QUICK REFERENCE

integrity™ V500

Generation 2 (G2)

Please refer to the Integrity™ User's Manual (D-11049) for complete software operating instructions*.

***A PDF of the User's Manual is on the desktop of your Integrity™ computer.**

CAUTION

Vivosonic Integrity V500 system is a standalone test device. The notebook computer is an integral part of the system that is customized to suit the specific needs of the Integrity V500 software.

Do not install ANY other software other than what is supplied with your Integrity V500 system. Failing to abide by this caution may result in system instability and/or failure to perform.

ELECTRODES

Vivosonic recommends the Ambu® Neuroline Electrodes or the Vermed® NeuroPlus for use with your Vivosonic Integrity V500 system. They have been tested and verified to work with our system and provide the optimal results. To order additional electrodes please contact Vivosonic Customer Support at: 877.255.7685 (Canada & US) or +1-416.231.9997 (Intl).

WINDOWS INTEGRITY V500 SETTINGS

Your Integrity V500 system has been optimized to work with the Windows Operating System. Vivosonic has configured the system settings to work with the hardware and software.

Do not change any Windows settings.

For more information on default setting please contact Vivosonic Customer Support.

VIVOSONIC CUSTOMER SUPPORT

Access our FAQ information at http://www.vivosonic.com/en/support/faq.html.

Questions can be directed to support@vivosonic.com.

877.255.7685 (Canada & US) or +1-416.231.9997 (Intl)

Name: **Integrity™ V500** (also referred to as Integrity™, or Integrity V500, or Integrity)
REF: V500

You are licensed to use this software to operate the Integrity V500 device. You do not have permission to use this software in any manner not related to the intended operation of this device. You may not supply or copy this software for use by any third parties.

Integrity™ software is protected by US Pat. No. 6,778,955, 7,286,983, and 8,484,270. Other patents pending in the U.S. and other countries.

The Amplitrode® is protected by US Pat. No. 7,206,625 and 7,548,774. Other patents pending in the US and other countries.

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Segurança

02864-09-05756

To ensure the safe operation of the Vivosonic Integrity™ System, please read and comply with the following warning and caution statements.

The following symbols will be used throughout the manual

 WARNING

Messages with this heading indicate serious adverse reactions, potential safety hazards, and limitations in use imposed by the issue labeled with a warning. The warning will identify steps that should be taken if the incident occurs.

 CAUTION

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

 ATTENTION

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

 NOTE

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

 TIP

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

CLINICAL USE

The Integrity™ V500 system provides valuable information for estimating hearing loss, and diagnosing cochlear and retro-cochlear function. It is intended to be used as part of a comprehensive audiologic test battery for auditory diagnosis. It is suitable for testing patients of all ages including newborns. To use this device properly, the operator must understand the basics of this device's performance, and operating instructions.

The Integrity™ V500 system is composed of a VivoLink™ with a variety of peripherals and a computer. The Integrity™ V500 is unique in its field because of the patient interface. The VivoLink™ and peripherals are wirelessly connected to the computer using Bluetooth® technology. The Bluetooth connectivity allows for the patient and the VivoLink™ to be up to 30 ft. (10 m) away from the computer during testing.

BEFORE YOU BEGIN

- ☐ Inspect equipment, connectors, and cables for damage.
- ☐ Check that the cables to your VivoLink™ are properly connected.
- ☐ Always charge your VivoLink™ batteries before use.
- ☐ Clean surfaces of equipment with disinfectant.
- ☐ Eliminate, where possible, the electro-magnetic noise in the room.

Proper insertion of battery pack

INSTALL THE BATTERY PACK INTO THE VIVOLINK™

Battery packs have a life expectancy of 5-7 months. You may have to replace the battery packs after this period*.

1. Open the VivoLink™ battery compartment.
2. Remove and set aside any previously used batteries.
3. Place the battery pack in the battery compartment as shown below. Make sure to orient the pull tab towards the outermost edge of the compartment.

**Batteries are not covered by your system warranty.*

Caution

Do not hold the Vivolink™ over a baby's body to avoid the battery pack from falling and hurting the baby.

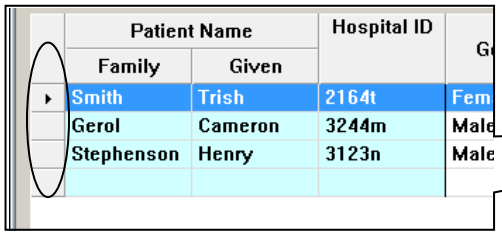
Integrity System Components Pending Purchased Configuration

1. V500 (VivoLink™)
2. A81 Amplitrode® (1-channel)
3. A82 Amplitrode® (2-channel)
4. A90 VivoAmp™ (1 and 2-channel)
5. VivoAmp™ Alligator clips
6. ER-3C-800 Insert Earphones
7. ER-2-800 Insert Earphones
8. ER3-60 Electrode Eartip Cables with snaps (for EcochG)
9. H-800 EP Headphones
10. H-801 EP Headphones
11. B71W Bone Conductor
12. P81-UG OAE Probe & Holder
13. P81-GP OAE Probe & Holder
14. Integrity™ Computer with Integrity™ Software
15. VivoCheck™
16. Battery pack and cradle

FIRST STEPS

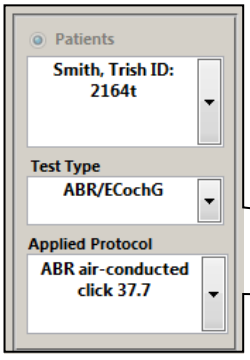
1. Power on your VivoLink™ and computer.
2. Double-click on the Integrity™ icon ( ) to activate the Launcher, which presents the user with the following options:
   - Perform Screening or Diagnostic testing.
   - Access learning and training materials from the Learning Library.
   - Configure the system.

   If you have not purchased the Screening or Diagnostic test type, the icon for that option in the Launch Bar will be disabled (grey).
3. If Screening is selected, refer to the ABR Screening section of this guide. If Diagnostic testing is selected, read the warnings and select **Agree** to continue to the **Patient Window**.
4. To create a new patient file you must click on an empty cell for either **Family** name, **Given** name, or **Hospital ID** and enter the information.
5. Identify patient to be tested from the list by clicking on the left most row header shown (the grey area shown below).



Click here to select patients

6. Click on the **Test** button to display the **Test Window**.
7. Select a **Test Type** from the side menu.
8. Wait until the initialization process is complete. This may require up to 20 to 30 seconds. The **wireless (Bluetooth) connection indicator** blinks on and off during this time.
9. When initialization is completed, check the following:
   - ☐ The **wireless (Bluetooth) connection indicator** on your VivoLink™ flashes on and off and the indicator on your computer screen is the color ***blue*** ( ).
   - ☐ The **battery indicator** on your computer, and replace the batteries when the indicator is low ( ).
10. Select an applied protocol.

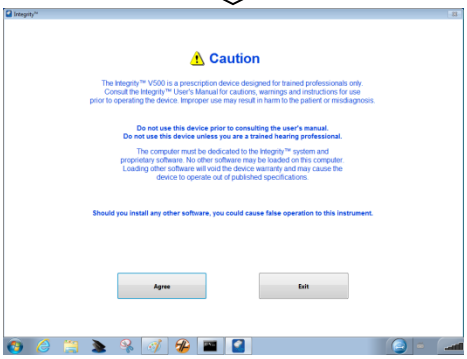


11. Prepare your patient according to the test type you have selected.
12. Initiate the test by selecting the **Start** button.

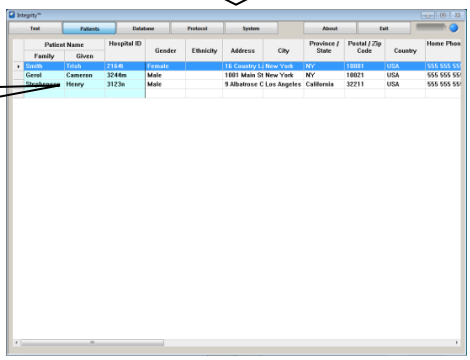
TIP

The Bluetooth connection safely operates within 30 ft. (10 m) of your computer.

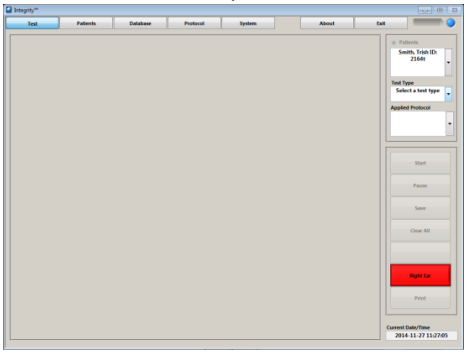
Launcher



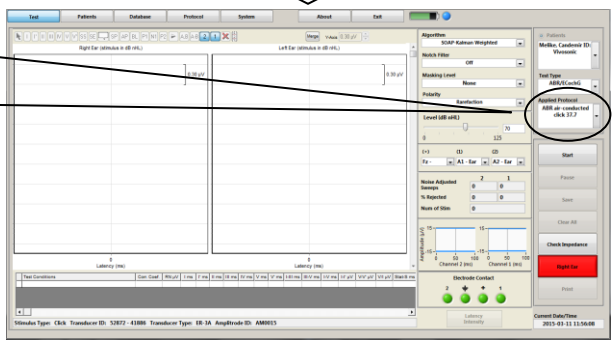
Caution Window



Patient Window



Test Window (no test selected)



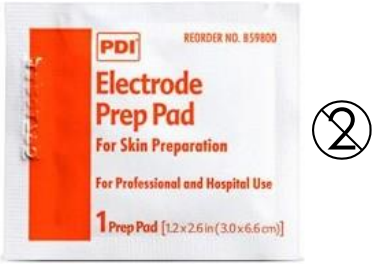
Connected (ABR test selected)

PATIENT PREPARATION FOR ABR, ABR SCREENING, ASSR, and 40 Hz ERP

One of the most important parts of obtaining quality data is the pre-test patient preparation. This includes proper skin preparation, electrode application, and ear tip insertion.

