vivosonic

# VivoCheck™ User Instructions

## Product Description

The VivoCheck™ is a small and practical device that helps you optimize the performance of your Integrity™ V500 software and checks that important system components are in proper working order[1].


The VivoCheck™ is simple to set up and use. A typical check of your Integrity™ system can be completed in a few minutes. Simply attach your Amplitrode®/VivoAmp™ to the clips on the casing and your insert earphones to the plastic adapter and run the Integrity™ software. The VivoCheck™ checks that the correct acoustic output is sent from the VivoLink™ via the insert earphones. Within seconds, you will see the input signal of a given stimulus and observe the noise filtering at work.

## Clinical Use

The VivoCheck™ is designed to be used by clinicians, audiologists, ENT specialists, and/or technicians who use the Integrity™ System in their practices.

Important clinical uses of the VivoCheck™:

- Checks that the Integrity™ system components are in proper working order
- Identifies the best location for testing
- Helps establish baseline data for future reference

## Setting up your VivoCheck™

Your VivoCheck™ works with your Integrity™ system and is connected to your Amplitrode®/ VivoAmp™ and insert earphones.

To set up your VivoCheck™:

1. Turn on the VivoLink™.
2. Launch the Integrity™ software and load the ABR test type.
3. Connect the Amplitrode®/ VivoAmp™ to the corresponding non-inverting and ground clip on the VivoCheck™. If using a single channel Amplitrode®/ VivoAmp™, the inverting electrode can be

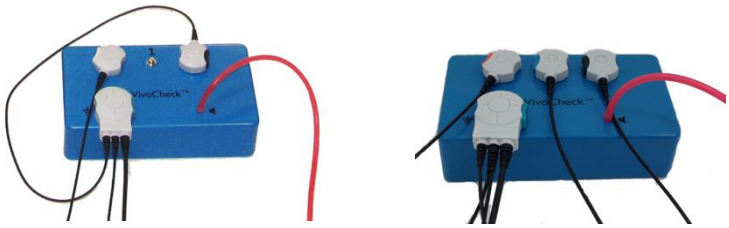
[1] Please note that the VivoCheck™ does not replace calibration of the Integrity™ system. Please calibrate annually or according to your institution's guidelines. The VivoCheck™ itself does not require calibration but should be confirmed after a full Integrity™ system calibration.

placed on either the '2' snap or the '1' snap. If using a dual channel Amplitrode®/VivoAmp™, both inverting electrodes are placed on the corresponding snaps.

4. Remove the white front tube adapter from the end of the right (red) ear tubing or left (blue) ear tubing of the insert earphones and store in a safe location.

**Remove the front tube adapter**

5. Fit the tubing over the small white plastic tip protruding from the casing of the VivoCheck™ box.



**Insert earphones and single channel and dual channel Amplitrodes®/VivoAmp™ attached to the VivoCheck™**

6. The Electrode Contact indicators on the Integrity™ test screen should be green when the Amplitrode®/VivoAmp™, is connected.


**Single and dual channel electrode contact indicators**

## Checking your Integrity™ System

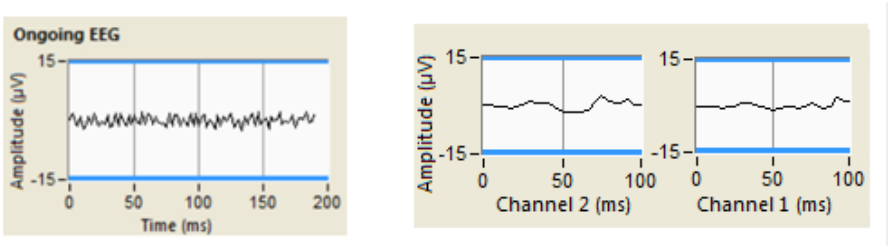
The VivoCheck™ provides these primary checks of your Integrity™ system:

- *Checks that the correct signal is sent from the VivoLink™ through the insert earphones.*
  This can be done via visual observation by looking at the shape of the waveform as well as determining the peak-to-peak amplitude of the waveform.
- *Tests the Amplitrode®/VivoAmp™.*
  Provides feedback via the Electrode Contact indicators on the Test screen.
- *Verifies the performance of the Integrity™ software and the SOAP-Kalman™ algorithm.*
  Displays changing waveform morphology as noise is filtered from the signal.

To check your Integrity™ system:

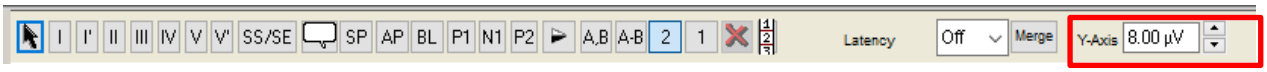
1. Set up your VivoCheck™.
2. Launch the Integrity™ software and load the ABR/ECochG test type.

