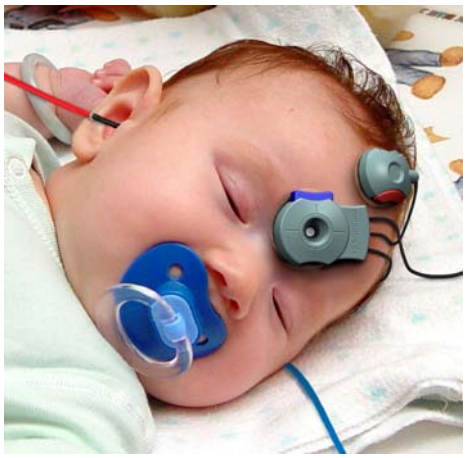
USER'S MANUAL

Integrity™

wireless revolution in audiology

Document 11049 Revision 2



Vivosonic brings you sophisticated and innovative technologies in a friendly, convenient and easy-to-use way.

vivosonic

clinical efficiency through innovation

Preface

Model: **V500**
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Safety

To ensure safe operation of the Vivosonic VivoLink™ and the Integrity™ ABR system please read and comply with the following warning and caution statements.

The following symbols will be used throughout the manual.

 WARNING

Messages with this heading indicate serious adverse reactions and potential safety hazards, limitations in use imposed by them, and steps that should be taken if they occur.

 CAUTION

Messages with this heading indicate Include information regarding any special care to be exercised by the practitioner and/or patient for the safe and effective use of the device. All precautions should be followed to ensure data and system integrity.

 ATTENTION

Messages with this heading indicate a possible loss of data. Follow the procedures to ensure data integrity.

 NOTE

Messages with this heading provide additional information that will increase the technician’s understanding of the operation of the system.

 TIP

Messages with this heading provide tips or alternate instructions for a procedure.

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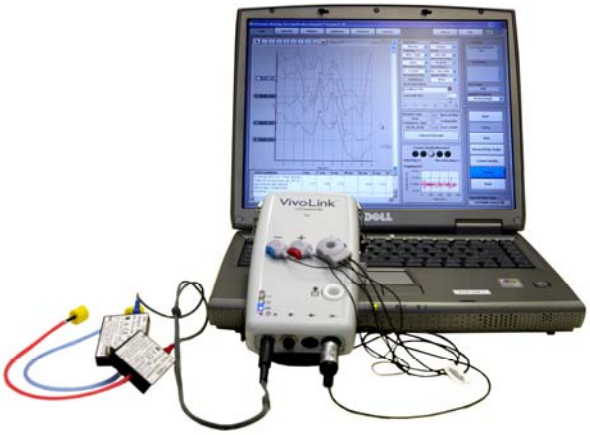
Chapter 1 General Information

Introduction

Indications for use of the Integrity™ system

Integrity™ is indicated for auditory evoked potential testing as an aid in detecting hearing loss and lesions in the auditory pathway.



Integrity is a prescription device. The labeling, instructions and user operations are designed for trained professionals.

Auditory Brainstem Responses (ABRs) are short latency auditory evoked potentials that have become widely accepted as a valuable test by a variety of professionals, such as audiologists, otolaryngologists, otologists, neurologists, pediatricians, and neonatologists.

This system can be used as a front-line objective audiometry tool as a part of a battery of diagnostic audiometric tests together with other audiometric techniques conducted with other devices such as conventional audiometry, tympanometry, middle ear muscle reflexes, eustachian tube function test, visual reinforcement audiometry, and other tests. However, the system is not intended to replace all other audiometers or audiometric tests.

The Integrity™ is suited for testing in patients of all ages: newborns, infants, children, and adults through seniors.

The system is designed for use in either a hospital or ambulatory setting: maternity wards, Intensive Care Units (ICUs), doctor's offices, Otolaryngology and Audiology clinics, schools, and occupational settings.

Auditory Brainstem Response (ABR)

Auditory Brainstem Response **(ABR)** is an objective electrophysiological test of the function and integrity of the auditory system from the inner ear to the brainstem. ABR is an electrophysiological response, which starts in the inner ear and spreads through the auditory nerve to the brainstem structures. It is recorded typically between 0 and 10 ms after the onset of an auditory stimulus

Click-evoked ABR is not frequency-specific and is used primarily for infant hearing screening and differential diagnostics (cochlear vs. retro-cochlear, auditory neuropathy/dissynchrony). **Tone burst ABR** is frequency-specific and typically used for evaluating hearing thresholds, mostly in newborns, infants, and young children. Tone burst ABR does not measure hearing loss, as does pure-tone audiometry; therefore, tone burst ABR results should be used as part of a test battery in conjunction with other audiometric tests, particularly with behavioral pure-tone audiometry whenever possible.

ABR amplitude is quite small compared to the evoked potential activity recorded at longer latencies. Wave V peak-to-trough amplitude rarely exceeds 1 microvolt[1] (µV), even at

[1] One microvolt is a millionth of a Volt.

high supra-threshold stimulus levels. At stimulus levels near threshold, ABR wave V amplitude may be 0.1 μV or smaller.

Auditory Evoked Potentials (AEP) recording

As a result of their small amplitude, and AEP signal is easily “drowned out” or lost due to noise composed of electrical potentials appearing on the scalp, i.e., physiologic noise, and non-physiologic noise, particularly low-frequency (LF) electric, LF magnetic, and radio-frequency (RF).

Sources of physiologic noise include the following: brain activity recorded as electroencephalogram **(EEG**), heart activity – electrocardiogram **(ECG)**, eye movements – electrooculogram **(EOG)**, and muscular activity – electromyogram **(EMG)**. While EOG and EMG can be largely reduced by sleep or sedation, EEG and ECG are not reduced by sleep. Moreover, EEG typically increases in sleep due to synchronization of the brain activity.

Sources of non-physiologic noise can be wireless computer networks, electronic medical devices, Personal Digital Assistants (PDAs), cellular phones, fax machines, photocopiers, power lines (mostly 50/60 Hz and its harmonics), luminescent lights, RF broadcasts, high-voltage equipment, and stimulus artifact radiation from stimulating transducers. Significant sources of electrical noise, which are often detected by the AEP amplifier, are caused by the time-varying and time-invariant electromagnetic fields that are present in many test environments where the electrode-lead wire-amplifier arrangement is employed. These time-varying electromagnetic fields are inductively and capacitively coupled with the lead wire that introduces noise from the electrode to the amplifier. A second significant source of noise is motion artifacts, i.e., the noise induced in the lead wire as it moves through a static (i.e., time-invariant) magnetic field.

ABR and noise parameters are summarized in Table 1.

Table 1 Signal and Noises in ABR Recording

Signal	Frequency, Hz	Amplitude, nV
AEP Signal		
ABR	**50 - 3,000**	**100 - 1,000**
Noises		
Electrooculogram (EOG)	0.5-10	10,000 - 500,000
(Electroencephalogram) EEG awake	3-40	5,000 - 10,000
(Electroencephalogram) EEG sleep	3-16	2,000 - 400,000
Electrocardiogram (ECG)	0.5-50 (up to 100)	80,000 - 2,000,000
Electromyogram (EMG)	30-500	10,000 - 2,000,000
LF Electric, LF magnetic, RF	Harmonics of 50/60 Hz, MHz, GHz	Up to 10,000,000

To reduce physiologic and non-physiologic noise, differential pre-amplifiers are used. In such pre-amplifiers, the signal of interest is measured as the difference between the electric potential in two signal electrodes called the non-inverting (positive) electrode, the inverting (negative) electrode. A common ground electrode is used to provide a common return path for current in the signal electrode leads. This differencing technique, called *common-mode rejection,* rejects noise that is common to both signal electrodes (non-inverting and inverting). When *common-mode rejection* is used in conventional pre-amplification it is not effective enough since the rejection degrades at frequencies above 20 kHz, and RF noises are not rejected at all.

AEP electrode impedance

Significant care must be taken by the clinician to properly attach AEP electrodes. AEP voltages are very small, which is why for AEP recording, critical signals (noise) are kept as low as possible. When the impedance between the skin and the electrodes applied to the skin is too high, there will be a high input impedance at the AEP pre-amplifier. Non-physiological noise will be higher, the signal-to-noise ratio will be lower, and the signal recording and detection will be longer.

In summary, electrodes, lead wires, and cables introduce additional noise and affect AEP recording.

The Integrity™ system

The Integrity™ system is the world's first wireless ABR recording system. It is multi-functional and was developed by Vivosonic to offer a solution to overcome AEP-recording difficulties. Vivosonic's solutions employed in this system include wireless Bluetooth® communications between the computer and the data collecting module, *in situ* amplification with the Amplitrode®, and a combination of an electrode and a pre-amplifier, which provide the following benefits:

- Largely reduced physiological and non-physiological noise resulting in fast, accurate, and clear ABR recordings.
- Mobility for the patient and the user.
- Less attention to electrode impedance due to monitoring of electrode contact quality mismatch.
- The electrodes can be quickly clipped and unclipped from the patient using easy release buttons on the electrode clips.
- Shorter lead wires mean fewer inconveniences than experienced with long lead wires and cables.
- Less risk of electrode-lead misconnection.

Innovations in the Integrity™ system

***In situ* pre-amplification:** For recording ABR, the system employs the Amplitrode®, the world's first *in situ* AEP pre-amplifier that largely reduces physiological noise and electromagnetic interferences. The system provides fast and reliable results in most clinical environments, even in those where an electromagnetically shielded room is unavailable.

Wireless communications: As in most conventional systems, a computer controls all tests, and then records, displays, and stores the results. An interface module generates stimuli and processes responses. However, different from all other systems, communication between the computer and the Interface Module, the VivoLink™, is wireless using Bluetooth® technology.

Bluetooth®: This wireless communications protocol enables computers and other digital devices to communicate via a broad radio frequency **(RF)** band. A Bluetooth® radio signal does not introduce noise itself because it has very low energy, and yet it is strong enough to communicate within about 30 ft (10 m), even through walls.

Unlike a radio broadcast, such as FM radio, Bluetooth® does not have a fixed carrier frequency. Rather, it is a random, noise-like digital signal composed of encoded zeros and ones. Encoding makes it extremely secure for data exchange, which is important in medical applications.

Bluetooth® has been implemented in many medical applications making it a natural choice for Auditory Electrophysiology. Vivosonic is first in the world to employ Bluetooth® for this function. More information on Bluetooth® can be found at www.bluetooth.com.

Signal-processing algorithms: The system uses a patented digital signal processing technique called the Kalman Filter. The Kalman Filter is a minimum mean-square error filter. [Li, 2002] This technique offers the operator a fast, accurate, reliable, and simple testing process, even in the presence of EMG noise from facial muscles.

Other features of the system

User friendly: The instrument allows flexible, user-defined test protocols, and provides comprehensive data management and analysis. The protocol screen and test screen both have a similar design, which allows for easy learning. The data-management system keeps a common patient list and combines results from ABR testing which makes finding results, review, and printing reports easy and efficient.

Data-management software includes a test planner, the patient database, and test-result database. It provides comprehensive data management suitable for individual offices, clinics, hospitals, research settings, and clinical networks.

The Integrity™ system is operated using a Windows XP® based computer and Integrity™ software. Stored measurements can be viewed and evaluated on the computer while running the control program. A summary of the results can also be printed. AEP procedures can be completed in a couple of minutes and then immediately prepared for the next patient. The length of the AEP tests depends on the protocol, auditory function, state of the patient, and the environment.

Quality assurance: Information contained in the patient test files allows for traceability and analysis of various factors that may affect the quality of testing.

Data integrity, confidentiality, and availability: Test results are password protected and cannot be modified once they have been stored. The results can be backed up using the internal storage means of the computer, or any external USB-connected storage medium such as a RAM drive or CD.

Full-page test report: The rest results can be printed to any optional office printer. The report will contain the patient information, unit ID, graphic test results, numeric test results, , and information on the testing facility.

User interface: The user interface is very simple and intuitive, and requires a minimum amount of training.

CAUTION

This device should be used to indicate auditory problems, not diagnose them.

The Integrity ™ system (Model V500) is an ABR recording system providing valuable information that allows estimating a hearing loss, and diagnosing cochlear and retro-cochlear function. While the Integrity ™ system indicates certain auditory problems, it should be used as a part of a wider audiologic test battery to arrive at an auditory diagnosis. In addition to these tests the patient must receive additional clinical testing using other techniques.

Use this device only as specified.

How the Integrity™ can enhance your practice

Integrity uses a database to store and retrieve test data. The database contains the patient information, the test conditions, and the protocol settings used for the test. The Integrity™ **Database** screen (Figure 42) is designed to function like commonly used spreadsheet applications such as Microsoft Excel, making it very easy to use and intuitive. From this screen, the health care professional can review and analyze test results as well as print and export the results.

The database is capable of storing millions of test results (depending on available hard disk Space) that are then accessible from one place.

Beyond reviewing individual test results, the user can select subsets of the test results using a multi-query function to print, archive, un-archive, and export the subset data.

Definitions

Definitions for some of the terms used in this manual, as well as terms used in the software, can be found in The Glossary of Terms.

Using This Manual

This User's Manual is intended to assist physicians, audiologists, and other trained health-care professionals in the safe and effective handling of the Integrity™ system. To use this device properly, the operator must understand the basics of this device's performance, and operating instructions. Chapter 1 covers safety features, precautions, and warnings. The chapters that follow provide the product descriptions, and details on how to use the Integrity™ system.

Intended Operator

The intended operator is a trained physician, audiologist, or other trained health-care professional licensed by local authorities to perform hearing assessment. This person must be trained in the assessment of auditory difficulties. To use this device, the operator will be required to fit the patient with the ER-3A earphones, affix the B-71 Bone Conductor and the electrodes to the patient, connect the patient to the VivoLink™, and conduct the test procedure.

Intended Environment

This device is intended for use in a clinical, ambulatory, or occupational environment suited to the needs of the patient.

WARNING

Operation of the Integrity™ system below the amplitudes and/or values specified for physiologic signals may cause inaccurate results.

The use of accessories, transducers and/or cables with the Integrity™ system other than those specified, with the exception of those sold by the manufacturer as the replacement parts for internal components, may result in an increase in EMR emissions or a decrease in the immunity of the system.

The Integrity™ system should not be used adjacent to or stacked with other medical instrument components. When space requires other components to be adjacent to or stacked with the Integrity™ system, the normal operation of those instruments should be verified.

Other instruments adjacent to or stacked with the Integrity™ system may cause interference with the VivoLink™ signal. This may be true even if those components comply with International Special Committee on Radio Interference (CISPR) emission requirements.

CAUTION

Medical instrumentation requires special precautions regarding Electromagnetic Compatibility (EMC). Medical instruments need to be installed according to the EMC shielding information provided in the accompanying documents.

The Electromagnetic Radiation (EMR) associated with portable and mobile radio frequency communication devices can interfere with instrumentation, affecting the operation or results.

CAUTION

This device is contraindicated for:

Patients who display signs of excessive earwax

If, upon inspection, it appears that excessive earwax is present, DO NOT insert the earphone in the ear canal. Inserting the earphone could force earwax to press against the eardrum resulting in damage to the ear. It could also cause incorrect ABR measurements and lead to misdiagnosis.

Patients with inflammation of the ear canal

If, upon inspection, it appears that the skin of the ear canal has signs of inflammation, DO NOT use this device. The ear tip will cause slight pressure that may cause mild abrasion and pain.

Patients who have ear canal blockage due to foreign particles

If, upon inspection, it appears that any foreign particles are present in the ear canal or any foreign particles block access to the eardrum, DO NOT insert the earphone into the patient’s ear.

Patients who display signs of discharge in the ear

If, upon inspection, any discharge is observed, DO NOT insert the earphone into the patient’s ear.

Patients who display skin damage

If a patient displays any signs of skin damage at the site of an electrode application (such as skin irritation (redness), scratches, bruises, sores, cuts, wounds, bleeding), DO NOT conduct skin preparation and application of the electrodes. Consult a dermatologist or other trained health-care professional.

CAUTION

Hazard: The patient experiences discomfort when the ear tip is inserted into the ear canal.

Remedy: The operator must check whether the ear tip selection was incorrect and replace with a properly fitting ear tip.

Hazard: Audible levels are uncomfortable for the patient.

Remedy: The operator must immediately select a lower setting for the stimulus levels. Signal inputs and outputs are intended only in connection to the specified equipment described in this manual.

Hazard: Skin at the site of the electrode application is damaged, for example: irritated (red), scratched, bruised, sore, cut, wounded, or bleeding.

Remedy: Do not conduct skin preparation and electrode application on areas of damaged skin. Choose another electrode location, wait until healing is complete, consult a dermatologist, or refer the patient to a health-care professional who is trained to deal with skin damage.

CAUTION

Please follow these recommendations to ensure the test data is accurate.

- Substitution of any supplied components with different components may result in measurement error.
- No other software may be installed onto the computer on which the Integrity™ software is installed.
- Handle the system with care.
- The system requires calibration of the transducers – ER-3A earphones and B-71 Bone Conductor – annually on each anniversary from the date of manufacture, and every time a transducer is dropped, subjected to mechanical shock, or immersed in a liquid substance. Otherwise, stimuli presented to the patient as specified may lead to incorrect test results and misdiagnosis.
- DO NOT force the ear tip into the ear canal.
- Always carry this device with you when traveling to avoid mishandling and damage of stored or checked luggage.
- DO NOT ship this device for service in packaging other than the packaging supplied with the system from the manufacturer, or comparable packaging.

Chapter 2 Configuration

System configuration

General configuration

The Integrity™ system is modular (Figure 1), consisting of the components found in Table 2.

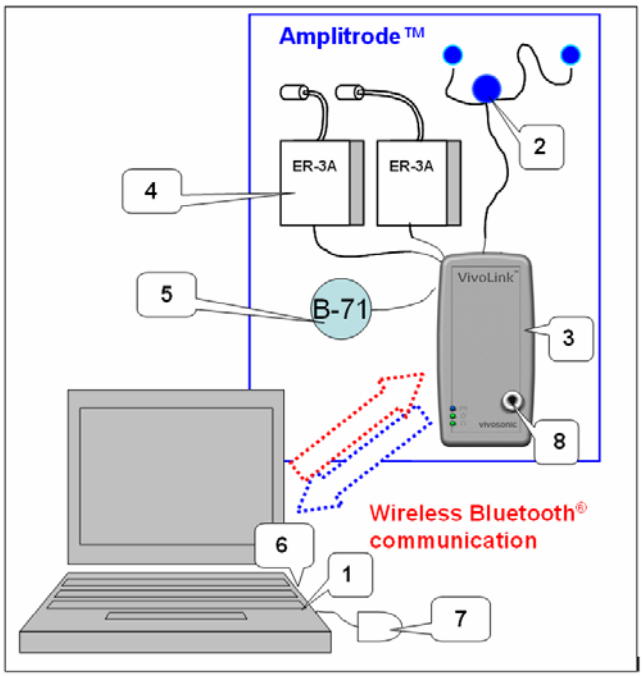


Figure 1 Integrity™ system

1 – Computer with Integrity™ software
2 – Amplitrode®
3 – VivoLink™
4 – ER-3A Earphones (transducers),
5 – B-71 Bone Conductor,
6 – Bluetooth® dongle (installed on back of computer)
7 – Mouse
8 – Probe adapter with Probe holder

Table 2 Components shipped with basic Integrity™ system purchase

VivoLink™ Wireless interface module – 1 pc
Accessories: 1. Amplitrode® – the in situ ABR pre-amplifier – for recording ABR – 1 pc 2. ER-3A earphones – for stimulating ABR and contralateral masking in AEP tests via air conduction – 1 pair: • Red, with red silicone tube, ear tip adapter, and clip - for the right ear. • Blue, with blue silicone tube, ear tip adapter, and clip - for the left ear. 3. B-71 Bone Conductor, with metal headband - for stimulating ABR via bone conduction (optional)

4. The Bluetooth® dongle (receiver), the size of a Flash memory stick.
5. Computer bag – 1 pc (not shown)
6. AA NiMH rechargeable battery and battery charger (not shown). This item can be purchased from any local battery supplier.

