Recommended electrode placement

NOTE

The patient’s skin must be prepared before the snap electrode pads can be attached.

The following electrode placement configurations are recommended for the Amplitrode®, which is optimized for a single-channel recording (Figure 61).

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

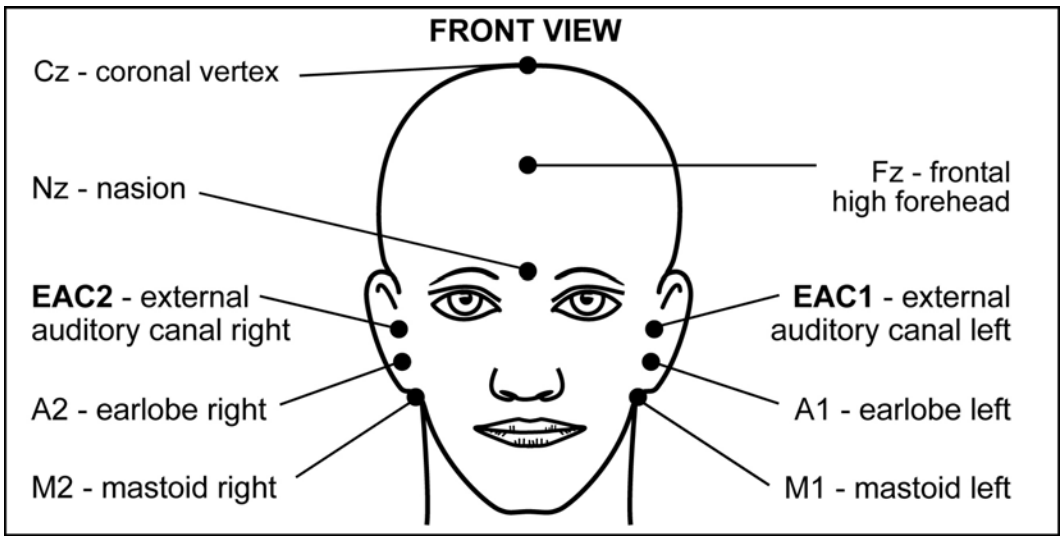


Figure 61 Typical electrode placement diagram - front view

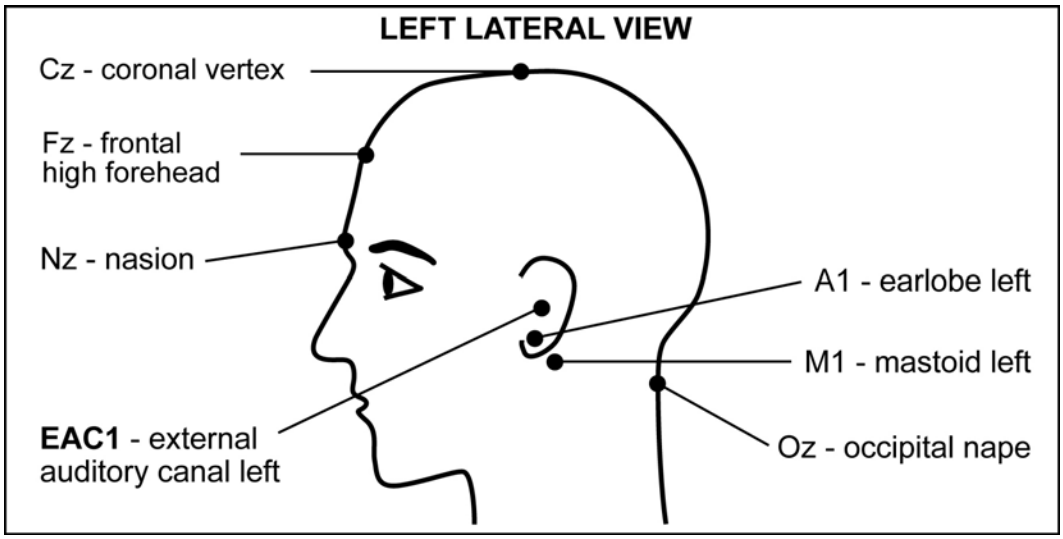


Figure 62 Typical electrode placement diagram - left lateral view

The recommended electrode sites are:

- Non-inverting electrode (active or positive): High forehead (Fz).

- Inverting electrode (reference or negative): Left mastoid (M1), right mastoid (M2), left earlobe (A1), right earlobe (A2); or nape (Oz).
- Amplitrode® (ground): low forehead (Fpz); nasion (N); opposite ear lope; or opposite ear canal.

ATTENTION

To ensure reliable waveforms, the electrode clips must be connected securely to the snap electrode pads.

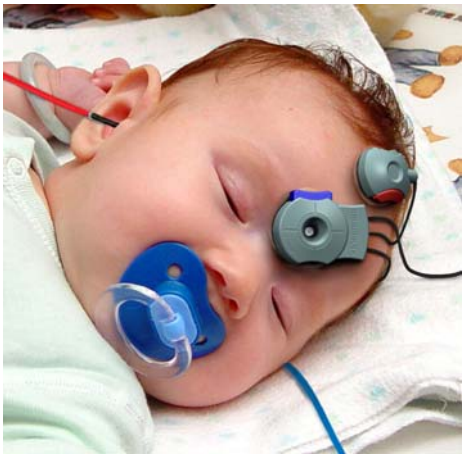


Figure 63 Amplitrode® and Electrode Clips Placement (shown on an infant)

Preparing the Patient

Skin preparation

The patient's skin must be clear and free of damage, malformations, or disease before starting the test.

CAUTION

Patients may incur additional skin damage.

If the patient's skin has wounds, scratches, bruises, or any other signs of damage, malformation, or disease do not proceed with the skin preparation or the placement of the electrodes.

1. Visually inspect the area of skin where the electrodes will be placed. If the skin is damaged, do not proceed with the test.
2. Carefully remove oil, dead skin particles, or foreign matter from the skin areas that will be in contact with the snap electrode pads.
3. Remove excessive moisture with a dry cotton ball or gauze pad.
4. Apply abrasive skin preparation cream or jelly on the cleaned skin surface, following the manufacturer's instructions for use.
5. Remove excessive abrasion cream or jelly with a cotton ball or gauze pad.

Application of the electrodes

Vivosonic recommends starting by connecting the Amplitrode® to the ground electrode connection. Once secure, connect the electrode clips to the snap electrode pads. The non-inverting (**+**) and inverting (**-**) electrodes are distinguishable by the "**+**" and "-" symbols located on the clips' upper surface.

6. Visually inspect the pouch with single-use electrode pads and check the expiration date indicated on the back of the pouch in the following format "YYYY – MM" (year – month), for example "2005 – 05).
7. Remove the single-use snap electrode pads from the plastic base and paste them on the prepared areas of the patient's skin. Refer to Figure 61 for details on the recommended locations of the electrodes.
8. Hold the electrode clip with two fingers so that the index finger is in the Holding Groove and the thumb depresses the Electrode Release Button.
9. Snap the Amplitrode® and the two electrode clips onto the electrode pads. When the electrode release button is let go, the electrode will be securely clipped to the electrode pad.
10. Check that the electrode is securely seated on the electrode pad.

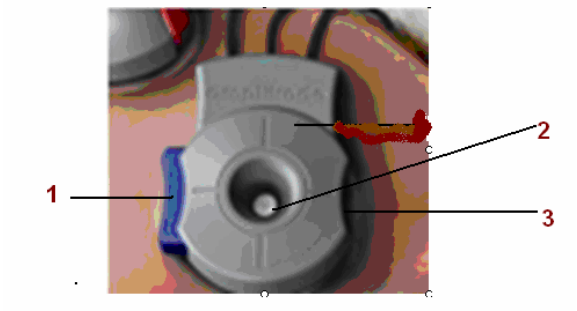


Figure 64 Amplitrode®
(**1** – Electrode Release Button **2** – Electrode Clip **3** – Holding Groove)

Checking electrode contact quality

A unique feature of the Integrity™ system is its ability to monitor the contact quality during ABR data collection. It checks the electrodes continuously to monitor for any changes of quality of its connection to the patient during the test procedure.

Contact quality monitoring start when the electrodes are attached to the patient. There are two places to monitor the contact quality, on the VivoLink™ and on the Test screen.

Contact Quality on the VivoLink

The easiest way of checking the contact quality is to monitor the VivoLink™ contact quality mismatch LED. It is located on the front panel of the VivoLink™ (Figure 5). This LED indicates a poor connection between the electrode and the patient from either the inverting or non-inverting electrodes.

When the LED is not lit there is no problem indicated.

An **Amber** lit LED indicates the inverting (-) electrode has poor contact with the patient.

A **Green** lit LED indicates the non-inverting (+) electrode has poor contact with the patient.

Contact Quality from the Test screen

The LED indicators represent the quality of the contact between the inverting or non-inverting electrode and the patient's skin. When the centre LED is lit, shown lit in Figure 28, there is no problem indicated. This is the optimal display representing a good contact quality.

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

Correcting poor contact quality

A poor connection will affect the results. When the contact quality of one active electrode is poor, follow these steps:

1. Wait for a couple of minutes – the contact quality will often decrease to an acceptable level on its own.
2. If the levels do not change, disconnect the non-functioning electrode (left LED's for inverting (-), right LED's for non-inverting (+)). Remove the electrode clip from the snap electrode pad and repeat the skin preparation procedure.
3. Apply a new snap electrode pad and reconnect the electrode clip.
4. Repeat contact quality checking.

ATTENTION

Identifying poor contact quality for two electrodes

If both electrodes have poor contact quality the LED may show only one electrode as being poor or the LED may erratically indicate one electrode and then the other electrode as poor.

If after fixing one electrode there is still a problem it is recommended to fix the other electrode before assuming a problem with the Amplitrode®.

Choose a transducer

To perform an *Air-conduction Test*, use the ER-3A Earphones. To perform a *Bone-conduction Test*, select the B-71 Bone Conductor.

ATTENTION

To perform an ABR test with ER-3A earphones the protocol selected must be configured to use the ER-3A Transducer Type. If it is not the stimuli will not be transmitted through the earphones.

To perform ABR test with B-71 Bone Conductor the protocol selected must be configured to use the B-71 Transducer Type. If it is not the stimuli will not be transmitted through the bone conductor.

ER-3A Earphones

To perform ABR or data collection via air conduction, insert ER-3A earphones (Figure 65).

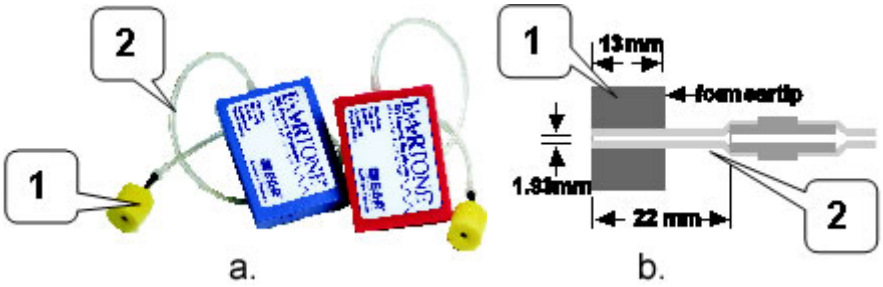


Figure 65 ER-3A earphones (a) and their foam ear tip dimensions (b)

1 – Foam ear tip **2** – silicone air-conducting tube inside the foam ear tip

If earphones are chosen for testing do the following:

6. Inspect the patient's ear canal, preferably with an otoscope (not included) for obstructions. If there is an excessive deposit of earwax, have an authorized health-care professional remove the earwax, as defined by local health-care regulations.
7. Observe the patient's ear canal and evaluate its size. Select an ear tip that would fit tightly yet comfortably in the patient's ear canal.
8. Install the ear tip onto the earphone as follows:

- Choose the ear tip to be installed.
- Gently place the ear tip into the earphone tube until there is a full stop.

9. Hold the ear tip with two fingers and compress it.
10. Insert the ear tip into the ear canal: the red transducer into the right ear, and blue into the left ear. Insert the ear tip slowly. Make sure the ear tip is inserted tightly in the cartilaginous part of the ear canal, not in the bony part, which would occlude the ear canal.

CAUTION

Do not insert the ear tip in the ear canal too quickly. This may cause excessive positive air pressure in the ear canal being occluded by the ear tip and may hurt the eardrum of the patient. There is a pressure release vent in the transducer, but it may not be sufficient to release excessive air pressure if the ear tip is inserted too quickly.

ATTENTION

Do not exceed hand force when inserting the ear tip. Make sure the silicone tube inside the ear tip is not bent or pressed. A misaligned tube would result in a change to the acoustic properties and may compromise the calibration or cause potential misdiagnosis.

B-71 Bone Conductor

To perform data collection using bone conduction, connect the B-71 Bone Conductor to either the left or right mastoid, or the forehead.

Secure the headband supplied with the B-71 Bone Conductor. Ensure that the entire circular surface of the Bone Conductor is in full contact with the skin.

WARNING

Patient may be injured.

The Bone Conductor headband is a steel spring designed to hold the bone conductor in place using no more than hand-tightened force. The headband is strong enough to injure the patient if it is released before full contact with the skin. When placing the bone conductor on the patient's head, do not release the headband until both the bone conductor and the opposite cushioned pad are in full contact with the skin.

WARNING

Strangulation may occur.

Do not put the B-71 Bone Conductor cable around the patient's neck.

Do not leave a patient unattended while preparing and conducting the bone-conduction test!

Preparation of the system

To prepare for a test, perform the following operations:

1. To ensure there is no visible mechanical damage, inspect the VivoLink™, Amplitrode®, Amplitrode® clips, Amplitrode® connectors, and Amplitrode® cable; ER-3A Insert Earphones and their connectors, cables, and silicone tubes; the B-71 Bone Conductor and its cable and connector.
2. Visually inspect the Amplitrode® and its clips to ensure they are clean of any debris.
3. Place the Amplitrode® and its clips on the parking snaps located on the front panel of the VivoLink™ (Figure 5).

CAUTION

Do not conduct any AEP test if by visual inspection you discover any visible mechanical damage. Report the problem to Vivosonic's local service representative or Vivosonic Customer Support. Do not try to repair the device yourself.

Do not conduct any AEP test if the Amplitrode® or its clips are congested with any debris which may cause improper electrical contact with the electrode-pad snaps and improper testing.

4. Switch on the computer.
5. Read the two Caution statements (Figure 10 and Figure 11), and choose **Agree**. Pressing **Agree** will open the software to the **Patients** screen (Figure 35).

   Pressing **EXIT** will shut down the computer.
6. To be able to perform tests select at least one patient's name from the list of existing patient or add a new patient name and select it for testing.
7. Switch **On** the VivoLink™ and monitor the power indicator (Figure 4). The power indicator which is located on the front panel (Figure 5) will turn on **green** if the batteries in the VivoLink™ are in good working condition. If the battery power is low the indicator will turn **amber**. Replace the batteries before starting.
8. Check the Bluetooth® connection of the VivoLink™ with the system computer. If connection has been established the VivoLink™ Bluetooth® indicator light (Figure 20) turns **blue**. When the connection has been lost the Bluetooth® LED indicator will appear not lit.

Protocol Parameters

The protocol parameters are entered using ABR Stimulus and Test Settings controls [Hall, 1990], [Hall, 1997], [Stapells, 2002], [Stevens, 2001, (Click)], [Stevens, 2001 (Tone Pip)]. To create a new protocol select an existing protocol and modify it.

The parameters, which can be preset in this protocol, are divided into two categories: **Stimulus Settings** and **Test Settings** (Figure 53).

