SOFTWARE USER'S GUIDE

Integrity™

wireless revolution in audiology

Preface

This manual is an advanced guide to the use of Integrity Software. For information about Integrity Hardware components and basic instructions on how to get started please refer to the Integrity V500 Quick Reference.

Model: **Integrity™ V500** (also referred to as Integrity™, or Integrity V500, or Integrity)
REF: V500
Document No: D-11049 ver. 8.4.1

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Safety

To ensure the safe operation of the Vivosonic Integrity™ 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, potential safety hazards, and limitations in use imposed by the issue labeled with a warning. The warning will identify steps that should be taken if the incident occurs.

 CAUTION

Messages with this heading indicate 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: Integrity™ Launcher

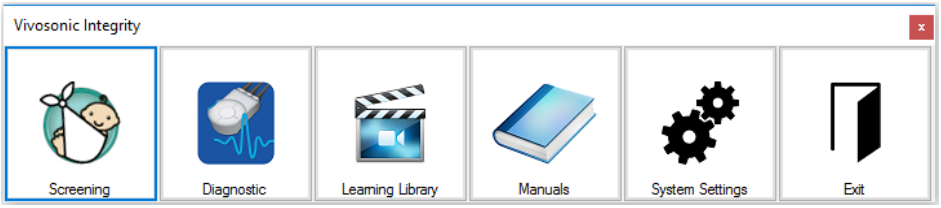


Figure 1. Integrity™ Launcher

Double clicking on the Integrity icon from the desktop brings up the Launcher, which presents the user with the option to perform screening or diagnostic testing, access learning and training materials from the Learning Library, and configure the system. If you have not purchased the screening or diagnostic test type, the icon will be greyed. To activate, the user has to purchase and then register a specific Software Activation Code. Please see System Settings for more information.

1. Screening

Selecting this icon launches the Integrity™ ABR Screening software. This test modality can be purchased and activated by registering the correct Software Activation Code in System Settings. Please see About Integrity™ ABR Screening for more information on how to use the Integrity™ ABR Screening software.

2. Diagnostic

Selecting this icon launches the Integrity diagnostic software. Tests available are ABR/ECochG, ASSR, 40 Hz ERP, DPOAE, and TEOAE modalities. These test modalities can be purchased and activated by registering the correct Software Activation Code in System Settings. For instructions on how to use the diagnostic modalities, please see Chapters 2 – 8 in this document.

3. Learning Library

This icon opens up the Learning Library, which provides the end user with guidance and best practices for using the Integrity system. Learning Library must be installed on the computer for this icon to be activated. There is also another shortcut on the desktop that will open the Learning Library directly.

4. Manuals

When this icon is clicked, it displays 3 instructional manual options for the user to choose from:

- User's Manual (Integrity™ V500 User's Manual)
- G2 Quick Guide (Integrity™ V500 Quick Reference [Generation 2])
- G1 Quick Guide (Integrity™ V500 Quick Reference [Generation 1])

When a selection is made, the document is launched in PDF.

5. System Settings

This icon is used to access the Settings window. The user can pair to a VivoLink, and enter their Software Activation Code that will be used to activate different modalities of the Integrity™ system.

To pair to a VivoLink:

1. Click on the System Settings icon (4th icon on the Launcher).
2. On the Settings window, click on '**Discover Bluetooth Devices**'.
3. From the new window that comes up, select the VivoLink that you want to pair to from the '**VivoLinks available**' drop-down menu. If the VivoLink ID is not listed under this drop-down list, please click on '**Rescan**'.
4. After the correct VivoLink ID is selected from the drop-down, click on '**Pair and Save**'.
5. On the Settings window, type in the **Software Activation Code** that came with your Integrity™ Launcher system, then click on '**Register**'.
6. Click **OK** on the dialog.
7. Close the Settings window.
8. Make sure you see the Launcher with the activated modalities, Screening or Diagnostic or both, depending on the Software Activation Code that was registered in Step 5.

6. Exit

Pressing the exit button will close the launcher. Any other applications that have been launched will remain open and must be exited individually.

Chapter 2: Five Screens of Integrity (Diagnostic)

The diagnostic functionality of the Integrity software is controlled in one of five screens, accessible through five tabs at the top left of the Integrity window.

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

The Patients Screen

The **Patients** screen contains patient information in a table. It lists patients who have been tested previously, and those who will be tested in the future. A scroll bar at the bottom of the screen allows you to view all columns of patient information.

To perform a test or plan a test, the patient must first be entered in this screen.

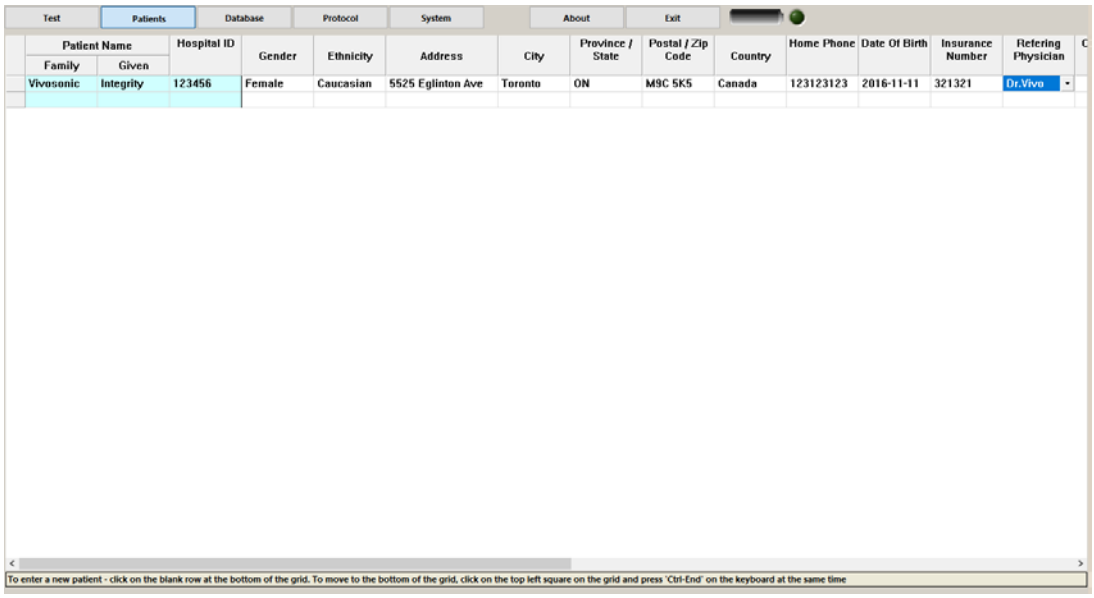


Figure 2. Patients Screen

Entering Patient Information

To create or update the patient list:

1. Select the **Patients** tab to open the **Patients** screen (Figure 2).
2. To enter patient information into the table, click on the desired cell with your mouse, and type your information into the cell.
3. Several columns allow you to type information into a cell, or select information from a list of items that you have previously entered.
4. To proceed to the next cell, press **Enter** on your keyboard (or click on the next cell with your mouse).
5. If you would like to scroll to the bottom of the grid to enter a new patient, click on the top left square on the grid and press 'Ctrl+End' on the keyboard at the same time.

You must complete at least one of the following fields for the patient: **Family** name, **Given** name, or **Hospital ID**. All of these fields are commonly used to uniquely identify the patient in the list.

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

Sorting the Table

The patients can be sorted by any field. 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 to indicate that the column has been sorted in ascending or descending order.
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:

1. Place the cursor on the line dividing the two column headings.
2. 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:

1. Place the cursor on the line dividing the two row headers.
2. Click and hold the line and drag it up or down to increase or decrease the height of the row below the line.

Entering Date of Birth

The **Date of Birth** column contains a drop-down calendar (Figure 3).

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 closes the calendar and places the date of birth in the field.

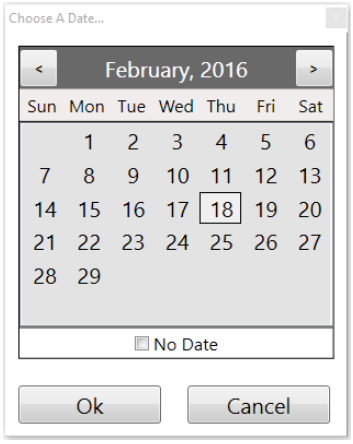


Figure 3. Drop-Down Calendar

Entering Time of Birth

This field is typically used when the patient is a newborn.

1. Select the appropriate field in the patient **Time of Birth** column to open a digital clock. The time is shown in the HH/MM/SS/AM-PM format.
2. Highlight the hour, and adjust the hour using the up and down arrows.
3. Highlight the minutes, seconds, AM/PM, and select the correct time using the arrows.
4. Press **OK.**

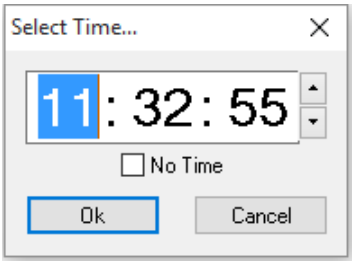


Figure 4. Drop-Down Clock

Selecting Patients

From the **Patients** screen, select one or more patients to test during a session.

1. Click the row header (the grey area of the table) to highlight the entire row of patient information (Figure 5).
2. To select another patient, hold the **Ctrl** key on the keyboard and click the row header to the left of another patient row.

To select a range of patients:

1. Select the first patient.
2. Hold the **Shift** key on the keyboard and click the last patient in the group.

Patients selected in the table appear in the **Patients** drop-down menu of the **Test** screen. Refer to Test Controls Drop-Down Menus on page 22.

Figure 5. Selected Patients in Patients Screen

The Test Screen

The **Test** screen is the main screen used to control the operation of the VivoLink when performing ABR/ECochG, ASSR, 40 Hz ERP, TEOAE, or DPOAE tests. The screen is designed to start, perform, and regulate testing, to monitor the results of the data collection, and to display the test results. It is also possible to control some protocol parameters from this screen.

Before the **Test** screen tab is enabled a patient must be created and selected in the **Patients** screen. Refer to Selecting Patients on page 19 for details.

Before any of the features on this screen can be used, the user must make sure that blue light indicator for the Bluetooth connection is on, and then a **Test Type** is selected. Once a test type is selected, the battery status will be shown.

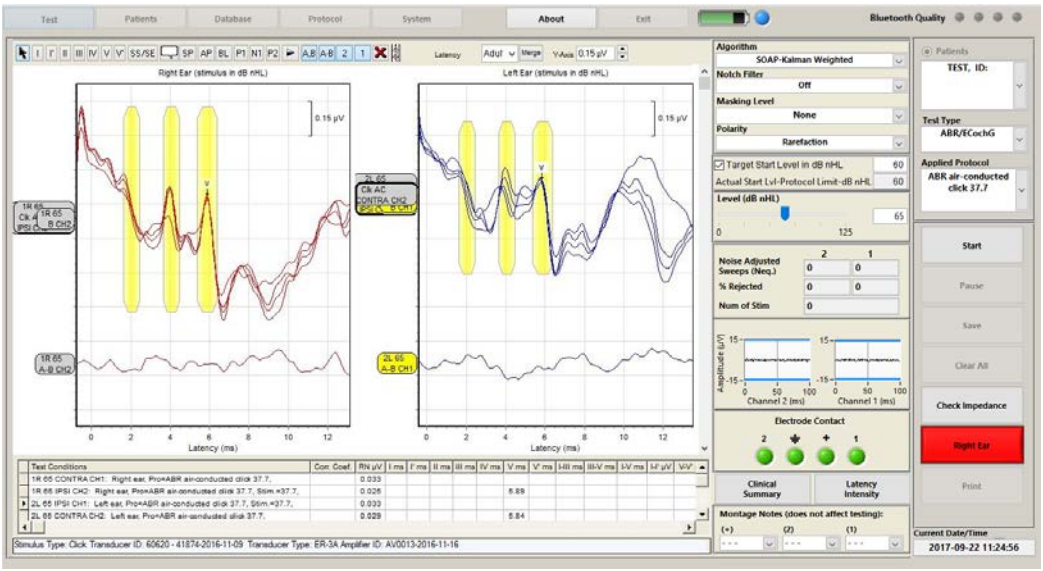


Figure 6. Test Screen

Selecting a Test Type

You must select a **Test Type** before the **Test** screen is available for use. The Test Type drop-down menu lists one or more test types or modalities (ABR/ECochG, ASSR, 40 Hz ERP, TEOAE, or DPOAE) for selection.

The Test Type drop-down menu is only available once your notebook computer has established communication with the **VivoLink**.

To select a test type:

1. Switch on your **VivoLink** to establish a connection between your computer and your VivoLink. The Test Type drop-down menu will become available for selection.
2. Select the desired test type from the **Test Type** drop-down menu.

Integrity currently supports these test types: ABR/ECochG, ASSR, 40 Hz ERP, TEOAE and DPOAE. Only those test types registered with your software license Activation Code will appear in the list.

1. Upon selecting a test type, you must wait for your VivoLink to reinitialize. The Bluetooth LED will turn off and then start blinking as the VivoLink™ reinitializes.
2. Typically the VivoLink requires 30 to 60 seconds to download the test-specific information. When complete, the blue LED on the VivoLink and the blue virtual LED on the upper-right corner of the Test Screen are lit.

Test-Specific Controls and Indicators

The **Test** screen has a Waveform Window that displays a graphical representation of the collected waveforms as a function of time and other test-specific indicators and controls.

The ABR/ECochG, ASSR, 40 Hz ERP, TEOAE, DPOAE, test screens have the same overall function, but differ in important test-specific details.

- The ABR/ECochG Test Screen on page 66
- The ASSR Test Screen on page 90
- The 40 Hz ERP Test Screen on page 93
- The TEOAE Test Screen on page 103
- The DPOAE Test Screen on page 117

Protocol Settings Section

The protocol settings section contains some captured test values and some selectable test parameters. To define protocols please refer to the following pages:

NOTE

The Protocol Screen is only available in full-featured configurations of Integrity and not in the Integrity "Lite" configuration.

- Define an ABR/ECochG Protocol on page 58
- Define an ASSR protocol on page 87
- Define a 40 Hz ERP Protocol on page 98
- Define a TEOAE Protocol on page 100
- Define a DPOAE Protocol on page 114

Test Controls Section

The test controls section includes four test control drop-down menus (Figure 7), test control buttons (Figure 10) and Test Controls Date and Time (Figure 16).

Test Controls Drop-Down Menus

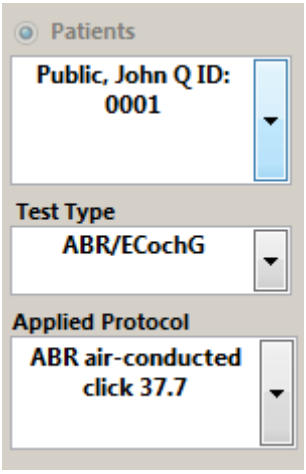


Figure 7. Test Controls drop-down menus

Patients

This list contains the names of patients selected from the **Patients** screen (Figure 2). The list does not include all patients in your database.

To select a patient to test:

1. Check that you have selected the desired patients from the **Patients** screen.
2. Select the **Patients** option on the **Test** screen to activate the drop-down menu.
3. Select the patient to be tested from the **Patients** drop-down menu.

Test Type

The Test Type drop-down menu contains the available test modalities (ABR/ECochG, ASSR, 40 Hz ERP, TEOAE, or DPOAE). You must first select a **Test Type** before the **Test** screen becomes available for use. Refer to Selecting a Test Type on page 20 for details.
Note that ABR and ECochG tests can be performed from the ABR/ECochG test type. The system will automatically perform the correct test type based on the protocol being used during waveform collection.

Applied Protocol

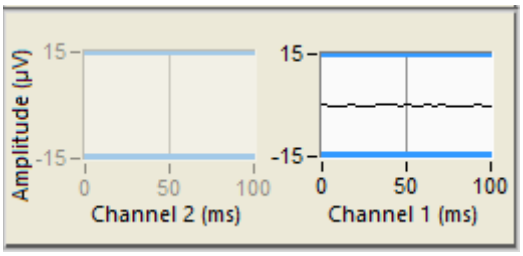
This list contains all the preset and custom designed protocols that have been created and are currently activated for the currently selected test type. The protocols specify all the test parameters.

ATTENTION

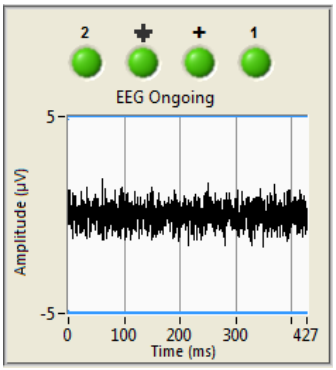
Improper configuration of test protocols may result in poor quality test results.

EEG Window

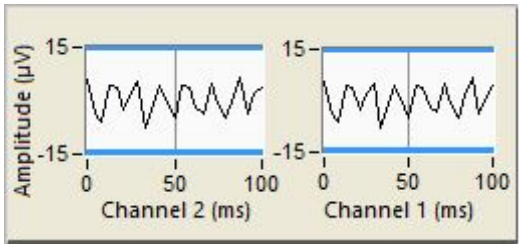
This area of the **Test** screen displays the **Electrode Contact Indicator** and a real-time EEG graph.



EEG Window for Channel 1 (ABR/ECochG)



EEG Window for ASSR and 40 Hz



EEG Window for Channel 2 (ABR/ECochG)

Figure 8. EEG Windows for different test types

Ongoing EEG

With an Amplitrode or VivoAmp plugged into the VivoLink, a real-time EEG is displayed in the EEG window of the Test Screen for ABR/ECochG and ASSR test types. This EEG signal is recorded by the electrodes and 150ms 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 ± 40 µV. However, to obtain better recordings, if the EEG amplitude increases beyond ± 5 µV (highlighted in the graph using a pair of horizontal blue lines) you may need the patient to relax further. High EEG levels may indicate that the test environment is too noisy for testing, or that electrode contact is poor. If the EEG amplitude does not decrease, the problem may be poorly placed electrodes. Readjust the electrodes and start again. Higher EEG might require a larger Algorithm Time to get more reliable results. If the Test Screen is idle for more than 20 minutes, the ongoing EEG pauses to conserve the battery power of the VivoLink

NOTE

The VivoAmp can only be used with a G2 system, and is not available for G1 systems.

*The **Ongoing EEG** graph shows a filtered EEG signal that passes through the ABR (30 – 500 Hz, slope 12 dB/octave) analog electrical filters of the Amplitrode or the VivoAmp, not an unfiltered "raw" EEG signal. If the analog notch filter (50 Hz or 60 Hz) of the VivoLink is switched **ON**, then the **Ongoing EEG** passes through this filter as well.*

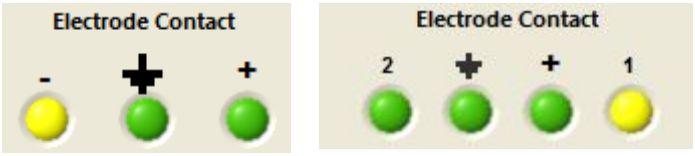
This signal does not pass through the digital high-pass and low-pass filters, which are set in the protocol and affect only the digitally processed (averaged or SOAP-Kalman weighted) recordings.

Electrode Contact

The status of the connections between the electrodes and the patient's skin is displayed visually using the virtual LEDs.

- The LED is not lit when the VivoLink if OFF.
- A **green** LED indicates that the corresponding electrode contact is detected.
- A flashing **amber** LED indicates that the corresponding electrode has lost contact with the patient's skin, or with the electrode clip. Check the electrode corresponding to the flashing LED for proper contact with the patient's skin and the electrode clip.

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



G1 System G2 System

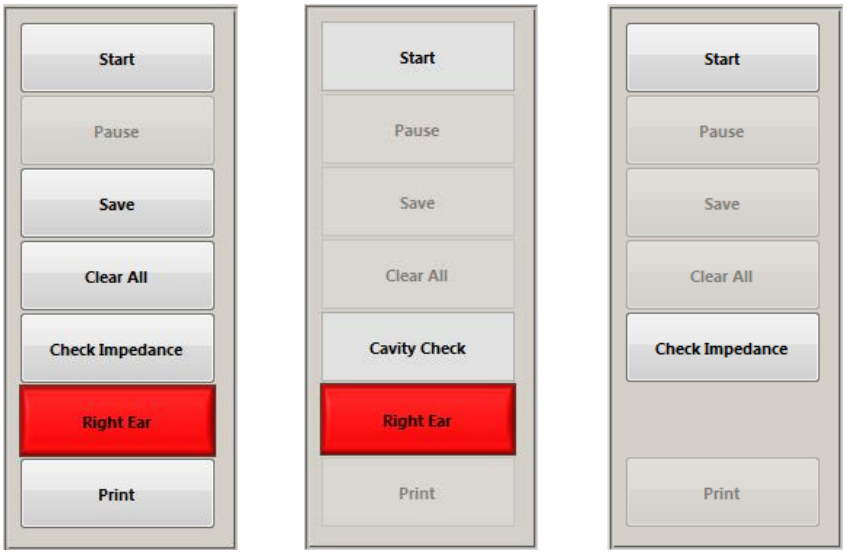
Figure 9. Poor Electrode Contact

What to do When Electrode Contact is not detected

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 or VivoAmp clips. If it is not a good connection, reconnect, replace, or fix it.

Test Control Buttons

The set of available test control buttons corresponds to the test type in use.



ABR/ECochG, 40 Hz ERP DPOAE and TEOAE ASSR

Figure 10. Test Control Buttons

Start/Stop button

A patient must be selected before a test can be started.

1. Start testing by pressing the **Start** button.
    - If the probes required for the test (Amplitrode or VivoAmp for ABR, ECochG, ASSR, 40 Hz ERP, or OAE probe for TEOAE or DPOAE) are properly connected to the VivoLink, the test will begin and the button label changes from **Start** to **Stop**.
    - If the appropriate probe is not connected, a warning will be displayed “Probe Not connected”, and the test cannot be started.
2. You can stop the test by pressing this same button now labeled **Stop.**

    When the **Stop** button is pressed the results for 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.

Pause/Resume button

The **Pause** button cannot be selected between test runs. The **Pause** button becomes active when the **Start** button is pressed. Space bar on the laptop can be used to Pause/Resume ABR/ECochG test types.

1. Press the **Pause** button to temporarily stop the test run.
2. This may be required if, for example, the earphone falls out of the patient’s ear.
3. To resume the data collection, press this same button now labeled **Resume**.

Save button

NOTE

The Save button is only available in full-featured configurations of Integrity and not in the Integrity “Lite” configuration. The Integrity “Lite” does have an “Archive” button in place of the “Save” button. When you “Archive” results, you will not be able to view them but they can be used by Vivosonic Customer Support to analyze results in case there is a need for them to do data review and troubleshooting. Archived results will also be available for review if you upgrade to the full-featured Integrity configuration in the future.

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

1. Press the **Save** button.
2. This opens the Save Result Confirmation dialog box (Figure 11).
3. 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.
4. The Save to this patient’s file drop-down list contains the name and personal ID of the patient.
5. Enter information into the desired fields (Examiner, Location, Comment 1, and Comment 2*),* or select preset data from the drop-down lists.
6. Some information cannot be modified (Test Type, Protocol Used, Unit ID, Ear Tested, Probe ID, and Ear Tip Used).
7. Press **OK**.
8. Press **Yes** when asked: *Are you sure?*

NOTE

When the DPOAE test type is used, only the last unsaved DP-gram is saved in the test record, although multiple consecutive test results may be displayed on the screen.

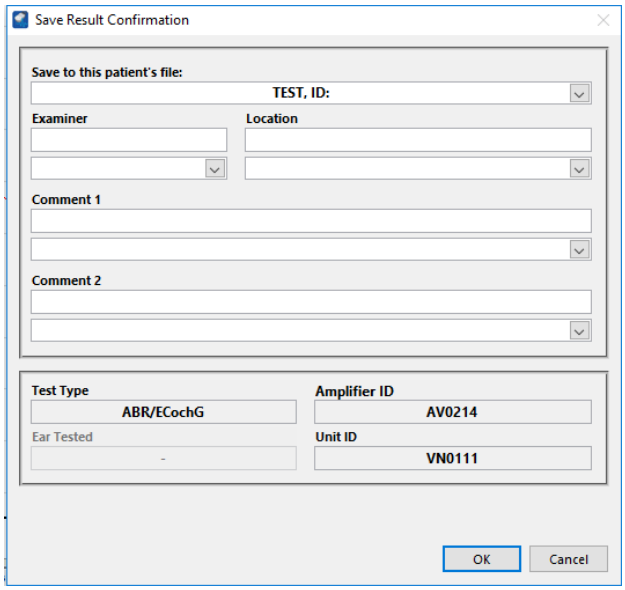


Figure 11. Save Result Confirmation

Clear All button

Use the **Clear All** button to discard all collected data and clear the **Waveform Window** and the **Waveform Information**.

CAUTION

Test data may be permanently lost.

Before discarding any data, please ensure that significant test results have been saved to the database or they will be permanently discarded.

To discard or clear a graph:

1. Press **Clear All**.
2. Press **OK** when asked *Are you sure you want to discard this record?* (Figure 12).
   - 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.

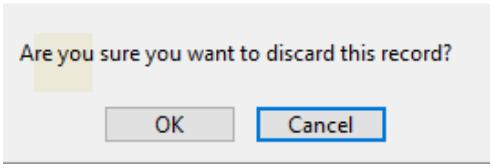


Figure 12. Dialog Box - Are you sure you want to discard this record?

Right Ear/Left Ear button

Select the ear to be tested by pressing the **Right Ear** or **Left Ear** button.

When the Right Ear is selected, the waveform trace in the **Waveform Window** (Figure 56) is **red**, the standard color used in audiologic practice. When the **Left Ear** button is selected, the waveform trace in the **Waveform Window** is **blue**.

NOTE

For ABR/ECochG, and 40 Hz ERP testing, the ear selected represents the earphone that the stimuli will be delivered to. For TEOAE and DPOAE testing, the ear selected represents the ear the probe has been inserted into. If Masking is selected in ABR or ECochG, the masking noise will be delivered to the ear that is contralateral to the ear selected for stimulation. The masking frequency characteristic is wideband, i.e. it includes the entire frequency band of the transducers used with Integrity. The masking shows uniformity within ±5dB for the range of 250Hz to 4.5kHz.

Check Impedance

The **Check Impedance** button performs a test to measure the impedance between electrodes applied to the patient. This button becomes available for test types ABR/ECochG, 40 Hz ERP, and ASSR.

For a G1 system

The difference between the inverting electrode (-) and non-inverting electrode (+) impedance mismatch in a **Generation 1 System (G1)**, enables clinicians to make appropriate adjustments to the electrodes. Before you begin a test, you can perform an impedance check to determine the degree of mismatch between the impedance values of the inverting and non-inverting electrodes applied to your patient. This feature requires that you use **VivoLink with Amplitrode A51, A61 or greater.**

For a G2 system

Similarly in a **Generation 2 System (G2)**, the true impedance values of all electrodes help clinicians to make necessary adjustments to the electrodes. Before you begin a test, you can perform an impedance check to show the true impedance values for all electrodes (inverting, non-inverting 1, non-inverting 2) instead of a mismatch value. This feature requires that you use **VivoLink with Amplitrode A81 or A82, or a VivoAmp.**

Typically, an impedance of less than 5 kOhms will yield the best test results.

To check the level of inter-electrode impedance:

Press the **Check Impedance** button on the **Test** screen.

A message instructs you to wait a few seconds for the test to complete.

The **Check Impedance** dialog box displays the impedance value and the status of the results.

- The indicator bar is **green** when the impedance is acceptable for testing purposes. You may begin testing.
- The indicator bar is **amber** when the electrode impedance is greater than 5 kOhms. You should adjust your electrodes for better test results.
- The indicator bar is **gray** when the electrode is disconnected. Testing should not proceed. You should check your electrodes.

1. Reconnect your electrodes as necessary.
2. Wait for the indicator bar to update and specify an acceptable value.

3. Close the Check Impedance dialog box and proceed with testing as appropriate.

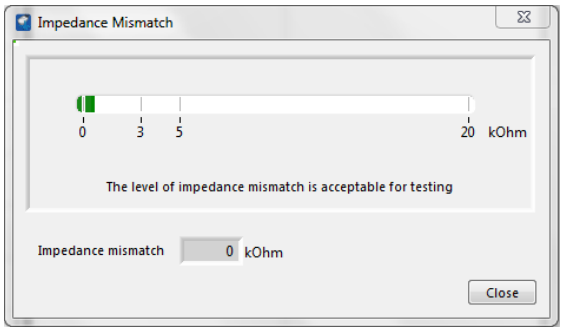


Figure 13. Check Impedance Mismatch Dialog Box (G1 System)

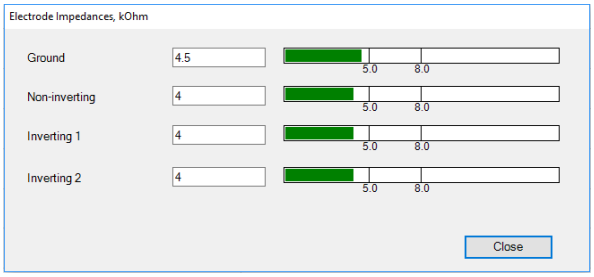


Figure 14. Check Impedance Dialog Box (G2 System)

Cavity Check (TEOAE and DPOAE)

The **Cavity Check** button runs a test to check that the OAE probe calibration is correct.

For TEOAE testing, the cavity check determines if the System Transient Response (TR) for TEOAE and noise floor are within their tolerances.

Similarly, for DPOAE testing, the cavity check determines if the System Distortion Product (DP) for DPOAE and noise floor are within their tolerances.

Print button

1. Use the **Print** button to print your test results.
2. The **Print Report Confirmation** (Figure 15) dialog box is displayed. The name and patient ID of the current patient appears in the **Print for this patient** field.
3. Print the data for the selected patient, or choose another patient from the **Print for this patient** drop-down list.
4. The system does not allow results to be printed if the **Print for this patient** field remains blank.
5. Enter new information into the desired fields (Examiner, Location, Comment 1, and Comment 2) or select preset data from the drop-down lists.
6. You can view information about the Test Type, Protocol Used, Unit ID, Ear Tested, Probe ID, and Ear Tip Used.
7. To initiate printing, press **OK**.
8. When the “Are you sure?” dialog box is displayed, press **OK** to continue printing.
9. Press **Cancel** to return to the **Print Result Confirmation** dialog box allowing changes to be made before printing.

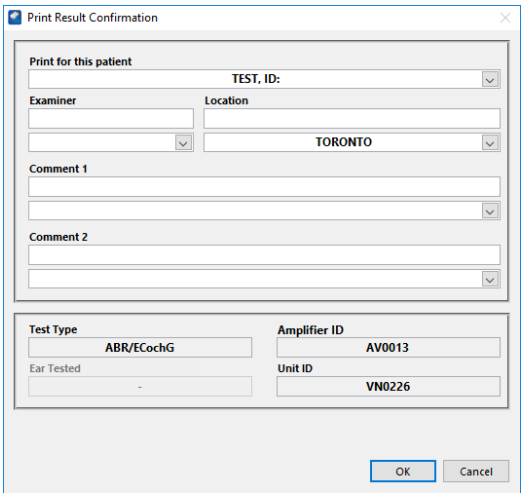


Figure 15. Print Result Confirmation

Current Day/Time

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

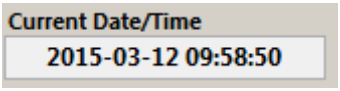


Figure 16. Test Controls Date and Time

NOTE

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

*If the date and time are incorrect, adjust the clock and calendar to a US regional time zone setting from the Windows Control Panel. Select **Start** | **Control Panel**.*

VivoLink™ Status

VivoLink Battery Indicator

The VivoLink power indicator, located at the upper right corner of the VivoLink's front panel represents the power left in the battery. On the **Test** screen, a battery indicator shows the measured voltage of the VivoLink batteries (Figure 17).

VivoLink Battery Voltage Indicator	Voltage Level
	Full battery.
	More than 75% full battery.
	Half full battery.
	Low battery.
	Battery is almost dead. Please replace the battery before starting another test.

Figure 17. VivoLink Battery Voltage Indicator

Green indicates the amount of life in the battery. When the power in the battery reaches a critically low value for testing, the battery indicator will be empty (shows no green).

When the batteries are almost out of power, the battery indicator will show exclamation marks. It is recommended that the batteries in the VivoLink be replaced before performing any further tests.

When the VivoLink Battery Indicator shows low battery, perform the following steps:

1. Save the collected data.
2. Switch **OFF** the VivoLink and change the batteries.

CAUTION

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 Vivosonic Integrity V500 ABR system uses Bluetooth communication between the patient interface (VivoLink and transducers) and the controlling PC computer. Patient sensitive data is entered on the PC but is not communicated via Bluetooth. Only electrophysiological measurement (ABR/OAE) data and device control instructions are communicated via BT between the PC and the patient interface(VivoLink). Furthermore this information is in a proprietary format that is specific to the Vivosonic system.

The **Bluetooth connection indicator** is a virtual LED located in the upper right corner of the **Test** Screen. It is **blue** when the computer and the VivoLink are connected after a **Test Type** has been selected. It is dark (appears not to be lit) prior to downloading a Test Type or when the Bluetooth connection has failed.

NOTE

The computer on which the Integrity operates should be Bluetooth-enabled or have a Bluetooth USB Adapter inserted into the computer's USB port.

Bluetooth connected

Bluetooth not connected (not lit)

Figure 18. Bluetooth® Connection Indicator

The System requires up to one (1) minute to download a Test Type to the VivoLink and establish the wireless connection. If the wireless connection is not established, a message is displayed stating the connection has failed (Figure 19).

This same message is displayed during data collection if the wireless connection is lost intermittently. If this wireless connection warning message appears, follow the troubleshooting Bluetooth Troubleshooting section.

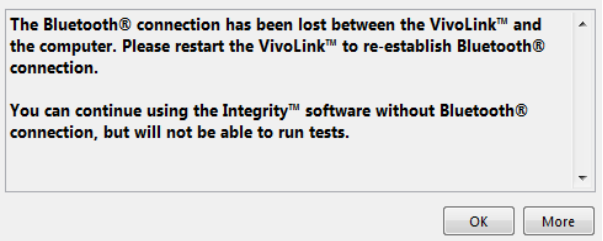


Figure 19. Bluetooth Connection Failed Message

Bluetooth Quality

The Bluetooth Quality indicator measures the quality of wireless data transmission between the VivoLink and the PC during testing. This optional indicator can be turned on or off from a selection in the System screen.

In rare circumstances AEP testing is done in locations where a specific frequency of high electromagnetic noise in the 2.4 GHz range affects the Bluetooth communications. One such area is near high powered Wi-Fi routers or repeaters. In these circumstances the amount of data that is transmitted wirelessly from the VivoLink to the computer algorithm may be affected, and this can lead to slower test results.

This indicator is only active during ABR testing. During a test, the more blue lights showing the better the quality of the Bluetooth transmission of data. If the Bluetooth Quality Indicator shows 3 or 4 blue lights then the speed of test results will not be affected by Bluetooth data transmission. Slow test results in these situations of good Bluetooth Quality is related to the effect of other EM or myogenic noise on data collection.

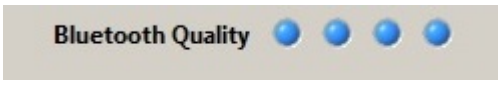
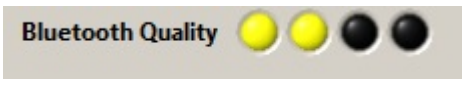
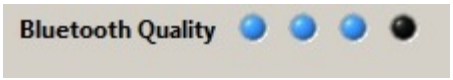
Good Transmission	Bad Transmission
	
Four Blue lights indicate that Bluetooth transmission is very good and should not affect test times.	Two yellow lights indicate a poor Bluetooth environment. Testing and data collection in this environment may take longer than expected.
	
Three Blue lights indicate some Bluetooth communication interference, but testing is still okay.	Single yellow light indicates a very poor Bluetooth environment and the user should consider testing in a different location.

Figure 20. Bluetooth Transmission Table

Bluetooth Troubleshooting

This section covers problems, possible causes, and some solutions.

Observed Problems	***Possible Causes***	***Possible Solutions***
Bluetooth® wireless connection has been disrupted.	1. The distance between the VivoLink™ and the Bluetooth® dongle (or Bluetooth®-enabled computer) is greater than Bluetooth® range of 30 feet (10 meters) 2. VivoLink™ is located in an area electro-magnetically shielded from the Bluetooth® dongle (or Bluetooth®-enabled computer) 3. Interference from other radio frequency devices	1. Please check and ensure this distance is within Bluetooth® range 2. a) Return VivoLink™ into an area electromagnetically transparent to the Bluetooth® dongle (or Bluetooth®-enabled computer) b) Alternatively, place the Bluetooth™ dongle in the shielded area and connect it to computer using a USB extension cord 3. Check and switch off other radio frequency devices
Bluetooth® wireless connection fails.	*1. VivoLink is not turned on* *2. VivoLink batteries are low, or dead* *3. VivoLink is out of range* *4. Software is out of sync* *5. OAE probe AND Amplitrode or VivoAmp plugged in simultaneously* *6.* If your computer uses a Bluetooth® dongle connection might be loose	*1. Ensure VivoLink is on* *2. Check battery voltage indicator to ensure VivoLink batteries are charged* *3. Make sure that distance between VivoLink and computer does not exceed 30 ft(10m)* *4. Switch VivoLink off and on* *5. Restart Integrity software* *6.* Please check and ensure that the dongle is plugged in a USB port of the computer to the full stop.
Bluetooth® disconnects frequently.	1. The Bluetooth connection may be interrupted by a local wireless network that is seeking to auto-connect to the computer. Disabling the wireless network may improve reliability of the Bluetooth driver *Do not disable the wireless network if it is required on this computer. 2. VivoLink batteries are low, or dead	1. Disable Wireless Network connection • Press 'Start' > 'Control Panel' > 'Network Connections' • Disable any activated wireless network connection by right clicking on 'Wireless Network Connections', and selecting 'Disable' *2. Check battery voltage indicator to ensure VivoLink batteries are charged*

ATTENTION

Do not attempt to repair any component of the system; this may cause it to function improperly. The Integrity System is not a field-repairable instrument. Call your distributor or Vivosonic Customer Support for all repairs.

Storing the Integrity System

1. Make sure to store all hardware equipment in a dry place, insert the Probe into the Probe Test Cavity after all OAE tests.
2. Press **Exit** in the top right corner of the screen.
3. Confirm that you would like to exit the software program.
4. Wait until the program closes.
5. Turn off the computer.

NOTE

The warm-up time (time it takes to see the desktop screen after the laptop turn on button is pressed) of out of factory computers shall not exceed 10 minutes.

The Database Screen

NOTE

The Database Screen is only available in full-featured configurations of Integrity and not in the Integrity "Lite" configuration.

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 test results.

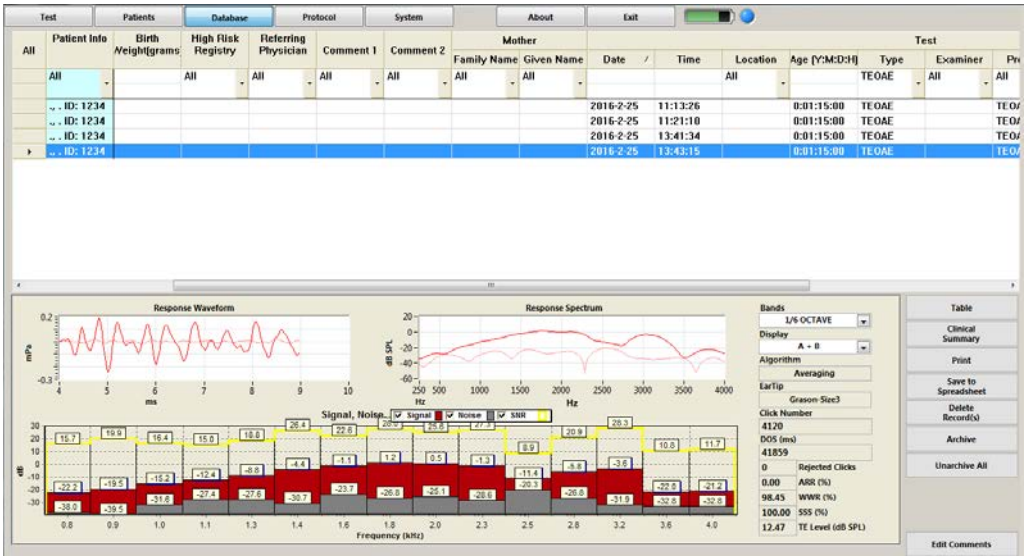


Figure 21. Database Screen showing TEOAE data

Using the Database

Accessing the Database

To access test results stored in the database:

1. Press the **Database** tab to open the Database screen. You may be prompted to enter a password if you setup a password on the System Screen.
2. Enter your password and press **OK**. **(The password is case-sensitive.)**

Entry to the Database can be password protected. To protect the privacy of patient test results, use the System screen to set your password. Refer to Change Password on page 53.

Documenting Test Results

The database is a powerful tool used to store and review test results electronically. It contains records of patient information, as well as information about test results and test conditions, including time and location, examiner, protocol used, outcomes, and comments.

Test data is automatically stored in the database. It can be retrieved through the Database screen as well as exported to other statistical software packages for further analysis.

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 Screen Description

The main **Database** screen is preview only. The display of the data can be changed but it will not affect the data or the data point calculations. This is true for all modalities.

NOTE

*To label and analyze the waveform in ABR/ECochG select the **Expand** button.*

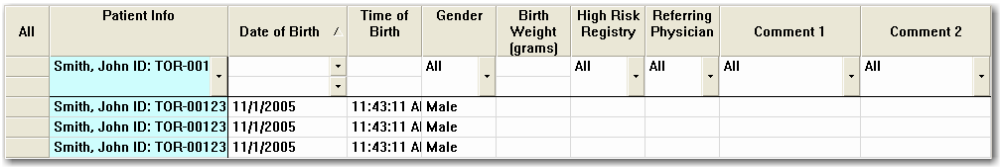
The database screen has the following structure:

Database Patient Table is located at the upper part of the screen. This table contains patients' information entered in the **Patients** screen.

Database Waveform Information is positioned at the lower part of the **Database** screen. The top portion of this window displays collected waveforms, waveform peak numeric values, and conditions of stimulation and recording. The lower part of this window contains either the waveform details in a chart or graph format.

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.

Database Patient Table



All	Patient Info	Date of Birth	Time of Birth	Gender	Birth Weight (grams)	High Risk Registry	Referring Physician	Comment 1	Comment 2
	Smith, John ID: TOR-001			All		All	All	All	All
	Smith, John ID: TOR-00123	11/1/2005	11:43:11 Al	Male					
	Smith, John ID: TOR-00123	11/1/2005	11:43:11 Al	Male					
	Smith, John ID: TOR-00123	11/1/2005	11:43:11 Al	Male					

Figure 22. Database Patient List — initial view

Test | Patients | Database | Protocol | System | About | Exit

Patient Name		Hospital ID	Gender	Ethnicity	Address	City	Province / State	Postal / Zip Code	Country	Home Phone	Date Of Birth	Insurance Number	Refering Physician	Comi
Family	Given													
Doe	John	1234m	Male	Caucasian	1 Pine Street	Toronto	ON	M9C 5K5	Canada	1231231234	2015-4-12	123456789	Dr.Vivo	comme
Doe	Jane	4321f	Female	Caucasian	2 Pine Street	Toronto	ON	M9C 5K5	Canada	9876543210	2015-4-16	98765432	Dr.Sonic	someth

Test | Patients | Database | Protocol | System | About | Exit

Patient Name		Hospital ID	Refering Physician	Comment 1	Comment 2	Additional Info	Mother Info			Patient Time Of Birth	High Risk Registry	Birth Weight (grams)	Results Available
Family	Given						ID	Family Name	Given Name				
Doe	John	1234m	Dr.Vivo	comment one	comment two	none	4321	Doe	Janet	11:28:49		2500	Yes
Doe	Jane	4321f	Dr.Sonic	something	no comment	no ad. info.	8765	Doe	Jessica	11:30:21		2000	No

Figure 23. Database Patient List — other fields scrolled right

The **Database Patient Table** contains patient information entered in the **Patients** screen, and test conditions and comments entered when the test results for the patient were saved. The scroll bar allows scrolling the table to the right and back 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 do not scroll.