Disposables:

1. Single-use foam ear tips for ER-3A (Figure 2) – for performing ABR tests
   - Starter kit includes:
     ER3-14A – 13 mm yellow – 50 pcs
     ER3-14B – 10 mm beige – 50 pcs
     ER3-14D –3.5mm red– 20 pcs
     ER3-14E – 4.00 mm red – 20 pcs
   - 50-Packs of the above – optional
2. Disposable **NeuroLine®**[2] snap electrodes, or equivalent single-use electrodes (Figure 3) – 25 per pouch
3. **PDI H04082 Germicidal Wipes** – for disinfecting the Amplitrode®. Starter kit includes 20 wipes (not shown)
4. Four (4) AA Alkaline non-rechargeable batteries (included)

Integrity® Software

1. Program running on a Bluetooth®-enabled Windows XP®-based PC.
   - Sent on a CD and installed on the PC if the system is purchased with a computer.
   - Sent on a CD if the system is purchased without a computer.
2. The Bluetooth® drivers
   - Installed on the PC and configured if the system is purchased with a computer.
   - Shipped on a CD if the system is purchased without a computer.
3. 2 Calibration CDs
   - Bone Conductor installation
   - Insert earphone installation

User's Manual

Optional Equipment

1. Auxiliary office printer (not shown)
2. B-71 Bone Conductor, with metal headband - for s125timulating ABR via bone conduction

Figure 2 Ear tips for AEP tests (ABR).
From the left to the right: ER3-14A, ER3-14B, ER3-14D, ER3-14E,

[2] NeuroLine® is a registered trademark of XLTEK Accessories.

Figure 3 NeuroLine® 103920 Electrodes for AEP tests

VivoLink™

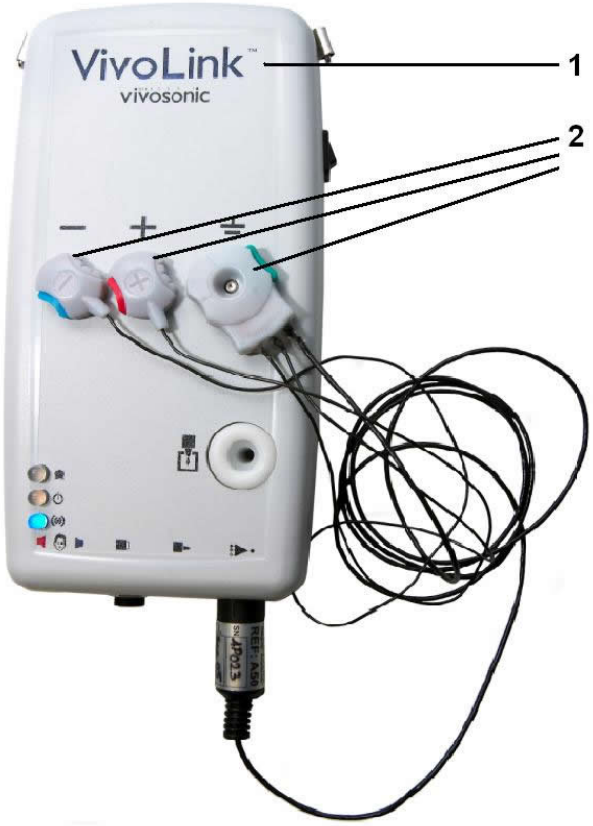


Figure 4 VivoLink™

VivoLink™ (1) is the world's first wireless interface module for auditory electrophysiology **(EP)**. VivoLink™ has the potential to be extended to other modalities such as Auditory Steady State Response **(ASSR)**, Distortion Product Otoacoustic Emission **(DPOAE)**, and Transient Otoacoustic Emission **(TOAE)** in the future. It is operated by a microprocessor, controlled from a remote computer through Bluetooth®.

Bluetooth® establishes a connection with the computer automatically, and once this happens, the user is informed by an LED indicator on the VivoLink™ and a virtual LED indicator in the computer software. VivoLink™ is a battery-powered device that works with

standard audiometric transducers: two ER-3A earphones and a B-71 Bone Conductor. It conducts ABR with the Amplitrode® (2) the world's first *in situ* EP pre-amplifier.

The VivoLink™ can be placed on an adult's chest and secured with a lanyard, placed next to a baby, or held by the baby's mother. Testing with the VivoLink™ can be performed anywhere within the reach of Bluetooth®, including situations where cabled instruments cannot be used at all.

Tests can be performed within approximately 30 ft (10m) of the software, even in an electromagnetically shielded booth. To perform a test in an electromagnetically shielded room connect the Bluetooth® dongle, to your computer via a USB-extension cord and put the cord through a hole in the booth wall. R emove the cable from the system to help reduce electromagnetic noise pickup and test time, depending on background noise in the testing area outside the shielded room. Ideally the shielded room will keep noise to a minimum.

In the case of an infant patient, the mother may carry the VivoLink™ and the baby and move around the room without the need to disconnect any electrodes, connectors, or transducers. This makes testing more comfortable and easier for the patient.

VivoLink™ presents various auditory stimuli to the patient through air and bone conduction such as a click or tone burst. It then records electrical responses from the Amplitrode® to the Integrity™ software.

VivoLink™ performs several essential functions:

1. Checks the inter-electrode contact quality mismatch.
2. Checks the wireless connection between VivoLink™ and PC.
3. Checks the VivoLink™ battery voltage (Refer to VivoLink™ battery indicator on page 30).
4. Presents auditory stimuli through earphones and bone conductor.
5. Transmits collected electrophysiological responses to the computer.

The transducers and Amplitrode® are connected to the VivoLink™ through the connector panel (Figure 6). To avoid any confusion while connecting peripheral accessories to the VivoLink™, all locations are marked with specific symbols on the front panel of the VivoLink™ over the locations of the actual connectors (Figure 5).

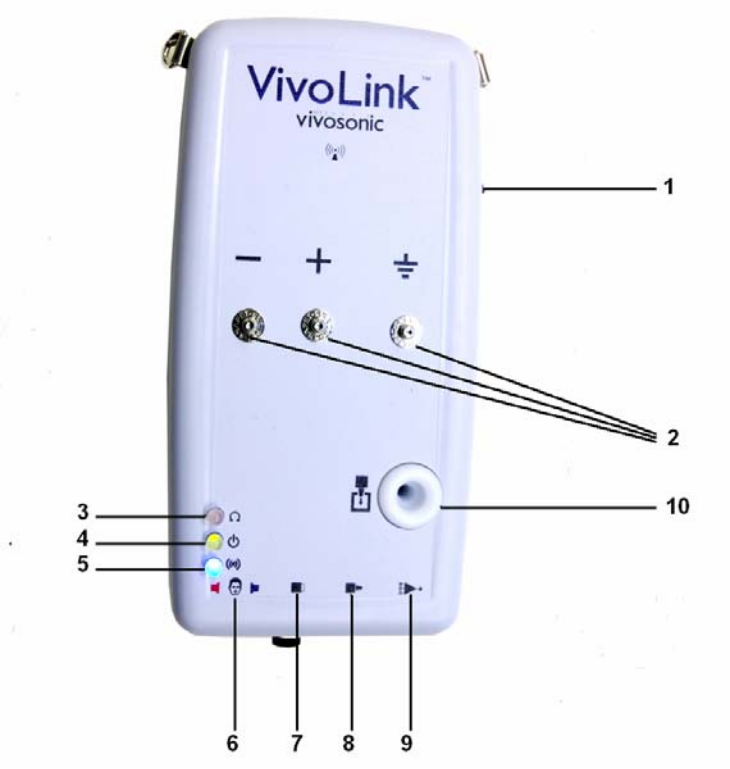


Figure 5 VivoLink™ Front Panel

1 - On/off switch
2 - Parking Snaps holding the Amplitrode® and its clips.
3 - Inter-electrode Contact Quality Mismatch LED indicator
4 - Power LED Indicator
5 - Bluetooth® LED indicator
6 – Symbol for ER-3A earphone connectors
7 – Symbol for B-71 Bone Conductor connector
8 – Symbol for OAE probe connector
9 – Symbol for Amplitrode® connector
10 – OAE Probe holder
Note - Lanyard rings (not shown)
See Appendix C for a description of the symbols printed on the front panel.

On/off switch, power LED indicator

The VivoLink™ runs on four (4) AA batteries. To ensure VivoLink™ will run properly and will last the entire test, make sure that the batteries are inserted properly into the battery compartment (Figure 8) (marked "**+**" and "**-**" on the battery poles, corresponding to the same markers of the battery compartment for each battery). Ensure the batteries are fresh. To turn on the VivoLink™ press the On/Off switch Figure 5 - #1) and check the Power LED Indicator (Figure 5 - #4). The Power LED Indicator will remain **green** if the batteries are in good working condition. If the batteries are low the indicator will be **amber** and if the batteries are spent the indicator will be **off** (not luminous).

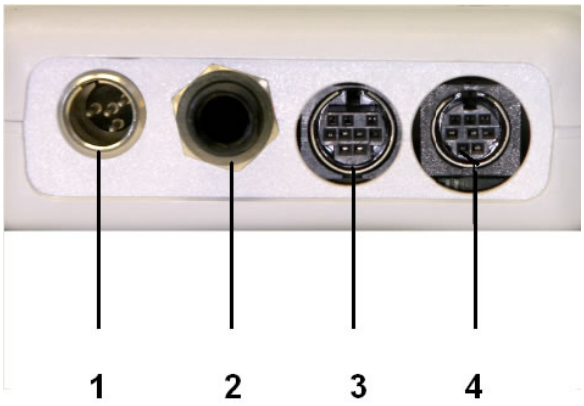


Figure 6 VivoLink™ Connector Panel

1 - ER-3A earphone
2 –B-71 Bone Conductor
3 –OAE Probe (currently unused)
4 - Amplitrode®.

Inter-electrode Contact Quality Mismatch LED Indicator

The Inter-electrode Contact Quality Mismatch LED Indicator (Figure 5 - #3) is **off** (not luminous) when the impedance mismatch between the non-inverting (positive) and inverting (negative) electrodes does not exceed 5000 Ohms.

This indicator turns **on** (luminous) when the impedance mismatch exceeds 5000 Ohms.

- **amber** when the inverting (negative) electrode impedance is higher than the non-inverting (positive) electrode impedance.
- **green** when the non-inverting (positive) electrode impedance is higher than the inverting (negative) electrode impedance.

When the LED is **on** it indicates a problem with the placement of the electrode whose impedance exceeds that of the other electrode.

Bluetooth® LED indicator

After VivoLink™ has been switched **on** Bluetooth® LED Indicator (Figure 5 - #5) starts flashing with **blue** colored light while the VivoLink™ Bluetooth® wireless circuit is establishing a connection with the Bluetooth® dongle inserted in the computer slot. Typically it takes about 30 – 60 seconds for the VivoLink™ Bluetooth® wireless circuit to communicate with a Bluetooth® computer dongle before the steady wireless connection will be established. The Bluetooth® LED indicator light will continue to flash during this time.

After setting up a wireless link between the computer and testing periphery, (VivoLink™) Bluetooth® LED Indicator will stop flashing. The Bluetooth® light will turn **blue** on the computer screen. If the Bluetooth® LED indicator continues to flash longer than 3 minutes without establishing proper wireless communication, switch **off** the VivoLink™, wait for approximately 60 seconds, and then turn VivoLink™ **on** again. If the problem persists refer to the Bluetooth troubleshooting in Appendix J.

Accessory connectors

Connectors for the Amplitrode®, OAE Probe, ER-3A Insert Phones, and B-71 Bone Conductor are located on the connector panel (Figure 5). To perform any testing, VivoLink™ and desirable transducer(s) should be connected to the Integrity™ through

the appropriate connectors. To establish a proper connection between peripheral accessories and VivoLink™, plug each device into the correct socket. Please check the specific symbols placed on the front panel of the VivoLink™ above the locations of the connectors (Figure 5).

Lanyard

The VivoLink™ can be hung around the patient's neck using a lanyard (Figure 7). The Lanyard is connected to two D-rings on the VivoLink™ with two detachable clips. The lanyard has a breakaway feature which allows for fast disconnection and re-connection, protecting the patient from strangulation as well as quick operation in case of an emergency.

Figure 7 VivoLink™ Lanyard.

1. Lanyard
2. Breakaway connection
3. D-rings
4. Clips

Battery Compartment

The VivoLink™ is powered by four (4) AA non-rechargeable Alkaline or Nickel-metal Hydride (NiMH) rechargeable batteries.[3]

The battery compartment (Figure 8) is located on the bottom panel of the VivoLink™ marked with an arrow. To open the battery compartment, slide the cover in the direction of the arrow. The four cells for AA batteries are marked with a "**+**" and "**–**" to ensure proper insertion of the batteries.

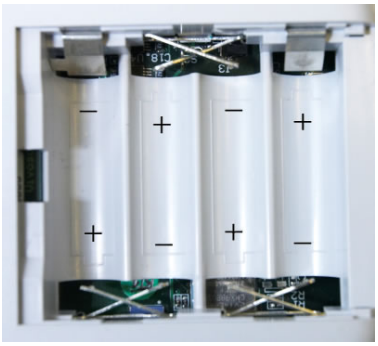


Figure 8 Battery compartment of the VivoLink™.

[3] Purchase Nickel-metal Hydride rechargeable batteries and charger from any local battery supplier.

Amplitrode®

The Amplitrode® is comprised of an integrated pre-amplifier and electrode in a combined unit that is affixed to the patient. The Amplitrode® (Figure 9) is controlled by VivoLink™ using ABR software modules. Significantly less noise is introduced into the signal detected by the amplifier as a result of the extremely short connection between the conductive portion of the electrode and the amplifier. Traditionally this connection could be as long as a meter or more.

The Amplitrode® amplifies a signal with a much higher signal-to-noise ratio than conventional electrode-to-lead, wire-to-amplifier arrangements resulting in artifact noise reduction.

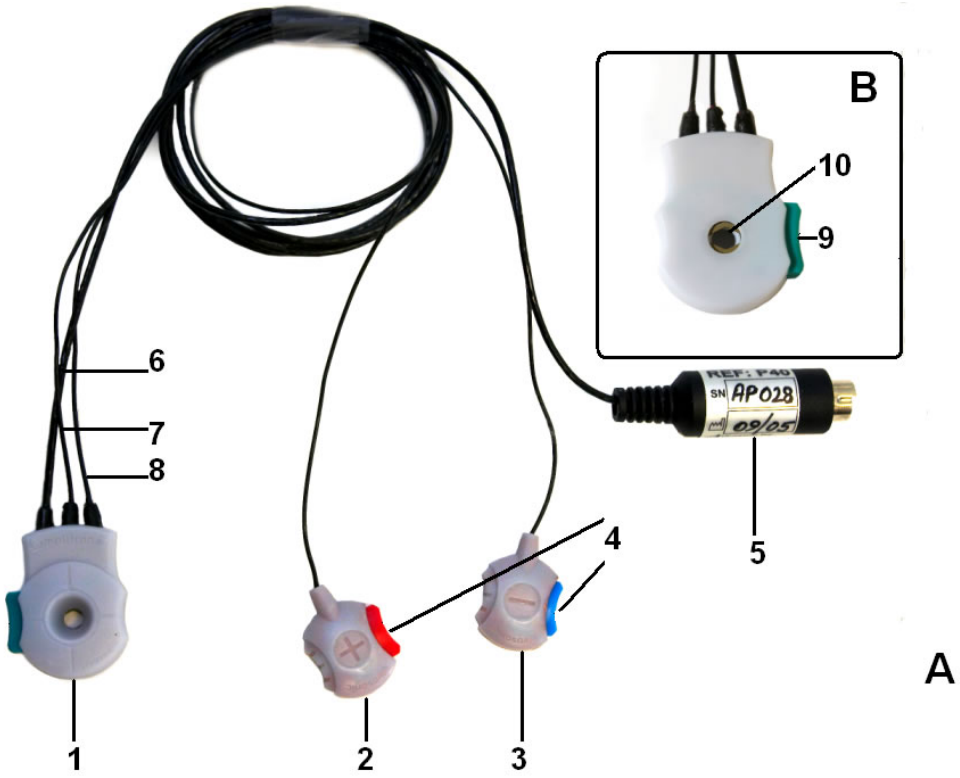


Figure 9 Amplitrode®

View A – General View
View B (insert) bottom view of the pre-amplifier

1. Pre-amplifier combined with ground electrode clip
2. Non-inverting electrode clip
3. Inverting electrode clip
4. Clip buttons
5. Amplitrode® connector with labeled serial number
6. Amplitrode® cord
7. Negative clip cord
8. Positive clip cord
9. Release button
10. Amplitrode® spring

The Amplitrode® is a new generation of pre-amplifiers used in Evoked Response Audiometry (**ERA**).

The integrated circuit built in to the Amplitrode® employs *chip-on-board* technology enabling the integrated circuit to be directly mounted to the conductive pad. The extraordinarily small size of the Amplitrode® and the absence of long and cumbersome lead-wires and cables make the unit exceptionally easy to use.

Clinical benefits of the new method and system

In situ AEP amplification achieves artifact noise reduction in at least three ways: First, at least one lead wire, the ground-electrode wire which is a significant source of wire-induced noise, is eliminated completely. Second, the remaining lead wires are as short as allowed by the size of the area of interest on the subject which is much shorter than the typical one-meter length (or greater) used in conventional EP systems. Third, motion artifacts are significantly reduced since both lead wires, electrodes and the pre-amplifier are each mounted to the patient and all move together. This reduces differential movement, and hence, differential artifact noise that otherwise would be induced in the lead wires through environmental electromagnetic fields.

CAUTION

The Amplitrode® could be damaged.

To prevent damage, the Amplitrode® should always be clipped onto the electrodes on the patient, clipped onto the Amplitrode® parking snaps on the VivoLink™, or held in the hands of the examiner. Always have the Amplitrode® connected to the patient while in use or to the parking snaps when not in use. DO NOT leave the Amplitrode® dangling from the VivoLink™.

To reduce the physiological and electromagnetic artifacts, the VivoLink™ filters signals *before* the first stage of AEP amplification. This will optimize the AEP recording.

VivoLink™ measures the electrode contact quality mismatch. This process allows for more clinically meaningful data and is easier to utilize than the conventional pre-testing impedance check. Measuring impedance in *real time* provides the clinician with ongoing valuable information on the test conditions without applying any current to the patient. This may be especially valuable when testing newborns and infants.

Specifications

Specifications for the Integrity™ are found in Appendix A.

Chapter 3 Preparation

Unpacking instructions

Retain the shipping carton and all packing materials in case the unit needs to be returned for repair or shipped to another location. Carefully unpack the Integrity™ briefcase and accessories. Open the briefcase and identify each of the supplied parts. (Refer to the packing list in the shipping carton. A general component list can be found in Figure 1.

Unpack the unit as follows:

1. Open the shipping carton.
2. Remove:
   - packing list
   - user manuals for the computer and printer if supplied by Vivosonic
   - warranty certificate
   - product registration form
3. Verify all parts were received by referring to the packing list. Please report any missing or damaged parts to the seller immediately.
4. Record the **serial number** of the instrument in a permanent location for future reference. The serial number can be found on the outside of the carton the system was sent in.
5. Complete the product registration form and send it to the address specified on the form.

Installation

CAUTION

Test data may be affected.

DO NOT use this device for any clinical application until all steps of the installation procedure have been completed.