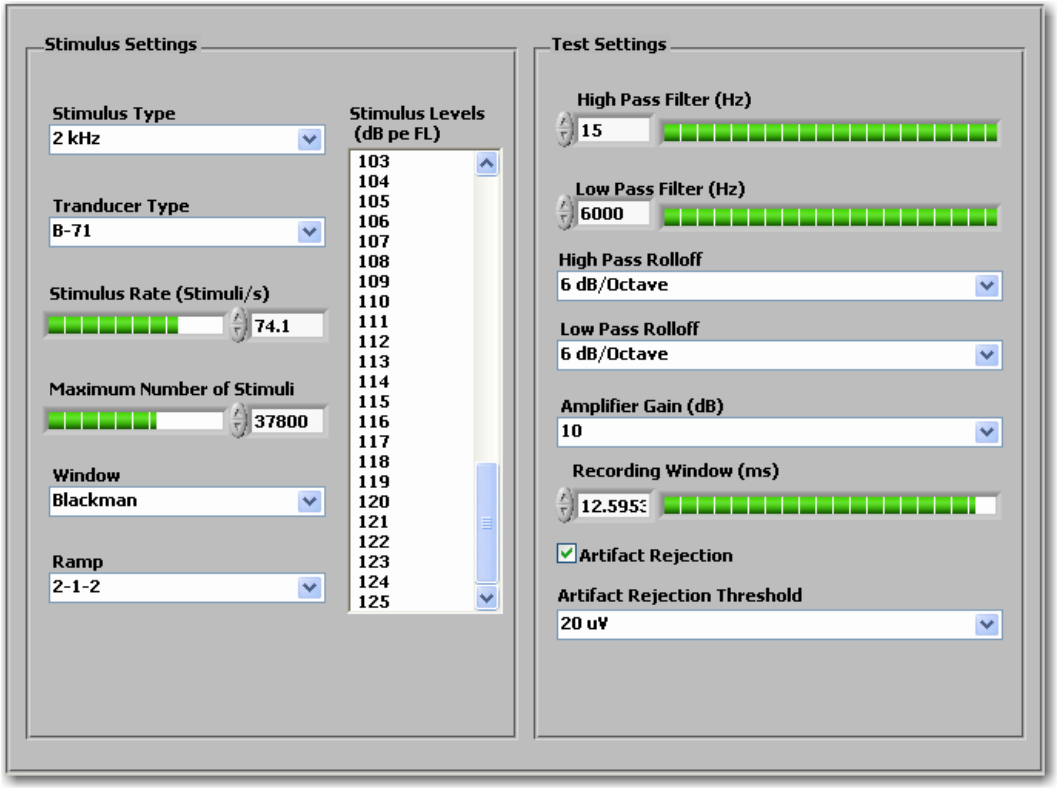


Figure 66 Protocol Stimulus and Test Settings Controls

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 the 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, recording window duration, and the artifact rejection threshold (relevant only when using the averaging algorithm).

Some test settings can only be modified on the **Test** screen. (Refer to Protocol Test Settings on page 31 for more details).

Stimulus Settings

Stimulus Type

The following stimulus types can be selected from the drop-down menu: click or tone bursts frequencies of **500 Hz, 1 kHz, 2 kHz, 3 kHz, and 4 kHz**.

Transducer Type

Two transducer types are available from the drop-down menu: the ER-3A earphone and the B-71 Bone Conductor.

Stimulus Rate (Stimuli/s)

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 7.1 to 99.0 (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. A parameter value can be set by dragging the control bar, and entering the number in it.

Maximum Number of Stimuli

The **Maximum Number of Stimuli** depends on the selected Stimulus Rate. For the lowest Stimulus Rate of 7.1 stimuli/s the **Maximum Number of Stimuli** is 5964. For the highest Stimulus Rate of 99 stimuli/s the **Maximum Number of Stimuli** is 83160. The smallest value this parameter can be set to is zero (0).

The **Maximum Number of Stimuli** can be selected several different ways: by dragging the control bar, entering the number in the control window, or clicking on the up arrow (to increase the number of stimuli) or down arrow (to decrease the number of stimuli).

Window

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

This setting is applicable to the tone-burst stimulation type only. The number of sinusoidal waves in the raise, plateau, and fall portions of the tone burst's waveform is controlled by this parameter. The selections available from the drop-down menu are 2-1-2 or 2-0-2 options.

NOTE

If **Click** is selected as the **Stimulus Type** both the **Window** and **Ramp** settings will be unavailable.

Stimulus Levels

The **Stimulus Level** defines either multi-level or single-level stimulation. To select a range for multiple level tests, press and hold the **Ctrl** key on the keyboard and highlight the required levels.

TIP

During the test session, while viewing the **Test** screen, it is possible to change the stimulus level using the **Level (dB pe SPL)** sliding bar (Figure 25). The slider indicates the value of the bottom level of the stimuli selected. When the slider is moved, only the lower end of the selected level range is changed.

If only one stimulus level was selected the slider will indicate that value. If the slider is moved it changes the value of the single level.

The **Stimulus Levels** can be selected from a range of values.

B-71 50 to 125 dB pe FL, -10 to 65 (1 dB increment)

ER-3A 0 to 125 dB pe SPL, -30 to 95 (1 dB increment)

For the ABR protocols created for testing using the Insert earphones, levels of stimulation could be expressed in dB nHL or in dB pe SPL depending on the selection made through the **System** screen.

The levels of stimulation for testing with Insert Earphones can be selected in a range from -30 to 95 dB nHL or from 0 to 125 in dB pe SPL.

For the ABR protocols created for testing using the B-71 Bone Conductor levels of stimulation could be expressed in dB pe FL or dB nHL.

Levels of stimulation for testing with bone conduction can be selected in a range from -10 to 50 or 60 dB nHL or from 50 to 110 or 120 in dB FL. Bone vibrator stimulation range depends on the **Stimulus Type** preset through the **Protocol** screen.

NOTE

Air-conducted stimuli are displayed in units of dB nHL or dB pe SPL. The bone-conducted stimuli are displayed in units of dB nHL or dB pe FL. These units are defined in the **System** screen.(Refer to Selecting the calibration units on page 67 for more details).

Test Settings

The **Test Settings** control the acquisition parameters of the ABR recording, such as high-pass filter (HZ), low-pass filter (HZ), high-pass rolloff, low-pass rolloff, amplifier gain, recording window (ms), artifact rejection, and artifact rejection thresholds.

High-Pass filter (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 Hz to 300 Hz.

Low-Pass filter (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 Rolloff and Low-Pass 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.

Amplifier Gain (dB)

This control regulates the post Amplitrode® gain. The available values are 0 (system default), 10, 20, and 40.

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 windows can be from 0 ms up to 30 ms.

The maximum **Recording Window** length depends on the **Stimulus Rate**. From 7.1 to 33.3 Stimuli/s the maximum window is 30 ms, at 33.4 Stimuli/s the maximum window is 29.9 ms and at 99 Stimuli/s the maximum window is 10.1 ms.

Artifact Rejection

This selection box is used to switch on and off the **Artifact Rejection Thresholds.** When this control box is selected the **Artifact Rejection Thresholds** field becomes active. If the control box is not selected the **Artifact Rejection Thresholds** field is unavailable.

Artifact Rejection Threshold

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

Performing an ABR Test

To conduct a measurement, perform the following steps.

Place the VivoLink™ on the patient:

This procedure includes preparing the skin and connecting the electrodes. Begin with the VivoLink™ **Off** and the Amplitrode® and electrode clips connected to the parking snaps.

Adult patient or an older child:

1. Connect the lanyard clips to the D-rings on the VivoLink™.
2. Disconnect the breakaway of the lanyard and place the longer part of the lanyard around the patient's neck.
3. Connect the breakaway of the lanyard to the VivoLink™. The patient may then be placed in a chair or on a couch, whichever is more comfortable for the patient and the operator. (Refer to Figure 7.)

Infant patient:

1. Place the VivoLink™ next to the infant on a flat surface, close enough for the Amplitrode®, ER-3A, and B-71 Bone Conductor cables to reach the infant.

   Alternatively, if the infant is held by a caregiver, the caregiver may hold the VivoLink™ in the hands along with the infant.

> CAUTION
>
> Injury to an infant may occur.
>
> Do not hold the VivoLink™ or any transducers over the infant's body or head. If any of the components are accidentally dropped, the infant may be injured.

1. Switch **On** the VivoLink™. Check the status of the VivoLink™ batteries and Bluetooth® connection.
2. Check that the Impedance Mismatch LED on the VivoLink™ is **off** (not luminous) while the Amplitrode® and its clips are snapped on the designated parking snaps on the VivoLink™.

ATTENTION

When the contact quality mismatch LED on the VivoLink™ is **On** (luminous) it indicates a poor contact between the electrodes and the patient's skin and may lead to incorrect measurements or misdiagnoses.

No light – means that the contact quality is good.

Amber light – means that the inverting (-) electrode does not have good contact with the patient's skin. Check the inverting electrode and if necessary, re-position the electrode, replace the snap electrode pad and prepare the skin again.

Green light – means that non-inverting (+) electrode does not have good contact with the patient's skin. Check the non-inverting electrode and if necessary, re-position the electrode, replace the snap electrode pad and prepare the skin again.

3. Prepare the patient's skin as described in Skin preparation on page 74.
4. Place the electrode pads on the skin and connect the Amplitrode® and electrode clips as described in Preparing the Patient on page 74.

CAUTION

Do not use electrodes if their expiration date has passed.

5. To prepare for an air-conduction test, install the ear tip into the testing ear as directed for the

ATTENTION

To perform an ABR test with ER-3A earphones the protocol selected must be configured to use the ER-3A Transducer Type. If it is not the stimuli will not be transmitted through the earphones.

To perform ABR test with B-71 Bone Conductor the protocol selected must be configured to use the B-71 Transducer Type. If it is not the stimuli will not be transmitted through the bone conductor.

6. ER-3A Earphones on page 77.

ATTENTION

To ensure proper fit on the transducer and proper operation, use only ear tips supplied by Vivosonic.

7. To prepare for a bone-conduction test, place the B-71 Bone Conductor on the patient's head. Refer to Application of the electrodes on page 75 for placement details.
8. In the **Test** Screen, select the type of test to be performed. (Currently only ABR is available.)
9. Select an appropriate protocol in 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.

10. Press either the **Right Ear** or **Left Ear** button.
11. Press **Start.** The **Start** button will change to a **Stop** button.
12. Monitor the **EEG Window** (Figure 28) and visually estimate the amplitude of the EEG signal.

TIP

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 ± 2-3 µV,

For 2,000 sweeps – within approximately ± 4-5 µV,

For 10,000 sweeps – within approximately ± 10 µV,

For 1,000,000 sweeps – within approximately ± 100 µV.

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

- Check the **Contact Quality Mismatch** LED status and ensure it is **Off** (not luminous). If it **On** (luminous) and is **amber**, check the inverting (-) electrode and replace the electrode or re-prepare the skin area if necessary. If it is **On** and **green**, check the non-inverting (+) electrode and replace the electrode or re-prepare the skin if necessary.
- Remove the Amplitrode® and its clips from the patient and snap them on the parking snaps of the VivoLink™.
- If the noise is still excessively high, relocate the electrodes.
- When the noise is reduced, reconnect the Amplitrode® and its clips to the patient and continue patient testing.

13. The instrument performs a test automatically. Pause the test temporarily by pressing **Pause**. Press **Continue** or the **Stop** button to proceed.
14. Whether the data collection is paused or stopped, all the data collected before pressing **Pause** can be saved by pressing **Save**. Refer to Test Control Buttons on page 26 for more information about Start/Stop, Pause/Continue, and Save features.

TIP

Every Start and Stop will create a new record. Save each record to have it displayed on the **Test Waveform Window** graph while the next test is taking place. If the record is not saved, it will not show on the graph when the next test is started.

15. Press **Discard/Clear Graph** to clear the **Test Waveform Window** graph before or after saving the results. If the graph is cleared before the results are saved, the data will be deleted.
16. Press **PRINT** to print the test results.
17. Repeat the above procedure to test the other ear.
18. Remove the ear tip from the ear. Pull the ear tip from the ear canal slowly. While removing the ear tip, slightly push it to the side to open a gap between the ear tip and the wall of the ear canal. This will allow air to enter the ear canal occluded by the ear tip.

CAUTION

Injury to the eardrum may occur.

Removing the ear tip from the ear canal too quickly may cause a negative air pressure in the occluded ear canal and result in injury to the eardrum.

19. Dispose of the used ear tip(s).

WARNING

Choking hazard!

To avoid accidental swallowing or inhalation of an ear tip, do not leave the used ear tip(s) within reach of a child.

Patients should be attended during preparation or testing.

ATTENTION

If there is no AEP response for either ear, check that the ER-3A Earphone is producing a sound. Listen to the earphone using a reasonably audible stimulus setting such as 50 dB nHL.

20. Remove the B-71 Bone Conductor from the patient’s head.
21. Carefully remove the electrode pads form the patient’s skin to avoid pain.

CAUTION

The ear tips and electrode pads are **single-use** only and should be disposed of immediately after use. To avoid transfer of disease, do not re-use the ear tips or the electrode pads on other patients.

22. Disinfect the Amplitrode® and its clips using disinfecting wipes (included with the Integrity™ system.

CAUTION

To avoid transfer of disease do not reuse the Amplitrode® and its clips without first disinfecting them.

Reviewing results

The results can be reviewed from the Database screen or a report of the results can be printed. To review test data:

1. Select the **Database** tab.
2. Select the patient required.
3. Review the data in the waveform window.
4. Select Expand to view the waveforms full screen.
5. Press Report to add a description of the test.
6. Press Print and

Storing the Integrity™ system

1. Press **Exit** in the top right corner of the **Test** screen. A dialog box with the following message will appear: “Are you sure you want to exit the instrument?”
2. Press **YES** to shut down the computer. The screen will turn black.
3. Close the computer lid (recommended to protect the screen and keyboard from collecting excessive dust).
4. Turn the power switch for the computer **Off**.
5. Turn the optional printer **Off.** (Refer to the computer and printer manufacturer’s User’s Guide for details.)
6. Unplug the computer power cord from the wall outlet.
7. Pack the VivoLink™ and accessories and place them back into their storage cases.

Chapter 6 Integrity™ System Care

Recharging Batteries

VivoLink™

Refer to the recharger manufacturer's User Manual for details on rechargeable Nickel-Metal Hydride batteries.

Computer

When the computer is running on battery power only, it can typically provide over an hour of testing without re-charging. Refer to the printer manufacturer's User Manual for instructions on how to monitor the status of the battery, and how to recharge the battery.

Replacing Batteries

VivoLink™

To replace the batteries:

Press lightly on the battery compartment cover and pull the cover in the direction of the arrow on the compartment.

Remove the old batteries and dispose of them according to local regulations.

Insert four new AA batteries, Ensure that the polarity is correct by aligning the "**+**" signs on the batteries with the "**+**" signs on the bottom of each of the four battery compartment cells (Figure 67).

