# Duet

Evoked Potentials and

Otoacoustic Emissions

in perfect harmony



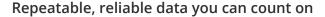


# the clinical solution you've been waiting for

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

### outstanding production

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.



- High definition responses
- · Cleaner, more robust responses

 Increased signal-to-noise ratio (SNR) Lower residual noise Reduced test times without compromising data quality all dressed up 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 most laptop computers 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

### stellar clinical performance

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

#### 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.

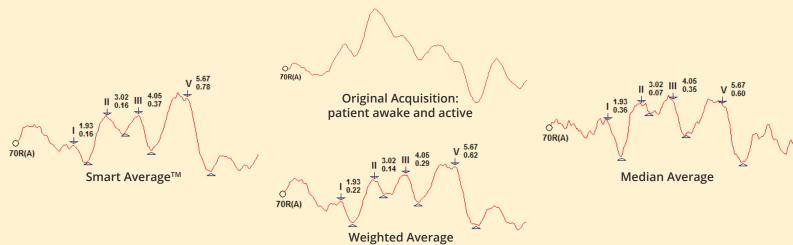
### new and improved user interface simplifies acquisition

- 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

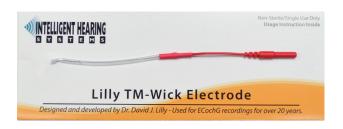
- · Option to automatically acquire and store data in sweep blocks for more powerful processing
- Easily analyze acquired waveforms using additional averaging techniques for further noise reduction
- · Averaging techniques includes traditional (linear), median, weighted, and Smart Average



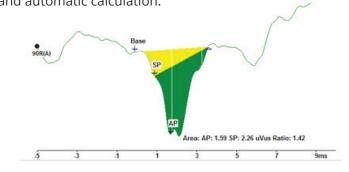
- · Objective response measurements provide indicators of recording quality, including SNR, RN, Fsp, and Fmp
- Automated averaging stopping rules using residual noise measures allow data to be acquired automatically with consistent quality and noise level criteria

## 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

- Dual channel system, with ability to use as a single channel, including automatic polarity switching
- · Change most test parameters with a single click
- · Adjustable 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
- · Display or hide a subtle grid or baseline
- · Split-sweep view to visualize single recording repeatability
- 2D and 3D Spectral Analysis

### streamlined workflow

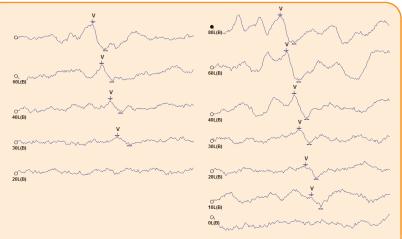
- Easily mark waveforms using over thirty pre-defined peak labels, or create your own custom labels.
   Easily adjust them using a mouse or keyboard
- View latencies and amplitudes of peaks directly on waveforms and in newly embedded recording information panel.
- Automatically arrange recordings by intensity, acquisition order, stimulus frequency, or rate
- Quickly resize the waveforms using the zoom in/out buttons
- Customizable page labels and attributes
- Multi-page display and reports with easy PDF reports
- · 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**

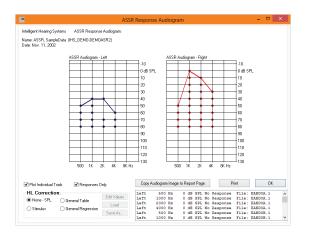
Full-featured screening and diagnostic Auditory Steady State Response System.

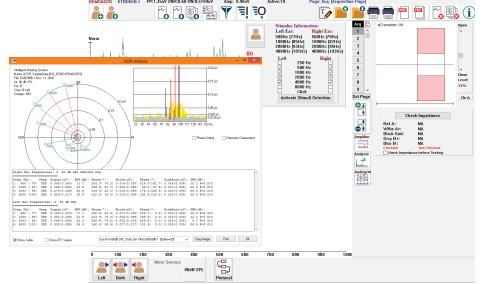
- Provides guick, accurate threshold detection using automated statistical analysis
- Test both ears at the same time, four frequencies per ear

