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Evoked Potentials and

Otoacoustic Emissions

in perfect harmony



many options, one smart system

the clinical solution you've been waiting for

We've listened to you and have integrated your feedback into a powerful platform for EP and OAE. We are excited to introduce the Duet: a sleek, portable, and versatile clinical evoked potential and otoacoustic emissions system.

stellar performance

Duet

Pomei

Over 30 years of engineering design experience, combined with unsurpassed expertise in evoked responses, have culminated in the next generation bio-amplifier to bring you superior data quality for evoked potentials and otoacoustic emissions.

Repeatable, reliable data you can count on

- High definition responses
- Cleaner, more robust responses
- Increased signal-to-noise ratio (SNR)
- Lower residual noise

Reduced test times without compromising data quality

ready for the clinic

The Duet is available in two base packages: Duet 2 Channel AEP, or Duet 2 Channel AEP & OAE. Choose from a variety of add-on modules for the ultimate in flexibility and versatility. Upgrade anytime with minimal or no down time.

Standard SmartEP modules:

- ECochG
- ABR (click, tone burst, iChirp)
- MLR
- LLR/CAEP

- P300/MMN
- eABR
- cVEMP, oVEMP
- ASSR

flexible enough for research needs

Advanced options for SmartEP:

- CLAD for high-rate stimulation
- Notched Noise Masking
- Advanced Auditory Research Module (AARM)
- Complex ABR
- Frequency Following Response
- Acoustic Change Complex
- CHIRP Stimulus Generation Module

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USB Development Kit

dressed up for performance

The newest member of the Universal Smart Box family, the Duet's sleek design is both ergonomic and portable.

- It is lightweight, at less than 4 lbs (2 kg)
- Fits perfectly under a 15 inch notebook PC
- Maximize your workspace by using it with its companion stand
- Built-in isolation and shielding: it can be used in any location, including the NICU and OR

Test in more places without sacrificing flexibility

Optional SmartEP modules:

Standard SmartOAE modules:

- DPOAE
- TEOAE
- SOAE

Chained-Stimuli ABR

Advanced options for SmartOAE:

- Contralateral, ipsilateral, and binaural TEOAE suppression
- Dual OAE probe system
- HF DPOAE for ototoxicity monitoring



SmartEP

The ideal clinical tool for recording ECochG, ABR, and more.

new and improved user interface simplifies acquisition

- Improved toolbar and button design for fast access to key features
- Easy access to all parameters from a simplified control panel and streamlined menus
- Quickly load your own or preset protocols
- Easily view ongoing EEG display for quick assessment of patient state during testing
- Great variety of options allow you to perform the tests the way you want
- Choose from a variety of stimuli, or generate or import your own custom stimuli
- On-screen and remote impedance checking using patient response alert box

smarter averaging display options

- Option to automatically acquire and store data in sweep blocks for more powerful processing
- Easily analyze acquired waveforms using additional averaging techniques for further noise reduction
- Averaging techniques includes traditional linear, median, and weighted



Duet

- Objective response measurements provide indicators of recording quality
- Automated averaging stopping rules using residual noise measures allow data to be acquired automatically with consistent quality and noise levels

the perfect duet for electrocochleography

Our next generation amplifiers combined with the non-invasive IHS Lilly TM-Wick Electrodes produce more robust and repeatable ECochGs.



Improved SP/AP amplitude and area curve ratio analysis and automatic calculation.



smart features

- Change most test parameters with a single click
- Set your own display scale
- Latency-Intensity graphs indicating normative data ranges are automatically generated from marked waveforms
- Quickly add, subtract, invert, time shift, or cross-correlate recordings
- Split-sweep view to visualize single recording repeatability
- 2D and 3D Spectral Analysis

streamlined workflow

- Easily mark waveforms using over thirty pre-defined peak labels, or create your own custom labels. Easily adjust them using a mouse or keyboard
- View latencies and amplitudes of peaks directly on waveforms and in newly embedded recording information panel.
- Automatically arrange recordings by intensity, acquisition order, stimulus frequency, or rate
- Quickly resize the waveforms using the zoom in/out buttons
- Display or hide a subtle vertical grid or horizontal baseline
- Multi-page display and reports
- Easy PDF report generation
- Auto-save reports on program exit

SmartEP-ASSR

Full-featured screening and diagnostic Auditory Steady State Response System.