SKIN PREPARATION FOR ELECTRODE PLACEMENT

1. Check that the skin tissue is undamaged and healthy.
   - ☐ Do not proceed with testing if the skin is damaged or unhealthy.
2. Gently clean the electrode site with a PDI electrode Prep Pad to remove dirt and excessive oil from the skin. The Prep Pad is intended for **single use only** and should not be reused to prevent patient cross-contamination.
   - ☐ Apply friction (not force) when cleaning the skin.
   - ☐ Avoid prepping the skin too much since this can lead to adverse skin reactions.
   - ☐ Use a new wipe for each electrode site.
3. Wait a few seconds until the area is dry before applying an electrode.
4. Before use, check the expiry date on the package. The electrodes have a limited shelf life after which they start to lose their effectiveness.

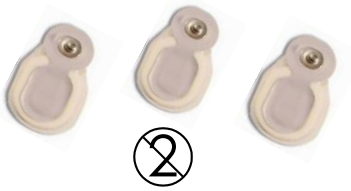


SKIN ELECTRODE AND AMPLITRODE®/VIVOAMP™ CLIP APPLICATION

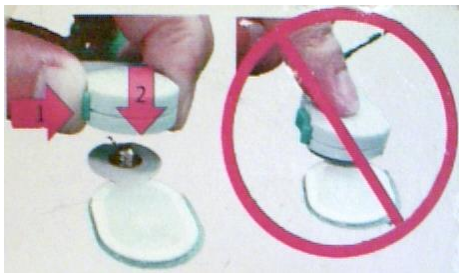
After proper skin preparation procedures, electrodes can be attached to the skin. The electrodes are intended for **single use only** and should not be reused to prevent patient cross-contamination and to ensure good electrode skin contact.

To apply an Ambu® Neuroline Electrode to the skin:

1. Remove the electrode from its plastic sheet.
   - ☐ Avoid touching the adhesive area of the electrode.
2. Place the electrode on the skin with the adhesive side down.
   - ☐ Apply gentle pressure on its outer edges. The entire periphery of the electrode should be in contact with the skin.
   - ☐ Avoid pressing on the center of the electrode as this causes the conductive gel to seep under the pad and will require removal and further skin preparation.
3. Attach the Amplitrode®/VivoAmp™ clip securely to the appropriate skin electrode site. The Amplitrode® clips use spring tension for grip. **Always** use the spring release button on the Amplitrode® clips when clipping to or unclipping from skin electrodes.



"Snap" Skin Electrodes



Do not push/pull the Amplitrode® clips on/off skin electrodes.

VivoTab™ Electrode and VivoAmp™ Alligator Clip Application

VivoTab™ Electrode

After proper skin preparation procedures, VivoTab™ electrodes can be attached to the skin. The VivoTab™ electrodes are intended for **single use only** and should not be reused to prevent patient cross-contamination and to ensure good electrode skin contact.

To apply a VivoTab™ Electrode to the skin:

1. Remove the electrode from its plastic sheet.
   - ☐ Avoid touching the adhesive area of the electrode.
2. Place the electrode on the skin with the adhesive side down.
   - ☐ Apply gentle pressure on its outer edges. The entire periphery of the electrode should be in contact with the skin.
3. Attach the VivoAmp™ alligator clip securely to the appropriate skin electrode site. The VivoAmp™ alligator clips use spring tension for grip. **Always** use the spring release button on the VivoAmp™ clips when clipping to or unclipping from skin electrodes (do not pull on the VivoTab electrodes).

Ear Tip Insertion

Insert Earphones Tips

Before starting a test using Insert Earphones ear tips, the ear canal must be clean, free of damage or disease, and clear of any obstructions to ensure good continuity between the surface of the ear tip and the tissue of the ear.

1. Inspect the patient's ear canal for obstructions.
2. If there is an excessive deposit of earwax, have an authorized healthcare professional remove the earwax, as defined by local healthcare regulations.
3. Check the patient's ear canal and select an ear tip that fits tightly, yet comfortably, in the patient's ear canal.
4. Attach the ear tips securely to the ends of the earphone tubes.
5. Roll the ear tip between two fingers and compress it.
6. Insert the ear tip slowly into the ear canal: place the red transducer into the right ear, and the blue transducer into the left ear.

AUDITORY BRAINSTEM RESPONSE (ABR)

CLINICAL USE

During ABR testing, your VivoLink™ presents various auditory stimuli to your patient through air or bone conduction such as a click or tone burst. It then records electrical responses using the Amplitrode® or VivoAmp™ to be evaluated by the Integrity™ software. See Chapter 5 of the User's Manual on the Computer desktop for details. For optimal results, patients should be sleeping or quiet and relaxed, during testing.

SETUP

1. You will need:
   - ☐ "Snap" electrodes
   - ☐ A81 Amplitrode®, A82 Amplitrode®, or A90 VivoAmp™
   - ☐ ER-3A-800/ER-3C-800 Insert Earphones, H-800/H-801 EP Headphones, or B71W Bone Conductor
   - ☐ PDI electrode Prep Pads
   - ☐ Cotton pads or gauze
2. Connect your Insert Earphones, EP Headphones, or Bone Conductor and your Amplitrode® or VivoAmp™ to your VivoLink™.
3. Attach the tubes on the Insert Earphones if they are not already attached.
4. Select the appropriate size of ear tips for your patient.
5. Attach the ear tips securely to the ends of the earphone tubes.

CHOOSE A TRANSDUCER

ER-3A-800/ER-3C-800 Insert Earphones

☐ Use when performing ABR testing using air conduction.

B71W Bone Conductor

☐ Use when performing ABR bone-conduction testing.
☐ To perform data collection, connect the B71W Bone Conductor to either the left or right mastoid or the forehead.
☐ Secure the headband supplied with the B71W Bone Conductor. Ensure that the entire circular surface of the Bone Conductor is in full contact with the skin. Only use the headband provided to maintain the proper sensitivity of the transducer.

H-800 Circumaural/H-801 Supra-aural EP Headphones

☐ Use when performing ABR testing using air conduction.
☐ Place the headphones over the ears and adjust the strap.

PREPARE THE PATIENT

Refer to the "Patient Preparation" section for:

☐ Ear preparation and ear tip insertion
☐ Skin preparation
☐ Electrode application

ELECTRODE SITES FOR ABR

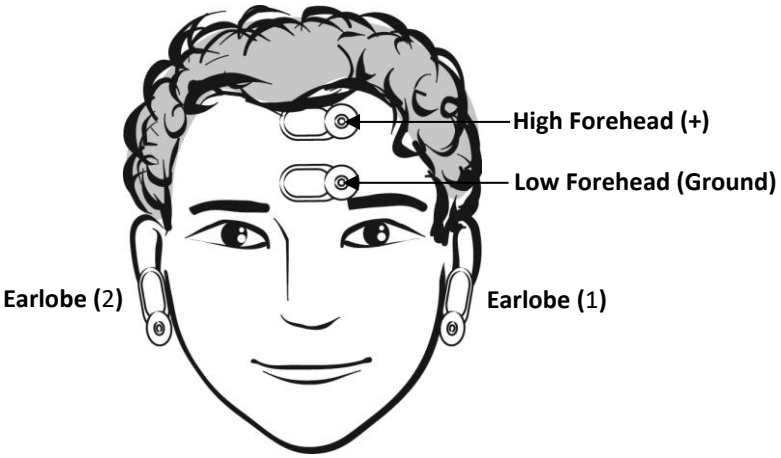
☐ **High forehead** – **black** clip (+)
☐ **Low forehead** – **green** clip (ground)

For 1-channel Operation (A81)

☐ **Earlobe right** or **left** – white clip (–)
(You can also use mastoid left or mastoid right)

For 2-channel Operation (A82/A90)

☐ **Earlobe left** – **blue** clip (1)
☐ **Earlobe right** – **red** clip (2)



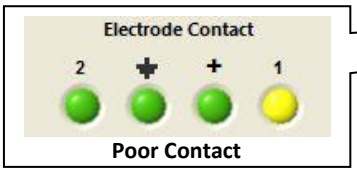
TIP

Place the high forehead electrodes as high as possible. When possible, use the earlobe sites rather than the mastoid sites. Also, move hair away to improve connectivity.