• 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





# **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

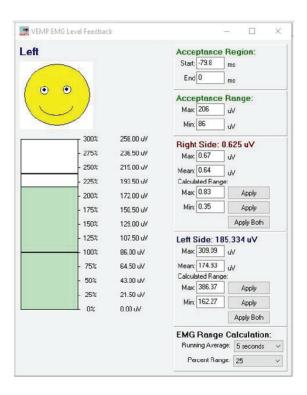
## improved bio-feedback options

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

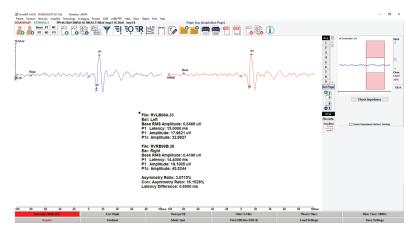






### smarter VEMP features

- 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



# AAR/FFR

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

## complete control of stimulus and acquisition timeline

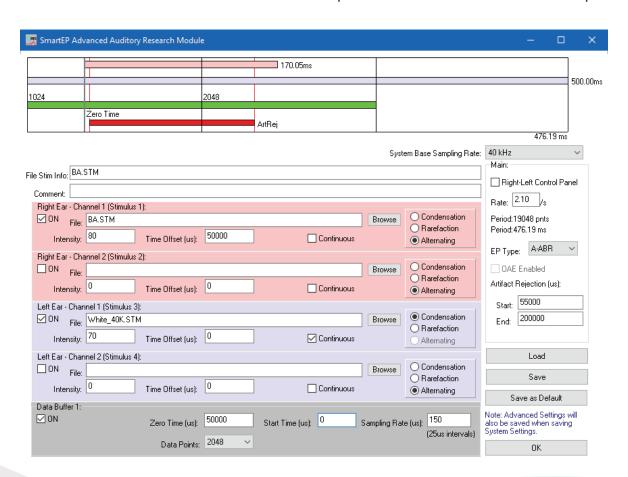
This add-on module for SmartEP allows users to customize every aspect of acquisition and stimulation, using an advanced and easy to understand interface; making it an ideal tool for the acquisition of Frequency Following Responses (FFR).

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

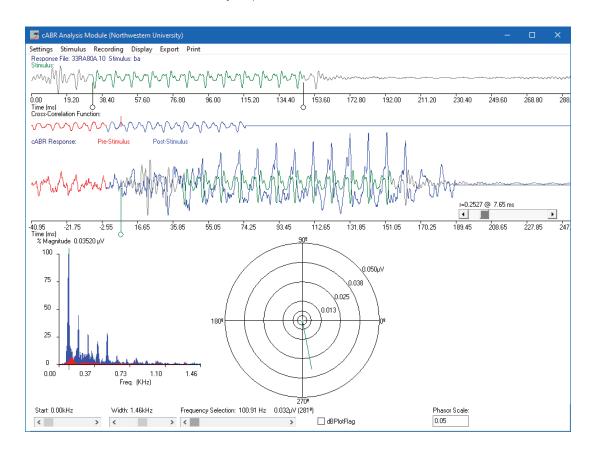


# **c**ABR

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

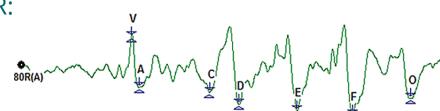


<sup>\*</sup>The Advanced Auditory Research Module, cABR Research Module, and Ultra-Shielded Insert Earphones are inteded for research use only; they are not for intended for use in diagnostic procedures.

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.

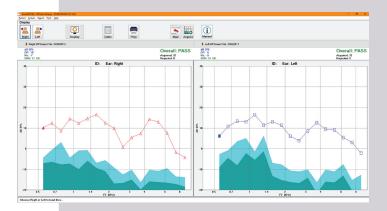
Visit the Auditory Neuroscience Lab website (www.brainvolts.northwestern.edu), directed by Dr. Nina Kraus, for information about the research supporting the cABR technology and about upcoming scientific talks by Dr. Kraus.

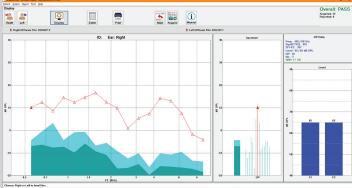


# **SmartDPOAE**

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
- · 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

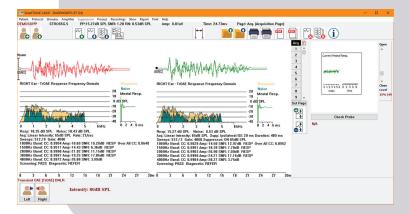




# **SmartTrOAE**

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.

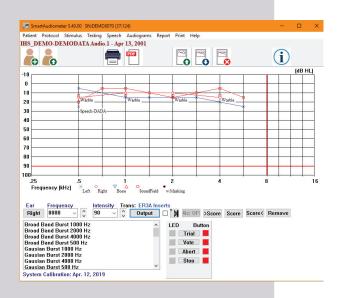
# complement your Duet

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

#### CAST<sup>TM</sup>

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, SPOAE, TEOAE Suppression **Audiometry**: Audiometer, VRA, VRISD

#### **EP AMPLIFIER**

**Channels**: Two channels. 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 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 32 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)

#### **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

tiles

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

**Frequencies**: 250, 500, 1000, 2000,

4000, and 8000 Hz

#### 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

#### **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

#### **High Frequency Transducers**:

Intensity: up to 100 dB SPL (up to 140 dB SPL at some frequencies) Frequency Range: 2,500 - 32,000 Hz

#### Sound Field:

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

#### Auxiliary:

Output channel for ipsilateral masking and stimulus mixing





# **Duet Technical Specifications**

#### **OAE AMPLIFIER**

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

#### **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); or tones

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: Contralateral, Ipsilateral,

and Binaural Suppression

#### **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:**

115-230 VAC, 560-350 mA 30W, 50/60 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

#### Max Altitude:

3000 m above sea level

#### **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

#### 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

#### **Medical Device Directive:**

93/42/EEC Class IIa

#### **Protection from Fluids:**

IPX0 – Ordinary equipment

#### **COMPUTER REQUIREMENTS**

#### Operating System:

Windows 10

#### Hardware Required:

Minimum 4 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