System setup for Vivosonic installed systems

If you have purchased the computer to use with the Integrity™ system, proceed to the next section “System setup for customer installed systems” on page 21. If you have purchased the computer from a Vivosonic dealer, please perform the following steps:

1. Open the packaging.
2. Remove all components of the system and connect as detailed in Figure 1.
3. Insert four (4) AA batteries into the battery compartment of the VivoLink™ (Figure 8).
4. Follow the computer manufacturer’s user manual to connect the power cable to the computer and plug the power cord into the AC power supply of a wall outlet.

ATTENTION

Before plugging in the power supply, ensure that the outlet is functioning. If it is not, the computer will initially run on the battery and then fail to operate.

5. Plug the supplied Bluetooth® dongle into the USB port on the computer on which it was installed.

ATTENTION

The Bluetooth dongle shall always be placed in the same USB port on the computer. Placing the dongle in a different port will cause the operating system to try to reinstall the Bluetooth® software driver.

6. Turn the computer on.
7. Adjust the clock and calendar settings in Windows® by pressing the Windows® button on the keyboard, and then double-clicking on the time on the bottom right corner of the computer screen. The time and date can also be adjusted from the Control Panel. Select **Start** | **Control Panel**.
8. Using the document *Integrity Installation*, found at the back of this manual's binder, follow the instructions to install and configure the Bluetooth drivers.
9. Restart the computer.
10. Verify all connections are secure.
11. If you intend to use an office printer supplied by Vivosonic install the cartridge and paper as described in its manufacturer's user guide. If the printer and the computer where both supplied by Vivosonic the printer driver will already installed on the computer and fully tested to operate with the system, as part of assembly procedure at Vivosonic.

ATTENTION

If your computer was purchased from Vivosonic, installation of printer drivers is NOT recommended. The computer has been tested and validated to work with the system and will be covered by the warranty to operate in this state.

Installation of some printer drivers may cause a conflict with the Integrity™ software and result in error messages and a failure to print.

12. Locate the computer power switch and turn it **on**. Wait for the computer to boot up and Windows XP® to start, which may take a few minutes.
13. When you switch the computer **On**, the Integrity™ program will automatically start.
14. Then a screen with two Caution statements appears (Figure 10)).
15. Read the Caution statements and press AGREE or EXIT. Pressing **Agree** will open the software to the **Test** screen. Pressing **Exit** will shut down the computer.

16. The system is ready to perform a test on a subject.

> **CAUTION**
>
> Possible damage to the Integrity™ system and its components may occur.
>
> DO NOT disconnect any of the devices or cables from the VivoLink™ when it is operating. This may cause damage to the system or its components.

17. Perform at least one successful ABR measurement on a subject as outlined in 0. This chapter describes typical operating steps from start to finish. Review these steps prior to using the Integrity™ System for patient testing.

> **ATTENTION**
>
> The Integrity™ is supplied with pre-set test protocols. Prior to clinical use, test-specific protocols must be defined. Pre-set default protocols recommended in the literature are described in Appendix G.

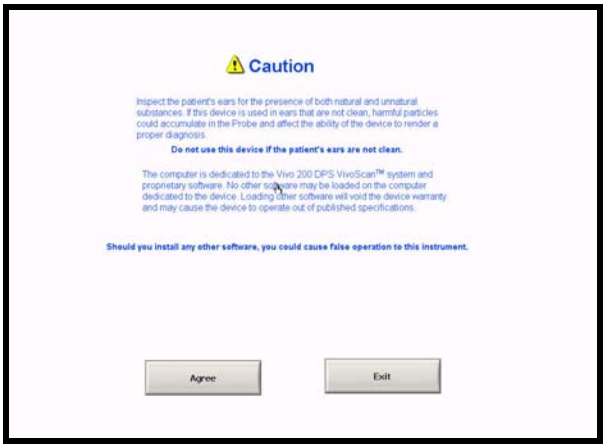


Figure 10 Caution screen

System setup for customer installed systems

If you did not purchase the computer from a Vivosonic representative and you are supplying your own computer to run the Integrity™ software, please perform the following steps:

1. Verify your computer is running before connecting to the Integrity™ System.
2. If you intend to use a printer with the Integrity™ System, use only models that are recommended by Vivosonic. Install the printer drivers, the cartridge and paper as described in its manufacturer's user guide.

NOTE

Only Windows®-compatible printers are recommended by Vivosonic for use with the Integrity™ software. Color printers are preferred. The Integrity™ software will use the default Windows® printer for printing. This printer can be on a network or local to the computer.

Vivosonic will only provide troubleshooting support on printers and computers that have been purchased and configured by Vivosonic.

3. Turn the computer **off**.
4. Open the packaging containing the Integrity™ components.
5. Remove all components of the system and connect as detailed in Figure 1**Error! Reference source not found.**.
6. Insert four (4) AA batteries into the battery compartment of the VivoLink™ (Figure 8).
7. Turn on the VivoLink™.
8. Plug the supplied Bluetooth® dongle into any free USB port on the computer.
9. Verify all connections are secure.
10. Locate the computer power switch and turn it **on**. Wait for the computer to boot up and Windows XP® to start, which may take a few minutes.
11. Adjust the clock and calendar settings in Windows® by pressing the Windows® button on the keyboard, and then double-clicking on the time on the bottom right corner of the computer screen. The time and date can also be adjusted from the Control Panel. Select **Start** | **Control Panel**.
12. Insert the supplied software CD in the CD drive of the computer and follow installation prompts that will appear.
13. Once the program is installed, Bluetooth® communication will establish automatically, and the **green** LED on the VivoLink™ will light.
14. The **Caution** screen appears (Figure 10).
15. Read the caution statements and press Agree or Exit.
    - Press **Agree** to open the software to the **Test** screen.
    - Press **Exit** to shut down the computer.
16. The system is ready to perform a test on a subject.

CAUTION

Possible damage to the Integrity™ system and its components may occur.

DO NOT disconnect any of the devices or cables from the VivoLink™ when it is operating. This may cause damage to the system or its components.

17. Perform at least one successful ABR measurement on a subject as outlined in 0. This chapter describes typical operating steps from start to finish. Review these steps prior to using the Integrity™ System for patient testing.

ATTENTION

The Integrity™ is supplied with pre-set test protocols. Prior to clinical use, test-specific protocols must be defined. Pre-set default protocols recommended in the literature are described in Appendix G.

Chapter 4 The Integrity™ System Screens

Integrity™ opens to the **Test** tab by default displaying the **Test** screen. There are six screens in the Integrity™ software: Test, Patients, Planner, Database, Protocol, and System. Each tab opens a screen. Refer to the pages listed below for details of the functions and information available on each screen.

- The Test Screen on page 24
- The Patients Screen on page 45
- The **Planner** Screen on page 48
- Deleting entries from the Planner list

To delete a test plan name from the table, select the test entry by clicking on the blank cell to the left of the patient's name, and press the **Delete** key on the computer keyboard.

- The Database Screen on page 50
- The Protocol Screen on page 61
- The System Screen on page 65

The Test Screen

The **Test** screen (Figure 11) is used when performing ABR tests on patients. This is the main screen used to control the operation of the VivoLink™. The **Test** screen is designed to start, perform, and regulate ABR testing, to monitor the results of ABR data collection, and to display the test results. Also, it is possible to control some of the protocol specifications.

Before any of the features can be used on this screen the Bluetooth® connection must be made (virtual LED is lit) and a patient must be created and selected. (See Selecting Patients on page 47 for details)

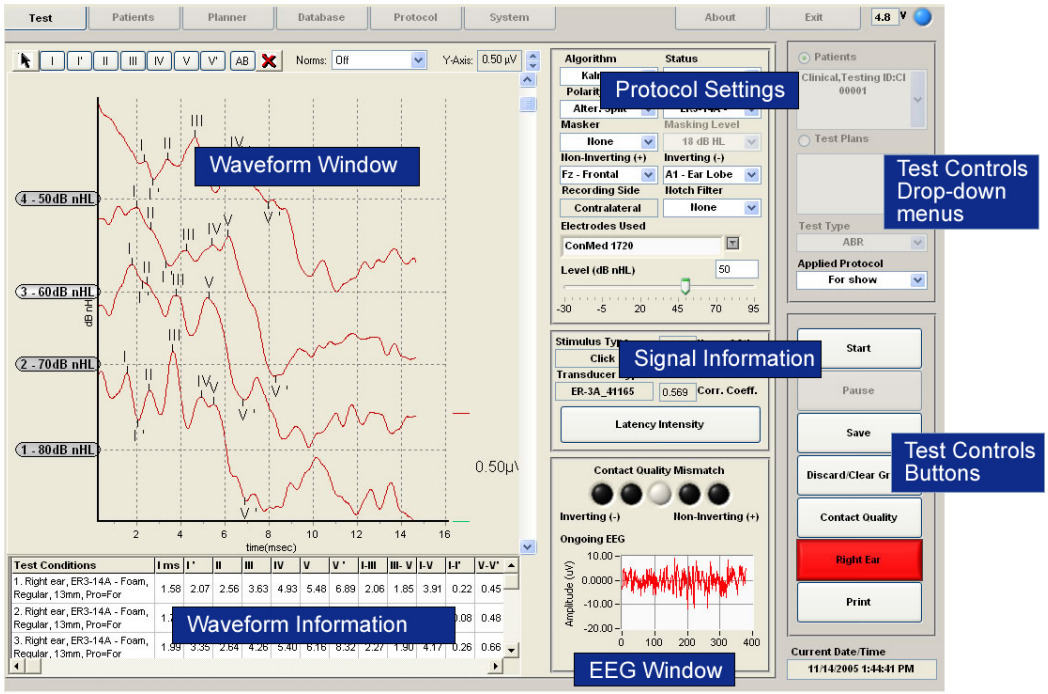


Figure 11 The Test Screen

Test Controls

There are three sections found on the right side of the **Test** screen that control general conditions of the ABR tests (Figure 11). They include four drop-down menus (Figure 12), control buttons (Figure 13), and the current date and time (Figure 17).

Figure 12 Test Controls Drop-down menus

Test Controls - Drop-down Menus

Patients

This list is filled with the names of patients who have been selected to be tested from the **Patient** screen (Figure 35). It does not include all patients that exist in the **Patient** screen. If there are no patients selected in the **Patient** screen then there will be no patient names in this list.

1. To select a patient, select the check box to the left of the window title, which will activate this drop-down menu and deactivate the **Test Plans** drop-down menu.
2. Click on the down arrow, found to the right of the window, and select the patient to be tested from the list.

Test plans

This list is filled with the names of patients who have been selected to be tested from the **Planner** screen (Figure 35). It does not include all patients that exist in

the **Planner** screen. If there are no patients selected in the Patient screen then there will be no patient names in this list.

1. To select a test type, select the check box to the left of the window title which will activate this drop-down menu and deactivate the **Patient's** drop-down menu above.
2. Click on the down-arrow found to the right of the window and select the test from the list.

Test Type

The current Integrity™ configuration only supports the **ABR** test type..

Applied Protocol

This list contains the all the pre-defined protocols that have been created and saved. The protocols specify all the test parameters such as Stimulus Settings and Test Settings.

To select a protocol, click on the down-arrow found to the right of the window and select the protocol from the list.

> ATTENTION
>
> Improper configuration of test protocols may result in poor quality test results.

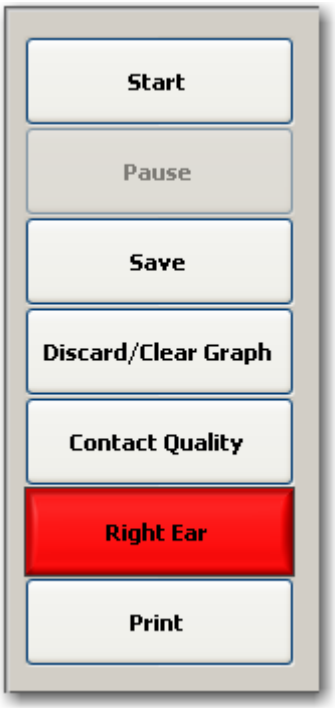


Figure 13 Test Control Buttons

Test Control Buttons

Start/Stop button

Before a test can be started a patient must be selected.

Start ABR testing by pressing the **Start** button. The ABR test will begin and the button text changes from **Start** to **Stop**. You can stop the test by pressing this same button now labeled **Stop.**

When the stop button is pressed all the data collected from the time the start button was pressed is displayed in the waveform window of the test screen. Use the **Database** screen to review any data collected before this run.

The **Pause** button is grayed out and inactive between test runs. When the **Start** button is pressed, the **Pause** button becomes active.

Pause/Resume button

When the **Start** button is pressed, the **Pause** button becomes active. Press the **Pause** button to temporarily stop the test run. This may be required if, for example, the earphone falls out of the patient's ear. To restart the data collection, press this same button now labeled **Resume**. Data collection will continue and the two data streams will be saved as one data run (waveform). The waveforms collected before pause was pressed can be reviewed on the test screen with the new data.

Save button

After completing the ABR data recording the results must be saved.

1. Press the **Save** button. This will open a **Save Result Confirmation** (Figure 14) dialog box.
2. Save the data to the pre-selected patient's file or choose another patient from the *Save to this patient's file* drop-down list.
3. The *Save to this patient's file* drop-down list contains the name and personal ID of the patient selected for testing. The patient list will appear if when the down-arrow is press.
4. Enter the information into the required fields (*Examiner, Location, Comment 1,* and *Comment 2)* or select preset data from the graph's drop-down lists.
5. Some information cannot be modified (Test Type, Protocol Used, Unit ID, Ear Tested, Probe ID, and Ear Tip Used).
6. Press **OK**.
7. Press **Yes** when asked *Are you sure?*

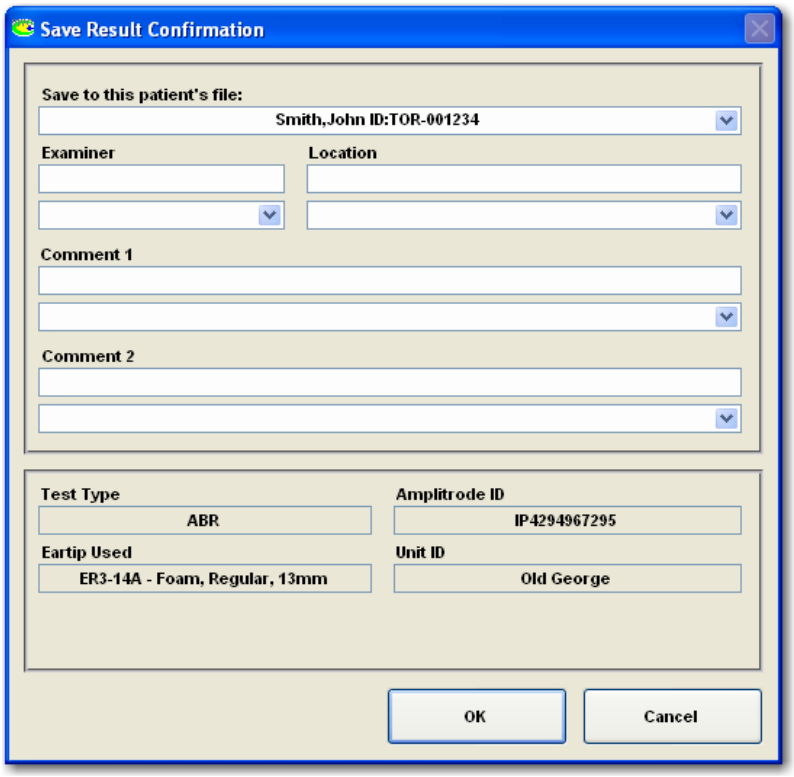


Figure 14 Save Result Confirmation

Discard/Clear Graph button

You can discard all collected data and clear the **Waveform Window** and the **Waveform Information** by pressing **Discard/Clear Graph** button.

1. Press Discard/Clear Graph.
2. Press **OK** when asked *Are you sure you want to discard this record?* (Figure 15). If you choose **OK**, the test results will be erased from the system's memory. If the test results have not been saved the data will be gone permanently.

   If you choose **Cancel,** the collected data will remain on the **Test** screen.

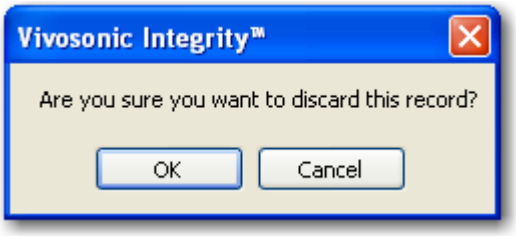


Figure 15 Dialog box - Are you sure you want to discard it?

CAUTION

Test data may be permanently lost.

Before discarding any data, please ensure that significant test results have been saved. If the data is required for review it must be saved before the information can be discarded or it will be permanently lost.

Contact Quality

The quality of the connections between the electrodes and the patient's skin is displayed visually using the virtual LED's. A poor connection is indicated by an amber LED for a poor connection with the inverting (-) electrode or a green LED for a poor connection with the non-inverting (+) electrode.

If a problem is evident, remove the electrode indicated, clean the skin, and apply a new snap electrode pad.

Refer to Quality Control Mismatch on page 38 for more details.

Right Ear/Left Ear button

Select the ear to test by pressing **Right Ear** or **Left Ear** button. When the **Right Ear** button is selected, the stimuli will be delivered through the ER-3A earphone to the right ear via the red tube. The waveform trace in the **Waveform Window** (Figure 30) will turn **red** to follow the color standards for audiologic practice. When the **Left Ear** button is selected, the stimuli will be delivered through the ER-3A earphone to the left ear via the blue tube. The waveform trace in the **Waveform Window** will be **blue**.

Print button

Print the results by pressing the **Print** button**.** The **Print Result Confirmation** (Figure 16) dialog box will be displayed The name and patient ID of the patient whose data is currently being collected will appear in the The *Print for this patient* drop-down list. Print the data for the patient selected or choose another patient from the *Print for this patient* drop-down list. Enter new information into *Examiner, Location, Comment 1, Comment 2* fields or select preset data from the drop-down lists.

NOTE

A new patient's name cannot be entered into *Print for this patient* field.

The *Print for this patient* dialog box shows information on the Test Type, Protocol Used, Unit ID, Ear Tested, Probe ID, and Ear Tip Used; data shown in those graphs cannot be modified.

To initiate printing, press **OK**. *Are you sure?* dialog box, will be displayed. Press **OK** to continue printing. Press **Cancel** to switch back to the **Print Result Confirmation** dialog box allowing changes to be made before printing.

The system does not allow the results to be printed if *Print for this patient* field remains blank. If you try to print data without entering the patient's name and ID, the message "*To print a test result, select a patient* or *create a new patient*" will appear on the screen.

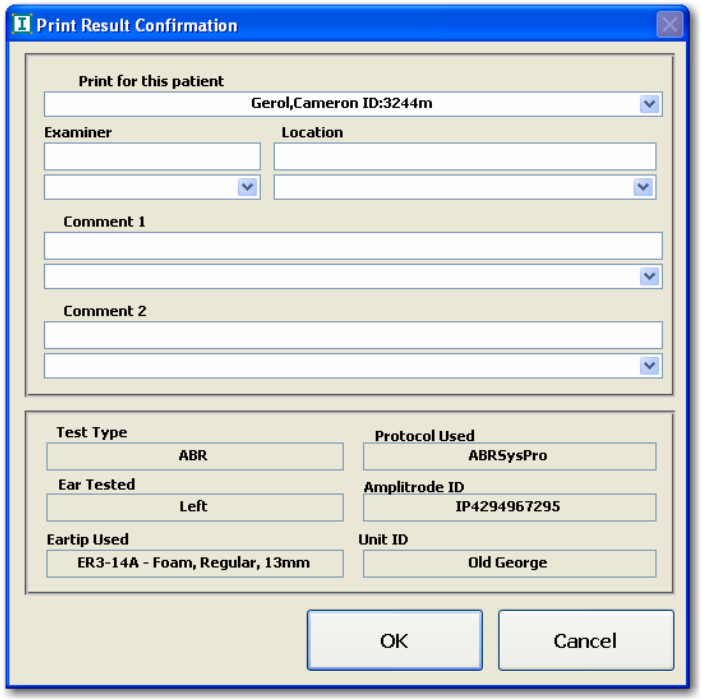


Figure 16 Print Result Confirmation

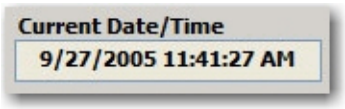


Figure 17 Test Controls Date and Time

Current Day/Time

Below the Test Control buttons is a box that displays the **Current Date** and **Current Time**. This is a read-only field. The date or time can only be changed using the Windows® configuration.

