Duet

Evoked Potentials and

Otoacoustic Emissions

in perfect harmony





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 present the Duet: a sleek, portable, and versatile clinical evoked potential and otoacoustic emissions system.

outstanding production

Over 40 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.



stellar clinical performance

The Duet is available in three base packages: Duet 2 Channel AEP, Duet 2 Channel AEP & OAE, or Duet 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

Optional SmartEP modules:

- P300/MMN
- eABR
- · Chained-Stimuli ABR
- · cVEMP, oVEMP
- ASSR

Standard SmartOAE modules:

- DPOAE
- TEOAE
- SOAE

Optional EP/OAE:

Simultaneous ABR/TEOAE

powerful research features

Advanced options for SmartEP:

- CLAD for high-rate stimulation
- Notched-Noise Masking
- · Advanced Auditory Research Module (AARM)
- Frequency Following Response (FFR)
- Complex ABR (cABR)
- Acoustic Change Complex (ACC)
- · Binaural Interaction Research Module (BI)
- · SmartEP-CAM Continuous Acquistion Module
- · Chirp Stimulus Generation Module

Advanced options for SmartOAE:

- TEOAE suppression: contralateral, ipsilateral, and binaural
- · Dual OAE probe system
- High Frequency DPOAE for ototoxicity monitoring



SmartEP

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

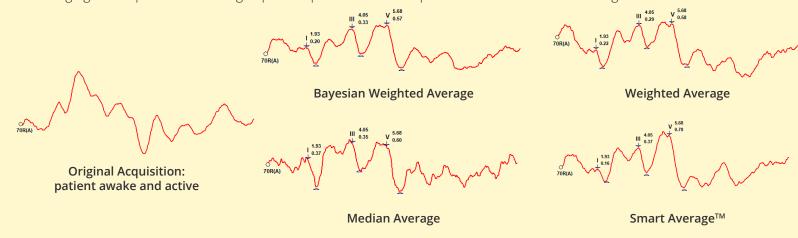
new and improved user interface simplifies acquisition

- Easy access to all parameters from a simplified control panel and streamlined menus
- Change most test parameters with a single click
- Dual channel system, with ability to use as a single channel, including automatic polarity switching
- · Quickly load your own or preset protocols
- Intuitive tool bar and button design for fast access to key features
- Easily view ongoing EEG display for quick assessment of patient state during testing; view one or both channels simultaneously
- 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 options

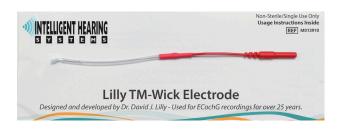
- · Record using various averaging methods, including Standard, Median, Weighted, Bayesian Weighted, and Smart Average
- · Recalculate block averaged recordings using any of the averaging techniques for further noise reduction
- Seamlessly switch between averaging methods during acquisition
- · Averaging techniques can be changed post-acquisition with the option to show as a new recording



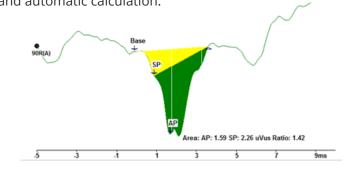
- · Objective response measurements provide indicators of recording quality, including SNR, RN, d-prime, Fsp, and Fmp
- Automated averaging stopping rules using residual noise measures allow data to be acquired automatically with consistent quality and noise level criteria

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

- · Adjustable display scale
- Latency-Intensity graphs indicating normative data ranges are automatically generated from marked waveforms
- Compare any two recordings with automatic latency difference calculation
- Quickly add, subtract, invert, time shift, or cross-correlate recordings
- Ability to show/hide the contralateral response when recording from both channels
- · Display or hide a subtle grid or baseline
- Split-sweep view to visualize single recording repeatability
- · 2D and 3D Spectral Analysis
- Peak extraction utility for advanced data analysis

streamlined workflow

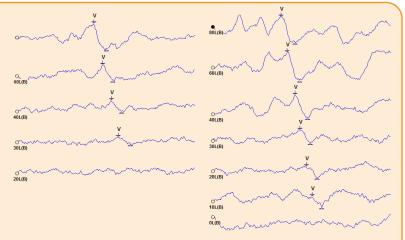
- Easily mark waveforms using over thirty pre-defined peak labels, or create your own custom labels. Easily adjust them using a mouse or keyboard
- View latencies and amplitudes of peaks directly on waveforms and in newly embedded recording information panel.
- Automatically arrange recordings by intensity, acquisition order, stimulus frequency, or rate
- $\boldsymbol{\cdot}$ Quickly resize the waveforms using the zoom in/out buttons
- · Customizable page labels and attributes
- Reports with multi-page display of EP, OAE and ASSR data with built-in PDF printing
- Customizable report printouts with options to show/hide parameters and peak label information
- · Auto-save reports on program exit

iChirp™ stimuli included

The intelligent Chirp for SmartEP and SmartEP-ASSR is included with all packages.