- Provides guick, accurate threshold detection using automated statistical analysis
- Test both ears at the same time, four frequencies per ear
- iChirp (broadband & frequency specific) for robust amplitudes and harmonic component analysis for improved threshold detection and reduced test times
- Automated audiogram generation in SPL and HL
- Cost effective add-on to SmartEP





iChirp[™] stimuli included

The intelligent Chirp for SmartEP and SmartEP-ASSR is included in the base package.

- Broad and narrow band (500, 1000, 2000, 4000 Hz)
- Improved threshold detection
- Robust amplitude responses
- Optimized wave V identification
- Optional, innovative custom chirp design utility

Beneficial for recording ABR in awake and active patients.



SmartVEMP

innovative solution for cVEMP and oVEMP

the VEMP solution you've been waiting for

The new & improved SmartVEMP option is the only device cleared by the FDA for oVEMP and cVEMP testing on patients of all ages (K163326). The most advanced VEMP module in the market has been enhanced to become the ideal clinical tool for recording oVEMP and cVEMP responses.



integrated EMG monitoring

SmartVEMP includes the ability to monitor EMG activity with the same recording electrodes: no need for additional EMG monitoring electrodes.

The module also features a user-friendly interface to easily choose the target EMG levels for your patient.

- Choose patient specific acceptance amplitudes for each side
- Automatically calculates the acceptance range
- User-defined acceptance and rejection regions
- Only averages sweeps with adequate EMG activity

On-screen EMG for easy viewing and monitoring patient state during testing

smarter VEMP features

- Quickly load preset cVEMP and oVEMP protocols
- Easy to mark peak labels using mouse or keyboard
- · Baseline automatically marked to the user-defined acceptance region
- Integrated baseline EMG response normalization
- Create a grand average using multiple recordings
- Easily compare left and right VEMP responses
- Automatic calculation of corrected amplitude and asymmetry ratios
- Amplitude corrections based on pre-stimulus EMG activity



improved bio-feedback options

Patient-friendly options for visual bio-feedback:

- Feedback box with LED indicators
- On-screen EMG level display with happy/sad face
- Animated videos for pediatric testing

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	- 175%	150.50 uV	Min: 0.	35	Apply	
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AAR/FFR

Advanced Auditory Research Module for Frequency Following Response and Acoustic Change Complex

complete control of stimulus and acquisition timeline

This add-on module for SmartEP allows users to customize every aspect of acquisition and stimulation, using an advanced and easy to understand interface; making it an ideal tool for the acquisition of Frequency Following Responses (FFR).

It permits the mixing of stimuli when the Notch-Noise masking hardware is installed and provides the user access to define times of acquisition by specifying delays and offsets for each stimuli selected.

- Use simple or complex stimuli, including tones, iChirps, speech stimuli, and noise.
- Define custom stimuli using the built-in conversion utility.
- Adjustable stimulus sampling rate: 40kHz, 20kHz, 10kHz, 5kHz.
- Use stimulus files up to 8 seconds in duration.
- Set stimuli to be presented at a specific time, or to be output continuously.
- Combine up to 2 stimuli per ear or present ipsilateral masking.

Optional ultra-shielded ER3 or ER2 insert earphones

cABR **Complex ABR Research Module**

Acquisition and Analysis of cABR:

- Includes pre-defined settings for complex stimuli, including speech syllables BA, GA, DA, and more.
- Users can create customized settings and stimuli.
- cABR specific label markers.
- Easy comparison of marked recordings.
- · Includes cABR analysis, spectrogram, and phaseogram tools.
- Analysis module includes a cross-correlation function, overlapping stimulus and response, and response power spectrum.
- Users can define the response analysis region, high pass, and low pass filters.
- Display of filtered and unfiltered spectrogram.
- Interfaces with MATLAB® modules for further analysis possibilities.

The Advanced Auditory Research Module, cABR Research Module, and Ultra-Shielded Insert Earphones are for research use only; they are not for use in diagnostic procedures.

Full functionality requires the Auxiliary Output Channel hardware and the Notched Noise Masking software option. Visit the Auditory Neuroscience Lab website (www.brainvolts.northwestern.edu) for information about the research supporting the cABR technology and about upcoming scientific talks by the Lab.

80R(A)

• Export data, cross correlation information, or power spectrum of recording for additional external analysis.

SmartDPOAE

Screening and diagnostic distortion product otoacoustic emissions.