NOTE:

It is important that the date and time settings are correct. Integrity™ uses the date and time to "stamp" the data files and to calculate the age of the patient at the time of testing.

If the displayed date and time are incorrect, adjust the clock and calendar settings in Windows® by pressing the Windows® button on the keyboard, and then double-clicking on the time on the bottom right corner of the computer screen. The time and date can also be adjusted from the Control Panel. Select **Start** | **Control Panel**.

VivoLink™ Condition

VivoLink™ battery indicator

VivoLink™ battery indicator is located at the upper right corner of the front panel (Figure 5 #4). The battery indicator shows the measured voltage of the VivoLink™ batteries on the indicator's information box.

Figure 18 VivoLink™ battery voltage indicator

This image shown here indicates either no battery or the battery is spent.

When the batteries are close to being out of voltage the following low battery message box will appear on the Integrity™ computer screen (Figure 19). Vivosonic recommends that the batteries in the VivoLink™ be replaced as soon as possible after this message appears.

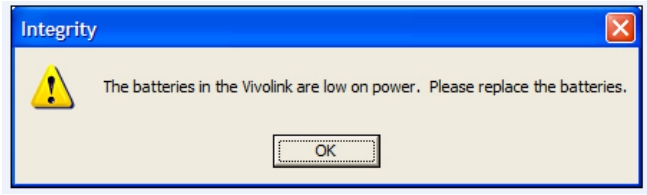


Figure 19 Low battery message box

1. Save the collected data.
2. Switch **Off** the VivoLink™ and change the batteries. (Refer to "Battery Compartment" on page 16.)

WARNING

Failure to change low voltage VivoLink™ batteries will cause interruption in data transmission between VivoLink™ and computer and may result in the loss of the collected response.

Bluetooth® connection indicator

The **Bluetooth® connection indicator** is a virtual LED located in the upper right corner of the Test Screen. It is **blue** (appears lit) when the computer and the VivoLink™ are connected or it is dark (appears not lit) when the Bluetooth® connection has failed.

Figure 20 Bluetooth® connection indicator

Bluetooth® connected (lit) Bluetooth® not connected (not lit)

The system can establish and maintain a wireless connection only when both the computer and the Bluetooth® dongle are configured correctly. (Refer to System setup for customer installed systems on page 21 for details on configuring the Bluetooth® dongle.)

It takes the system approximately 30 seconds to 1 minutes to establish the wireless connection. If the wireless connection is not established a message is displayed stating the connection has failed (Figure 21).

This same message will be displayed during data collection if the wireless connection is lost intermittently.

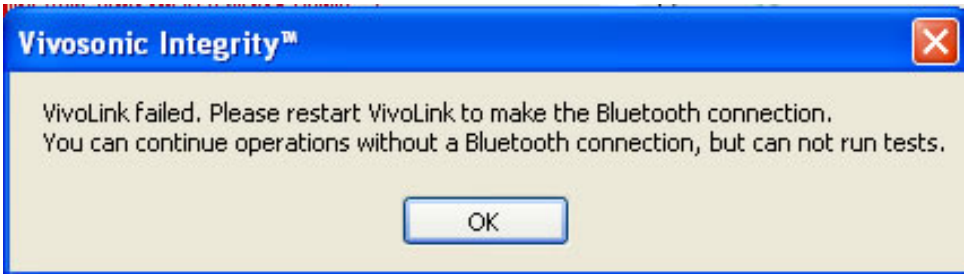


Figure 21 Bluetooth connection failed massage

If this wireless connection warning message appears, follow the troubleshooting suggestions found in Table 3 on page 91.

NOTE

The computer on which the Integrity™ operates should be Bluetooth®-enabled and have a Bluetooth® dongle inserted into the computer's USB port. (Refer to System setup for customer installed systems on page 21 for details on configuring the Bluetooth® dongle.)

Protocol Test Settings

These **Protocol Test Settings** are found in the center of the **Test** screen. Not all of the protocol settings are preset conditions available only from the Protocol screen.

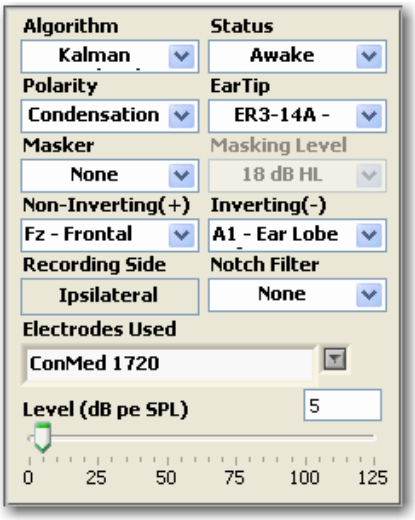


Figure 22 Protocol test settings

Vivosonic™ has developed a set of protocols that can be manipulated during the test procedure [Hall, 1990], [Hall, 1997], [Stapells, 2002]. These settings can be changed at any time between data collection while performing a test.

Algorithm

This control regulates application of the methods of processing the ABR waveforms. There are two processing algorithms to choose from: **Averaging** and **Kalman Filter**. **Kalman Filter** is the system's default algorithm.

Averaging is a signal processing algorithm, which utilizes the standard time averaging technique so that equal weighting is given to the collected ABR data. Weights are based on the noise in the response. Waveforms contaminated with artifacts above certain Artifact Rejection Thresholds (ART) are excluded from averaging.

Kalman Filter is a signal processing algorithm that is used in ABR testing to optimally select the waveform weights. Unlike **Averaging**, the **Kalman Filter** technology weights (or a linear minimum mean-square error filter) are inversely proportional to the amount of noise in the collected response. In other words the system gives less weight to the noise-contaminated responses and emphasizes the less noisy responses. This method processes signals in real time without rejecting any time segments, even those containing significant artifacts. [Li 2002]

Status

Select the patient's status of arousal from the drop-down menu. The entries are **Asleep**, **Awake**, and **Mixed**. Awake is a default setting.

Polarity

This control regulates the voltage characteristic of the stimulus. Stimulus polarity selection depends on the goal of the testing.

From the drop-down menu select Condensation, Rarefaction, Alternating, or Alternating split.

Condensation denotes a polarity as the initial displacement of the stimulus, produced with a positive-voltage electrical signal and an outward movement of the acoustic transducer.

Rarefaction denotes a polarity as the initial displacement of the stimulus, produced with a negative-voltage electrical signal and an inward movement of the acoustic transducer.

Alternating denotes a polarity as interchangeable, presenting rarefaction and condensation polarity stimuli characteristics. The responses of two consecutive stimuli are sent to one buffer (A) then the responses of the next two consecutive stimuli are sent to the other buffer (B). Thus, each buffer will get the responses from both condensation and rarefaction stimuli.

Alternating split denotes a polarity as interchangeable, presenting rarefaction and condensation polarity stimuli characteristics. The polarity alternates which buffer the responses are sent to. Buffer (A) will receive only responses from condensation stimuli and the other buffer (B) will receive only responses from the rarefaction stimuli. Thus, each buffer only receives responses from a specific stimulus.

EarTip

Select the size of the ear tip from the drop-down menu. Refer to Figure 2 to view the types available.

Masker

This control regulates the introduction of contralateral wideband masking noise. To apply masking through the ER-3A transducer opposite to the ear which is stimulated with ABR stimuli (clicks or tone bursts) select **Wide Band Noise** from the control drop-down menu. To test without masking select **None** (system default).

Masking Level

The masking level defines the contralateral masking noise (dB HL). When a masking value is selected the VivoLink™ will produce wide-band noise.

There are no necessary adjustments to the Reference equivalent threshold sound pressure level (RETSPL) values that accompany narrow-band noise, as per ANSI S3.6-2004, 6.3.1. The conversion from dB HL to dB SPL is based on the RETSPL value for the insert earphones in an occluded ear simulator (Table 7 in ANSI S3.6-2004 manual).

The masking dB SPL value is calculated for the root mean spare (**rms**) of the masking signal. As such, the dB SPL of the overall masking signal will differ with the type of stimulus, such that the **rms** of the masking signal will match that of the dB HL at the corresponding frequency of the stimulus signal (Click signals are treated as having a frequency of 1 kHz).

Select the level from 10 to 110 dB HL in 1 dB increments.

Non-Inverting (+) and Inverting (-) Electrode

These two fields allow the user to select the location of the Amplitrode® inverting and non-inverting electrodes on the patient.

NOTE

The **Non-Inverting (+)** and **Inverting (-)** field entries provide important information on the condition of data collection and the location of the electrodes during the tests. These settings will *not* affect the data. The information will be saved with the data and may be used when the data is reviewed. This information cannot be changed after it is saved. Ensure that the information is correct before saving the results.

Select the down arrow of the required electrode location and highlight an appropriate entry to define the (+) an (-) electrode locations on the patient.

The possible electrode locations available from the drop-down menus are as follows:

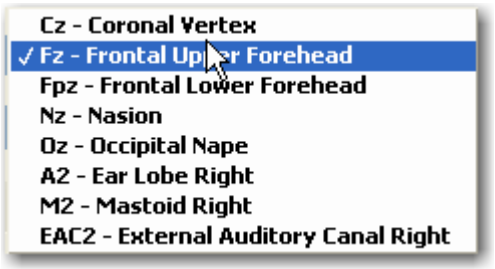


Figure 23 Non-Inverting (+) electrode drop-down list shown

Refer to the location diagram in Figure 61 on page 73.

[Hall, 1990], [Hall, 1997], [Stapells, 2001].

Recording side

This field is not user-selectable. Its selection is dependant on the non-inverting (+) or inverting (-) electrode selected and the ear chosen for stimulation. It includes:

1. **Ipsilateral** –the non-inverting electrode is located on the same side of the head as the ear being stimulated.
   - With the right ear selected for testing any combination of Cz, Fpz, Nz, Oz locations for the non-inverting (+) electrode and A2, M2, EAC2 for the inverting (-) electrode.

- With the left ear selected for testing any combination of Cz, Fpz, Nz, Oz locations for the non-inverting (+) electrode and A1, M1, EAC1 for the inverting (-) electrode.

2. **Contralateral** – the non-inverting electrode is located on the opposite side of the head as the ear being stimulated.
   - With the right ear selected for testing any combination of Cz, Fpz, Nz, Oz locations for the non-inverting (+) electrode and A1, M1, EAC1 for the inverting (-) electrode.
   - With the left ear selected for testing any combination of Cz, Fpz, Nz, Oz locations for non-inverting (+) electrode and A2, M2, EAC2 for the inverting (-) electrode.
3. **Medial** – the non-inverting and inverting electrodes are located along the sagittal plane of the head (any combination of Cz, Fpz, Nz, Oz locations).
4. **Horizontal** – the non-inverting electrode is located on the stimulus-contralateral mastoid, earlobe or ear canal, while the inverting electrode is located on the stimulus-ipsilateral mastoid, earlobe or ear canal (any combination of A1, A2, M1, M2, EAC1, EAC2 locations).

NOTE

The **Recording Side** entries provide important information on the location of data collection with respect to the stimulation location. These settings will *not* affect the data. The information will be saved with the data and may be used when the data is reviewed. This information cannot be changed after it is saved. Ensure that the information is correct before saving the results.

[Hall, 1990], [Hall, 1997], [Stapells, 2001]

Notch Filter

The notch filter is designed to reduce the interference from electrical activity (power line noise of **50 Hz, 60 Hz**). To disable the filter select **None** from the drop-down menu (system default).

Electrodes Used

Select the electrode type from the drop-down menu or type the electrode brand into the field. t.

Figure 24 List of electrodes available for testing

Level (dB pe SPL)/Levels (dB nHL)

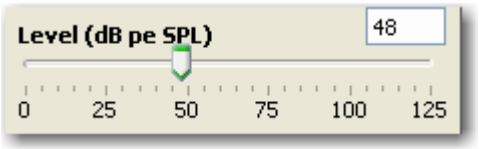


Figure 25 Level (dB pe SPL) bar.

The stimulation level sliding bar displays and regulates the levels of stimulation provided to the data recording (Figure 25). The initial position of the slider depends on the **Stimulus Levels (dB nHL)** defined in the protocol selected. (Refer to The Protocol Screen on page 61 for more details.) When testing with a single level protocol, the slider will be positioned on the value of the selected level. When testing with a multi-level protocol, the slider will be positioned on the lowest level. The values (or range) selected for the multi-level protocol are marked with blue color in the **Stimulus Level** field on the **Protocol** screen. Using the slider bar on the **Test** screen will change the level without switching to the **Protocol** screen. This change can be made only while the test collection is stopped.

The units displayed are defined in the **System** screen (see The System Screen on page 65). Below are the units and range of values that can be selected based on the transducer type.

ER-3A

- Units - dB nHL or dB pe SPL
- Range - 30 to 95 dB nHL or from 0 to 125 in dB pe SPL

B-71

- Units - dB pe FL or dB nHL
- Range - 10 to 50 or 60 dB nHL or 50 to 110 or 120 in pe FL

NOTE

The bone conductor stimulation range depends on the **Stimulus Type** defined in the protocol selected. VivoLink™ has a maximum stimulus level of 50 dB nHL for click and 500 Hz for tone-burst stimulus types. The maximum of 60 dB nHL level is for 1000 - 4000 Hz tone-burst stimulus types.

The increment of the **Levels** (1, 2, 5, 10, 15, 20, dB etc.) depend on the **Stimulus Levels** control settings defined in the protocol selected. Refer to The Protocol Screen on page 61 for details on defining a protocol.

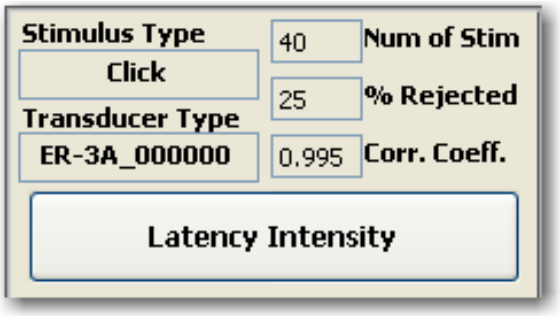


Figure 26 Signal information

Signal Information

During and after the data collection the **Signal Information** section of the **Test** screen will display information about the collected waveform.

Stimulus Type

The **Stimulus Type** (click or tone-burst frequency) is displayed in this field as a reminder of the main test parameters defined by the protocol selected.

Transducer Type

The **Transducer Type** (ER-3A or B-71) is displayed in this field to remind the operator of the main test parameters defined by the protocol selected. This information also includes the transducer serial number.

Number of Stimuli (Num of Stim)

This information box displays the number of stimuli presented in the test. The value counts up as the test is running. If the test runs to completion, the value should be equal to the value of the maximum **Number of Stimuli** defined in the protocol selected, otherwise it displays the number of stimuli counted at the time the test was stopped.

% Rejected

This information box displays the percentage of the rejected ABR responses. Responses are rejected when the amplitude exceeds the preset **Artifact Rejection Threshold** value defined in the protocol selected.

> NOTE
>
> The system displays the percentage of the rejected stimuli only when **Averaging** was selected under **Algorithm** control on the **Test** screen.

Correlation Coefficient (Corr. Coeff.)

During the time of testing, two buffers are used to collect the data. The two buffers (A and B) each receive half of the responses. The waveform displayed is an averaged A plus B response (combined waveform).

The **Correlation Coefficient** is a calculated correlation between the curves collected in A and B buffers. The **Correlation Coefficient** indicates the degree to which the collected waveforms in A and B are repeatable.

Latency intensity

This button is used to display a graph of the latency versus the intensity values of a patient based on known data defined by the age of the patient. When selected, a window opens displaying the *Latency-Intensity Graph* (Figure 27). Select the patient age range from the **Latency Normals** drop-down list to display the data supplied for that age., [Hood, 1998], [Gorga, 1987], [Gorga, 1989], [Zimmerman, 1987]

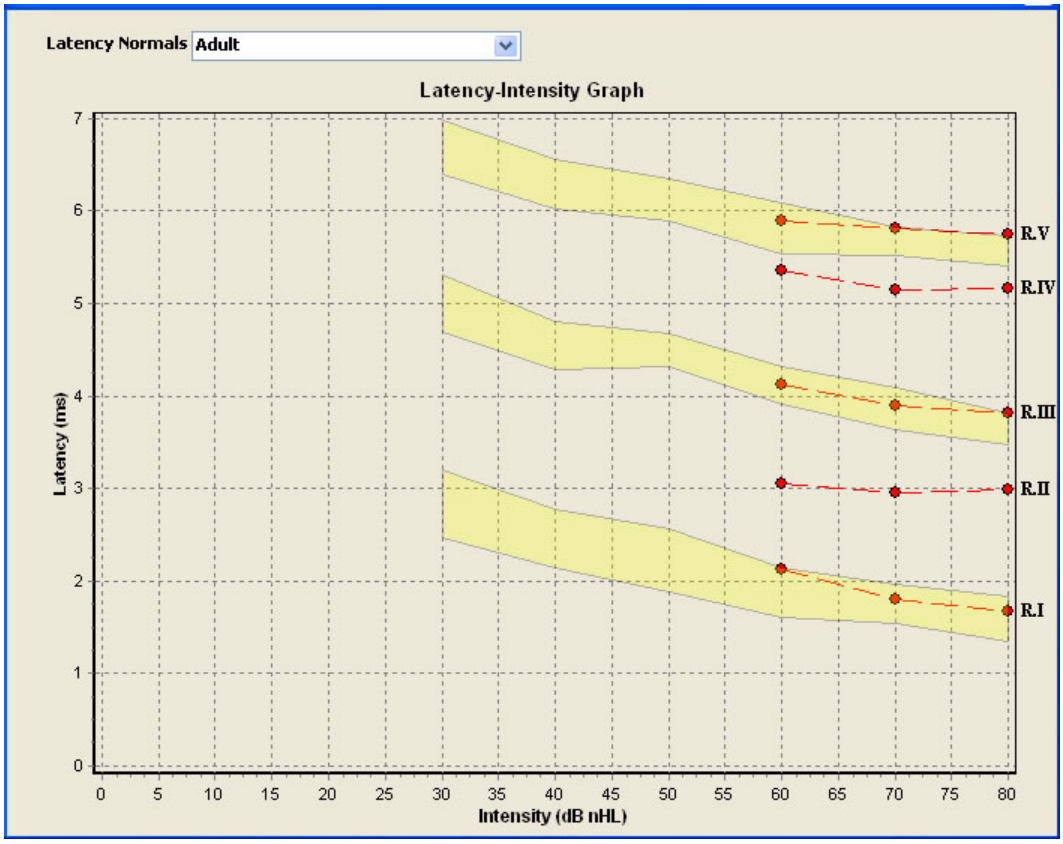


Figure 27 Latency-Intensity graph (adult) [Hood, 1998]

Before the graph can be populated the waves must first be labeled with the I, III, and V wave labels in the Waveform Window. (See Figure 30 for details.)

The latency values (in ms) for the I, III, and V waves are plotted against the intensity level. The latency graphs and dots are color coded (red for the right ear and blue for the left). Normative data can be displayed on the Latency-Intensity graph [Hood, 1998], [Gorga, 1987], [Gorga, 1989], [Zimmerman, 1987] as an average value ± 2 STD in the form of vertical bars. To view normative data (raw) go to the following file:

C:\INTEGRITY V1.0\ActiveX Controls\LatencyNormals.ini

on the Integrity™ system. If more then one waveform was collected for the same ear with the same level of stimulation and the waves were marked with the average latency value, these waves will be displayed on the Latency-Intensity graph.