- 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.



2000 Hz tone burst ABR (left) vs 2000 Hz iChirp ABR (right)

SmartEP-ASSR

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

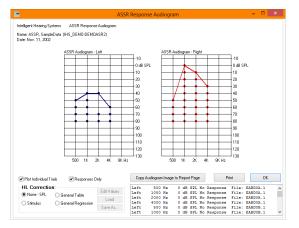
- · Provides quick, accurate threshold detection using automated statistical analysis
- Test both ears at the same time, four frequencies per ear

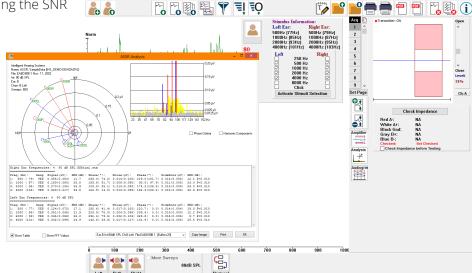
• iChirp (broadband & frequency specific) for robust amplitudes and harmonic component analysis for improved threshold detection and reduced test times

· Automated audiogram generation in SPL and HL

 Ability to save all recording data for ASSR, including the SNR and RN for future analysis

· Cost effective add-on to SmartEP





SmartVEMP

Innovative solution for cVEMP and oVEMP

the VEMP solution you've been waiting for

The new & improved SmartVEMP option is cleared by the U.S. FDA for oVEMP and cVEMP testing on patients of all ages. 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 EMG level acceptance amplitudes for each side
- Automatically calculates the EMG acceptance range
- User-defined acceptance and rejection time regions
- Only averages sweeps with adequate EMG activity

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

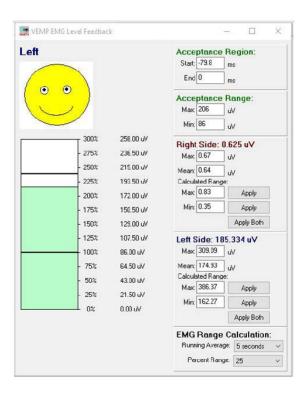
improved bio-feedback options

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

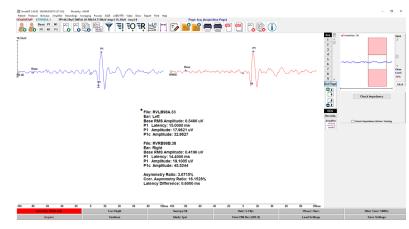






smarter VEMP features

- 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



Sample oVEMP Recordings



AARM/FFR

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

complete control of stimulus and acquisition timeline

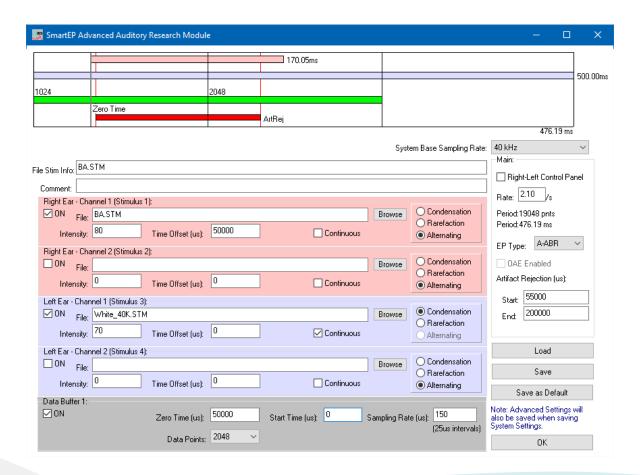
This add-on module for SmartEP allows users to customize every aspect of acquisition and stimulation, using an advanced and easy to understand interface; making it an ideal tool for the acquisition of Frequency Following Responses (FFR).