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.

Comments 1 and 2

The comment fields are filled automatically with information from the **Patients** screen and from the comments that were entered when the test results were saved. The first set of comment fields holds information entered in the **Patients** screen (Figure 2). The second set of comment fields, found in the **Test** information block of the database patient list contains information that was entered when the test data was saved (Figure 11).

Sort the table information and adjust the column width

These features operate the same way as the tables in the **Patients** screen. Refer to Sorting the Table on page 17 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** to highlight the record.

The collected waveforms are displayed in the **Database Waveform Window** and data is displayed in the **Database Waveform Information** table.

Query the database

The database can be queried using the values available in each column.

To display specific database entries that match the selection criteria:

1. Select the arrow found in the first row under the specific column header. This displays the query values for that field in a drop-down list.
2. Select as many of these values as needed.
3. Click with the mouse anywhere outside the drop-down list. The table is updated to include records that meet the query values selected.
4. Select values from as many columns as required to refine the database query.

The **Date of Birth**, **Time of Birth**, and **Birth Weight** columns allow querying of a range of values. Set the first value of the range with the upper arrow and the second value with the lower arrow.

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.*

Select multiple test records

You can select more than one test record from the **Database Patient Table**. This allows you to view or apply features on multiple records at one time.

1. Click the row header (the grey area of the table) to the left of the **Patient Info** column. This highlights the entire test record.
2. To select another test record, hold the **Ctrl** key on the keyboard and click the row header of another patient record.

To select a range of test records:

1. Select the first test record.
2. Hold the **Shift** key on the keyboard and click the last test record. All the patients between the first and last selected record will be highlighted.

NOTE

*System will blank out the **Database Wave Information Window** in case of multiple test records selection, **except** for selecting DPOAE test records that are generated with the same protocol.*

Database Waveform Information Windows

This window displays patient data that has been saved to the database. The waveforms and labeled peak numeric values are the same as those in the **Waveform Window** and **Waveform Information** chart of the **Test** screen.

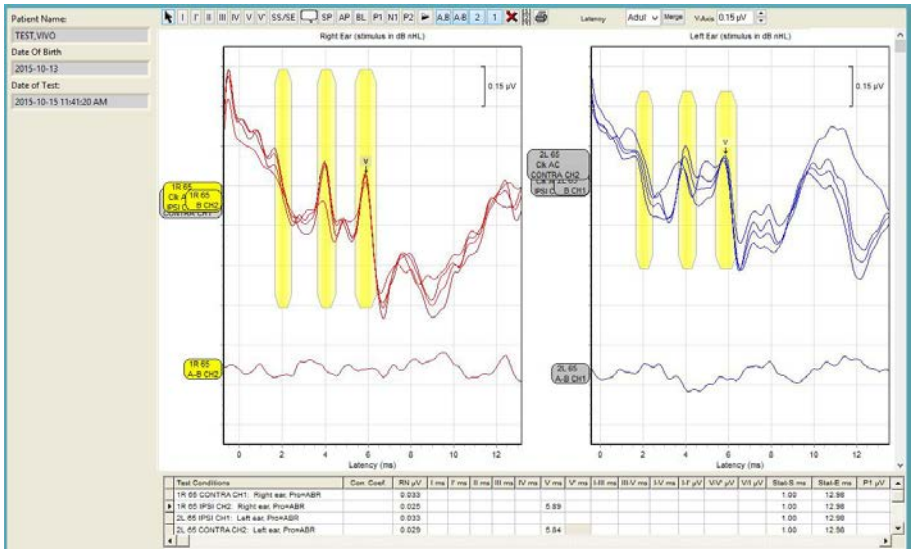


Figure 24. ABR Database Preview Screen

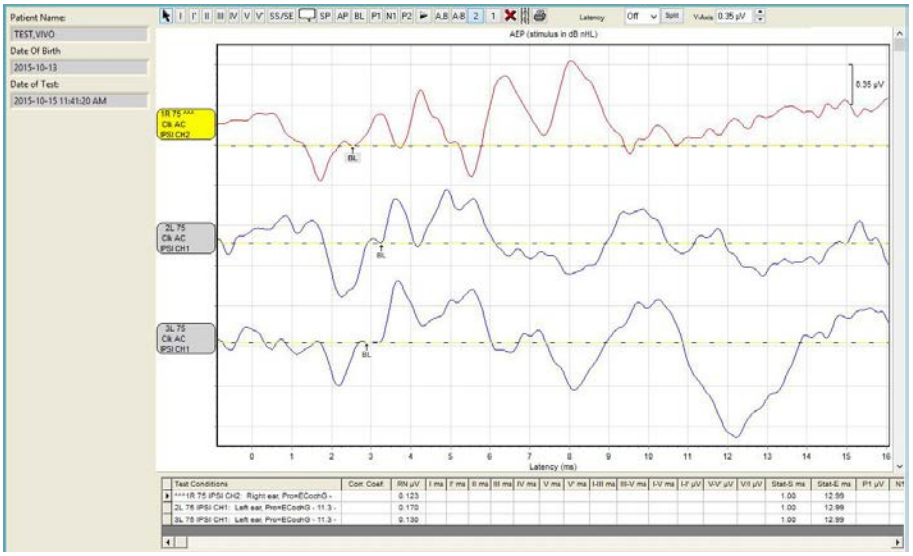


Figure 25. ECochG Database Preview Screen

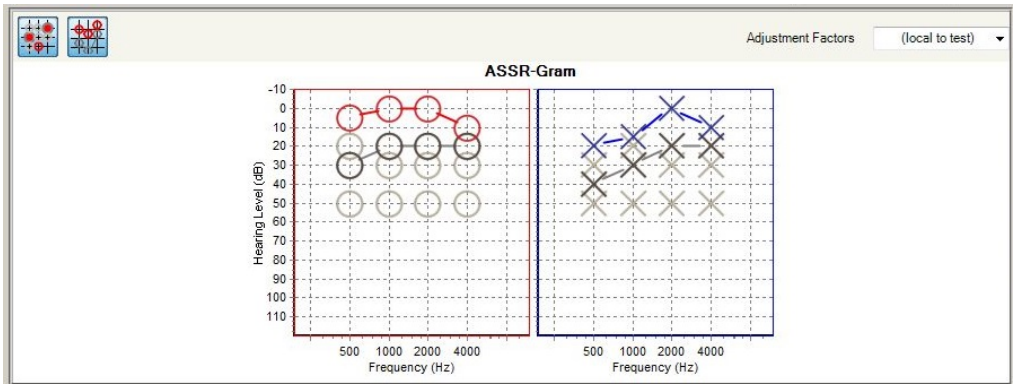


Figure 26. ASSR Database Preview Screen

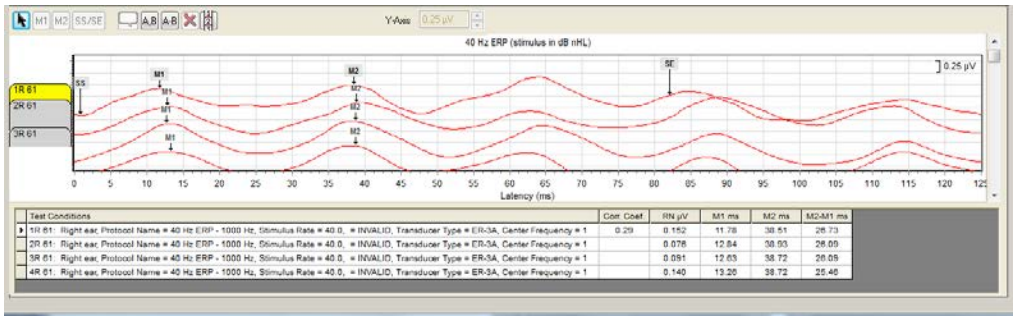


Figure 27. 40 Hz ERP Database Preview Screen

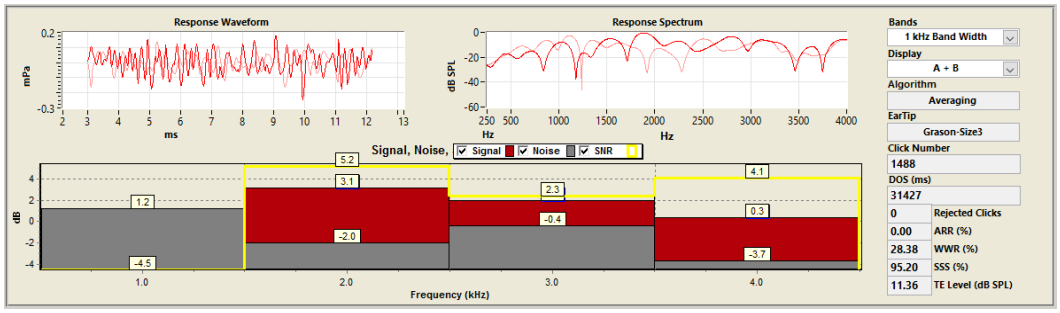


Figure 28. TEOAE Database Preview Screen

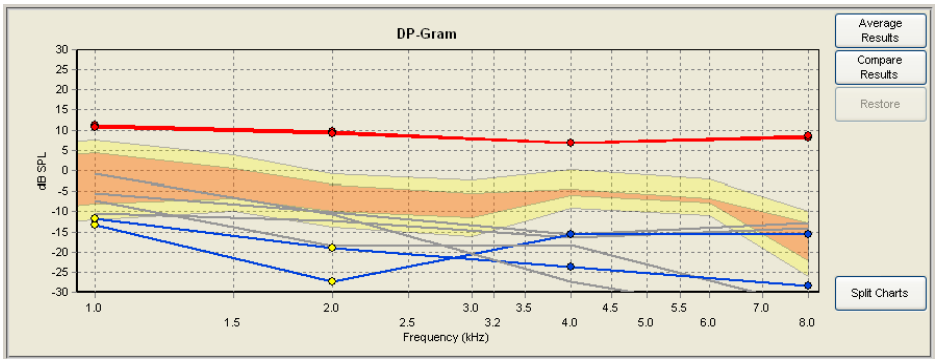


Figure 29. DPOAE Database Preview Screen

Refer to the following sections for test-specific details:

- The ABR Database Screen Waveforms on page 83
- The ASSR Database Screen on page 92
- The 40Hz Database Screen on page 99
- TEOAE Database Screen on page 111
- DPOAE Database Screen on page 125

Database Controls

The database control buttons (Figure 30), located to the right of the **Database Waveform** Window, provide options to create reports, print, view, and save the data from the test.

When multiple test records are selected, the control button functions are applied to all the selected test records. Refer to Select multiple test records on page 36.

The set of database control buttons depends on the selected test type. **Clinical Summary**, **Print**, **Save to Spreadsheet, Delete**, **Archive**, **Un-archive All,** and **Edit Comments** are available for all test types.

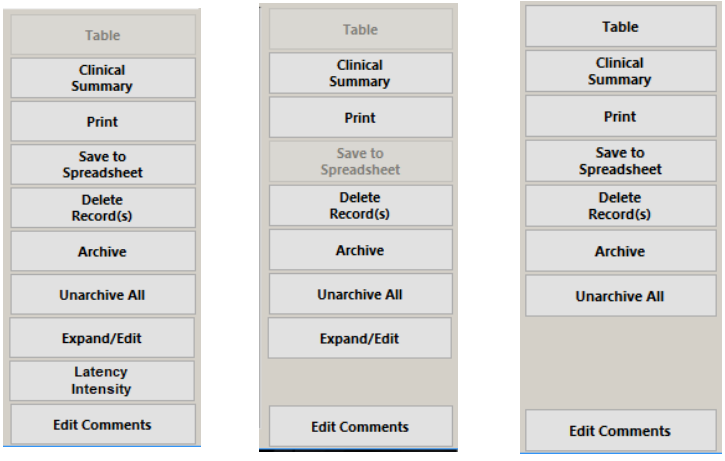


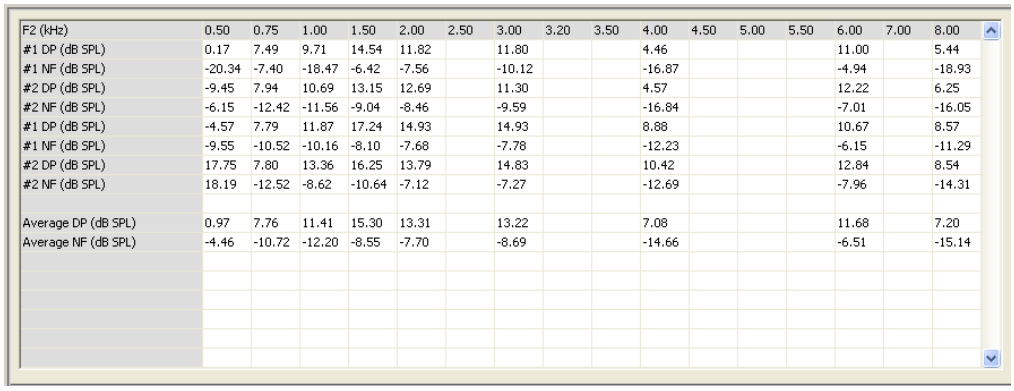
Figure 30. Database Controls

Table/Graph button (DPOAE and TEOAE)

When selected, the **Table** button displays the signal and noise information for the selected records in a tabular format. This table replaces the graphical view of the data. At the same time, the button label changes from **Table** to **Graph**.

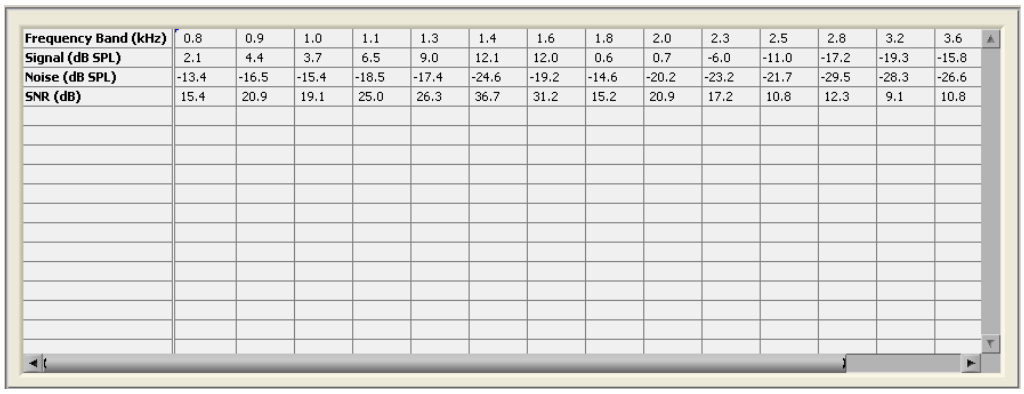
Select the **Graph** button to restore the graphical view of the data. The button label changes from **Graph** to **Table**.

The **Table** button is enabled only for multiple DPOAE test records that have been generated using the same protocol.



F2 (kHz)	0.50	0.75	1.00	1.50	2.00	2.50	3.00	3.20	3.50	4.00	4.50	5.00	5.50	6.00	7.00	8.00
#1 DP (dB SPL)	0.17	7.49	9.71	14.54	11.82		11.80			4.46				11.00		5.44
#1 NF (dB SPL)	-20.34	-7.40	-18.47	-6.42	-7.56		-10.12			-16.87				-4.94		-18.93
#2 DP (dB SPL)	-9.45	7.94	10.69	13.15	12.69		11.30			4.57				12.22		6.25
#2 NF (dB SPL)	-6.15	-12.42	-11.56	-9.04	-8.46		-9.59			-16.84				-7.01		-16.05
#1 DP (dB SPL)	-4.57	7.79	11.87	17.24	14.93		14.93			8.88				10.67		8.57
#1 NF (dB SPL)	-9.55	-10.52	-10.16	-8.10	-7.68		-7.78			-12.23				-6.15		-11.29
#2 DP (dB SPL)	17.75	7.80	13.36	16.25	13.79		14.83			10.42				12.84		8.54
#2 NF (dB SPL)	18.19	-12.52	-8.62	-10.64	-7.12		-7.27			-12.69				-7.96		-14.31
Average DP (dB SPL)	0.97	7.76	11.41	15.30	13.31		13.22			7.08				11.68		7.20
Average NF (dB SPL)	-4.46	-10.72	-12.20	-8.55	-7.70		-8.69			-14.66				-6.51		-15.14

Figure 31. DPOAE test results in tabular format for multiple averaged test records



Frequency Band (kHz)	0.8	0.9	1.0	1.1	1.3	1.4	1.6	1.8	2.0	2.3	2.5	2.8	3.2	3.6
Signal (dB SPL)	2.1	4.4	3.7	6.5	9.0	12.1	12.0	0.6	0.7	-6.0	-11.0	-17.2	-19.3	-15.8
Noise (dB SPL)	-13.4	-16.5	-15.4	-18.5	-17.4	-24.6	-19.2	-14.6	-20.2	-23.2	-21.7	-29.5	-28.3	-26.6
SNR (dB)	15.4	20.9	19.1	25.0	26.3	36.7	31.2	15.2	20.9	17.2	10.8	12.3	9.1	10.8

Figure 32. TEOAE test record result in tabular format

Clinical Summary button

Use the Clinical Summary feature to add comments about your test results.

1. Select the Clinical Summary button to open the **Clinical Summary Window** (Figure 33).
2. You may write comments for the record.
3. Close the Clinical Summary window to save your comments.

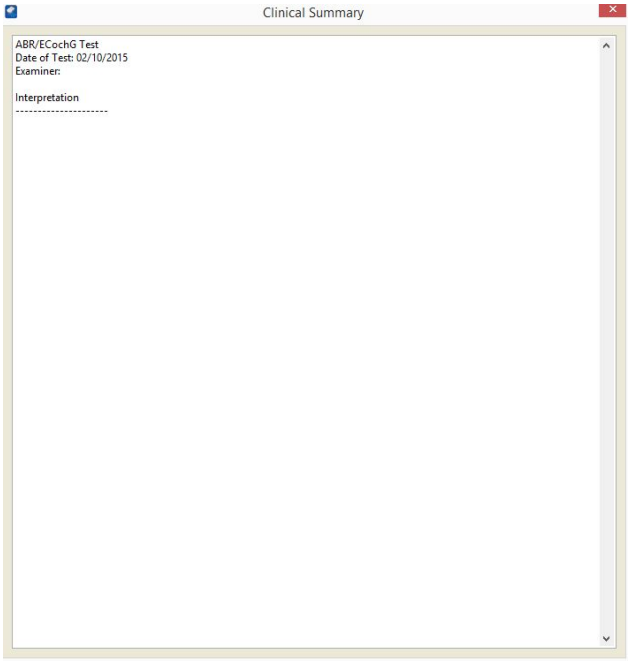


Figure 33. Clinical Summary Window

Print button

You can print a report of your test results. Your report may include waveforms, test conditions, protocol details, patient information, and comments.

To print a report:

1. Select the desired patient records to print.
2. Press **Print.** This displays the **Print Report** dialog box (Figure 34).

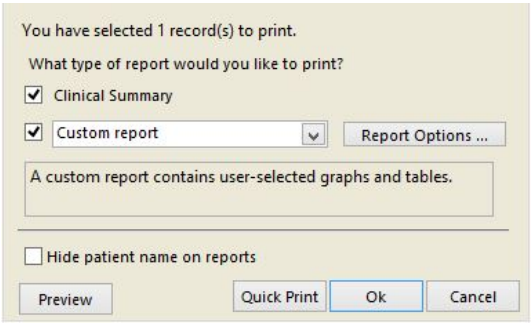


Figure 34. Print Report Dialog Box

3. Select the type of report you would like to print (Figure 35). In addition to a Clinical Summary report, you can choose to print one of three types of reports: an Abbreviated Report, a Comprehensive Report, or a Custom Report.
    - A **Clinical Summary** includes the comments and observations you have recorded for the test session.
    - An **Abbreviated report** is typically a short report. It contains essential graphs and charts, in addition to key test conditions.

- A **Comprehensive report** contains all available test data including graphs, charts, tables, test conditions, protocol parameters, and detailed information about the patient, the test facility, and the test instrumentation used.
- A **Custom report** contains the information you have selected from the **Report Options** dialog box (Figure 36).
- A **Short report with clinical summary** is an **Abbreviated Report** with Clinical Summary appended at the end.
- For each test type, there are options to include graphs or charts; tables of data; all test conditions or key test conditions only; and, protocol settings. You can also include detailed information about the patient, the test facility, and the test instrumentation used.
- You may choose the **Hide patient name on reports** option.
- Press **OK** to proceed to a standard Windows **Print** dialog box.
- Or, press **Preview** to view the contents of your report before printing it.
- From the **Print** dialog box, you can choose your printer.
- If you choose the **VivosonicPDF** printer (installed with Integrity), your reports will be saved in a PDF format on your computer. You can modify the file directory on the save dialog.
- Each file is assigned a default file name that includes both the date and time that the file was created. You can change the default file name from the **Save As** dialog box.

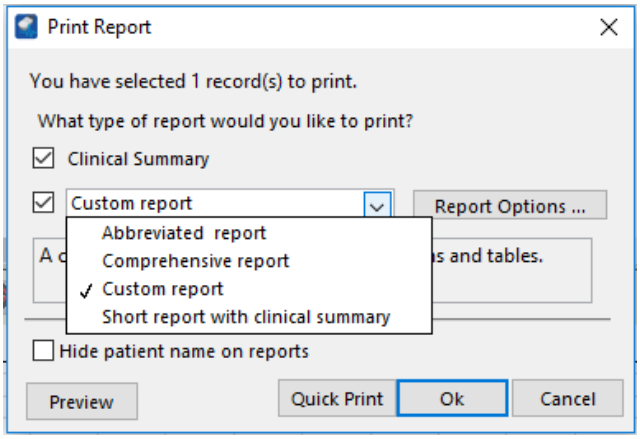


Figure 35. Print a Custom Report

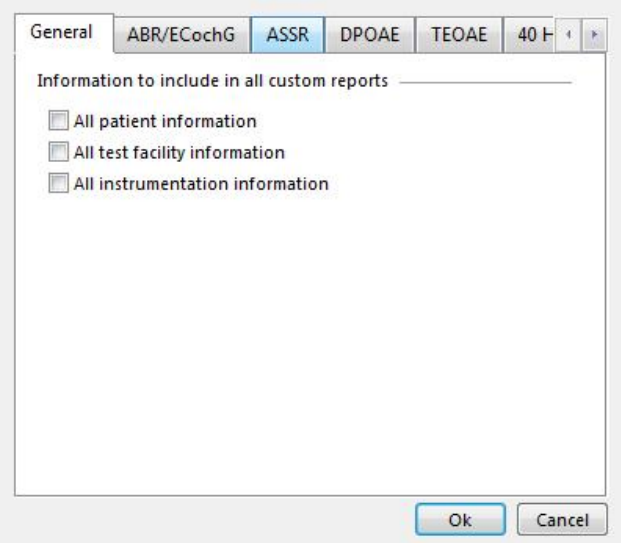


Figure 36. Report Options Dialog Box

Save To Spreadsheet button

This button allows you to export tabular data to a comma delimited file to be used with database and spreadsheet software applications that can import this type of file, for example Microsoft Excel[1].

1. Select the **Save to Spreadsheet** 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 comma delimited file will be created.

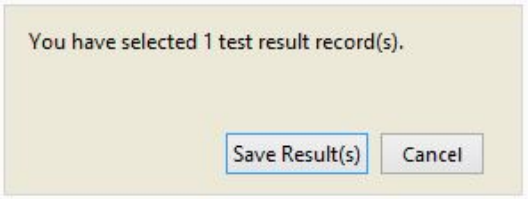


Figure 37. Export Test Result

Delete Record(s) button

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.

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

Archive button

The **Archive** feature allows you to “hide” selected patient records. This is useful when there are too many records to review. It can be time-consuming to look through all of the data to find a record that has “good” results which are representative of that patient’s data.

1. Select the results that you want to hide.
2. Press **Archive**. The selected records will disappear from the database table.

NOTE

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

Unarchive All button

To **Unarchive** results that have been previously archived, press **Unarchive All**. All archived results are re-displayed in the table.

Expand/Edit button (ABR/ECochG and 40 Hz ERP)

To make changes to the calculations of points on the waveform select **Expand**. A window will open containing only the waveform graph and the activated waveform edit buttons (e.g.: peak labels, baseline label, stop and start peak labels, notes, etc.)

Latency Intensity button (ABR)

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 53. Latency-Intensity Graph). Select the patient’s age range from the **Latency Norms** drop-down list to display the data supplied for that age. (Hood, 1998), (Gorga, 1987), (Gorga, 1989), (Zimmerman, 1987), (Elsayed et al, 2015)

The **Latency-Intensity** button is disabled during performing the test. It is enabled as soon as the test is stopped, and there is an actual waveform displayed on the screen.

Edit Comments button

Click on the Edit Comments button to change the value of the Comment 1 or Comment 2 field for the selected record (Figure 11). The Comment 1 and Comment 2 fields are used for searching and sorting purposes, and should not be used for clinical information.

The Protocol Screen

NOTE

The Protocol Screen is only available in full-featured configurations of Integrity and not in the Integrity "Lite" configuration. Integrity "Lite" does not allow you to customize protocols.

The **Protocol** screen allows you to create, save, activate, deactivate, and delete test protocols. If you have set a password on the System Screen, you will be prompted to enter a password. Refer to Change Password on page 53.

NOTE

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

The **Protocol** screen has three general sections:

- Protocol List
- Query
- Settings

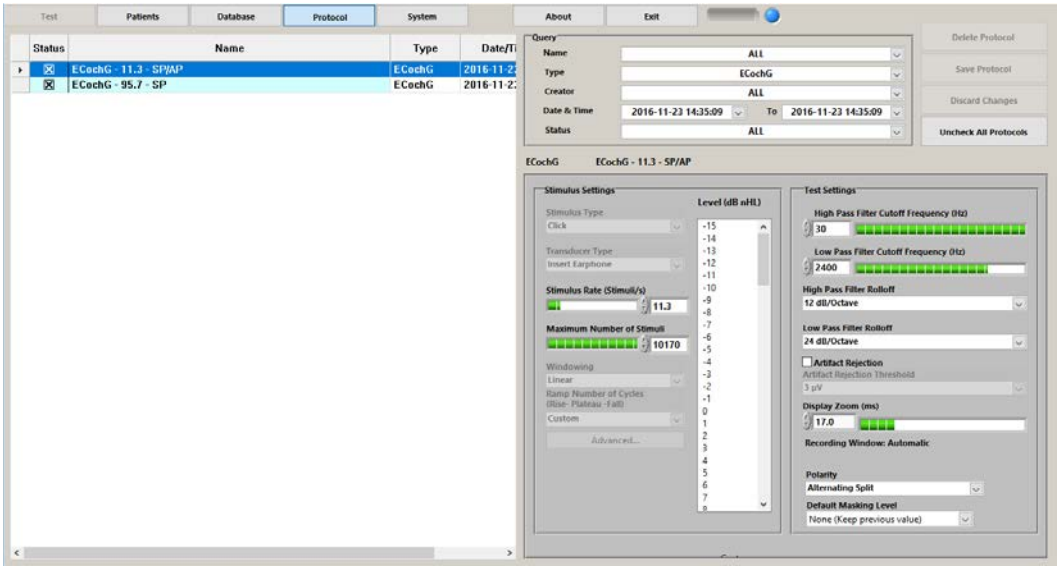


Figure 38. Protocol Screen showing an EOchG protocol

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 40). The Integrity System comes with several preset protocols.

Use the scroll bar on the bottom of the list to view all columns in the table.

Protocol Query

Use the **Query** feature to find specific protocols based on one or more criteria: name, type, creator, date/time of creation, and status of the protocol.

The **Protocol List** automatically updates to show only the protocols that match your selected criteria.

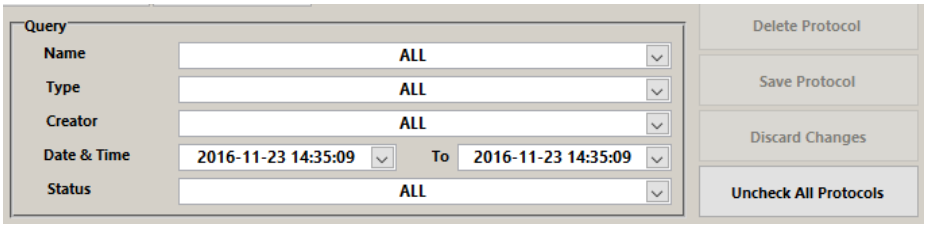


Figure 39. Protocol Query

Protocol Settings

The configuration of a protocol depends on the test to be performed. For more details about the protocol settings and defining a protocol refer to the following:

- Define an ABR/ECochG Protocol on page 58
- Define an ASSR protocol on page 87
- Define a 40 Hz ERP Protocol on page 98
- Define a TEOAE Protocol on page 100
- Define a DPOAE Protocol on page 114

Activate and Deactivate Protocols

The **Status** column of the **Protocol List** indicates which protocols are active. Those protocols marked with an “x” (Figure 40) are active and available for use in the **Test** screen.

To activate or deactivate a protocol, toggle the **Status** box on or off.

Status	Name	Type	Date/Time	Creator
☒	ASSR - 80 Hz	ASSR	2016-2-5 16:	
☒	40 Hz ERP - 1000 Hz	40 Hz ERP	2016-2-5 16:	
☒	40 Hz ERP - 2000 Hz	40 Hz ERP	2016-2-5 16:	
☒	40 Hz ERP - 4000 Hz	40 Hz ERP	2016-2-5 16:	
☒	40 Hz ERP - 500 Hz	40 Hz ERP	2016-2-5 16:	

Figure 40. Protocol List with activated protocols

Uncheck All Protocols

The Uncheck All Protocols button is located under the Query field of the Protocol Screen (Figure 39). Clicking this button deselects all the protocols in the Protocol Screen. Protocols can be activated again by toggling on the Status box.

Create a New Protocol

You can create a new protocol from an existing protocol. You cannot modify a protocol and then save the protocol with the same name.

To create a new protocol:

1. Select the protocol that you wish to modify. Highlight the protocol by selecting the row header (the grey area of the Protocol List).
2. Modify the parameters of the protocol, including description and comments.
3. Press the **Save Protocol** button. The Protocol dialog box (Figure 41) appears.
4. Enter your **Protocol Name** and the **Creator** of the protocol.
5. Save your protocol with a new name.
6. Press **OK**.

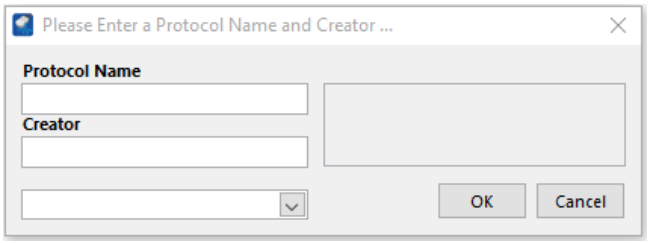


Figure 41. Protocol Dialog Box

Discard Changes to a Protocol

You can undo all changes that you have made to the current protocol settings.

1. Press the **Discard Changes** button to undo all changes that you have made to a protocol.
2. A message will prompt you to confirm your action before continuing.
3. Press **OK** to confirm that you want to discard all of your changes.

Delete a Protocol

Only protocols that have never been used can be deleted.

1. Select the unwanted protocol from the protocol list.
2. Press the **Delete Protocol** button in the protocol Query area (Figure 39). The Delete Protocol dialog box appears.
3. Press **OK** to confirm the delete action.

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.

The System Screen

The **System** screen is used to define the battery type, register new test modalities, setup/change the user password, define units, select transducers, and backup, merge, and restore the database.

The first time you use Integrity, configure the system from the **System** screen before any other task is started.

The **System** screen has five sections:

- System configuration
- System configuration controls
- Organizational information
- Database controls
- Bluetooth Discovery

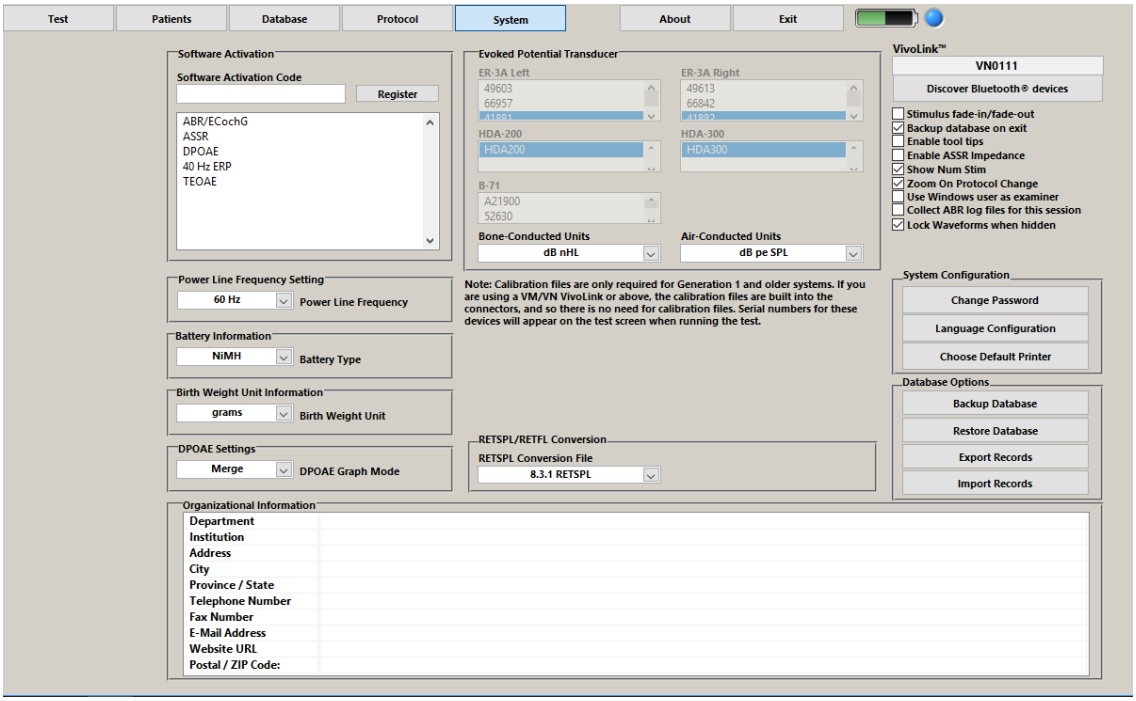


Figure 42. System Screen

System Configuration Selection and Controls

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

Software Activation

The **System** screen displays the test modules that have been activated for you to use.

Power Line Frequency Setting

Use the Power Line Frequency Setting to specify the default value for the **Notch Filter** and to optimize the SOAP™ performance for different power line environments.

You can select either 50 Hz or 60 Hz from the **Power Line Frequency Setting** list.

Battery Information

The VivoLink uses one of two different types of batteries. This field defines which type is in use, and is needed to determine how much power remains in the battery's life.

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

Birth Weight Unit Information

You can set the units that are used when specifying the patient's birth weight in the **Patient** screen and the **Database** screen.

Select either Grams (metric) or lb:oz (Imperial measure) from the **Birth Weight Unit Information** list.

DPOAE Settings

Both the Test screen and Database screen allow you to toggle the view of your DP-grams from a merged view to a split view, and vice versa. Refer to Split / Merge Charts on page 122 for details.

To set the default view for your DP-grams, select either Split or Merge from the ***DPOAE Settings*** list.

Exporting Records

You can export individual or all records in a database to a file that you can archive or re-import at a later date.

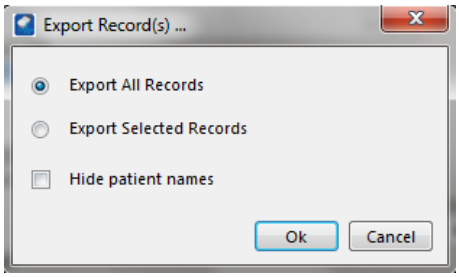


Figure 43. Export Records Dialog Box

Export All Records with export all of the records in the database with results.

Export Selected Records will only export the records which you currently have selected in the database screen.

The checkbox "Hide patient name on reports" is used to remove the first and last name of the patient, and replace the patient ID with a DateTime. This can be used for showing your results without compromising the name of your patients.

Transducers and Calibration Units

Selecting the appropriate transducer

If you have a G2 system, all peripherals have calibrations built into the devices and do not require a calibration file to be selected in the **System** screen.

If you have a G1 system, then the AEP stimulus transducers' (insert earphones, bone conductor and circumaural earphones) calibration data is located in the computer and the appropriate transducer must be selected.

As such, before you begin a test session, check the **System** screen to ensure that the appropriate transducers, identified by serial numbers (for insert earphones and bone conductor), are selected in the transducer lists: insert earphones, or bone conductor. This is important to acquire more accurate test results. HDA-200 is identified by a generic number for the calibration file that can be used for any HDA-200 circumaural earphones; similarly HDA-300 calibration files can be used for HDA-300 circumaural earphones.

If you replace your insert earphones or bone conductor at any time, or if you recalibrate these transducers, you must install the calibration files using the **Calibration CD**. Note that for EP circumaural earphones, a calibration CD is not needed.

Adding new insert earphones and bone conductor and calibration files:

1. Exit the Integrity software program before you begin.
2. Copy all files from the Calibration CD to:

   C:\Program Files (x86)\Vivosonic\Integrity\Calibration Data
3. Start the Integrity software program, and go to the System screen.
4. Select the serial numbers of the transducers that you wish to use.

CAUTION

Selecting a serial number that does not match the transducer in use 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 default calibration units for your transducers are set in the **System** screen.

- For insert earphones or circumaural earphones, select either **dB nHL** or **dB peSPL** from the Air Conduction Units drop-down list.
- For bone conductor, select either **dB nHL** or **dB peFL** from the Bone Conduction Units drop-down list.

The units you select are used by the **Stimulus Levels** field of the **Protocol** screen, as well as, the **Level** parameter of the **Test** screen.

Hearing level conversions

It is possible to change the conversion between dB nHL and dB peSPL. The default values for conversion files rounded to the nearest dB, are listed in the folder location: **C:\Program Files (x86)\Vivosonic\Integrity\Conversion Files**

Integrity includes two different sets of Reference Equivalent Threshold Sound Pressure/Force Level conversion files (RETSPL, RETFL), which are selectable from a drop down in the System Screen. The default selection, “8.3.1 RETSPL”, is the standard conversion files that have been used in the past, and also the conversion file that is always used with G1 systems. The second option, “8.3.3 RETSPL” is a new set of conversion files that have been collected for the 8.3.3 software.

To change the values please edit the following text file on the Integrity computer. Use a text-only editing application (such as Windows Notepad®) 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.

NOTE

The OAE Probe (G1 and G2 systems) and insert earphones *(G2 systems only) are calibrated by the manufacturer and do not require calibration by the user. The calibration data is stored in a memory chip (EEPROM) in the transducer connector, and is automatically read by VivoLink prior to running a test.*

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.

Stimulus fade-in/fade-out

When this is checked, Integrity will fade in and fade out the stimulus.

Backup Database on Exit

When this is checked, the Integrity system will automatically make a backup of the entire database when the program is shut down.

NOTE

The Database is only available in full-featured configurations of Integrity and not in the Integrity "Lite" configuration so the backup data will not be available to you if you have the Integrity "Lite" configuration.

Enable Tooltips

When this is checked, the Tooltips on the buttons and features will be enabled. When the user moves the mouse over a control or button and after a brief pause an explanation will be shown.

Enable ASSR Impedance

This is an option only for the ASSR test screen. When this option is selected, the user is required to check impedance before starting an ASSR test.

Show Num Stim

This is an option only for the ABR/ECochG test screen using the SOAP algorithms. When this option is selected, number of stimuli is displayed on the test screen as well as the number of noise adjusted sweeps (Neq).

Zoom on Protocol Change

This is an option only for the ABR/ECochG test screen. Different protocols may have different display zoom settings. When this option is selected, the display zoom of ABR/ECochG test screen is automatically adjusted to that of the selected "Applied Protocol".

Use Windows user as examiner

This option is universal for each test. When this option is selected, the account name that is used to sign in to the computer is shown as the examiner name when a test is run and is saved to the database. This default setting can be changed by the user when saving a test record.

Collect ABR log files for this session

This option is only for the ABR/ECochG test and is a Research / Customer Support feature. When selected, data log files are created for all ABR testing performed until the application is restarted. Please contact Vivosonic for instructions as to the use of these log files.

Discover Bluetooth Devices

This button allows you to search and pair to a VivoLink. In the dialog box that appears, you can search, select and pair to a VivoLink.

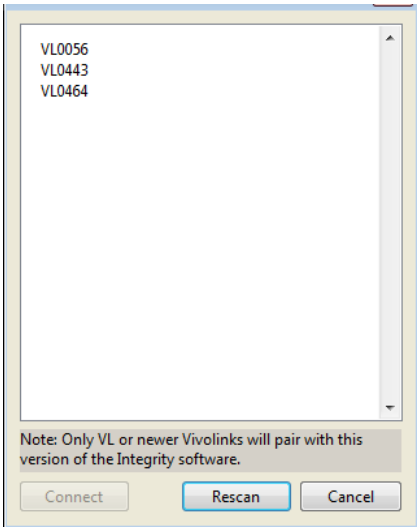


Figure 44. VivoLink Connect Dialog Box

If you are already paired to a VivoLink the application will notify you of this, and will ask that you switch the power off to your VivoLink in order to connect to a different one. Integrity version 7.2 and beyond will only work with VivoLinks starting with the serial numbers VL or above, and will not pair with older hardware (VB, VP, VK serial number VivoLinks).

When switching a connection to a new VivoLink, the software will require to be shut down and started up again.

Change 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**.

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

CAUTION

A System without a password may compromise patient confidentiality.

*A password may be needed to access the **Protocol** and **Database** screens. A password will prevent unauthorized users from having access to the patient test results stored in the database. The password also prevents unauthorized users from deleting defined protocols.*

Language Configuration

The language of the Integrity™ software can be changed, if there is an approved language file for the corresponding version of the software. This configuration button also allows the user to change formatting with the Date Format, Decimal Separator, Thousand & Decimal Separator, and Time Format options.

Choose Default Printer

Set the default printer for Integrity to use. Clicking on this button will show the following dialog box.

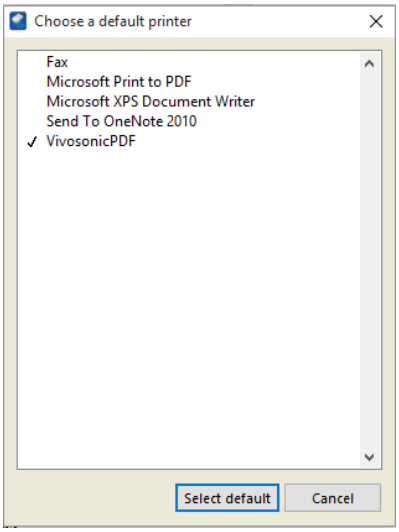


Figure 45. List of Printers Installed on the System

Click on the name of the appropriate printer and click on the Select default button to set that printer as the default printer in Integrity. Click on the cancel button to dismiss the dialog box and do nothing.