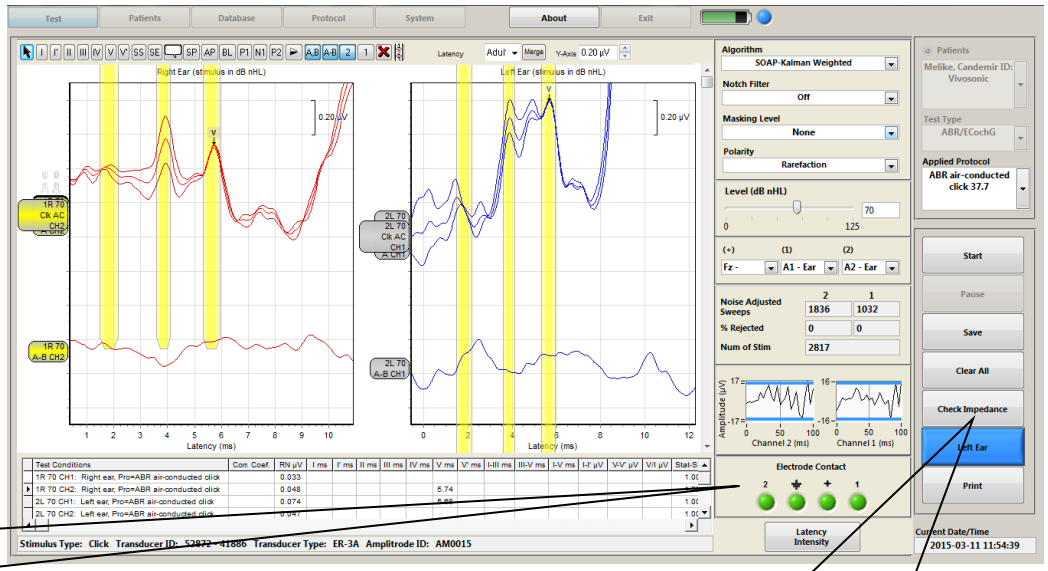
Electrode Contact

The green lights for the ground, (+), (1), and (2) terminals of the electrode contact window of the screen indicate electrode contact. If an electrode were to fall off during the testing, the contact indicators would flash yellow as displayed below. If you are using an A81 Amplitrode, the (2) terminal will be disabled.

If a problem is evident, remove the electrode indicated and reapply.



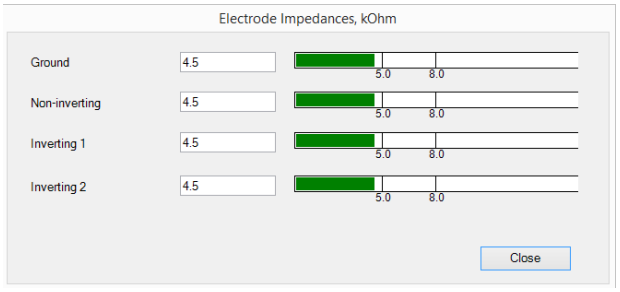
Poor Contact



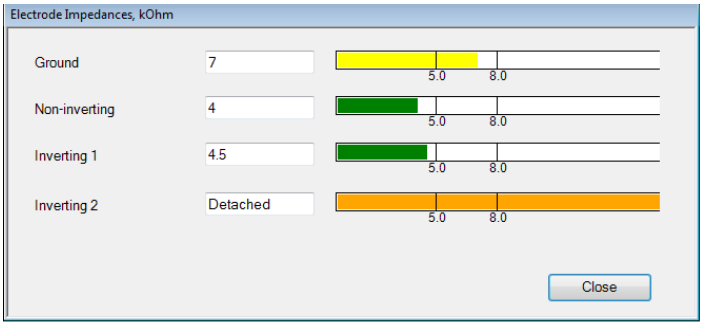
ABR Test Window

Check Impedance

The "Check Impedance" feature will measure and display the impedance of each patient electrode. A message will be displayed stating either that the level is acceptable or it will indicate which electrode needs to be reapplied. Before reapplying the electrode, repeat the skin preparation procedure. See User's Manual on Computer Desktop.



Acceptable level of impedance



Unacceptable impedance level

Run the Test

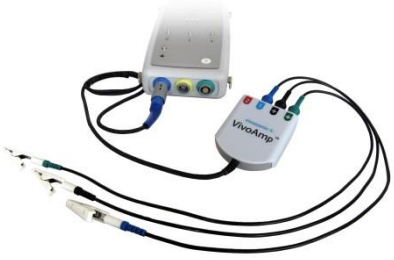
1. Select the appropriate protocol.
   Please refer to the "Integrity™ User's Manual PDF" on the computer desktop for more detailed instruction.
2. Select the appropriate ear, choosing **Right Ear** or **Left Ear**.
3. Indicate the location of the inverting and non-inverting electrode clips.
4. Press the **Start** button to initiate the test.
5. After the test is complete, choose "Save" to save the record or "Clear All" to delete the record.

CLINICAL USE

ABR Screening is intended to be used with infants from 34 weeks gestational age to 6 months. For optimal results, infants should be sleeping or quiet and relaxed, during screening. Soft clicks are delivered to the ears at sound levels of 30 or 35 dB nHL. Operators should be trained in the proper use and care of the system.

SETUP

1. You will need:
   - ☐ VivoTab™ Electrodes
   - ☐ A90 VivoAmp™ with 3 alligator clips (Green, Black, and Blue)
   - ☐ ER-3C-800 Insert Earphones
   - ☐ PDI electrode Prep Pads
   - ☐ Cotton pads or gauze
2. Connect your Insert Earphones and VivoAmp™ to your VivoLink™.
3. Attach the tubes on the Insert Earphones if they are not already attached.
4. Select the appropriate size of ear tips for your patient.
5. Attach the ear tips securely to the ends of the earphone tubes.



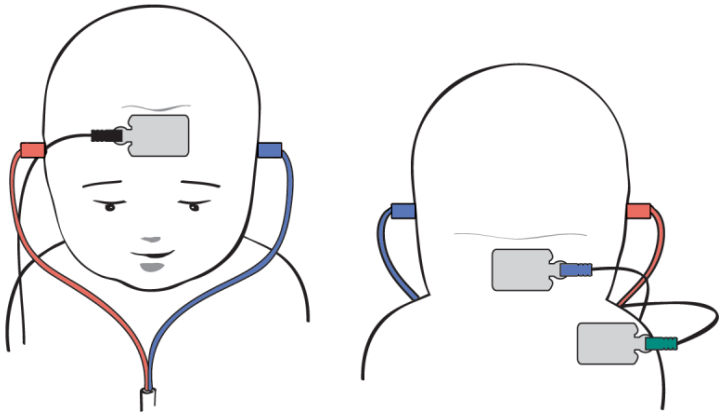
A90 VivoAmp™ with alligator clips

CHOOSE A TRANSDUCER

PREPARE THE PATIENT

Refer to the "Patient Preparation" section for:

- ☐ Electrode application
- ☐ Ear preparation and ear tip insertion
- ☐ Skin preparation



ELECTRODE SITES FOR ABR SCREENING

- ☐ **High forehead** – **black** clip (+)
- ☐ **Shoulder** – **green** clip (ground)
- ☐ **Nape of neck** – **blue** clip (–)

RUN A SCREENING TEST

1. Select the **Auto ABR Test** button on the **Main screen**.
2. Enter information into the **Patient Information screen** on your computer, or select from the **Patient ID** list.
3. Proceed to the **Test screen**.
4. Select the **Start Test** button.
5. Wait for Integrity ABR Screening to check the set-up of your system.
6. Wait for a Pass or Refer.
   - ☐ **Pass** indicates hearing of sound
   - ☐ **Refer** indicates potential hearing loss
   - ☐ **Incomplete** indicates the test was not completed
7. Print a label. If necessary, rescreen at a later time.
8. Gently remove ear tips, then electrodes. If removal is difficult, dissolve the adhesive hydrogel with water.
9. Power off your VivoLink™ until the next patient is ready to test.
10. Clean your equipment.

ELECTROCOCHLEOGRAPHY (EcochG)

Clinical Use

For EcochG testing VivoLink™ presents auditory stimuli to your patient's ear through air conduction using click stimuli. It then records electrical responses from the gold ear tip electrodes. For optimal results, patients should be sleeping or quiet and relaxed, during testing.