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

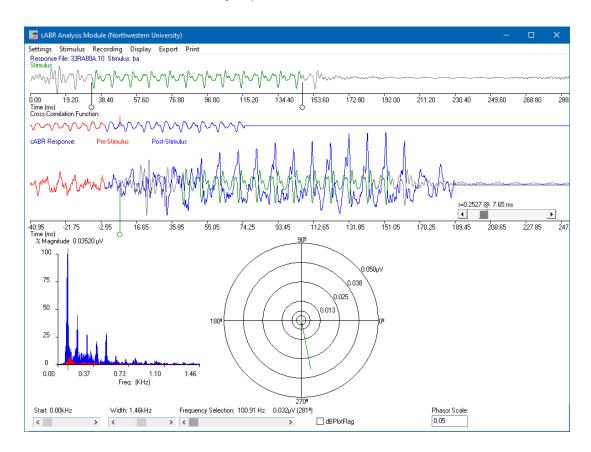


cABR

Complex ABR Research Module*

Acquisition and Analysis of cABR:

- Includes pre-defined settings for complex stimuli, including speech syllables BA, DA, GA, 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
- Export data, cross correlation information, or power spectrum of recording for additional external analysis
- Interfaces with MATLAB® modules for further analysis possibilities

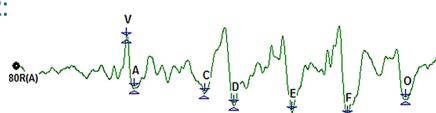


^{*}The Advanced Auditory Research Module, cABR Research Module, and Ultra-Shielded Insert Earphones are inteded for research use only; they are not for intended for use in diagnostic procedures.

Full functionality requires the Auxiliary Output Channel hardware and the Notched Noise Masking software option.

Research supporting this technology was developed by Dr. Nina Kraus and colleagues as Northwestern University.

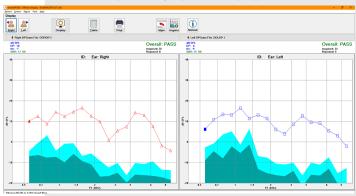
Visit the Auditory Neuroscience Lab website (www.brainvolts.northwestern.edu), directed by Dr. Nina Kraus, for information about the research supporting the cABR technology and about upcoming scientific talks by Dr. Kraus.

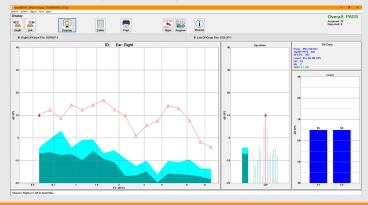


SmartDPOAE

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 test accuracy
- · Ability to record additional sweeps or retest specific frequencies after acquisition is completed
- Easy-to-interpret colorful DPGrams and detailed information for each frequency tested
- Full color printout of DPGram and recording information table
- · View DPGrams from multiple test sessions on the same screen for easy comparison and monitoring
- · 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

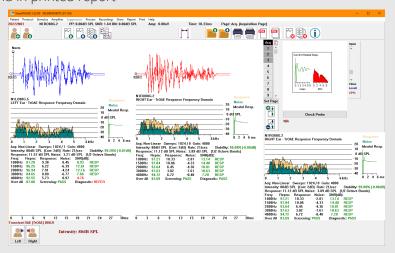




SmartTrOAE

Screening and diagnostic transient evoked and spontaneous otoacoustic emissions.

- Efficient recording of Transient Evoked Otoacoustic Emissions (TEOAE), including Click-Evoked OAE (CEOAE) and Tone-Burst evoked OAE (TBOAE), and Spontaneous OAE (SOAE)
- Automatic probe-fit check with in-ear calibration and stimulus stability measure as a quality indicator
- Pass or Refer indicator based on user-selected passing criteria including reproducibility per band and overall
- Show FFT spectral energy for each band or as aggregate measure of ½ octave bands
- · Easily review multiple recordings on the same screen using the integrated analysis panel
- · Customizable display showing recordings as time domain recordings, or with spectral plot and data table
- Color indicators to easily display whether the user-selected criteria were met for reproducibility, SNR, stability measures, and Pass/Fail information
- · Display of reproducibility of TEOAE on screen and in printed report
- Displays of the OAE time signal, frequency analysis, the ear canal response, and full range of spectral values (signal and noise)
- Time-Frequency plots can be used to illustrate how the frequency composition of the OAE, Noise, and SNR change over time
- Ability to add two or more recordings to create a grand average
- Ability to export recordings to ASCII files
- Dual-probe and Suppression Analysis Module options for the acquisition of contralateral, ipsilateral, and binaural TEOAE suppression recordings