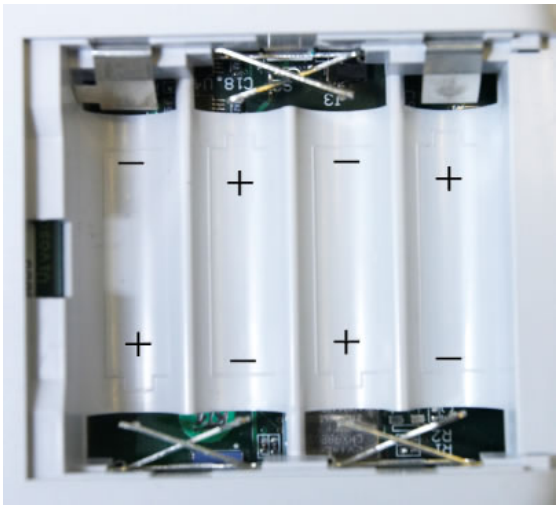


Figure 67 Battery compartment of the VivoLink™

CAUTION

Injury to the patient or operator and damage to the VivoLink™ may occur.

If any of the four batteries are installed backwards, the reversed polarity may cause excessive current through this battery. The excessive current can accelerate discharge and leakage of the battery acid, which can burn skin and may permanently damage the device.

If the Integrity™ is not going to be used for some time, remove the batteries from the VivoLink™ and store them in a cool, safe place. If the batteries are left in the VivoLink™ for a prolonged period of time they may discharge and leak the battery acid into the battery compartment, which can burn skin and may permanently damage the device.

Computer

See the computer manufacturer's User Manual.

Chapter 7 Troubleshooting

Problems, Causes and Solutions

ATTENTION

Do not attempt to repair the instrument; this may cause it to function improperly.

The Integrity™ System is not a field-repairable instrument. Call your distributor of Vivosonic Customer Support for all repairs.

Table 3 Troubleshooting Problems, Causes and Solutions

Problem Observed	Possible Causes	Possible Solutions
The computer does not boot.	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 The ON switch is located in the center of the right side of the computer or check your computer's user manual.
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 to work with the Integrity™ System may be used.
There is no signal from the transducer (ER-3A or B-71).	The wrong ear has been chosen. The earphone is not inserted properly.	• Verify that the appropriate ear tip is chosen. • Verify that the foam earphone has been placed in the ear canal properly. • Verify the B-71 is affixed properly to the patient.
The Bluetooth® wireless connection fails.	The VivoLink™ has not been turned on. The VivoLink™ batteries are low or dead. The VivoLink™ is out of range. The software is out of sync.	• Make sure that VivoLink™ is switched on. • Check the battery voltage (Figure 18) to make sure that VivoLink™ batteries

		are charged. • Make sure that distance between VivoLink™ and the computer has not exceed 30 ft (10 m). • Press **RETRY CONNECTION** button. • Switch the VivoLink™ off and on. • Restart the Integrity™. • Refer to the Bluetooth® Troubleshooting section of Appendix J.
The EEG signal is above ±40 µV and is not coming down.	The electrodes may be poorly placed.	• Readjust the electrodes and start again.
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 AEP response for either ear while testing with the ER-3A	The ear is not getting the stimulus sent from the VivoLink™	• Check that the ER-3A earphone is producing a sound. Listen to the earphone using a reasonably audible stimulus setting such as 50 dB nHL. • Change the ER-3A transducers. • If there is still no sound, call Customer Support to determine if the problem is the connection on the VivoLink™

CAUTION

Do not install printer drivers and do not use office printers that are not tested and validated to work with the system, and supplied by Vivosonic. This may cause improper instrument functioning, failure to print, and error messages.

Chapter 8 Appendices

Appendix A Technical Specifications

Intended use	Hearing screening and clinical assessment in newborns, infants, children, and adults.
Digital Signal Processing (DSP) method	The Kalman Weighted method, a patented method using a Linear Minimum Mean-Square Error Filter, also called the Kalman Filter (US Patents 6,463,411 and 6,778,955), is used to estimate ABR signals recording and a time-averaging method. [Li 2002]
Test procedure	Non-invasive.
Patient participation/response	Not required – ABR is objective.
Diagnostic environment	VivoLink™ will perform in a variety of environments (hospital, ambulatory, or home). A sound-proof room is typically not required.
Compliant Transducers and cables	Compliant with the requirements of EN60601-1-2:2001 Sections 36.201, 36.202 – ER-3A earphones attached to 55.5 ± 2.5 cm cable – B-71 Bone Conductor attached to 72” cable – OAE probe attached to 80 cm cable
Compliant Accessories	Compliant with the requirements of EN60601-1-2:2001 Sections 36.201, 36.202 Amplitrode® cables length: – between VivoLink™ and ground clip – 1 Meter – between ground clip and “+” clip” – 25 cm – between ground clip and “-“ clip – 40 cm VivoLink™ - wireless interface module
Electrode type	Single-use Ambu® Neuroline 720-00-S snap electrodes or equivalent.
Amplitrode® filters	For ABR: 30 – 3000 Hz. Slope: 12 dB/octave.
Frequency bands and bandwidth of reception	The receiver operates in 79 bands separated by 1MHz, centered at 2402 MHz through 2480 MHz with a bandwidth of +/- 20 parts per million
Frequency characteristics of the modulation and the effective radiated power of transmission	For all frequencies: Modulation Type: IQ Modulation Frequency Characteristics (where centre frequency F0 = 2F1-F2): Average delta F1 Modulation = 165 kHz (+10/-25 kHz) Maximum delta F2 Modulation = 125 kHz Effective Radiated Power: +1 dBm (+/- 3dB)
ABR Numeric Latencies Peak Accuracy of Labeled Peaks	Peaks I, II, III, IV, and V, within an accuracy of 0.026 ms.
Amplitrode® gain	For ABR: 15000,
VivoLink™ gain	Selectable: 0 dB, 10 dB, 20 dB, and 40 dB.
VivoLink™ filters	Selectable notch filter settings: 50 Hz, 60 Hz, and “no filter”.

VivoLink™ resolution	Analog-to-digital (A/D) conversion (in recording channels): 24 bit. Digital-to-analog (D/A) conversion (in stimulation channels): 16 bit.
Automatic pre-testing procedures	The measurement of the electrode contact quality.
Ear tips	Type: Disposable, foam or PVC for AEP testing.
Power source	The VivoLink™ is powered by four AA batteries. The system ships with eight Nickel-Metal Hydride (NiMH) rechargeable batteries, a charger and 4 AA Alkaline batteries.
Electrical path to the patient	In ABR test: from the VivoLink™ through the Amplitrode® and Electrodes. There is no electrical hazard to the patient, as the VivoLink™ is battery-operated.
Safety standards compliance	The products gained the following regulatory clearances and approvals: • USA: FDA clearance under 510(k) K043396. • Canada: Health Canada Medical Device License No. 67609. • European Union: CE Registration No. DE/CA09/0170/1207 to 1212. • CB Test Certificate CA/023/ITS (testing to standards for safety of electrical equipment)
	Independent testing and audits verified that the products adheres to the following standards: • CB Scheme certificate (Compliance to national deviations for 67 countries) • CSA C22.2 NO 601.1 (R2001) (Medical electrical equipment – general requirements for safety) • EN 980:2003 (Graphical symbols for use in the labeling of medical devices) • EN 55011:1998 (Limits and methods of measurement of Radio disturbance Characteristics of Industrial, Scientific and Medical Radio- Frequency equipment) • EN 60601-1-1 (2001) (Collateral standard: safety requirements for medical electrical systems (Part 1)) • EN 60601-1-2:2003 (Collateral standard. Electromagnetic compatibility requirements and tests) • EN 60601-2-40 (Medical electrical equipment- Particular requirements for the safety of electromyographs and evoked response equipment (IEC 60601-2-40:1998)) • FCC Part 15 (Title 47 CFR Part 15, Radio frequency devices) • IEC 60601-1-4:2000 (General requirements for safety – collateral standard for Programmable electrical medical systems) • ISO 13485:2003 (Medical devices - Quality management systems) • ISO 14971:2000 (Medical devices - Risk management for medical devices) • UL 60601-1:2003 UL (Standard for safety - Medical electrical equipment)
Environmental Conditions for Transport and Storage	• Ambient temperature of -40C to +70C, • Relative humidity of 10% to 100%, • Atmospheric pressure range of 500hPa to 1060hPa.
Potential Electromagnetic or other interference	There are no special measures that need to be taken to protect the instrument from interference. However the instrument may be interfered with other equipment, even if this equipment complies with

	CISPR emissions requirements.
Minimum Computer Requirements	• Microsoft® Windows XP® Home or Professional. • Service Pack 1 or above • CPU clock speed >= 1GHz • RAM = 256 Mbytes • Available free hard drive space after installation of operating system = 500 Mbytes • Display resolution = 1024 pixels x 768 pixels • Computer mouse • CD-ROM drive • At least 3 USB ports.
Radio frequency related specifications	RF Output Power rating: 4 dB mW maximum Operating frequency range: 2.400 – 2.4835 GHz Modulation Types: GFSK
Software	Integrity™ control software.
Printers (optional)	Any printer connected to the network shared by the Integrity™ System or any computer configured to run from the Integrity System..

Appendix B Items tracked in the Integrity Database

The following items can be entered by the user and tracked by the database.

1. Patient family name
2. Patient give name
3. Hospital ID number
4. Insurance number
5. Mother's family name
6. Mother's given name
7. Gender
8. Ear (Right, Left)
9. Ethnicity
10. Address
11. State/Province
12. Zip/Postal code
13. Country
14. Telephone number
15. Date of birth
16. Time of birth
17. Age (calculated at time of test)
18. Birth Weight (Grams or Pounds:Ounces)
19. High risk registry
20. Patient comment 1
21. Patient comment 2
22. Referring Physician
23. Location of test
24. Mother’s family and give names
25. Mother’s ID number
26. Examiner
27. Date of test.
28. Time of test
29. Protocol name
30. Stimulus parameters (Types of stimuli and levels)
31. Stimulus parameters (Tone frequencies and levels)
32. Stimulus parameters (Modulated frequencies and levels)
33. Number of ABR collected response (calculated)
34. ABR stimulus polarity
35. Transducer type
36. Electrode placement
37. DPOAE levels at test frequencies
38. Noise Floor levels at test frequencies
39. TEOAE response waveform

40. TEOAE levels in user-defined frequency bands
41. TEOAE noise floor in user-defined frequency bands
42. ABR response waveforms
43. Latency values of the ABR peaks
44. I peak latency (positive peak)
45. I’ peak latency (negative peak)
46. II peak latency
47. III peak latency
48. IV peak latency
49. V peak latency (positive)
50. V’ peak latency (negative)
51. I - III inter-peak latency
52. III - V inter-peak latency
53. I – I’ peak-to-peak amplitude
54. V – V’ peak to peak amplitude
55. ABR wave V Input/Output function
56. Type of test(ABR)
57. Test comment 1
58. Test comment 2

Appendix C ABR Preset Protocols

ABR air-conducted click threshold protocol	
Protocol screen settings	
Stimulus Type	Click
Transducer Type	ER-3A insert earphones
Stimulus Rate	27.7 /sec
Window	Disabled
Ramp	Disabled
High Pass Filter	30 Hz
Low pass Filter	1500 Hz
High Pass Rolloff	12 dB/oct
Low Pass Rolloff	12 dB/oct
Amplifier Gain	0
Recoding Window	20 ms
Artifact Rejection	Disabled
Artifact Rejection Threshold	Disabled
Test screen	
Algorithm	Kalman
Polarity	Condensation
Masker	Disabled
Masking Level	Disabled
Noniverting	F_z
Inverting	A_1, A_2, M_1, M_2
Recording Side	Ipsilateral
Notch Filter	Disabled
Level dB nHL	Defined by an Audiologist

Neurologic test protocol	
Protocol screen	
Stimulus Type	Click
Transducer Type	ER-3A insert earphones
Stimulus Rate	17.7 /sec
Window	Disabled
Ramp	Disabled
High Pass Filter	30 Hz
Low pass Filter	3000 Hz
High Pass Rolloff	12 dB/oct
Low Pass Rolloff	12 dB/oct
Amplifier Gain	0
Recoding Window	15 ms
Artifact Rejection	Disabled

Artifact Rejection Threshold	Disabled
Test screen	
Algorithm	Kalman
Polarity	Alternating split
Masker	Disabled
Masking Level	Disabled
Noniverting	F_z
Inverting	A_1, A_2, M_1, M_2
Recording Side	Ipsilateral
Notch Filter	Disabled
Level dB nHL	80 dB nHL

ABR air-conducted 500 Hz tone-burst threshold protocol	
Protocol screen	
Stimulus Type	500 Hz
Transducer Type	ER-3A insert earphones
Stimulus Rate	27.7 /sec
Window	Blackman
Ramp	2-0-2
High Pass Filter	30 Hz
Low pass Filter	1500 Hz
High Pass Rolloff	12 dB/oct
Low Pass Rolloff	12 dB/oct
Amplifier Gain	0
Recoding Window	25 ms
Artifact Rejection	Disabled
Artifact Rejection Threshold	Disabled
Test screen	
Algorithm	Kalman
Polarity	Condensation
Masker	Disabled
Masking Level	Disabled
Noniverting	F_z
Inverting	A_1, A_2, M_1, M_2
Recording Side	Ipsilateral
Notch Filter	Disabled
Level dB nHL	Defined by an Audiologist

ABR air-conducted 1000 Hz tone-burst threshold protocol
Protocol screen

Stimulus Type	1000 Hz
Transducer Type	ER-3A insert earphones
Stimulus Rate	27.7 /sec
Window	Blackman
Ramp	2-0-2
High Pass Filter	30 Hz
Low pass Filter	1500 Hz
High Pass Rolloff	12 dB/oct
Low Pass Rolloff	12 dB/oct
Amplifier Gain	0
Recoding Window	25 ms
Artifact Rejection	Disabled
Artifact Rejection Threshold	Disabled
Test screen	
Algorithm	Kalman
Polarity	Condensation
Masker	Disabled
Masking Level	Disabled
Noniverting	F_z
Inverting	A_1, A_2, M_1, M_2
Recording Side	Ipsilateral
Notch Filter	Disabled
Level dB nHL	Defined by an Audiologist

ABR air-conducted 2000 Hz tone-burst threshold protocol	
Protocol screen	
Stimulus Type	4000 Hz
Transducer Type	ER-3A insert earphones
Stimulus Rate	27.7 /sec
Window	Blackman
Ramp	2-0-2
High Pass Filter	30 Hz
Low pass Filter	1500 Hz
High Pass Rolloff	12 dB/oct
Low Pass Rolloff	12 dB/oct
Amplifier Gain	0
Recoding Window	25 ms
Artifact Rejection	Disabled
Artifact Rejection Threshold	Disabled
Test screen	
Algorithm	Kalman
Polarity	Condensation

Masker	Disabled
Masking Level	Disabled
Noniverting	F_z
Inverting	A_1, A_2, M_1, M_2
Recording Side	Ipsilateral
Notch Filter	Disabled
Level dB nHL	Defined by an Audiologist

ABR air-conducted 3000 Hz tone-burst threshold protocol	
Protocol screen	
Stimulus Type	3000 Hz
Transducer Type	ER-3A insert earphones
Stimulus Rate	27.7 /sec
Window	Blackman
Ramp	2-0-2
High Pass Filter	30 Hz
Low pass Filter	1500 Hz
High Pass Rolloff	12 dB/oct
Low Pass Rolloff	12 dB/oct
Amplifier Gain	0
Recoding Window	25 ms
Artifact Rejection	Disabled
Artifact Rejection Threshold	Disabled
Test screen	
Algorithm	Kalman
Polarity	Condensation
Masker	Disabled
Masking Level	Disabled
Noniverting	F_z
Inverting	A_1, A_2, M_1, M_2
Recording Side	Ipsilateral
Notch Filter	Disabled
Level dB nHL	Defined by an Audiologist