Setup

1. You will need:
   - ☐ One "Snap" electrode
   - ☐ A81 Amplitrode® or A90 VivoAmp™
   - ☐ ER-3A-800/ER-3C-800 Insert Earphones
   - ☐ ER3-26A or ER3-26B ear tips
   - ☐ ER3-60 Electrode Eartip Cables with snaps
   - ☐ PDI electrode Prep Pads
   - ☐ Conductive gel
   - ☐ Cotton pads or gauze

ER3-26A & ER3-26B ear tips

2. Connect your Insert Earphones and your Amplitrode® or VivoAmp™ to your VivoLink™.
3. Attach the EcochG Electrode Eartip Cables to the Insert Earphones if they are not already attached.
4. Select the appropriate size of gold electrode ear tips for your patient.
5. Attach the ear tips securely to the ends of the electrode ear tip cables.
6. Place insert through plastic tube and fasten to gold plated nipple.
7. Check that the gold-plated clips make good reliable contact with the gold foil covering the electrode ear tips.
8. Clip the inverting (-) Amplitrode® or (1/2) VivoAmp™ clip to the snap on the cable that corresponds to the ear to be tested to display the EcochG trace AP up.
9. Clip the non-inverting (+) Amplitrode® or (1/2) VivoAmp™ clip to the snap on the cable that corresponds to the other ear.
   - ☐ *Use the reverse set up to get the EcochG trace AP down.*

Gold foil covered ear inserts attached to cable

Apply Ground Electrode and Clip For 1-channel ECochG (A81/A90)

For EcochG testing, one snap electrode is applied to the **low forehead** of your patient. This electrode functions as the ground electrode. The green Amplitrode® or VivoAmp™ clip is attached to this electrode**.**

Setup

Gold Electrode Ear Tip Insertion

1. The Ear Canal must be completely unobstructed for a successful result.
2. Coat the ear tip thinly with conductive gel.
3. Hold the ear tip with two fingers and gently compress it.
   - ☐ Avoid damaging the gold foil.
4. Carefully insert the ear tip into the ear canal.
   - ☐ Red transducer into the right ear.
   - ☐ Blue transducer into the left ear.
   - ☐ The ear tip should fit snugly, yet comfortably.
5. Wait until the ear tip has completely expanded in the ear canal.
6. Check that the gold-plated clips continue to have good contact with the gold foil of the ear tips.

Run the Test

1. Select the appropriate protocol.
   Please refer to the "Integrity™ User's Manual PDF" on the computer desktop for more detailed instructions.
2. Press the **Start** button to initiate the test.
3. After the test is complete, choose "Save" to save the record or "Clear All" to delete the record

AUDITORY STEADY-STATE RESPONSE (ASSR)

CLINICAL USE

ASSR testing produces frequency-specific information, and provides an objective and accurate estimate of the behavioral pure-tone audiogram. It is well-suited for testing infants, young children, and other individuals unable to provide reliable behavioral responses. See Chapter 7 of the User's Manual on Computer Desktop for details. For optimal results, patients should be quiet and relaxed during testing. For 80 Hz ASSR, patients may be sleeping; but, for 40 Hz ASSR, patients should not be sleeping.

SETUP

1. You will need:
   - ☐ "Snap" electrodes
   - ☐ A81 Amplitrode®, A82 Amplitrode®, or A90 VivoAmp™
   - ☐ ER-3A-800/ER-3C-800 Insert Earphones or H-800/H-801 EP Headphones
   - ☐ PDI electrode Prep Pads
   - ☐ Cotton pads or gauze
2. Connect your Insert Earphones or EP Headphones and your Amplitrode® or VivoAmp™ to your VivoLink™.
3. Attach the tubes on the Insert Earphones if they are not already attached.
4. Select the appropriate size of ear tips for your patient.
5. Attach the ear tips securely to the ends of the earphone tubes.

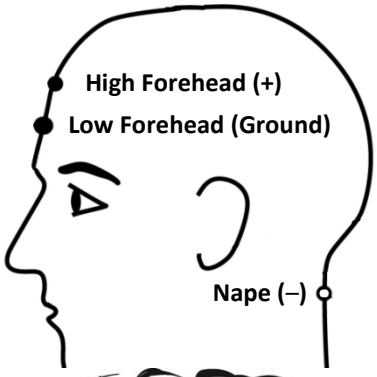
ENVIRONMENT FOR AN ASSR TEST

Adult Patient or an Older Child

- ☐ The patient may be placed in a chair or on a couch, whichever is more comfortable for the patient and the operator.
- ☐ Tests are conducted with the patient relaxed, lying down or in a chair with the neck supported. Patients are encouraged to sleep during the test.

Infant Patient

- ☐ Tests are conducted with the infant sleeping or lying down and very relaxed.
- ☐ Place the VivoLink™ next to the infant close enough for the Amplitrode® or VivoAmp™ and Insert Earphones or EP Headphones cables to reach.



1-channel Montage

PREPARE THE PATIENT

Refer to the "Patient Preparation" section for:

- ☐ Ear preparation and ear tip insertion
- ☐ Skin preparation
- ☐ Electrode application

ELECTRODE SITES FOR ASSR

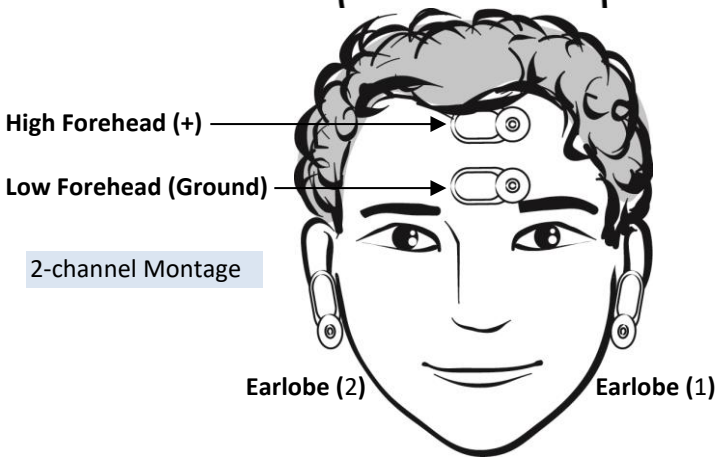
- ☐ **High forehead** – **black** clip (+)
- ☐ **Low forehead** – **green** clip (ground)

For 1-channel Operation (A81)

- ☐ **Nape** – white clip (–)

For 2-channel Operation (A82/A90)

- ☐ **Earlobe left** – **blue** clip (1)
- ☐ **Earlobe right** – **red** clip (2)



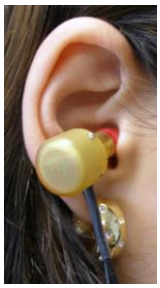
2-channel Montage

RUN THE TEST

1. Perform an impedance check (see previous section).
   - ☐ *Good impedance is crucial for ASSR testing.*
2. Select the appropriate protocol and montage.
   Please refer to the "Integrity™ User's Manual PDF" on the computer desktop for more detailed instructions.
3. Press the **Start** button to initiate the test.
4. After the test is complete, choose "Save" to save the record or "Clear All" to delete the record.

TRANSIENT EVOKED OTOACOUSTIC EMISSIONS (TEOAE)
DISTORTION PRODUCT OTOACOUSTIC EMISSIONS (DPOAE)

CLINICAL USE



For TEOAE testing, VivoLink™ generates a click signal via the OAE probe. This evokes an otoacoustic emission response (OAE) from the cochlea of the inner ear which is recorded by Integrity™ to assess cochlear hair cell function.

For DPOAE testing, VivoLink™ generates two pure tones (primaries) that are presented simultaneously to the cochlea via the OAE probe. This evokes an intermodulation distortion product that is generated by the human cochlea and recorded by Integrity™ to be used to assess cochlear hair cell function.

Currently there are two different OAE probes available for the Integrity™ V500. These probes have similar functionality and the choice is based on user preference. The **P81-GP OAE probe** is Vivosonic's original probe design. The **P81-UG OAE probe** is a new version of probe design. Refer to Chapter 8 and 9 of the User's Manual on the Computer Desktop for details.

OAE Probe P81-GP Cavity Check

OAE Probe P81-UG Cavity Check

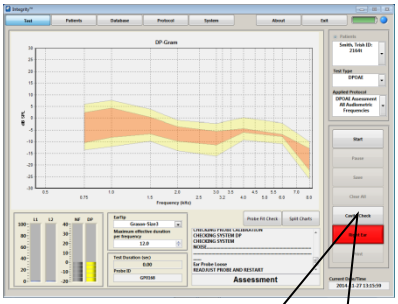
SETUP

1. You will need: Eartips. Ex. GP Eartips.
2. Connect either of the OAE probes to your VivoLink™.

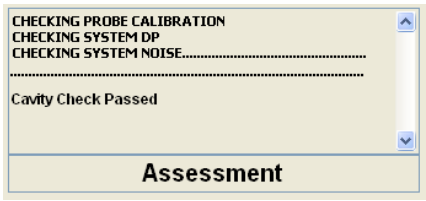
CAVITY CHECK

Before you begin testing, you can perform a cavity check to ensure that your OAE probe is correctly calibrated.

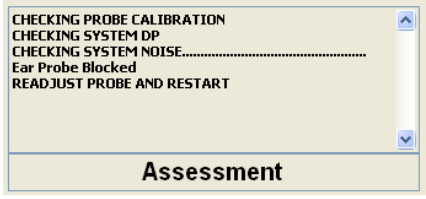
1. Place your OAE probe into the OAE probe holder.
2. Select the **Cavity Check** button on the **Test Window.**
3. Wait for the results to appear in the message area of the **Test Window**.
4. You can proceed with testing when the messages indicate "Cavity Check Passed".
   - ☐ *If cavity check fails, inspect the probe for debris and clean the probe if necessary. Reinsert the OAE probe into the holder and run the test again. Refer to User's Manual for more detail.*



Select "Cavity Check"



Cavity Check – Pass



Cavity Check - Fail

OAE PROBE INSERTION

Inspect your patient's ear canal to ensure there is no obstruction.