Database Options

NOTE

The Database is only available in full-featured configurations of Integrity and not in the Integrity "Lite" configuration so the backup data features are not available in the Integrity "Lite" configuration.

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 Backup File As** will appear.
2. Select the drive and folder location. Use the button with a folder on it to browse the computer and select a drive.
3. Press **Save**. The file will be saved on the selected drive with a default file name.
4. The file will be named as follows: Vivosonic Integrity (version number) Database Backup – (current date) – (current time).BAK
5. For example, a file saved on May 1, 2015 at noon is saved as "Vivosonic Integrity 8.2 Database Backup – 2015.05.01 – 12.00.00.BAK".
6. You can change the default file name.

CAUTION

To prevent permanent loss of data due to hard drive failure, it is recommended that the database be backed up regularly. Vivosonic Inc. 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 **Please** c**hoose a Database backup file** will appear.
2. Select the required database file from the saved drive and folder location. The selected file should be a ZIP file with .BAK extension that is previously created through the **Backup Database** option.
3. Press **OK**.

CAUTION

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 test result records and associated protocols on the hard drive of the notebook computer, USB Flash Drive, or any other medium that is connected the 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 Record(s)**. The **Save Record(s)** dialog box is displayed.
5. Select **Save Selected Records** to save only the records highlighted in the list.
6. Select **Save All Records** to save the entire list of patient test records.
7. Press **OK**.

Merging Saved Records to the Database

This feature is useful if you have more than one Integrity System and you want to combine your records into one database.

Use the **Merge Records to Database** feature to integrate records that were saved using the **Save Selected Records** function.

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**.
4. If the selected file does not exist, a dialog box labeled **Select a File** will appear with “File not found. Please verify the correct file name was given”.
5. By pressing **OK** a dialog box labeled **Select a File** will appear for the user to select the file.
6. Press **Cancel** to end the merging process.

In case of a mismatch between the imported record data and data that has already been saved on the Integrity System′s database, a message box will be displayed with the patient/protocol record that has the mismatch.

- Press **Yes** to overwrite the already saved data in the Integrity System's database with the newly imported data.
- Press **No** to ignore the conflict, and don't modify the already saved data in the Integrity System's database.
- Press **Cancel** to cancel the whole importing process.

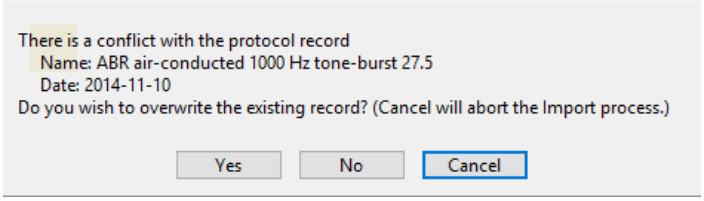


Figure 46. Merging Database Conflict Warning

Organization Information

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

Chapter 3: Overview for ABR/ECochG Testing

Steps to Perform an ABR/ECochG Test

1. Prepare the patient and equipment according to the instructions in the Integrity V500 Quick Reference.
2. In the **Test** screen, select ABR as the **Test Type**.
3. Select an appropriate protocol from the **Applied Protocol** drop-down menu.

   CAUTION

   Improper configuration of test protocols may result in poor quality test results. Use clinically validated protocols for screening and assessment.
4. Press either the **Right Ear** or **Left Ear** button.
5. Press **Start** to begin a test. The **Start** button changes to a **Stop** button.
   - Press **Pause** to stop the test temporarily.
   - Press **Continue** or the **Stop** button to proceed.

Refer to Test Control Buttons on page 24 for more information about Start/Stop, Pause/Continue, and Save features.

TIP

*Every Start and Stop creates a new record. If you save each record, you can display your results in the **Test Waveform Window** graph while the next test is taking place. If a record is not saved, it will not show on the graph when the next test is started.*

Monitor the EEG Window (Figure 8) and visually estimate the amplitude of the EEG signal.

TIP

The lower the EEG value, the better the electrode contact. Re-apply the electrodes if the EEG remains above +/- 50 µV.

- *+/- 10 µV or less is best*
- *+/- 20 µV may still be acceptable*
- *+/- 50 µV indicates a problem, reapply the electrodes*

The noise floor in ABR tests depends on the number of sweeps and the recorded EEG noise. For example, to achieve a 0.1 µV noise floor in an ABR test, you will need to observe the ongoing EEG amplitude within the following limits:

- *For 1,000 sweeps – within approximately ± 3-4 µV*
- *For 2,000 sweeps – within approximately ± 4-5 µV*
- *For 10,000 sweeps – within approximately ± 10 µV*

When excessive noise is found in an AEP test, do the following:

1. *Monitor the status of the **Electrode Contact LED Indicator**. If the LED is **amber**, adjust your electrodes for better contact. If necessary, replace electrodes or re-prepare the skin area.*
2. *You may also **Check Impedance** to identify the impedance values of the electrodes. If the indicator bar is **amber** or **gray**, then check and adjust*

your electrodes.

Remove the electrodes, re-prepare the patient's skin and replace the electrodes. When the noise is reduced, reconnect the Amplitrode or VivoAmp and its clips to the patient and continue patient testing.

1. Press **Save** to save the data collected.
2. Press **Clear All** to clear the **Test Waveform Window**. If the graph is cleared before the results are saved, the data will be lost.
3. Press **Print** to print the test results.
4. Repeat the above procedure to test the other ear.

Reviewing Results

1. Select the **Database** tab.
2. Select the patient required.
3. Review the data in the **Waveform Preview Window**.
4. Select **Expand** to view the waveform's full screen.
5. Perform data analysis by labeling peaks on the waveform.
6. Press the **Clinical Summary** button to add comments about the test.
7. Press **Print.**

Electrode Contact

Integrity continuously monitors electrode contact during ABR and ECochG data collection. This ongoing monitoring provides a basic indication of whether the signal electrodes are in contact with the patient's skin. Poor contact between the electrodes and the patient will affect test results.

Always start a test by ensuring that electrode contact is good. You may also check the EEG signal. If the signal is very noisy with a peak-to-peak value greater than +/-20 µV, a contact problem may exist. In addition, you may wish to perform an impedance test to determine the quality of contact and the presence of signal artifact.

Please refer to **Electrode Contact** on page 24 for more details.

Check Impedance

Please refer to **Check Impedance** on page 27 for detailed information.

Define an ABR/ECochG Protocol

Protocol parameters are set from the **Protocol** screen using ABR Stimulus and Test Settings. To create a new protocol, modify an existing protocol, and then save it with a new name.

Some protocol settings may also be modified from the **Test** screen. Refer to The ABR/ECochG Test Screen on page 66 for more details.

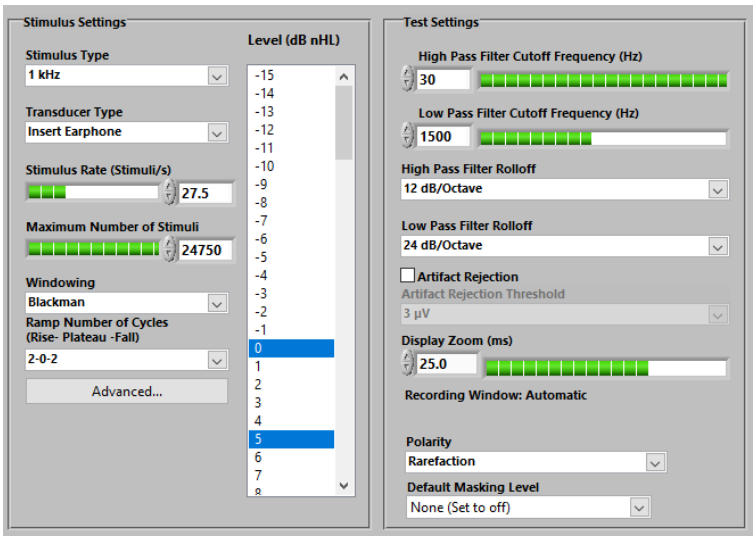


Figure 47. Protocol Stimulus Settings and Test Settings

The parameters, which can be preset in this protocol, are divided into two categories: **Stimulus Settings** and **Test Settings**.

- The **Stimulus Settings** are used to select the stimulation parameters such as stimulus type, stimulus level, maximum number of stimuli, stimulus rate, stimulus window, waveform ramp setting, and transducer type.
- The **Test Settings** control the acquisition conditions of the waveform recording, such as high-pass and low-pass filter settings, high-pass and low-pass filter rolloff, the amplifier gain, display zoom (ms), and the artifact rejection threshold (relevant only when using the averaging algorithm).

Stimulus Settings

Recommended Stimulus Settings for Diagnostics

Stimulus Type: Click

Stimulus Rate (stimuli/second)

Certain stimulus rates are known to have high interference with AC Power Line, VivoLink internal harmonics, and local environment. A slower stimulus rate will create a better ABR waveform for diagnostics.

Refer to Table 1 on page 60 for Recommended ABR Stimulus Rates (stimuli/second).

Recommended Stimulus Settings for Threshold Testing

Stimulus Rate (stimuli/second)

A faster rate (such as 49.8 stimuli/s) will create a better ABR waveform for threshold estimation. However, higher rates can also create a mid-latency response overlap in awake subjects making the results hard to interpret.

Refer to Table 1 on page 60 for Recommended ABR Stimulus Rates (stimuli/second).

Understanding the Settings on the Protocol Screen

Stimulus Type

The following stimulus types can be selected from the drop-down menu: click, chirp, or tone burst frequencies of **500 Hz, 1 kHz, 2 kHz, 3 kHz, and 4 kHz. The 6 kHz and 8 kHz stimuli are also available with ER-2 insert earphones only.** (± 5% at all frequencies).

Transducer Type

Three transducer types are available from the drop-down menu: the insert earphones, circumaural earphones and the Bone Conductor.

Stimulus Rate (stimuli/second)

The Stimulus Rate can be set for click and tone-burst stimuli. Select the number of stimuli to produce per second from the range of 1 to 99.0 (± 5% in 0.1 increments). Changing the **Stimulus Rate** will result in a change in the wave latency delay and in the early wave's amplitude.

Although the stimulus rate may be set anywhere in the above specified range, the use of certain stimulus rates are recommended because when they are implemented by the VivoLink internal clock they are not synchronized with 50 and 60 Hz power line frequencies and their harmonics.

Refer to Table 1 for Recommended ABR Stimulus Rates (stimuli/second).

Table 1. Recommended ABR Stimulus Rates (stimuli/second)

7.6	30.8	52.3	74.8
8.3	31.0	53.1	75.7
9.8	32.9	54.4	76.6
10.3	33.8	55.4	77.7
11.3	34.0	56.8	78.3
12.4	35.6	57.3	79.8
13.8	36.3	58.0	80.5
14.7	37.7	59.4	81.5
15.4	38.3	60.3	82.4
16.4	39.9	61.9	83.7
17.7	40.3	62.6	84.5
18.6	41.2	63.6	85.9
19.3	42.1	64.5	86.3
20.2	43.9	65.9	87.1
21.5	44.5	66.8	88.6
22.9	45.8	67.0	89.6
23.9	46.5	68.0	90.3
24.9	47.5	69.9	91.3
26.7	48.7	70.1	92.6
27.5	49.8	71.8	93.5
28.3	50.2	72.3	94.6
29.3	51.6	73.2	95.7

Maximum Number of Stimuli

This setting depends on the selected Stimulus Rate. For the lowest Stimulus Rate of 1 stimuli/s, the Maximum Number of Stimuli is 900. For the highest Stimulus Rate of 99 stimuli/s, the Maximum Number of Stimuli is 89100.

Windowing

This setting is applicable to the tone-burst stimulation type only. The window defines the shape of the tone-burst waveform, which follows the rise, plateau, and fall portions of the stimulus. The tone-burst signal can be Rectangular, Linear, or Blackman waveform. The Blackman gated window is most commonly used.

Ramp Number of Cycles (Rise – Plateau – Fall)

This setting is applicable to the tone-burst stimulation type only. The number of sinusoidal waves in the rise, plateau, and fall portions of the tone-burst's waveform is controlled by this parameter. The selections available from the drop-down menu include:

- 0-4-0, and 0-5-0 in case Rectangular option is selected for **Windowing**
- 2-0-2 or 2-1-2 in case Linear option is selected for **Windowing**
- 2-0-2, and 2.5-0-2.5 in case Blackman option is selected for **Windowing**
- Custom… for all Windowing. This brings up the advanced dialog box.

NOTE

*When **Click or Chirp** is selected as the Stimulus Type both the **Windowing** and **Ramp Number of Cycles** and Advanced settings are unavailable.*

Advanced… (Advanced settings for Ramp Number of Cycles)
This button brings up the Advanced Windowing dialog box.

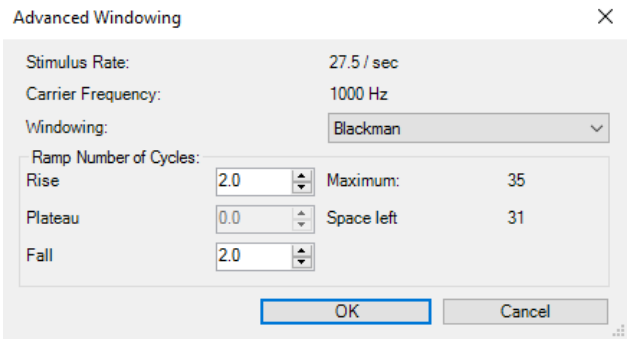


Figure 48. Advanced Windowing

This allows the rise, plateau, and fall Number of Cycles to be set to custom values. The options available on this dialog box are:

- **Windowing –** This allows the shape of the tone-burst waveform to be specified.
- **Rise, Plateau, and Fall** – This allows the rise, plateau and fall portions of the tone-burst waveform to be specified.
- **OK** – This accepts the settings for the custom toneburst
- **Cancel –** This reverts the settings for the custom toneburst back to their previous values.

Stimulus Levels

A single stimulus level or a range of stimulus levels may be selected. The available levels depend on the **Stimulus Type** preset through the **Protocol** screen.

A single fixed stimulus level may selected by clicking with the mouse on that level.

To select a range of levels for multiple-level tests:

1. Press and hold the **Shift** key on the keyboard.
2. Highlight the first and last stimulus level in the required range.

To select a set of non-contiguous (individual) stimulus levels:

1. Press and hold the **Ctrl** key on the keyboard.
2. Highlight each required level.

Table 2. Stimulus Levels Ranges

Transducer Type	Unit	Stimulus Type	Stimulus Levels Range
Air Conducted Insert Earphones	dB pe SPL	Click	23 – 137
		500 Hz	10 – 130
		1 kHz	11 – 130
		2 kHz	16 – 130
		3 kHz	18 – 130
		4 kHz	20 – 130
		Chirp	9 – 79
		Stimulus Type	**Stimulus Levels Range**
Air Conducted HDA 200 Circumaural Earphones	dB pe SPL	Click	18 – 137
		500 Hz	12 – 130
		1 kHz	10 – 130
		2 kHz	10 – 130
		3 kHz	12 – 130
		4 kHz	19 – 130
		Chirp	9 - 69
		Stimulus Type	**Stimulus Levels Range**
Air Conducted HDA 300 Circumaural Earphones	dB pe SPL	Click	10 – 137
		500 Hz	24 – 129
		1 kHz	17 – 130
		2 kHz	10 – 130
		3 kHz	10 – 132
		4 kHz	10 – 134
		Chirp	18 – 73
		Stimulus Type	**Stimulus Levels Range**
Bone Conducted Bone Conductor	dB pe FL	Click	52 - 142
		500 Hz	67 - 157
		1 kHz	54 - 144
		2 kHz	49 - 139
		3 kHz	46 - 136
		4 kHz	46 - 136

TIP

*During the test session, it is possible to change the stimulus level from the **Test** screen using the **Level** **(dB pe SPL)/ (dB nHL)** slider bar. Refer to Level* **(dB pe SPL)/ (dB nHL)** *on page 68 for details.*

NOTE

Air-conducted stimuli are displayed in units of dB nHL or dB pe SPL.

Bone-conducted stimuli are displayed in units of dB nHL or dB pe FL.

*These units are set in the **System** screen. Refer to Selecting* the calibration units *on page 50 for more details.*

Test Settings

These control the acquisition parameters of the ABR recording, such as high-pass filter cutoff frequency (Hz), low-pass filter cutoff frequency (Hz), high-pass filter rolloff, low-pass filter rolloff, display zoom (ms), artifact rejection, and artifact rejection thresholds.

Recommended Test Settings

High Pass Filter Cutoff Frequency (Hz):	30
Low Pass Filter Cutoff Frequency (Hz):	1500
High Pass Filter Rolloff:	12 dB/Octave
Low Pass Filter Rolloff:	24 dB/Octave

High-Pass Filter Cutoff Frequency (Hz)

The digital high-pass filter is used to filter out low frequency noise. The filter can be set to a value in the range of 30 – 300 Hz.

Low-Pass Filter Cutoff Frequency (Hz)

The digital low-pass filter is used to filter out high frequency noise. The filter can be set to a value in the range of 1000 – 3000 Hz.

High-Pass Filter Rolloff and Low-Pass Filter Rolloff

Rolloff is defined as the rate of attenuation of a filter, expressed in dB per octave. The high-pass rolloff filters the low frequencies and the low-pass rolloff filters the high frequencies. Select the high-pass rolloff to filter either 6dB/octave or 12dB/octave and the low-pass rolloff to filter either 12 dB/octave or 24 dB/octave.

Artifact Rejection

This selection box controls the availability of the **Artifact Rejection Thresholds** function.

Artifact Rejection Threshold

The Artifact Rejection Threshold is used to exclude certain noise levels from the averaging calculations. The value selected (3, 5, 10, 15, 20, or 25 µV) defines the lowest level of the incoming electrophysiological activity which contains excessive electric noise and will be rejected from signal processing. This field is only accessible when the **Artifact Rejection** control box is selected.

Display Zoom (ms)

The **Display Zoom** determines the maximum latency value (ms) on the ABR/ECochG graph on Test Screen. The user has the option to manually zoom into the graph every time a test is being performed, or adjust the Display Zoom on Protocol Screen once and save it for use in future tests.

Recording Window (ms)

The **Recording Window** is a time period after the stimulus is presented to the patient, during which the response is averaged and analyzed. The Recording Window is optimized for ideal test conditions in the algorithm, and is set to automatic under Protocol Screen.

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 polarity.

NOTE

If you are performing a test at low frequencies (at or below 1000 Hz) using tone bursts and have alternating polarity the ABR morphology will most likely be poor and it may be difficult to detect Wave V.

Default Masking Level

When a masking value is selected, the VivoLink produces wide band noise, as defined in ANSI S3.6-2004, 6.3.2, in the contralateral ear. The masking drop-down box (Figure 49) allows the user to select either a delta masking (Stimulus (dbSPL) -10 to -40 dB) or an absolute masking (10 to 100 dB HL) value.

For air conduction testing, the delta masking option takes the current stimulus level in dB nHL and converts it to dB peSPL. This value is then converted to root mean square (rms) and used for the masking noise. For bone conduction testing, the delta masking option first gets the equivalent insert earphone dB nHL value of that of the bone conductor, then converts to dB peSPL based on the stimulus type. It is then converted to root mean square (rms) and used for the masking noise.

The absolute masking option converts the dB HL to dB SPL, based on the RETSPL value for the insert earphones in an occluded ear simulator (Table 7 in ANSI S3.6-2004 Manual) for the insert earphones and the IEC 60318-1 with Type 1 adapter (Table 6 in ANSI S3.6-2004 Manual) for the circumaural earphones, based on the ipsilateral stimulus type (with click and chirp stimuli considered to have a frequency of 1 kHz. This rms value is used for the masking noise.

Select the level from 10 to 100 dB HL in 1 dB increments.

Please note that the units (dB nHL or dB SPL) can be selected on the system screen, under the Evoked Potential Transducer section.

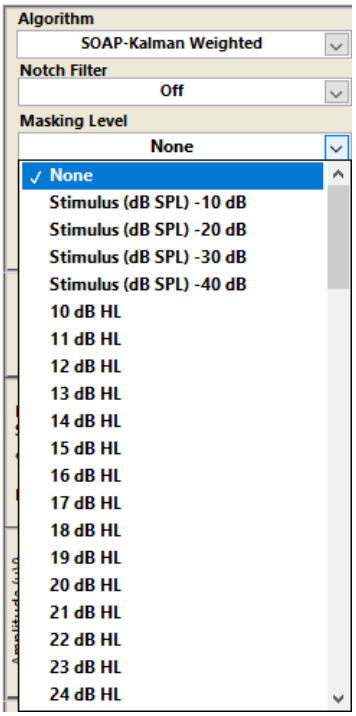


Figure 49. Masking Level drop-down on Test Screen

Letter ‘m’ will be added next to the trace number, and ear tested for all traces run with contralateral masking (Figure 50).

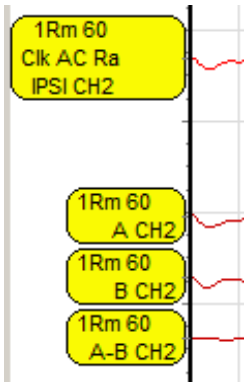


Figure 50. Waveform Handle with Masking Turned On

During the Test

The ABR/ECochG Test Screen

Right Ear/Left Ear Button

Select the ear to test by pressing the **Right Ear** or **Left Ear** button. When the **Right Ear** button is selected, the stimuli are delivered to the patient's right ear. The waveform trace in the **Waveform Window** (Figure 56) is **red** to follow the color standards for audiologic practice. When **Left Ear** button is selected the stimuli is delivered to the left ear. The waveform trace in the **Waveform Window** is **blue**.

Test Protocol Parameters for ABR

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. Vivosonic has developed a set of protocols that can be manipulated during the test. These settings can be changed during a test session between data collection.

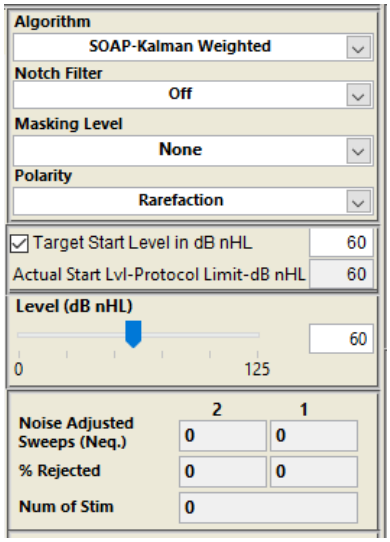


Figure 51. Protocol Test Settings and Sweeps Information

Algorithm

This control regulates application of the methods of processing the ABR waveforms. There are two processing algorithms to choose from: **Averaging** and **SOAP-Kalman Weighted**. SOAP-Kalman Weighted 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.

SOAP-Kalman Weighted is a signal processing algorithm that is used in ABR testing to optimally weight the patients' responses so that responses with less myogenic artifact are given more weight than responses that are more contaminated with artifact. SOAP (SNR-Optimized Adaptive Processing) is Vivosonic's unique patented implementation of Kalman filtering which allows ABR acquisition with subjects who are awake and not relaxed, while minimizing the effects of electrical interference. This method processes signals in real time without rejecting any time segments, even those containing significant artifacts. (Li 2002) Independent of the selected protocol settings, when SOAP-Kalman Algorithm type is selected on the test screen, artifact rejection will be ignored to get the most out of the collected signals.

When ABR is collected on a subject who is relaxed throughout the test, SOAP-Kalman Weighting yields the same result as conventional averaging. When the subject moves intermittently during the test and produces myogenic artifacts, the SOAP-Kalman Weighting algorithm will yield a result that is less contaminated by noise than a result obtained under the same conditions with conventional averaging.

SOAP-Kalman Plus (SOAP Plus) is a modified version of Vivosonic's original SOAP-Kalman weighted averaging algorithm. SOAP Plus has been recently developed to improve ABR response detection in a high electrical noise environments. In addition to the current SOAP algorithm SOAP Plus analyzes and reduces noise in multiple discrete frequency bands. It improves the SNR of the processed response waveform. A by-product of the SOAP Plus algorithm may be slightly reduced absolute amplitudes of the ABR peaks. However these peaks should be easier to identify because of the reduced noise in the response. The reduction in peak amplitude is shown only to be significant when testing at very high stimulus rates. Therefore, SOAP-Kalman PLUS is not recommended for very high stimulus rate tests when absolute peak amplitude is an important clinical metric (e.g., fast rate ECochG).

The default algorithm is the original SOAP Kalman algorithm. If the signal response contains sinusoidal noise that is not averaged out as the test goes on you may consider stopping, choosing the SOAP-Kalman Plus algorithm and repeating the run. It is suggested to run approximately 1000 noise adjusted sweeps before stopping and changing algorithm.

Notch Filter

The notch filter is designed to reduce the interference from electrical activity or power line noise of 50 Hz or 60 Hz. To disable the notch filter select **Off** from the drop-down menu.

The default frequency for the notch filter, either 50 Hz or 60 Hz, can be set from the **System** screen using the **Power Line Frequency Setting**. Refer to on Power Line Frequency Setting on page 48.

Masking Level

The masking level defines the contralateral masking noise (dB HL). When a masking value is selected, the VivoLink produces wide band noise. Masking Level that is selected on Test Screen will overwrite the Masking Level that is set as default on Protocol Screen. Please refer to Default Masking Level on Page 64 for more information.

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. Polarity type that is selected on Test Screen will overwrite the Polarity that is set as default on Protocol Screen. Please refer to Polarity on Page 64 for more information***.***

Level (dB pe SPL)/ (dB nHL)

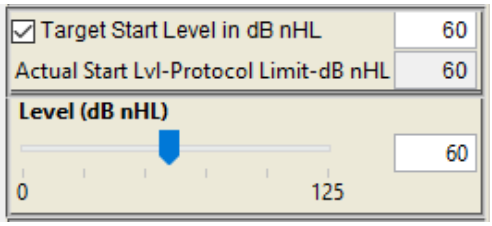


Figure 52. Stimulus Level Bar (showing dB nHL)

The stimulus level slider bar displays and regulates the levels of stimulation provided to the data recording. The initial position of the slider depends on the **Target Start Level in dB nHL**, and the **Stimulus Levels (dB nHL)** defined in the protocol selected. If the Target Start Level is less than the minimum Stimulus Level selected on Protocol Screen, the minimum stimulus level selected on protocol screen, indicated as **Actual Start Lvl – Protocol Limit-dB nHL** on test screen, will be used as the default value of the sound level.

1. When testing, the slider is positioned at the lowest stimulus level for that protocol, in coherence with the Target Start Level. The full range of values is selected on the Protocol screen. Use the slider bar on the **Test** screen to change the initial stimulus level.
2. Target Start Level feature can be turned on by checking the box beside the label named **Target Start Level in dB nHL.** The Target Start Level is set to 40 dB nHL by default when it's turned on. If the Target Start Level is not checked, then the lowest protocol level will be selected on the test screen by default.
3. The units of the Level Bar are set in the **System** screen, either dB nHL or dB peSPL for air conductive stimuli and either dB nHL or dB peFL for bone conductive stimuli. However, the units for the Target Start Level, and Actual Start Level cannot be changed; they are always indicated in dB nHL.
4. Target Start Level in dB nHL can be changed by the user by typing in a value in the text box on the Test screen. When the value is changed, it is saved by the software until the user changes the Target Start Level to another value.
5. Actual Start Lvl-Protocol Limit-dB nHL value cannot be changed, since this value is calculated by the software by comparing the Protocol Levels, and the Target Start Level.

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 applies to 1000 - 4000 Hz tone-burst stimulus types.*

*The increment in **Level** (1, 2, 5, 10, 15, 20, etc. dB) depends on the **Stimulus Levels** control settings defined in the selected protocol.*

Noise Adjusted Sweeps

The number of Noise Adjusted Sweeps applies only when the SOAP-Kalman Weighted algorithm is in use.

Although SOAP-Kalman weighting makes ABR acquisition on awake, non-relaxed subjects more practical, more sweeps are required to acquire an ABR on a non-relaxed subject with the same signal-to-noise ratio that would have been obtained if the subject were completely relaxed. The Noise Adjusted Sweeps value indicates the number of sweeps that would yield the same signal-to-noise-ratio as the current SOAP Kalman-weighted ABR waveform if the patient's EEG had remained minimally quiet throughout the test.

% 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 selected protocol.

NOTE

*The system displays the percentage of rejected stimuli only when the **Averaging** algorithm is selected on the **Test** screen.*

Number of Stimuli (Num of Stim)

The Number of Stimuli applies only when the **Averaging** algorithm is in use.

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 selected protocol, otherwise it displays the number of stimuli counted at the time the test was stopped. This feature can be turned on/off by checking/unchecking the box beside '**Show Num Stim**' on the system screen.

EEG Window

Please refer to EEG Window on page 23 for detailed information.

Ongoing EEG

Please refer to Ongoing EEG on page 23 for detailed information.

Electrode Contact

Please refer to Electrode Contact on page 24 for detailed information.

Clinical Summary Button

Please refer to Clinical Summary button on page 40 for detailed information.

Latency-Intensity Button

The Latency-Intensity button is used to display a graph of the latency versus the intensity values of a patient's recording based on the age of the patient. When selected, a window opens displaying the **Latency-Intensity Graph** (Figure 53. **Latency-Intensity Graph**). Select the patient's age range from the **Latency Norms** drop-down list to display the data appropriate for that age. (Hood, 1998), (Gorga, 1987), (Gorga, 1989), (Zimmerman, 1987), (Elsayed et al, 2015)

The Latency-Intensity button is available for selection when a waveform is displayed on the screen. However, before the Latency-Intensity graph can be populated, the waves must first be labeled with I, III, or V in the **Waveform Window** (Figure 56).

When more than one waveform is collected for the same ear, at the same level of stimulation, and the waves are marked with the average latency value, these waves are displayed on the Latency-Intensity graph.

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 is displayed on the Latency-Intensity graph as an average value ± 2 standard deviation, in the form of vertical bars. To view normative (raw) data open the following file:

C:\Program Files (x86)\Vivosonic\Integrity\Integrity Norms\ABR\ LatencyNorms.ini

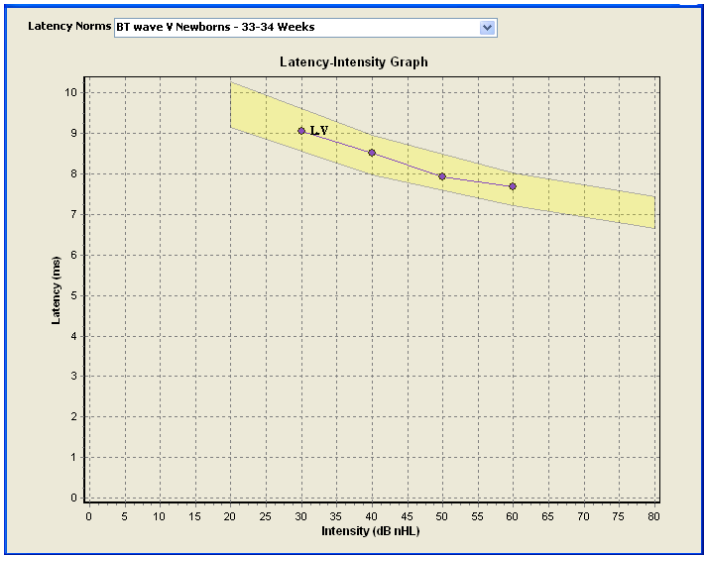


Figure 53. Latency-Intensity Graph

Montage Notes

These two fields allow you to select the location, for documentation purposes only, of the non-inverting (“+”) and inverting (“-“for G1 systems, “1” and “2” for G2 systems) electrodes on your patient.

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

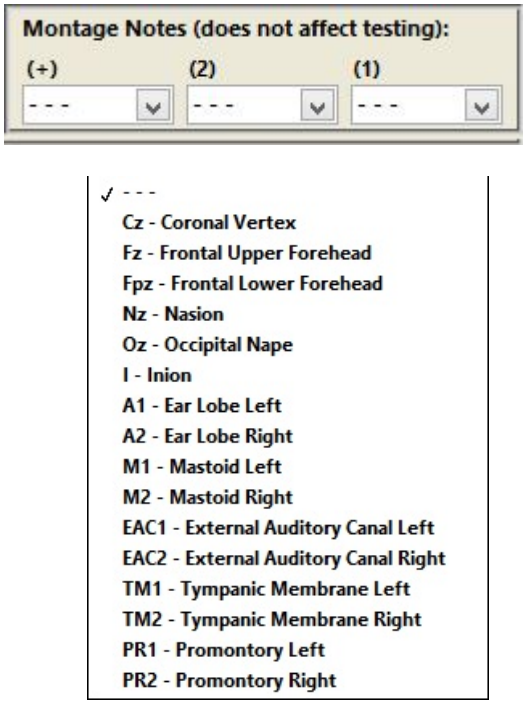


Figure 54. Electrode Drop-Down List

Signal Information

During and after data collection, the **Signal Information** area of the **Test** screen displays information about the collected waveform.

Figure 55. Signal Information

Stimulus Type

Click, chirp, or tone-burst frequency is displayed in this field as defined by the protocol.

- **Broadband Chirp for ABR**

  The broadband chirp is a wide band chirp ranging from 350 to 5050 Hz. The frequency-specific stimulus delays were selected for maximum output performance near 40 dB nHL. As such, the improved chirp performance of a larger wave V amplitude decreases as the intensity increases; we have limited the maximum chirp intensity to 60 dB nHL, above which it is recommended to use a click. In addition, the latency of this chirp was offset by the length of the chirp (i.e. time = 0 ms represents the time when the last of the stimulus leaves the transducer).

Transducer ID

Transducer ID shows the serial number of the selected transducer.

Calibration Date Information

The date shown after Transducer ID and Amplifier ID is the last calibration date of the transducers. When the Calibration Date is over a year old, it is highlighted in yellow. The transducer may still be used for testing, but the user is warned to have their transducer calibrated as soon as possible.

Transducer Type

Insert earphones, bone conductor or circumaural earphones is displayed in the transducer type field as defined by the protocol.

Waveform Window

This Waveform Window displays the graphic representation of the collected waveform as a function of the amplitude (µV) of the signal over time (ms).

The waveforms collected from the left and right ears are displayed on the same graph and are distinguished by the color of the waveform. Recordings for the right ear are indicated by red waveforms, and recordings for the left ear are indicated by blue waveforms.

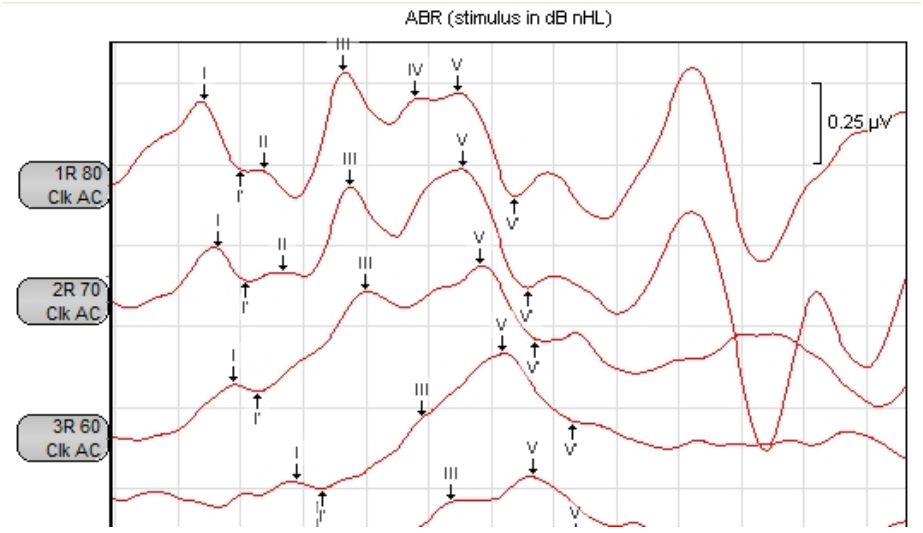


Figure 56. Waveform Window with recorded data with a G1 system

The **Waveform Window** is used when monitoring data in real time and when analyzing and labeling waveforms. Each **Start** and **Stop** during a test session produces a new waveform. To zoom or magnify the waveform window, drag your mouse from left to right. To restore the display to its original magnification, drag your mouse from right to left.

You can also view a single latency value by pointing to a waveform with your mouse pointer. The Latency and Amplitude values are displayed in a small window in the upper right corner of the window.

Split/Merge Chart on the ABR/ECochG Test Screen

You can change the way your waveforms appear on the screen and in printouts using the Split/Merge function. When the chart is split, waveforms collected on the left ear appear on the right side of the screen, and waveforms collected on the right ear appear in the left part of the screen.

The top of the screen contains a button which toggles the view of the chart between the merged and split state. Depending on the current view, it will read either “Split” or “Merge”.

Figure 57. Split/Merge buttons from the top of screen

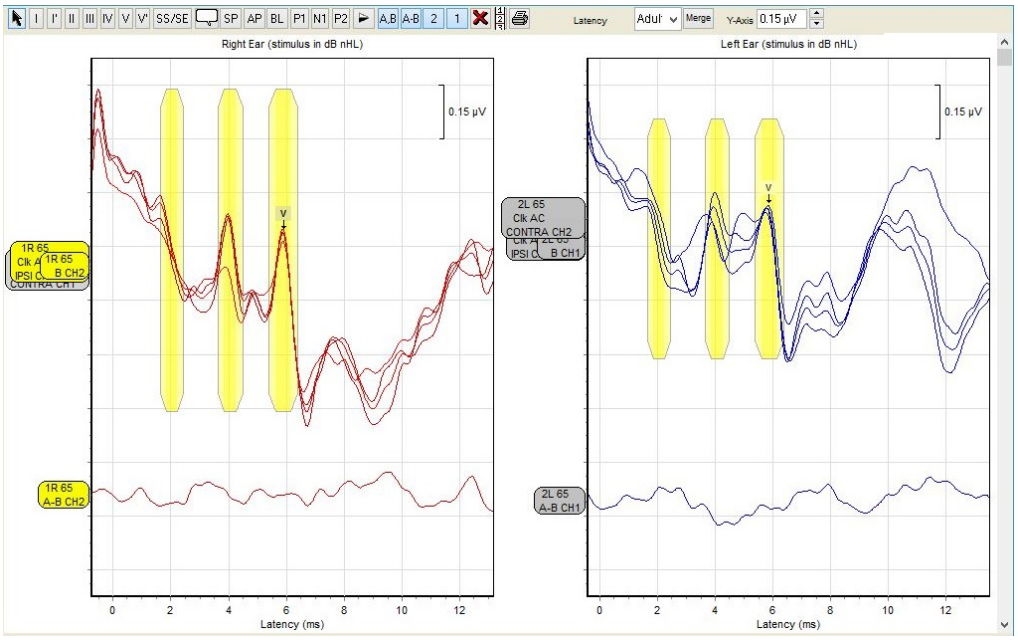


Figure 58. Right/Left Ear Split Chart view with a G2 system

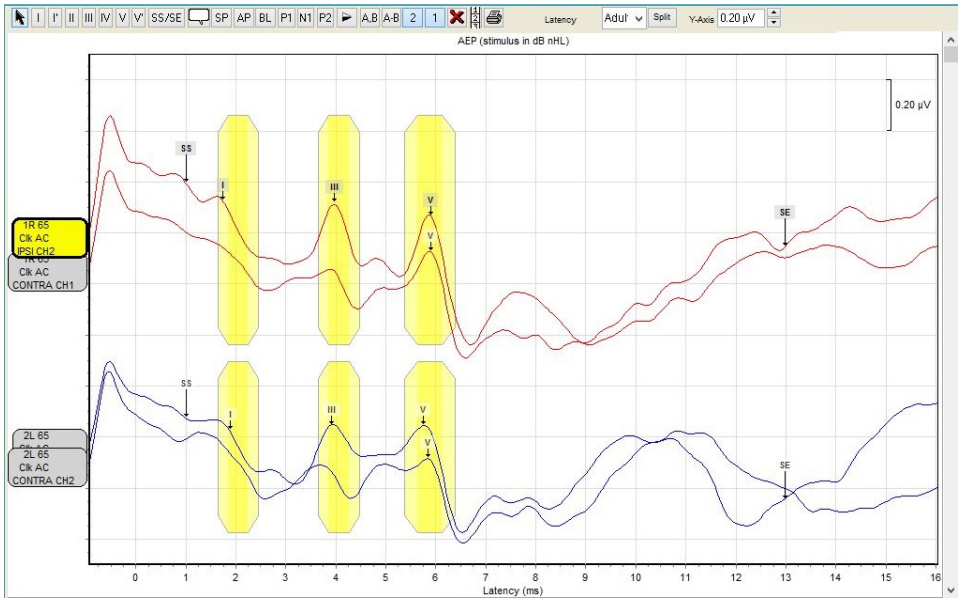


Figure 59. Merged Right/Left view with a G2 system

Waveform Handle

Each waveform is supplied with an individual handle located to the left of the graph.

	Unselected handle	Selected handle
G1 System	1R 65 1kHz AC R	2L 65 1kHz AC R
G2 Sytem	1R 65 1kHz AC R IPSI CH2	2L 65 1kHz AC R IPSI CH1

Figure 60. Waveform Handles

All waveform handles have a tagging line which displays the following information:

- The waveform **number** identifies the relative order in which the waveform was collected. The same number is also displayed in the **Waveform Information** to associate the waveform with its corresponding data.
- **R** or **L** indicates the recording as the **right** ear or the **left** ear.
- The **stimulus level** of this test according to the unit selected in the System screen.
- The second line describes the stimulus used, where:
  - Clk = click
  - Chp = chirp
  - AC = air conducted
  - BC = bone conducted
  - 500-4kHz = Tone Burst using that frequency

- **IPSI** or **CONTRA** (on a G2 system) indicates ipsilateral and contralateral traces. Both the ipsilateral and the contralateral traces will be of the same color.

  Ipsilateral – the 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, Fz, 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, Fz, Fpz, Nz, Oz locations for the non-inverting (+) electrode and A1, M1, EAC1 for the inverting (-) electrode.

  Contralateral – the 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, Fz, 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, Fz, Fpz, Nz, Oz locations for the non-inverting (+) electrode and A2, M2, EAC2 for the inverting (-) electrode.

- Channel (on a G2 system) of the non-inverting electrodes, where **CH1** is assumed to be placed on the left side and **CH2** is assumed to be placed on the right side.

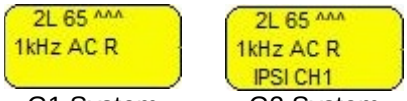
To select a waveform, click on its handle. You can use the handle to drag the waveform along the vertical axis.

To select multiple waveforms, press the **Ctrl** key on your keyboard and click on the handle of each waveform. You can move all selected waveforms at once.

Inverting Waveform tool

By selecting a waveform and clicking on the  inverting button on the toolbar, the selected waveform is flipped along the horizontal access. This can be done to any waveform even the current collecting waveform.

When a waveform has been inverted from its original collected state, the handle for the waveform will show a "^" in the title, and in the test conditions table it will be marked as "waveform inverted".



G1 System G2 System

Figure 61. Handle of an Inverted Waveform

Label a Waveform

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

1. Select the handle of the waveform to be labeled.
2. Select a label from the labeling buttons (Figure 62) at the top of the **Waveform Window**.