ABR air-conducted 4000 Hz tone-burst threshold protocol	
Protocol screen	
Stimulus Type	4000 Hz
Transducer Type	ER-3A insert earphones
Stimulus Rate	27.7 /sec

Window	Blackman
Ramp	2-0-2
High Pass Filter	30 Hz
Low pass Filter	1500 Hz
High Pass Rolloff	12 dB/oct
Low Pass Rolloff	12 dB/oct
Amplifier Gain	0
Recoding Window	25 ms
Artifact Rejection	Disabled
Artifact Rejection Threshold	Disabled
Test screen	
Algorithm	Kalman
Polarity	Condensation
Masker	Disabled
Masking Level	Disabled
Noniverting	F_z
Inverting	A_1, A_2, M_1, M_2
Recording Side	Ipsilateral
Notch Filter	Disabled
Level dB nHL	Defined by an Audiologist

ABR bone conducted test protocol for click	
Protocol screen	
Stimulus Type	Click
Transducer Type	B-71
Stimulus Rate	7.1 /sec
Window	Disabled
Ramp	Disabled
High Pass Filter	30 Hz
Low pass Filter	3000 Hz
High Pass Rolloff	12 dB/oct
Low Pass Rolloff	12 dB/oct
Amplifier Gain	0
Recoding Window	25 ms
Artifact Rejection	Disabled
Artifact Rejection Threshold	Disabled
Test screen	
Algorithm	Kalman
Polarity	Alternating split
Masker	Disabled
Masking Level	Disabled
Noniverting	F_z
Inverting	A_1, A_2, M_1, M_2

Recording Side	Ipsilateral
Notch Filter	Disabled
Level dB nHL	Defined by an Audiologist

ABR bone conducted 500 Hz tone-burst threshold protocol	
Protocol screen	
Stimulus Type	500 Hz
Transducer Type	B-71
Stimulus Rate	7.1 /sec
Window	Blackman
Ramp	2-0-2
High Pass Filter	30 Hz
Low pass Filter	3000 Hz
High Pass Rolloff	12 dB/oct
Low Pass Rolloff	12 dB/oct
Amplifier Gain	0
Recoding Window	25 ms
Artifact Rejection	Disabled
Artifact Rejection Threshold	Disabled
Test screen	
Algorithm	Kalman
Polarity	Alternating split
Masker	Disabled
Masking Level	Disabled
Noniverting	F_z
Inverting	A_1, A_2, M_1, M_2
Recording Side	Ipsilateral
Notch Filter	Disabled
Level dB nHL	Defined by an Audiologist

ABR bone conducted 1000 Hz tone-burst threshold protocol	
Protocol screen	
Stimulus Type	1000 Hz
Transducer Type	B-71
Stimulus Rate	7.1 /sec
Window	Blackman
Ramp	2-0-2
High Pass Filter	30 Hz

Low pass Filter	3000 Hz
High Pass Rolloff	12 dB/oct
Low Pass Rolloff	12 dB/oct
Amplifier Gain	0
Recoding Window	25 ms
Artifact Rejection	Disabled
Artifact Rejection Threshold	Disabled
Test screen	
Algorithm	Kalman
Polarity	Alternating split
Masker	Disabled
Masking Level	Disabled
Noniverting	F_z
Inverting	A_1, A_2, M_1, M_2
Recording Side	Ipsilateral
Notch Filter	Disabled
Level dB nHL	Defined by an Audiologist

ABR bone conducted 2000 Hz tone-burst threshold protocol	
Protocol screen	
Stimulus Type	2000 Hz
Transducer Type	B-71
Stimulus Rate	7.1 /sec
Window	Blackman
Ramp	2-0-2
High Pass Filter	30 Hz
Low pass Filter	3000 Hz
High Pass Rolloff	12 dB/oct
Low Pass Rolloff	12 dB/oct
Amplifier Gain	0
Recoding Window	25 ms
Artifact Rejection	Disabled
Artifact Rejection Threshold	Disabled
Test screen	
Algorithm	Kalman
Polarity	Alternating split
Masker	Disabled
Masking Level	Disabled
Noniverting	F_z
Inverting	A_1, A_2, M_1, M_2
Recording Side	Ipsilateral
Notch Filter	Disabled

Level dB nHL	Defined by an Audiologist

ABR bone conducted 3000 Hz tone-burst threshold protocol	
Protocol screen	
Stimulus Type	3000 Hz
Transducer Type	B-71
Stimulus Rate	7.1 /sec
Window	Blackman
Ramp	2-0-2
High Pass Filter	30 Hz
Low pass Filter	3000 Hz
High Pass Rolloff	12 dB/oct
Low Pass Rolloff	12 dB/oct
Amplifier Gain	0
Recoding Window	25 ms
Artifact Rejection	Disabled
Artifact Rejection Threshold	Disabled
Test screen	
Algorithm	Kalman
Polarity	Alternating split
Masker	Disabled
Masking Level	Disabled
Noniverting	F_z
Inverting	Ai, A_2
Recording Side	Ipsilateral
Notch Filter	Disabled
Level dB nHL	Defined by an Audiologist

ABR bone conducted 4000 Hz tone-burst threshold protocol	
Protocol screen	
Stimulus Type	4000 Hz
Transducer Type	B-71
Stimulus Rate	7.1 /sec
Window	Blackman
Ramp	2-0-2
High Pass Filter	30 Hz
Low pass Filter	3000 Hz
High Pass Rolloff	12 dB/oct
Low Pass Rolloff	12 dB/oct

Amplifier Gain	0
Recoding Window	25 ms
Artifact Rejection	Disabled
Artifact Rejection Threshold	Disabled
Test screen	
Algorithm	Kalman
Polarity	Alternating split
Masker	Disabled
Masking Level	Disabled
Non-inverting	F_z
Inverting	A_1, A_2, M_1, M_2
Recording Side	Ipsilateral
Notch Filter	Disabled
Level dB nHL	Defined by an Audiologist

Appendix D Guidance and Manufacturer's Declaration

Emissions

All Equipment and Systems

The Integrity™ is intended for use in the electromagnetic environment specified below. The customer or user of the Integrity™ should ensure that it is used in such an environment.

Emission Test	Compliance	Electromagnetic Environment – Guidance
RF Emissions CISPR 11	Group 1	The Integrity™ uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	The Integrity™ is suitable for use in all establishments, including domestic, and those directly connected to the public low-voltage power supply network that supplies buildings used for used for domestic purpose.
Harmonics IEC 61000-3-2	Class N/A	
Flicker IEC 61000-3-3	N/A	

Equipment and Systems that are NOT life-supporting

The Integrity™ is intended for use in the electromagnetic environment specified below. The customer or user of the Integrity™ should ensure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment-Guidance
			Portable and mobile communications equipment should be separated from the Integrity™ by no less than the distances calculates/listed below:
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	V1=3 Vrms	D=(3.5/V1)(Sqrt P)
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 MHz	E1=3 V/m	D=(3.5/V1)(Sqrt P) 80 to 800 MHz
			D=(7/E1)(Sqrt P) 800 MHz to 2.5 GHz Where P is the max. power (watts) and D is the recommended separation distance (meters). Field strength from fixed transmitters, as determined by an electromagnetic site survey, should be less than the compliance levels (V1 and E1). Interference may occur in the vicinity of equipment containing a transmitter.

Immunity

All Equipment and Systems

The Integrity™ is intended for use in the electromagnetic environment specified below. The customer or user of the Integrity™ should ensure that it is used in such an environment

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
ESD IEC 61000-4-2	±6kV Contact ±8kV Air	±6kV Contact ±8kV Air	Floors should be wood, concrete or ceramic tile. If floors are synthetic, the r/h should be at least 30%
EFT IEC 61000-4-4	±2kV Mains ±1kV I/Os	N/A Battery Operated Device	N/A
Surge IEC 61000-4-5	±1kV Differential ±2kV Common	N/A Battery Operated Device	N/A
Voltage Dips/Dropout IEC 61000-4-11	>95% Dip for 0.5 Cycle 60% Dip for 5 cycles 30% Dip for 25 Cycles >95% Dip for 5 Seconds	N/A Battery Operated Device	N/A
Power Frequency 50/60 Hz Magnetic Field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be that of a typical commercial or hospital environment

Note: ESD compliance is dependent on a single layer of heat shrink being installed on the insert earphone connector. If this is not installed, the connector shell should not be touched during operation.

Radio Transmissions

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one of more of the following measures:

- Reorient or relocate the receiving antenna
- Increase the separation between the equipment and receiver
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

Warning: Changes or modifications not expressly approved by Vivosonic, Inc. could void the user's authority to operate the equipment

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference and (2) this device must accept any interference received, including interference that may cause undesired operation.

Appendix E Recommended Separation Distance

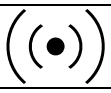
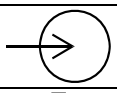
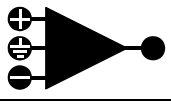
This appendix covers the recommended separation distance between portable and mobile radio frequency devices and the Integrity™ system.

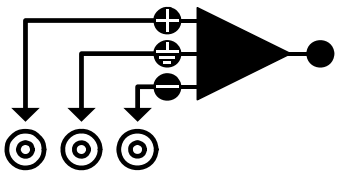
Equipment and Systems that are NOT life-supporting.

The Integrity™ is intended for use in the electromagnetic environment in which radiate 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™ as recommended below, according to the maximum output power of the communication equipment.

Max Output Power (Watts)	**Separation (m) 150kHz to 80 MHz** **D= 1.1667(Sqrt P)**	**Separation (m) 80 to 800MNz** **D=1.1667(Sqrt P)**	**Separation (m) 800MHz 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 F Symbols Used on the Instrument

Label Symbol	Description
	Read accompanying documentation
	On (power)
	Off (power)
	Wireless communication established
	Standby
	Impedance
REF:	Reference or Model Number
SN:	Serial Number
	Date of Manufacture
	Type BF equipment
CE 0120	CE Mark with notified body number
US C entela Certified 7644 UL 2601 CSA 601.1 EN 60601-1	Entela certification.
	Input voltage
	Cell (battery)
AA	Cell size
Alkaline	Alkaline battery
NiMH	Nickel Metal Hydride battery (NiMH)
	Connector for Amplitrode®.
	Connector for OAE Probe (not implemented)
	Connectors for ER-3A earphones (red – the right ear, blue – the left ear)

	Connector for B-71 Bone Conductor
	Probe Holder.
	Parking Snaps for the Amplitrode® and its clips on the VivoLink™.
	Caution. Fragile. Sensitive to mechanical shock.
	Made in Canada.
	FCC mark

Appendix G Overview of Clinical Applications

This is a brief overview of the clinical applications for AEP procedures. Refer to Appendix I for references regarding this information.

General Information on ABR

What is ABR?

Auditory brainstem response (ABR) is an objective electrophysiological test of the function and integrity of the auditory system from the inner ear to the brainstem. ABR is an electrical response starting in the inner ear that travels through the auditory nerve and balance nerve, to the brain stem.

What are the clinical applications of ABR?

- Hearing screening in newborns.
- Estimating hearing levels in difficult to test patients, i.e., mentally disabled, autistic, developmentally delayed, infants and small children.
- Evaluating patients with suspected retro-cochlear pathology.
- Evaluating patients with Meniere's disease or similar disorders.
- Diagnostics of Auditory Neuropathy/Dissynchrony.
- Intra-operative monitoring of the function of the Cochlea and the 8th cranial nerve.

Appendix H ABR Latency Normative Data

UCLA School of Medicine Norms for Infants

Wave V Mean Latency as Function of Click

Table 4 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 chronologic 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 5 Boys Town norms for newborns

Conception age in weeks		Wave V latency (msec)			
		20 dB	40 dB	60 dB	80 dB
33 – 34	Mean	9.72	8.48	7.62	7.05
	SD	0.56	0.49	0.41	0.39
35 – 36	Mean	9.61	8.42	7.58	7.02
	SD	0.67	0.54	0.43	0.38
37 – 38	Mean	9.57	8.29	7.45	6.94
	SD	0.74	0.51	0.44	0.42
39 – 40	Mean	9.36	8.11	7.30	6.82
	SD	0.57	0.49	0.40	0.38
41 – 42	Mean	9.31	8.08	7.20	6.69
	SD	0.54	0.35	0.29	0.29
43 – 44	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 msec, 13/sec, monaural, Beyer DT48 earphones; acquisition – filters, 100 – 3000 Hz; amplification, 100,000; sweeps, 1,024; analysis time, 15 msec; 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 Level in Children Ages 3 Months to 3 Years

Table 6 Boys Town norms for infants

Age in months		Latency (msec)				
		Wave V				Wave I
		20 dB	40 dB	60 dB	80 dB	
3 – 6	**Mean**	8.72	7.43	6.73	6.25	1.59
	SD	0.53	0.36	0.33	0.32	0.17
6 – 9	**Mean**	8.59	7.28	6.56	6.10	1.59
	SD	0.61	0.38	0.29	0.26	0.16
9 -12	**Mean**	8.31	7.05	6.31	5.90	1.59
	SD	0.54	0.37	0.29	0.27	0.18
12 – 15	**Mean**	8.28	7.10	6.30	5.91	1.59
	SD	0.60	0.45	0.33	0.27	0.17
15 – 18	**Mean**	8.33	7.00	6.24	5.84	1.58
	SD	0.61	0.38	0.24	0.27	0.14
18 – 21	**Mean**	8.22	6.95	6.19	5.74	1.55
	SD	0.62	0.36	0.18	0.19	0.12
21 – 24	**Mean**	8.05	6.79	6.14	5.71	1.57
	SD	0.58	0.33	0.29	0.26	0.17
24 – 27	**Mean**	8.30	6.89	6.09	5.71	1.53
	SD	0.46	0.29	0.22	0.19	0.14
27 – 30	**Mean**	7.98	6.75	6.08	5.60	1.59
	SD	0.42	0.33	0.28	0.22	0.19
30 – 33	**Mean**	8.12	6.79	6.07	5.68	1.56
	SD	0.53	0.32	0.31	0.27	0.16
33 – 36	**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 msec, 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 msec; 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 for the primary components of the ABR

Table 7 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.

Appendix I References

This appendix contains references for The ABR latency and amplitude values, terms, abbreviations, the definitions for the Glossary of Terms, and a summary of clinical applications of ABR found in Appendix G.

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.

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Glossary of Terms

The following definitions are used in this manual and can also be found in the Integrity ™ software instrument screens.

The terms shown here where defined using the information referenced in Appendix I.