1. Do not proceed with testing if the ear canal is blocked.
2. Select the appropriate ear tip according to the size of the ear canal.
3. Attach the ear tip to the OAE probe.
4. Slowly and carefully insert the probe and ear tip into the ear canal.
   - ☐ Insert the ear tip slowly to avoid excessive air pressure in the ear canal.
   - ☐ The ear tip should fit snugly yet comfortably.

RUN THE TEST

1. Select the appropriate protocol.
   Please refer to the "Integrity™ User's Manual PDF" on the computer desktop for more detailed instructions.
2. Select the appropriate ear, choosing **Right Ear** or **Left Ear.**
3. Press the **Start** button to initiate the test.
4. After the test is complete, choose "Save" or "Clear All" to delete the record.

40 Hz EVENT-RELATED POTENTIAL (40 Hz ERP)

CLINICAL USE

The 40 Hz ERP is recorded from the scalp when a stimulus with a repetition rate of approximately 40 Hz is applied. The stimulus is a composite of pure tones modulated at 40 Hz. The 40 Hz ERP primarily represents mid-latency response peaks that are separated by approximately 25 ms, the 40 Hz period. The 40 Hz ERP can be used to estimate the threshold of hearing but it may be significantly affected by the patients' attention, state of consciousness and age. For optimal results, patients should be quiet and relaxed during testing, but not sleeping.

SETUP

1. You will need:
   - ☐ "Snap" electrodes
   - ☐ A81 Amplitrode®, A82 Amplitrode®, or A90 VivoAmp™
   - ☐ ER-3A-800/ER-3C-800 Insert Earphones or H-800/H-801 EP Headphones
   - ☐ PDI electrode Prep Pads
   - ☐ Cotton pads or gauze
2. Connect your Insert Earphones or EP Headphones and your Amplitrode® or VivoAmp™ to your VivoLink™.
3. Attach the tubes on the Insert Earphones if they are not already attached.
4. Select the appropriate size of ear tips for your patient.
5. Attach the ear tips securely to the ends of the earphone tubes.

ENVIRONMENT FOR A 40 HZ ERP TEST

Adult Patient or an Older Child

- ☐ The patient may be placed in a chair or on a couch, whichever is more comfortable for the patient and the operator.
- ☐ Tests are conducted with the patient relaxed, lying down or in a chair with the neck supported. Patients should remain awake.

Infant Patient

- ☐ 40 Hz ERP testing may not yield repeatable results in infants. If, nevertheless, you wish to conduct tests on infants, conduct the tests with the infant lying down and very relaxed but not while the infant is sleeping.
- ☐ Place the VivoLink™ next to the infant, close enough for the Amplitrode® or VivoAmp™ and Insert Earphones or EP Headphones cables to reach.

PREPARE THE PATIENT

Refer to the "Patient Preparation" section for:

- ☐ Ear preparation and ear tip insertion
- ☐ Skin preparation
- ☐ Electrode application

ELECTRODE SITES FOR 40 HZ ERP

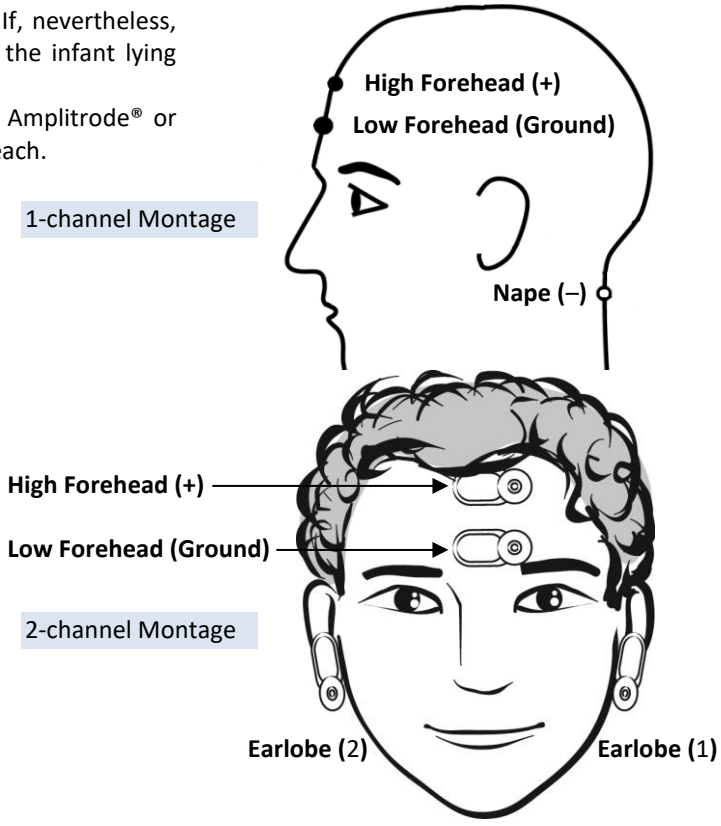
- ☐ **High forehead** – **black** clip (+)
- ☐ **Low forehead** – **green** clip (ground)

For 1-channel Operation (A81)

- ☐ **Nape** – white clip (–)

For 2-channel Operation (A82/A90)

- ☐ **Earlobe left** – **blue** clip (1)
- ☐ **Earlobe right** – **red** clip (2)

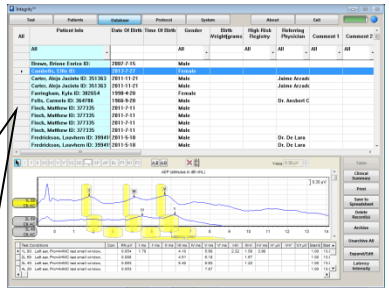


RUN THE TEST

1. Perform an impedance check (see previous section).
   - ☐ *Good impedance is crucial for 40 Hz ERP testing.*
2. Select the appropriate protocol.
   Please refer to the "Integrity™ User's Manual PDF" on the computer desktop for more detailed instructions.
3. Press the **Start** button to initiate the test.
4. After the test is complete, choose "Save" to save the record or "Clear All" to delete the record.

WORKING WITH YOUR DATABASE

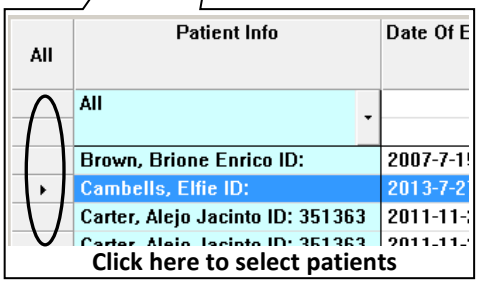
Your Integrity™ system uses a database to store patient and test data for future analysis. The **Database Window** retrieves this data and provides tools to review and analyze your patient's test results. From the database, you can also query, print, export, delete, and archive test records. Refer to Chapter 4 of the User's Manual on the Computer Desktop for details about the Database and other screens.



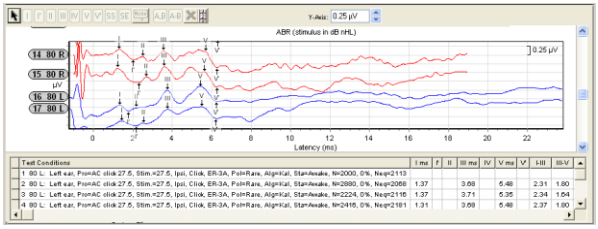
Database Window

VIEW YOUR DATABASE

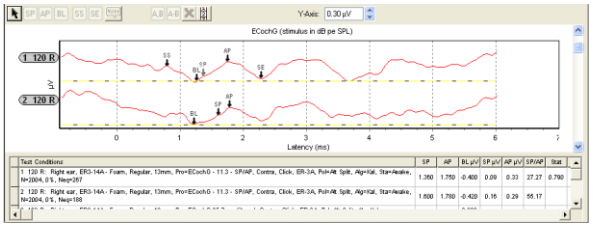
1. Select the **Database** tab.
2. Enter your password. Your password is case-sensitive. It is set in the **System Window**. The default password is blank.
3. Highlight a record in the database by clicking on the leftmost row header (grey area) to preview the test results. Each test type has a different database preview window seen in the figures below.