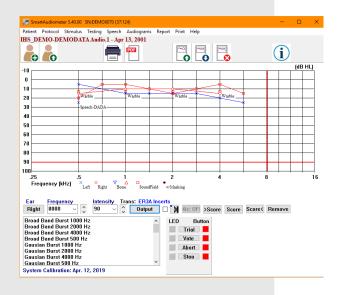
complement your Duet

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

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, and 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



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

CASTTM

Classification of Audiograms by Sequential Testing quickly selects the best-fitting audiogram from 9 common patterns, for fast and efficient screening.

$OHTA^{TM}$

Optimized Hearing Test Algorithm is designed to test four frequencies, non-sequentially using 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.

Duet Technical Specifications

Duet is a sleek, portable, and versatile clinical evoked potential and otoacoustic emission device.

GENERAL SPECIFICATIONS

Evoked Potentials: ECochG, ABR, MLR, LLR/CAEP, SN10, Chained Stimuli ABR, eABR, P300, MMN, FFR, cABR, cVEMP, oVEMP, ASSR

Otoacoustic Emissions: DPOAE, TEOAE (CEOAE & TBOAE), SOAE, TEOAE Suppression

Audiometry: Audiometer, VRA, VRISD

EP AMPLIFIER

Channels: Full two channel device with 2 inverting and 2 non-inverting inputs. Single channel operation with automatic polarity switching and single channel electrode cable

Gain: 5,000 - 200,000 (adjustable)

High Pass Filter:

0.1 - 300 Hz, (adjustable) -6 dB/Oct, -24 dB/Oct @ 70 Hz

Low Pass Filter:

30 - 5,000 Hz (adjustable) -6 dB/Oct, -24 dB/Oct @ 500 Hz

Digital Filters:

Finite Impulse Response (FIR/ Smoothing), Band Pass, Notch

A/D Converter: 16-bit

Sampling rate:

200 to 40,000 Hz (adjustable)

Recording Window:

-2.5 s to 2.5 s (max)

User definable in AARM up to 10s

Data points:

1024 per waveform Up to 4096 in AARM

Artifact Rejection Level: Adjustable: 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: 1,000 Hz Measuring range: 1 - 25 kOhms

EP STIMULUS

Stimulus:

Clicks, Tones, Broadband iChirp and Narrowband / Octave Band iChirps, Complex, Speech, and user-defined files

Stimulus duration:

Defined in µsec or cycles Click: 100 µs default (adjustable) Tones and user files: 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, or Alternating polarity

Stimulus Rate:

0.1 - 200 per second, (dependent on stimulus duration) Rates > 200/s available in CLAD

Stimulus Output:

Up to 132 dB SPL (transducer dependent) Attenuation Range: 150 dB Level Accuracy: +/- 1dB D/A: 16-bit

Frequency:

Range: up to 40 kHz (transducer dependent) Frequency Accuracy: +/- 1 percent

Masking:

Level: up to 125 dB SPL
Frequency Response: Flat to 20kHz
(transducer limits determine roll off)
Types: Specific or relative to stimulus
level. Contralateral or Ipsilateral. White
Noise or Notched Noise. SAL

VEMP

Integrated Patient Feedback:

Video Monitor LED Feedback Box (optional)

P300

Stimulus Presentation Options

2-4 stimuli random
50/50 sequential or random
Reject or accept common after odd
Optional stimulus jitter by percentage
Trigger-out with custom offset timing

TRANSDUCERS

ER-3C Insert Earphones:

Intensity: up to 132 dB SPL Frequency Range: 125 - 10,000 Hz Total Harmonic Distortion: <1% @1kHz

ER-2 Insert Earphones:

Intensity: up to 120 dB SPL Frequency Range: 125 - 16,000 Hz

DD45 Headphones:

Intensity: up to 120 dB SPL Frequency Range: 125 - 8,000 Hz Total Harmonic Distortion: <1% @1kHz

DD450 Headphones:

Intensity: up to 120 dB SPL Frequency Range: 125 - 16,000 Hz Total Harmonic Distortion: <1% @1kHz

B71 Bone Conductor:

