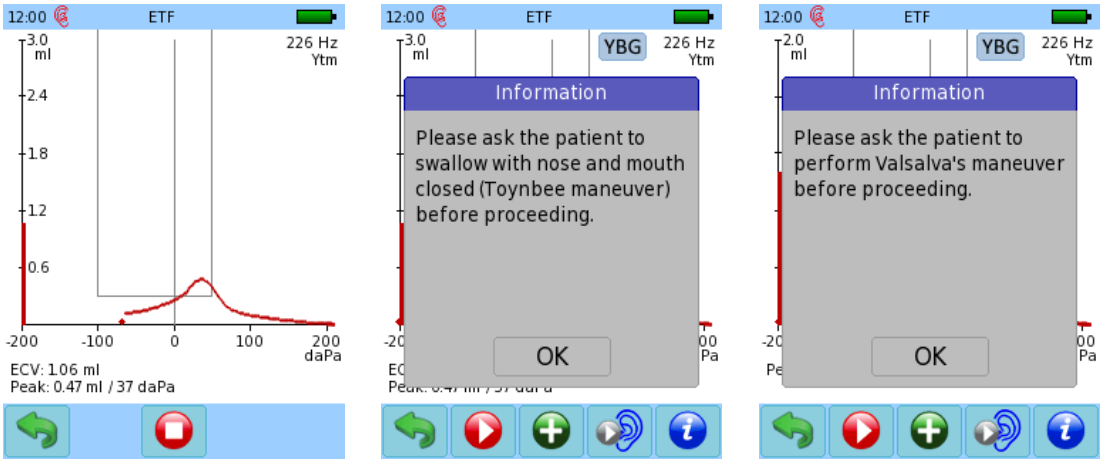

Figure 86: Non-perforated eardrum Eustachian tube function measurement (left: first tympanometry measurement without any intervention; middle: message box for second tympanometry measurement with Toynbee maneuver; right: message box for third tympanometry measurement with Valsalva maneuver)

The result of the non-perforated eardrum ETF test is plotted showing all three tympanograms (see *Figure 87*), i.e., the standard tympanogram and the two tympanograms with the Toynbee and Valsalva maneuver, respectively.

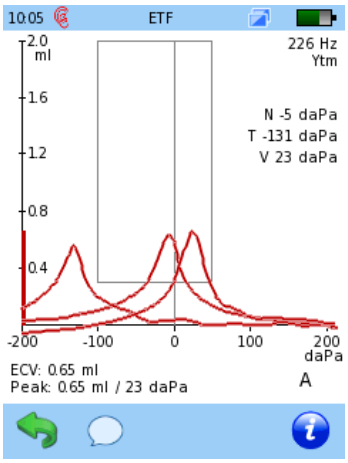

Figure 87: Non-perforated eardrum Eustachian tube function result

Perforated Eardrum

This Eustachian tube function test can be used if the tympanic membrane is perforated. This test pressurizes the ear canal and the middle ear if 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 (see *Figure 88*). Special care must be taken to ensure an airtight fit of the ear probe during testing in order to make sure that the observed pressure drop is due to the Eustachian tube function and not due to leakage.

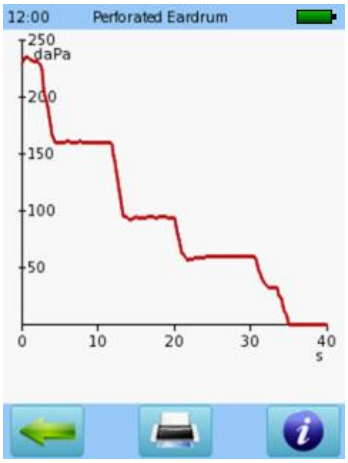

Figure 88: Perforated ear drum Eustachian tube function result

Patulous Eustachian Tube

This Eustachian tube function test can be used for patients with a patulous Eustachian tube, i.e., the Eustachian tube stays permanently or intermittently open. The test performs a high resolution admittance measurement, similar to an acoustic reflex measurement, but without stimulus. The admittance change is recorded and plotted for 20 seconds. 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 these cases.

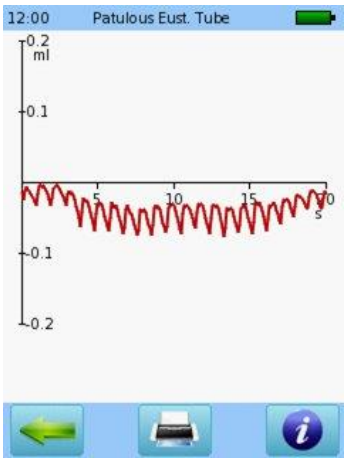

Figure 89: Patulous Eustachian tube result with the heartbeat rhythm of a patient visible in the admittance curve

LITERATURE

- Smith ME, Tysome JR (2015): Tests of Eustachian tube function: a review, Clinical Otolaryngology 40, p. 300-311.

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