3. A labeling button remains active until a different labeling button, or the arrow (selection) button, is selected.

Figure 62. Waveform Labeling Buttons

4. Place the cursor over the waveform to be labeled. Note that the location jumps to the peaks (peak positives) and troughs (peak negatives) of the wave.
5. When the correct peak or valley has been identified, click the mouse to place the label.
6. 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), (Elsayed, 2015) will appear in the Waveform Information Chart (Figure 68).
7. Once placed on the wave, the label can be deleted or moved.
8. Select another labeling button to place a different label, or use the arrow button to select another waveform.

To move a label, select the label and place it again following the steps above.

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.

A labeling button remains active until another labeling button is selected or the arrow button is selected.

Waveform Labels

Integrity provides several tools for marking your waveforms. The button marked SS – SE is used to mark the start and end region of the x-axis of the graph to be used for statistical data. Included in the list is a note feature, which allows you to attach a short blurb of text to the waveform.

SS/SE

Mark the start and end of the statistical data using the Statistical Start / Statistical End (SS/SE) button.

Note

The **Note** button is used to add comments to the graph.

Figure 63. Note Callout

To add a note:

1. Select the **Note** button.
2. Please the cursor over the waveform in the location desired.
3. Click the location to place the note.
4. Click inside the note box to start typing the content.
5. Use the pen icon in the top right corner to edit a previous note.
6. Use the minimize icon in the top right corner to reduce the size of the note.
7. Use the **X** icon in the top right corner to delete the icon.

A,B Display

The **A,B** button is used to display the independent A,B buffers, of which half the number of sweeps in buffer A, and the other in buffer B. The main waveform, A+B, is the amalgamated waveform comprised of A, and B.

1. Select the desired main waveform.
2. Press the **A,B** button located next to the Waveform Labeling buttons (Figure 62).
3. The main waveform, A+B, splits into its' A, and B buffers.
4. To hide the **A,B** buffers, press the **A,B** button again.
5. When the main A+B waveform is moved while A,B buffers are displayed, the A,B traces are locked to the A+B waveform by default. However, buffers A and B can still be moved individually on the graph area. This feature can be turned on/off on the system screen by selecting the "Lock Waveforms when hidden" check box.

A-B Display

The **A-B** button is used to display a waveform as a calculation of buffer A minus buffer B of the received signal. This display represents the noise floor.

When the main waveform, A+B, is moved while the A-B waveform is displayed, the A-B waveform is locked to the main A+B waveform by default. However, A-B waveform can still be moved individually on the graph area. This feature can be turned on/off on system screen by selecting the "Lock Waveforms when hidden" check box.

Figure 64. Waveform Window with A,B and A-B Display

Moving waveform displays together

Select the handle of the A-B waveform to move it around the graph. Select the handle of the original waveform to move both the original (A+B) and the A-B waveforms together.

Unlink waveform displays

To unlink two waveforms right click on the original waveform handle (A+B). A chain icon will appear above the handle. Click the chain icon. The waveforms that were previously moved together can now be moved independently of each other.

Figure 65. Linked and Unlinked Waveform Icon

Delete Waveform Button

To delete a wave from the Waveform Window:

1. Select a waveform handle.
2. Press the  button to delete the selected waveform.
3. Answer **Yes** when asked if you want to delete the wave.

To delete multiple waveforms, press and hold the **Ctrl** key while you select each waveform, then press the **Delete** (X) button. You will be prompted to confirm the deletion of all the selected waveforms.

NOTE

*The Delete button is unavailable when there is only one waveform selected or when all waveforms have been selected. To remove all waveforms on the graph, select the **Clear All** button.*

Page Break View

This button () is used to view the waveforms on a page. This allows you to make adjustments to the layout of your waveforms before printing.

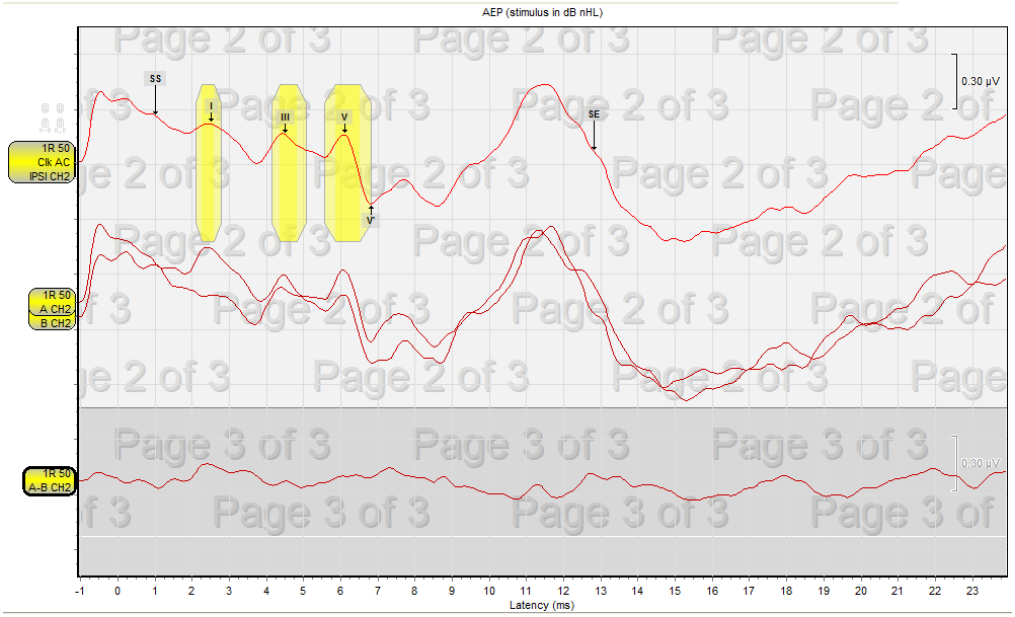


Figure 66. Page Break View

Latency Norms

Integrity provides a graphical presentation of the normative data for latencies I, III and V. The list contains normative data for **click stimulus only**.

To view normative latency data for waves I, III and V, do the following:

1. Select one or more waveforms.
2. Select the **Latency Norms** drop-down list to view the normative data list.
3. Latency norms that match, or most closely match, the stimulus intensity level of the selected waveform, are listed at the top. All available norms are listed below this.
4. The normative data graphs for waves I, III and V latencies will be shown in the **Waveform Window** as short yellow vertical bars representing +/- 2 standard deviations from the population mean (Figure 56).
5. The **Waveform Information Chart** (Figure 68) displays the normative data title and the level of intensities for the latency norms shown.

You can also view a single latency value by pointing to a waveform with your mouse pointer. The Latency and Amplitude values are displayed in a small window in the upper right corner of the screen.

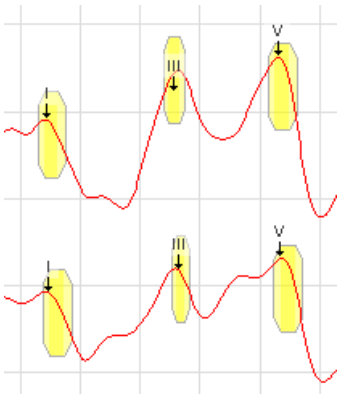


Figure 67. Latency Norms

For the source and value of the ABR latency normative data, refer to Appendix A: ABR Latency Norms Data.

NOTE

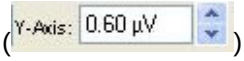
Custom latency norms can be introduced to the system by editing the Latency Norms file:

C:\Program Files (x86)\Vivosonic\Integrity\Integrity Norms\ABR\ LatencyNormals.ini

When editing the Latency Norms file, 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.*

It is recommended 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 are no international standardized data available at this time.

Y-Axis Scale

Use the **Y-axis scale** (

) located at the top of the **Waveform Window** to change the scale of the amplitude. The scale can be any value between 0.05 to 100.0 µV.

Changing the scale affects only the display – it does not affect the recorded data.

Use the up or down arrow to increase or decrease the scale by steps of 0.05 µV. If you type a value in the field, the scale will display to the nearest 0.05 µV step.

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 56).

Test Conditions	Corr. Coef.	RN µV	I ms	I' ms	II ms	III ms	IV ms	V ms	V' ms	I-III ms	III-V ms	I-V ms	I-I' µV	V-V' µV
1R 60 IPSI CH2: Right ear, Pro=ABR air-conducted click 27.5, Stim.=27.5, User Montage=---, Click, ER-3A, Pol=Rare., Alg=Kal., N=3376, Rej.=0%, Neq.=3200, CFILE=8.3.3 RETSPL	0.10	0.012	1.67	2.25	3.08	3.65	4.07	5.53	6.00	1.98	1.88	3.86	0.01	0.03

Figure 68. Waveform Information Chart

For each collected waveform, the **Waveform Information Chart** displays this information:

1. The **wave number** corresponding to the handle of each waveform. This appears as the first number in each row of the **Test Conditions** column.
2. The **Test Conditions** column also lists the test conditions for each waveform.
    - Stimulated ear: Right ear, Left ear
    - Transducer type: insert earphones, circumaural earphones or bone conductor
    - Protocol used (Pro)
    - Stimulus type: Click, 0.5K, 1.0K, 2.0K, 4.0K
    - Stimulus rate: e.g. 27.7 or 37.7
    - Stimulus Polarity (Pol), Con (Condensation), Rare (Rarefaction), Alt (Alternating), and Alt Split (Alternating split)
    - Response processing algorithm (Alg): Kal (SOAP-Kalman Weighted), Ave (Averaging), SOAP-Kalman Plus
    - Number of stimuli (N)
    - Percentage of rejected stimuli (will be displayed only if averaging signal processing algorithm was applied)
    - Noise adjusted sweeps (Neq)
    - Stimulus rate
    - Information about the used conversion file is only printed when 8.3.3 RETSPL file is used: CFILE=8.3.3 RETSPL
    - Invert status of waveform.
3. Latency values for each labeled peak, in milliseconds with an accuracy of 0.01 ms
    - I – III interpeak latency. The value is displayed only when peaks I and III have been labeled.
    - III – V interpeak latency. The value is displayed only when peaks III and V have been labeled.
    - I – V interpeak latency. The value is displayed only when peaks I and V have been labeled.
    - Wave I amplitude. The value is displayed only when the positive (**I**) and negative (**I'**) peaks of wave I are labeled.
    - Wave V amplitude. The value is displayed only when the positive (**V**) and negative (**V'**) peaks of wave V are labeled.
    - P1-N1µV used for ABR extended window measurements
    - N1-P2 µV used for ABR extended window measurements
    - P1-N1 ms – latency of these two markers used for ABR extended window testing
    - N1-P2 ms - latency of these two markers used for ABR extended window testing
    - P1, N1, P2 ms value and µV values
    - ECochG labels (SP,AP, BL)
4. Statistical Start and Statistical End points (**SS/SE**)

5. Correlation Coefficient (**Corr, Coef**). The **Correlation Coefficient** indicates the degree to which the collected waveforms in A and B are repeatable in a specific interval that is defined by **SS**/**SE.**

6. Residual Noise (**RN**) - Residual Noise is a statistical measure of the noise remaining in the ABR (A+B trace) after processing and averaging. It is the standard deviation of the (A-B) noise estimate, measured from 1 to 13 msec and is given in units of 'µV rms'.

If no repeatable response is visible in the A and B waveforms there are two possibilities – either there is no response to the stimulus or there is a response but it is undetectable because there is too much noise. RN is used as a criterion to determine when there is no response to the stimulus. As a rule of thumb, threshold-level ABR responses are usually visible when the RN is less than about **0.02** µV rms, so if there is no repeatable response and RN is less than **0.02** µV rms, it can be assumed that there is no clinically significant response.

NOTE

*For effective use of the correlation statistic refer to Appendix D:*Effective Use of Correlation Coefficient

Use the **Latency-Intensity** button to display your latency values graphically. Refer to Figure 53. **Latency-Intensity Graph** on page 70.

NOTE

The SS value must be placed so that the SE is greater than SS. If SS is greater than SE than the Correlation value (Corr.) of the two points will be invalid.

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 in the **Waveform Window** to display the corresponding data at the top of the chart.*

Close the Test Screen

Your test data must first be saved or discarded before you leave the **Test** screen.

To exit the **Test** screen:

1. Press the **Save** button to save your data to records in the database.
2. Press the **Clear All** button to remove all test data from the screen.

Any data that has not been saved will be deleted. A warning dialog box will prompt you to confirm your action.

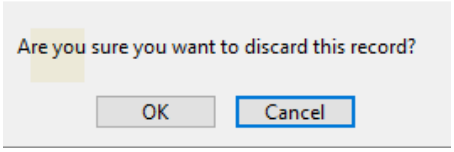


Figure 69. Are you sure you want to discard this record?

Post Test Review

The ABR Database Screen Waveforms

To view test data that has been saved in the database:

1. Select the **Database** tab to view the initial preview screen.
2. Select the **Expand** button for a full screen view of your data (Figure 71). This view allows you to label waveforms and use the analysis functions.

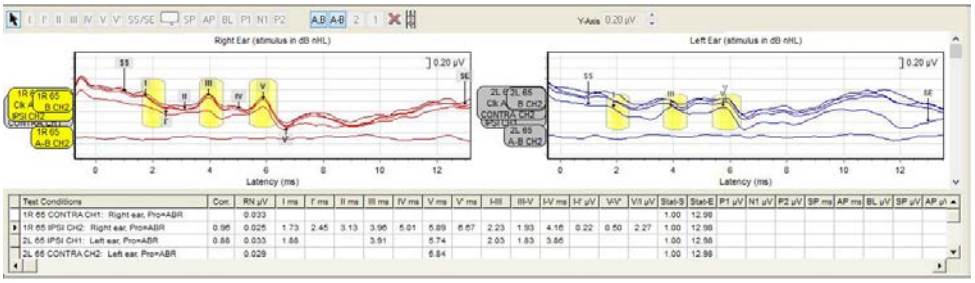


Figure 70. Database Waveform Information for ABR

Figure 71. Expanded Database Waveform Window

The following functions are available from the **Expanded Database Waveform Window**:

- Activate (highlight) a waveform by selecting the waveform's handle.
- Move highlighted waveforms along the vertical axis.
- Label the peaks of the highlighted waveform using the waveform markers.
- Place Statistical Start and Statistical End (SS/SE) markers to define the period in which correlation coefficient will be calculated

NOTE

*For effective use of the correlation statistic refer to Appendix D:*Effective Use of Correlation Coefficient

- View A-B, A, or B trace.
- Change the waveform's presentation scaling.
- Delete the highlighted waveform.
- View the page break preview
- Print a complete test record for the selected trace.
- 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 waveform's 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 are stored in the database and displayed in 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**.*

Database Controls

The database controls for ABR include two unique buttons: **Expand** and **Latency-Intensity**. Refer to Database Controls on page 39 for details about the other buttons.

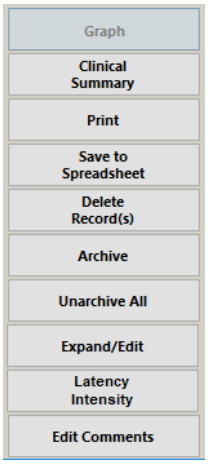


Figure 72. Database Controls for ABR

Expand/Edit button

The waveforms can be displayed in a full screen format for easier viewing (Figure 71).

1. Select the **Expand/Edit** button.
2. Select the red X ( ) to close the **Expanded Database Waveform Window**.

Latency-Intensity button

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

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

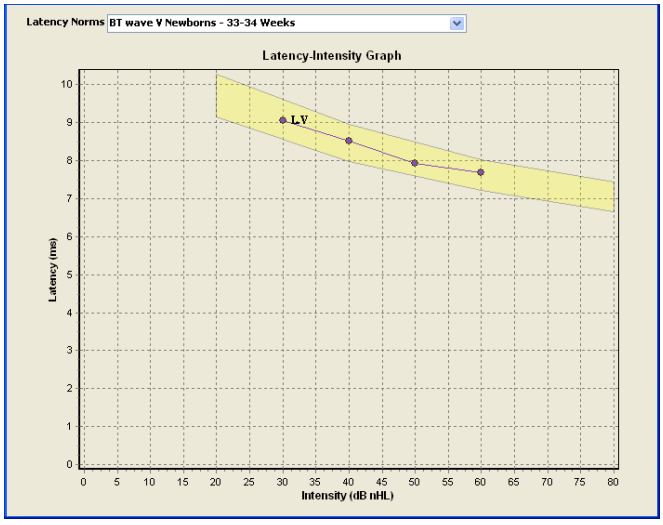


Figure 73. Latency-Intesity Graph

Residual Noise

Residual Noise (RN) is a statistical measure of the noise remaining in the ABR (A+B trace) after processing and averaging. It is the standard deviation of the (A-B) noise estimate, measured from 1 to 13 msec and is given in units of 'µV rms'. Residual noise measure is updated with every updated A and B trace.

If no repeatable response is visible in the A and B waveforms there are two possibilities – either there is no response to the stimulus or there is a response but it is undetectable because there is too much noise. RN is used as a criterion to determine when there is no response to the stimulus. As a rule of thumb, threshold-level ABR responses are usually visible when the RN is less than about 0.02 µV rms, so if there is no repeatable response and RN is less than 0.02 µV rms, it can be assumed that there is no clinically significant response.

ABR Auto-Recovery

Should Windows crash during a test, Integrity will recover the data for you when you restart the machine.

The software will start as normal and present a dialog box as follows:

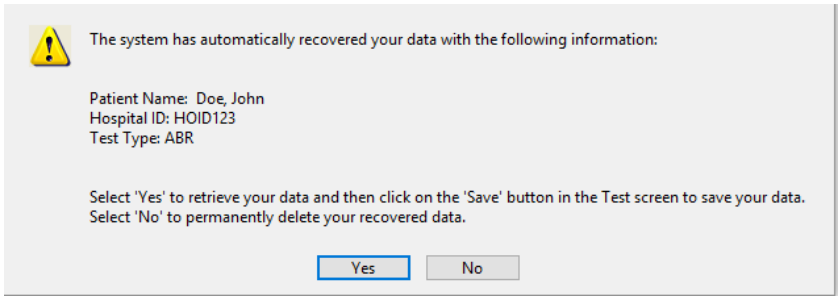


Figure 74. ABR Auto-Recovery Dialog Box

Selecting ″No″ will delete this recovered data **PERMANENTLY**.Selecting ″Yes″ automatically takes you to the ABR Test screen with the recovered traces.

Chapter 4: Performing an ASSR Test

Place the VivoLink on the Patient

1. Prepare the patient according to the instruction in the Integrity V500 Quick Reference.
2. In the **Test** screen, select ASSR as the **Test Type**.
3. Select an appropriate protocol from the **Applied Protocol** drop-down menu.

   CAUTION

   Improper configuration of test protocols may result in poor quality test results. Use clinically validated protocols for screening and assessment.
4. You may choose to override protocol parameters (such as frequencies to be tested) and the range of stimulus levels in the **Test** screen.
   a. The specific frequencies to be tested for each ear can be selected using the frequency selection boxes located in the ASSR-gram.
   b. Choose a Masking Type value. This control regulates the introduction of contralateral wideband masking noise.
      - Select **Wide Band Noise** to apply masking through the insert earphones or circumaural earphones opposite to the ear which is stimulated with the selected stimuli. The masking frequency characteristic is wideband, i.e. it includes the entire frequency band of the transducers used with Integrity.
      - Select **None** to test without masking. This is the System default.
   c. The range of levels for all the stimuli can be adjusted using the slider controls shown below.
   d. The starting level of each of the stimuli may be set to the same level using the universal adjustment bar or individually set by sliding the starting point indicator
5. There is a setting in the **System** screen that forces an impedance check to be done prior to pressing the **Start** button.
6. Press **Start** to begin a test. The **Start** button changes to a **Stop** button.
   - Press **Pause** to stop the test temporarily.
   - Press **Resume** or the **Stop** button to proceed.

   Refer to Test Control Buttons on page 23 for more information about Start/Stop, Pause/Continue, and Save features.
7. Monitor the **EEG Window** (Figure 8) and visually estimate the amplitude of the EEG signal.

   TIP

   The lower the EEG value, the better the electrode contact. Re-apply the electrodes if the EEG remains above +/- 50 µV.
   - *+/- 5 µV (illustrated via two horizontal blue lines) or less is best*
   - *+/- 20 µV may still be acceptable, but will require longer Algorithm Time*
   - *+/- 50 µV indicates a problem, reapply the electrodes*

   When excessive noise is found in an AEP test, do the following:
   *A. Monitor the status of the **Electrode Contact LED Indicator**. If the*

*LED is **amber**, adjust your electrodes for better contact. If necessary, replace electrodes or re-prepare the skin area.*

B. *You may also **Check Impedance** to identify the impedance between electrodes. With the new G2 system, an absolute impedance value for each electrode can be determined. If the indicator bar is **amber** or **gray**, then check and adjust your electrodes.*
Remove the electrodes, re-prepare the patient's skin and replace the electrodes. When the noise is reduced, reconnect the Amplitrode or the VivoAmp and its clips to the patient and continue patient testing.

8. The ASSR-Gram in the Test Screen will illustrate the progress of the test. Check marks in each of the four frequencies indicate that these frequencies are being tested and a threshold has not been found. A green halo around a test point indicates that the corresponding frequency and level is being tested. A yellow halo around a test point indicates that testing at that frequency and level has been temporarily paused. Testing will resume automatically.
9. Tests may pause when stimulus from that run exceeds OSHA recommendations for daily noise exposure; however, the audiologist can chose to override this warning. The audiologist should use their professional judgment when performing ASSR tests over prolonged period.
10. Testing may be paused at any time by pressing the PAUSE button in the Test Screen. This may be necessary when the subject moves a lot; however, small movement and coughing will not affect the overall measurement process.
11. The Probability and Noise estimate graphs at the bottom of the screen will also show the progress of the test. The Probability graphs indicate the likelihood of presence of an ASSR at the corresponding frequency for the particular stimulus level. The Noise Estimate graphs give the noise estimate of the incoming signal at the corresponding frequency for the particular stimulus level. These will tend to decrease as the test progresses and more data is processed.
12. There are 3 controls above the ASSR-Gram. From left to right they are: a toggle to show or hide ASSR trials, a toggle to show or hide the ASSR thresholds without the ASSR adjustment factors applied, and a dropdown to set ASSR adjustment factors. An ASSR adjustment factor is applied to an ASSR threshold to estimate actual hearing thresholds because ASSR thresholds typically overestimate behavioral thresholds. If you select the Modify option at the bottom of the list, these adjustments can be modified in a separate pop-up.
13. Press **Save** to save the data collected.
14. Press **Clear All** to clear the **ASSR-gram Window**. If the graph is cleared before the results are saved, the data will be lost.
15. Press **Print** to print the test results.

Show/Hide Trace and Adjustment Factors Button

The two buttons located on the top left of the ASSR screen in both the test screen and the database screen are used to show features on the ASSR-Gram. Specifically, the ability to show the trace history and the ability to show the adjustment factors.

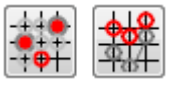


Figure 75. Trace History and Adjustment Factors button

The trace history button is used to show all of the levels that were tested. The Adjustment factor button shows the adjusted values relating to an audiogram. Note that it is required that the ASSR test finished and found thresholds in order to show adjusted results.

Define an ASSR Protocol

Test parameters are set from the **Protocol** screen. To create a new protocol, modify an existing protocol, and then save it with a new name. All ASSR protocol settings may also be modified from the Test screen.

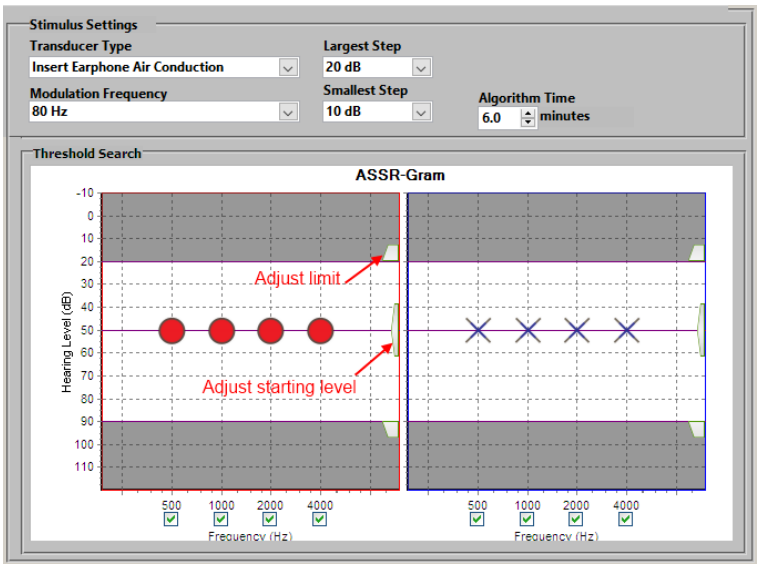


Figure 76. ASSR Protocol Stimulus Settings and Threshold Search

The parameters of ASSR protocol are divided into two categories: Stimulus Settings and Threshold Search.

The Stimulus Settings are used to select the stimulation parameters such as modulation frequency, automatic threshold search steps (largest and smallest step sizes) and Algorithm Time.

The Threshold Search controls the specific frequencies to be tested (500 Hz, 1k Hz, 2k Hz, and 4k Hz) in each ear and, maximum and minimum stimulus levels for automated searching of threshold.

Stimulus Settings

Transducer Type The user may select insert earphones or circumaural earphones.

Modulation Frequency: The user may select either 40 Hz or 80 Hz family of modulation frequencies. The 80 Hz modulation frequency is recommended for a calm and relaxed subject. Response to 40 Hz modulation frequency is only present in awake subjects.

Largest Step: This parameter determines the step size of successive stimulus levels when an ASSR response is detected at the preceding level.

Smallest Step: This parameter determines the step size of successive stimulus levels when an ASSR response is not detected at the preceding level.

Algorithm Time: This is approximately the maximum test time allotted per level per frequency per ear. If an ASSR response is not obtained with this allotted time, a stimulus at a higher level is delivered to that ear at the same frequency. If the automated search reaches either end of the range of stimulus levels and no responses are obtained within the allotted Algorithm Time, a corresponding symbol is placed at that level to indicate that the true threshold exists beyond the threshold.

Threshold Search

Maximum/minimum stimulus levels: Use the slider controls indicated in above figure to adjust maximum and minimum stimulus levels for automated threshold searching.

Initial stimulus levels: The initial stimulus level for each frequency can be adjusted. Use the slider control to adjust the default stimulus level set in the protocol. To set the initial stimulus level for a specific frequency, move the individual "threshold search control" for that frequency to the desired stimulus level. For example, if you are testing the right ear and you wish to set the initial stimulus level for 2k Hz to 60 dB, drag the corresponding threshold search control (*i.e.*, red circle) to 60 dB.

Test frequencies: Stimulus frequencies presented to each ear may be selected using check boxes located immediately below each of the four frequencies per ear. These frequencies are approximately the center frequency of the chirp stimulus that is specific to Integrity's ASSR test modality.

CAUTION

Prolonged testing at high levels of stimulation can cause damage to the hearing system. The practitioner should exercise professional judgment when setting the maximum stimulus level.

During the Test

The ASSR Test Screen

EEG Window

Please refer to EEG Window on page 23 for detailed information.

Ongoing EEG

Please refer to Ongoing EEG on page 23 for detailed information.

Electrode Contact

Please refer to Electrode Contact on page 24 for detailed information.

Close the Test Screen

Your test data is automatically saved throughout testing.

To exit the **Test** screen:

1. If you want to save your results in the database, press the **Save** button to save your data to records in the database.
2. Press the **Clear All** button to remove all test data from the screen.

   Any data that has not been saved will be deleted. A warning dialog box will prompt you to confirm your action.

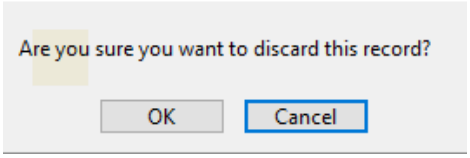


Figure 77. Are you sure you want to discard this record?

ASSR Auto-Recovery

Should Window's crashes during a test, Integrity will recover the file for you when you restart the machine, and ask you if you would like to continue testing that patient. The software will start as normal and present a dialog box as follows:

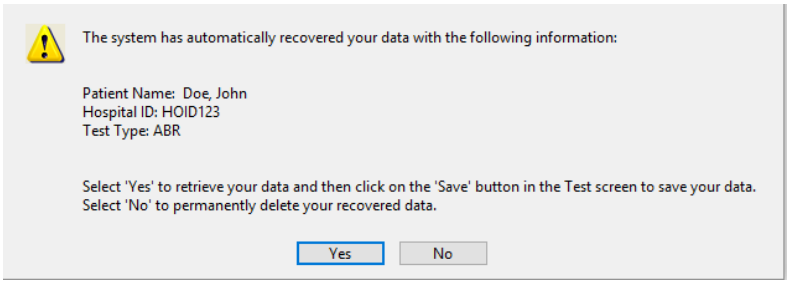


Figure 78. Recover ASSR Record Dialog Box

Selecting ″No″ will delete this recovered record **PERMANENTLY**.

Selecting ″Yes″ will automatically take you to the ASSR Test screen with the recovered test in *Pause* mode. You may continue to test as normal where you had left off.

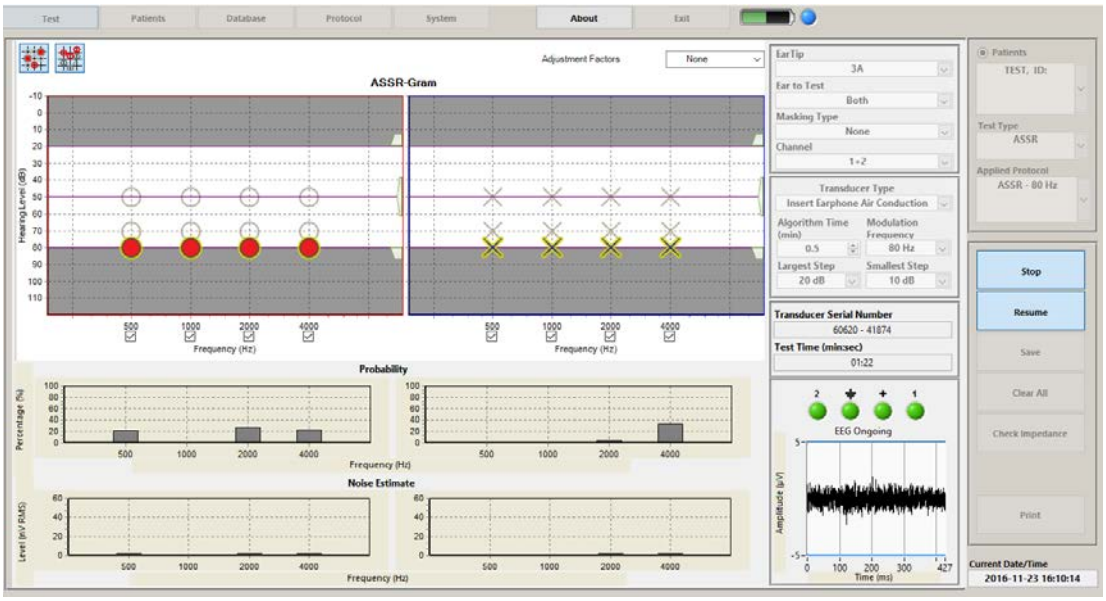


Figure 79. A recovered ASSR Test in pause mode

Post Test Review

The ASSR Database Screen

To view test data that has been saved in the database:

1. Select the **Database** tab.
2. Find the record with the ASSR results that you want to see.
3. Select the row by clicking on the button beside the record.
4. ASSR results will appear below the list of records.

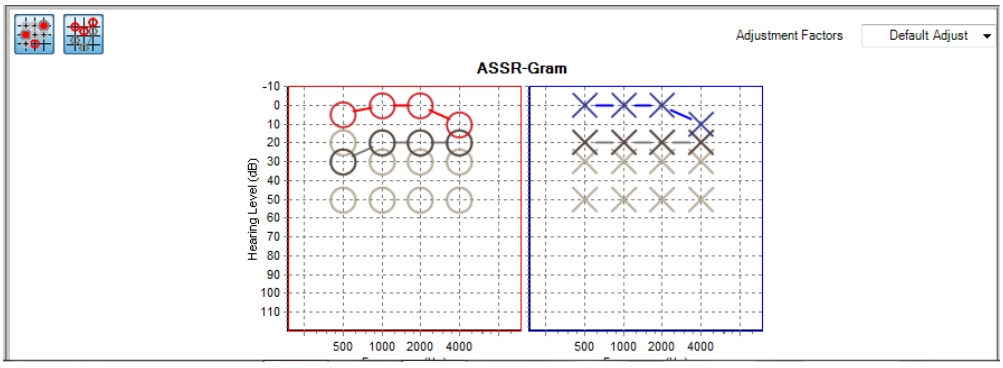


Figure 80. ASSR result from Database Screen

Note that the show / hide buttons for the trace history and adjustment factors can be used from the database screen, as well as the usual test screen functions (print, add clinical summary, delete, archive etc..).

Chapter 5: Overview of 40 Hz Event-Related Potential Testing

40 Hz ERP Test Preparation

1. Prepare the patient according to the instructions in the Integrity V500 Quick Reference.
2. Choose a patient from the patient list.

   To perform a test, select at least one patient name from the list of existing patients, or add a new patient name.
3. Open the **Test** screen and select 40 Hz ERP from the **Test Type** list.

   The Bluetooth LED starts to flash when your computer recognizes the presence of the VivoLink and begins to download information to it.

   When the download of information is complete, the Bluetooth LED stops flashing and remains solid blue. If the connection is lost during the download process, the Bluetooth LED indicator appears unlit.

The 40 Hz ERP Test Screen

To conduct a 40 Hz ERP test, perform the following steps:

1. In the **Test** screen, make sure 40 Hz ERP is selected as the **Test Type**.
2. Select an appropriate protocol from the Applied Protocol drop-down menu.
3. You may choose to override protocol parameters (such as frequency to be tested) and the stimulus levels in the Test screen.
   a. Choose a Masker value. This control regulates the introduction of contralateral wideband masking noise.
      - Select **Wide Band Noise** to apply masking through the insert earphones or circumaural earphones opposite to the ear which is stimulated with 40 Hz stimuli. The masking frequency characteristic is wideband, i.e. it includes the entire frequency band of the transducers used with Integrity.
      - Select **None** to test without masking. This is the System default.

   b. The specific frequency to be tested for each ear can be selected using the Center Frequency drop-down menu.

   c. The range of levels for all the stimuli can be adjusted using the slider and/or edit box Level control shown below.

   d. When using a 2-Channel Amplifier, the 40 Hz ERP will default to an ipsilateral test. This means that when the testing ear is set to Right, the channel will automatically be set to 2. Similarly, when switching the ear to Left, the channel will automatically set to 1. However, to keep the same channel for testing both ears, the channel must be manually selected from the Channel drop down.

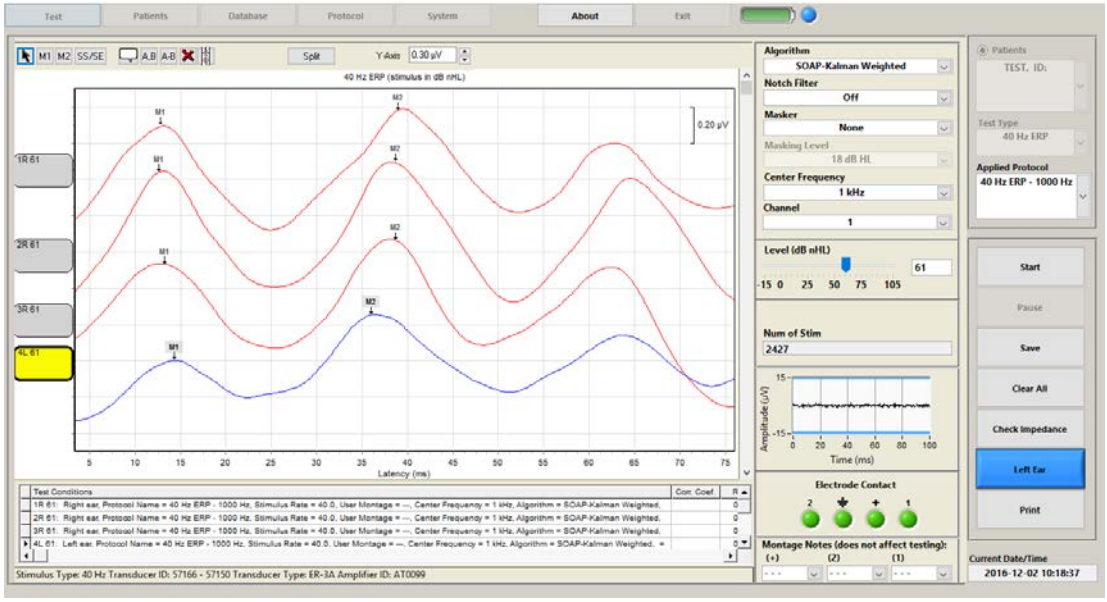


Figure 81. 40 Hz ERP Test Screen

Check Impedance

Please refer to Check Impedance on page 27 for detailed information.

Start the Test

Press **Start** to begin a test. The **Start** button changes to a **Stop** button.

- Press **Pause** to stop the test temporarily.
- Press **Resume** or the **Stop** button to proceed.

Refer to Test Control Buttons on page 23 for more information about Start/Stop, Pause/Continue, and Save features.

EEG Window

TIP

Please refer to EEG Window on page 23 for detailed information.

The lower the EEG value, the better the electrode contact. Re-apply the electrodes if the EEG remains above +/- 50 µV.

- *+/- 5 µV (illustrated via two horizontal blue lines) or less is best*
- *+/- 20 µV may still be acceptable*
- *+/- 50 µV indicates a problem, reapply the electrodes*

Electrode Contact

Please refer to Electrode Contact on page 24 for detailed information.

Waveform Window

This Waveform Window displays the graphic representation of the collected waveform as a function of the amplitude (µV) of the signal over time (ms).

The waveforms collected from the left and right ears are displayed on the same graph and are distinguished by the color of the waveform. Recordings for the right ear are indicated by red waveforms, and recordings for the left ear are indicated by blue waveforms.

The **Waveform Window** is used when monitoring data in real time and when analyzing and labeling waveforms. Each **Start** and **Stop** during a test session produces a new waveform.

To zoom or magnify the waveform window, drag your mouse from left to right. To restore the display to its original magnification, drag your mouse from right to left.

You can also view a single latency value by pointing to a waveform with your mouse pointer. The Latency and Amplitude values are displayed in a small window in the upper right corner of the window.

Waveform Handle

Each waveform is supplied with an individual handle located to the left of the graph.

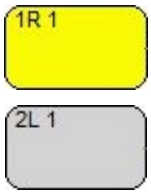


Figure 82. Waveform Handles

All waveform handles have a tagging line which displays the following information:

- The waveform **number** identifies the relative order in which the waveform was collected. The same number is also displayed in the **Waveform Information Chart** (Figure 68) to associate the waveform with its corresponding data.
- **R** or **L** indicates the recording as the right ear or the left ear.
- The **stimulus level** of this test according to the unit selected in the System screen.

To select a waveform, click on its handle. You can use the handle to drag the waveform along the vertical axis.

To select multiple waveforms, press the **Ctrl** key on your keyboard and click on the handle of each waveform. You can move all selected waveforms at once.

Waveform Labels

The 40 Hz ERP test screen allows you to mark 2 peaks in the 40 Hz ERP waveform to measure the time between peaks. For a 40 Hz waveform the time between successive peaks should be approximately 25 +/- 1 ms. To mark the peaks use the ″m1″ and ″m2″ cursor tools in the upper left corners of the test screen. The time between m1 and m2 is displayed in the table underneath the waveform.

Note

The **Note** button is used to add comments to the graph.

Figure 83. Note Callout

To add a note:

1. Select the **Note** button.
2. Please the cursor over the waveform in the location desired.
3. Click the location to place the note.
4. Click inside the note box to start typing the content.
5. Use the pen icon in the top right corner to edit a previous note.
6. Use the minimize icon in the top right corner to reduce the size of the note.
7. Use the **X** icon in the top right corner to delete the icon.

A,B Display

The **A,B** button is used to display the independent A,B buffers, of which half the number of sweeps in buffer A, and the other in buffer B. The main waveform, A+B, is the amalgamated waveform comprised of A, and B.

1. Select the desired main waveform.
2. Press the **A,B** button located next to the Waveform Labeling buttons (Figure 62).
3. The main waveform, A+B, splits into its' A, and B buffers.
4. To hide the **A,B** buffers, press the **A,B** button again.
5. When the main A+B waveform is moved while A,B buffers are displayed, the A,B traces are locked to the A+B waveform by default. However, buffers A and B can still be moved individually on the graph area. This feature can be turned on/off on the system screen by selecting the "Lock Waveforms when hidden" check box.

A-B Display

The **A-B** button is used to display a waveform as a calculation of buffer A minus buffer B of the received signal. This display represents the noise floor.

When the main waveform, A+B, is moved while the A-B waveform is displayed, the A-B waveform is locked to the main A+B waveform by default. However, A-B waveform can still be moved individually on the graph area. This feature can be turned on/off on system screen by selecting the "Lock Waveforms when hidden" check box.

Moving waveform displays together

Select the handle of the A-B waveform to move it around the graph. Select the handle of the original waveform to move both the original (A+B) and the A-B waveforms together.

Unlink waveform displays

To unlink two waveforms right click on the original waveform handle (A+B). A chain icon will appear above the handle. Click the chain icon. The waveforms that were previously moved together can now be moved independently of each other.

Figure 84. Linked and Unlinked Waveform Icon

Delete Waveform Button

To delete a wave from the Waveform Window:

1. Select a waveform handle.
2. Press the  button to delete the selected waveform.
3. Answer **Yes** when asked if you want to delete the wave.

To delete multiple waveforms, press and hold the **Ctrl** key while you select each waveform, then press the **Delete** (**X**) button. You will be prompted to confirm the deletion of all the selected waveforms.

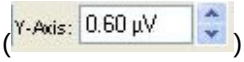
NOTE

*The Delete button is unavailable when there is only one waveform selected, or when all waveforms have been selected. To remove all waveforms on the graph, select the **Clear All** button.*

Page Break View

This button () is used to view the waveforms on a page. This allows you to make adjustments to the layout of your waveforms before printing.

Y-Axis Scale

Use the **Y-axis scale** (

) located at the top of the **Waveform Window** to change the scale of the amplitude. The scale can be any value between 0.05 to 100.0 µV.

Changing the scale affects only the display—it does not affect the recorded data.

Use the up or down arrow to increase or decrease the scale by steps of 0.05 µV. If you type a value in the field, the scale will display to the nearest 0.05 µV step.

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**.

For each collected waveform, the **Waveform Information Chart** displays this information:

The **wave number** corresponds to the handle of each waveform. This appears as the first number in each row of the **Test Conditions** column.

The **Test Conditions** column also lists the test conditions for each waveform.

- Stimulated ear: Right ear, Left ear
- Protocol used (Pro)
- Center Frequency: 0.5K, 1.0K, 2.0K, 4.0K
- Number of stimuli (N)
- Noise adjusted sweeps (Neq)
- m1 latency, m2 latency and the difference between m1 and m2.

Defining a Custom 40 Hz ERP Protocol

Test parameters are set in the **Protocol** screen. To create a new protocol, modify an existing protocol, and then save it with a new name. All 40 Hz ERP protocol settings may also be modified from the Test screen.