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(tm) system offers the standard **Averaging** method and the **Kalman Weighted** averaging method.
Alternating Stimulus Polarity	Alternating presentation of rarefaction and condensation polarity stimuli.
Amplitrode®	An integrated pre-amplifier and electrode into a combined unit for attaching or affixing to a subject.
Artifact	Unwanted signal that may interfere with the measurement of desired signals.
Artifact Rejection Threshold (ART)	The sound pressure level in µV above which the detected acoustic signal is considered an artifact..
Auditory Brainstem Response (ABR)	Auditory evoked potential originating from the cranial nerve VIII and auditory brainstem structures.
Averaging	ABR processing algorithm, which uses a standard time averaging technique when equivalent weighting is given to each ABR collected response. Weights assigned to each collected ABR response are based on the noise in that response. Sweeps contaminated with artifacts above a certain artifact-rejection threshold (ART) are excluded from the averaging.
Bone vibrator	A transducer that is used to present sounds to the skull that reached the Cochlea through the head tissues and bones, i.e. bypassing the middle ear.
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 µsec.
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).
Component	A peak or wave in the response waveform.
Common Mode Rejection (CMR)	A noise reduction technique implemented by the differential amplifier where an identical (common) noise at two electrodes is subtracted from the electrophysiologic response.
Condensation (Positive) Stimulus Polarity	The initial displacement of the stimulus, produced with a positive-voltage electrical signal and an outward movement of the acoustic transducer.
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 SPL	The logarithmic ratio of the RMS sound pressure of an acoustic signal, P_{rms} to the reference sound pressure, P_0 = 20 µPa = 2 * 10^{-5} Pa, calculated as: SPL (dB) = 20 * log (P_{rms}/P_0).
dB peSPL	The decibel level of a 1000 Hz tone at an amplitude equivalent to the peak of a transient signal such as a click.
Eartip	A part of the ER-3A earphone, typically made of soft plastic, that is inserted onto 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.
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.
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
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 its scalp with the Amplitrode®, which is positioned on the ground electrode.
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.
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, **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).
Latency	A time interval between two events (e.g. the stimulus and response).
Low pass filter	A filter that passes electrical energy below a specific cutoff frequency and

	eliminates (filters out) energy above the 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.
Microvolt (µV)	One millionth of a Volt.
Microsecond (µs)	One millionth of a second.
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.
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.
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.
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.
Peak	A component of an evoked response waveform, or the extreme amplitude for the component; often used to describe-voltage components.
Peak equivalent force level (peFL)	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 (click).
Peak equivalent sound pressure level (peSPL)	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 voltage characteristic of the stimulus or waveform response. 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.
Preamplifier	An electronic device that receives an electric 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.
Protocol	A set of parameters, typically user-defined, that instructs the system how to automatically perform a test. It covers stimulus settings, DSP settings, etc.
Rarefaction (negative) Stimulus Polarity	The initial displacement of the stimulus, produced with a negative-voltage electrical signal and inward movement of the acoustic transducer
Rate	The number of stimulus repetitions per unit of time, usually 1 second.
Repetitions (Sweeps)	The number of single reoccurring events, such as a waveform, that are presented in a set period of time.
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 rate	Number of stimuli presented per second.
Stimulus level	The sound level of an acoustic stimuli 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 L_1/L_2format, for example 65/55 dB SPL.
Test	A complete sequence of stimuli presentation and response recording performed according to a protocol within one test session.
Test Type	The type of tests 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 then 1 sec).
Transducer	An electroacoustic devise for converting one form of energy into another.
VivoLink™	The world's first wireless interface module used in auditory electrophysiology. It is a universal platform: It can perform ABR, ASSR, 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.

Appendix J Bluetooth® Troubleshooting

Introduction

This document has been written to describe the process of troubleshooting the Bluetooth installation. Please read the instructions in their entirety and following the suggestions before calling for technical support.

I connect my dongle to my computer and nothing happens

If no activity takes place after inserting the Bluetooth dongle to the computer it is because the Bluetooth driver has not been installed.

Please follow the Bluetooth driver installation instructions from page - 3 - to page - 18 - of the Installation Instructions to install the drivers and configure the services and security for Bluetooth.

I insert the dongle to the back of the computer and the Bluetooth icon in the system tray remains off.

If your Bluetooth icon (), which is found in the system tray, in the lower right corner of the screen is turned off it could be for the following reasons:

1. The Bluetooth Driver is not properly installed

   Action - Re-install the Bluetooth driver and ensure that the settings have been configured correctly.

2. the Bluetooth dongle is not plugged in into the proper USB connection.

   Ensure that the Bluetooth driver is installed and that the dongle is connected to the same port as it was during the driver installation.

3. The Bluetooth dongle may not be connected properly.

   To ensure that the dongle is properly connected check that the LED on the dongle is lit. If the LED is NOT lit, remove the dongle and then connect it again.

I have installed the Bluetooth driver and made the proper connection to the VivoLink but the connection is not recognized after a system shutdown.

This problem is usually caused by incorrectly configured Windows® Bluetooth settings. If the Bluetooth driver does not recognize the previous settings do the following:

1. Please follow the installation instructions for the Bluetooth Drivers and Services from page - 3 - to page - 12 -of the Installation Instructions found at the back of this User's Manual binder.

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INSTALLATION INSTRUCTIONS

Integrity™

wireless revolution in audiology

Installation Instructions, Document 11049 Revision 2 as addendum to User's Manual

Table of Figures

Installation Instructions

Introduction

This document will provide step-by-step instructions to install the Integrity™ software.

Installation Requirements

To properly install Integrity on your system you will need the following:

- Integrity Install Disk
- Bluetooth Dongle
- Bluetooth Driver Disk
- VivoLink™
- Amplitrode®
- Computer with the following system requirements:
  - 1GHZ Processor
  - Microsoft® Windows XP® Professional or Home Edition
  - 256MB of RAM
  - At least 500MB of available hard-disk space

Bluetooth Drivers and Services

Before installing Integrity on the system it is important to install and configure the Bluetooth drivers and services.

Installing Bluetooth Drivers

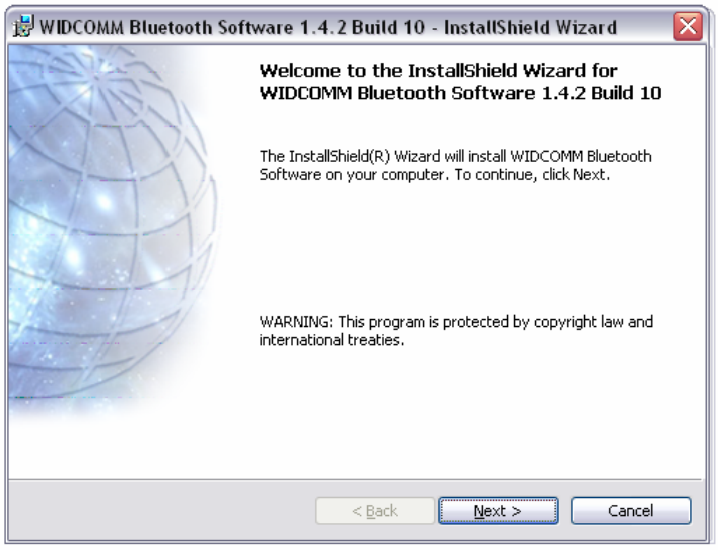
IMPORTANT

Before inserting the Bluetooth Driver CD please ensure that the **Bluetooth Dongle is properly connected to the computer.**

1. Connect the Bluetooth Dongle to the computer.
2. Insert the disk labeled **Bluetooth.** Once the disk is in it will automatically start up and the following screen should be displayed.

Installation Screen Capture 1 Bluetooth introduction

3. Press **Dongle BTW 1.4.10**. The Bluetooth installation welcome screen will be displayed.
4. Press **Next** to begin the Bluetooth driver installation.

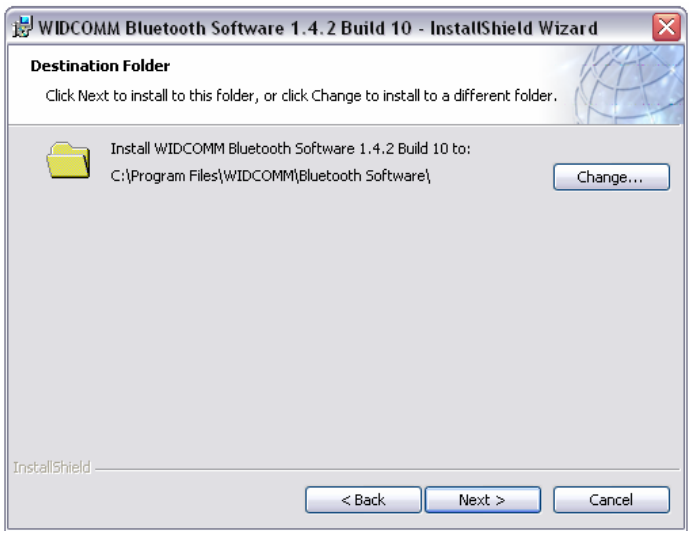


Installation Screen Capture 2 Bluetooth installation welcome

NOTE

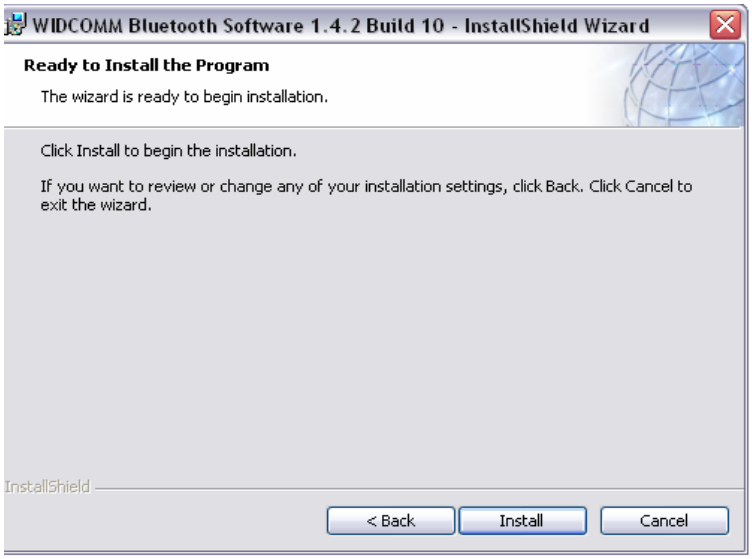
If you have not already installed your Bluetooth Dongle it is important to do so now.

5. Click **Next**, the license agreement will appear. Read the agreement.
6. Press **I accept the terms in the license agreement.** The next window that appears is the Destination Folder window. This window will allow you to choose the folder on your computer where the driver files will be installed.



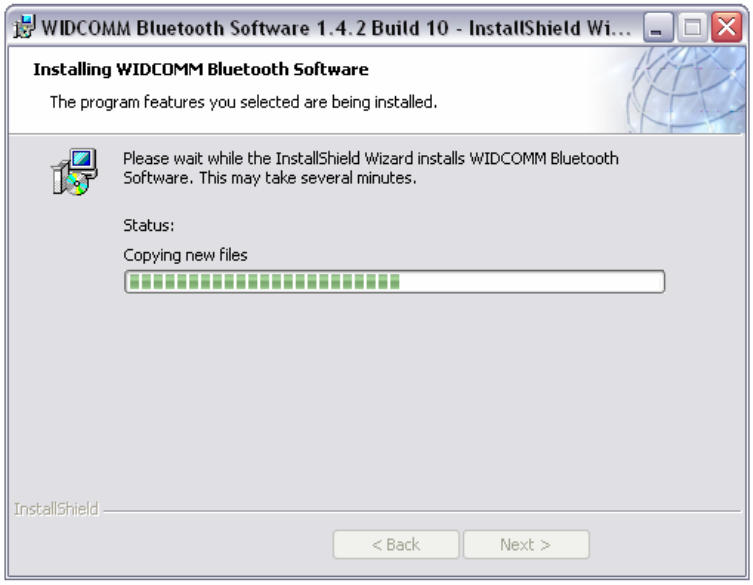
Installation Screen Capture 3 Destination

7. Press **Next** to accept the current folder or press **Change** to change the destination folder of the Bluetooth driver to a different folder.
8. Press **Next**. The next window that will appear is the installation review window.



Installation Screen Capture 4 Destination Folder

9. Press **Install** to begin the installation of your Bluetooth Driver. Installation window will appear once the installation has begun.

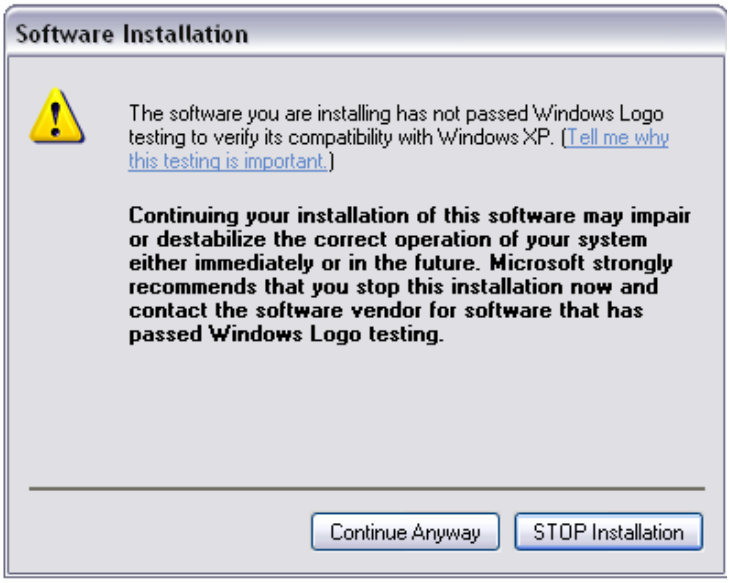


Installation Screen Capture 5 Installing WIDCOM**M**

10. When the files are being installed a Drive Signature Notice will be displayed. Press **Cancel** to continue with the installation.

Installation Screen Capture 6 Driver Signature Notice

11. During the installation a warning window will appear stating “The software you are installing has not passed Windows® Logo testing…” The Integrity™ software requires this warning to be bypassed. Please press **Continue Anyway**.



Installation Screen Capture 7 Warning - Windows® Logo Testing

NOTE

Vivosonic Inc. has verified the compatibility of the Integrity™ software with Windows XP®.

12. The InstallShield Wizard Complete window will be displayed once the driver is completely installed. Press **Finish** to resume the Bluetooth configuration.

Rename a Windows® Bluetooth file.

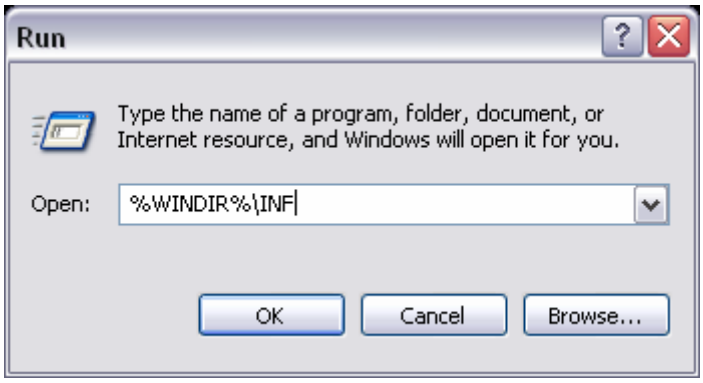
The Bluetooth driver must be configured to be able to properly function with the Integrity™ system.

Once the initial driver has been installed a specific Windows® Bluetooth file bust be renamed.