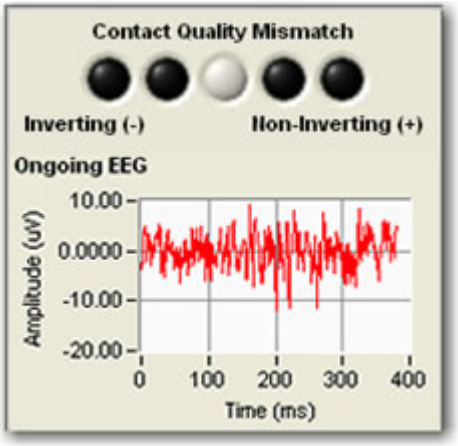


Figure 28 EEG window

EEG Window

This section of the **Test** screen contains the Contact Quality Mismatch indicator and a real-time EEG graph.

Quality Control Mismatch

The LED indicators represent the contact quality of the inverting and non-inverting electrode with the patient during the time the electrodes are in use. When the centre LED is lit, shown lit in Figure 28, there is no problem indicated. This is the optimal display representing a balanced signal from both electrodes.

When the left (amber) LED indicator is lit this indicates a problem between the connection of the inverting (-) electrode and the patient. When the right (green) LED indicator is lit this indicates a problem with the connection between non-inverting (+) electrode and the patient. Refer to Figure 29.

A poor connection will affect the results. Remove the electrode affected, remove the snap electrode pad from the patient, replace the snap electrode pad, and perform the patient preparation again to reapply the electrode.

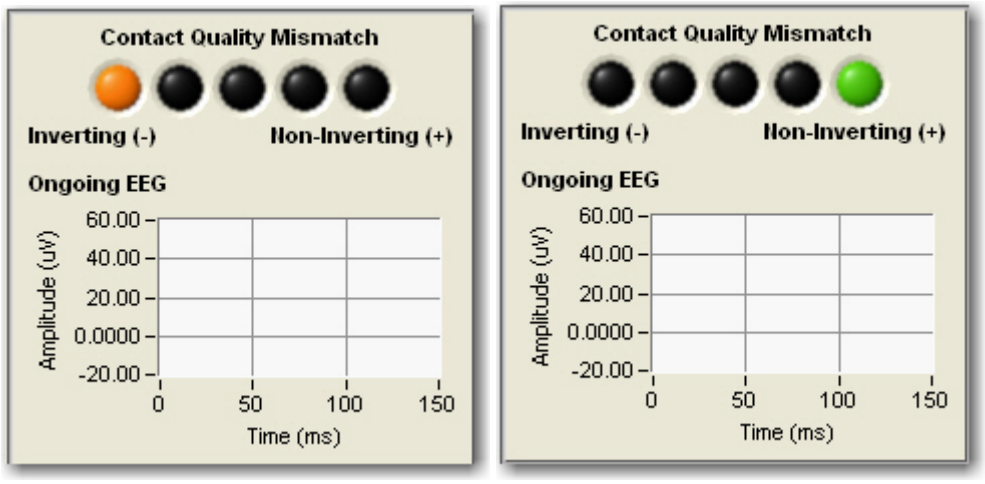


Figure 29 Poor contact quality

What to do when the Impedance Mismatch is exceeded

When this message is displayed follow these steps to restore an acceptable impedance level:

1. Check the status of the snap electrode pads. Fix, replace or reapply one or both of the snap electrode pads if necessary.
2. Check the connection between the disposable electrodes and Amplitrode® clips. If it is not a good connection, reconnect, replace or fix it.

Ongoing EEG

A real-time EEG signal is displayed in the **Ongoing EEG** graph at the bottom of the **Test** screen. This EEG signal is recorded by the electrodes and 150 ms of the signal is displayed at a time. The amplitude scale on the graph changes automatically when the amplitude of the recorded EEG signal changes. Usually EEG collected from a relaxed patient are within ± 40µV. If the EEG amplitude increases beyond ± 40µV you may want to wait for few minute to allow the patient to calm down. If EEG amplitude does not decrease, the problem may be poorly placed electrodes. Readjust the electrodes and start again.

NOTE

It is important to understand that the **Ongoing EEG** window shows a filtered EEG signal that passes through the ABR (30 – 3000 Hz, slope 12 dB/octave) analog electrical filters of the Amplitrode®, not an unfiltered "raw" EEG signal. In addition, if the analog notch filter (50 Hz or 60 Hz) of the VivoLink™ is switched **on**, then the **Ongoing EEG** will be passing through this filter as well.

Note: this signal does not pass through the digital high-pass and low-pass filters, which are set in the protocol and affect only the digitally processed (averaged or Kalman-filtered) recording.

Waveform Window

This window displays the graphic representation of the collected waveform as a function of the amplitude (µV) of the signal over time (ms) (Figure 30)**.**

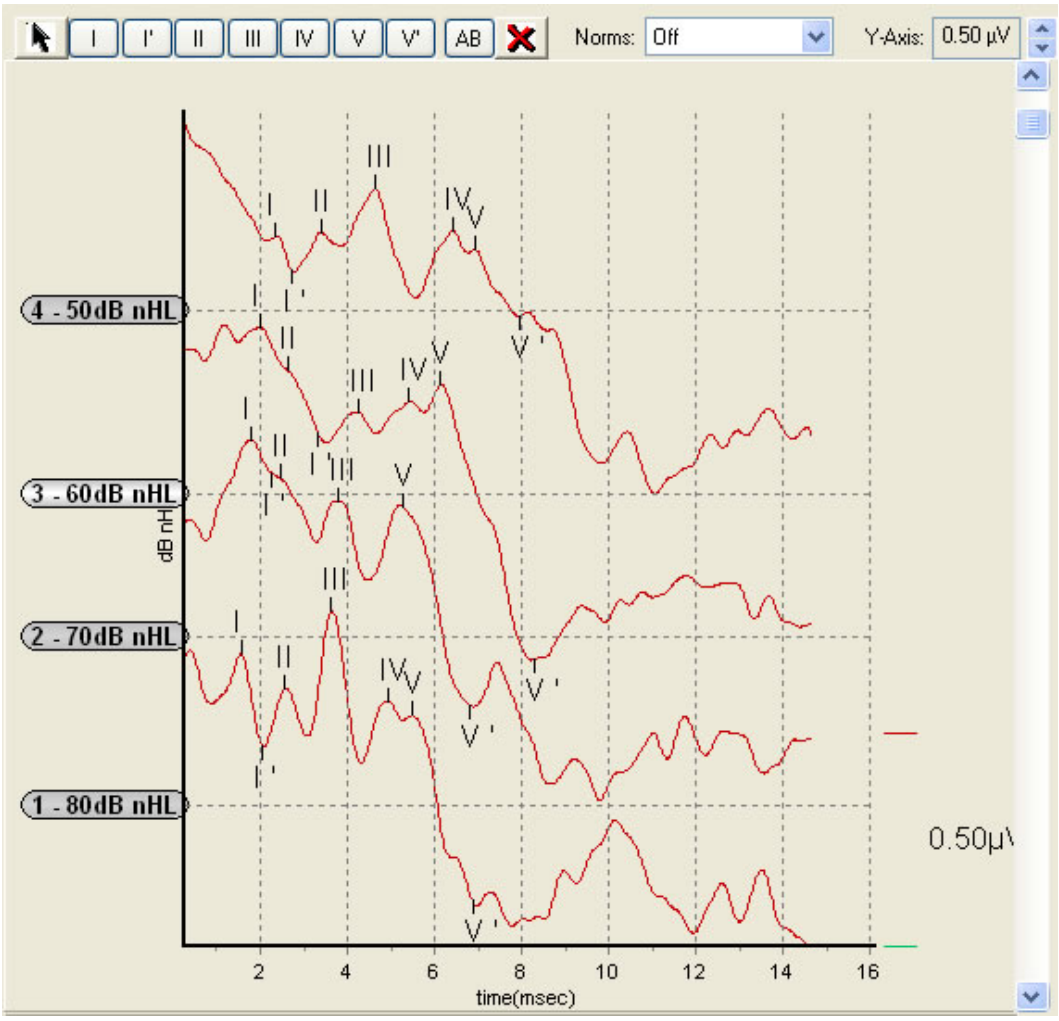


Figure 30 Waveform Window – collected data for analysis

The **Waveform Window** can be used when monitoring data in real time and when analyzing and labeling waveforms for the recently collected data. Each test **Start** and **Stop** produces a new waveform at the top of the graph, moving the previous data towards the bottom of the graph.

The waveforms collected from the left and right ears are displayed on the same diagram and are distinguished by the color of the waveform (red waveform - right ear, and blue waveform - left ear).

Figure 31 Waveform handle

Each waveform is supplied with an individual handle located to the left of the graph. All the waveform handles have a waveform tagging line which displays the following information:

- The waveform **number** marks the order in which the waveforms were collected. This is the number the waveform's information is given when displayed in the **Waveform Information** chart (Figure 33).
- **Stimulus Level** applied to the data collection.

To highlight any of the waveforms, click on its handle. The highlighted waveform and its handle will become brighter. You can move the highlighted waveform along the vertical axis by dragging it with the handle.

Label a Waveform

To label a waveform and calculate its latency follow these steps:

1. Select the handle of the wave to be labeled.
2. Select a label from the labeling buttons at the top of the **Waveform Window** (Figure 30).
3. Place the cursor over the waveform where the label will be placed. Note that the location will jump to the peaks (peak positives) and troughs (peak negatives) of the wave.
4. When the correct peak or valley has been identified, click the mouse to place the label.
5. To move a label, select the label and place it again following the steps above. Once placed on the wave, the label cannot be deleted, only moved.

The selected peak will be marked with the chosen wave number and the calculated peak-related latency values [Hood, 1998], [Gorga, 1987], [Gorga, 1989], [Zimmerman, 1987] will appear in the **Waveform Information** chart (Figure 33).

Figure 32 Waveform labeling buttons

> NOTE
>
> Use the "**I, II, III, IV,** and **V**" buttons with Roman numerals to label the positive peaks. Use the "**I'** and **V'**" buttons to label the negative peaks of waves **I** and **V**. Labeling the negative peaks is essential for calculating the peak-to-peak amplitude.
>
> Labeling the negative peaks will not affect the latency calculation.

> NOTE
>
> The arrow button, located first in the label selection, is used to disable the selected label.
>
> Once selected, a wave labeling button will remain active until another labeling button is selected or the arrow button is selected.
>
> Once a wave label is placed on a wave it cannot be deleted only moved.

AB Display

The **AB** display mode is used to change the displayed waveform into the recorded components of the A and B buffered information.

1. Select the waveform desired.
2. Press the **AB** button located next to the **Waveform labeling buttons**.

The single waveform will split into A and B components.

3. To switch back to the combined waveform, select one of the split waveforms and press **AB** again.

Waveform Delete button

To delete a wave from the Waveform Window:

1. Select a waveform handle.
2. Press the button with the **X** on it.
3. Answer "**Yes**" when asked if you want to delete the wave.

Latency norms

Integrity™ provides a graphical presentation of the normative data for Latencies I and V. To view normative latency data for waves I and V, do the following:

1. First label the wave. (See Label a Waveform on page 41 for details.)
2. Select the **Latency Norms** down arrow to view the normative data list.
3. The normative data graphs for waves I, III, and V latencies will be shown in the **Waveform Window** in the format of yellow vertical bars.
4. The **Waveform Information** chart (Figure 33) will display the normative data title and the level of intensities for the latency norms shown.

NOTE:

Vivosonic recommends that each clinic create its own normative data which reflect the specific character of the tested population and the protocols used for their data collection. The preset normative data can be used to compare the results collected with the same stimulus, recording, and subject parameters. There is no international standardized data available at this time.

The Latency Normative file is located at:

C:\INTEGRITY V1.0\ActiveX Controls\LatencyNormals.ini

Use the same data entry standard as the predefined latency data already in the file to add custom data. Once added, the new data will appear as a selection in the **Latency Norms** drop-down box.

For the source and value of the ABR latency normative data please refer to (Appendix H). [Hood, 1998], [Gorga, 1987], [Gorga, 1989], [Zimmerman, 1987]

Y-axis Scale

Use the **Y-Axis Scale** field located at the right upper corner of the **Waveform Window** (Figure 30) to change the Y-axis scale of the amplitude. The scale can be set to any value between 0.05 µV to 4.0 µV.

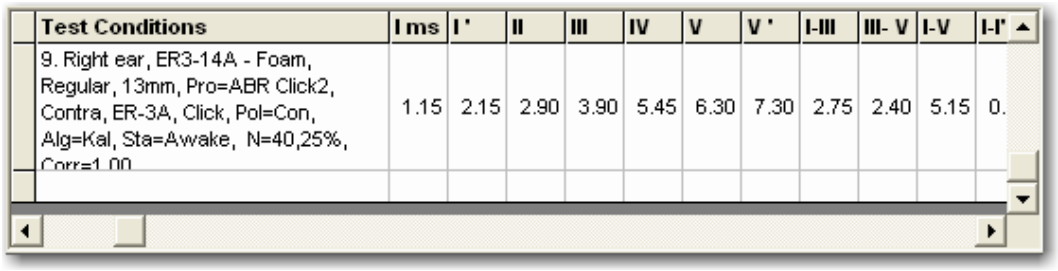
To change the scale:

Select the up or down arrow to the right of the **Y-Axis** value.

Changing the size affects only the display on the screen – it does not influence the recorded data.

Waveform Information Chart

This chart contains the numeric representation of the peak and peak-to-peak latencies of the waves shown in the **Waveform Window** (Figure 33)**.**



Test Conditions	I ms	I '	II	III	IV	V	V '	I-III	III- V	I-V	I-I'
9. Right ear, ER3-14A - Foam, Regular, 13mm, Pro=ABR Click2, Contra, ER-3A, Click, Pol=Con, Alg=Kal, Sta=Awake, N=40,25%, Corr=1.00	1.15	2.15	2.90	3.90	5.45	6.30	7.30	2.75	2.40	5.15	0.

Figure 33 Waveform Information chart

For each collected waveform, the **Waveform Information** chart displays the following data:

- The corresponding wave number (in this case waveform 9), will be the same as the wave number displayed on the waveform handle (Figure 31 shows waveform 1 as an example). The information for this waveform is displayed in the **Test Conditions** column of the **Waveform Information** chart.
- A brief summary of the conditions of the stimulation displayed in the **Test Conditions** column:
  - Stimulated ear: Right Ear, Left Ear
  - Transducer type: ER-3A or B-71
  - Ear tip type and size
  - Protocol used (Pro)
  - Recording side: Ipsi (Ipsilateral), Contra (Contralateral)
  - Stimulus type: Click, 0.5K, 1.0K, 2.0K, 4.0K
  - Stimulus Polarity (Pol): Con (Condensation), Rare (Rarefaction), Alt (Alternating), and Alt Split (Alternating split)
  - Response processing algorithm (Alg): Kal (Kalman Weighted), Ave (Averaging)
  - Patient Status (Sta): Awake or Mixed
  - Number of stimuli (N)
  - Percentage of the rejected stimuli (will be displayed only if Averaging signal processing algorithm was applied)
  - Correlation coefficient between the waveforms collected in the A and B buffers
- Latency values for each labeled peak, in milliseconds (ms) with the accuracy of 0.01 ms.
- I – III interpeak latency. The value can be displayed only if peaks I and III have been labeled.
- III – V interpeak latency. The value can be displayed only if peaks III and V have been labeled.

- I – V interpeak latency. The value can be displayed only if peaks I and V have been labeled.
- Wave I amplitude. The value can be displayed only if the positive (**I**) and negative (**I'**) peaks of wave I are labeled.
- Wave V amplitude. The value can be displayed only if the positive (**V**) and negative (**V'**) peaks of wave V are labeled.

TIP

To find specific data in the **Waveform Information** chart use the chart's vertical scroll bar to find the desired waveform. Alternatively, select the handle of the waveform of interest in the **Waveform Window** and the matching data will be displayed at the top of the chart.

Use the **Latency Intensity** button (Figure 26) to display this data graphically.

Leave the Test screen

The other screen tabs will be disabled when the data on the screen has not been saved. To exit the **Test** screen the test data must first be saved or discarded.

1. Press **Save** to create the current records in the database.
2. Press **Discard/Clear Graph** to remove the data from the screen. If it is not saved first it will be deleted. A warning dialog box will ask if you want to discard the record.

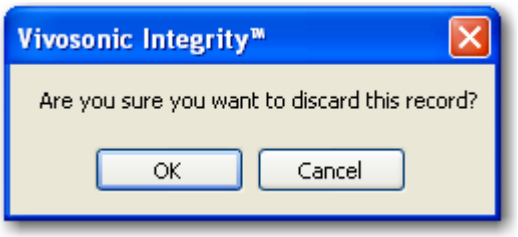


Figure 34 Are you sure you want to discard the record(s)?

The Patients Screen

The **Patients** screen lists all the patients who have been defined on the system, whether they have been studied previously or they will be studied in the future. To perform a study or to plan a study, the patient must first be created in this screen.

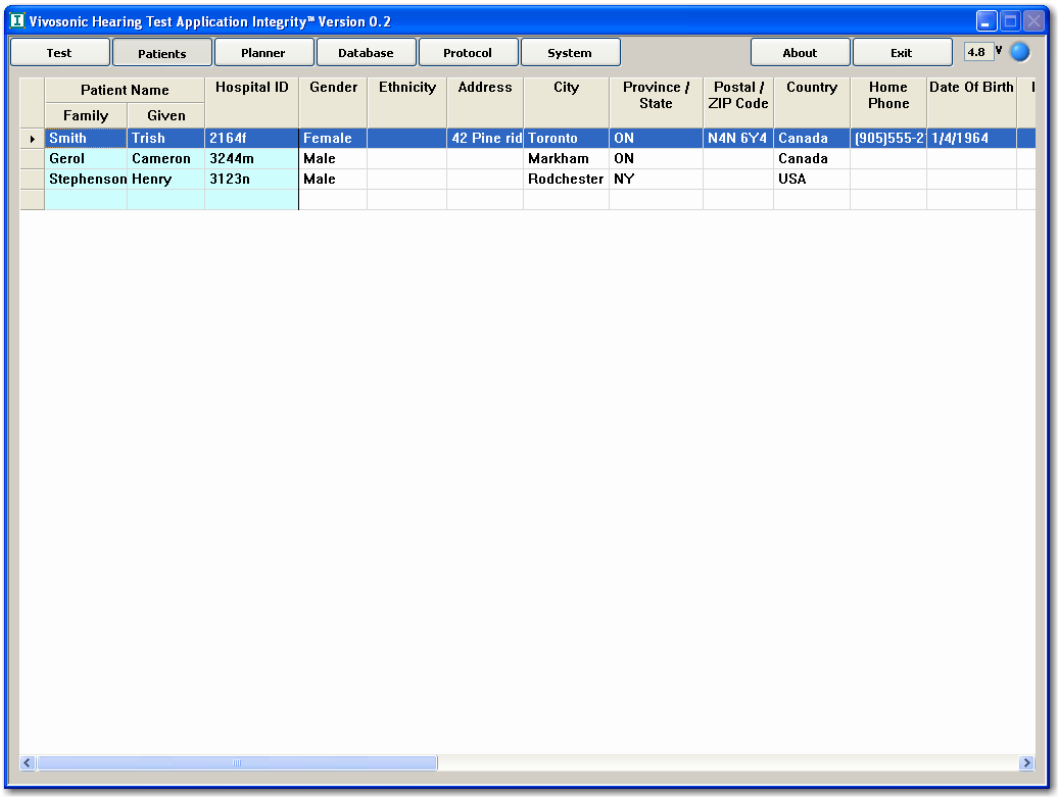


Figure 35 The Patients Screen

The **Patients** screen contains a table with the patient information listed in columns. A horizontal scroll bar at the bottom of the screen allows the user to scroll the entire table to see all of the patients' information. The vertical scroll bar appears only after the patient list grows beyond the length of the screen (approximately 20 patients).