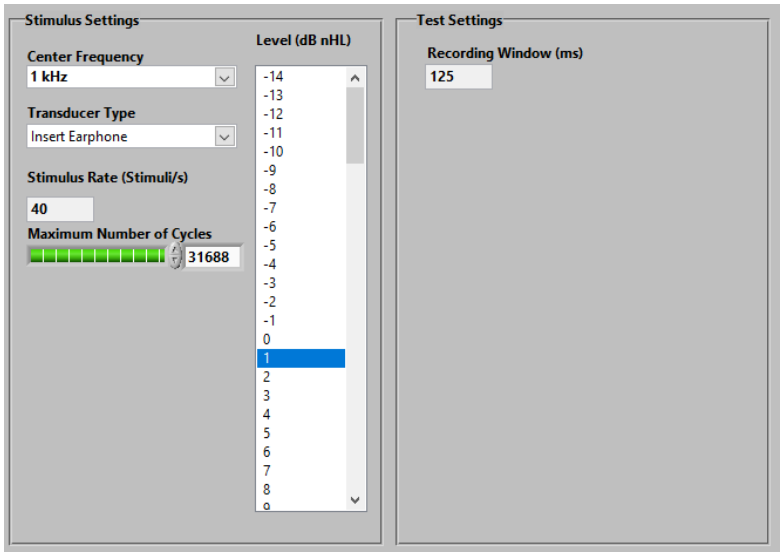


Figure 85. 40 Hz ERP Protocol Stimulus Settings and Threshold Search

The 40 Hz ERP protocol settings are used to select the default center frequency (500Hz, 1kHz, 2kHz, and 4kHz), the maximum number of 40 Hz cycles to test and the stimulus levels to test.

CAUTION

Prolonged testing at high levels of stimulation can cause damage to the hearing system. The practitioner should exercise professional judgment when setting the maximum stimulus level.

Post Test Review

The 40Hz Database Screen

To view test data that has been saved in the database:

1. Select the **Database** tab.
2. Find the record with the 40Hz results that you want to see.
3. Select the row by clicking on the button beside the record.
4. A preview of the test results will appear at the bottom of the screen.
5. Click on the Expand/Edit button to view the results in a large window, with the ability to add or change the placement of markers.

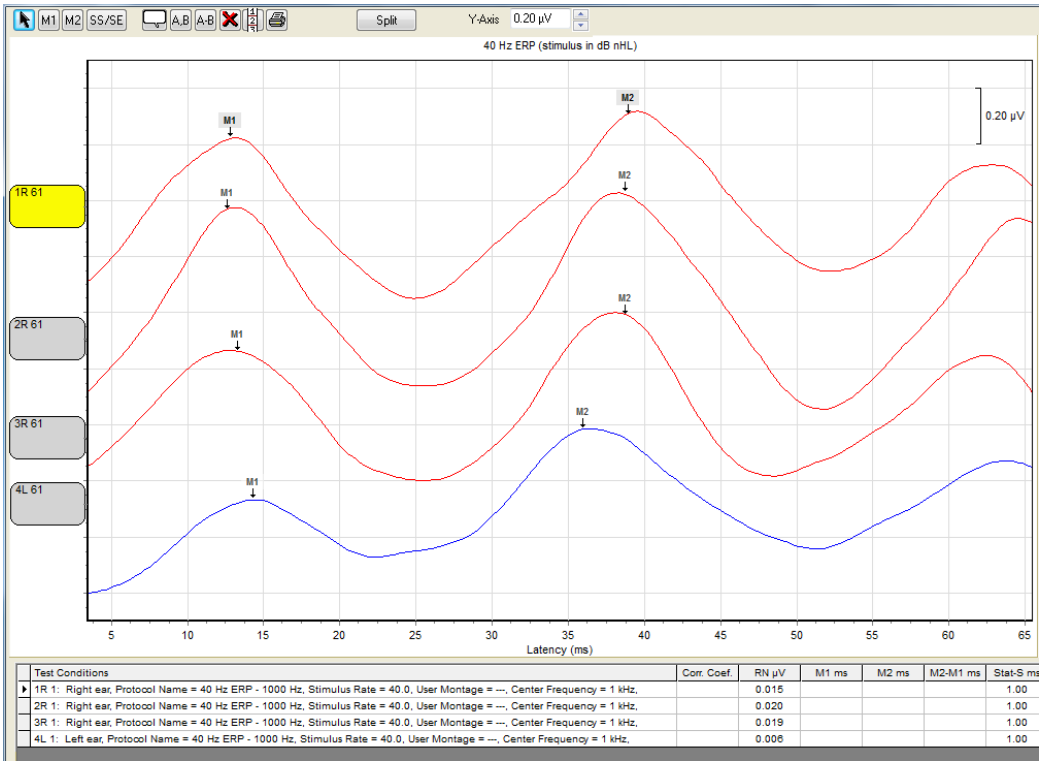


Figure 86. 40 Hz Test result from Database Expand Edit button

Note that all markers can be placed or moved and are saved in the database. The usual test screen functions (print, add clinical summary, delete, archive etc.) can also be performed from the main database screen on 40Hz results.

Chapter 6: Overview of TEOAE Testing

1. Choose a patient from the **Patients** screen.

   To perform a test, select at least one patient name from the list of existing patients, or add a new patient name.

2. Open the **Test** screen and select TEOAE from the **Test Type** list.

   The Bluetooth LED starts to flash when your computer recognizes the presence of the VivoLink and begins to download information to it.

   When the download of information is complete, the Bluetooth LED stops flashing and remains solid blue. If the connection is lost during the download process, the Bluetooth LED indicator appears unlit.

3. The OAE Probe calibration and the system may then be checked by pressing the Cavity Check button on the Test screen. The Cavity check is measured in the cavity of the OAE Probe holder.

   If the Probe calibration is correct and the System Transient Response (TR) and noise floor are within their tolerances, the system status is reported in the Message and Assessment Window as “Cavity Check Passed”

   If there is a problem with OAE Probe calibration, excessive System TR, system noise, or ambient noise, then a message describing the problem(s) will appear in the Message and Assessment Window.

   Follow the instructions on the screen. If a problem persists, contact Customer Support.

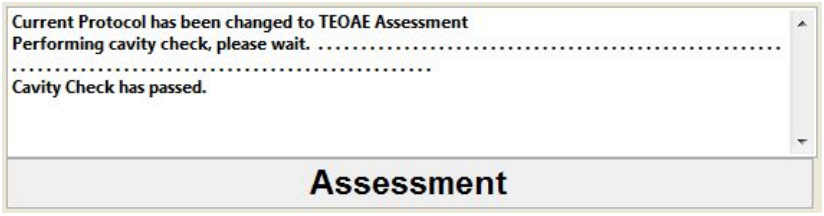


Figure 87. Message and Assessment Window

Define a TEOAE Protocol

Protocol parameters for TEOAE are set from the **Protocol** screen.

To create a new protocol, you must modify an existing protocol, and save it with a new name. Refer to Protocol Settings on page 46 for instructions.

Protocol parameters which can be preset from the **Protocol** screen include: Stimulus Parameters, Test Controls, Operating Mode, Pass/Refer Criteria, and Validity Criteria.

- **Stimulus Parameters** are used to select the stimulus mode, stimulus duration, stimulus interval and stimulus level.
- **Test Controls** set the acquisition conditions of the waveform recording, such as high-pass and low-pass filter settings, recording window, number of clicks, and the artifact rejection threshold (relevant only when using the averaging algorithm).
- **Operating Mode** has an assessment criteria section that allows the user to define the Pass/Refer criteria of an assessment screening.

- **Pass/Refer Criteria and Validity Criteria** are used for TEOAE screening to determine whether the result is Pass, Refer or Insufficient.

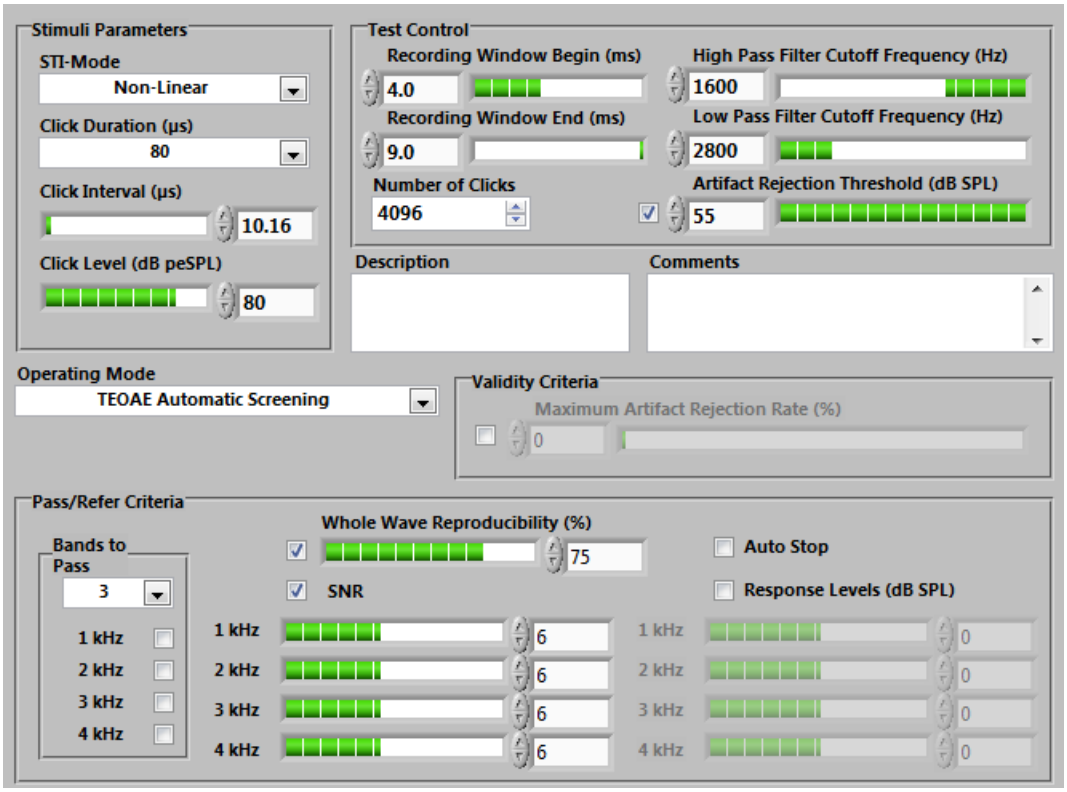


Figure 88. TEOAE Protocol Parameters

Stimuli Parameters

STI-Mode

The Stimulus mode (**STI-Mode**) can be selected has two selectable options, Linear or Non-Linear. In the Linear mode, all clicks are of the same amplitude. In the Non-linear mode, clicks are presented in series of four, one “large” and three “small”, which cancels out the linear contribution of the stimulus artifact.

Click Duration

The click duration is the duration of the electrical pulse that drives the OAE probe’s receiver, measured from 50% of its maximum value during turn-on until it reaches 50% of its maximum value during turn-off. There are two selectable options: 80 and 120 microseconds.

The electrical pulse drives the receiver in the OAE probe to produce the transient acoustic stimulus. The duration of the actual acoustic stimulus depends on the characteristics of the cavity in which it is placed.

Click Interval

The **Click Interval** setting is the time (in milliseconds) from the onset of one click to the onset of the next click. The interval may be set in the range of 10 milliseconds to 25 milliseconds.

Although the **Click Interval** may be set anywhere in the above specified range, the use of certain intervals are recommended because when they are implemented by the VivoLink internal clock they are not synchronized with 50 and 60 Hz power line frequencies and their harmonics. The recommended intervals are listed in Table 3.

Table 3. Recommended TEOAE Intervals (in ms)

10.33	18.29
10.16	19.49
10.95	20.79
11.26	21.05
12.82	21.12
13.55	22.67
14.07	22.98
14.85	23.14
16.83	24.39
17.77	24.80

Click Level

The **Click Level** setting is the peak equivalent (dB peSPL) value of the click stimulus adjusted based on the measured volume in the ear (60 to 85 dB peSPL).

Test Control

Recording Window

The Recording Window is the period of time following the stimulus in which the TEOAE response is recorded (0.5 ms to “n” ms, where “n” = Click Interval - 1.1 ms).

Number of Clicks

The Number of Clicks is the total number of clicks presented to record a TEOAE response, including accepted, with artifacts below Artifact Rejection Threshold, and rejected due to excessive artifacts.

High Pass Filter Cutoff Frequency

The High Pass Filter Cutoff Frequency parameter is the cutoff frequencies for the high-pass filter that may be used to reduce the effect of ambient noise and artifacts caused by the stimulus in the response (750 Hz to 2000 Hz).

Low Pass Filter Cutoff Frequency

The Low Pass Filter Cutoff Frequency parameter is the cutoff frequencies for the low-pass filter that may be used to reduce the effect of ambient noise and artifacts caused by the stimulus in the response (2000 Hz to 6000 Hz).

Artifact Rejection Threshold

The Artifact Rejection Threshold (ART) is the sound pressure level in dB SPL above which the detected acoustic signal is considered an artifact (24 to 47 dB SPL).

Operating Mode

This drop-down field allows the user to select three operating modes:

- Automatic Screening (which uses Pass/Refer Criteria)
- Manual Screening
- Assessment

Pass/Refer Criteria

The **Pass/Refer Criteria and Validity Criteria** are used for TEOAE screening to determine whether the result is Pass, Refer, or Insufficient. Although the infrastructure for TEOAE screening is built into the Integrity V500, the default screening protocols are provided only as examples; their sensitivity and specificity has not been verified on the Integrity V500. As those values are dependent on the population being screened, it is recommended that each site generate their own statistics for their populations of interest. To make these default protocols available in the Test Screen, go to the Protocol Screen and select the checkbox which is next to the desired protocol and under the Status column.

- **Bands to Pass** refers to the number of frequency bands required to satisfy the PASS criteria.
- **SNR Criterion** refers to the maximum allowable Signal-to-Noise Ratio, i.e. the difference between the TEOAE level and Noise Floor level in decibels (dB).
- **Minimum Response Level (MRL)** is only relevant for TEOAE Automatic Screening. In the protocol screen, when the user selects this operating mode they can select a response level threshold for 1, 2, 3 and 4 kHz bands. The MRL is displayed in the message window on the test screen and is updated live to say if each frequency passes or fails its specific response level threshold of the protocol. These signal levels at specific frequencies have to be reached for a response to qualify as a Pass in Automatic Screening.
- **Whole-Wave Reproducibility (WWR %)** refers to the percentage of recorded A and B waveforms that require a cross-correlation to satisfy the PASS criteria.
- **Auto Stop** is a function that stops Automatic Screening once the set criteria has been met.

During the Test

The TEOAE Test Screen

The TEOAE Test screen has features similar to the test screens of other test modalities.

This section of the manual describes the unique functions of the TEOAE Test screen.

Figure 89. TEOAE Test Screen

Response Waveform and Response Spectrum Windows

The two graphs at the top of the **Test** screen display the TEOAE **Response Waveform** in the time domain on the left and **Response Spectrum** in the frequency domain on the right.

For the purposes of analysis, TEOAE responses are divided into two phases, the 1st, 3rd, 5th, etc. responses are called the A phase and the 2nd, 4th, 6th, etc. responses are called the B phase. When the average A response is highly correlated to the average B response, this is an indication that a repeatable TEOAE has been detected. The difference between the A and B responses is a measure of the noise in the system.

When “A+B” is selected as the Display parameter, then the residual noise will be displayed in the Response Waveform and Response Spectrum graphs as the lighter trace. This is calculated from subtracting the B trace from the A trace and dividing the result by two. The noise values used in the Signal, Noise and SNR plot are calculated as the root-mean-square (rms) of the residual noise trace shown in the Response Spectrum graph for the appropriate frequency bin.

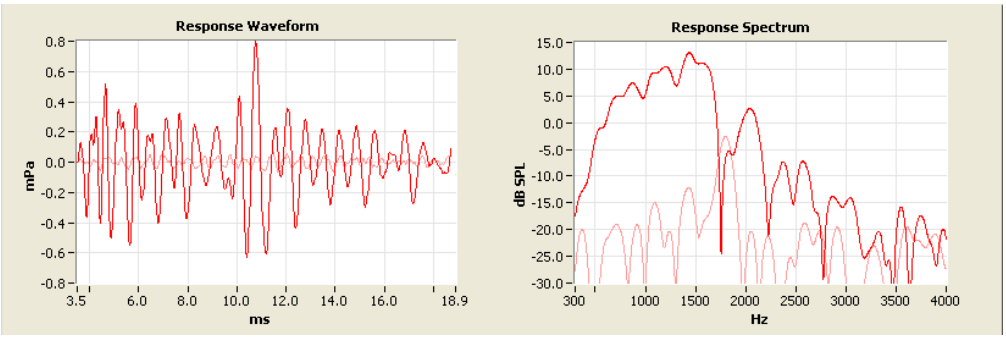


Figure 90. Response Waveform and Response Spectrum Windows

Signal, Noise and SNR (SNS) Chart

Beneath these Response Waveform and Response Spectrum windows is a chart that displays the **Signal, Noise and SNR** (Signal-to-Noise Ratio) for a range of frequency bands. The bandwidth and center frequency of each band can be selected from the Test Value fields (Figure 93) at the bottom of screen labeled **Bands**.

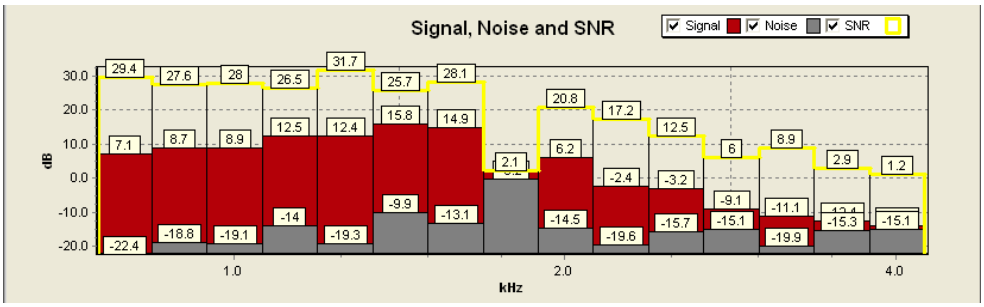


Figure 91. Signal, Noise and SNR graph

Test Control Buttons

Only the **Check Cavity** button is specific to OAE procedures. Refer to page 23 for more information about the Start/Stop, Pause/Resume, Save, Clear All, Right/Left Ear, and Print buttons.

Figure 92. Test Control buttons

Cavity Check

Procedure performed to ensure the probe is working and is in good condition, *i.e.*, no acoustical change has occurred since the probe programming. The procedure is performed with the probe inserted in the Probe Holder on the VivoLink.

VivoLink applies a TE stimulus to the probe receiver.

Integrity measures the actual sound pressure levels of the transient stimulus received by the microphones of the probe at the probe inlet.

Integrity reads the actual sound pressure levels with the Probe Characteristic Constants (PCC) stored in the built-in EEPROM of the probe and compares it to the measured value.

Integrity measures the residual signal from 3.5 to 25 ms after the stimulus to ensure that System TR (a false transient response synchronized to the stimulus due to inherent non-linear system) is within specification.

Integrity measures noise from 3.5 to 25 ms after the stimulus to ensure that System Noise (a false response due not synchronized to the stimulus) is within specification.

If the differences between the actual levels and PCC are within ±3 dB, and the noise and System TR are within tolerance the probe passes the cavity check. Otherwise the probe fails cavity check and the test status area of the screen (bottom right hand corner) reports the failure.

Test Value Fields

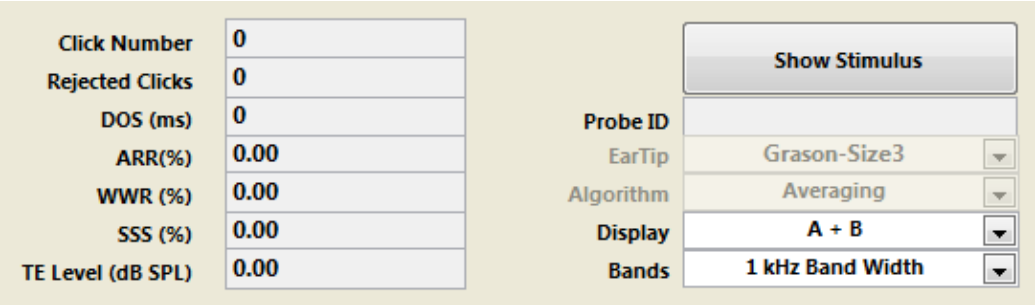


Figure 93. Test Value Fields and Show Stimulus Button

Click Number – are the number of clicks presented to the ear so far

Rejected Clicks – are the number of click rejected because the response exceeded the Artifact Rejection Threshold (ART) set in the protocol

DOS (ms) – is the duration of stimulus so far in milliseconds (= number of clicks x inter-pulse interval)

ARR (%) – Artifact Rejection Rate in per cent (=100% x Rejected Clicks / Click Number)

WWR (%) – Whole Wave Reproducibility (= correlation of A and B responses)

SSS (%) – Stimulus Stability Score in per cent (= 100% x Average stimulus instantaneous peak value / Maximum stimulus instantaneous peak value).

TE Level (dB SPL) – is the overall root mean square level of the TE response.

Show Stimulus Display

Use the **Show Stimulus** button to display the raw recording of the signal showing clicks and the click spectrum (Figure 94). This button is available during testing.

In the Linear mode, the click signals must be equal in size, while the Non-linear mode requires a larger click followed by three smaller clicks of an opposite polarity. During testing, check that the click spectrum is reasonably flat between 500-5000 Hz. The click spectrum will not be absolutely flat because of standing waves in the ear canal.

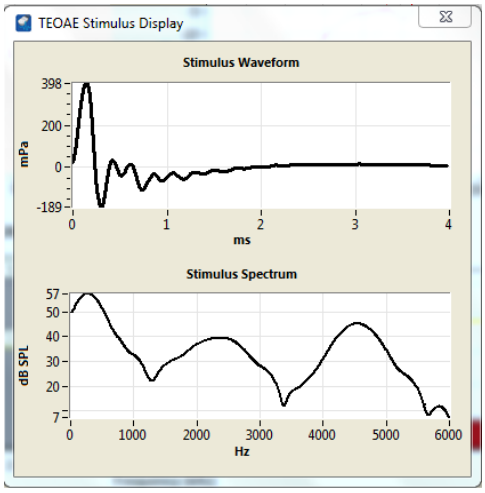


Figure 94. Stimulus Display

Message and Assessment Window

The top section of this window displays messages about the assessment as well as messages about the probe generated by the Check Cavity feature.

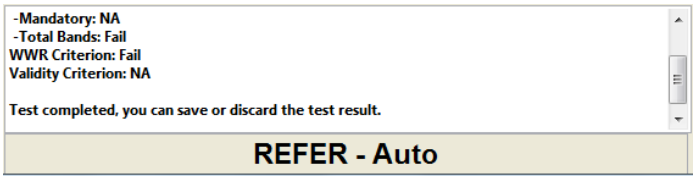


Figure 95. Message and Assessment Window (REFER-Auto)

In **Automatic Screening** mode, a **Pass, Refer**, or **Test Insufficient** message appears in the assessment field immediately upon completion of an assessment. The assessment field directly below the message window informs the technician that the patient has passed preset screening values, or that the patient should be referred for further diagnosis.

There are three possible values that are displayed as a result of an assessment:

- **Pass-auto** – indicates that the patient has passed all the criteria pre-set in the screening protocol. The parameters and their pass value will be listed in the message window directly above the Pass-Auto message.
- **Refer-auto** – indicates that the patient has not passed all the criteria pre-set in the screening protocol and that the patient should be referred to a specialist for a complete diagnosis. The parameters and their pass/refer value will be listed in the message window directly above the Refer-Auto message.
- **Insuff** – indicates that the results are too inconsistent to make an automated pass/refer decision. If this message appears, the acoustic conditions of the test may be inadequate to make the screening decision according to the criteria pre-set in the screening protocol.

  If this is the case, try the following:

Check the Probe fit in the ear and reinsert probe. It may be partly blocked by the ear canal wall or it may have become loose in the ear canal during the rest run.

Choose another ear tip. If an ear tip is too small it can let excessive noise in the occluded Ear Canal and cause an increase of the noise floor; if the tip is too big, it may get wrinkled and also let excessive noise in the occluded Ear Canal.

Reduce ambient noise or change test location for a quieter place if possible.

Use ear muffs. The Probe design allows using various types of ear muffs. The deeper the ear muff cups, the better. Ear muffs can significantly reduce ambient noise and make OAE testing possible in otherwise excessively noisy places, such as noisier general offices, schools, and occupational settings. To use ear muffs, first insert the Probe, then place the muffs on the patient's head as described in the user's manual for the ear muffs. Make sure the Probe is not misplaced by the ear muffs.

Test Protocol Parameters

There are no protocol parameters set in the **Test** screen for TEOAE tests. However, there are four (4) selectable fields that may be defined for each test.
These fields include: Ear Tip, Algorithm, Display, and Bands.

Ear Tip

This field allows you to specify the type of ear tip used on the probe. A variety of predefined ear tips are available for selection.

Algorithm

This control regulates application of the methods of processing the TEOAE waveforms. There are two processing algorithms to choose from: **Averaging** (system default) and **SOAP-Kalman Weighted Averaging**.

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

SOAP-Kalman Weighting is a signal processing algorithm that is used in TEOAE testing to optimally weight the patients' responses so that responses with less artifact from patient and environmental noise are given more weight than responses that are more contaminated with artifact. SOAP-Kalman weighting allows TEOAE acquisition with subjects who are in environments that are intermittently noisy. This method processes signals in real time without rejecting any time segments, even those containing significant artifacts. (Li 2002)

When TEOAE is collected on a subject who is in an environment with a constant amount of noise throughout the test, SOAP-Kalman Weighting will yield the same result as conventional averaging. When the subject makes noise intermittently during the test, the Kalman Filter will yield a result that is less contaminated by noise than a result that would be obtained under the same conditions with conventional averaging.

Display

For the purposes of analysis, TEOAE responses are divided into two phases, the 1st, 3rd, 5th, etc. responses are called the 'A' phase and the 2nd, 4th, 6th, etc. responses are called the B phase. When the average 'A' response is highly correlated to the average 'B' response, there is an indication that a repeatable TEOAE has been detected. The difference between the 'A' and 'B' responses is a measure of the noise in the system.

The user may choose from one of two **Display** modes in the TEOAE. In "A+B" mode, the average of the 'A' and 'B' responses are displayed in **dark blue** (or red for the right ear) and the noise is displayed in light blue (or pink). In "A and B" mode, the 'A' response is displayed in **dark blue** (or **red**) and the 'B' response in light blue (or pink).

Bands

This field allows the user to define the length of the viewable bandwidth The bandwidths available are: 1 KHz (linearly spaced) or 1, 1/2, 1/4 and 1/6 octaves, logarithmically spaced.

Performing a TEOAE Test

In-the-Ear Test

The system automatically performs an In-the-Ear test at the beginning of the TEOAE test to ensure the position of the OAE Probe in the ear canal, with the ear tip installed on the probe, fit correctly for the patient. This ensures that there is no leakage of sound from the ear canal, and that the acoustic outlets and inlets of the probe are not blocked.

With the OAE probe in the cavity, confirm the OAE Probe and the system is working correctly by selecting **Cavity Check** on the **Test** screen. Refer to

Cavity Check on page 105 for details. Three of the most common probe-check messages are displayed below.

Figure 96. Probe-check message - Passed

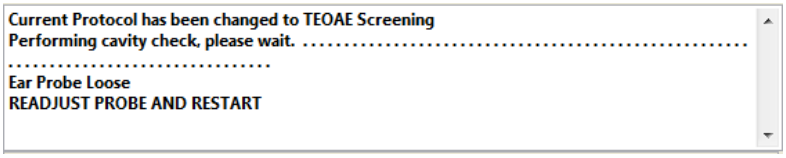


Figure 97. Probe-check message - Readjust

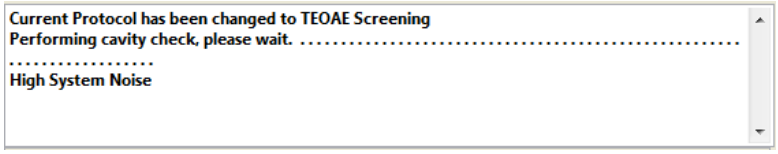


Figure 98. Probe-check message - Noise

Define the Test

To conduct a TEOAE measurement, perform the following steps:

1. In the **Test** screen, select TEOAE from the **Test Type** drop-down menu. Wait for the Bluetooth LED to turn solid blue to indicate that the software has initialized the TEOAE test.
2. Select an ear to test. Refer to the Integrity V500 Quick Reference for instructions on inserting the OAE Probe.
3. Select the patient to test from the **Patients** drop-down list in the Test Screen.
4. Select an appropriate protocol from the **Applied Protocol** drop-down menu. Refer to Define a TEOAE Protocol on page 100 for information on defining a custom protocol.

   CAUTION

   Improper configuration of OAE test protocols may result in poor quality test results. Only use clinically validated protocols for screening and assessment.

5. Press either the **Right Ear** or **Left Ear** button.
6. Press **Start** to begin a test. The **Start** button changes to a **Stop** button.
   - Press **Pause** to stop the test temporarily.
   - Press **Continue** or the **Stop** button to proceed.

   Refer to Test Control Buttons on page 23 for more information about Start/Stop, Pause/Continue, and Save features.
7. If the test is Automatic Screening the test outcome window will show **PASS-auto**, **REFER-auto**, or **TEST INSUFFICIENT-auto**.

   If **TEST INSUFFICIENT- auto** appears, the acoustic conditions of the test may be inadequate to make the screening decision according to the criteria pre-set in the protocol. In this case try the following:

   - **Check the OAE Probe fit in the ear and reinsert probe**. It may be partly blocked by the ear canal wall or it may have become loose in the ear canal during the rest run. The probe fit checks to ensure the position of the OAE Probe in the ear canal, with the ear tip installed on the probe is fit correctly for the patient. This will ensure there is no leakage of sound from the ear canal and that the probe's acoustic outlets and inlets are not blocked by ear wax or the ear canal wall.

     If the probe is inserted properly the ear tip end will be positioned approximately at the end of the cartilaginous part of the ear canal.
   - **Choose another ear tip**. If an ear tip is too small it can let excessive noise in the occluded ear canal and cause an increase of the noise floor. If the tip is too big, it may get wrinkled and also let excessive noise in the occluded ear canal.
   - **Reduce ambient noise** or change the test location for a quieter place if possible.
   - **Use ear muffs**. The OAE Probe design allows using various types of ear muffs. The deeper the ear muff cups, the better. Ear muffs can significantly reduce the ambient noise and make OAE testing possible in otherwise excessively noisy places, such as noisier general offices, schools, and occupational settings. To use ear muffs, first insert the OAE Probe, then

place the ear muffs on the patient's head over the probe as described by the manufacturer. Make sure the probe is not misplaced by the ear muffs.

8. Press **Save** to save the test results to the database.

   Press **Clear All** to clear the **Test Waveform Window**. If the graph is cleared before the results are saved, the data will be lost.

   Press **Print** to print the test results.

   CAUTION

   *To ensure that the data is saved in the correct patient's file you must ensure that the patient's name and ID are both correct as they appear in the dialog box. If the name or the ID is incorrect press **Cancel** and select the correct patient from the patient list or enter a new patient in the **Patient** screen.*

9. Repeat the above procedure to test the other ear.

Post Test Review

TEOAE Database Screen

The TEOAE Database screen is similar to other test modalities. The functions unique to the TEOAE Database screen are described in this section.

Refer to The Database Screen on page 33 for a general description of the Database screen.

Figure 99. TEOAE Database Screen

The **Database** screen displays the following information:

- Patient Test Information
- Waveform Information
- Database Controls

Monitoring OAE Changes Over Time

The database allows you to compare baseline tests and follow-up tests at later dates. By comparing tests over time it is possible to monitor changes in OAE results which indicate the potential development of ototoxicity and noise-induced hearing loss, as well as treatment of otitis media.

Patient Test Information

This table contains patient information entered in the **Patients** screen. Refer to Database on page 35 for a full description of the function of this portion of the database screen.

Database Waveform Information

This window displays waveform data in the form of a Signal, Noise and SNR (SNS) Graph, along with conditions of stimulation and recording.

The **SNS Graph** contains signal, noise and SNR responses in a bar graph format. Use the **Signal, Noise** and **SNR** checkboxes to display corresponding information in the bar graph.

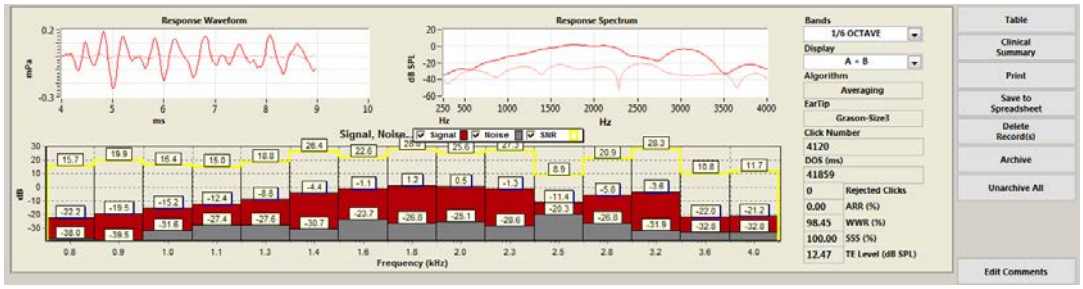


Figure 100. Database Waveform Information for TEOAE

Database Controls

The **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. Refer to Database Controls on page 39 for a description of these buttons.

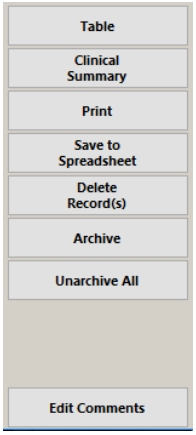


Figure 101. Database Controls for TEOAE

Chapter 7: Overview of DPOAE Testing

Specific DPOAE Test Preparation

1. Refer to the Integrity V500 Quick Reference for instructions on how to prepare the patient for the OAE test.
2. Select a patient's name from the **Patient** screen, or add a new patient name.
3. Open the **Test** screen and select DPOAE from the **Test Type** list.

   The Bluetooth LED starts to flash when your computer recognizes the presence of the VivoLink and begins to download information to it.

   When the download of information is complete, the Bluetooth LED stops flashing and remains solid blue. If the connection is lost during the download process, the Bluetooth LED indicator appears unlit.
4. The OAE Probe calibration and the system may then be checked by pressing the Cavity Check button on the Test screen. The Cavity check is measured in the 1 cc cavity of the OAE Probe holder on the VivoLink.
   - If the Probe calibration is correct and the system Distortion Product (DP) and noise floor are within their tolerances, the status will be reported as "Cavity Check Passed" in Figure 102**.**
   - If there is a problem with OAE Probe calibration, excessive system DP, or system noise, then a message describing the problem(s) will appear in Figure 103.

Follow the instructions on the screen. If the problem persists, contact Customer Support.

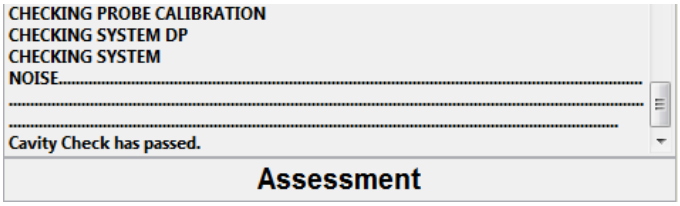


Figure 102. Message and Assessment Window (Cavity Check - Pass)

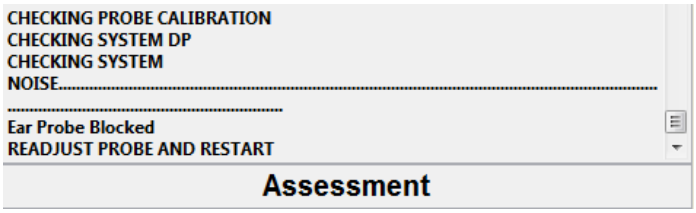


Figure 103. Message and Assessment Window (Cavity Check—Fail)

Perform a Probe Fit Check to ensure that the position of the OAE Probe in the ear canal, with the ear tip installed on the probe is fit correctly for the patient. This will ensure that there is no leakage of sound from the ear canal, and that the acoustic outlets and inlets of the probe are not blocked. Refer to Probe Fit Check on page 121 for details.

Define a DPOAE Protocol

DPOAE protocol parameters are entered using DPOAE controls on the **Protocol** screen. To create a new protocol, select the **Protocol** tab, modify an existing DPOAE protocol, and then save it with a new name.

NOTE

It is not possible to overwrite or edit an existing protocol. When an existing protocol is modified it must be saved under a new name.

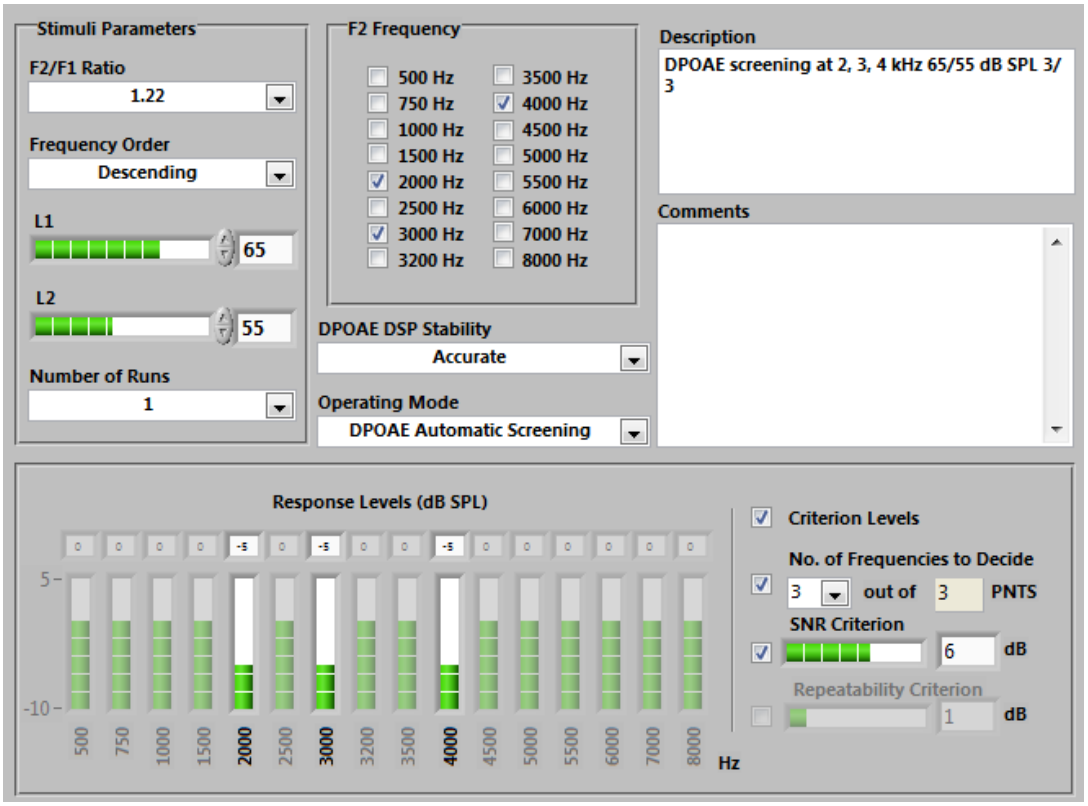


Figure 104. DPOAE Protocol Parameters

The **Stimulus Parameters** are used to select the stimulus and frequencies settings.

F_2/F_1 Ratio can be selected from the drop-down menu as 1.20 or 1.22.

Frequency order can be selected from the drop-down menu as Ascending or Descending. Descending order is sometimes chosen when the higher frequencies are of more interest, and the patient, particularly infant or child, is restless.

L_1 and **L_2,** the levels of primary tones, f_1 and f_2, can be set at 40-75 dB SPL with 1 dB step. You can set them in three ways: (a) place the pointer on the bar and drag its right end to the required position, while watching the number above indicating the exact value of the parameters, (b) by clicking on the window and entering the necessary number, and (c) by clicking on the up-down arrows.

Number of Runs, which defines the number of automatic repetitions of the test, can be selected from the drop-down menu as 1 or 2.

NOTE

If the number of runs is set to 1, then repeatability cannot be calculated and repeatability Criterion will be disabled.

F_2 Frequency can be selected from 16 frequencies: 500, 750, 1000, 1500, 2000, 2500, 3000, 3200, 3500, 4000, 4500, 5000, 5500, 6000, 7000, and 8000 Hz. A minimum of two frequencies should be selected per DPOAE protocol.

DPOAE DSP Stability, which defines the speed and accuracy of DPOAE measurement. This parameter can be set at Accurate, Medium, and Fast.

- **Accurate** setting requires the DPOAE signal to be stable for 0.4 seconds within ±1 dB SPL from its median value. It yields the most accurate DPOAE measurement, and is the default setting of this control. This setting can be used in any test, but particularly when accuracy is a priority, for example for ototoxicity or noise-induced hearing loss monitoring and diagnostic tests.
- **Medium** setting requires the DPOAE signal to be stable for 0.3 seconds within ±2 dB SPL and can be used for assessment tests.
- **Fast** setting requires the DPOAE signal to be stable for 0.2 seconds within ±3 dB SPL. This setting can be used when the speed of testing is more important than its accuracy. A fast setting helps to avoid transient acoustic artifacts such as baby's noises, footsteps, door slamming, equipment beeps, etc.

It is recommended that you use the **Accurate** setting when possible, and switch to **Medium** or **Fast** only when measuring with **Accurate** is difficult or impossible because of significant transient noises.

Operating mode includes: DPOAE Automatic Screening, DPOAE Manual Screening, and DPOAE Assessment. A test decision made in Automatic operating mode cannot be changed.

- When **Automatic** is selected, the program makes a pass-refer decision automatically according to the set screening criteria.
- When **Manual** is selected, the program makes a PASS, REFER, or Test Insufficient decision automatically.

  After a test run, three decision buttons appear at the bottom of the **Test** screen; these allow you to modify the decision manually.
- When **Assessment** is selected, the DP-gram is recorded, but there is no screening decision.

The **Pass/Refer Criteria** are used to determine whether the result is Pass, Refer, or Insufficient. Although the infrastructure for DPOAE screening is built into the Integrity V500, the default screening protocols are provided only as examples; their sensitivity and specificity has not been verified on the Integrity V500. As those values are dependent on the population being screened, it is recommended that each site generate their own statistics for their populations of interest. To make these default protocols available in the

Test Screen, go to the Protocol Screen and select the checkbox which is next to the desired protocol and under the Status column.

- **Criterion Levels** which include **Response Levels** and **No. of Frequencies to Decide** can be enabled or disabled.
- **Response Levels** are the minimum DPOAE signal levels at corresponding frequencies that have to be reached for a response to qualify as a Pass in Automatic Screening. You can set them from -10 to +5 dB SPL - with 1 dB step - by dragging the bars up and down, or entering the number in the window above each bar. When this criterion is enabled and, these boundary levels are shown as a dashed blue line in the DP-gram graphs in the Test Screen. The decision algorithm treats the measured DPOAE levels differently depending on whether they are below or above this boundary line.
- **No. of Frequencies to Decide** refers to the minimum number of F_2 points in the DP-gram that need to satisfy the set PASS criteria in order to produce an overall Pass decision. This is the number in the left field that should be set to at least half number of selected frequencies in this protocol. However, the number in the right field shows automatically the total number of selected test frequencies.