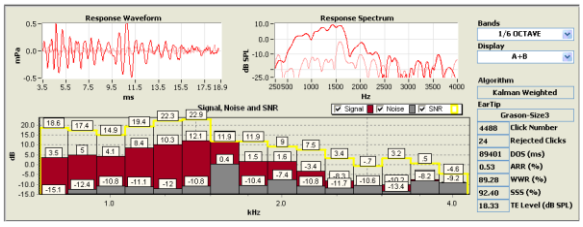
Click here to select patients



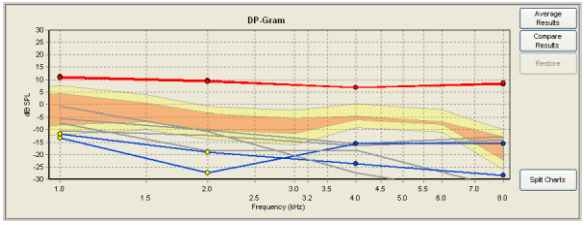
ABR Database Preview



ECochG Database Preview



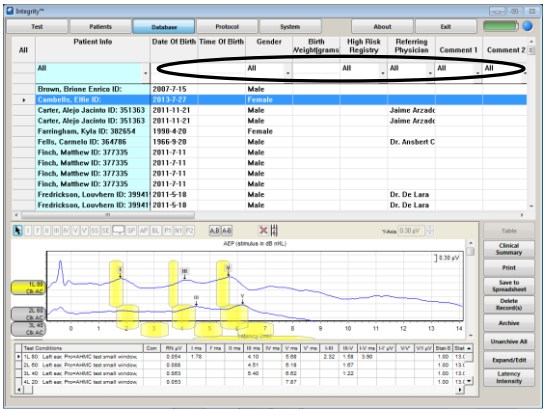
TEOAE Database Preview



DPOAE Database Preview

QUERY THE DATABASE

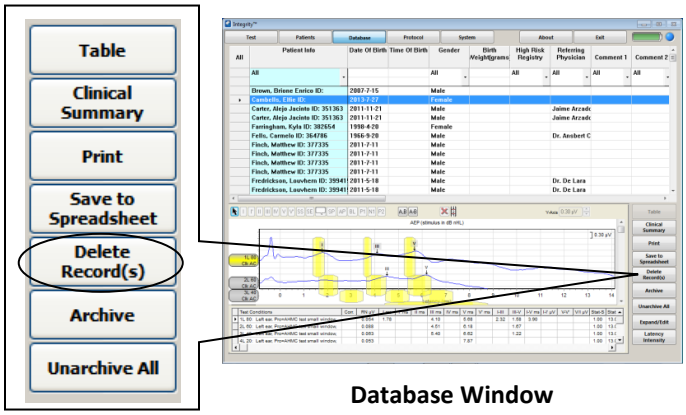
1. Select a column in the query area of the **Database Window**. *For example, "Patient Info" is a common column to query.*
2. Select a value from the dropdown list to view a subset of the records in your database. *For example, select the name of a patient to view only the records for that patient.*



Query Area of Database Window

DELETE RECORDS

1. You may first want to back up your database using the **Backup Database** function on the **System Window** (see below).
2. Identify your patient from the list by clicking on the left most row header shown (the grey area).
   - ☐ To select more than one patient, hold the **Ctrl** key and click on the desired row header.
   - ☐ To select a range of patients, hold the **Shift** key and click on the last patient in the group.
3. Select the **Delete Records(s)** button to permanently remove the selected records from your database.



Database Window

BACKUP AND RESTORE YOUR DATABASE

The backup feature makes a copy of your entire database. To prevent permanent loss of data due to hard drive failure, it is recommended that your database be backed up regularly. The system backs up automatically as well when the system is closed.

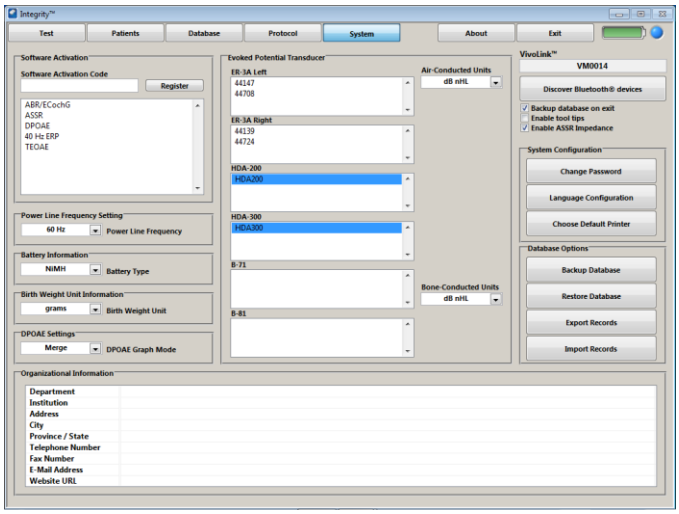
BACKUP YOUR DATABASE

1. Select the **System** button to display the **System Window.**
2. Select the **Backup Database** button.
3. Complete the **Save Backup File As** window with the location and name of your .BAK backup file.

RESTORE YOUR DATABASE FROM A PREVIOUS BACKUP

1. Select the **System** button to display the **System Window.**
2. Select the **Restore Database** button.
3. Specify the location and name of the desired .BAK backup file.

Note: Restoration of your database will overwrite your existing database.

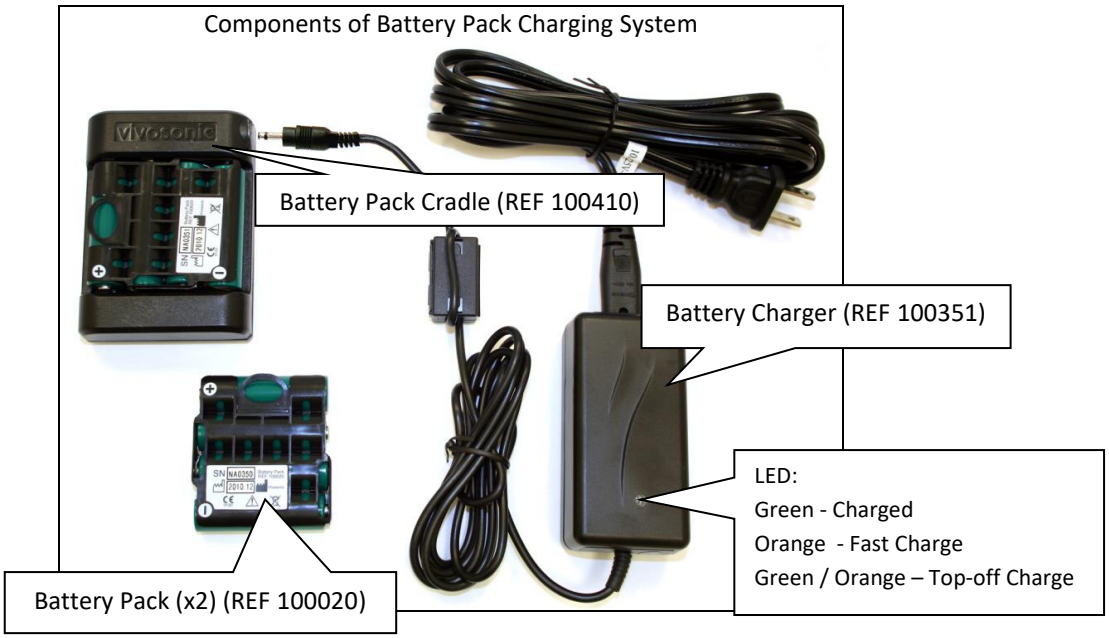


System Window

OTHER FUNCTIONS

For information regarding exporting data, printing forms, archiving records, or merging records, please refer to the ***"Integrity™ User's Manual PDF"*** on the computer desktop for more detailed instructions.

INSTRUCTIONS FOR USING THE BATTERY PACK CHARGING SYSTEM



CHARGING THE BATTERY PACK USING THE BATTERY PACK CRADLE

Prior to using the Battery Pack(s), please fully charge the battery using the Battery Charger and the Battery Pack Cradle as follows:

- Attach the silver connector on the Battery Charger to the silver port on the Battery Pack Cradle.
- Place the Battery Pack in the Battery Pack Cradle so that the + and – icons on the Battery Pack and the Battery Pack Cradle point in the same direction.
- Plug the power lead on the Battery Pack Charger to a wall socket.

WARNING

- ****** WHEN CHANGING BATTERY PACK TO RECHARGE, UNPLUG THE BATTERY CHARGER FROM THE WALL, PLACE THE NEW BATTERY PACK INTO THE CRADLE AND THEN PLUG THE CHARGER BACK INTO THE WALL. THE LED LIGHT WILL SHOW ORANGE or GREEN/ORANGE WHEN CHARGING.*** While the Battery Pack is charging, do not simultaneously touch the patient (or earth ground) AND either a) the Battery Pack terminals, or b) the Battery Pack Cradle terminals.
- Use only Vivosonic Battery Packs (REF 100020). Use of other batteries may damage the charging system and/or the batteries, and endanger the user.
- Use only the Battery Charger (REF 100351) and Battery Pack Cradle (REF 100410), supplied with your product, to charge the Vivosonic Battery Packs (REF 100020). Do not use the Battery Charger (REF 100351) and Battery Pack Cradle (REF 100410) to charge any other batteries.
- The Battery Packs are meant to be replaced after about five to seven months of regular use. Please ensure that local laws are obeyed when disposing these Battery Packs. Do not discard batteries into unsorted municipal waste.
- Ensure that the Battery Packs are inserted in the correct orientation when placed in the Battery Pack Cradle and when placed in the medical device.
- The Charging System should not come in contact with any liquids, or be exposed to extreme humidity. Discontinue use of the Charging System if any one of these conditions occurs and contact Vivosonic's technical support team for further assistance, 1-877-255-7685 (Canada & US), 1-416.231.9997 (Intl).
- Remove the Battery Pack from the VivoLink™ when the Integrity product is not in use.