The patient information is entered directly in the fields corresponding to the patient. To create or update the patient list:

1. Select the **Patients** tab. The **Patient** screen will open (Figure 35).

Follow the procedure "The width and height of the columns and rows are adjustable.

To widen a column, place the cursor on the line dividing the two column headings. Click and hold the line and drag it to the right or left to increase or decrease the size of the column on the left.

To adjust the height of a row, place the cursor on the line dividing the two row headings. Click and hold the line and drag it up or down to increase or decrease the height of the row below the line.

2. Entering patient information" on page 46 to add patient information. The minimum information required is the patient's **Family** name, **Given** name, and **Hospital ID**, which uniquely identify the patient in the list.

Sorting the table

The patients can be sorted by any information. Only one column at a time can be used to sort the information.

1. Select a column heading to sort the patients using that column's information (e.g., Date of Birth). An arrow will appear in the column heading indicating which direction (ascending or descending) the information in that column has been sorted.
2. Select the column again to sort the information in the opposite direction (descending or ascending).
3. To sort by another column, select another column heading.

Adjusting the columns and rows

The width and height of the columns and rows are adjustable.

To widen a column, place the cursor on the line dividing the two column headings. Click and hold the line and drag it to the right or left to increase or decrease the size of the column on the left.

To adjust the height of a row, place the cursor on the line dividing the two row headings. Click and hold the line and drag it up or down to increase or decrease the height of the row below the line.

Entering patient information

To enter any patient information, double-click on the cell and type in the information. Some columns contain cells with drop-down menus that provide a list of all items entered in that column: Gender, Ethnicity, City, Province/State, Country, Referring Physician, Comment 1, Comment 2, and High Risk Registry. These lists are dynamic and grow as the patient list grows.

For example if the first patient lives in Toronto and the next patient entered lives in New York City, then when the third patient is being entered, the city list will contain Toronto and New York City. Type the city name directly in the cell to add a new city entry or select a city from the list. This feature significantly speeds up data entry for repeated information, and prevents various spellings of the same information.

There is additional patient information for newborns and infants: mother's information, including mother's ID, family name, and given name, the infant's time of birth, high-risk registry category, and birth weight.

Entering Date of Birth

The **Date of Birth** column contains a drop-down calendar (Figure 36). To enter a date:

1. Select the arrow on the right side of the field to open the calendar.
2. Select a day from the appropriate year and month. This will close the calendar and create the date of birth in the field.

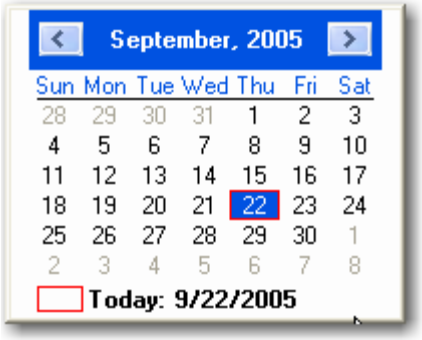


Figure 36 Drop-down calendar

Entering Time of Birth

This field will be used most often when the patient is a newborn.

1. Select the appropriate field in the patient **Time of Birth** column. This will open a digital clock showing the time in the HH/MM/SS/AM-PM format (Figure 37).
2. Highlight hour and adjust the hour using the up (increase) and down (decrease) arrows.
3. Highlight the minutes, seconds, AM/PM, and select the correct time using the arrows.
4. Press **OK.**

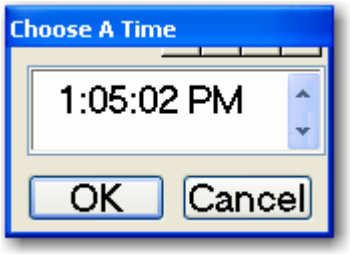


Figure 37 Drop-down clock

Selecting Patients

Select one or more patients who will be tested during a testing session.

Click the row heading to the left of the patient Family name. The entire patient row will be highlighted (Figure 38).

To select another patient, hold the **Ctrl** key on the keyboard and click the row heading to the left of another patient row.

To select several consecutive patients, select the first patient in the required list as stated above. Hold the **Shift** key on the keyboard and click the last patient required in the list. All the patients between the first and last selected will be highlighted.

Only the highlighted patients selected here will appear in the **Patients** drop-down menu of the **Test** screen (Figure 12).

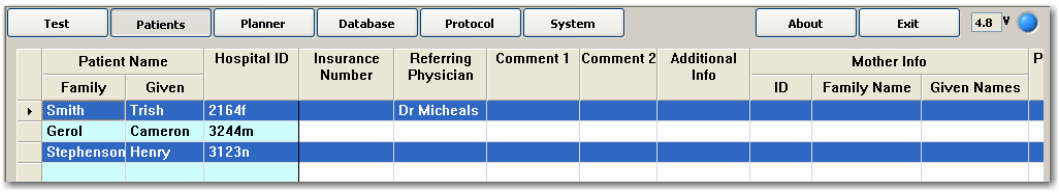


Figure 38 Selected patients in Patients screen

The Planner Screen

Use the **Planner** screen to pre-plan tests hours or months in advance of the actual test (Figure 39). This feature gives the operator the ability to plan upcoming test procedures, to keep track of patients who need to be tested or re-tested, assign personnel to perform the tests, and identify the time and location of the tests. This will streamline the testing process, and reduce the chance of missing a patient, which may be particularly important in cases after an event that might have affected the hearing system, such as chemotherapy or other ototoxic treatments.

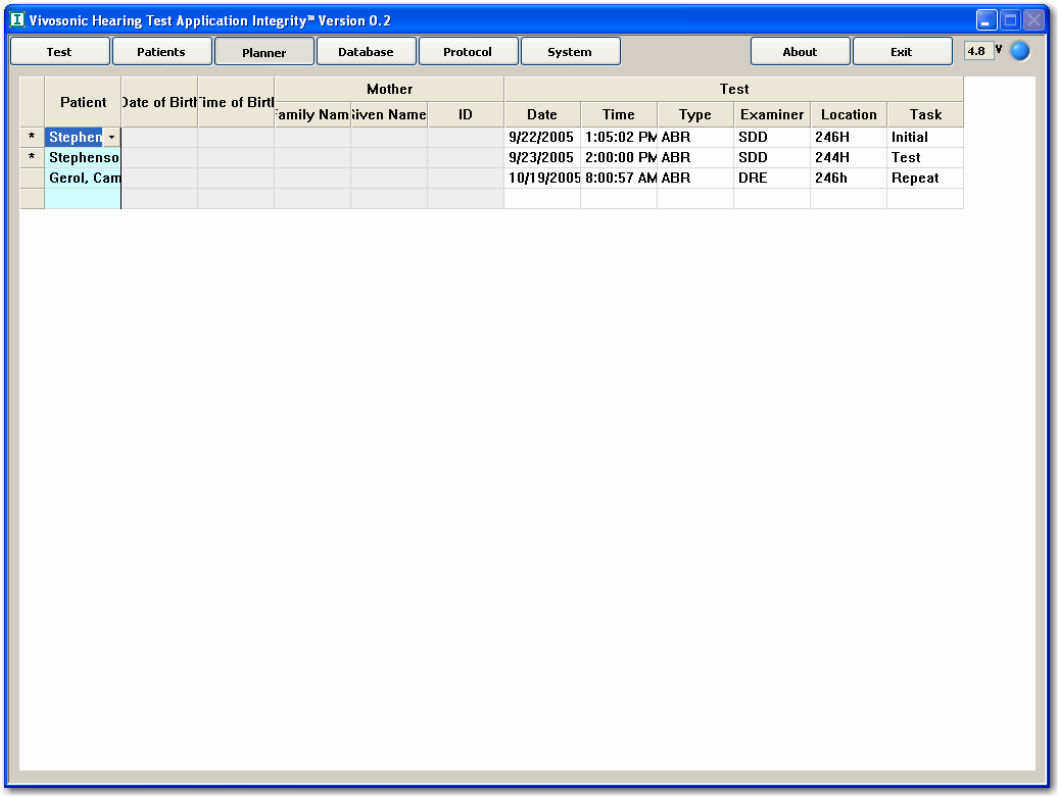


Figure 39 The Planner Screen

To plan the test schedule, press the **Planner** tab which opens the **Planner** screen. It consists of a table similar to the **Patients** screen, with two differences: First, you cannot enter patient information in this table, only select the patients you plan to test from the patient list, and second, you can add details of the test to the patient information.

> **NOTE**
>
> The test details will be saved with the specific test and not with the general patient information.

Details that can be added are:

- Mother's information (Family Name, Given Name, and Hospital ID)
- Test information (Date, Time, Type, Examiner, Location, and Task)

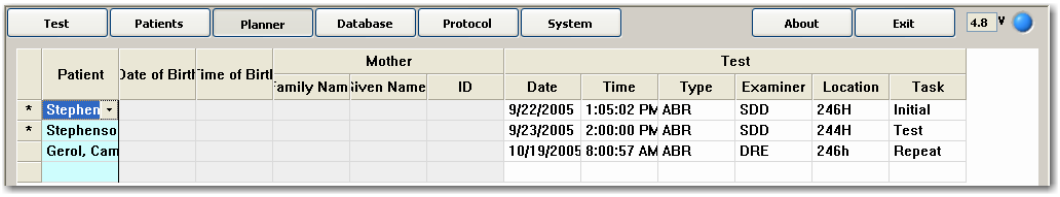


Figure 40 Planned patient list

Selecting a Patient

To add a patient to the planner:

1. Select a blank field in the **Patient** column. This will open a drop-down list of all the patients entered in the **Patients** screen. If the list is too long, a scroll bar appears on the right side of the drop-down menu.
2. Select the patient from the list. The patient will be added to the planner list. Patient, Date of Birth, and Time of Birth, as well as Mother's Family Name, Given Name, and ID.

Mother's Information

Family Name, Given Name, and Hospital ID

These three fields are valuable when the patient is a newborn.

Test Information

The **Date of Test** column contains a drop-down calendar (Figure 36), the same as used in the **Patients** screen. To enter a date:

1. Select the arrow on the right side of the **Date** field. This will open the calendar.
2. Select a day from the appropriate year and month. This will close the calendar and create the date of birth in the field.

Time of Test

Define the time the test is scheduled by using the following steps.

1. Select the appropriate field in the patient **Time** column. This will open a digital clock showing the time in the HH/MM/SS/AM-PM format (Figure 37).
2. Highlight hour and adjust the hour using the up (increase) and down (decrease) arrows.
3. Highlight the minutes, seconds, AM/PM, and select the correct time using the arrows.
4. Press **OK.**

Type of Test

This column contains a drop-down menu with the available tests on the Integrity™ system.

Click the arrow and select the test required.

Examiner, Location, and Task

These three columns define the test conditions that may affect how test results will be analyzed. Different examiners may perform tests in different orders, the locations (such as ICU, maternity wards, and audiology offices) may affect how the data is collected and the task or goal of the study may change which part of the test is the most important.

These fields contain dynamic drop-down menus. Once a value has been entered it becomes a choice in the drop-down menu list.

1. Select the arrow of the drop-down menu.
2. Select an item from the list.
3. Alternatively, type a new value into the field.

Selecting Tests

To define a testing schedule, select one or more tests that will be performed in consecutive order.

To select a test, press the blank grey cell to the left of the patient's name. This will highlight the test entry (Figure 41).

To select multiple test entries, hold down the **Ctrl** key on the keyboard and select all required patients.

To select patients listed consecutively in this planner screen, select the first patient required, then hold down the **Shift** key on the keyboard and select the last patient in the required list. All of the names will now be highlighted.

Selected test entries will appear in the **Test Plans** list in the **Test** screen.

	Patient	Date of Birth	Time of Birth	Mother			Test					
				Family Name	Given Name	ID	Date	Time	Type	Examiner	Location	Task
*	Stephenso						9/22/2005	1:05:02 PM	ABR	SDD	246H	Initial
*	Stephenso						9/23/2005	2:00:00 PM	ABR	SDD	244H	Test
	Gerol, Cam						10/19/2005	8:00:57 AM	ABR	DRE	246h	Repeat
*	Smith, Tris	1/4/1964					10/6/2005	1:58:46 PM	ABR	BHS	244H	Repeat
▸	Smith, Tris	1/4/1964					10/6/2005	4:51:02 PM	ABR	BHS	244H	Repeat

Figure 41 Selected tests in the Planner screen

TIP

Some tests shown in the Planner screen may be denoted by an asterisk to the left of the patient's name. This asterisk identifies tests from the past.

To avoid confusion, ensure that the tests selected for current testing have a current date.

Deleting entries from the Planner list

To delete a test plan name from the table, select the test entry by clicking on the blank cell to the left of the patient's name, and press the **Delete** key on the computer keyboard.

The Database Screen

The Integrity™ system uses a database to store patient and test data for future analysis. The **Database** screen retrieves this data and provides tools to review and analyze a patient's test results.

The **Database** screen is password protected. By default there is no password. Vivosonic recommends that the entry to this screen be password protected to ensure patient data privacy. Use the **System** screen to set a new password. (See Changing the Password on page 68).

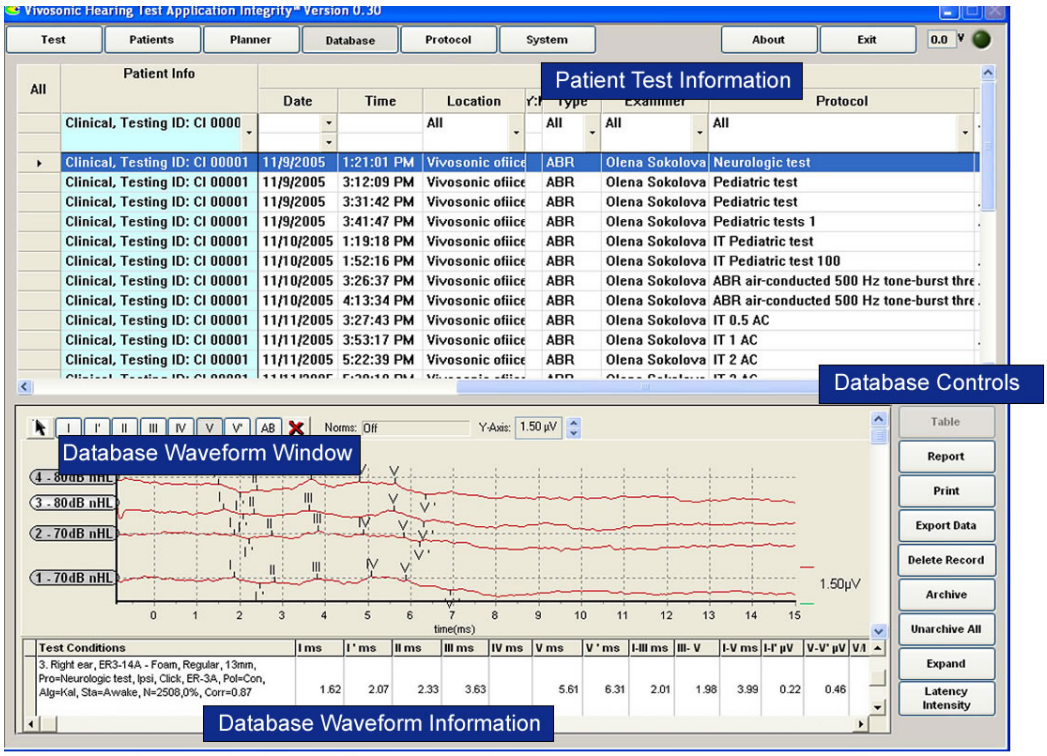


Figure 42 The Database Screen

Using the Database

Documenting test results

A database is a very powerful tool to store and review test results electronically. It contains records of patient information, as well as information on the test results and test conditions, including time and location, examiner, protocol used, outcomes, and comments. The test data is automatically stored in the database. It can be retrieved through the Database screen as well as exportable to other statistical software packages for further analysis.

Monitoring data changes over time

It is important to do baseline tests to be able to compare future test data reliably. Comparability of the results is necessary in order to be able to statistically identify any changes in a patient's test results over time. Baseline tests make it possible to accurately identify the development of conditions such as ototoxicity and noise-induced hearing loss.

Quality assurance

The database can be an essential part of your quality assurance system. To ensure reliable diagnosis the data analysis must be consistent even when the test conditions are not, for instance results obtained by different examiners, at different test times, on different ages of patients, and various test locations.

These variations must be taken into account when analyzing the patient data. When a variation in a particular condition is affecting the data, changes can be made to correct the issue, such as relocating tests to an appropriate room, acoustically modifying a test location, additional personnel training, or strictly enforcing protocol use. These measures may significantly improve the consistency of data collection, resulting in a reduction of post test analysis and increasing the reliability of the results.

Database function

Database access

4. To access the test-result in the database and review the stored results, press the **Database** tab.

> NOTE
>
> The Database screen is password protected. By default there is no password. Vivosonic recommends that the entry to this screen be password protected to ensure patient data privacy. Use the System screen to set a new password. (See on Changing the Password on page 68.)

5. Enter your password and press **OK**.

> NOTE
>
> The password is case-sensitive.

Database screen description

The main **Database** screen has the following structure (Figure 42):

- **Database Patient List** table is located at the upper part of the screen. This table contains patient's information entered in the **Patients** screen and the test conditions entered in the **Planner** screen.
- **Database Waveform Window** is positioned at the lower part of the **Database** screen. This window displays collected waveforms, waveform peak numeric values, and conditions of stimulation and recording.
- **Database Waveform Information** is a table that is located directly below the waveforms. This table contains the test conditions defined by the protocol selected, the marked peak values, and the latency calculations.
- **Database Controls** are located on the right side of the Database screen. The controls provide post-analysis functions on the data, such as report generation.

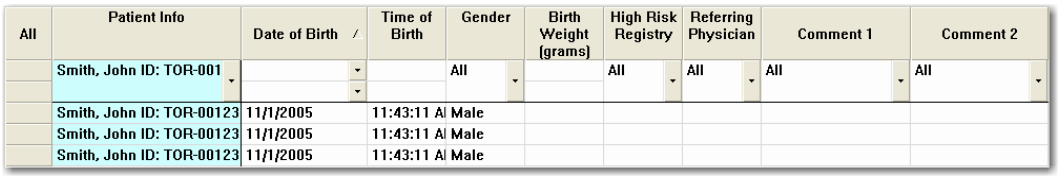


Figure 43 Database Patient list – initial view

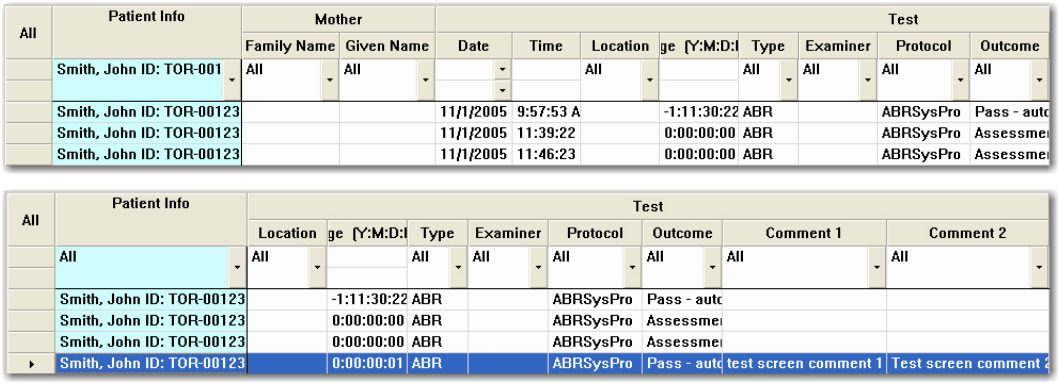


Figure 44 Database Patient list – other fields scrolled right

Database Patient List table

The **Database Patient List** table contains patients information entered in the **Patients** screen and the test conditions entered in the **Planner** screen. The scroll bar allows scrolling the table to the right and backing to the left, and seeing items in all of the columns. The first three columns on the left, containing patient's family and given names and Hospital ID, serve to uniquely identify the patient in the list, and are not scrolling.