  If the No. of Frequencies to Decide is disabled, then all of the frequencies are required to pass in order to make a PASS decision.
- **SNR Criterion** refers to the maximum allowable Signal-to-Noise Ratio, i.e. the difference between DPOAE level and Noise Floor level in decibels (dB). SNR Criterion allowed range is from 3 to 10 with 1 dB step.
- **Repeatability Criterion** refers to the maximum allowable difference in decibels (dB) between two runs of the DP-gram in a single test at each of the test frequencies, if there are two automatic runs of the test. The allowable criterion range is from 1 dB to 10 dB.
- **SNR Criterion** and **Repeatability Criterion** can be enabled or disabled.
- **Description** text box allows you to type in an extended description of the protocol which may reflect the use of the protocol, key parameters etc., for example: DP screening at 2, 3, 4 kHz 60/50 3/5, which means a protocol for DPOAE screening at f2 = 2, 3, and 4 kHz, with L2/L1 = 60/50 dB SPL, and with the number of frequency to decide equal to 3 out of 3 frequencies tested.
- **Comment** text box allows you to enter information associated with the protocol you create. For example, you may wish to type a note that the protocol you create is based on a certain published study, or created for a particular population, test setting, clinical use, or research project. These factors may also be reflected in the name of the protocol you create, for example: M. Gorga, et al. (2000).

During the Test

The DPOAE Test Screen

The DPOAE test screen has the same components as other test types screen (Waveform Information and Test Controls) with some different functions. This section of the manual will describe the unique functions of the DPOAE test screen.

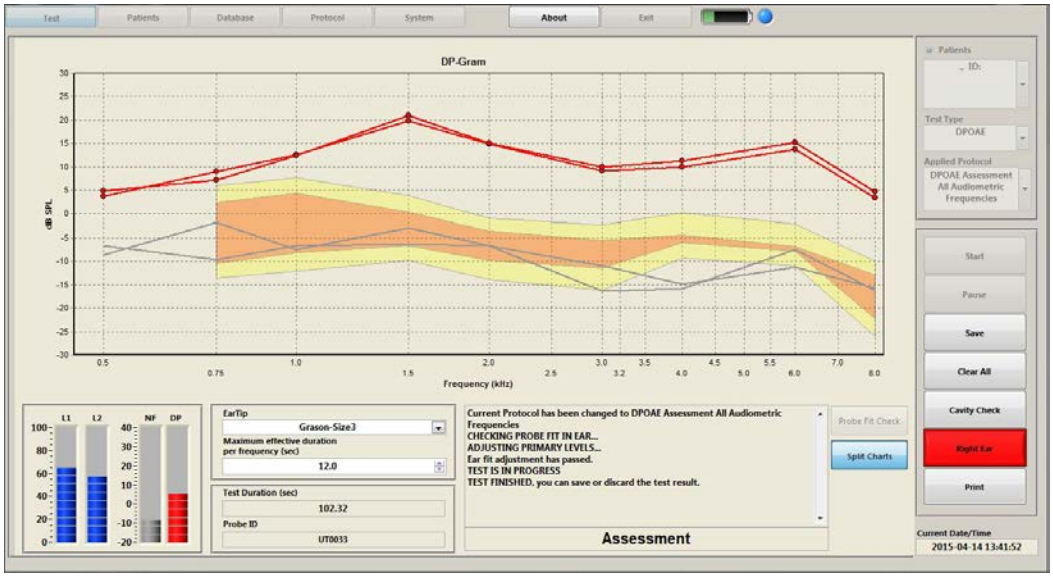


Figure 105. DPOAE Test Screen - Assessment

DP-Gram

The graph on the top right shows the **DP-gram**: The **y-axis** represents sound levels in dB SPL, while the **x-axis** represents the frequency of f_2 in kHz.

DPOAE levels at each f_2 frequency are shown as color dots:

a) Red dots for the right ear and blue dots for the left ear if the DPOAE levels are equal to or above the noise floor.
b) Yellow dots for both ears if DPOAE level is below the noise floor (thick gray lines).
c) Gray dots for both ears if the testing has timed out for that frequency (i.e., DSP Stability criterion has not been met. DSP stability can be adjusted in the test protocol screen.)

The color lines connect the measured DPOAE levels: red for the right ear and blue for the left ear.

Noise Floor levels at the DPOAE frequencies corresponding to the respective f_2 frequencies are shown as thick gray lines.

You can view the specific frequency, DPOAE (DP) level, noise floor (NF), and signal to noise ratio (SNR) for each point recorded on your DP-gram. To view the values for a specific point, use your mouse pointer to hover near that point on your DP-gram. The values are displayed in a small window in the upper right corner of the DP-gram.

DP Norms are displayed on the DP-gram using two bands.

- 95% of the normal hearing population (threshold less than 20 dB at all frequencies) will have DPOAE levels above the bottom light colored band on the graph.
- 95% of the hearing impaired population (with 20 dB hearing loss at the frequency displayed) will have DPOAE levels that are below the top light colored band on the graph.
- 90% of the normal hearing population (threshold less than 20 dB at all frequencies) will have DPOAE levels above the dark colored band on the graph.
- 90% of the hearing impaired population (with 20 dB hearing loss at the frequency displayed) will have DPOAE levels that are below the dark colored band on the graph.

This means that, with 95% and 90% confidence, one can rule out the probability of hearing impairment in patients whose DPOAE's are all above the light and dark colored bands, respectively.

Similarly, one can rule out the probability that the patient has normal hearing at any given frequency, with 95% and 90% confidence, for patients whose DPOAE's are below the light and dark bands, respectively.

For patients whose DPOAE levels are within the dark colored band, one cannot make any statistically significantly conclusions about the patient's hearing from the DPOAE test alone.

The provided DPOAE Norms values are automatically displayed if the protocol parameters for the current test match the parameters that were used in collecting these norms, *i.e.,* L1, and L2 are 65 and 55 dB SPL respectively, and F2/F1 ratio is 1.22.

To view normative data (raw) go to the following file on your Integrity computer:

C:\Program Files (x86)\Vivosonic\Integrity\Integrity Norms\DPOAE\Default_DPOAE_Norm.xml

For the source and value of the DPOAE norms data please refer to Appendix B: DPOAE Norms Data.

NOTE

It is recommended that each clinic create its own norms data which reflect the specific character of the tested population and the protocols used for data collection. The preset norms data can be used to compare the results collected with same stimulus parameters.

DPOAE Criterion Levels, in case of applying a screening protocol, **DPOAE Response Levels Criterion** defined in the Protocol Screen are shown as the dashed black line in the DP-Gram. Refer to page 114 for more details about the DPOAE Criterion Levels.

The DP-Gram that is obtained from consecutive multiple test results overlapped on the graph and identified by colors for the right and left ear, until the user chooses to clear the graph.

For each frequency where the NF is greater than the DP level, the regularly red or blue colored dot (right and left ear, respectively) is replaced with a yellow dot.

Sound Level indicators

Bars in the lower right corner of the screen represent the sound-level indicators. The two blue bars (titled **L1** and **L2**) on the left show the levels of the two primary stimulus tones, the two right bars indicate the Noise Floor (**NF**) and DPOAE (**DP**) levels in dB SPL as measured by the Probe microphone at the acoustic inlet of the Probe. These four indicators are continuously updated.

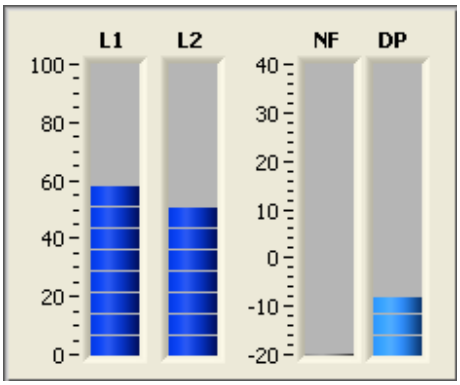


Figure 106. Sound Level Indicators

The bar next to the right (titled **NF**) shows the Noise Floor level at the DPOAE frequency in dB SPL as measured at the inlet to the microphone sound canal of the Probe.

The Noise Floor is measured the following way: first, the algorithm calculates an average of the signal power at two frequencies around the DPOAE frequency, one frequency below and one frequency above the DPOAE frequency, separated by 1 Hz steps. Then the obtained average value is converted into dB SPL and presented as the Noise Floor.

The bar titled **DP** shows the measured **DPOAE** level in dB SPL. This bar is color-coded: it turns **yellow** when the DPOAE level is below the Noise Floor level and either **red** (if the right ear is being tested) or **blue** (if the left ear is being tested) when the DPOAE level is equal to or above the Noise Floor level.

NOTE

The Probe microphone is intended to measure primarily OAEs coming from the eardrum, not the levels L_1 and L_2 of the primaries coming from the Probe. Because of standing sound waves in the occluded ear canal, the measured levels L_1 and L_2 typically are not equal to the set primary levels, especially at frequencies higher than 2 kHz. This happens because the primary levels L_1 and L_2 are calibrated using an Occluded Ear Simulator (Zwislocki Coupler) in which the microphone membrane's position mimics the position of the eardrum. In contrast, ***L1*** *and* ***L2*** *indicators show the levels measured at the inlet of the microphone sound canal of the Probe, i.e. at a distance from the eardrum. Such a distance introduces standing waves that make the primary levels different at the eardrum and at the inlet to the microphone sound canal of the Probe. Nevertheless, these indicators are important because they show that the primary tones are actually presented into the ear canal.*

The Noise Floor (NF) indicator is also very useful for checking the seal of the ear canal. When the NF value is fluctuating around a level of 10 dB SPL or higher, it indicates that the seal is poor. In such a case, you may need to reinsert the Probe, or select another ear tip, or use ear muffs.

You can also check background noise using the NF indicator. When the Probe is inserted in the Probe Holder, the level should be below -15 dB SPL. The level of a reasonably quiet office is about -20 dB SPL.

Test Protocol Parameters

There are no protocol parameters that can be set in the **Test** screen for the DPOAE tests. However, there are two (2) selectable fields that help define the test: Ear Tip and Maximum Effective Duration per Frequency.

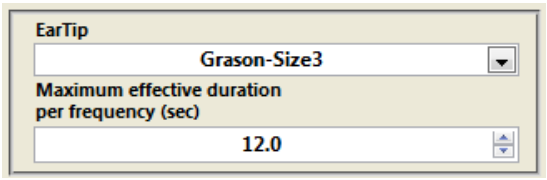


Figure 107. DPOAE Test Protocol Parameters

Ear Tip

This field allows the user to define the type of ear tip used on the probe. A variety of predefined ear tips are in the list.

Maximum Effective Duration per Frequency (sec)

This field allows optimizing the measurement duration for a particular testing situation. Users can set the maximum duration for detection of a stable DPOAE signal among possible artifacts.

This parameter can be changed using its control buttons with up and down arrows found on the left of this control, or by typing a number in its edit box. The available range for this control is 0.5 to 120 sec. Higher values may be useful in noisier environments. This will depend on the testing situation: in a quiet environment and cooperating patient you will typically need no more than 2-3 seconds per frequency; in more complicated situations you may allow for a longer duration.

If the DPOAE stability criterion are not met within the maximum effective duration, then the system will present its best estimate of DP and NF values.

Test Value Fields

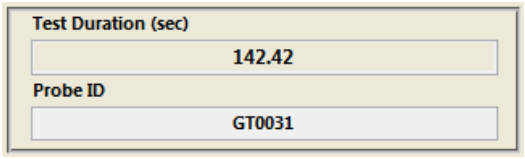


Figure 108. DPOAE Test Value Fields

Test Duration (sec) – is the duration from the pressing of the **Start** button until the completion of testing all DPOAE frequencies. If the test includes two runs, test duration represents time for both runs.

Probe ID – is a unique ID for the OAE probe that is used during the test.

Probe Fit Check

With the probe in the ear of the patient, you can perform the Probe Fit Check to ensure that there is no leakage of sound from the ear canal, and that the acoustic outlets and inlets of the probe are not blocked.

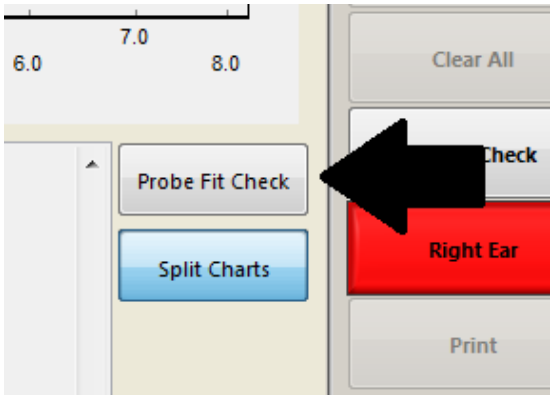


Figure 109. Probe Fit Check Button

The probe fit check includes the following steps:

1. The system applies simultaneously two signals to two receivers of the OAE probe to produce two pure tones with a frequency ratio 1.22
2. The system measures the actual sound pressure levels of the two tones received by the microphones of the probe at the probe inlet.
3. The test result is displayed in the Message and Status Window.

   Possible failure messages include:

   - Ear probe is loose

     When the Ear probe is loose, try using a larger ear tip. Also, clean the probe and then restart the test.

   - Ear probe is blocked

     When the Ear probe is blocked, clean the probe and then restart the test.

In the Ear Adjustment Test

The software does an **In the Ear Adjustment Test** that is performed in the background during a DPOAE test. In the Ear Adjustment test is designed to check if the OAE probe is in the patient's ear before the test is started, and after all test runs. If at any point during the test session, and in the ear adjustment test fails the user will be notified with a message box.

The user will be informed if the probe fit check determines that the probe is loose. However in this case, the DPOAE test will continue running and the in-the-ear adjustment will try to compensate for the loose probe. This may cause the loose probe to require more compensation then what can be produced from the VivoLink at high stimulus levels. In the event that this occurs, the user is recommended to either readjust the probe to get a better fit and/or reduce the stimulating level.

High Noise Dialog

The high noise dialog box (Figure 110) is shown during DPOAE testing when either (a) the OAE probe is loose in the patient's ear, or (b) there is high noise in the test room. Notwithstanding the dialog box, the test continues until it is finished or stopped by the user.

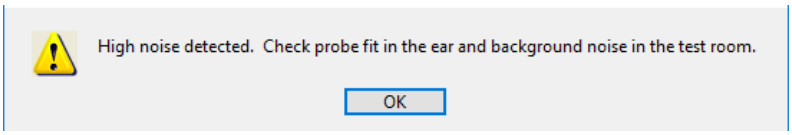


Figure 110. High Noise dialog

Split / Merge Charts

This feature allows you to activate a single button to toggle your view of the DP-gram from a split view to a merged view. The button changes its label to Split Charts or Merged Charts when activated.

- A merged view displays both the left and right ears in one chart.
- A split view displays the results of each ear in separate charts.

You can set the default view in the **System** screen. Refer to DPOAE Settings on page 49.

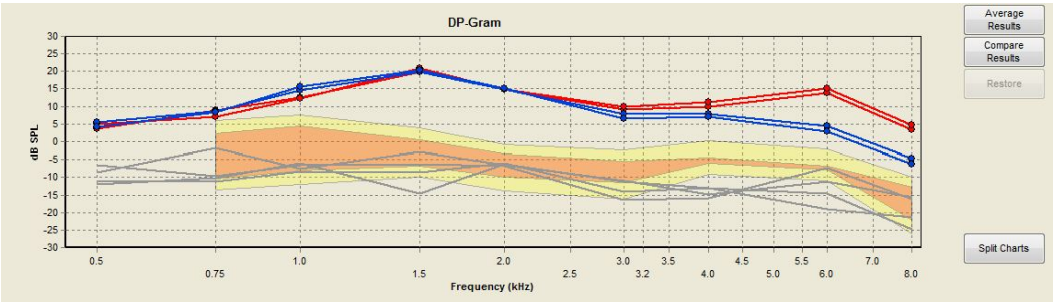


Figure 111. DPOAE Merge Charts

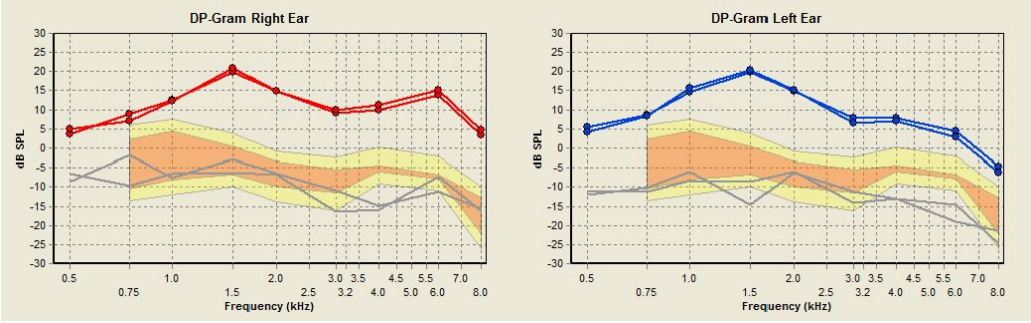


Figure 112. DPOAE Split Charts

Message and Assessment Window

The message and assessment window appears below the DPOAE chart. The top section of this window displays messages about the current test being performed and its status. This includes used protocol, probe insertion, probe calibration, the cavity check test, or the test in process.

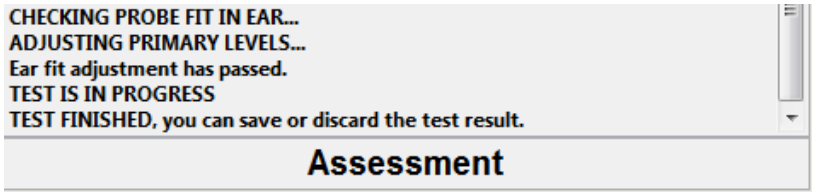


Figure 113. Message and Assessment Window (Assessment)

The bottom section displays the test outcome. Test outcome is **Assessment** for tests performed in assessment mode. In **Automatic Screening** mode, either **PASS, REFER**, or **Insufficient** message will appear in test outcome field immediately after completion of the test. The test outcome field is provided as a screening feature that will indicate if a patient has passed preset screening criteria whether the patient should be referred for further diagnosis. There are three possible values that are displayed as a result of an automatic screening:

In **Automatic Screening** mode, a **Pass, Refer**, or **Test Insufficient** message appears in the assessment field immediately upon completion of an assessment. The assessment field directly below the message window informs the technician that the patient has passed preset screening values, or that the patient should be referred for further diagnosis.

There are three possible values that are displayed as a result of an assessment:

- **Pass-auto** — indicates that the patient has passed all the criteria pre-set in the screening protocol. The parameters and their pass value will be listed in the message window directly above the Pass-Auto message.
- **Refer-auto** — indicates that the patient has not passed all the criteria pre-set in the screening protocol and that the patient should be referred to a specialist for a complete diagnosis. The parameters and their pass/refer value will be listed in the message window directly above the Refer-Auto message.
- **Insuff** — indicates that the results are too inconsistent to make an automated pass/refer decision. If this message appears, the acoustic conditions of the test may be inadequate to make the screening decision according to the criteria pre-set in the screening protocol.

  If this is the case, try the following:

  Check the Probe fit in the ear and reinsert probe. It may be partly blocked by the ear canal wall or it may have become loose in the ear canal during the test run.

  Choose another ear tip. If an ear tip is too small, it can let excessive noise in the occluded Ear Canal and cause an increase of the noise floor; if the tip is too big, it may get wrinkled and also allow excessive noise in the occluded Ear Canal.

  Reduce ambient noise or change test location for a quieter place if possible.

Use ear muffs. The Probe design allows using various types of ear muffs. The deeper the ear muff cups, the better. Ear muffs can significantly reduce ambient noise and make OAE testing possible in otherwise excessively noisy places, such as noisier general offices, schools, and occupational settings. To use ear muffs, first insert the Probe, and then place them on patient's head as described in the manual for the ear muffs. Make sure the Probe is not misplaced by the ear muffs.

NOTE

Test result for Automatic Screening protocols is detected automatically by the System, and cannot be modified by the user. To be able to modify the test result, Manual Screening protocol should be used instead.

In **Manual Screening** mode, the algorithm detects the test outcome at the end of the test or when you stop the test. At this point, you can select an alternative assessment result that will be saved in the database along with the test record.

A message box will prompt you to confirm the assessment result that you have selected.

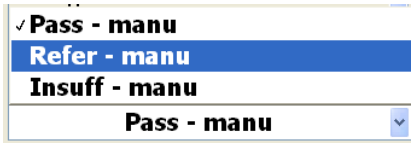


Figure 114. Select test outcome when in manual mode of operation

Test Control Buttons

The Start/Stop, Pause/Resume, Save, Clear All, Right/Left Ear and Print buttons operate in the same manner for all test types. Refer to page 23 for details.

Figure 115. Test Control Buttons

Cavity Check Button

Cavity check is a procedure performed to ensure the probe is working and is in good condition, *i.e.*, no acoustical change has occurred since the probe was calibrated. The procedure is performed with the probe inserted in the Probe Holder on the VivoLink.

The cavity check includes the following steps:

1. VivoLink applies two signals to the two receivers of the probe to produce two pure tones with frequency ratio: 1.22
2. Integrity measures the sound pressure level of the system DP received by the microphones of the probe at the inlet of the probe.
3. Integrity measures noise after the stimulus to ensure that System Noise (a false response due not synchronized to the stimulus) is within specification.
4. VivoLink reads the actual sound pressure levels with the Probe Characteristic Constants (PCC) stored in the built-in EEPROM of the probe and compares it to the measured value .
5. If the differences between the actual levels and PCC are within ±3 DB, and the noise and system DP are within tolerance the probe passes the cavity check. Otherwise the probe fails cavity check
6. Test result will be displayed in the message and assessment area of the screen (bottom right hand corner).

You can stop the Cavity Check by selecting the **Cancel** button on the Cavity Check message.

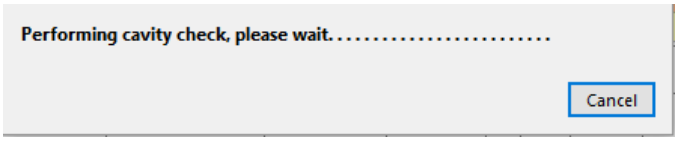


Figure 116. Cavity Check In Progress Message

Post Test Review

DPOAE Database Screen

The DPOAE Database screen is similar to other test modalities. The functions unique to the DPOAE Database screen are described in this section.

Refer to The Database Screen on page 33 for a general description of the Database screen.

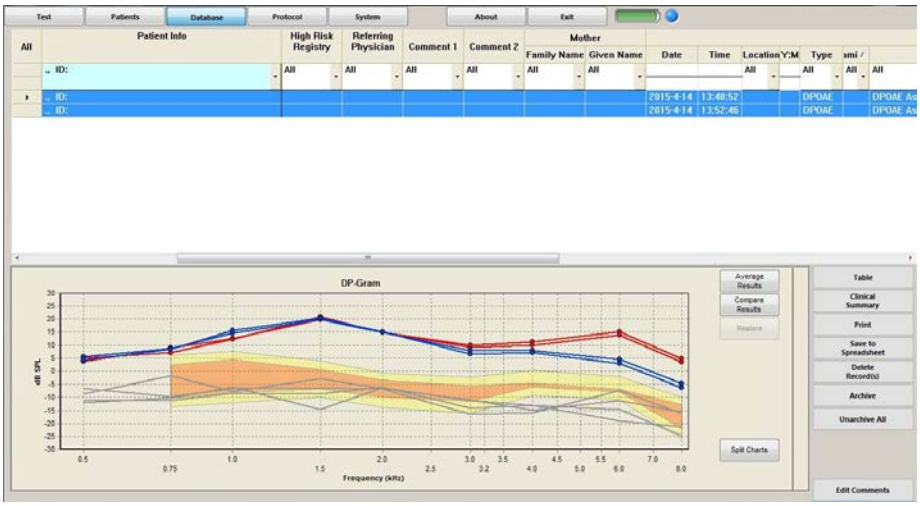


Figure 117. DPOAE Database Screen with Norms Data

Monitoring DPOAE over time

The database allows the user to compare baseline tests and follow-up tests at later dates. By comparing tests over time it is possible to monitor changes in DPOAE results which indicate the potential development of ototoxicity and noise-induced hearing loss, as well as treatment of otitis media.

Multiple DPOAE test results that are saved in different records, provided that they are generated using the same protocol, can be displayed on one DP-Gram graph on the Database screen.

The **Database** screen contains the following information:

- Patient Test Information
- Waveform Information
- Database Controls

Patient Test Information

This table is located at the upper part of the screen. This table contains patient information entered in the **Patients** screen, and the test conditions entered when the test is saved. Refer to Database on page 35 for a full description of the function of this portion of the database screen.

Database DP-Gram

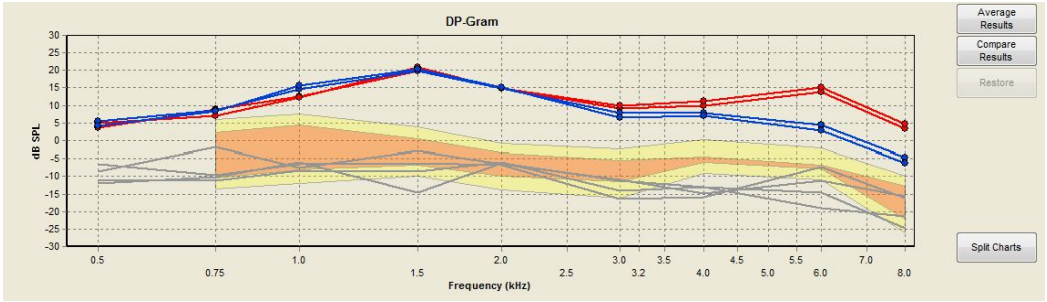


Figure 118. Database DP-Gram for DPOAE

The DP-gram window displays collected DPOAE data. You can view the specific frequency, DPOAE (DP) level, noise floor (NF), and signal-to-noise ratio (SNR) for each point recorded on your DP-gram.

To view the values for a specific point, use your mouse pointer to hover near that point on your DP-gram. The values are displayed in a small window in the upper right corner of the DP-gram.

NOTE

The provided DPOAE Norms values are automatically displayed if the protocol parameters for the selected test records are matching the parameters that are used in collecting these norms data.

For the source and value of the DPOAE norms data please refer to Appendix B: DPOAE Norms Data.

Average Results

This option allows averaging selected data. Data to be averaged are all runs from all records selected in the **Patient Test Information Chart**. Average results option will

average both DPOAE, and noise floor NF levels. It is required that all the selected records be from the same protocol.

Compare Results

This option allows comparing the DPOAE and Noise Floor (NF) level differences across two test records. It is required that the two selected test records use the same protocol.

NOTE

The Compare Results button is only available when two test records are selected. The Print button is unavailable when comparing results.

Restore

This button is provided to allow restoring the DP-Gram to its original status as it is generated in the test screen after performing an averaging or comparing calculation.

NOTE

Averaged or compared DP, and Noise Floor levels may be represented in a tabular numeric format by clicking on the Table button of the Database Controls.

Split / Merge Charts

This feature allows you to activate a single button to toggle your view of the DP-gram from a split view to a merged view. The button changes its label to Split Charts or Merged Charts when activated.

- A merged view displays both the left and right ears in one chart.
- A split view displays the results of each ear in separate charts.

You can set the default view in **System** screen. Refer to DPOAE Settings on page 49.

Database Controls

The **Database Controls** are located on the **Database** screen. The controls provide post-analysis functions on the data, such as report generation.

The **Print** button is unavailable when the **Average Results** or **Compare Results** view is active. Refer to Database Controls on page 39 for details about these buttons.

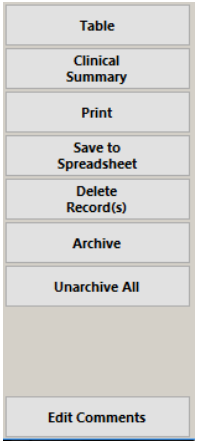


Figure 119. Database Controls for DPOAE

Chapter 8: Integrity ABR Screening

About Integrity™ ABR Screening

Integrity ABR Screening is a modality that can be added to the Integrity V500 G2 (Generation 2) System only, providing both hearing screening and auditory diagnostic assessments on one system. Early detection of hearing loss in infants is critical for the normal development of speech and language, learning, and social skills. Integrity™ ABR Screening is an advanced hearing screening system that identifies potential hearing loss with accuracy and efficiency. It is fully automated to detect the presence or absence of an auditory brainstem response (ABR) of newborns and infants.

Clinical use

Integrity™ ABR Screening is designed to work optimally with healthy infants from *34 weeks gestational age to 6 months*. Soft clicks are delivered to the ears at sound levels of 30 or 35 dB nHL, while electrodes detect the electrophysiological signals from the auditory brainstem.

An Integrity™ ABR Screening test produces a **Pass**, **Refer**, or **Incomplete** outcome. It does not make a hearing diagnosis. The outcome may indicate normal hearing, the need for auditory diagnostic testing, or the need for subsequent rescreening. Mild hearing loss, and hearing loss at a specific (isolated) frequency, is not identified. Results that indicate possible hearing loss should be reviewed by a Physician, audiologist, or qualified hearing specialist for follow-up and clinical intervention.

The outcome of every screening is saved to your computer. This allows you to view your results at a later time. You also have the option to print your results to include in your patient records.

Safety and Precautions

Integrity™ ABR Screening should be used by a trained operator. It is recommended that operators complete training and a competency evaluation before administering a hearing screening test.

You should follow these precautions when using Integrity™ ABR Screening.

Integrity™ ABR Screening computer

Following the "Guidance for Industry, FDA Reviewers and Compliance on Off-The-Shelf Software Use in Medical Device," issued by FDA on September 9, 1999, the customers should not use any software other than that specified, as it will violate the safety, effectiveness and design controls of your Integrity™ ABR Screening system and that such use may result in an increased risk to users and patients. Unauthorized alteration of software provided, including downloading non-validated or unauthorized off-the-shelf software may void or breach existing service agreements and warranties. For additional information, contact Vivosonic Customer Support.

VivoLink™

Your Integrity™ VivoLink™ is approved to UL STD 60601-1, IEC STD 60601-1-1, and IEC 60601-2-40 for electrical safety. Standard precautions for the use of electrical devices in a critical care environment should be followed at all times.
Always power off, unplug, and remove the battery pack from your VivoLink™ before cleaning it. Failure to do so may result in serious injury or damage to your VivoLink™.
Remove the battery pack from your VivoLink™ when storing it when not used regularly, or for an extended period of time.
Use only Vivosonic battery packs in your VivoLink™. Use of other battery packs may cause damage to your system and endanger your patient.
Use only the battery charger (CELL-CON NiCd/NiMH Charger, Model 452115-NA) supplied with your Integrity™ system.

VivoTab™ electrodes

Cautions and warnings for the VivoTab™ electrodes are marked on the package. Please read the package prior to using the electrodes.
The electrodes are “single use only” products. They should be disposed of after use to prevent disease transmission and adverse skin reactions.
Do not apply the electrodes to fragile, damaged, or compromised tissue, or to patients with marked jaundice.
If removal of the electrodes is difficult, dissolve the hydrogel adhesive with water to avoid tearing skin.
Use only VivoTab™ electrodes that have been specially designed for infants, and clinically validated for use with Integrity™ ABR Screening. The use of electrodes from other manufacturers can lead to unreliable test outcomes, and Vivosonic cannot guarantee the performance of your Integrity™ ABR Screening system.

Insert earphones

When using insert earphones, always use with disposable ear tips. Failure to do so may result in cross-contamination between patients. Care must be taken to properly attach the disposable ear tips to the insert ear phones.

Infection control

Infection control procedures which prevent cross-contamination between patients are a critical part of patient care. Your Integrity™ ABR Screening (which includes the VivoLink™, insert earphones, VivoAmp™, and all cables) should be cleaned with a disinfectant such as Audiologist's Choice Audio Wipes™ or isopropyl alcohol wipes before placing them into an incubator or bassinet. Follow your hospital's infection control procedures.

The VivoTab™ electrodes, and immittance tips are disposable "single use only" items which should be discarded after every use. Please read the warnings and cautions marked on the package for proper use.

Environmental conditions for operation and storage

Integrity™ V500 System and all its parts are designed to operate in an environment with these conditions:

Ambient temperature:	+10 °C to +40 °C
Relative humidity:	30% to 75%
Atmospheric pressure range:	700 hPa to 1060 hPa
Altitude:	Up to 4600 m above sea level

Environmental conditions for storage of your Integrity™ ABR Screening:

Ambient temperature:	-40 °C to +70 °C -40 °C to +27 °C (electrodes)
Relative humidity:	10% to 100%
Atmospheric pressure range:	500 hPa to 1060 hPa

Getting Started

Your Integrity™ ABR Screening System is a medical device dedicated to hearing screening testing. This chapter will help you get started with your system.

Infant hearing screening criteria

The medical condition of the infant must always be considered before a hearing screening test. Please refer to the Quick Reference Guide for contraindications for use.

In addition, there are practical guidelines to consider when scheduling an infant for a hearing screening test. Follow the criteria below for more efficient and reliable screening outcomes.

- ☐ Infant is sleeping or in a relaxed state. If an infant is continuously crying, it may increase the test time beyond the 7.5 minutes and may cause the result to be a Refer.
- ☐ Infant is ready, or scheduled, for discharge from the hospital
- ☐ Infant is in an open crib with no ventilator or tubes
- ☐ Infant's ears should be clear of debris and/or vernix caseosa
- ☐ In the NICU, the infant is ready to be discharged from the NICU

Tips

1. A good time to screen is immediately after feeding when the infant is calm and relaxed.
2. Swaddling may also help to keep the infant calm.
3. You may want to delay screening until 20 hours after birth when the vernix caseosa has naturally cleared from the ear.
4. Ensure that you have adequate time to perform a hearing screening test before the infant is discharged from the hospital or NICU.

How to set up your system

All parts of your Integrity™ ABR Screening are shipped together, ready for you to set up. Plug your computer into an electrical wall outlet. On your VivoLink™, connectors and labels are color-coded for easy assembly. Match the colors of the connectors and plugs, and insert the connectors securely into the plugs. The connectors should fit easily with minimal force.
Your VivoLink™ and all of its accessories (VivoAmp™, 3-lead with electrode clips, cables and connectors, disposable electrodes) can be placed in the bassinet with your patient.

Note: Your VivoAmp™ has 4 electrode leads (ground, non-inverting, Channel 1, and Channel 2). However, the setup of the Integrity™ ABR Screening system only requires 3 electrode leads, specifically ground (green), non-inverting (black) and inverting Channel 1 (blue). Please remove Channel 2 (red) from the VivoAmp™ base during ABR Screening.

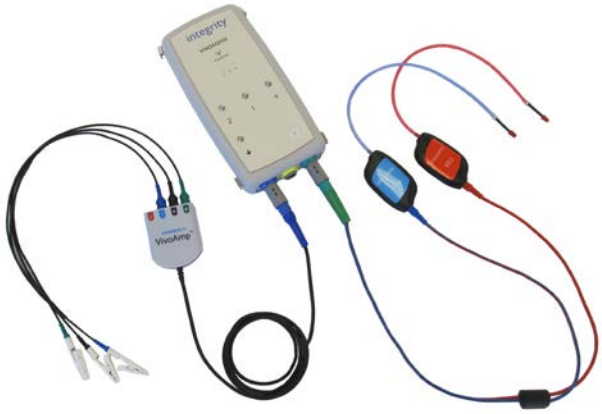


Figure 120. Setup of Your VivoLink™ for Integrity™ ABR Screening

Your Integrity™ ABR Screening VivoLink™

Your Integrity™ ABR Screening VivoLink™ works with your computer to determine the hearing screening outcome of your patient. You may find it convenient to hold the VivoLink™ in your hand or place it in your patient's bassinet.

3-Leads with Electrode Clips

Your VivoAmp™ has 4 electrode leads (ground, non-inverting, Channel 1, and Channel 2). However, the setup of the Integrity™ ABR Screening system only requires **3 electrode leads**, specifically ground (**green**), non-inverting (**black**) and inverting Channel 1 (**blue**). Please remove Channel 2 (red) from the VivoAmp™ base during ABR Screening.

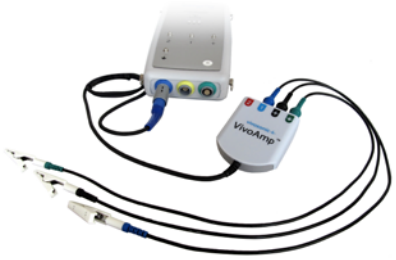


Figure 121. 3-leads with alligator electrode clips

Electrodes

When applied to the skin at the appropriate sites, the electrodes conduct electrophysiological signals from the brain. The proper application of the electrodes on the skin, and a secure attachment to the electrode clips, are necessary to obtain a correct screening outcome.

Each electrode has adhesive gel, referred to as "hydrogel" on the back. The gel ensures that your electrodes stick to your patient's skin, and remain in place during testing. The electrodes are easily removed by gently peeling them away from the skin, or by applying water to the hydrogel (which dissolves). The electrodes should be disposed of after a single use.

Insert Earphones

A means of delivering clicks to the ears is through the use of insert earphones. These must be properly inserted in the ear canal of the infant to achieve proper acoustic seal. The sound level of the clicks, either 30 or 35 dB nHL, is selectable by your Integrity™ ABR Screening Administrator.

Figure 122. Insert earphones

Different ear canal sizes can be accommodated through the use of different types and sizes of ear tips. There are three types of disposable ear tips available that can be used for testing:

- Infant Ear Tips (ER3-14D, and ER3-14E – "black and red")
- Foam Ear Tips (ER3-14B – "beige foam")
- Immittance Ear Tips (KR036 – "yellow", MF003 – "blue", MF007 – "green")
    - To use the immittance ear tips, the tubes that are connected to the insert earphones must be replaced with the ER3-06 ear tubes that have a special adaptor at the end.

Vivosonic recommends using the Infant Ear Tips (ER3-14D, and ER3-14E – "black and red") or the pediatric Foam Ear Tips (ER3-14B – "beige foam") for larger ear canals. However, for ear canals that are too large for the infant ear tip, and too small for the pediatric foam tip, then Vivosonic recommends using the appropriate size immittance tip.

Note: It is necessary to exchange the rubber tube when switching between the regular and immittance tips.

Please contact customer support for purchasing these tips and adapters.

The insert earphones and your VivoLink™ require a periodic calibration check by the manufacturer's representative to ensure that the sound levels delivered are accurate.

How to power on your system

To operate your Integrity™ ABR Screening, you will need to power on both your computer and your VivoLink™. While testing, your computer can be plugged into an electrical outlet, or can be powered by its battery. Your VivoLink™, however, can only operate when powered by its battery pack.

To power on your computer:

1. Press the **power button**.
2. On the desktop, click on the Integrity Icon. When the Launcher appears, select ABR Screening.

To power on your VivoLink Press the **power button** on your VivoLink™. The 3 LED lights will blink when it's turned on.

Figure 123. Main Screen

Your computer and your VivoLink™ work together

For your Integrity™ ABR Screening system to operate, your computer and your VivoLink™ must communicate with one another through a wireless connection. The wireless technology requires that your computer and your VivoLink™ be no more than 30 feet (10 meters) apart.

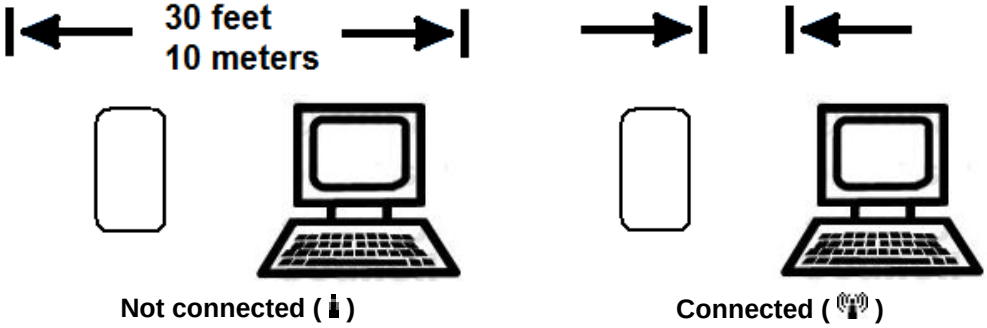


Figure 124. Connection indicators

When you power on your system, your computer and your VivoLink™ try to connect. There is a **wireless connection indicator ( )** on your computer screen that shows the status of the wireless connection.

Charging The Battery Pack

Whenever you power on your VivoLink™, you should check that the state of charge is sufficient to complete a hearing screening test of both ears. The **battery indicator** on your computer shows the level of charge remaining. When the indicator shows **Battery low** ( ), plug your batteries into its battery charger. It can require *up to 2 hours* to fully charge ( ) the batteries.

If you notice that a fully charged battery pack depletes in less than 3 hours of testing, it may be time to replace your battery pack with a new one. Please refer to "Battery low" section in this manual.

Warnings

⚠ Use only Vivosonic battery packs designed for your VivoLink™. Use of other batteries may damage your system and endanger your patient.

⚠ Use only the battery charger (CELL-CON NiCd/NiMH Charger, Model 452115-NA) supplied with Integrity™ ABR Screening.

Tip To ensure the ready operation of your Integrity™ ABR Screening system, charge your batteries at least two hours before your scheduled screening tests, and whenever the battery is low ( ).

Care, cleaning, and storage of your system

Integrity™ ABR Screening has several components. Although the system is designed to require minimal maintenance, there are some basic procedures you should follow to ensure that your system is in proper working order.

You should inspect and clean your Integrity™ ABR Screening system before each use, and properly store it when it is not in use.

Care of your system

Routinely inspect your Integrity™ ABR Screening system for wear and damage before each use. If your system is damaged in any way or is not working properly, contact Vivosonic Customer Support and do not use your system.

- ☐ Inspect all components including your VivoLink™, VivoAmp™, and insert earphones
- ☐ Inspect all cables for fraying, damage, and loose connections. Your cables must be attached securely to its respective parts for the reliable performance of your system.
- ☐ Inspect all connectors and clips for visible mechanical damage

On a regular basis, a technical specialist should perform a thorough inspection of all parts and components of your system. Once a year, your system should be calibrated by the manufacturer's representative to maintain its optimal performance.

Cleaning your system

Proper infection control procedures require that equipment is cleaned prior to use, for every patient. You should follow your infection control procedures to avoid cross-contamination.

The external surfaces of your system can be wiped with Audiologist's Choice Audio Wipes™, isopropyl alcohol pads, or a soft cloth lightly dampened with alcohol or a similar disinfectant.

As you clean your Integrity™ ABR Screening system:

- ☐ Avoid spraying or pouring liquid directly onto the VivoLink™, VivoAmp™, or insert earphones
- ☐ Be careful not to stretch or damage cables as you clean them
- ☐ Pay particular attention to the parts that may contact your patient's skin

Warning

⚠ Always remove the battery pack from your VivoLink™ before cleaning it. Failure to do so may result in serious injury and/or damage to your VivoLink™.

Storing your system

The proper storage of your system helps to prevent damage to it, and ensures that a hearing screening test can be performed when needed. Below are the recommended storage conditions of the Integrity™ ABR Screening system:

Screening computer	☐ Your Integrity™ ABR Screening computer is a dedicated hearing screening device. It should not be used for other purposes.
VivoLink™	☐ Plug your battery pack into its battery charger when not in use ☐ Remove the battery pack from your VivoLink™ when your system is not in regular use, or is stored for an extended period of time
VivoAmp™	☐ The VivoAmp™ can remain connected to your VivoLink™ ☐ The 3-leads with electrode clips can remain connected to the VivoAmp™ ☐ Suspend the cables out of the way to prevent damage to them
Insert earphones	☐ The insert earphones can remain connected to your VivoLink™ ☐ Suspend the cables out of the way to prevent damage to them ☐ Care must be taken not to pinch or damage the sound tubes during storage

Automated ABR

Automated ABR is a simple, quick, and effective hearing screening test. The results of the screening provide an indication of the ability to hear sound. Soft sounds or clicks (called "stimulus") are delivered into the ears to stimulate the auditory brainstem. Electrodes are used to detect small *electrophysiological responses from the auditory brainstem*. The presence of an auditory brainstem response (ABR) indicates that the infant hears the soft sounds, while the absence of a response indicates potential hearing loss.