13. From the Windows® **Start** menu select **Run**.

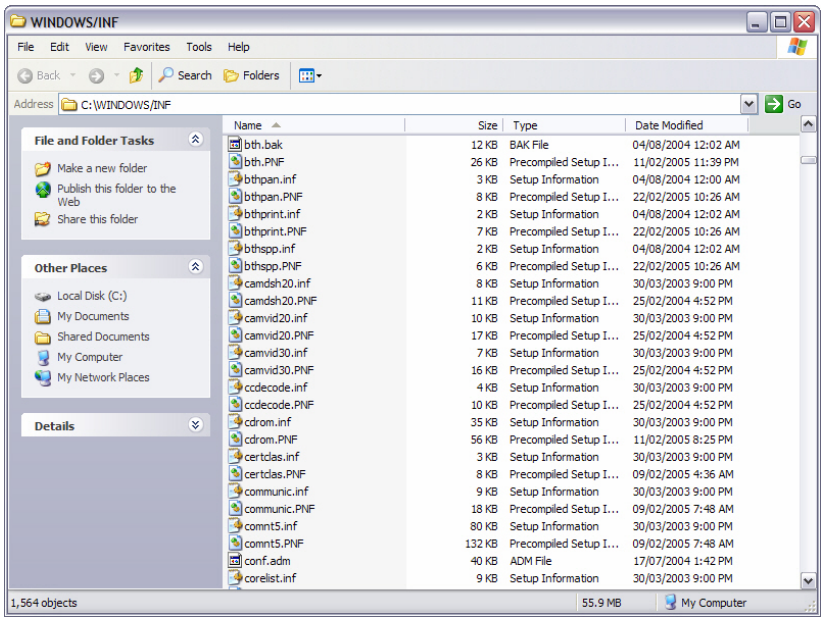
Configuration Screen Capture 1 Start | Run menu

14. Enter **%WINDIR%/INF**



Configuration Screen Capture 2 Run Windows® INF directory

15. Press **OK.** The Windows® INF directory will open.



Configuration Screen Capture 3 Windows® INF directory

16. Find the file called **Bth.inf**.

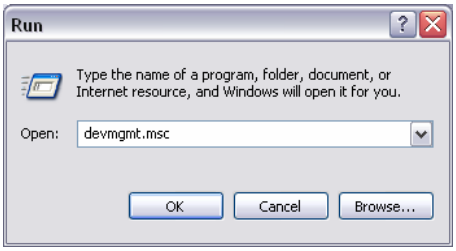
NOTE

The file Bth.inf may also be displayed as BTH if your system does not display file extensions.

17. Right-click the file Bth.inf.
18. Select **Rename**. Rename this file **Bth.bak**.
19. Press **Enter**.
20. Close the window by selecting **File** | **Close** from the main menu on the top right side of the window.

Update the Bluetooth driver

1. From the Windows® **Start** menu select **Run**. Refer to Configuration Screen Capture 1.
2. This time type **devmgmt.msc** in the text field.

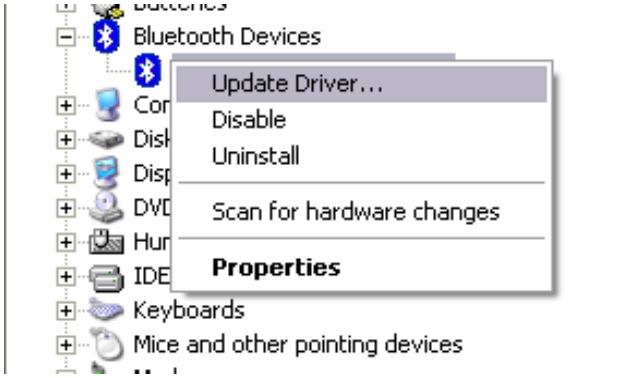


Configuration Screen Capture 4 Run Device Manager

3. Press **OK**. A directory listing the different device will display

Configuration Screen Capture 5 Device Manger

4. Click the ⊞ sign beside **Bluetooth Devices** to expand the list of options for Bluetooth.
5. Right-click the first option under **Bluetooth Devices**, an options window will open.



Configuration Screen Capture 6 Options window

6. Select **Update Driver…** from the options. The Found New Hardware window will open.

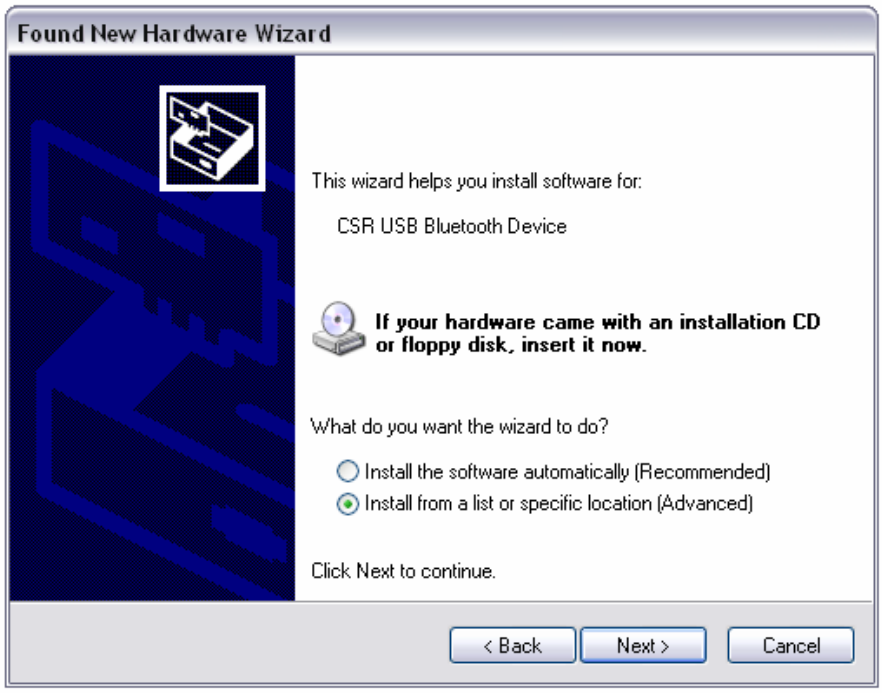
Configuration Screen Capture 7 New Hardware Window

7. Select **Yes, this time only**.
8. Press **Next**. The hardware wizard will continue the update.

NOTE

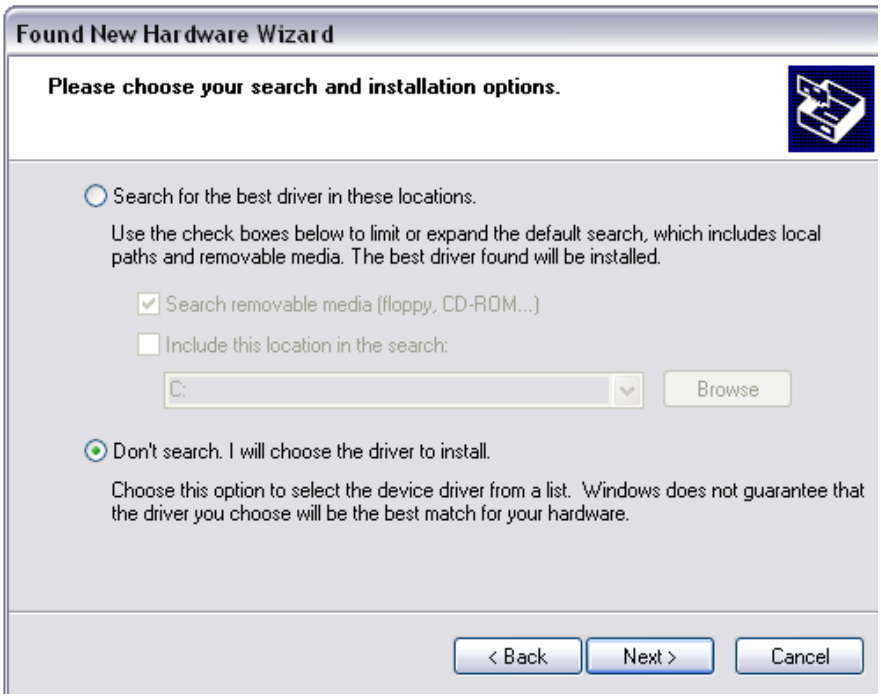
Windows® may choose the proper CSR USB Bluetooth driver to install the files automatically when **Next** is pressed. If Windows® did install your drivers automatically proceed to Bluetooth Services

Configure the Bluetooth Settings on page - 12 -

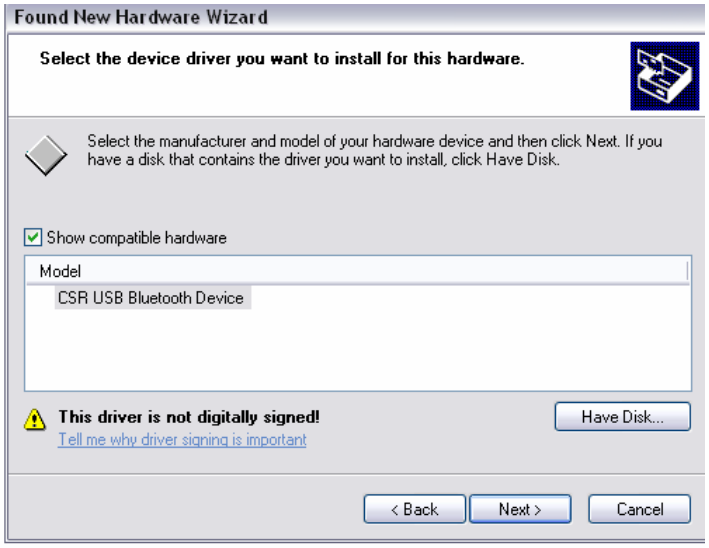


Configuration Screen Capture 8 Install from specific location

9. Select **Install from … a specific location (advanced)**.
10. Press **Next**. The next window will appear.



11. Select **Don't search. I will choose the driver to install** and press **Next**.
    Windows® will then scan for all compatible drivers for your Bluetooth device. Once the scan is complete you will be given a list to choose from which may consist of one or more drivers.



Configuration Screen Capture 9 Device list

12. Select CSR USB Bluetooth Device and press Next.

    The system will then begin to download all of the appropriate files for the new Bluetooth Driver. Once the download and installation is complete, the *Completing the Found New Hardware Wizard* window will be displayed.

13. Press **Finished**.

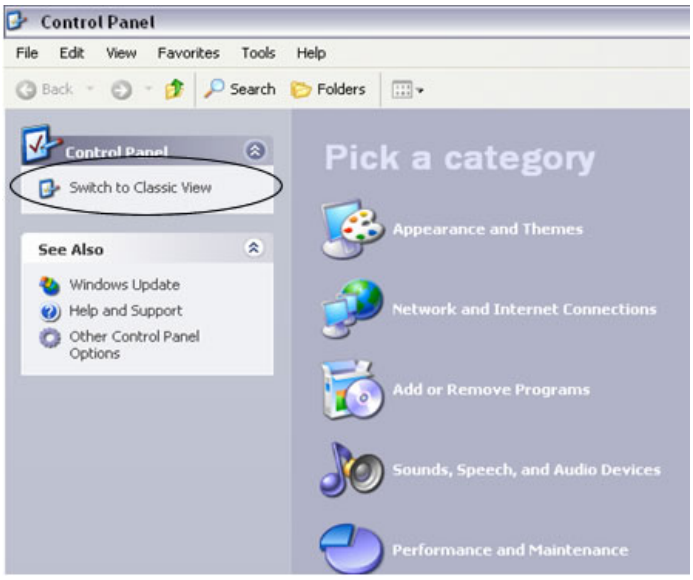
The Bluetooth device drivers are now installed.

Bluetooth Services

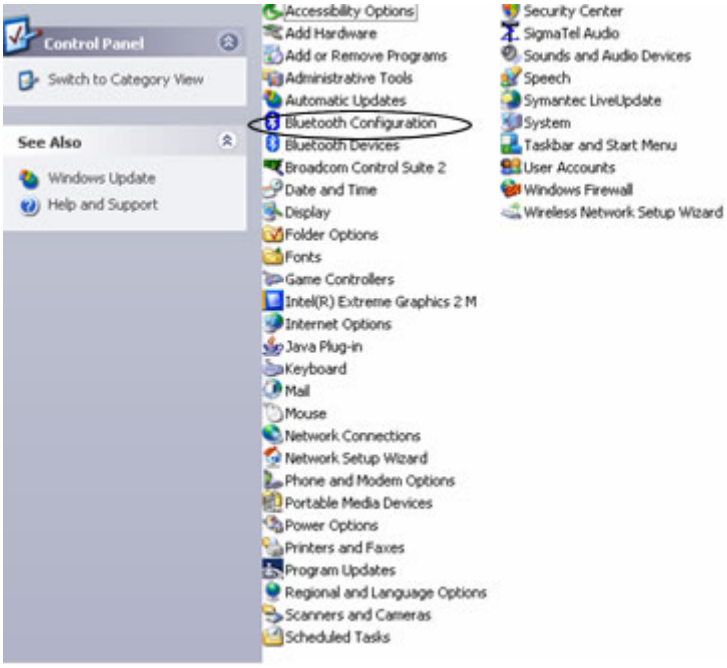
Configure the Bluetooth Settings

Once the Bluetooth driver has been installed it is important to properly configure the setting.

1. From the **Start** menu select **Control Panel**. Refer to Configuration Screen Capture 1 on page - 7 -
2. Once in Control Panel ensure that it is in Classic View (refer to Configuration Screen Capture 11). If not then select **Switch to classic view** from the left of the screen of the Category View (Refer to Configuration Screen Capture 10)**.**



Configuration Screen Capture 10 Control Panel - Category View

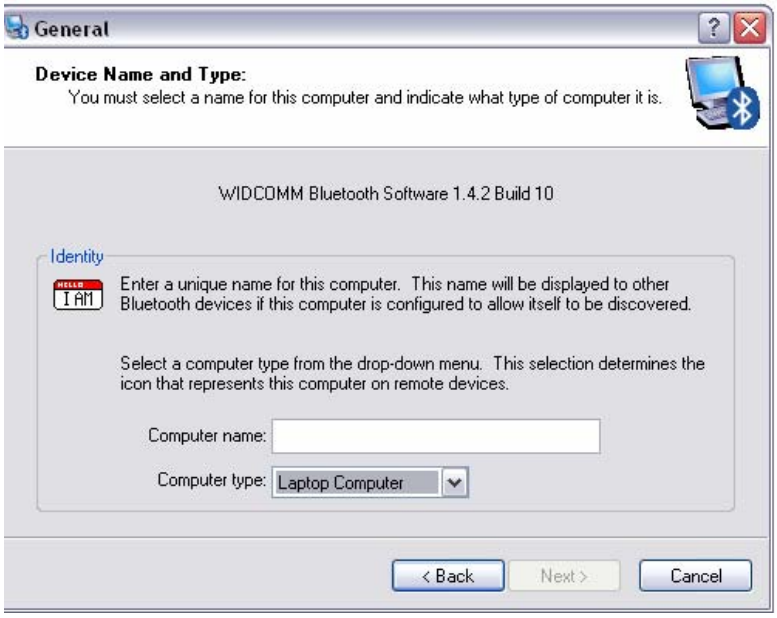


Configuration Screen Capture 11 Control Panel - Classic View

3. Select **Bluetooth Configuration** from the list in Control Panel (shown with a circle in the figure above). The Initial Bluetooth Configuration Wizard will open.