When the vertical size of the table exceeds the screen size, a vertical scroll bar appears to the right of the table. It allows navigating through the table up and down.

NOTE

The patient's **Age** is a calculated value. When the data is saved Integrity™ calculates the age using the time and date of the test and the Date of Birth entered into the patient data.

Comments 1 and 2

The comment fields are filled automatically with information from the **Test** and **Patient** screens. The first set of comment fields holds information entered in the **Patient** screen (Figure 35). The second set of comment fields, found in the **Test** information block of the database patient list, is filled with the information that was entered when the test data was saved (Figure 14).

Sort the table information and adjust the column width

These features operate the same way as the tables in the **Patient** screen. Refer to page 46 in the **Patients** screen section for more details.

Select and unselect results

To display specific database entries in the **Database Waveform Window**:

Select the blank cell to the left of the patient's name in the **Database Patient List** table to highlight the record. The collected waveforms will be displayed in the **Database Waveform Window** and data will be displayed in the **Database Waveform Information** table.

Database Query

The database can be queried using the values available in each column. To display specific database entries that matches the selection criteria:

1. Select the arrow under in the first row under the column header to display the query values for that field. The values will appear in a drop-down list.
2. Select as many of these values as needed. The table will instantly be updated to include records that meet the query values selected.
3. Select values from as many columns as required narrowing the database query.
4. The **Date of Birth**, **Time of Birth**, and **Birth Weight** columns allow querying of a range of dates, times and weights. Set the first value of the range with the upper arrow and the second value with the low arrow, found in the first row under the heading of the column to query.

TIP

To view only the records from a specific patient performed by a specific examiner, select the patient's name from the drop-down list under the **Name** column and the examiner's name from the drop-down list under the **Examiner** column. Only the records meeting these two requirements will be displayed.

Database Waveform Window and Information Table

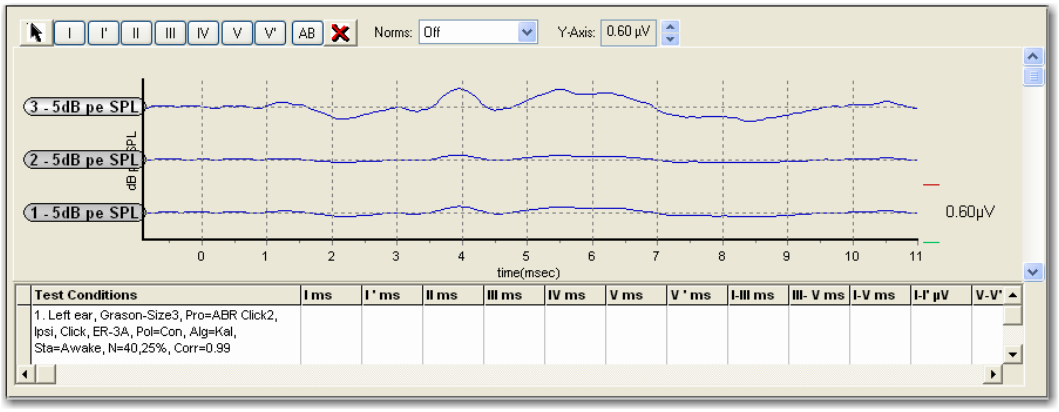


Figure 45 Database Waveform Window and Information table

This window is used to display patient's data after the test has been completed and saved. The window displays data as waveforms and labels peak numeric values. This is the same display seen in the **Waveform Window** and **Waveform Information** chart on the **Test** screen (Figure 11) during the test. The graph can be viewed full screen by selecting the **Expand** button in the **Database Controls** (Figure 46).

All of the following functions are available from either view (full or compressed) of the **Database Waveform Window**:

- Activate (highlight) a waveform by selecting the waveform's handle.
- Move highlighted waveforms along the vertical axes.

- Label the peaks of the highlighted waveform using the waveform markers.
- Change waveforms presentation scaling.
- Delete the a highlighted waveforms.
- Introduce or remove latency norms by selecting the appropriate age related normative values from the **Norms** list.
- Review the conditions of the stimulation and the waveforms' numerical values of the labeled peaks in the **Database Waveform Information** chart.

NOTE:

All peaks previously labeled on the **Test screen** during or after the testing will be stored in the database and displayed at the **Database Waveform Window** of the **Database** screen.

All numeric values of the previously labeled peaks will be displayed in the **Database Waveform Information** chart.

Any subsequent peak labeling changes made to the database and saved will overwrite the previously stored label values.

Database Controls

The database control buttons (Figure 46), located to the right of the **Database Waveform Window**, provide options to create reports, print, view, and save the data from the test.

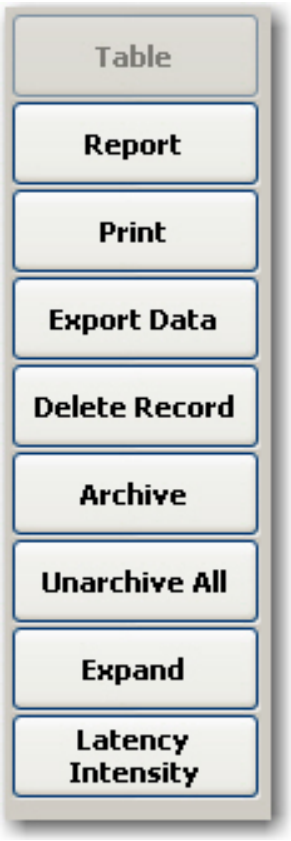


Figure 46 Database Controls

Table

This button is not currently used.

Report

The **Report** feature allows the user to add comments about the test results.

1. Select the **Report** button to open a **Report screen** (Figure 47).
2. Write a report for the session and save it in the database.
3. Select the red X ( ) to save the report comment to the patient's record.

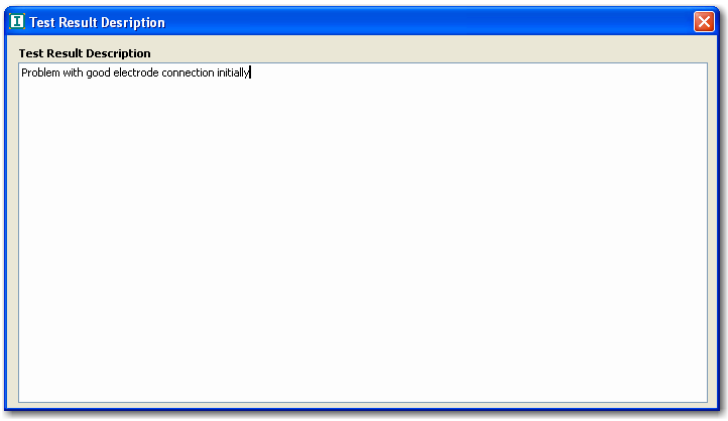


Figure 47 Test report screen

Print

Results, including waveforms, patient information, and comments can be printed as a report.

1. Select the required patient results to print by highlighting the records.
2. Press **Print.**
3. A dialog box (Figure 48) will appear. Press **Print Test Result** to send the report to the printer**.**

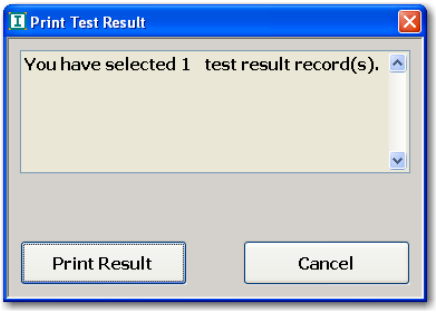


Figure 48 Print Test Result dialog box

Select a report type from the *Select a Report Type* drop-down box (Figure 49). There are three options to choose from: **All**, **Test Report**, or **Test Results**.

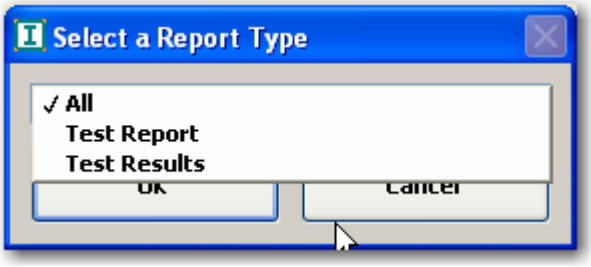


Figure 49 Print Test Result dialog box

If **All** is selected, the following information will be printed:

1. Test centre information
2. Patient information
3. Report information
4. Instrumentation information

5. Test results:
   - Waveform graph
   - Latency vs. Intensity graph
   - Numeric test results table (This table includes the test parameters and the labeled wave latency values)
6. Protocol parameters table

If **Test Report** is selected, the report will contain the information entered via the **Report** button (Figure 47):

1. Test centre information
2. Patient information
3. Report information (This is the information entered via the **Report** button.)

If **Test Results** is selected, the following information will be printed:

1. Test centre information
2. Patient information
3. Test results:
   - Waveform graph
   - Latency vs. Intensity graph
   - Numeric test results table (This table includes the test parameters and the labeled wave latency values)
4. Protocol parameters table

Export Data

This button allows the user to export data to a common delimited file to be used in any database related software application that can import this type of file, for example Microsoft Excel[4].

1. Select the **Export Data** button.
2. Select a location to save the file. Press the folder button to browse to the correct directory.
3. Enter a name for the exported file.
4. Press **Export Test Result**. The common delimited file will be created.

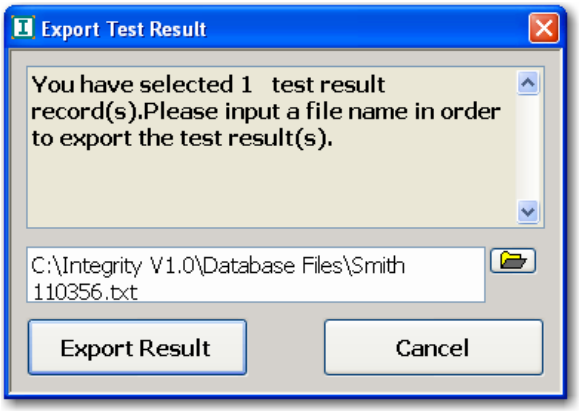


Figure 50 Export Test Result

[4] Excel is a registered trademark of Microsoft Corporation.

Deleting records from the database

Records can be deleted from the database. To delete a record:

1. Highlight the record to delete.
2. Press the **Delete** button. The record will be deleted from the database.

Archiving

The Archive feature allows selected patient records to be “hidden”. This is useful when there are too many records from the same patient on the same test session to review. It may be time consuming to look through all the data to find a record that is known to be representative. Identify the results that are representative (“good”) of that patient’s data.

1. Select the results that are not required by highlighting the record.
2. Press **Archive**. The selected records will disappear from the patient table.

If all the results that are not required for analysis are hidden using the archive feature only the required records will be visible in the patient list reducing the time it takes to find specific results.

This is particularly important when averaging data results. Once the data that is not required for the statistical analysis has been archived, the results from those records will not be used by Integrity™ when performing statistical analysis.

> NOTE
>
> Archived data is not deleted or removed from the database. It is merely hidden from the patient record table and not used.

Un-archiving results

To un-archive results that have been previously archived, press **Unarchive All**. All archived results will be returned and shown in the table.

Expand

The waveforms can be displayed in a full screen format for easier viewing.

1. Select the **Expand** button.
2. Select the red X () to return to the compressed **Database Waveform Window**.

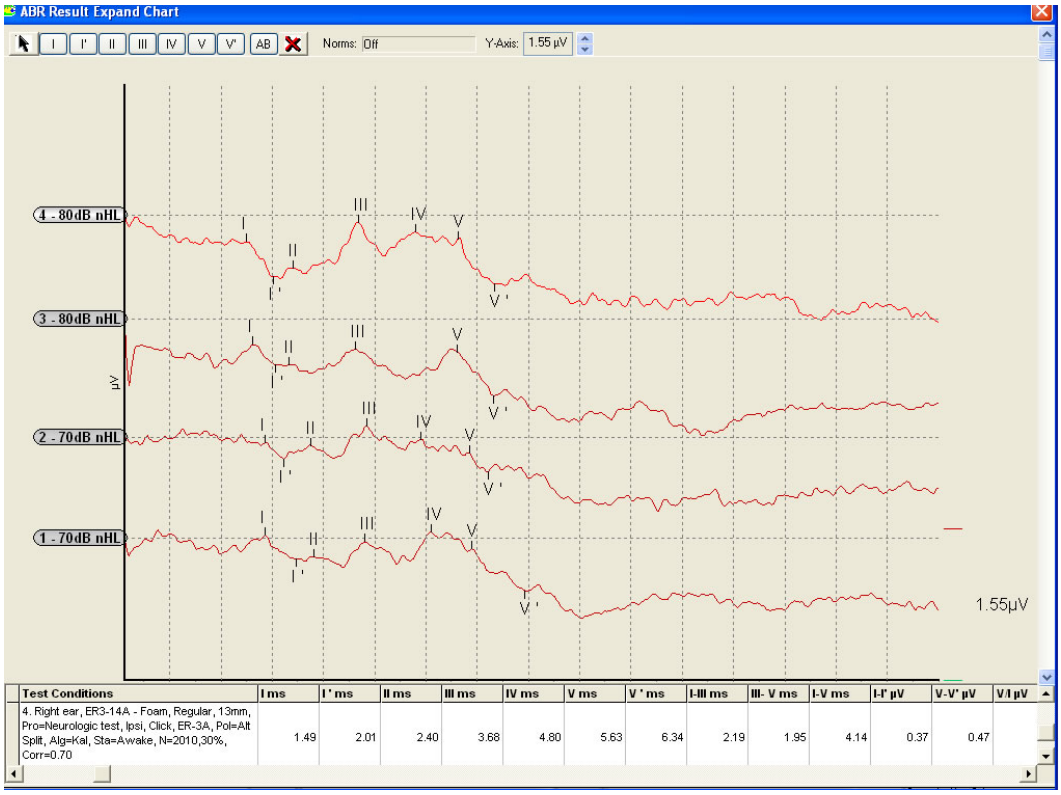


Figure 51 Expanded Database Waveform Window

Latency-Intensity graph

The Latency-Intensity button opens a view of the results in a Latency vs. Intensity graph.

1. Press **Latency-Intensity** to view the graph.
2. Select the red X ( ) to close the graph.

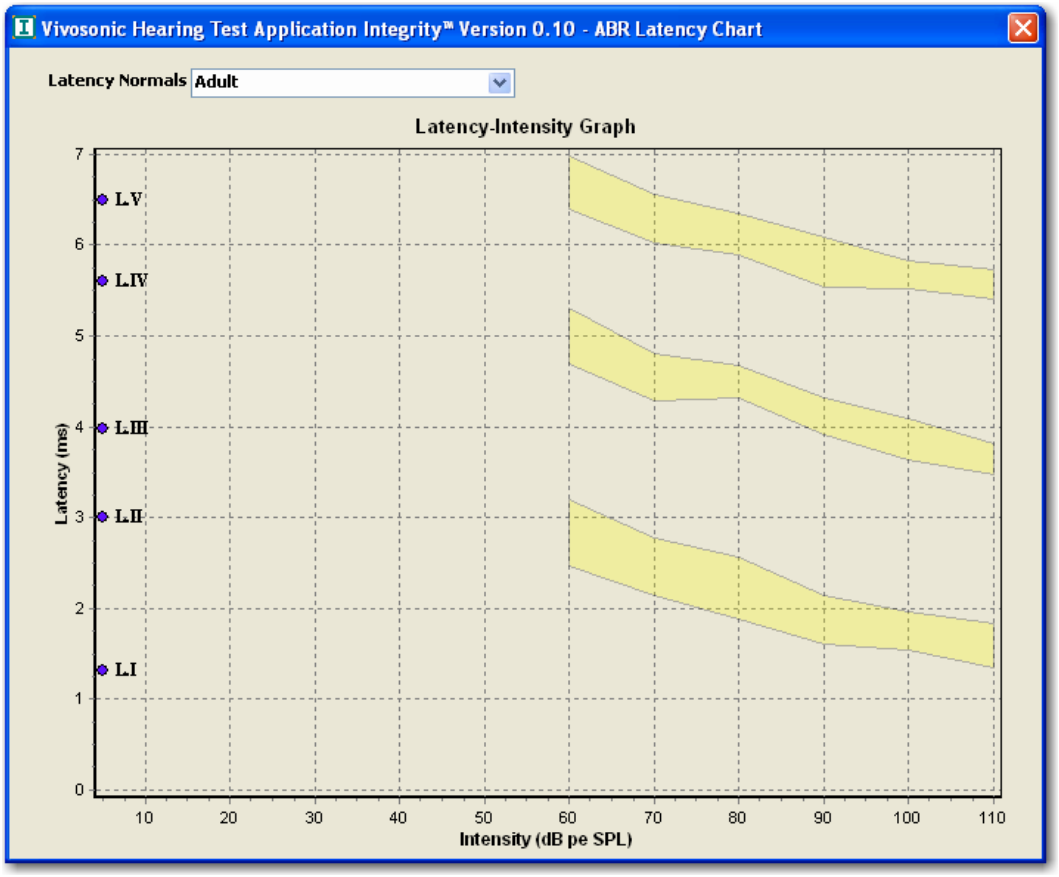


Figure 52 Latency-Intensity Graph - adult norms shown

The Protocol Screen

The **Protocol** screen allows the user to create, save, activate, deactivate, and delete test protocols.

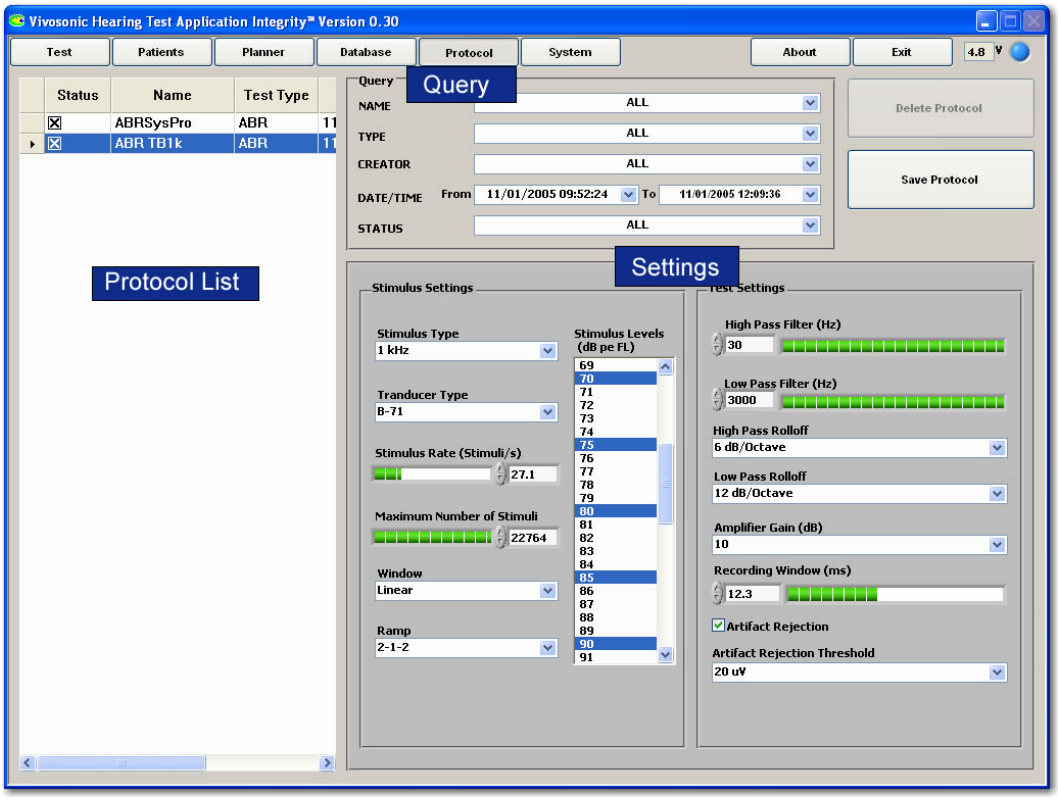


Figure 53 The Protocol Screen

Like the **Database** screen the **Protocol** screen is password protected. The same password set for the **Database** screen is used to access the **Protocol** screen. (Refer to Changing the Password on page 68 for details on how to set the password.)