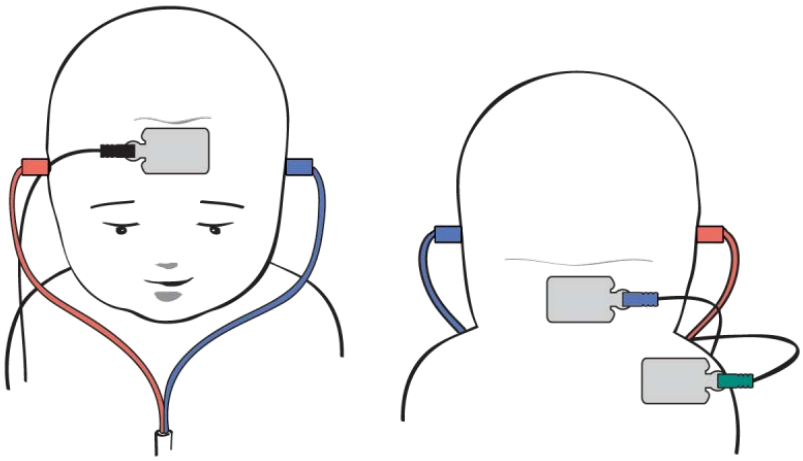


Figure 125. Automated ABR testing with insert ear phones

Automated ABR presents soft sounds to the ear as a series of clicks called “stimulus”. The clicks are delivered by the insert earphones. The sound level of these clicks is set by your Integrity™ ABR Screening Administrator to either 30 or 35 dB nHL (decibels normal Hearing Level).

VivoTab™ electrodes are placed at three sites on your patient (high forehead, nape of the neck, and shoulder) to detect the auditory brainstem response. The electrophysiological signals are amplified and information about these signals is sent wirelessly from your VivoLink™ to your computer.

Your computer analyzes the responses and determines the screening outcome. The outcome is displayed on your computer and your VivoLink™.

Pass	This outcome indicates that a consistent ABR was detected. Your patient was able to hear the clicks (or stimulus).
Refer	This outcome indicates that no ABR was detected during the screening time. Your patient should be referred to an audiologist for further diagnostic testing. It is critical that proper screening procedures are followed to minimize the incidence of a *false Refer* outcome.
Incomplete	This indicates that you stopped testing before a Pass or Refer outcome could be determined. You should attempt to screen the patient again and wait for a Pass or Refer outcome.

Before you begin

Here is a checklist of the basic procedures to follow before performing an Integrity™ ABR Screening hearing screening test. In addition, your hospital may require you to obtain written consent from your patient’s caregiver before testing.

- ☐ Recharge VivoLink™ batteries, and computer when the batteries are low (▭)
- ☐ Inspect equipment, connectors, and cables for damage
- ☐ Clean surfaces of equipment with Audiologist’s Choice Audio Wipes™, isopropyl alcohol, or similar disinfectant
- ☐ Check that the cables to your VivoLink™ are properly connected
- ☐ Minimize noise in the room

You will need the following supplies on hand:

- ☐ VivoTab™ electrodes
- ☐ Ear tips for use with insert earphones
- ☐ Alcohol wipes
- ☐ Skin prepping gel
- ☐ Cotton pads dampened with water

Important notes:

1 Use *only* VivoTab™ electrodes with your Integrity™ ABR Screening system. These electrodes are required for the proper operation of your system. They are specially designed and clinically validated for infant use. The use of electrodes supplied by manufacturers other than Vivosonic Inc. Can lead to unreliable results.

Before use, check the expiry date on the package. The electrodes have a limited shelf life after which they lose their effectiveness.

To prevent disease transmission and adverse skin reactions, dispose of electrodes after a single use.

2 Use ear tips specifically manufactured for use with the insert ear phones. These include Infant Ear Tips, Foam Ear Tips, and Immittance Ear Tips. Care must be taken to ensure that the ear tip is flush with the tip of the adapter. Dispose of the ear tips after single use.

Step 1. Power on and connect to computer

Once you have inspected and cleaned your Integrity ABR Screening™ system, you are ready to power it on.

To power on your Integrity™ ABR Screening system and establish a wireless connection:

1. Power on both your computer and your VivoLink™. Wait until you see the Integrity™ ABR Screening Main **screen** displayed on the computer.
2. Check that your VivoLink™ has successfully connected ( ) to your computer. The **wireless connection indicator** on your computer shows the connection status.

   If your VivoLink™ fails to connect to your computer (or loses connection), the indicator shows a “not connected” status ( ).

   - ☐ Check that your computer and your VivoLink™ are both powered on, and that your VivoLink™ is less than 30 feet (10 meters) from your computer
   - ☐ Minimize obstructions between your computer and your VivoLink™ that may interfere with the wireless connection

Step 2. Start Automated ABR

To start Automated ABR:

1. Select the **Auto ABR Test** button on the Integrity™ ABR Screening Main screen.
2. Enter demographic information in the **Patient Information** screen before you proceed with testing.

3. Check that the battery level of your battery pack is sufficient to complete a test.
   The **battery indicator** on your computer shows the level of charge.
   A fully charged battery ( ) ensures that you can screen several patients one after the other.

   ☐ When the indicator shows **Battery low** ( ), it is recommended that you recharge your batteries before you begin a test

Figure 126. Auto ABR Test button

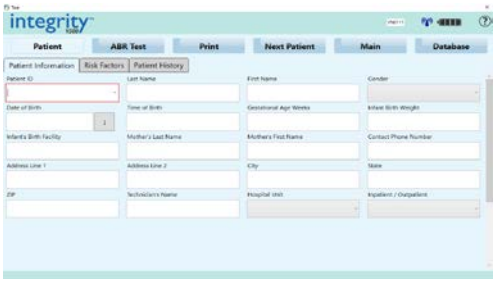


Figure 127. Patient Information screen

Step 3. Enter patient information

Before you can start a test, you need to enter information to identify your patient. If your patient has never been tested before, you may need to create a new patient record. Patients who have previously been tested, or who have an existing patient record, can be selected from a list.

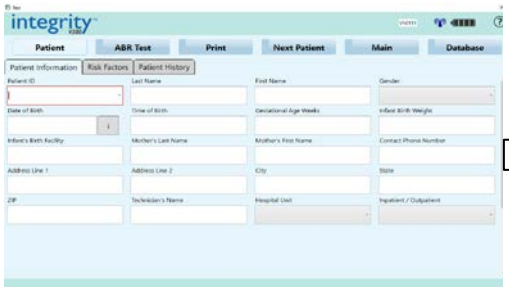


Figure 128. Patient Information screen

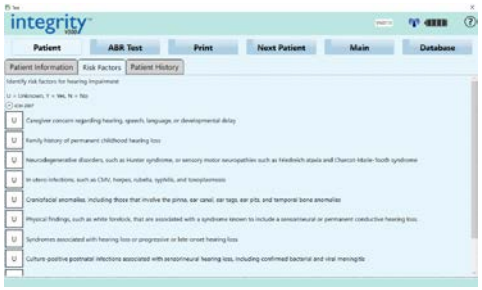


Figure 129. Risk Factors Screen

Create a new patient record

To create a new patient record:

1. Type your patient's unique identification number into the **Patient ID** field on the **Patient Information screen**.
   This is a mandatory field that must be completed before you begin a test.
2. Fill in other mandatory fields on this page in a similar manner.
   Mandatory fields are displayed with a red border. These fields are set by your Integrity™ ABR Screening Administrator.
3. Complete other information pages such as the **Risk Factors** and **Patient History** as required by your clinic.

Select an existing patient record

To select an existing patient record from a list of patients:

1. Select your patient from the **Patient ID** list.
2. Check that the other fields are updated with the selected patient's information.
3. Change information as needed.

Step 4. Proceed to the Test screen

Once you have entered your patient's information, select the **ABR Test** button to proceed to the **Test screen**.

A typical hearing screening requires you to test both ears of your patient. Integrity™ ABR Screening automatically tests both ears, one ear immediately after the other. This is the most efficient way to complete a test. You may, however, choose the option to test only one ear.

Step 5. Apply electrodes

Electrodes are used to detect the response of the auditory brainstem to the stimulus. Proper skin preparation and application of the electrodes is essential for an optimal hearing screening test.

Warnings

⚠ Do not apply the electrodes to damaged or unhealthy tissue, or to patients with visible jaundice.

⚠ Please refer to "Safety and Precautions" on page 128 for additional warnings.

Electrode sites

There are three electrode sites for automated ABR screening. The **Test screen** shows you the proper placement of the electrodes for screening.

1. Center **high FOREHEAD** with black clip attached
2. Center **NAPE of the neck** with blue clip attached
3. Right or left **posterior SHOULDER** with green clip attached

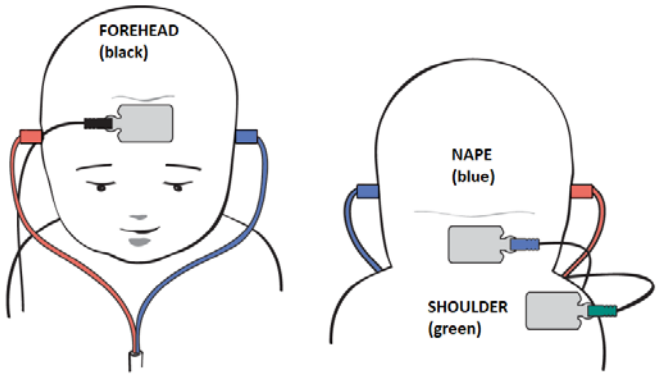


Figure 130. Electrode sites

Skin preparation

Before applying electrodes to the infant, you must prepare the skin at each electrode site. Poor skin preparation can increase the time to screen and contribute to *false Refer* outcomes.

It is important to follow recommended clinical procedures to avoid damage to the skin. In particular, extra care must be taken with the fragile skin of premature infants.

To prepare the skin at an electrode site:

1. Check that the skin tissue is undamaged and healthy.
   - ☐ Do not proceed with a hearing screening test if the skin is damaged or unhealthy
2. Gently clean the electrode site with an alcohol wipe to remove dirt and excessive oil from the skin.
   - ☐ Apply friction (not force) when cleaning the skin
   - ☐ Avoid using pressure when prepping near an infant's fontanel
   - ☐ Avoid prepping the skin too much since this can lead to adverse skin reactions
   - ☐ Use a new wipe for each electrode site
3. Follow the alcohol wipe with a skin prepping gel to exfoliate the skin. The skin prepping gel is available on demand. Please contact customer support for purchase instructions.
4. Wipe off excess gel.
5. Wait a few seconds until the area is dry before applying an electrode.

Tip If the skin is moist or oily, gently wash each site with soap and water before attaching electrodes. Take care to remove all traces of soap, and dry the area before placing the electrodes on the skin.

Apply electrodes and clips

After proper skin preparation procedures, electrodes can be attached to the skin. The VivoTab™ electrodes are specially designed for the sensitive skin of infants. The electrodes are intended for a "single use only" and should not be reused.

To apply an electrode to the skin:

1. Attach the **3-leads (black, blue, green) with electrode clips** securely to the three electrodes on the plastic sheet.
2. **<u>Note:</u> Your VivoAmp™ has 4 electrode leads (ground, non-inverting, Channel 1, and Channel 2). However, the setup of the Integrity™ ABR Screening system only requires <u>3 electrode leads</u>, specifically ground (green), non-inverting (black) and inverting Channel 1 (blue). Please remove Channel 2 (red) from the VivoAmp™ base during ABR Screening.**
3. Remove an electrode from the plastic sheet.
   - ☐ Avoid touching the adhesive area of the electrode
4. Place the electrode at the appropriate electrode site with the adhesive side down.
   - ☐ black clip to high FOREHEAD
   - ☐ blue clip to NAPE of neck
   - ☐ green clip to SHOULDER

5. Apply gentle pressure and smooth the entire electrode until it sticks to the baby's skin.
6. If an electrode fails to stick properly, discard it. Prepare the site again, and then apply a new electrode.

Tips

1. The electrodes are best applied to clean, dry skin.
2. Ensure that the electrode cables are not tightly stretched. Any pull on an electrode during testing may cause the electrode impedance to change and/or an electrode to fall off.
3. Orient all electrodes in the same direction towards the VivoAmp™. This makes it easier to manage the 3-leads with electrode clips so that electrodes are not accidently pulled or peeled off.

   Note: Your VivoAmp™ has 4 electrode leads (ground, non-inverting, Channel 1, and Channel 2). However, the setup of the Integrity™ ABR Screening system only requires 3 electrode leads, specifically ground (green), non-inverting (black) and inverting Channel 1 (blue). Please remove Channel 2 (red) from the VivoAmp™ base during ABR Screening.

Step 6. Apply insert earphones

During a test, Integrity™ ABR Screening delivers soft clicks to the ears via insert earphones. This section describes the proper application of insert earphones. Disposable ear tips are used with the insert ear phones to prevent cross-contamination between patients.

Warnings

⚠ Gently insert the ear tip in the infant`s ear canal. This will prevent buildup of positive pressure in the ear canal.

⚠ Use a different size ear tip if the ear tip is too loose or cannot fit in the ear canal.

Steps for using **Infant Ear Tips**:

1. Visually examine the ear canal for obstruction.
2. Ensure that the sound tube is not blocked.
3. Confirm that the sound stimulus is audible by holding the sound tube close to your ear and briefly running the test.
4. Attach the Infant Ear Tip completely to the nipple of the sound tube.
5. Insert the ear tip well into the ear canal.

Steps for using **Foam Ear Tips**:

1. Visually examine the ear canal for obstruction.
2. Ensure that the sound tube is not blocked.
3. Confirm that the sound stimulus is audible by holding the sound tube close to your ear and briefly running the test.
4. Attach the Foam Ear Tip completely to the nipple of the sound tube.
5. Roll the foam tip between the fingers so that it collapses into the smallest diameter possible.
6. Insert the ear tip well into the ear canal.
7. Allow the foam tip to expand in the ear canal. This will ensure good acoustic seal.

Points to note when using **Immittance Ear Tips**:

Probe fit is the most important part of the screening process.

- Always use the largest size ear tip possible. Attach the ear tip as described previously.
- Briefly listen to the clicks produced by the insert earphones to ensure that they are operational.
- Open the baby's ear canal by pulling back and down on the pinna. This will help maintain a good probe fit. Release the pinna after you insert the probe. This will allow the ear canal to fall snugly around the probe.
- Use firm pressure while giving the probe a quarter turn to insert in the ear canal. This creates a downward twisting motion that will ensure that the probe is inserted into the ear to obtain a tight seal. Aim the probe towards the infant's nose.
- To confirm that you have a good fit, gently tug on the probe after you have inserted it into the ear canal. You should feel some resistance and the probe should not slide out easily.
- **Do not hold the probe while administering the test**. Any unintentional motion can damage the baby's ear canal. You may also unintentionally interfere with the measurement system by introducing acoustic noise.
- Clip the small box attached the sound tubes (blue and red in colour) to the crib or blanket so that the probe stays fully supported in the ear canal.

Step 7. Begin screening

With your Integrity™ ABR Screening system properly connected, and with the electrodes, and insert earphones in place on your patient, you are ready to begin screening. At the beginning of every test, Integrity™ ABR Screening automatically checks the connection of the cables, and the fit of the electrodes on your patient before it proceeds.

Under typical conditions, an Integrity™ ABR Screening Automated ABR hearing screening test requires no more than approximately 15 minutes to complete. In a quiet environment, a calm patient with no hearing loss can complete testing in significantly less time.

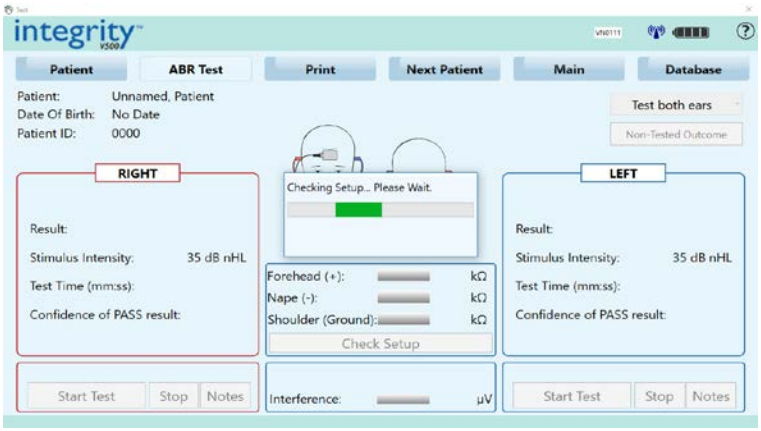


Figure 131. Checking setup

To begin a hearing screening test:

1. Select the **Start Test** button on the **Test screen**.
2. Wait for Integrity™ ABR Screening to complete a check of your setup.

   Integrity™ ABR Screening notifies you only if it detects potential problems with your setup. The system pauses until appropriate actions are taken and no further problems are detected.

   - ☐ Poor connection of cables
   - ☐ No electrode contact on the skin
   - ☐ High electrode impedance values

   When the check is successfully completed, Integrity™ ABR Screening automatically proceeds to screen the first ear. During this time, Integrity™ ABR Screening continues to monitor your setup to ensure it remains optimal.
3. Wait for the **Confidence of PASS result** to approach 100% for each ear. Avoid interrupting a test if the Confidence of PASS result does not change for a while.

   This value provides an indication of the probability that your patient can hear the stimulus. From time to time, the value may not increase as test conditions such as the muscular activity of your patient, and noise and interference in the environment change.
4. Wait for a Pass or Refer outcome for each ear.

   - ☐ Avoid touching the electrodes during screening
   - ☐ Avoid touching the insert earphones during screening

   If you stop the test before it is complete, the outcome is considered Incomplete.

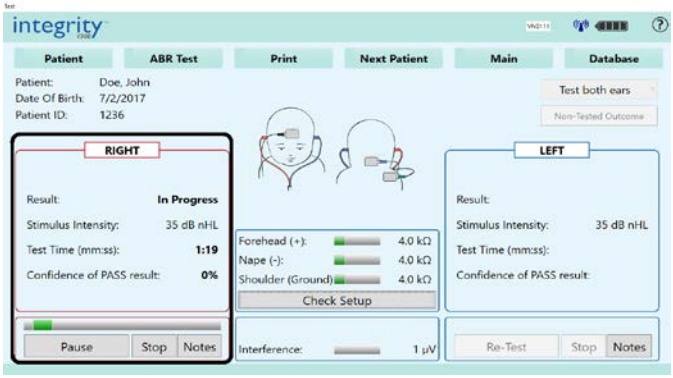


Figure 132. Test in progress

The importance of electrode impedance

Electrode impedance provides an indication of how well the electrodes are adhering to your patient's skin. Low impedance values make the ABR recording less susceptible to interference in the environment. Acceptable impedance depends on good skin preparation and the proper application of the electrodes.

Integrity™ ABR Screening automatically checks impedance levels before every test. The **Electrode Impedance indicators** on your computer show the impedance level for each electrode. A low impedance level for each electrode is desirable.

> *Testing does not proceed if impedance values are determined to be too high (orange bar).* Instead, your Integrity™ ABR Screening system prompts you to adjust the electrodes, and continues to repeatedly check for acceptable impedance levels.

Indicator Bar	Meaning
Green	Indicates an acceptable level of impedance. Testing proceeds.
Yellow	Indicates impedance can be improved. Testing proceeds.
Orange	Indicates a high level of impedance. Testing will not proceed until each electrode shows an acceptable impedance level (or you by-pass the automatic impedance check).

When impedance values are high

When impedance is high (orange bar), you can attempt to reduce impedance levels by applying new electrodes.

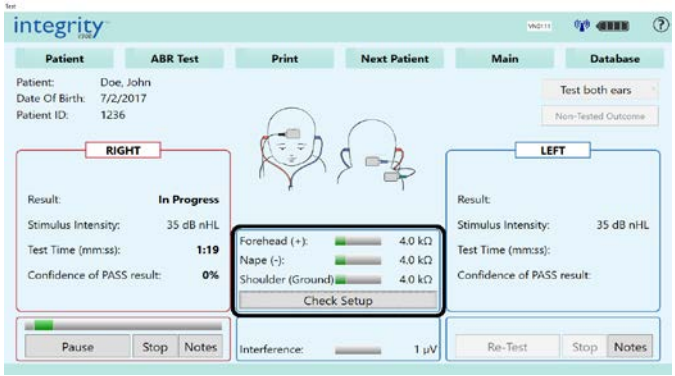


Figure 133. Electrode Impedance

To re-apply new electrodes:

1. Gently remove electrodes that show high impedance values and discard them. High impedance values are indicated by an orange bar on the **Test screen**.
2. Prepare the skin again, making sure to use a skin prepping gel to exfoliate the skin.
3. Wipe off excess gel.
4. Wait a few seconds until the areas are dry before applying new electrodes.
5. Attempt to start screening again.

If impedance values continue to remain high, check the setup of your Integrity™ ABR Screening system. You can also check the impedance of your system to determine if it is functioning properly.

Check the impedance of your system

To check the impedance of your Integrity™ ABR Screening system:

1. Attach the three electrode clips to the VivoLink™ securely.
2. Select the **Check Setup** button on the **Test screen**.
3. Observe the color of the Electrode Impedance indicators.
   - ☐ All indicators should show an acceptable level of impedance (green bar)
   - ☐ If impedance values are high (orange bar), check for damage to all electrode clips, cables, and connections to your VivoLink™.

Tip Regularly check the impedance of your system before you apply electrodes to your patient.

The importance of reducing noise and interference

During a hearing screening test, keep all sources of noise and interference to a minimum. Excessive noise or interference can prolong testing and contribute to a *false Refer* outcome. That is, a patient who has normal hearing may be suspected of having a hearing loss. As a consequence, the patient will likely undergo unnecessary follow up diagnostic testing.

Acoustic noise

The environment in which you perform your testing is critical. A quiet location leads to faster and more reliable results. Meanwhile, a noisy environment makes it difficult to detect the soft clicks and increases the risk of a *false Refer* outcome.

It is important to minimize audible acoustic noise in your test environment. If noise continues to be a problem, consider screening at another time or in another location.

Interference

Fans, lights, cellular telephones, pagers, computers, and similar devices in the surrounding environment can emit electrical and magnetic signals that interfere with the much smaller signals of the auditory brainstem. This is referred to as “electrical and magnetic interference.” Minimize the use of non-essential equipment and devices. If interference continues to be a problem, consider screening in another location.

Muscle activity

It is important that the infant is calm and relaxed throughout the test. A restless or moving infant generates muscle activity, a type of interference referred to as “myogenic noise.” Too much muscle activity generates unwanted signals that are picked up by the electrodes and make it more difficult to detect the small signals of the auditory brainstem. Testing should be performed when your patient is quiet and resting, or sleeping.

The **Interference indicator** on the **Test screen** displays an orange bar when myogenic noise and/or electrical and magnetic interference are unacceptable. First ensure that your patient is calm. If the indicator remains orange, then check for potential sources of other interference.

Step 8. Pass, Refer, Incomplete

Integrity™ ABR Screening automatically stops screening when it determines an outcome of Pass or Refer for each ear.

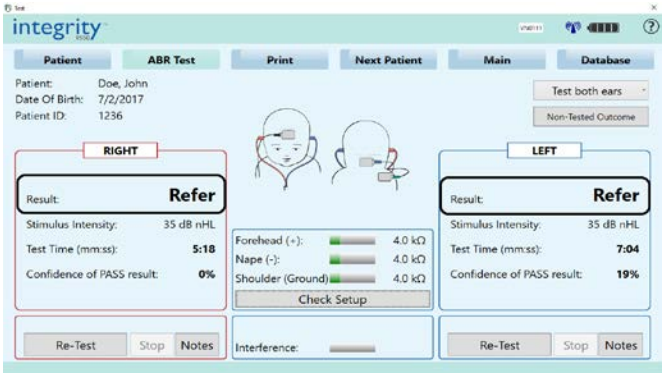


Figure 134. Test results

The actions that you take at this point depend on the result of the screening test, and your specific procedures. Typical actions are summarized in the following table.

OUTCOME	DESCRIPTION	TYPICAL ACTIONS
Pass	This outcome indicates that a consistent ABR is detected. Your patient was able to hear the clicks (or stimulus).	**1. Save and print result** **2. Test next patient**
Refer	This outcome indicates that no ABR is detected. Your patient should be referred to an audiologist for further diagnostic testing.	**1. Rescreen, as appropriate** **2. Save and print result** **3. Rescreen at another time or refer to an audiologist**
Incomplete	This outcome indicates that the test was not completed. The test was stopped before a Pass or Refer outcome could be determined. You should attempt to screen the patient again and wait for a Pass or Refer.	**1. Rescreen, as appropriate** **2. Save and print result** **3. Rescreen at another time**

Non-Tested Outcome

In situations where you are unable to screen the patient, the **Non-Tested Outcome** button can be used. Various non-tested outcomes can be chosen from a list which is saved on the database for record.

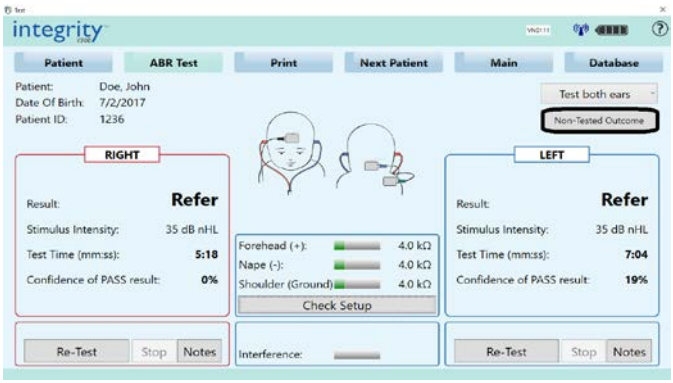


Figure 135. Non-Tested Outcome button

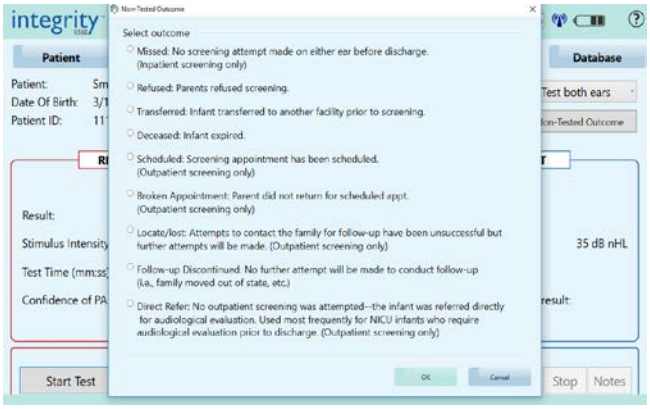


Figure 136. Non-Tested Outcome selection screen

OUTCOME TYPES

Missed: No screening attempt made on either ear before discharge. (Inpatient screening only)

Refused: Parents refused screening.

Transferred: Infant transferred to another facility prior to screening

Scheduled: Screening appointment has been scheduled. (Outpatient screening only)

Broken Appointment: Parent did not return for scheduled appt. (Outpatient screening only)

Locate/lost: Attempts to contact the family for follow-up have been unsuccessful but further attempts will be made. (Outpatient screening only)

Follow-up Discontinued: No further attempt will be made to conduct follow-up (i.e., family moved out of state, etc.)

Direct Refer: No outpatient screening was attempted—the infant was referred directly for audiological evaluation. Used most frequently form NICU infants who require audiological evaluation prior to discharge. (Outpatient screening only)

Save and print result

At the end of each test, the results are automatically saved to the Integrity™ ABR Screening database which is part of your system. Your Integrity™ ABR Screening Administrator can review your test results, and the results of any patient in the database.
Your clinical institution will typically require you to record your patient's hearing screening outcome. Integrity™ ABR Screening can print results which you can then include in your patient's medical file. Details about this feature are provided in Step 9. Print Results.

Test next patient

If you are screening several patients one after the other, you can use the **Next Patient** button to test another patient. This displays the **Patient Information screen**, ready for you to enter information about your next patient.

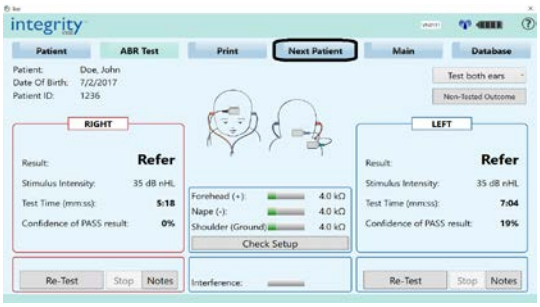


Figure 137. Next Patient button

Rescreen

Some hearing screening procedures require you to attempt another screening when one ear, or both ears, receive a Refer outcome. This situation may arise when the potential for a *false Refer* outcome exists.

- ☐ A restless patient, excessive acoustic noise, too much interference, and/or improper test procedures, may prolong test time and yield a *false Refer* outcome.
- ☐ Shortly after birth, excessive vernix in the ear canals frequently results in a *false Refer* outcome. Rescreening may be recommended after 20 hours once the vernix disappears.

Figure 138. Re-test button

Important note:

Repeated rescreening increases the risk of receiving a *false Pass* outcome, commonly referred to as a "false negative" result. *The consequence of a false Pass is that an actual hearing loss may go undetected.* If either ear receives a Refer outcome on the first test, it is recommended that you screen only once more, preferably at another time.

If you choose to rescreen immediately, be sure to correct or improve test conditions before you rescreen. Ensure that your patient is quiet and calm, noise and interference is reduced, electrode impedance is acceptable, and proper test procedures are followed. If acceptable test conditions cannot be achieved immediately, consider rescreening at a later time, or in another location under better conditions.

To rescreen:

1. Before you begin, ensure that test conditions that may contribute to a *false Refer* outcome have been minimized.

   - ☐ Refer to “The importance of electrode impedance on page 144.
   - ☐ Refer to “The importance of reducing noise and interference on page 145.
   - ☐ Refer to “Habits for successful screening on page 151.

2. Select the **Re-test** button on the **Test screen** to start screening.

   If the option to Test both ears is set, testing begins on one ear and then proceeds automatically to the other ear until outcomes are obtained for both ears. To test only one ear, set the option to test either the left ear or right ear only.

Step 9. Print Results

The patient’s printouts can be customized to fit to a label printer or a full page printout. Instructions are provided in your Integrity™ ABR Screening Database and Administration Manual. The label printout option requires the purchase of the Dymo® Label Printer. Please contact customer support for purchase instructions.

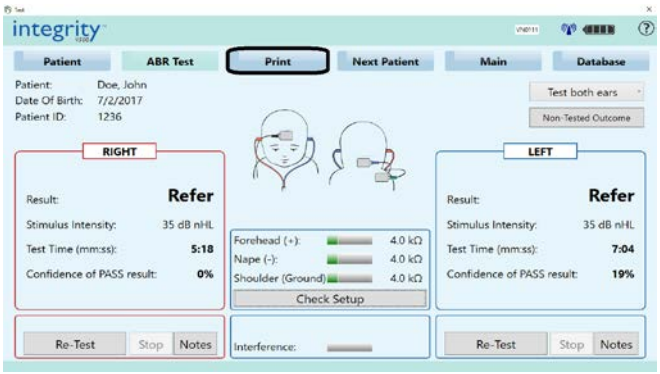


Figure 139. Print button

Figure 140. Print Preview – Full Page

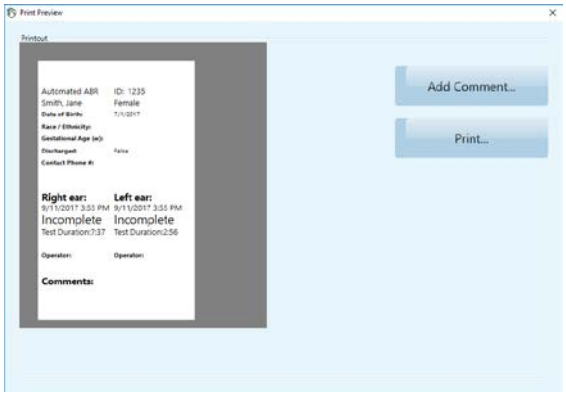


Figure 141. Print Preview – Label

Step 10.Final steps

When a screening test is complete:

1. Power off your VivoLink™.
2. When using insert earphones:
    a. Gently pull on the black tube attached to the end of the sound tube to remove the ear tip from the ear canal. This will prevent buildup of negative pressure during removal of the ear tip.
    b. Remove the foam ear tips from the sound tube`s nipple or OAE tips from the immittance probe tip adapters and dispose of the tips according to your infection control procedures.
3. Carefully remove the electrode clips from the electrodes.
4. Gently remove the electrodes from your patient. If removal is difficult, dissolve the adhesive hydrogel with water.
    - ☐ Blot water on the hydrogel using lightly dampened cotton pads.
    - ☐ Wait until the hydrogel dissolves.
5. Dispose of the electrodes according to your infection control procedures.
6. After each patient, always clean the insert earphones and other equipment that may contact patients.
    - ☐ Remember to power off and unplug equipment before cleaning.
    - ☐ Wipe external surfaces with Audio Wipes™, isopropyl alcohol, or similar disinfectant.

    Please refer to Care, cleaning, and storage of your system.
7. Proceed to test your next patient. Or, shutdown your Integrity™ ABR Screening system and store it.
    - ☐ Recharge your VivoLink™ batteries if necessary.

Habits for successful screening

Certain conditions can prolong test time and may lead to a *false Refer* outcome. You should attempt to provide more optimal conditions prior to, and during, screening.

If you find that the time required to complete a screening test is consistently about 15 minutes, the maximum test duration allowed by Integrity™ ABR Screening, please follow these guidelines.

1. Calm your patient	Screening is best performed when your patient is quiet and relaxed, or sleeping. Feeding and swaddling may help to calm some infants.
2. Properly insert the insert earphones	If using foam ear tips, roll the foam tip into the smallest diameter possible using your fingers and insert the ear tip well into the ear canal. Allow the foam to expand to acoustically seal the ear canal.
3. Check electrode contact	Good electrode contact (adhesion) with your patient's skin is needed to better detect the responses from the auditory brainstem.
4. Minimize acoustic noise	Speak softly; turn off radios and other unneeded equipment that produces noise.
5. Minimize interference	If possible, turn off fans, lights, cell phones, pagers, and other such equipment in the test environment that may produce electrical and magnetic interference.
6. Consider blocked ear canals	In the first few hours after birth, vernix caseosa (a protective white substance) can block, or partially block, the ear canal. If you suspect this is a problem, you may want to rescreen another day. Typically, vernix disappears naturally 20 hours after birth.

Data Reporting

Depending on the practices of your organization you may have to forward weekly/monthly reports to your supervisors. An easy way to do this is to use the **USB Export** option.

Figure 142. USB Export button

Report Setup

Before generating a report, ensure patient and test record information is selected. This can be done by selecting the **USB Export** button then selecting the **Set up Report…** button on the bottom right corner of the window. In the report setup window you can chose:

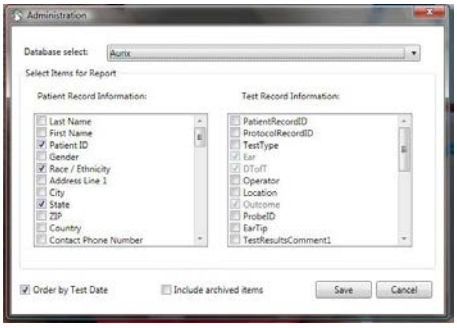


Figure 143. Report Setup Screen

- Which database the reports are generated from
- Which patient record information is shown in the report
- Which test record information is shown in the report
- Whether to order by Test Date
- Whether to include archived items

Generating Report

After selecting the **USB Export** button you will be prompted to:

1. Insert USB Drive – Insert USB drive/memory stick into any USB port found on the laptop. Ensure that only one USB drive is inserted at a time.

2. Choose Reporting Type – Choose data ranging from Last 7 Days, Monthly Report for desired month and year, or select a custom report range from the calendar window.

3. Generate Report – Select the **Generate Report** button to export the data range to the USB Drive.

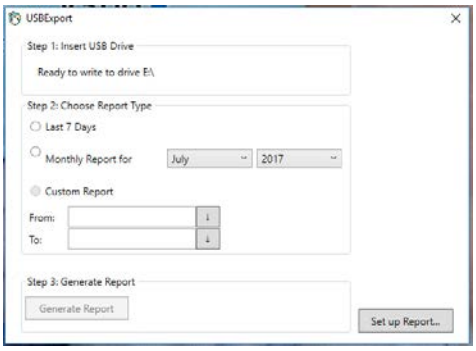


Figure 144. USB Export Window

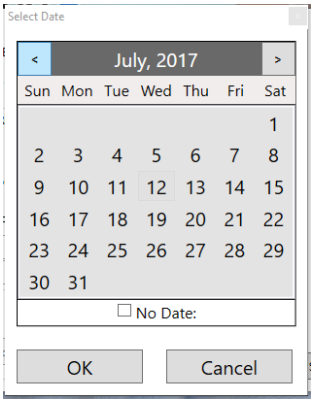


Figure 145. Calendar Window

Troubleshooting

This section describes solutions to problems that you may encounter as you use your Integrity™ ABR Screening system.

If you continue to experience problems, please contact Vivosonic Customer Support (support@vivosonic.com) for assistance.

U.S. and Canada: +1 (877) 255-7685 x2
International: +1 (416) 231-9997 x2

Battery low

The **battery indicator** shows **Battery low (** **)** when your VivoLink's™ battery level is insufficient to complete a test. If the level of charge falls below this level, *your VivoLink™ automatically shuts off* until its batteries are charged.

- ☐ Connect your battery pack to its battery charger
- ☐ Recharge your batteries before you begin a new test
- ☐ Refer to "Charging The Battery Pack**"** on page 134.
- ☐ You can expect a new battery pack, which is fully charged, to hold its charge for about 10 hearing screening tests. However, this estimation varies depending on your frequency and pattern of use. If you notice that a fully charged battery pack ( ) depletes in less than 3 hours of testing, it may be time to replace your battery pack with a new one. With daily use, your VivoLink's™ rechargeable battery pack may need to be replaced every 3 or 4 months.

Cables connected?

There may be a problem with one or more of your cable connections.

- ☐ Check the connector and cable from your VivoLink™ to the insert earphones
- ☐ Check the connector and cable from your VivoLink™ to the VivoAmp™ to the electrode clips
- ☐ Refer to "How to set up your system on page 131.

Electrode contact off

During screening, the electrodes need to maintain good contact with your patient's skin. When electrode contact cannot be detected, Integrity™ ABR Screening pauses and identifies which electrodes may have lost contact. You will need to correct the situation to proceed with testing.

- ☐ Attempt to adjust the problem electrode until it adheres to the skin
- ☐ Check that the attached cables are not pulling on the electrodes
- ☐ If an electrode has fallen off, clean the skin and apply a new electrode at the site
- ☐ Please also refer to "Step 5. Apply electrodes on page 139 for proper skin preparation and application of electrodes

Impedance is high (or very high)

Testing does not proceed when electrode impedance is unacceptably high.

- ☐ Check all electrodes for proper contact with your patient's skin
- ☐ When adhesion is poor, clean the skin and apply new electrodes
- ☐ Check the setup of your system
- ☐ Check the impedance of your system
- ☐ Refer to "The importance of electrode impedance on page 144 to learn more about electrode impedance and how to handle high impedance levels

VivoLink™ does not power on

Your VivoLink™ does not power on, or automatically powers off.

- ☐ Check that your VivoLink™ has charged batteries
- ☐ When the battery level is low, recharge your VivoLink™ batteries for a minimum of 30 minutes
- ☐ Refer to "Charging The Battery Pack on page 134" section of the manual for more information.
- ☐ Refer to "Battery low on page 153 for more information.

VivoLink™ does not connect

Your Integrity™ ABR Screening VivoLink™ does not automatically connect to your computer.

- ☐ Restart your VivoLink™ by powering it off and on
- ☐ Check that the "wireless radio switch" on your computer has not been accidently switched off
- ☐ Try pairing to the VivoLink again:
    - o Start Integrity Launcher > System Settings > Discover Bluetooth Devices > Click on Rescan button > Select the VivoLink to connect to from the drop-down menu > Pair and Save > Type in the Software Activation Code for ABR Screening> Register > Close Settings window > Launch Screening
- ☐ Refer to "Your computer and your VivoLink™ work together" on page 133 for more information.
- ☐ Switch the Hardware Wireless Radio Switch Off and On while the Integrity™ ABR Screening VivoLink™ is On
- ☐ Instructions supplied by your computer manufacturer describe how to switch on the wireless feature of your computer through hardware and software settings. Follow these instructions to switch on your computer's Bluetooth™ feature.

VivoLink™ loses connection

Your VivoLink™ may lose its wireless connection to your computer when the distance between your VivoLink™ and your computer is more than 30 feet (10 meters).

- ☐ Move your VivoLink™ closer to your computer until your VivoLink™ automatically connects to your computer
- ☐ Minimize obstructions between your computer and your VivoLink™ that may interfere with the connection
- ☐ Check that your VivoLink™ is powered on and that its batteries are not depleted
- ☐ Restart your VivoLink™ by powering it off and on
- ☐ Refer to “Your computer and your VivoLink™ work together” on page 133 for more information.

Maximum test time

You are notified when Integrity ABR Screening™ reaches total test duration of *approximately 15 minutes for both ears*. The test is stopped automatically, and the outcome is reported as a Refer for the ear(s) that did not complete testing.

If you suspect that the outcome may be a *false Refer* due to excessive noise, interference in the environment, restless patients, and/or a blocked ear canal, follow these guidelines before you rescreen your patient:

- ☐ Calm your patient
- ☐ Check fit of insert earphones tips
- ☐ Check electrode contact
- ☐ Minimize acoustic noise (sounds) in your environment
- ☐ Minimize electrical and magnetic interference
- ☐ For newborns, wait 20 hours after birth for vernix caseosa to disappear
- ☐ If test time continues to be excessive, it is recommended that you test at a later time, or test in a quieter location
- ☐ Refer to “The importance of electrode impedance on page 144.
- ☐ Refer to “The importance of reducing noise and interference on page 145.
- ☐ Refer to “Habits for successful screening on page 151.

Patient name

Integrity™ ABR Screening requires you to identify a patient before you proceed with testing.

- ☐ Enter your patient’s identification information on the **Patient Information screen**
- ☐ Check that your patient’s name appears correctly on the **Test screen**
- ☐ Refer to “Step 3. Enter patient information” on page 138 for more information.

Problems printing

Check that your printer has sufficient paper, and that there is no paper jam. Refer to the manufacturer’s instructions for troubleshooting assistance.

Loose insert earphones

Insert earphones should fit snugly in the patient's ears to minimize the level of acoustic noise in the ear canal which may interfere with the soft clicks (stimulus) delivered to the ears. You will need to correct the situation to proceed with testing.

- ☐ Check that the insert earphones fit snugly in the ear canals
- ☐ Check that there is nothing touching the insert earphones
- ☐ Check that the attached cables are not pulling on the insert earphones
- ☐ Refer to "Step 6. Apply insert earphones" on page 141 for more information.

Too much interference

The **Interference indicator** on the **Test screen** displays an orange bar when myogenic noise and/or electrical and magnetic interference are unacceptably high. Testing is paused when your Integrity™ ABR Screening system detects too much interference for an extended period of time. You will need to correct the situation to proceed with testing.