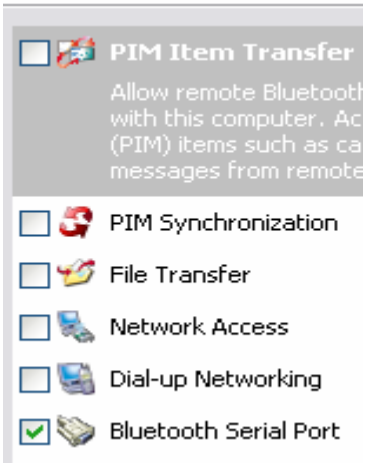
Configuration Screen Capture 12 Initial Bluetooth Configuration Wizard

4. Ensure all the boxes are checked.
5. Press **Next**. The Bluetooth general information will be displayed.



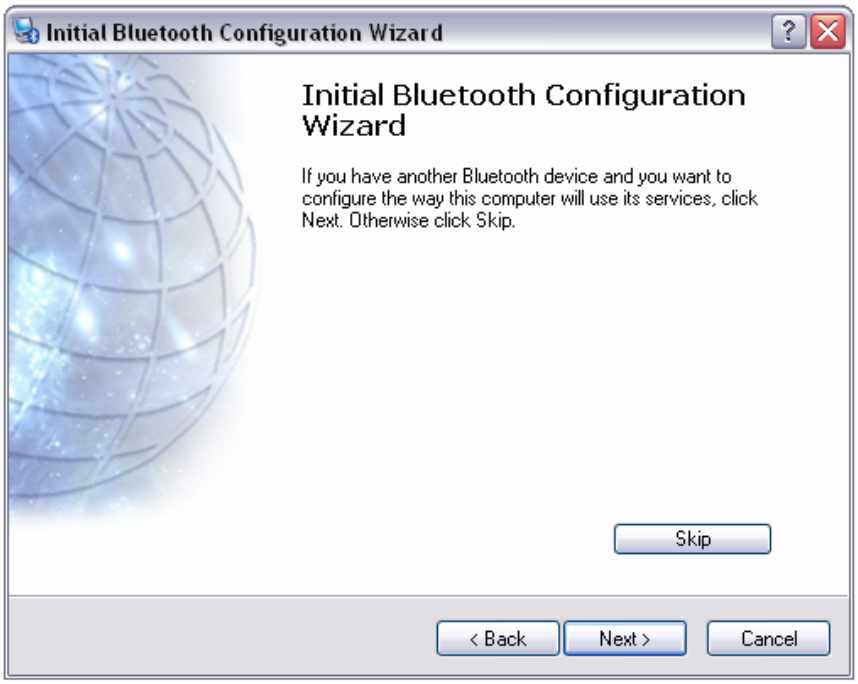
Configuration Screen Capture 13 Bluetooth general information

6. Ensure that the **Computer name** field contains the name of your computer and that **Computer type** is properly selected (Windows XP® based computer).
7. Once your computer name is entered the **Next** button will become selectable.
8. Press **Next**.
9. The next step is to configure the services available for the Bluetooth. Press **Next** on the service introduction page to display the services available.



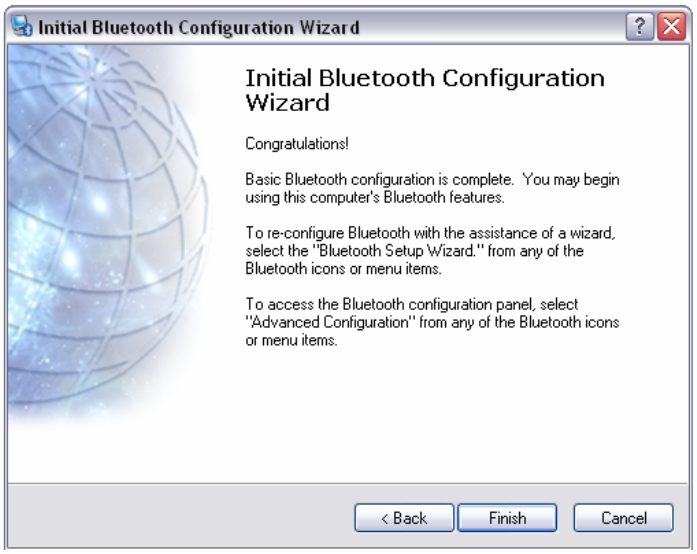
Configuration Screen Capture 14 Services available

10. The only service Integrity will require is the Bluetooth Serial Port. Ensure the **Bluetooth Serial Port** service is selected with a check and that all of the other services (including the ones not shown in the figure above) are not selected by clearing their respective checkboxes.
11. Press **Next.** Windows® will now continue setting the options for Bluetooth. This may take several minutes. Once the settings have been changed the following window will appear.



Configuration Screen Capture 15 Configure services

12. Press **Skip** to continue.

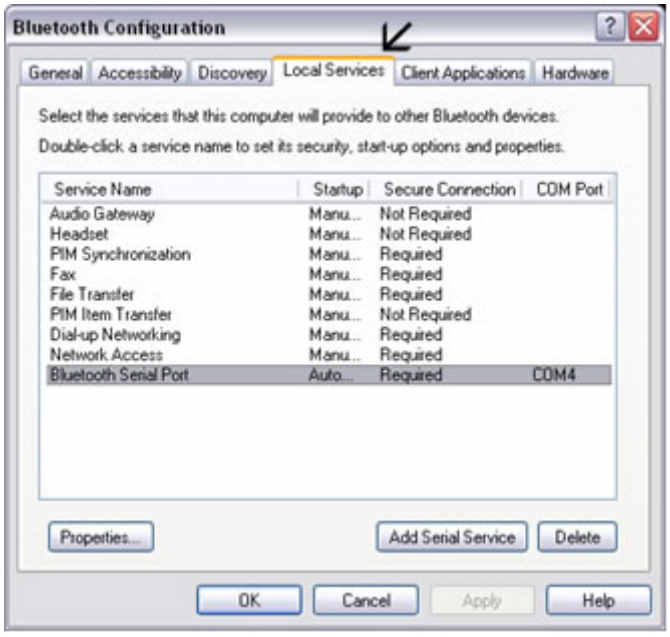


Configuration Screen Capture 16 Congratulations

13. When the screen reads “Congratulations” the configuration of the Bluetooth driver and setting is complete.
14. Press **Finish** to close the Bluetooth Configuration Wizard.

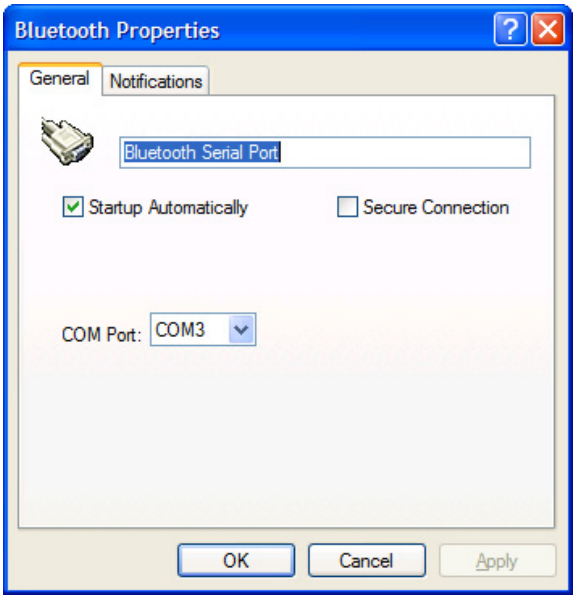
Bluetooth Security Settings

1. From the **Start** menu select **Control Panel**. Refer to Configuration Screen Capture 1 on page - 7 -
2. Select **Bluetooth Configuration** from the list in Control Panel (shown with a circle in the Configuration Screen Capture 11). This time the Bluetooth Configuration window will open.
3. Select the **Local Services** tab.



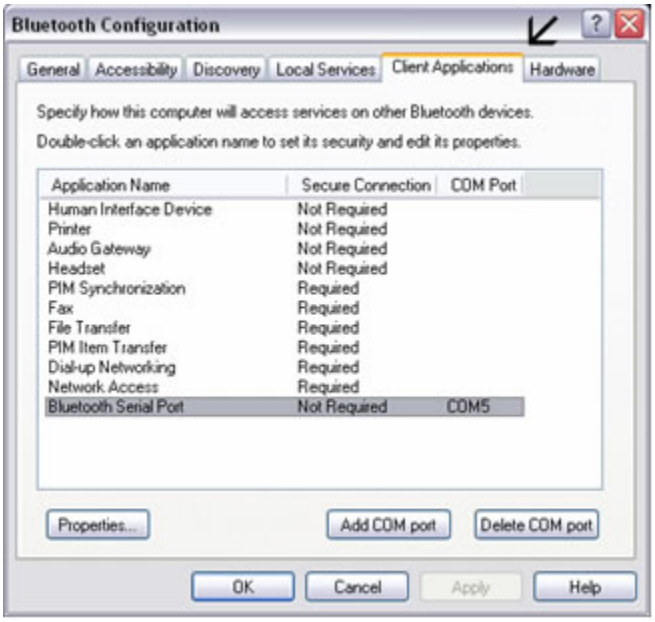
Configuration Screen Capture 17 Configuration - local services

4. Highlight **Bluetooth Serial Port** and press the **Properties** button on the lower left-hand side of the window. The Bluetooth Properties dialog window will open.



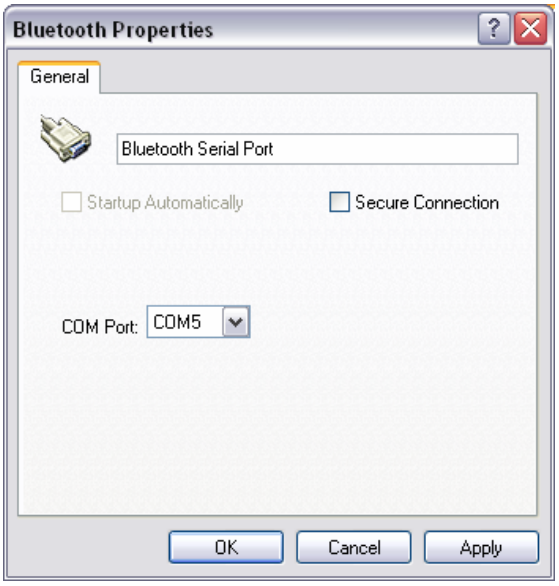
Configuration Screen Capture 18 Local Services properties dialog

5. Ensure the: **Startup Automatically** is checked and that the **Secure Connection** checkbox is not selected.
6. Press **Apply** and then press **OK**. This will close the properties dialog and return the Bluetooth Configuration window.



Configuration Screen Capture 19 Configuration - client services

7. Select the Client Applications tab.
8. Highlight **Bluetooth Serial Port** and press the **Properties.** The properties dialog window will open.



Configuration Screen Capture 20 Client services properties dialog

9. Ensure that **Secure Connection** checkbox is not selected.
10. Press **Apply** and then press **OK**. This will close the properties dialog and return the Bluetooth Configuration window. Refer to Configuration Screen Capture 19.
11. Press **OK** to close the Bluetooth Configuration window.

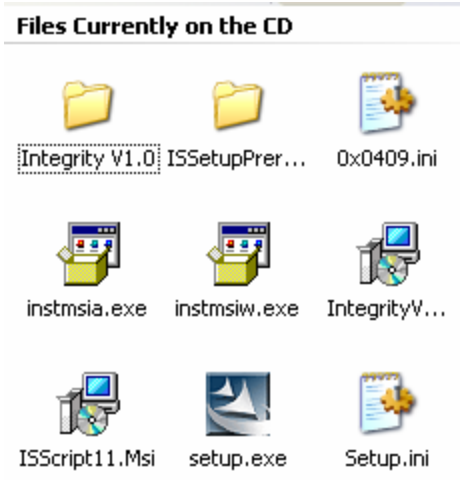
This completes the Bluetooth hardware and software configuration for Integrity.

Integrity

This section of the installation will deal with installing the Integrity system software on the computer.

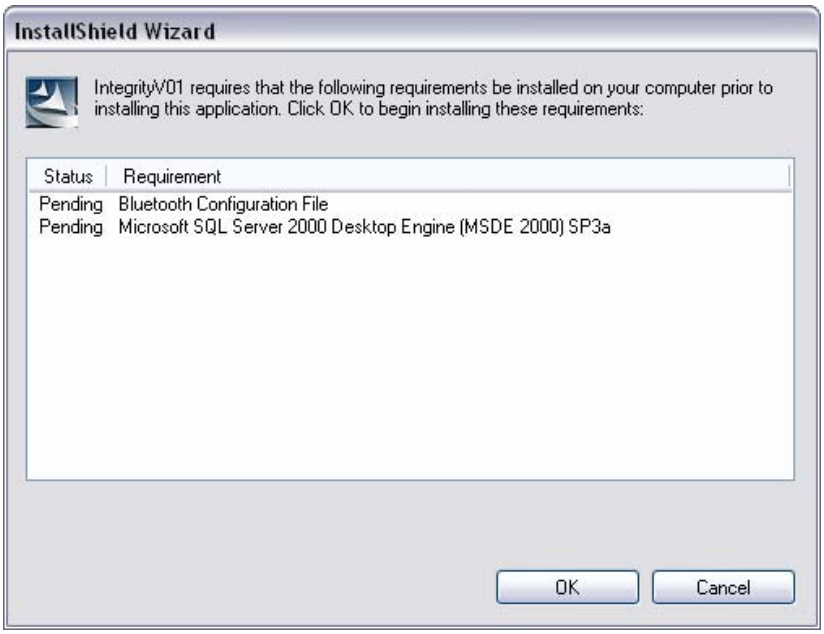
1. Remove the CD labeled **Integrity** from its sleeve and place it in the CD tray in the computer.
2. Wait a few seconds for the CD to auto load.

   If it does not automatically load select **Start** | **My Computer** from the bottom left corner of Windows®. Double-click on the CD drive and this will open the directory containing the following files.



Configuration Screen Capture 21 Files on Integrity CD

3. Double-click **Setup.exe** to open the InstallShield Wizard and begin the installation.
4. Before the InstallShield starts installing Integrity it first confirms that two required files are on the computer. Refer to Configuration Screen Capture 22.



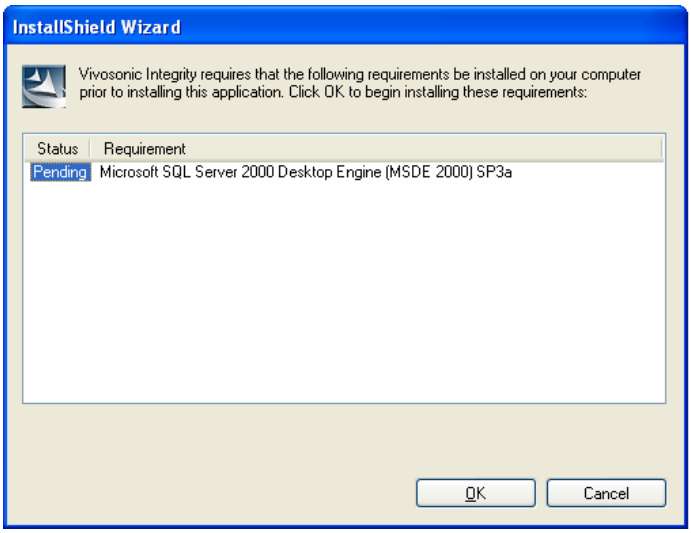
Configuration Screen Capture 22 Confirm required software

5. Press **OK.** The InstallShield will begin installing the two required files.

   The first install is the Bluetooth Configuration files which will add certain files to your system used by Integrity's main install.

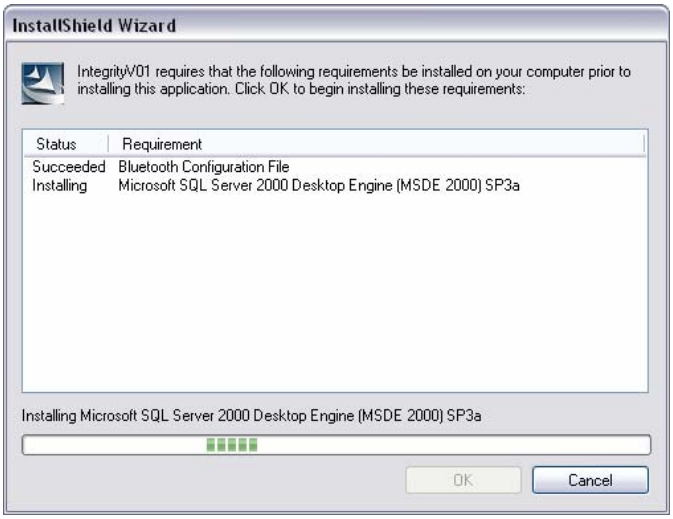
Configuration Screen Capture 23 Bluetooth configuration files

Once the files have been installed the InstallShield prompt for the **Microsoft SQL Server 2000 Desktop Engine (MSDE)** install to start.