Intensity: up to 69 dB HL (96 dB SPL) Frequency Range: 250 - 4,000 Hz Total Harmonic Distortion: <2% @1kHz

B81 Bone Conductor:

Intensity: up to 82 dB HL (109 dB SPL) Frequency Range: 250 - 8,000 Hz Total Harmonic Distortion: <1% @1kHz

ER-10D OAE Probe:

Intensity: up to 100 dB SPL Frequency Range: 125 - 16,000 Hz

Sound Field:

Amplifier and speakers intensity and frequency range dependent on sound field components

Auxiliary:

Output channel for ipsilateral masking and stimulus mixing

High Frequency Transducers:

Intensity: up to 100 dB SPL (up to 140 dB SPL at some frequencies)
Frequency Range: 2,500 - 40,000 Hz





Duet Technical Specifications

ASSR

Gain: 100,000

High Pass Filter: 30 Hz **Low Pass Filter**: 300 Hz

Stimulus:

Clicks, Tones, Broadband iChirp and Octave Band iChirps, and user-defined

riies

Simultaneous testing of both ears
Test up to four frequencies per ear

Frequencies: 250, 500, 1000, 2000,

4000, and 8000 Hz

DPOAE

Modes: DP OAE, DP I/O Function **Stimulus**: 2 Pure Tones, user defined start, end and F2/F1 ratio

375 - 12,000 Hz, Standard 375 - 16,000 Hz, High Frequency

Levels: 65/55 SPL

(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

TEOAE

Probe: Single or Dual

Stimulus: Click, 75 µs default (adjustable), tones or user files

Stimulus Frequency Range:

250 to 6,000 Hz

Presentation:

Linear or non-linear train

Level: 0 - 95 dB SPL (adjustable) Stimulus Rate: 1-50/s (adjustable) Response analysis frequencies:

300 - 6,000 Hz

Frequency Analysis (FFT): 1024 points FFT Frequency Resolution: 39.1 Hz

Acquisition Time: 25.56 ms

Suppression: Contra, Ipsi, and Binaural

OAE AMPLIFIER

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

DATA AND SECURITY

Encryption: Advanced Encryption Standard (AES) to encrypt patient demographic information (PHI), using a 256-bit key

Data Export: Ability to export to external patient databases such as Oz-eSP, HiTrack and other hospital systems using HL7 protocols (customization fee may apply)

PHYSICAL CHARACTERISTICS:

Dimensions:

38.2 x 25 x 4.76 cm (15 x 9.8 x 1.9 in)

Weight:

1.36 Kg (3 lbs)

POWER REQUIREMENTS

Internal Power Supply:

100-240 VAC, 0.77 mA 47 - 63 Hz

Fuse Type:

Time Lag (Slow-Blow) Fuses 2A, 250V~ (IEC 60127-2 compliant)

ENVIRONMENT

Degree of Mobility:

Portable Equipment

Location:

Indoor use

Temperature:

Operating: 15°C - 35°C (59°F - 95°F) Transport: -20°C - 50°C (-4°F - 122F°) Storage: 0°C - 50°C (32°F - 122°F)

Relative humidity:

Operating: 15% to 90% at 40 °C non-condensing

Ambient Pressure:

Operating: 98 kPa -104 kPa Storage: None Specified

Warm-up Time:

None at room/operating temperature

QUALITY SYSTEM

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

REGULATORY COMPLIANCE

FDA cleared and compliant with Regulation (EU) 2017/745 (MDR)

STANDARDS COMPLIANCE

Safety and Electromagnetic Compatibility:

IEC 60601-1 Class II, Type BF (Safety) IEC 60601-1-2 (EMC)

IEC 60601-2-40 (EP)

Calibration and Test Signals:

IEC 60645-3

Electroacoustics -Audiometric Equipment

IEC 60645-6:2009 Type 1 IEC 60645-7:2009 Type 1

Protection from Fluids:

IPX0 - Ordinary equipment

COMPUTER REQUIREMENTS

Operating System:

Windows 10 or Windows 11

Hardware Required:

Minimum 8 GB RAM
Minimum 5 GB hard drive space
Mouse or other pointing device
1 USB Port

Display:

900 pixels minimum vertical resolution, Full HD recommended

Power Supply:

Grounded, 3-prong power supply, Compliant with IEC 60950

External Storage:

Removable media, network drive, or secure Internet storage site for data backup (recommended)

Printer:

Software includes PDF printing capabilities, hardware printer optional