- ☐ First, relax and calm your patient
- ☐ If possible, turn off fans, lights, pagers, cellular telephones and other equipment that may produce electrical and magnetic interference
- ☐ If interference continues to be a problem, consider screening at another time or in another location
- ☐ Refer to "The importance of reducing noise and interference on page 145.

Screening Specifications

INTEGRITY™ ABR SCREENING	
Input Power	Internally powered by Vivosonic rechargeable battery pack (4 AA NiMH Batteries @ 1.2 VDC each)
Applied Part Type	BF 
Medical Device Classification	II: as per Rule 10 of Schedule 1 of SOR/98-282 - The Canadian Medical Devices Regulations IIa: as per Rule 10 of Annex IX of Council Directive 93/42/EEC Concerning Medical Devices (MDD)
Software Safety Classification	Class A – No injury or damage to health is possible (IEC 62304:2006)
Wireless Communication Type	Bluetooth: 2.402 to 2.480 MHz, Hopping Wireless Communication Range: 30 feet (10 meters)
Dimensions of Main Unit	L 7.1" (18 cm) x W 3.6" (9.1 cm) x H 1.2" (3.2 cm)
Weight of Main Unit	0.92 lb. (417 g) with battery pack
GMDN Category	04 Electro Mechanical Medical Devices
100410 Battery Pack Cradle connected to 100351 Battery Charger	
Classification	Class II
Input Power	100 - 240 VAC 50 - 60 Hz max 0.35 A

Integrity™ ABR Screening Signal Processing

Integrity™ ABR Screening system is the latest development in infant hearing screening. It incorporates the latest developments in signal processing based on a foundation of proven methodology.

The method used in the Integrity™ ABR Screening system is the dual buffering method, which stores the average of half the responses in one buffer (Buffer A) and the other half of the responses in a second buffer (Buffer B). For detection of ABR, the ratio of the A and B average to the A and B difference is used as a statistic. The A and B buffers are selected using a patent pending technique that ensures that the variance ratio is not by biased by the particular responses that comprise each of the buffers. Signals are preprocessed using Kalman weighted averaging (also known as Kalman filtering), according to the method of Leski[1] and a proprietary technique to estimate the expected noise in each response.

The variance ratio statistic is used to evaluate if there is a significant difference between the signal and the noise. If there is a significant difference then there is a high probability that the patient can hear the stimulus. The variance ratio threshold is set so that the sensitivity of the screening test is 98% for the detection of moderate to severe unilateral hearing loss and 99.96% for bilateral hearing loss. The specificity of the test will vary with the patient population, e.g., infants during their first few hours of life are more likely to have blocked ear canals due to vernix. The specificity also depends on the test environment because the probability of ABR detection decreases when the environment is noisy. In ideal test environments with normal hearing babies who have no external obstructions (such as vernix), the specificity of the test is expected to exceed 96%.

The sound stimulus is factory set to 35 dB nHL. The level of sound intensity is adjustable to two possible levels: 30 or 35 dB nHL. While the sound level is calibrated at these different levels we recommend that the sound level be kept at 35 dB nHL. If the stimulus level is set to a lower level then the specificity of the test may decrease.

[1] Leski, JM (1991). New concept of signal averaging in time domain. Annual International Conference of IEEE Eng Med Biol13(1), p.367-368.

Chapter 9: Troubleshooting

This chapter covers problems, possible causes, and some solutions.

ATTENTION

Do not attempt to repair any component of the system; this may cause it to function improperly.

The Integrity System is not a field-repairable instrument. Call your distributor or Vivosonic Customer Support for all repairs.

WARNING

Only Vivosonic Integrity V500 transducers should be plugged into the VivoLink.

Table 4. Troubleshooting Problems, Causes, and Solutions

Problem Observed	Possible Causes	Possible Solutions
The computer does not start up.	• The battery is dead and the computer is not plugged in. • The power outlet is not working. • The computer is not turned **on**.	• Charge the battery. • Try plugging the computer into a power outlet that is known to work. • Switch the computer on. Check your computer's User Manual for the location of the switch.
The system starts and operates, but displays error messages.	• Printer drivers (or other non-Integrity System peripheral drivers) installed on the system by the operator may not be compatible with the Integrity System.	• Please contact Customer Support. • Only printer drivers that have been tested and validated by Vivosonic Inc. to work with the Integrity System may be used.
There is no signal from the transducer (For ABR/ECochG, ASSR, and 40 Hz ERP, only)	• The wrong ear has been chosen. • The earphone is not inserted properly. • The stimulus level has been set to 0 dB nHL or another low value. • The gold electrode ear tip not making good connection with the ear canal wall. (ECochG only) • Cable damage.	• Verify that the appropriate ear tip is chosen. • Verify that the foam earphone has been placed in the ear canal properly. • Verify the bone conductor is affixed properly to the patient. • Check that the walls of ear canal are clean and clear of obstructions.
There is no signal from the transducer (bone conductor). (For ABR only)	• The bone conductor transducer is not placed correctly. • The wrong ear has been chosen • The stimulus level has been set to 0 dB nHL or another low value.	• Verify that the appropriate ear is chosen. • Verify the bone conductor is affixed properly to the patient.

The EEG signal is above ±40 µV and is not coming down. (For ABR/ECochG, ASSR and 40 Hz ERP only)	• The electrodes may be poorly placed. • Old electrodes.	• Readjust the electrodes and start again. • Use new package and place in re-sealable bag.
Cannot change the password.	• The old password is being typed incorrectly.	• Check the Num Lock is set if using the number pad. • Check that the Caps Lock is not set. • Verify the password has not been changed already. • Contact Customer Support.
There is no response for either ear while testing.	• The ear is not getting the stimulus sent from the VivoLink.	• Check that the transducer is producing a sound. Listen to the earphone using a reasonably audible stimulus setting such as 60 dB nHL. • For OAE tests change the OAE probe using the cavity check function. • For AEP tests perform a test using the “Amplitrode Test” protocol with the Amplitrode or the VivoAmp connected to the snaps on the VivoLink. • If there is still no response, call Customer Support to determine if the problem is the connection on the VivoLink.
OAE Probe does not produce any sound	• The probe may be damaged. • The probe is not connected properly. • The OAE probe is blocked by ear wax or another substance.	• Check the probe for obvious damage • Check the OAE probe for ear wax and clean it if necessary. • Perform a Cavity Check • Test with another ‘good’ probe. If it does not produce sound contact Vivosonic Inc. • Check the connection of all cables and connections

OAE Probe produces poor quality sound	• The probe may be damaged. • There may be a loose or damaged cable.	• Check the probe using the Cavity Check procedure found on page 105 • Test with another ‘good’ probe. If it does not produce sound contact Vivosonic Inc. • Check the connection of all cables and connections • Check the battery level on the VivoLink

Recommended Separation Distance

This Appendix covers the recommended separation distance between portable and mobile radio frequency devices and the Integrity System.

The Integrity System is intended for use in electromagnetic environments in which radiation disturbances are controlled. The customer or user of the Integrity can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile Radio Frequency Communication Equipment and the Integrity System as recommended below, according to the maximum output power of the communication equipment.

Equipment and systems that are NOT life-supporting

Max. Output Power (Watts)	**Separation (m) 150 kHz to 80 MHz** **D= 1.1667(Sqrt P)**	**Separation (m) 80 to 800 MHz** **D=1.1667(Sqrt P)**	**Separation (m) 800 MHz to 2.5GHz** **D=2.3333(Sqrt P)**
0.01	0.11667	0.11667	0.23333
0.1	0.36894	0.36894	0.73785
1	1.1667	1.1667	2.3333
10	3.6894	3.6894	7.3785
100	11.667	11.667	23.333

Appendix A: ABR Latency Norms Data

UCLA School of Medicine Norms for Infants

Wave V Mean Latency as Function of Click

Table 5. UCLA School of Medicine norms for infants

Age in weeks		25 dB	35 dB	45 dB	55 dB	65 dB	75 dB
Newborn	**Mean**	8.92	8.53	8.05	7.76	7.50	7.24
	SD	0.58	0.68	0.63	0.51	0.50	0.47
2 wk	**Mean**	8.50	8.05	7.70	7.37	7.10	6.89
	SD	0.51	0.42	0.40	0.34	0.37	0.36
4 wk	**Mean**	8.41	7.98	7.60	7.32	7.07	6.87
	SD	0.45	0.38	0.35	0.35	0.35	0.35
6 wk	**Mean**	8.25	7.80	7.46	7.18	6.93	6.73
	SD	0.32	0.32	0.30	0.31	0.28	0.28
9 wk	**Mean**	8.13	7.69	7.32	7.04	6.78	6.61
	SD	0.40	0.34	0.32	0.31	0.28	0.26
12 wk	**Mean**	8.04	7.63	7.24	6.96	6.76	6.59
	SD	0.36	0.30	0.29	0.29	0.26	0.24
26 wk	**Mean**	7.80	7.44	7.10	6.83	6.58	6.38
	SD	0.37	0.46	0.42	0.38	0.31	0.29
Adult	**Mean**	7.32	6.82	6.46	6.10	5.89	5.75
	SD	0.40	0.30	0.25	0.23	0.23	0.23

Data collected for a click rate of 33.3 clicks/s. Infants were categorized by chronological age (weeks after birth).

Source: Zimmerman, M.C., Morgan, D.E., Dubno J.R. (1987). Auditory Brain Stem Evoked Response Characteristics in Developing Infants. *Annals of Otology, Rhinology, Laryngology*, 96, 291-299. Used with permission from the publisher.

Boys Town Norms for Newborns

ABR Latency and Amplitude Values as a Function of Intensity Level in Newborns

Table 6. Boys Town norms for newborns

Conception age in weeks	Wave V latency (msec)				
		20 dB	40 dB	60 dB	80 dB
33 – 34 wk	**Mean**	9.72	8.48	7.62	7.05
	SD	0.56	0.49	0.41	0.39
35 – 36 wk	**Mean**	9.61	8.42	7.58	7.02
	SD	0.67	0.54	0.43	0.38
37 – 38 wk	**Mean**	9.57	8.29	7.45	6.94
	SD	0.74	0.51	0.44	0.42
39 – 40 wk	**Mean**	9.36	8.11	7.30	6.82
	SD	0.57	0.49	0.40	0.38
41 – 42 wk	**Mean**	9.31	8.08	7.20	6.69
	SD	0.54	0.35	0.29	0.29
43 – 44 wk	**Mean**	9.16	7.94	7.08	6.53
	SD	0.53	0.51	0.33	0.32

Data collected under the following measurement parameters: stimulus – click, 0.1 ms, 13/sec, monaural, Beyer DT48 earphones; acquisition – filters, 100 – 3000 Hz; amplification, 100,000; sweeps, 1,024; analysis time, 15 ms; electrodes, Cz-Mi.

Infants were categorized by conceptional age in weeks (gestational age at birth plus number of weeks since birth).

Source: Gorga, M.P., Reiland, J.K., Beauchaine, K.A., Worthington, D.W, Jesteadt, W. (1987), Auditory brainstem responses from graduates of an intensive care nursery: normal patterns of response. *Journal of Speech and Hearing Research*, 30, 311-318. Used with permission from ASHA and M. Gorga.

Boys Town Norms for Infants

ABR Latency Values as a Function of Intensity Levels in Children Aged 3 Months to 3 Years

Table 7. Boys Town norms for infants

Age in months		Latency (ms)				
		Wave V				Wave I
		20 dB	40 dB	60 dB	80 dB	
3 – 6 mt	**Mean**	8.72	7.43	6.73	6.25	1.59
	SD	0.53	0.36	0.33	0.32	0.17
6 – 9 mt	**Mean**	8.59	7.28	6.56	6.10	1.59
	SD	0.61	0.38	0.29	0.26	0.16
9 -12 mt	**Mean**	8.31	7.05	6.31	5.90	1.59
	SD	0.54	0.37	0.29	0.27	0.18
12 – 15 mt	**Mean**	8.28	7.10	6.30	5.91	1.59
	SD	0.60	0.45	0.33	0.27	0.17
15 – 18 mt	**Mean**	8.33	7.00	6.24	5.84	1.58
	SD	0.61	0.38	0.24	0.27	0.14
18 – 21 mt	**Mean**	8.22	6.95	6.19	5.74	1.55
	SD	0.62	0.36	0.18	0.19	0.12
21 – 24 mt	**Mean**	8.05	6.79	6.14	5.71	1.57
	SD	0.58	0.33	0.29	0.26	0.17
24 – 27 mt	**Mean**	8.30	6.89	6.09	5.71	1.53
	SD	0.46	0.29	0.22	0.19	0.14
27 – 30 mt	**Mean**	7.98	6.75	6.08	5.60	1.59
	SD	0.42	0.33	0.28	0.22	0.19
30 – 33 mt	**Mean**	8.12	6.79	6.07	5.68	1.56
	SD	0.53	0.32	0.31	0.27	0.16
33 – 36 mt	**Mean**	8.10	6.82	6.06	5.68	1.56
	SD	0.68	0.38	0.31	0.27	0.15

Data collected under the following measurement parameters: stimulus–click, 0.1 ms, 13/sec, monaural, Beyer DT48 earphones, 0 dB = 30 dB peSPL; acquisition–filters, 100 – 3000 Hz; amplification, 100,000; sweeps, 1,024; analysis time, 15 ms; electrodes, Cz-Mi.

Gorga, M.P., Kaminski, J.R., Beauchaine, K.L., Jesteadt, W., Neely, S.T. (1989). Auditory brainstem responses from children three months to three years of age: normal patterns of

response. *Journal of Speech and Hearing Research*, 32, 281-288. Used with permission from ASHA and M. Gorga.

Absolute and Interwave Latency Values

These latency values are for the primary components of the ABR.

Table 8. Absolute and interwave latency values

Stimulus Intensity dB nHL		I	II	III	IV	V	I – III	III – V	I - V
90	**Mean**	1.53	2.53	3.58	4.56	5.37	2.05	1.79	3.84
	SD	0.11	0.09	0.09	0.17	0.12	0.14	0.14	0.16
80	**Mean**	1.62	2.68	3.68	4.68	5.47	2.06	1.79	3.85
	SD	0.12	0.11	0.08	0.22	0.12	0.11	0.09	0.14
70	**Mean**	1.82	2.79	3.85	4.92	5.64	2.03	1.79	3.82
	SD	0.17	0.12	0.13	0.24	0.16	0.11	0.12	0.11
60	**Mean**	2.04	2.98	4.06	5.11	5.88	2.02	1.72	3.75
	SD	0.20	0.15	0.21	0.31	0.25	0.12	0.10	0.11
50	**Mean**	2.43	3.69	4.60	5.43	6.19	2.02	1.56	3.64
	SD	0.17	0.10	0.23	0.25	0.32	0.19	0.18	0.19
40	**Mean**	3.01	4.05	4.94	5.65	6.65	1.85	1.71	3.60
	SD	0.25	0.18	0.25	0.49	0.32	1.85	1.71	3.60
30	**Mean**	-	-	5.45	-	7.24	-	1.74	-
	SD	-	-	0.30	-	0.42	-	0.26	-
20	**Mean**	-	-	5.56	-	7.52	-	1.88	-
	SD	-	-	0.57	-	0.63	-	0.23	-

Source: Linda J. Hood. Clinical Applications of the Auditory Brainstem Response. Singular Publishing Group, Inc. 1998, San Diego, 285 pages. Used with permission from publisher.

Cincinnati Children's Hospital Norms for Infants

ABR Latency Values in children aged 0 to 6 months.

Table 9. Cincinnati Children's AC Norms for infants[1]

Age in months	Air Conducted Tone Burst Latency (ms)				
	Wave V				
	Stimulus Intensity (dB nHL) / Frequency		10 dB	20 dB	30 dB
0 – 6 mt	500 Hz	Mean	15.3	14.9	14
		SD	2.3	0.95	1.8
	1 kHz	Mean	13.6	12.9	11.5
		SD	1.7	1.3	0.9
	2 kHz	Mean	11	9.9	9.3
		SD	1.3	0.5	0.9
	4 kHz	Mean	9.4	9.3	8.2
		SD	0.7	1.1	0.7

Table 10. Cincinnati Children's BC Norms for infants[1]

Age in months	Bone Conducted Tone Burst Latency (ms)				
	Wave V				
	Stimulus Intensity (dB nHL) / Frequency		10 dB	20 dB	30 dB
0 – 6 mt	500 Hz	Mean	15.9	15.6	13.8
		SD	1.9	1.4	1.8
	1 kHz	Mean	14.1	13.5	11.9
		SD	1.7	1.8	1.4
	2 kHz	Mean	12.8	12.1	10.4
		SD	1.5	1.1	1
	4 kHz	Mean	11	10.5	8.9
		SD	2.1	1.6	1.4

[1]Elsayed AM, Hunter LL, Keefe DH, Feeney MP, Brown DK, Meinzen-Derr JK, Baroch K, Sullivan-Mahoney M, Francis K, Schaid LG (2015). Air and Bone Conduction Click and Tone-Burst Auditory Brainstem Thresholds Using Kalman Adaptive Processing in Nonsedated Normal-Hearing Infants. *Ear & Hearing,* Electronic Publication. DOI: 10.1097/AUD.0000000000000155.

Appendix B: DPOAE Norms Data

The table below provides the 95th and 90th percentiles from the impaired distributions and the 10th and 5th percentiles from the normal distributions as a function of frequency.

		Frequency							
		750	**1000**	**1500**	**2000**	**3000**	**4000**	**6000**	**8000**
Percentile	**95th (Impaired)**	5.95	7.65	3.83	-0.9	-2.3	0.18	-2.08	-9.97
	90th (Impaired)	2.4	4.4	0.43	-3.5	-5.55	-4.42	-6.88	-12.85
	10th (Normal)	-10.4	-8.1	-6.73	-9.85	-11.5	-5.93	-7.84	-22.2
	5th (Normal)	-13.6	-12.05	-9.8	-13.9	-16.25	-9.23	-11.0	-26.0

Data collected under the following measurement parameters:

- L1 = 65 dB SPL
- L2 = 55 dB SPL
- F2/F1 Ratio = 1.22

Source:

Gorga, M., Neely, S., Ohlrich, B., Hoover, B., Redner, J, Peters, J. (1997) From laboratory to clinic: A large scale study of Distortion Product Otoacoustic Emissions in ears with normal hearing and ears with hearing loss. Ear & Hearing, V. 18, No. 6, pp. 440-455.

Appendix C: Glossary of Terms

The following definitions are used in this manual and can also be found in the Integrity software instrument screens.

A-collected Waveform	The cumulative response waveform obtained by averaging the successive response waveforms in recording window collected in the odd numbers of Response Collection Periods (RCP).
Acoustic coupler	Cavity of predetermined shape, volume, and acoustic impedance such as Occluded Ear Simulator (Zwislocki Coupler) that couples the Probe and a measuring microphone of the sound level meter and is used for calibration of stimuli.
Air conduction	A mode of presenting auditory stimuli via earphones placed over the ear or within the ear canal.
Algorithm	The algorithm field allows selection of the signal processing algorithm used to combine successive ABR responses. The Integrity System offers the standard **Averaging** method and the **SOAP-Kalman Weighted** averaging method.
Alternating Stimulus Polarity	Alternating presentation of rarefaction and condensation polarity stimuli.
Ambient noise level	Sound level of the acoustic noise that is present in the surrounding environment and produced by acoustical sources other than the sources of interest, i.e. the Probe and the Ear.
Amplitrode	An integrated pre-amplifier and electrode in a combined unit for attaching or affixing to a subject.
Artifact	Unwanted signal that may interfere with the measurement of desired signals.
Artifact Rejection (AR)	A process to discard the Response Collection Period (RCP) in which an artifact is detected.
Artifact Rejection Rate (ARR)	The number of rejected response collection periods (RCP) expressed as a percentage of the total number of cumulative response collection periods.
Artifact Rejection Threshold (ART)	The sound pressure level in µV above which the detected acoustic signal is considered an artifact.
Assessment	A user-selectable test procedure that performs tests without automatic qualification of results.
Auditory Brainstem Response (ABR)	Auditory evoked potential originating from the cranial nerve VIII and auditory brainstem structures.
Authorization	Permission to access protected features or data.
Automatic Screening	A user-selectable test procedure that automatically qualifies a test result using user-defined pass-refer criteria.
Averaging	ABR and TEOAE processing algorithm, which uses a standard time averaging technique when equivalent weighting is given to each collected response. Sweeps contaminated with artifacts above a certain artifact-rejection threshold (ART) are excluded from the averaging.
B-collected waveform	The cumulative response waveform obtained by averaging the successive response waveforms in recording window collected in the even numbers of Response Collection Periods (RCP).
Bone Vibrator	A transducer that is used to present sounds to the skull that reaches the cochlea through the head tissues and bones, i.e., bypassing the middle ear.

Cavity Check	Procedure performed to ensure the OAE probe is working and is in good condition, *i.e.*, no acoustical change has occurred since the probe programming. The procedure is performed with the probe inserted in the Probe Holder on the VivoLink. The test includes checking System NF, probe calibration, and System TR in case of TEOAE test, or System DP in case of DPOAE test.
Channel	A single set of inputs into an Auditory Evoked Potential system (e.g.: from one pair of electrodes) or a single output from a stimulus generator (e.g.: to the right earphone).
Click	Short-duration, broadband sound produced by applying a short electric pulse to the receiver of the probe, typically around 100 µs for ABR and 80-120 µs for TEOAE.
Click Bandwidth	The frequency range of the click spectrum within 6 dB from its maximum.
Click Duration (CD)	Duration of an electric pulse driving the receiver to elicit a click, in microseconds (µs).
Click Interval (CI)	The time interval between the onsets of two successive clicks.
Click Level (CL)	Sound pressure level of clicks in dB peSPL (peak-to-peak equivalent SPL) as defined in IEC 60645-3.
Common Mode Rejection (CMR)	A noise reduction technique implemented by the differential amplifier where an identical (common) noise measured at two electrodes is subtracted from the electrophysiological response.
Component	A peak or wave in the response waveform.
Condensation (Positive) Stimulus Polarity	The initial displacement of the stimulus, produced with an outward movement of the acoustic transducer.
Contralateral TEOAE Suppression	TEOAE response changes caused by stimuli presented to the ear opposite to the one where TEOAE is recorded.
Customizable	Settings that can be changed by the user.
Database	An organized collection of data.
dB HL	A decibel scale referenced to acceptable standards for normal hearing (0 dB is averaged normal hearing for each audiometric test frequency).
dB nHL	A decibel scale used in auditory brainstem response measurement referenced to average behavioral thresholds for click or tone-burst stimuli collected on a small group of normal hearing patients.
dB peSPL	The decibel level of r.m.s value of a long duration sinusoidal signal which, when compared under the same test conditions with a short duration output signal from the transducer under test, has the same peak-to-peak value (i.e. difference between the extreme positive and the extreme negative values) as the short duration signal. For clicks and broadband chirps, the long duration sinusoidal signal is at 1 kHz. For tone bursts, the long duration sinusoidal has a frequency equal to that of the primary (carrier) frequency of the tone burst (IEC 60645-3).
dB SPL	The logarithmic ratio of the RMS sound pressure of an acoustic signal, Prms to the reference sound pressure, P0 = 20 µPa = 2 * 10-5 Pa, calculated as: SPL (dB) = 20 * log (Prms/P0).
DP level	Sound Pressure Level of Distortion Product Otoacoustic Emissions measured at the probe acoustic inlet.
DP-gram	A graph that presents DP level and Noise Floor as functions of stimulus frequency, typically f2.

DPOAE	Distortion Product Otoacoustic Emissions.
DPOAE Stability	User-selectable criterion of Vivosonic DPOAE Algorithm stability: • Accurate (default): DPOAE Algorithm will stop processing when it finds the DP amplitude variation at a point in current frequency range is less than ±1 dB SPL and whose SNR is greater than 14 dB within 0.4 seconds. • Medium: DPOAE Algorithm will stop processing when it finds the DP amplitude variation at a point in current frequency range is less than ±2 dB SPL and whose SNR is greater than 10 dB within 0.3 seconds. • Fast: DPOAE Algorithm will stop processing when it finds the DP amplitude variation at a point in current frequency range is less than ±3 dB SPL and whose SNR is greater than 8 dB within 0.2 seconds.
DSP	Digital Signal Processing.
Duration of stimulation (DOS)	The sum of clicks intervals presented to record a TEOAE response less one click interval, plus the time between the onset of the last click and the end of recording window. Practically, it can be approximated by the multiple of the number of all clicks presented and the click interval, for example 1000 x 20 ms = 2000 ms.
Ear Tip	A part of the insert earphones, typically made of soft plastic, that is inserted into the ear canal and used to test for acoustic isolation of the ear canal from the environment.
Earphone	A device for presenting a sound stimulus to the ear, consisting of an acoustic transducer for converting an electrical signal into sound and a cushion that couples the transducer to the ear.
Electro-cochleography (ECochG)	A method of diagnosis that uses low potential electrodes (e.g. gold electrode ear tip (sometimes known as TIPtrode), transtympanic, and tympanic membrane electrodes) to measure the inner ear's Auditory Evoked Potential (AEP) response to stimulation. This method of analysis is used for the diagnoses of conditions like Meniere's disease.
Electroence-phalograph (EEG)	An instrument used to study and record brain activity.
Envelope (Window)	The shape of the overall waveform of an acoustic stimulus that follows the rise, plateau, and fall portions of the stimulus.
Epoch	A time period, such as the analysis time in evoked response measurement.
f_1, f_2	Frequencies of stimuli for DPOAE test. They are also called primaries ($f_1<f_2$, usually $f_2/f_1=1.20$ or 1.22 and Selected f_2 : 500 Hz, 750 Hz, 1000 Hz, 1500 Hz, 2000 Hz, 2500 Hz, 3000 Hz, 3200 Hz, 3500 Hz, 4000 Hz, 4500 Hz, 5000 Hz, 5500 Hz, 6000 Hz, 7000 Hz, 8000 Hz
F_{DP}	The frequency of DPOAE, in this device $f_{DP}=2f_1-f_2$.
Fall time	The time from the maximum amplitude of the stimulus, or the end of the plateau, to some measure of baseline (zero voltage).
Filter	An electronic device for eliminating electrical energy in a specific frequency region while allowing other frequencies to pass.
Gain	Increase in amplitude or energy of an electrical signal amplification. Gain is the difference between the input signal and the output signal.
Ground	A connection from a piece of electronic equipment, or a person to the actual ground or a relatively large metal structure that will provide an electrical ground. The ground electrode from a person is connected to the grounding circuit on an evoked response system. A good ground connection reduces electrical interference in evoked response recording.
GUI	Graphic User Interface

Hearing Screening	Hearing testing in a certain population in order to identify persons with hearing loss based on a certain definition of hearing loss and screening criteria.
High-Pass Filter	A filter that passes electrical energy above a specific cutoff frequency to eliminate (filters out) energy below that frequency.
In situ	In the natural position or place on the patient.
In situ Pre-Amplification	Pre-amplifies the AEP signal at the scalp with the Amplitrode, which is positioned on the ground electrode.
In the Ear Test	
Inter-Peak Latency	The difference in milliseconds between two peaks of ABR waveform, such as the difference between the latencies of ABR Wave I and III.
Inverting electrode	An electrode that is attached to the negative voltage input (inverts the input by 180º) of a differential amplifier. This electrode is typically placed on the earlobe, mastoid, or nape of the neck in ABR recording.
L1, L2	Levels (dB SPL) of DPOAE primaries, where L1 is the level of f_1 and L2 is the level of f_2.
Latency	A time interval between two events (e.g., the stimulus and response).
Linear Stimulation Mode	TEOAE stimulation when all clicks in a test are of the same polarity and level.
Low-Pass Filter	A filter that passes electrical energy below a specific cutoff frequency and eliminates (filters out) energy above that frequency.
Masking (Masker)	The constant level of the background noise presented to the non-tested ear in an audiometric procedure or ABR measurement.
Mastoid	A portion of the temporal bone located behind the external ear.
Microsecond (µs)	One millionth of a second.
Microvolt (µV)	One millionth of a volt.
Millisecond (ms)	One thousandth of a second.
nHL	Normalized hearing level. The decibel level of sound that lacks a standardized reference, as opposed to standardized pure-tone audiometry levels. It is referred to behaviorally determined normative levels, obtained from a group of normally hearing listeners and expressed in dB nHL.
Noise floor (NF)	Minimum noise level achievable with a measurement system.
Noise level	Sound Pressure Level of noise measured at the probe acoustic inlet.
Non-Inverting Electrode	The electrode that is attached to the positive voltage (non-inverting) input of a differential amplifier. This electrode is typically placed on the high forehead in ABR recording.
Nonlinear Stimulation Mode	TEOAE stimulation when four clicks are presented in series, the first three (a, b, and c) of the same polarity and level, and the forth (d) click, also called balancing click, of the opposite polarity and the amplitude is three times greater than that of the preceding three clicks, i.e. the Click level is 9.54 dB higher, for example 70.45 and 80 dB peSPL.
Notch Filter	A type of filter used in evoked response measurement, designated to reduce interference from power line noise – 50 Hz or 60 Hz depending on the region of the world. Notch filter may introduce filter distortion in AEP, and is recommended to be switched off in most tests unless a strong electrical interference is present.
Number of Clicks (NOC)	The total number of clicks presented to record a TEOAE response, including accepted, with artifacts below Artifact Rejection Threshold, and rejected due to excessive artifacts.

Occluded Ear Simulator	Occluded ear simulator for the measurement of earphones coupled to the ear with ear inserts, as per IEC 711-1981, ANSI S3.25-1979 (R 1986), for example Brüel & Kjær Ear Simulator Type 4157.
Octave	Frequency range in which the higher frequency limit is two times higher than the lower limit, for example between 1 kHz and 2 kHz.
Otoacoustic Emissions	Stimulated and non-stimulated faint sounds produced by oscillations of the Outer Hair Cells in the Cochlea that can be measured in the occluded Ear Canal.
Pass	Screening test outcome when screening 'pass' criteria are met.
Pass – Auto	PASS screening outcome obtained by automatic screening procedure when screening criteria have been met.
Pass – Manual	PASS screening outcome when the user considers that the test results have met the user's screening criteria.
Pass – Refer Criteria	Criteria for qualification of screening-test results as Pass or Refer.
Peak	The maximum or minimum amplitude value of an evoked response waveform.
Peak Equivalent Force Level (pe FL)	The numeric value of the sound pressure vibratory force level of a long duration sinusoidal signal which, when fed to the same transducer under the same test conditions, has the same peak-to-peak sound pressure of a vibratory force amplitude as the transient signal.
Peak Equivalent Sound Pressure Level (pe SPL)	The decibel level of a 1000 Hz tone at an amplitude equivalent to the peak of a transient signal such as a click.
Polarity	The sign of the voltage of the stimulus or waveform response (positive or negative. Response polarity depends on the location of the electrode plugged into the positive input versus the electrode plugged into the negative voltage input of the differential physiological amplifier relative to the neural generator.
Pre-amplifier	An electronic device that receives an electrical signal, such as an evoked potential, directly from the electrodes, and increases the amplitude of the signal before it is sent on for further processing such as amplification, filtering, and averaging.
Probe	Electro-acoustic device for presentation of acoustic stimuli into the occluded ear canal and recording acoustic responses from the occluded ear canal. The Probe contains receivers and microphone(s).
Probe Fit Check	The probe fit checks to ensure the position of the OAE Probe in the ear canal, with the ear tip installed on the probe is fit correctly for the patient. This will ensure there is no leakage of sound from the ear canal and the probes acoustic outlets and inlets are not blocked.
Probe Programming	Procedure performed by Vivosonic Production Utility Software on each individual Probe to program the built-in EEPROM of the probe to record the Probe ID, and Probe calibration data.
Probe, General-use (GP)	Probe designed for testing all ages, from infants through adults.
Protocol	A set of parameters, typically user-defined, that instructs the system how to automatically perform and analyze a test. It covers stimulus settings, DSP settings, etc.
Rarefaction (negative) Stimulus Polarity	The initial displacement of the stimulus, produced with an inward movement of the acoustic transducer.
Rate	The number of stimulus repetitions per unit of time, usually 1 second.
Recording Window (RW)	Time period over which a response waveform is recorded, particularly in TEOAE tests. Typically it is within the click interval.

Recording Window Beginning	Time between the click onset and the beginning of recording window.
Recording Window End	Time between the click onset and the end of recording window.
Refer	Screening test outcome when screening 'pass' criteria are not met.
Refer – Auto	REFER screening outcome obtained by automatic screening procedure when screening criteria have not been met.
Refer – Manual	REFER screening outcome when by the user considers that the test results have not met the user's screening criteria.
Repetitions (Sweeps)	The number of single reoccurring events, such as a waveform, that is presented in a set period of time.
Response Collection Period (RCP)	Time period over which a TEOAE response waveform is collected. In linear mode, it is the same as the recording window. In non-linear mode, it is the aggregate of four recording windows.
Response Spectrum	Amplitude spectrum of the response waveform.
Response Waveform	Time-averaged waveforms sampled during Response Collection Period.
RMS	Root-mean-square value.
Screening	A user-selectable test procedure that qualifies a screening test result using user-defined pass-refer criteria.
Screening outcome	Screening-test result qualification, typically Pass or Refer. If a test result cannot be qualified by Pass or Refer, it is insufficient (invalid).
Signal-to-Noise Ratio (SNR)	The difference in dB between the levels of DPOAE and the Noise Floor at each DPOAE frequency.
SNR Criterion (SNRC)	User-defined minimum SNR that the user considers suggesting the presence of physiological response, for example DPOAE or TEOAE.
SOAP-Kalman Weighted	This signal processing algorithm combines successive ABR responses through the assignment of weights to each response. A higher weight is assigned to "better" responses (i.e., those with less noise contamination). The weights are optimally selected through the use of the Kalman filter, which acts as a linear minimum mean-square error filter. As such, SOAP-Kalman Weighted signal processing (a) gives less weight to the noise-contaminated responses and (b) emphasizes less noisy responses. In addition, this method processes signals in real time without rejecting any time segments (even those containing significant artifacts).
Sound Level	Sound pressure level indicated by a sound level meter, with dynamic response and weighting characteristics conforming to the requirements of IEC 651 or ANSI S.1.4. When not otherwise qualified, the term denotes a weighted sound level.
Stimulus	Sound energy presented to the patients through the transducer.
Stimulus Level	The sound level of an acoustic stimulus as measured in an acoustic coupler, usually an Occluded Ear Simulator (Zwislocki Coupler). In DPOAE tests, the levels of primaries are typically presented in the L1/L2 format, for example 65/55 dB SPL.
Stimulus Rate	Number of stimuli presented per second.
Stimulus Stability Score (%) (SSS)	The ratio (in % rather than dB, while 1 dB is approximately 10%) between The first click level and the final click level over the duration of stimulation, as measured by the system.

Stimulus Waveform	The waveform of acoustic signal produced by the probe, as recorded by the system.
Sweep	A single stimulus repetition (particularly, a single click in either linear or non-linear TEOAE mode), and recording response to this single stimulus.
System DP	Distortion Product produced by system hardware. As an index scaling the system quality, it contains the DP levels at all DP frequency points corresponding to the reference frequencies (f2).
System NF	Noise Floor of system hardware in the absence of physiological response.
System TR Check	The procedure performed by the system when the probe is placed in probe holder to make sure the system transient response is ignorable according to the designed bottom line.
System Transient Response (System TR)	Transient Response of system hardware. As an index scaling the system quality, it contains the averaged response waveform as the reaction of the system hardware to the specified stimuli.
TE Level	Root Mean Square of the TE response waveform, expressed in dB SPL.
TEOAE	Transient Evoked Otoacoustic Emissions.
TEOAE high-pass filtering	High-pass filtering of TEOAE-response signal to improve response quality in TEOAE screening, especially neonatal screening, by removing low-frequency noise; recommended with cut-off frequency 1.2 kHz with ≥12 dB per octave slope [Kemp et al., 2001].
TEOAE stimulus adjustment	A process to compensate for the difference between the click levels in the real ear and the occluded ear simulator where the OAE Probe is calibrated.
in situ	This is accomplished by creating the same click level, as measured at the probe's acoustic inlet, both in the occluded ear simulator and in situ. The measure of the in situ click level is its peak equivalent SPL, as measured by Integrity, when equal to the peak equivalent SPL measured by Integrity when the click level in the occluded ear simulator is equal to nominal values. For example the system will measure the same peSPL both in the occluded ear simulator and in situ when the occluded ear simulator measures a click level of 80 dB peSPL.
TEOAE Test Invalid	TEOAE automatic screening test result that does not allow making a Pass-Refer decision.
TEOAE Test Valid	The TEOAE automatic screening test conditions that make a Pass-Refer screening-outcome decision,
TEOAE test validity	Condition of a TEOAE test result that allows making a Pass-Refer decision.
Test	A complete sequence of stimuli presentation and response recording performed according to a protocol within one test session.
Test Insufficient	Screening test outcome when the ambient noise does not allow the system to make a definite 'pass' or 'refer' decision.
Test Insufficient – auto	Screening outcome obtained by automatic screening procedure when the system cannot decide whether or not the screening criteria have been met.
Test Insufficient – manual	Screening outcome decided by the user when the user cannot decide whether screening outcome is Pass or Refer.
Test outcome	A decision in a screening test: Pass, Refer, or Test Insufficient.
Test result	A result of complete sequence of stimuli presentation and response recording performed according to a protocol obtained in a single test, for example a single DP-gram or a single TEOAE record.
Test Type	The type of test measurements performed by a device.
Tone Burst	A brief pure tone stimulus having a rapid rise and fall time with a duration sufficient enough to be perceived as having tonality (usually less than 1 sec).
Transducer	An electroacoustic device for converting one form of energy into another.

Tympanic membrane	The thin membrane that separates the liquid-filled inner ear from the air-filled middle ear. Also known as the eardrum.
VivoAmp	An integrated pre-amplifier with detachable electrode cables.
VivoLink	The world's first wireless interface module used in auditory electrophysiology. It has a universal platform: it can perform ABR, ECochG, ASSR, 40 Hz ERP, DPOAE, and TEOAE tests, and has the potential to add other testing modalities on the same platform. (Note—not all modalities are released yet, only ABR is currently available.) It is operated by a microprocessor, controlled from a remote computer through Bluetooth®, and powered by batteries.
Wave	The rise and fall of a voltage. A wave component is usually attributed to neural activity (action potential or dendritic activity) of a generator or several generators of a response.
Wave Reproducibility	The degree to which a recorded waveform can be reproduced in another similar recording event.
Waveform	A form or shape of a wave, represented graphically as magnitude in a function of time.
Whole Wave Reproducibility	Also called Whole A, B Waveform Reproducibility, or simply Repro. Cross-correlation between A- and B- collected waveforms in recording window, expressed in percentage format.

Appendix D: Effective Use of Correlation Coefficient

The reliability of the correlation coefficient statistic and the threshold value of correlation coefficient to indicate repeatability depend on 3 variables:

- the window size (time difference between the SS/SE markers);
- the filter parameters; and
- the frequency spectrum of the electrical noise contaminating the ongoing EEG.

Based on the average EEG noise spectrum collected from 100 babies, we have estimated the statistical confidence in the correlation statistic. The actual statistical confidence will vary with the EEG noise spectrum, so the following should be used as a rough guideline.
The following table represents 2 recommended sets of parameters for estimating response reliability from the correlation statistic:

SS/SE time window (ms)				SS/SE time window (ms)			
11				9			
low pass filter (Hz)				low pass filter (Hz)			
1500				1500			
correlation target				correlation target			
0.7				0.8			
high pass filter (Hz)	30	60	100	high pass filter (Hz)	30	60	100
Confidence (%)	91	92	95	Confidence (%)	91	92	95

For further explanation of the table, as an example, if the stimulus protocol is set up with a low pass filter of 1500 Hz and a high pass filter of 30 Hz and the SS/SE are placed 11ms apart, then a correlation value of 0.7 indicates repeatability with a 91% confidence level. A higher correlation target with a smaller window will have the same degree of confidence.

Appendix E: Integrity V500 Factory Calibration

Factory calibration methods are as follows:

- Calibration files for G1 insert earphones, bone conductor, and circumaural earphones are stored in the “Calibration Data” directory of the Integrity software.
- Calibration for G2 insert earphones, bone conductor, and circumaural earphones are stored in the E^2PROM of the transducer.
- Calibration for G1/G2 Amplitrode, VivoAmp and G1/G2 OAE probes are stored in the E^2PROM of the transducer.
- Insert Earphone stimuli and OAE probe stimuli are measured in an occluded ear simulator, Brüel & Kjær Type 4157 conforming to IEC 60318-4, ANSI S3.25, and ITU-T P.57 Type 2.
- Circumaural earphones are factory calibrated in dB SPL by Sennheiser Electronic Corporation in a B&K 4153 artificial ear with a DB 0843 adapter plate conforming to IEC 60318-1.
- The bone-conductors are calibrated in dB FL (re 1 µN) using the Larson Davis AEC201-A with the AMC493B artificial mastoid. The Target Level is measured using a nominal Hearing Level of 40 dB and RETFL conforming to ISO 389-3 and ANSI S3.6.
- Calibration of clicks, chirps and tone bursts in dB peSPL (peak-to-peak equivalent) is performed following the IEC 60645-3 procedure for calibrating short duration stimuli.
- Reference tone bursts for calibration measurements are all 4 cycles in duration, first peak with rarefaction polarity, multiplied by a Blackman window, with a repetition rate of 13.8/s.
- Reference clicks are rarefaction polarity100 µs in duration with a repetition rate of 13.8/s with time domain characteristics in accordance with IEC 60645-3.
- Reference chirp is a rising chirp from 350 to 5050 Hz, with its energy equally distributed in the frequency domain, and duration of 5.55 ms.
- Calibration of clicks and tone bursts in dB nHL for the circumaural earphones follows the RETSPL values according to ISO 389-6 standard.
- Calibration of clicks and tone bursts in dB nHL for the Insert Earphone transducers were measured as the mean behavioral threshold for reference tone bursts in 25 otologically normal ears (18-25 years of age) using an Integrity system and Insert Earphone transducers.
- Calibration of chirps in dB nHL was done as the mean behavioral threshold for the reference chirp stimulated at 20/s in 6 otologically normal ears using an Integrity system and both Insert Earphone transducers as well as for the circumaural earphones.
- For wideband masking, 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) for the insert earphones and the IEC 60318-1 with Type 1 adapter (Table 6 in ANSI S3.6-2004 Manual) for the circumaural earphones.
- For more information concerning sound attenuation characteristics of the transducers, please consult the third party manufacturer directly.

- The masking dB SPL value is calculated for the root mean square (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. For Click and Chirp stimuli 1 kHz dB HL is used to calculate the dB SPL for the masker.

  Acoustic input for TEOAE and DPOAE measurements are calibrated at the acoustic inlet of the OAE Probe using a B&K 4192 pressure-field microphone. The acoustic output for TEOAE and DPOAE measurements are calibrated using the B&K 4157 artificial ear which conforms to IEC 60318-4 using a nominal value from 100 Hz to 8 kHz for both speakers for DPOAE and a 80 µs and 120 µs pulse at both speakers for TEOAE.

  In TEOAE and DPOAE measurements, the probe output is automatically adjusted after the first 100 clicks to compensate for the difference between the patient's ear canal volume and the volume of the occluded ear simulator used for calibration.

ATTENTION

The Integrity V500 System is factory calibrated. The factory calibration is valid for one year. The system must be checked annually and recalibrated if necessary. The Integrity V500 System can be checked and recalibrated using the Vivosonic Calibration System. Please contact Vivosonic or your local distributor to arrange for annual calibration.

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