> NOTE
>
> Access to the **Protocol** screen is password protected to ensure that only authorized personnel can create and manage the test protocols.

The Protocol screen has three general sections (Figure 53):

- Protocol List
- Query
- Settings

The functions associated with these three sections are defined below.

Creating Protocols

Protocol List

All created protocols are saved in the Protocol database accessible from the **Protocol** screen. All saved protocols are displayed in the list on the left side of the protocol screen (Figure 54). The Integrity™ system comes with several preset parameters. Refer to Appendix C for a list of the preset protocols.

Only the first four columns in the table are visible. Use the scrollbar on the bottom of the list to view the other columns in the table.

> **NOTE**
>
> Once a protocol has been used to acquire patient data it cannot be deleted from this list. Only protocols that have not been used to obtain any test results can be deleted from the protocol database. This ensures the integrity of the test data saved in the database.

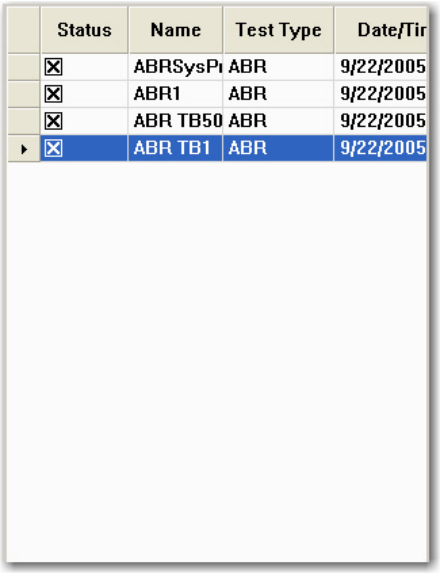


Figure 54 Protocol List

Activating and deactivating protocols

Activated protocols are shown with the box selected in the Status column of the Protocol list. All protocols that are active will be available for selection in the **Test** screen. To activate a protocol:

1. Click in the box located to the left of the protocol name in the Status column of the Protocol list (Figure 54). An "*x*" will appear in the box indicating that the protocol is now active.
2. Click on the "*x*" in the box to deactivate the protocol.

Protocol Query

If there are numerous protocols in the protocol database, the protocol list will be long. It may be challenging to find one specific protocol in the list. The **Query** feature is designed to help find protocols in a lengthy list.

The **Query** feature is found in the top middle of the **Protocol** screen. To find a protocol in a long list of protocols, use the query feature to search using these five variables: type, name, creator, date/time of creation, and status of the protocol.

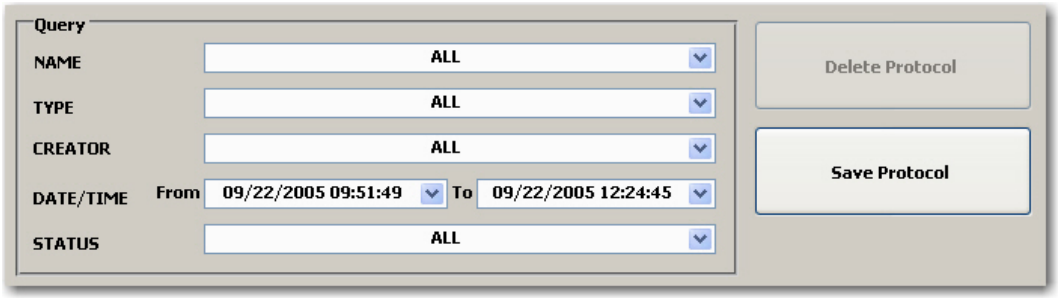


Figure 55 Protocol Query

- Select a variable to filter the list, from one or more of the drop-down fields in the query.

When the selection is made the list will automatically update showing only the protocols that fit all the criteria of the query.

Protocol Settings

The configuration of a protocol will depend on the test to be performed. Refer to Protocol Parameters on page 79 for more details about the protocol settings and defining a protocol. To create a new protocol:

1. Select the blank cell to the left of any protocol in the Protocol List. This will highlight the protocol.
2. Modify the parameters of the protocol, including description and comments. (Refer to Protocol Parameters on page 79 for more details.)
3. Press **Save Protocol** to the right of protocol Query (Figure 55). A dialog box (Figure 56) will appear.
4. Enter the protocol name and the name of creator.
5. Press **OK**.

NOTE:

A saved protocol cannot be modified. Once created, a protocol cannot be *saved* under the same name. To make any changes to a protocol, save the changed protocol under another name.

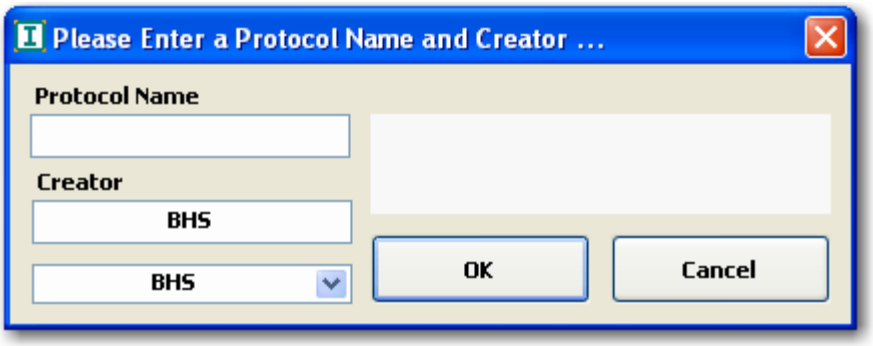


Figure 56 Protocol dialog box

If you have created a new protocol and try to perform any action other than saving it, the Change Protocol dialog box (Figure 57) will appear.

1. Press **YES** to save the protocol before continuing with other functions.
2. Press **NO** to continue modifying the protocol before naming it.

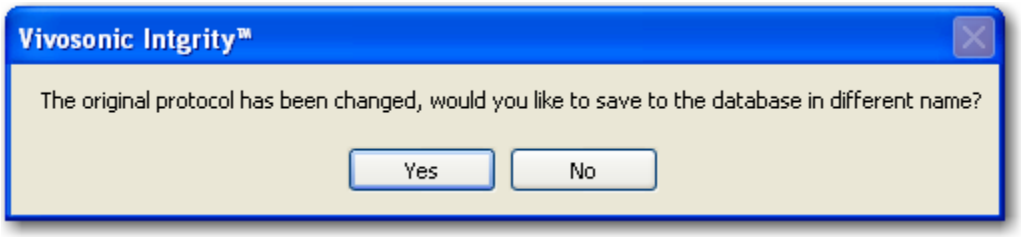


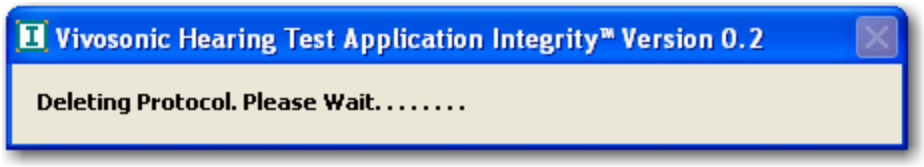
Figure 57 Change Protocol dialog box

Deleting a protocol

Only protocols that have never been used can be deleted.

1. Select the unwanted protocol from the protocol list.
2. Press **Delete Protocol** to the right of the protocol query (Figure 55). The Delete Protocol dialog box (Figure 58) will appear.
3. Press **OK** to confirm the selected protocol is to be deleted.

Figure 58 Protocol deletion dialog box



The System Screen

The **System** screen is used to define the peripherals (printer and battery), change the user password, define units, transducer selection, and backup, merge and restore the database. The System screen has four sections:

- System configuration
- System configuration controls
- Organizational information
- Database controls

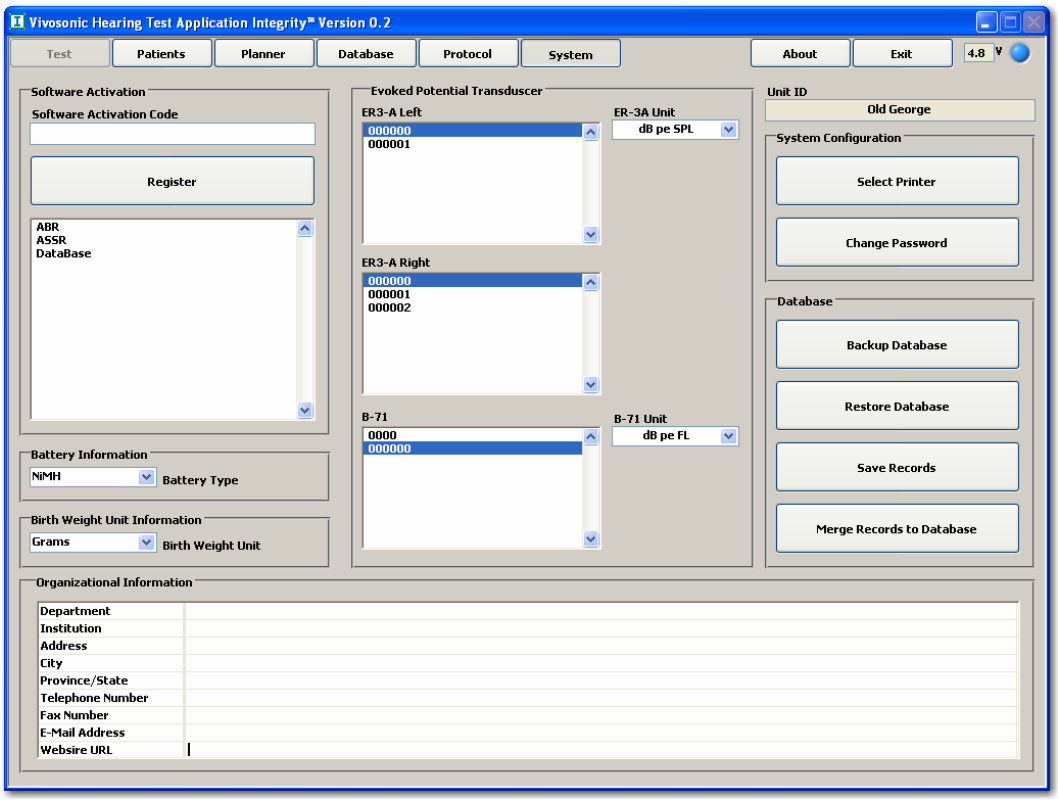


Figure 59 The System screen

The first time the Integrity™ system is used, it should be configured using the **System** screen before any other task is started. Vivosonic also recommends that the system configuration be checked every time prior to running a test.

System Configuration Selection and Controls

The system configuration section of the **System** screen provides specific information about the Integrity™ system components.

Software Activation

The Integrity™ system has a modular design. The module field will show which modules have been activated. (Currently ABR and Database are the only two modules available.)

If, in the future, another module is purchased, an activation code will be sent to the purchaser.

1. Enter the activation code into the **Software Activation Code** field.
2. Press **Register**. This will activate the new module and the new module will be added to the activated modules list located below the **Register** button.

Battery Information

The VivoLink™ can run one of two different types of batteries. This field defines which type of battery is powering the VivoLink™. The Integrity™ system uses this information to determine how much power is remaining in the battery's life.

- Select either **NiMH** (Nickel Metal Hydride) or **Alkaline** from the **Battery Type** drop-down list.

Birth Weight Unit Information

The Birth Weight Unit field defines the units that are used when describing the patient's birth weight in the **Patient** and **Database** screens.

- Select either the **Grams** (metric) or **lb:oz** (Imperial measure) units from the drop-down menu for the birth weight.

Transducers and Calibration Units

Selecting the appropriate transducer

The Integrity™ system is supplied with two transducers, an ER-3A and a B-71. The serial numbers for each of these transducers have been coupled to the system software at the factory if the computer was purchased from Vivosonic Inc.

If the computer has been configured by the user, the calibration files must be installed using the CD shipped with the Integrity® system. Instructions to install the calibration files can be found on page - 26 - of the Installation Instructions found in the back of this manual's binder.

Additional transducers can be added to the list by installing the transducer coupling information provided on a disk with the purchase of any new transducer supplied by Vivosonic.

The serial numbers for all the transducers that have been coupled to the system software are displayed in the appropriate transducer fields. In addition to providing the serial number, it also provides the calibration data for the specifically selected transducer.

- Select the transducer required for the test by highlighting its serial number.

CAUTION

Results may be incorrect.

Selecting a serial number that does not match the transducer used may result in test data that cannot be confirmed or reproduced. The serial number ensures the correct calibration data, specific to that transducer, is being used during data collection and analysis.

Selecting the calibration units

The calibration units define whether the data will be reported as:

- **dB nHL** or **dB peSPL** for the ER-3A tests, or
- **dB nHL** or **dB peFL** for the B-71 tests

These are the units displayed in the **Stimulus Levels** field on the **Protocol** screen and the units of the **Level** parameters on the **Test** screen.

- Select the unit from the drop-down list for each transducer type.

Hearing level conversions

It is possible to change the conversion between dBnHL and dBpeSPL. The default values, rounded to the nearest dB, can be found in Table A, Table B and Table C.

Table A dB nHL conversion for Bone Conductor B-71

Frequency	dB peFL at 0 dB nHL
500 Hz	67
1 kHz	54
2 kHz	49
3 kHz	46
4 kHz	41
Click	61

Table B dB HL conversion for Insert Earphone ER-3A

Frequency	dB SPL at 0 dB HL
500 Hz	10
1 kHz	6
2 kHz	12
3 kHz	13
4 kHz	15
Click	6

Table C dB nHL conversion for Insert Earphone ER-3A

Frequency	dB peSPL at 0 dB nHL
500 Hz	22
1 kHz	25
2 kHz	20
3 kHz	24
4 kHz	26
Click	25

To change the values please edit the following text file on the Integrity Windows XP® computer. Only use a text-only editing application to modify the file and do not change the formatting of the file. Ensure it is saved with the txt extension after modifying the files:

- Bone Conductor B-71: "ABR B-71 dB nHL to dB pe FL.txt"
- Insert Earphone ER-3A: "ABR ER-3A dB HL to dB SPL.txt"
- Insert Earphone ER-3A: "ABR ER-3A dB nHL to dB pe SPL.txt"

The Files are located in the following directory:

- C:\Integrity V1.0\Conversion File\

Unit ID

Each VivoLink™ has its unique serial number, which will appear at the **Unit ID** information control. This is an informational field only and cannot be edited.

Select Printer

The **Select Printer** button opens a dialog box that is used to define the printer used to print test reports.

1. Press **Select Printer**. A dialog box labeled **Printer Select** will appear.
2. Select the connected system printer from the list.
3. Press **OK**.

Changing the Password

The password will secure access to the **Database** and **Protocol** screens. To change the password:

1. Press Change Password.
2. Enter the old password. The system is delivered with no set password. Leave this field blank when configuring the password for the first time.
3. Enter the new password. If this field is left blank the password will be removed.
4. Enter the new password again in the **Confirm Password** field.
5. Make a note of the new password, and store it in a secure location.
6. Press **OK**.
7. If the old password was entered incorrectly or the new password confirmation was entered incorrectly the password will not be changed. Repeat the steps to attempt to change the password again.

NOTE

The password is case sensitive and can include numbers and letters.

CAUTION

A system without a password may compromise patient confidentiality.

A password is needed to access the **Protocols** and **Database** screens. A password will prevent unauthorized users from having access to the patient test results stored in the database, as required by local regulations such as HIPAA in the USA. The password also prevents unauthorized users from deleting defined protocols.

TIP:

If the password is misplaced or forgotten, please contact customer support for help.

Database Controls

Backing up records

The Backup Database feature will make a backup copy of the entire database to a specified file, on the Integrity™ system.

1. Press **Backup Database**. A dialog box labeled **Save As** will appear.
2. Select the drive and folder location. Use the button with a folder on it to browse the network and select a drive.
3. Enter an appropriate file name.
4. Press **Save**. The file will be saved on the selected drive in a Custom Pattern format (*.mdb) text file.

CAUTION

Test data may be lost.

To prevent permanent loss of data due to hard drive failure, it is recommended that the database be backed up regularly. Vivosonic™ recommends a scheduled backup time, for instance once a week, or after a set number of tests.

Restoring the database

The database can be restored to the Integrity™ system.

1. Press **Restore Database**. A dialog box labeled **Open** will appear.
2. Select the required database file from the saved drive and folder location.
3. Press **OK**.

CAUTION

Test data may be lost.

When a database is restored it will be permanently replaced with the database currently on the Integrity™ system.

Saving selected records

The **Save Records** feature allows a user to save some or all of the patients' records on the hard drive of the notebook computer, USB Flash Drive, or any other medium that is connected to a USB port of the notebook computer.

1. Change to the **Database** screen.
2. Highlight the required records from the **Database Patient List**.
3. Select the **System** tab.
4. Press **Save Records**. The **Save Record(s)** dialog box (Figure 60) will appear.
5. Select **Save Selected Records** to save the highlighted records. (Select **Save All Records** to save all test data from the entire patient record list in the **Database** screen.)
6. Press **OK**.

Figure 60 Save records dialog box

Merging saved records to the database

Use the **Merge Records to Database** feature to integrate records that where saved using the **Save Selected Records** function into another Integrity™ system's database.

1. Press **Merge Records to Database**. A dialog box labeled **Select a File** will appear.
2. Select the file containing the saved records.
3. Press OK.

NOTE

Merge Records to Database feature was created for users who have more than one Integrity™ system.

Organization information

Enter information about your organization in the appropriate fields. This information will appear in the patient record printouts.

Chapter 5 General Operating Procedures

WARNING

Patient injury may occur.

Testing is to be performed by a trained health-care professional licensed by local authorities.

TIP

There are two ways to access the buttons and text fields on the screen:

1. Press **Tab** and **Shift + Tab** on the keyboard to step through the button and text field options on the page. A button or text field will be highlighted when it is selected.
2. Move the cursor using a pointing device such as a touchpad or mouse.

Adjust the values using the up arrow and down arrow keys in the bottom right corner of the Windows XP® based computer keyboard or type directly into the fields.

ATTENTION

The Integrity™ system is supplied with default protocols (Appendix C). Prior to clinical use, an appropriate user-defined protocol must be created. Refer to Protocol Parameters on page 79.

Before starting a test review the functionality of the Integrity™ system screens (Chapter 4).

Preparing for a test

Distinguishing electrode clips

For the best ABR testing results, it is important to position the electrode clips properly (Figure 61). The Amplitrode® is designed to significantly reduce the risk of electrode misplacement. The Amplitrode® is a combination of an electrode and an AEP pre-amplifier; which is mounted directly on the ground electrode.

The length of the lead to the inverting electrode clip is just long enough to reach from the nasion to the nape of the neck or mastoid for 99% of the adult population. The lead between the Amplitrode® and the non-inverting electrode clip is long enough to reach from the nasion to the hairline for 99% of the adult population.

Refer to the Amplitrode® diagram (Figure 9) for details on the configuration of leads and electrodes.