3. Select the appropriate VivoCheck protocol. Refer to section 'Selecting the Correct VivoCheck™ Protocol' for more information on selecting the appropriate protocol.
4. Ensure the polarity is set to Rarefaction.
5. If the right tubing is attached to the VivoCheck™, click the Right Ear button in the Integrity™ test screen. If the left tubing is attached, click the Left Ear button.
6. Ensure that the EEG scale is as flat as possible and ideally within ±15 µV. It may be necessary to move both the VivoCheck™ and VivoLink™ away from the laptop or powerlines to achieve this scale.




**Acceptable EEG amplitudes reflecting low electromagnetic noise detected by the VivoCheck™ with single and dual channel systems**

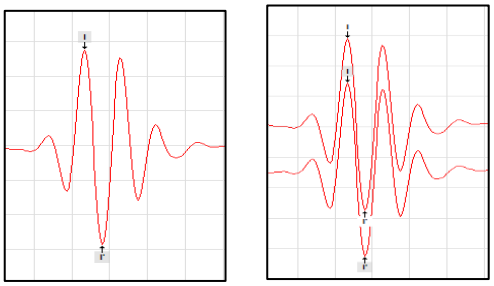
7. Press 'Start.' Once the tone-burst waveform appears, increase the y-axis scale so that the entire waveform is visible within the graph.




**Increase the y-axis scale to view the entire tone-burst waveform**

Watch the SOAP-Kalman™ algorithm clean the signal, filtering unwanted noise and artifacts. In an area with low electromagnetic noise, it should not require more than approximately 200 Noise-Adjusted Sweeps for a clean signal to appear.

8. Place the wave I marker on the highest peak and the wave I' marker on the lowest trough.



**Single and dual channel tone-burst waveforms with I and I' markers to indicate the peak to peak amplitude**

9. Verify that the I-I' value in the Integrity™ Test Conditions table is within the range specified on the back of your VivoCheck™ for the specific type of Amplitrode®/VivoAmp™, you're testing. This value indicates that the correct stimulus signal is being sent from the VivoLink™ to the insert earphones at a hearing level of 101 dB pe SPL.
10. Repeat steps 5 – 9 to test the insert earphone tubing for the other ear.

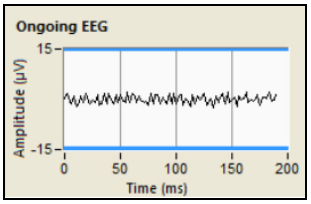
11. If amplitude values are not within the given range, confirm that the correct protocol, stimulus level and ear are being tested. Contact Vivosonic Customer Support if values remain out of range.

## Identifying the Best Location for Testing

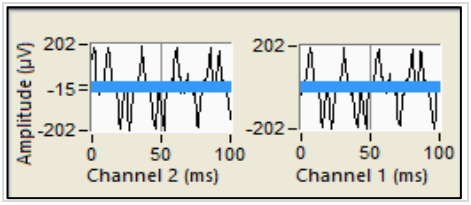
Your Integrity™ system's advanced technologies enable reliable testing in less than ideal conditions. However, it is recommended that testing be conducted in a location with minimal electromagnetic interference. This enables faster test times and cleaner signals. The VivoCheck™ can help you identify the best location for testing by providing an indication of the electromagnetic interference in the immediate environment.

To identify the best location for testing:

1. Place your Integrity™ system in the desired location for testing.
2. Connect your VivoCheck™ to your Integrity™ system.
3. Select the appropriate VivoCheck protocol and observe the EEG indicator and waveform. Refer to section 'Selecting the Correct VivoCheck™ Protocol' for more information on selecting the appropriate protocol.
   - EEG amplitudes that are within the ±15 µV range indicate ideal levels of electromagnetic noise in the environment.
   - If the EEG displays an area with electromagnetic noise that is outside of the ±15 µV range, attempt to find a position with an EEG range as low as possible. With higher levels of noise, it may take the SOAP™ algorithm longer to scrub out the noise.
4. Repeat steps 1-3 to find a location with minimal electromagnetic interference.




**Indicates low electromagnetic noise (best for testing)**



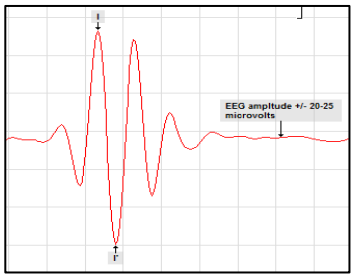

**Indicates high electromagnetic noise**

## Determining Baseline Data

It is of value to collect a baseline waveform from the VivoCheck™ in your testing location. This baseline waveform will enable you to compare noise in the environment if you suspect conditions have changed and are affecting your measurements.