- Fast and easy setup with up to 41 frequencies per ear in a single test
- Automatic probe-fit check and in-ear calibration for increased accuracy
- Easy-to-interpret colorful DPGrams and detailed information for each frequency tested
- Clear Pass or Refer indications based on user-selected passing criteria
- User-customizable display of normative ranges on the DPGram facilitates response analysis
- High frequency option for ototoxicity monitoring
- Built-in scripting feature allows you to define sequences of frequencies and intensities for automated data collection
- Optional graphical display of noise standard deviation for improved interpretation

Smart Audiometer

PC-based screening audiometer.

- Automatic generation of pure tones from 250 Hz to 16 kHz, depending on stimulator used
- Includes a wide array of stimulus files at 500, 1000, 2000, and 4000 Hz: warble tone, narrowband burst, small band burst, broadband burst, Gaussian burst, pure tones
- Ability to use custom stimuli
- Includes standard clinical '5-up/5-down' Adult Self-Test automated routine using the response box accessory
- Print detailed reports with sequence information, frequency tables, and threshold information
- Built in audiogram markers for different stimulator types
- Optional speech discrimination module

SmartTrOAE

Screening and diagnostic transient evoked and spontaneous otoacoustic emissions.

- Fast and easy test setup and data analysis
- Automatic probe-fit check and in-ear calibration
- Clear Pass or Refer indications based on user-selected passing criteria
- Displays of the OAE time signal, frequency analysis and the ear canal response
- Use clicks, tones, or user-defined stimulus files
- Time-Frequency plots can be used to illustrate how the frequency composition of transient OAE responses, Noise, and SNR change over time

Available in the Duet is a dual-probe option that allows for the acquisition of contralateral, ipsilateral, and binaural TEOAE suppression recordings.

This option includes a Suppression Analysis module for temporal and spectral comparison of control and suppression data.

Intelligent VRA

Automated visual reinforcement audiometry.

- Increased reliability & accuracy by a single examiner
- Choose from our variety of 4 and 10 second colorful, animated wide-screen video clips, or use your own video clips
- Use one of our three automated test routines, administer a speech discrimination paradigm (IVRISD), or run a VRA test manually
- Probe Trials maintain patient attention while testing near threshold
- · Control Trials allow you to determine the reliability of a test
- Trial-by-trial reports include detailed information for each test sequence
- Final report includes audiogram and threshold for each frequency tested

complement your Duet Expand your capabilities by adding either of the following audiometry options to your Duet.

CAST™

Classification of Audiograms by Sequential Testing selects the bestfitting audiogram from 9 patterns, for fast and efficient screening.

OHTA™

Optimized Hearing Test Algorithm is designed to test four frequencies, non-sequentially in an intensity staircase fashion.

5-up/5-down

Automated 'step-up, step-down' intensity staircase procedure for testing thresholds at up to four selected frequencies.

Specifications

EP Amplifier

Two channels A/D Converter: 16-bit Sampling rate: 200 to 40000 Hz (adjustable) Recording Window: -2.5 s to 2.5 s (max) User definable in AARM up to 10 s Data points per waveform 1024 Up to 4096 in AARM Adjustable Gain: 5,000 - 200,000 Adjustable High Pass and Low Pass filters HPF: -6 dB/Oct, -24 dB/Oct @ 70 Hz LPF: -6 dB/Oct, -24 dB/Oct @ 500 Hz High Pass: 0.1 - 300 Hz Low Pass: 30 - 5000 Hz Digital Filters: Finite Impulse Response (FIR/ Smoothing), Band Pass, Notch. Adjustable artifact rejection level (0-100%) and any region within the analysis time window Line Frequency Notch Filter: 50 or 60 Hz (-12 dB/Oct) Common Mode Rejection: ≥ 110 dB @ 1 kHz, ≥ 110 dB @ 60/50 Hz, notch filter off Noise Level: ≤ 0.27 uV RMS Input Impedance: > 10 MOhms Electrode Impedance: measuring frequency 1000 Hz, measuring range 1 - 25 kOhms

OAE Amplifier

Sampling Rate: 40 kHz A/D Converter: 16-bit Frequency Accuracy: 0.01% from selected