Batteries are not covered by your system warranty.


WARNING: **CONTRAINDICATIONS**

This device is contraindicated for patients with these conditions:

Patients who display signs of excessive earwax
If, upon inspection, it appears that excessive earwax is present, DO NOT insert the ear tip in the ear canal. Inserting the ear tip could force earwax to press against the eardrum resulting in damage to the ear. It could also cause incorrect measurements and lead to an incorrect assessment.

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

Patients who have ear canal blockage due to foreign particles
If, upon inspection, it appears that any foreign particles are present in the ear canal or any foreign particles block access to the eardrum, DO NOT insert the ear tip into the patient's ear.

Patients who display signs of discharge in the ear
If, upon inspection, any discharge is observed, DO NOT insert the ear tip into the patient's ear.

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

Patients with involuntary sudden head motions
Do NOT place the insert earphones, gold electrode ear tip, or the OAE Probe, in the ear of patients who have involuntary sudden head motions. Such a motion could result in a self-inflicted injury of the inner ear.

Patients who cannot be still
Do NOT place the insert earphones, gold electrode ear tip, or the OAE Probe in the ear of a patient who is actively resisting insertion or displays involuntary movements. Such a motion could result in a self-inflicted injury of the inner ear.


WARNING

General Testing

- Testing is to be performed by a trained healthcare professional licensed by local authorities.
- This equipment is not suitable for use in the presence of an inflammable anesthetic mixture with air, oxygen or nitrous oxide.
- Changes or modifications not expressly approved by Vivosonic Inc. could void the user's authority to operate the equipment.
- To avoid accidental swallowing of inhalation of an ear tip, do not leave ear tip(s) within reach of a child. Patients should be attended during preparation and testing.
- Tympanic membrane and inner ear damage may occur resulting in possible infection and hearing loss. Cleaning of the ear canal and insertion of the electrode ear tip should be performed by a trained and licensed healthcare professional.
- DO NOT force the ear tips into the patient's ear canal. Excessive force could cause damage to the Tympanic membrane, rupturing the eardrum and possibly damaging the inner ear, which could result in infection and hearing loss.
- Simultaneous connection of a patient to high frequency (HF) surgical equipment and evoked response equipment (this equipment) may result in burns at the site of the skin electrodes, as well as possible damage to this equipment.
- If at least one applied part (such as an Amplitrode® electrode lead) is connected to the patient, do not let any other applied part contact other conductive parts, including earth ground.
- If at least one applied part (such as an Amplitrode® electrode lead) is connected to the patient, and the patient is also wearing the Bone Conductor, make sure the Bone Conductor plug contacts only its connector on the VivoLink, not any other conductive parts, including earth ground.

ABR Testing

- 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 may 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.
    - Strangulation may occur.
    - Do not put the B71W Bone Conductor cable around the patient's neck.
    - Do not leave a patient unattended while preparing and conducting the bone-conduction test.

EcochG Testing

- Removing the gold electrode 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.


WARNING

Hazard: The patient experiences discomfort when the ear tip is inserted into the ear canal.
Remedy: The operator must check whether the ear tip selection is incorrect and replace with a properly fitting ear tip.

Hazard: Audible levels are uncomfortable for the patient.
Remedy: The operator must immediately select a lower setting for the stimulus levels.

Hazard: In ABR testing skin at the site of the electrode application is damaged, for example, irritated (red), scratched, bruised, sore, cut, wounded, or bleeding.
Remedy: Do not conduct skin preparation and electrode application on areas of damaged skin. Choose another electrode location, wait until healing is complete, consult a dermatologist, or refer the patient to a healthcare professional trained to deal with skin damage.


WARNING

Electronic Disposal

- DO NOT dispose of equipment in unsorted, municipal garbage.
- Take discarded equipment to the appropriate electronic waste disposal facility.

Environmental Conditions for Transport and Storage

Integrity (with Battery Pack)

- Ambient temperature of -20 °C to +50 °C (for 30 days)
- Ambient temperature of -20 °C to +40 °C (for 90 days)
- Ambient temperature of -20 °C to +30 °C (for 1 year)
- Relative humidity of 10% to 100%
- Atmospheric pressure range of 500 hPa to 1060 hPa

Integrity (without Battery Pack)

- Ambient temperature of -40 °C to +70 °C
- Relative humidity of 10% to 100%
- Atmospheric pressure range of 500 hPa to 1060 hPa

Environmental Conditions for Use

- Ambient temperature of 10 °C to 39 °C
- Relative humidity of 30 % to 75 %
- Atmospheric pressure range of 700 hPa to 1060 hPa


CAUTION

Following the "Guidance for Industry, FDA Reviewers and Compliance on Off-The-Shelf Software Use in Medical Device", issued by FDA on September 9, 1999, the customers should not use any software other than that specified, as it will violate the safety, effectiveness and design controls of our Integrity V500 and that such use may result in an increased risk to users and patients.

Unauthorized alteration of software provided, including downloading non-validated or unauthorized off-the-shelf software may void or breach existing service agreements and warranties. For additional information, contact Vivosonic Inc.'s Customer Support.


CAUTION

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

- Substitution of any supplied components with different components may result in measurement error.
- No other software may be installed onto the computer on which the Integrity™ software is installed.
- Handle the system with care.
- The system requires calibration of the transducers – A81/A82 Amplitrodes, A90 VivoAmp, Insert Earphones, B71W Bone Conductor, OAE probes, and EP headphones – annually on each anniversary from the date of manufacture, and every time a transducer is dropped, subjected to mechanical shock, or immersed in a liquid substance. Otherwise, stimuli presented to the patient as specified may lead to incorrect test results and misdiagnoses.
- DO NOT force the ear tip into the ear canal.
- Always carry this device with you when traveling to avoid mishandling and damage of stored or checked luggage.
- DO NOT ship this device for service in packaging other than the packaging supplied with the system from the manufacturer, or comparable packaging.
- Signal inputs and outputs are intended for analysis only in connection to the specified equipment described in this manual.
- The product DOES NOT require sterilization. Alcohol can be used to clean the transducers.
- This equipment does not have protection against water penetration (IPX0).
- The system can only be repaired by Vivosonic Inc. or authorized dealers of Vivosonic Inc.

Immunity

The Integrity System 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.

Equipment and systems that are NOT life-supporting

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 calculated, 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 for all equipment and systems

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 Sec	N/A. Battery Operated Device	N/A
Power Frequency 50/60 Hz Magnetic Field IEC 61000-4-8	3A/m	3A/m	Power frequency and magnetic fields should be that of a typical commercial or hospital environment.

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

Emissions

The Integrity System 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.

All equipment and systems

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 domestic purpose.
Harmonics IEC 61000-3-2	Class N/A	
Flicker IEC 61000-3-3	N/A	

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.

This device complies with Part 15 of the FCC Rules and RSS 210 of Industry Canada. 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 of this device.


CAUTION: Exposure to Radio Frequency Radiation.

This device must not be co-located or operating in conjunction with any other antenna or transmitter.


WARNING

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

BASIC TROUBLESHOOTING

Fully charged battery pack loses charge after < 1 hour.	• Replace your battery pack with a new one
The system starts, but displays error messages.	• Printer drivers installed by the operator may not be compatible with the Integrity System. • Contact customer support if this problem persists.
Bluetooth® wireless connection fails.	• Move your Link within 30 ft. (10 m) of your computer. • Power off and on your VivoLink™ to reset it. Check for low battery ( ). • Refer to the Bluetooth Troubleshooting section of the Integrity V500 User's Manual installed on the Integrity Computer. • Contact customer support if this problem persists.
Noise remains high after troubleshooting (diagnostic)	• Retest at another time.
Noise remains high after troubleshooting (screening)	• Rescreen at another time.
Maximum test time is reached	• Calm patient, reduce noise and interference. Rescreen as appropriate.

Customer Support: 1-877-255-7685 (Canada & US), 1-416.231.9997 (Intl)

This product requires little maintenance. It is still recommended that a trained technician check the product every 12 months.
For the sanitizing/disinfecting wipes, please refer to the manufacturer's cautions and instructions for use, storage, and disposal.

AMPLITRODE®, VIVOAMP™, AND ELECTRODE CLIPS

The Amplitrode®, VivoAmp™, and the electrode clips should be wiped with disinfecting wipes after each use.

ABR TRANSDUCER AND ELECTRODES

ER-3A-800/ER-3C-800

The ear tips of the ER-3A-800/ER-3C-800 Insert Earphones, and the snap electrode pads are both disposable and should be properly disposed of after each use.

B71W Bone Conductor

The B71W and the headband should be disinfected with sanitizing wipes after each use.

CLEANING THE OAE PROBE

For sanitary reasons and to maintain acoustic performance, the Probe must be kept clean of any visible particles, such as earwax, dead skin, and any other debris.