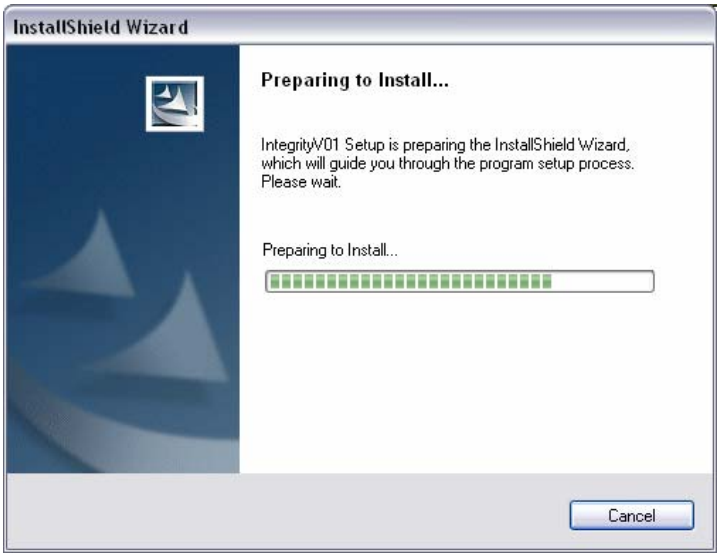
Configuration Screen Capture 24 MSDE install start

6. Press **OK**.



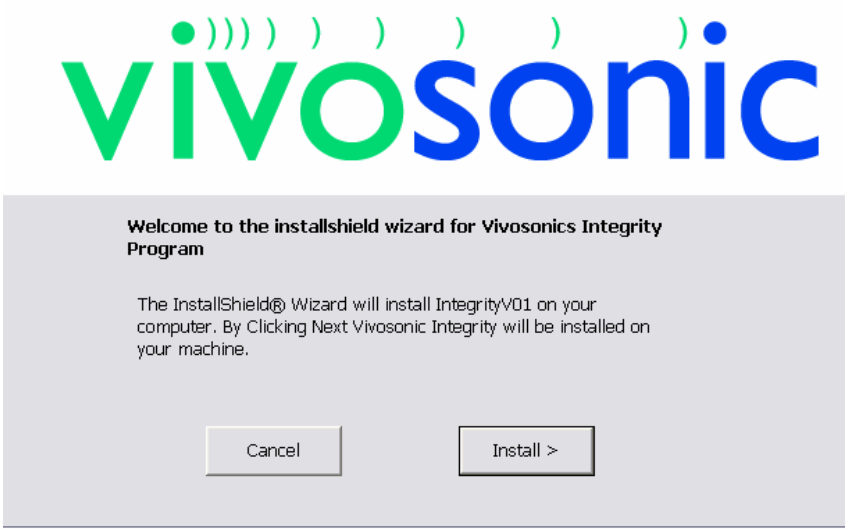
Configuration Screen Capture 25 MSDE initialization

7. Once MSDE has initialized, it will begin to install onto your machine.
8. When the installation is complete the computer will reboot.
9. Once the computer has finished rebooting, Integrity will initialize for its installation.



Configuration Screen Capture 26 Integrity initialization

10. When the initialization is complete the Vivosonic welcome screen will be displayed.

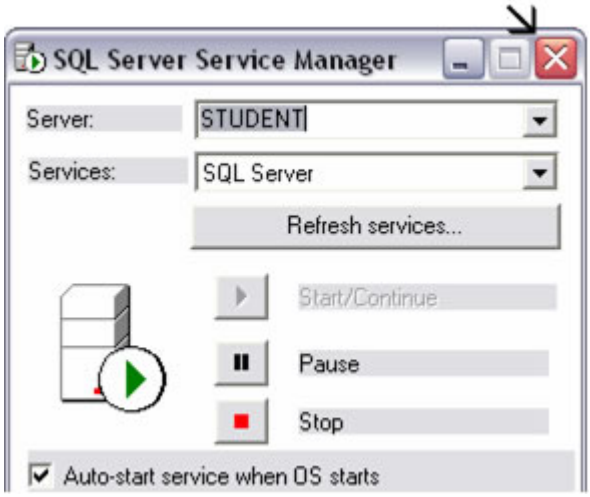


Configuration Screen Capture 27 Vivosonic welcome

11. Press **Install.**

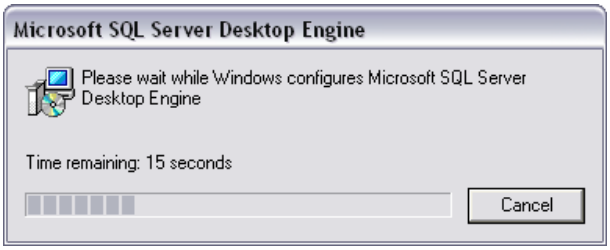
12. When the installation is almost complete the SQL Server Service Manager will launch.

    The SQL Server window can be closed using the  at the top-right corner of the window.



Configuration Screen Capture 28 Close SQL Server

13. When SQL Server Service Manager has been launched a second application (Jet to MSDE) will quickly install and close.



Configuration Screen Capture 29 MSDE installation

Once the Microsoft SQL Server Desktop Engine has finished running **Vivosonic InstallShield Wizard Complete** screen will be displayed. Integrity is now installed on the computer.

Configuration Screen Capture 30 Vivosonic InstallShield wizard complete

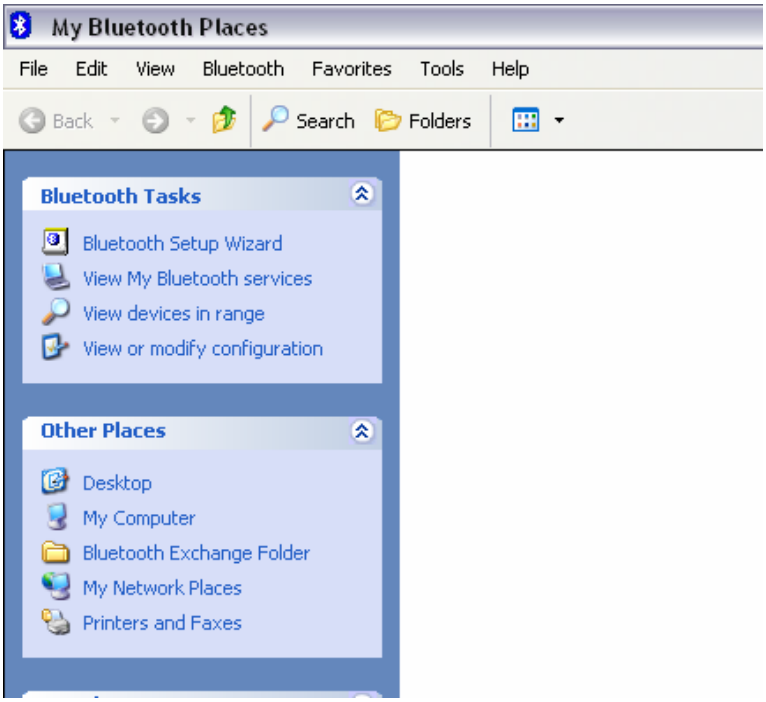
Establishing a Connection

The wireless connection between VivoLink and the Integrity system must be established.

1. Turn on the VivoLink.
2. Double-click the Bluetooth icon on your Windows® taskbar.

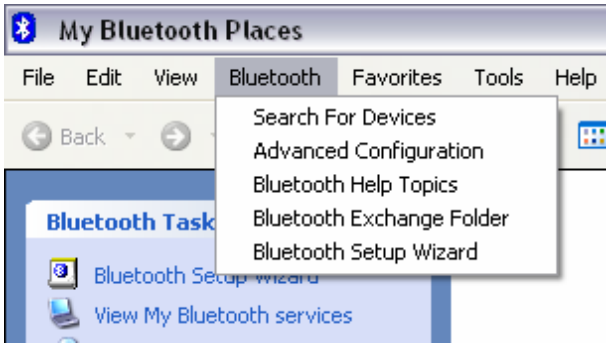
Configuration Screen Capture 31 Bluetooth icon

3. The Bluetooth Places window will open.



Configuration Screen Capture 32 Bluetooth places

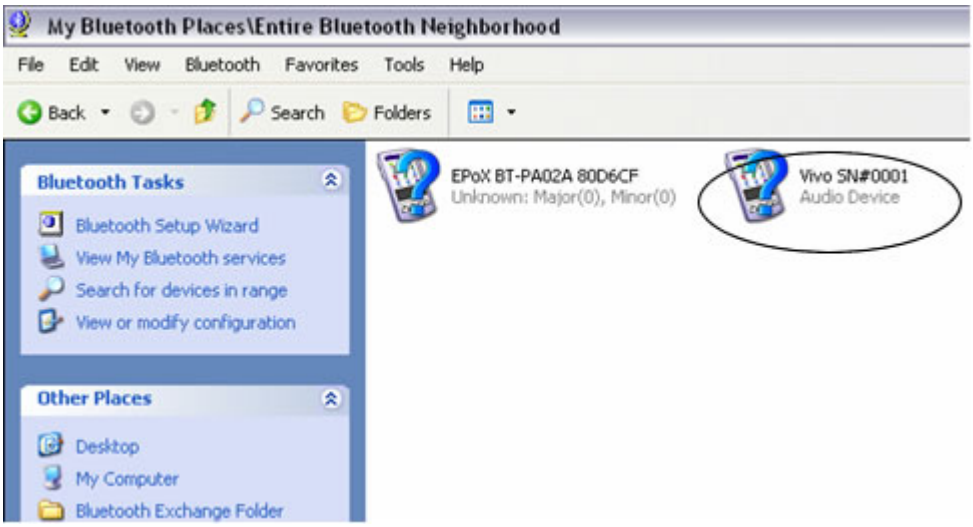
4. Select **Bluetooth** from the main menu. A drop-down list of options will be displayed.
5. Select **Search for Devices**.



Configuration Screen Capture 33 Bluetooth options

6. Windows® will begin to look for all Bluetooth Devices. Once Windows® has finished checking for all Bluetooth devices, the VivoLink device should appear.

   If it does not appear, ensure that the VivoLink is turned on and has sufficient battery power.

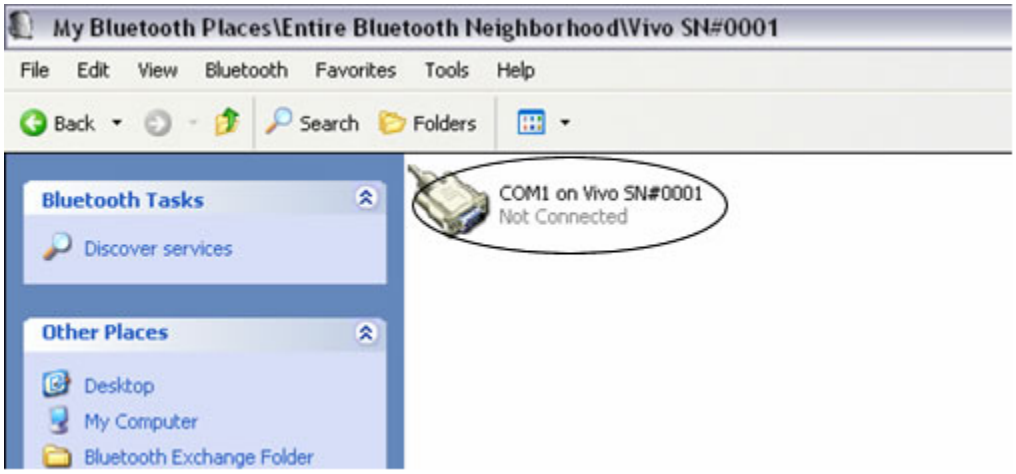


Configuration Screen Capture 34 VivoLink device found

7. VivoLink should appear with the following name:

   Vivo SN#XXXX where XXXX is the serial number.

8. Double-click the VivoLink icon. The VivoLink directory will open.



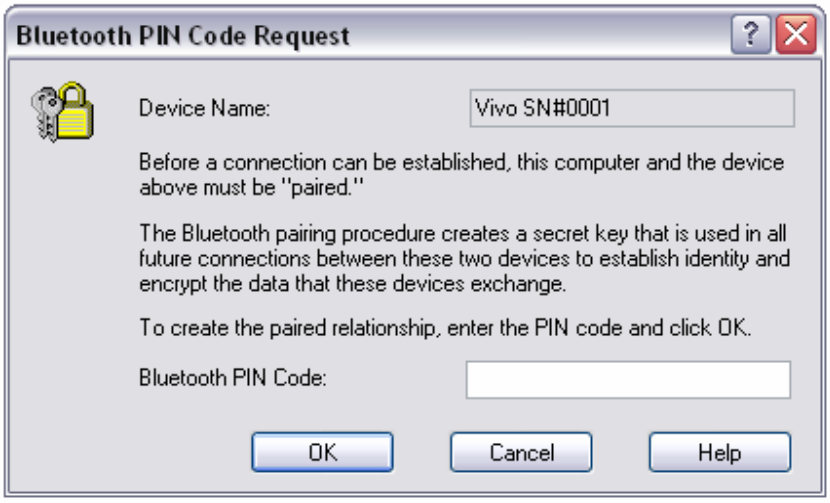
Configuration Screen Capture 35 VivoLink directory

9. Double-click the icon labeled **COM1 on Vivo SN#XXXX.**

   The system will attempt to connect to the VivoLink. A Connecting message will be displayed at the bottom left-hand corner of the screen. In the Windows® taskbar (bottom right corner) a bubble will appear on the Bluetooth icon.

Configuration Screen Capture 36 Connecting window and taskbar

10. Double-click the Bluetooth icon in the taskbar. The **Bluetooth PIN Code Request** window will open.

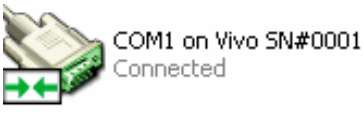


Configuration Screen Capture 37 PIN code request

11. Enter the Bluetooth PIN code - *5150*.
12. Press **OK**. The COM1 window will open.

Configuration Screen Capture 38 COM1

13. Press **OK**. The connecting window will show the message “Connected”.



Configuration Screen Capture 39 Connected

14. Close this window using the red X ( ). The Integrity system is ready to be used.

Calibration Files Installation Instructions

Requirements

The Integrity system installation instruction must be completed first. If the Integrity system cannot connect to the VivoLink because Integrity has not been installed, please go back and complete this process first. Refer to page - 2 -

CAUTION:

Possible loss of calibration files

This procedure will overwrite calibration files that already exist on the Integrity V500 system. Before beginning this installation it is recommended that the current file directory is backed up. Make a copy of the following file directory:

C:\Integrity V1.0\Calibration Data\”

Instructions

1. Make sure that the Integrity V500 software is not currently running.
2. Place the Calibration CD into the CD ROM.
3. Copy ALL files from the Calibration CD to the following directory on the Integrity V500 computer:

   C:\Integrity V1.0\Calibration Data\
4. Restart the computer. The new calibration files will not be used until the computer is restarted.