SmartDPOAE

Stimulus: 2 Pure Tones, user defined start, end and F2/F1 ratio 375 - 12000 Hz, Standard 375 - 16000 Hz, High Frequency Levels: 65/55 (user defined L1, L2, 0-80 dB SPL) Response Points per Octave: 1-10 (user defined), up to 41 frequencies per DPGram Frequency Analysis (FFT) points: 4096 FFT Frequency Resolution: 9.8 Hz Standard, 15.6 Hz High Frequency Acquisition Time: 102.24 ms DP I/O Function

SmartTrOAE

Stimulus: click, 75 us default (adjustable); or tones Stimulus Frequency Range: 250 to 6000 Hz Presentation: Linear or non-linear train Level: 0 - 95 dB SPL (adjustable) Stimulus Rate: 1-50/s (user defined) Response analysis frequencies: 300 - 6000 Hz Frequency Analysis (FFT) points: 1024 FFT Frequency Resolution: 39.1 Hz Acquisition Time: 25.56 ms Contralateral, Ipsilateral, and Binaural Suppression Dual probe option

SmartEP

Stimulus: Clicks, Tones, Broadband iChirp and Octave Band iChirps, Complex, Speech, and user-defined files Stimulus duration in usec or cycles

Click: 100 us default (adjustable) Tones: up to 500 ms (adjustable); up to 4 seconds using AARM

Stimulus Envelopes: Rectangular, Blackman, Exact Blackman, Cosine, Cosine Squared (Hanning), Cosine Cubed, Extended Cosine (Rise/ fall time), Triangular (Bartlett), Trapezoidal (Rise/ fall time), Gaussian

Stimulus presentation:

Continuously or only while acquiring Rarefaction, Condensation, Alternating Stimulus Rate: 0.1 - 200 per second, (dependent on stimulus duration) Rates > 200/s available in CLAD Level Accuracy: +/- 1dB Attenuation Range: 150 dB Frequency Accuracy: +/- 1 percent Masking Level: up to 125 dB SPL Masking Frequency Response: Flat to 20kHz (transducer limits determine roll off) Masking Types: Specific level or relative to stimulus level. Contralateral or Ipsilateral

White Noise or Notched Noise SAL

Transducers

ER-3C Insert Earphones: Intensity: up to 132 dB SPL Frequency Range: 125 - 10000 Hz ER-2 Insert Earphones: Intensity: up to 118 dB SPL Frequency Range: 125 - 16000 Hz TDH Headphones: Intensity: up to 120 dB SPL Frequency Range: 125 - 12000 Hz B71 Bone Conductor: Intensity: up to 125 dB SPL Frequency Range: 250 - 4000 Hz B81 Bone Conductor: Intensity: up to 138 dB SPL Frequency Range: 250 - 8000 Hz

ER-10D OAE Probe: Intensity: up to 100 dB SPL Frequency Range: 125 - 16000 Hz Sound field amplifier and speakers intensity and frequency range dependent on individual model Auxiliary output channel for ipsilateral masking and stimulus mixing

Quality System

Manufactured, designed, developed, and marketed under ISO 13485 certified quality systems.

SmartEP-ASSR

Gain: 100K High Pass Filter: 30 Hz Low Pass Filter: 300 Hz Stimulus: Clicks, Tones, Broadband iChirp and Octave Band iChirps, and user-defined files Frequencies: 250, 500, 1000, 2000, 4000, and 8000 Hz Simultaneous testing of both ears Test up to four frequencies per ear

Power Requirements

115-230 VAC, 560-350 mA 30W, 50/60 Hz Fuse Type: Time Lag (Slow-Blow) Fuses 2A, 250V~ (IEC 60127-2 compliant)

Operating Environment

Portable Equipment Indoor use Operating temperature: 15 °C - 35 °C Relative humidity: 15% to 90% at 40 °C noncondensing Altitude: 0 - 3000 m Ambient Pressure: 98kPa -104 kPa

Storage

Temperature: 0 °C - 50 °C Atmospheric Pressure: none specified

Standards Compliance

Safety: IEC 60601-1 Class II, Type BF EMC: IEC 60601-1-2 EP: IEC 60601-2-40 Medical Device Directive: Class IIa 93/42/EEC Protection from Fluids: IPX0 – Ordinary equipment

Computer Requirements

Windows 10 operating system Minimum 4 GB RAM Minimum 5 GB hard drive space Min display vertical resolution of 900 px, Full HD recommended. Grounded, 3-prong power supply Compliant with IEC 60950 Mouse or other pointing device One available USB Port Removable media, network drive, or secure Internet storage site for data backup (recommended) Printer (optional)

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