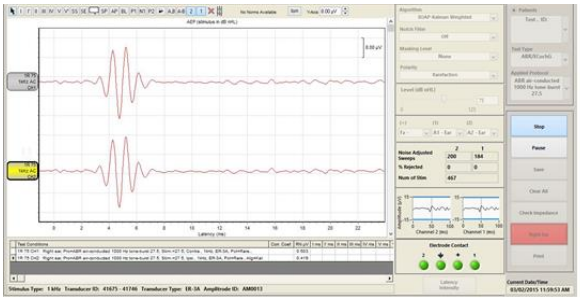
1. Set up your VivoCheck™ and Integrity™ system.
2. Select the appropriate VivoCheck protocol and start a test. Refer to section 'Selecting the Correct VivoCheck™ Protocol' for more information on selecting the appropriate protocol.
3. Take note of your system set up as well as the general EEG amplitude showing the level of electromagnetic noise in the environment. A good way to do this would be to take a screenshot of your EEG and save it on the computer.

4. Attach a comment to your waveform indicating the amplitude and scale of the EEG present while testing. Save the tone-burst waveform.



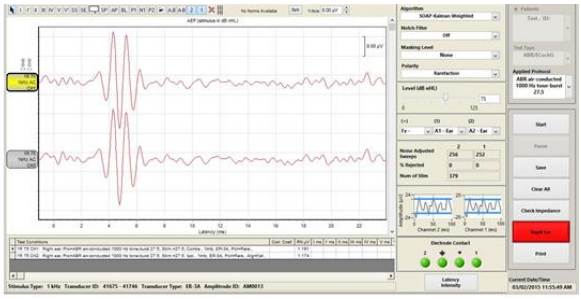

5. The saved EEG data and tone-burst waveform can be used for future reference to determine whether ambient electrical noise in this location has changed.

In noisy environments, it will take longer for the Integrity™ software to filter the noise.



**Baseline data**

**-collected in a low noise environment, shows a clean waveform obtained within 200 Neq and an EEG with amplitudes of 2-3 µV.**



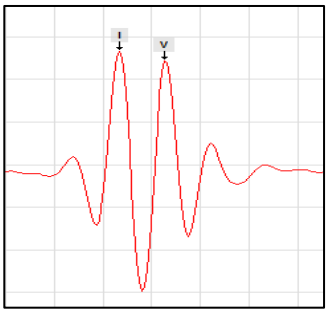
**Data collected at a later date**

**-significantly noisier than the baseline data, therefore it will take longer to achieve a clean tone-burst waveform.**

## Calculating the Tone-Burst Frequency

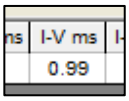
An additional benefit to using the VivoCheck™ is the ability to confirm the frequency of the tone-burst signal.

1. Set up your VivoCheck™ and Integrity™ system.
2. Select the appropriate VivoCheck protocol and start a test. Refer to section 'Selecting the Correct VivoCheck™ Protocol' for more information on selecting the appropriate protocol.
3. Place a wave I marker on the first peak of the waveform and a wave V marker on the second peak of the waveform.




**Tone-burst waveform with wave I and wave V markers placed**

4. In the Test Conditions table, there is a column indicating the latency for I-V. This value represents the frequency of the tone-burst waveform within ± 0.08 ms.




**I-V indicates a period of 0.99 ms which corresponds to a frequency of approximately 1000 Hz**

## Impedance Values

The VivoCheck™ has a built-in impedance mismatch of 6 kΩ. However, in areas of high noise, this impedance value may increase or decrease. The system should be placed in a less noisy location to achieve best results.

| Integrity™ versions 5.2.2 to 8.0 | Integrity™ versions 8.1 and higher |
|---|---|
| Impedance mismatch = 6 ± 1 kΩ in an ideal environment | Ground: 5 ± 3 kΩ<br>Non-Inverting: 1 ± 1 kΩ<br>Inverting 1: 6 ± 1 kΩ<br>Inverting 2: 6 ± 1 kΩ<br><br>in an ideal environment |

Inverting 2 is for a dual channel Amplitrode®/ VivoAmp™.

## Teaching with the VivoCheck™

The VivoCheck™ can be used to teach about stimulus frequency, polarity, window envelopes and number of cycles. Viewing different stimulus frequencies is accessible with the 500, 1000 or 2000 Hz tone burst (note: 4000 Hz cannot be viewed because of filtering). An instructor may also use the VivoCheck™ to demonstrate Rarefaction, Condensation, and Alternating polarity, as well as Blackman vs. Linear gating and a 4-cycle vs. 5-cycle stimulus. Importantly, the values and calculations described above are only valid for 1000 Hz in the Protocols specified above; these values or calculations in this document cannot be applied to other stimuli or polarity types, and larger variations in stimulus-frequency calculations may be observed.

## Selecting the Correct VivoCheck™ Protocol

Select the appropriate VivoCheck protocol based on your Integrity™ system and software version.

| System | Software Version | RETSPL Displayed on System Screen | Protocol to Use |
|---|---|---|---|
| **Integrity G2** | 8.3.3 and higher | 8.3.3 RETSPL | VivoCheck (8.3.3 RETSPL) protocol |
| **Integrity G2** | 8.3.1 and lower | 8.3.1 RETSPL | VivoCheck protocol |
| **Integrity G1** | 8.3.1 and lower | n/a | ABR air-conducted 1000 Hz tone-burst 27.5 at 101 dB pe SPL |