1. During cleaning of the Probe, hold the Probe tip down to avoid pushing the debris deeper into the sound canals of the Probe.
2. Brush off any visible debris from the Probe surface with the mini-brush.
3. Remove remaining particles from the Probe ditches with the all-purpose pick.
4. Remove particles from the sound canals and vent with the wax removal tool. The vent (a tiny hole above the cable at the back of the Probe) is to ensure the release excessive pressure from the occluded ear canal.

DISINFECTING THE OAE PROBE

1. The Probe should be wiped with disinfecting wipes after each use. Hold the Probe tip down to avoid any ear wax or sanitizing liquid from entering the microphone sound canals.
2. Gently clean the Probe with a sanitizing wipe, and dispose of the wipe after use. Excessive force is not needed.
3. Insert the Probe tightly into the tapered hole of the Probe Holder.
4. Wipe off any excess liquid, and allow the Probe to dry for about an hour.
5. Perform a Probe Cavity Check. If a problem is detected, contact Customer Support. The problem may be due to residual ear wax on the microphone sound canals.

ECOCHG GOLD ELECTRODE EAR TIP

Properly disposed of the gold electrode (TIPtrode) ear tips after each use.

CARING FOR THE VIVOLINK

The VivoLink may be wiped with disinfecting wipes after each use.

CARING FOR THE COMPUTER

See the computer manufacturer's User Manual.

DISPOSAL OF ELECTRONIC EQUIPMENT (WEEE)

The equipment shall not be disposed of as unsorted municipal waste and shall be collected separately as electrical and electronic equipment, as applicable, as specified by Directive 2012/19/EU of The European Parliament and The Council of the European Union on Waste Electrical and Electronic Equipment (WEEE).

SYSTEM COMPONENTS

Item (Common to all Configurations)	REF/Model/Part #	Qty
System Carrying Case	VIV-BAG-1	1
Computer (with Integrity Software loaded)	M500-C	1
USB Computer Mouse	Mouse-Optical	1
Main Unit (VivoLink)	V500	1
Battery Pack	100020	2
Battery Pack Cradle	100410	1
Battery Charger	100351	1
Operator Quick Reference Guide	D-11049-2 (this document)	1
Super Sani Cloth wipes	H04082 (Manufacturer: PDI)	10
Pediatric Shoulder Strap (2 pcs)	V51-PS	1
Item (If ABR and/or ASSR and/or 40 Hz ERP Ordered)	**REF/Model/Part #**	**Qty**
Single-channel Amplitrode® (if Ordered)	A81	1
Dual-channel Amplitrode® (if Ordered)	A82	1
VivoAmp™	A90	1
Insert Earphone	ER-3C-800	1
Bone Conductor	B71W	1
Ear Phone Adapter Set	ER3-06 (ABR)	1
"Snap" Skin Electrodes	Ambu® Neuroline 720 (72000-S)	2 pkgs
Foam Eartips 13 mm	ER3-14A (Manufacturer: Etymōtic Research)	1 pkg
Foam Eartips 10 mm	ER3-14B (Manufacturer: Etymōtic Research)	1 pkg
Silicone Eartips 3.5 mm	ER3-14D (Manufacturer: Etymōtic Research)	1 pkg
Silicone Eartips 4.0 mm	ER3-14E (Manufacturer: Etymōtic Research)	1 pkg
Ear Tip Set (6 Each: KR006, KR036, MF-003)	ER3-V3-P (Manufacturer: Etymōtic Research)	1 pkg
PDI Electrode Prep Pads	B59800 (Manufacturer: PDI)	24
VivoCheck	FA014	1
EP Headphones (if Ordered)	H-800	1
Item (if ABR Screening is Ordered)	**REF/Model/Part #**	**Qty**
VivoAmp™	A90	1
VivoAmp™ Alligator clips	WA065	1
Insert Earphone	ER-3C-800	1
VivoTab™ Electrodes	100001	10 pkgs
Insert Earphones Eartips Kit	RA063	1
Ear Phone Adapter Set	ER3-06 (ABR)	1
Foam Eartips 10 mm	ER3-14B (Manufacturer: Etymōtic Research)	1 pkg
Silicone Eartips 3.5 mm	ER3-14D (Manufacturer: Etymōtic Research)	1 pkg
PDI Electrode Prep Pads	B59800 (Manufacturer: PDI)	24
Item (If OAE Ordered)	**REF/Model/Part #**	**Qty**
GP OAE Probe	P81-GP	1
GP OAE Probe Test Cavity	100399	2
GP OAE Probe Ear Tip Set	GRS-TS210 (Manufacturer: Grason & Associates)	1
GP OAE Probe Cleaning Kit	HAL2573	1
UG OAE Probe (if Ordered)	P81-UG	1
UG OAE Probe Test Cavity (if Ordered)	A80-14-1-0	1
UG OAE Probe Ear Tip Set (if Ordered)	BPT3-4 (Manufacturer: Otodynamics)	1
Item (If ECochG Ordered)	**REF/Model/Part #**	**Qty**
ECochG Electrode Cable	ER3-60	1
Spectra 360 Electrode Gel	12-02 (Manufacturer: Parker Laboratories)	1 tube
Gold Foiled Ear Tips 13 mm	ER3-26A (Manufacturer: Etymōtic Research)	1 pkg
Gold Foiled Ear Tips 10 mm	ER3-26B (Manufacturer: Etymōtic Research)	1 pkg

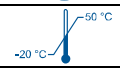
Additional/replacement parts may be ordered in any of the following ways:

- Contact Vivosonic Customer Support at: 877.255.7685 (Canada & US) or +1-416.231.9997 (International).
- Order online at http://www.vivosonic.com/order-accessories-howtobuy/
- Order through their local distributor.

Please contact Vivosonic, or your local distributor, for a detailed price list.

V500	
Input Power	Internally powered by Vivosonic rechargeable battery pack (4 AA NiMH Batteries @ 1.2 VDC each)
Applied Part Type	BF 
Medical Device Classification	II: as per Rule 10 of Schedule 1 of SOR/98-282 - The Canadian Medical Devices Regulations IIa: as per Rule 10 of Annex IX of Council Directive 93/42/EEC Concerning Medical Devices (MDD)
Software Safety Classification	Class A – No injury or damage to health is possible (IEC 62304:2006)
Wireless Communication Type	Bluetooth: 2.402 to 2.480 MHz, Hopping Contains transmitter module FCC ID: ED9LMX9838, IC: 1520A-LMX9838 Wireless Signal Strength: 0.66 mW EIRP Emission Designation: 2M00G1D Duty Cycle: 77.02% Wireless Communication Range: 30 feet (10 meters)
Dimensions of Main Unit	L 7.1" (18 cm) x W 3.6" (9.1 cm) x H 1.2" (3.2 cm)
Weight of Main Unit	0.8 lb. (363 g) with battery pack
UMDNS Code	10-228
GMDN Category	04 Electro Mechanical Medical Devices
100410 Battery Pack Cradle connected to 100351 Battery Charger	
Classification	Class II
Input Power	100 - 240 VAC 50 - 60 Hz max 0.35 A

SYMBOLS USED ON THE INSTRUMENT

Label Symbol	Description
	Read accompanying documentation
	Do not re-use. Single use only.
	Non-ionizing electromagnetic radiation (Device is capable of wireless communication)
	Electrode Contact Indicator
	Toggle ON/Standby
	Wireless communication established
+	Parking Snap for the black (+) Amplitrode®/VivoAmp™clip.
1	Parking Snap for either the blue (Channel 1) Amplitrode®/VivoAmp™ clip or the white (-) Amplitrode® clip.
2	Parking Snap for either the red (Channel 2) Amplitrode®/VivoAmp™ clip or the white (-) Amplitrode® clip.
	Parking Snap for the green (Ground) Amplitrode®/VivoAmp™ clip.
REF	Reference or Model Number
SN	Serial Number
	Date of Manufacture
	Manufacturer
EC REP	Authorized representative in the European Community
	Type BF equipment
	Caution. Fragile. Sensitive to mechanical shock. (Usually found on packaging.)
	Keep Dry
	Input voltage
V	Voltage
	Direct Current (DC) Voltage
	Cell (battery)
AA	Cell size
NiMH	Nickel Metal Hydride battery (NiMH)
CE 0120	CE Mark with notified body number
TÜV SÜD 81763	TÜV SÜD certification
FC	FCC mark
Segurança	The National Institute of Metrology, Standardization and Industrial Quality (Inmetro). UL do Brasil (UL of Brazil)
ANATEL 02864-09-05756	Agência Nacional de Telecomunicações Brazilian telecommunications regulator + our registration number
	The equipment shall not be disposed of as unsorted municipal waste and shall be collected separately as electrical and electronic equipment, as applicable, as specified by Directive 2012/19/EU of The European Parliament and The Council of the European Union on Waste Electrical and Electronic Equipment (WEEE).
Ver	The version of the list of components
IPX0	This equipment does not have protection against water penetration.
	This equipment is not suitable for use in the presence of an inflammable anesthetic mixture with air.
	This equipment is not suitable for use in the presence of an inflammable anesthetic mixture with oxygen or nitrous oxide.
	Does not contain latex.
	Environmental temperature range for transport and storage.