

HEARLab System

Maintenance Manual

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Chapter 1: Specifications

HEARLab™ ACA device consists of a hardware platform (HEARLab) and a software platform that work together to perform acoustically evoked cortical response measurements.

1.1 Hardware platform

1.1.1 Computer

Physical configuration	Standalone desktop base unit
Base unit dimensions	H, W, D : 4.5", 15.7", 13.9": 11.4cm, 39.9cm, 35.3cm
Base unit weight	10.4 kg
Display	Standalone 17" LCD monitor
Keyboard	Standard 104-key PC keyboard
Mouse	Standard optical mouse

1.1.2 Electronics for acoustic presentation & monitoring

Physical configuration	Standalone Stimulus Controller (SC) box
SC dimensions	H, W, D: 4.7", 12.6", 11.5": 12cm, 32cm, 29cm
SC weight	2.7kg
Sound Field Speaker	8 Ohms 5 Watts
Speaker dimension	H, W, D: 5.7", 5.3", 3.2": 14.5cm, 13.5cm, 8.0cm
Insert earphones	ER3A 50 Ohms Left and Right
Bone vibrator	B71 Bone oscillator 100 Ohms
Monitoring microphone	0.55" diameter, 1.63" length (3.25" including cable connector)

1.1.3 Electrode interface

Physical configuration	Standalone Electrode Processor (EP) box
EP dimensions	H, W, D: 2.2", 4.2", 9.0": 5.5cm, 10.5cm, 23cm
EP weight	0.5kg
Electrode cables	60" (150cm) cable with amplifier integrated in connector button
Active	1, yellow
Reference	1, blue
Ground	1, black
Electronic amplification	Analogue differential amplification of 1210 times
Low pass filter	Analogue, 12 dB/octave from 4kHz
High pass filter	Analogue, 6dB/octave below 0.3 Hz

1.2 Software platform

Operating system	Windows XP
Data management	Embedded MySQL

1.2.1 HEARLab ACA Software

Hearing tests available	Aided Cortical Assessment (ACA) Cortical Threshold Estimate (CTE)
Utilities	Check electrode impedance Quick check stimulus presentation Monitor ambient noise level in 1/3 octave spectrum

1.2.2 Acoustic stimulation ACA

Stimuli type	Speech sounds extracted from running speech
Duration	/m/ 30mS /g/ 20mS /t/ 30mS
Repetition period	1125mS
Number of epochs	User select
Polarity	Alternating
Levels	55 or 65 or 75 dB SPL* user selectable
Transducer	Free field loudspeaker
Masking	Nil, non target ear may be blocked with ear-plugs
Output accuracy	±6 dB (200-6000 Hz)

1.2.3 Acoustic Stimulation CTE

Stimuli type	Short duration pure tone burst
Burst duration	40 mS
Rise time	10 mS
Fall time	10 mS
Tone frequencies	500, 1k, 2k, 3k, 4k Hz
Repetition rate	1125 mS
Number of stimulus	User select
Polarity	Alternating
Transducer	Bone vibration: B71 or Insert earphones: EARTone 3A
Output accuracy	±3 dB
Levels - bone	0 – 70 dB HL, 1k – 4k Hz, 5 dB steps 10 - 60 dB HL, 500 Hz
Levels – earphones	10 – 110 dB HL, 5 dB step size
Masking signal	Narrow band noise, insert phones only

Masking levels	0dB to -40dB user selectable relative to test level
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1.2.4 Response Acquisition: ACA & CTE

Recording channels	2; response waveform, stimulus waveform
Time window	-200mS to +700mS relative stimulus start
Sampling rate	1000 Hz
A/D resolution	16 bits
Number of epochs	User selectable and interruptible
Signal to noise indicator	A red or yellow or green dot indicating good or satisfactory or poor strength of signal relative to overall level of noise
User controls on testing	Start, pause, stop and volume of acoustic monitoring
Other test status	Test level, number of epochs accepted or rejected, time elapsed and latest P values

1.2.5 Evoked cortical response processing

Latency	Time marking responses to stimuli: +/- 5mS
Amplitude	Response voltage: +/- 0.5 μ V
Response extraction	Averaging of responses time locked to stimuli
Response detection	Hotellings-t2 statistic, probability that the trace observed was caused the subject detecting the stimulus
Response differentiation	MANOVA statistic, probability that responses to the different speech sounds are different from each other, ACA only
Signal and noise quality	Displays status on the level of residual noise

1.2.6 Test results screen

Grand averages	Waveform(s) of final averaged cortical response(s)
Stacked traces	For CTE only. Waveforms of final average responses to the same tone burst frequency presented at different levels
Detection statistical analysis	Final P values and their history
Difference statistical analysis	Final P values and their history, ACA only
Summary of test conditions	Ear tested, aided or unaided, electrode condition, stimulus, masking, transducer, test duration and number of accepted epochs.
Comment	Space for user to add comments (recording keeping)

1.2.7 Test records

Test information	All information in the test results screen
Subject information	Name and test of birth
User controls	Store, recall, selection of records

1.2.8 Information displayed during response acquisition

EEG	Trace showing the most recent 9 epochs
Latest response	Waveform of the latest epoch
Averaged responses	Waveform(s) of time locked cumulative average(s) of response(s)
Detection statistics	Trace(s) of P value(s) resulting from detection statistical analysis
Differentiation statistics	Trace(s) of P value(s) resulting from MANOVA, ACA only
Signal to noise indicator	A red or yellow or green dot indicating good or satisfactory or poor strength of signal relative to overall level of acquired noise
Other test status	Test level, number of epochs accepted or rejected, time elapsed and latest P values

1.2.9 User test controls during response acquisition

Soft buttons	Start, pause and stop and volume of acoustic monitoring
Volume control	Vary the monitoring level of acoustics in the test space

1.2.10 Environmental

Operating temperature	10 to 35 degrees C
Operating humidity	20% to 85% (non-condensing)
Permissible ambient SPL, CTE	In accordance with ISO 8253-1
Permissible ambient SPL, ACA	< 30dB SPL, 1/3 octave spectrum, 200 Hz to 6300 Hz (measureable with software tool provided)
EMC specifications	Radiated and conducted emissions CISPR11 Electrostatic Discharge Immunity: IEC 61000-4-2 Radiated RF Immunity: IEC 61000-4-3 Fast Transient/Burst Immunity: IEC 61000-4-4 Surge Immunity: IEC 61000-4-5

1.2.11 Power supply

AC input voltage range	100~240Vac
AC input frequency	47~63Hz
AC input current	1 ampere slow blow fuse required 8.0/4.0A (PC 5.0 + LCD 1.2 + SC 1.35)

1.2.12 Safety

Type of protection	Class 1
Degree of protection	Type BF
Mode of operation	Continuous

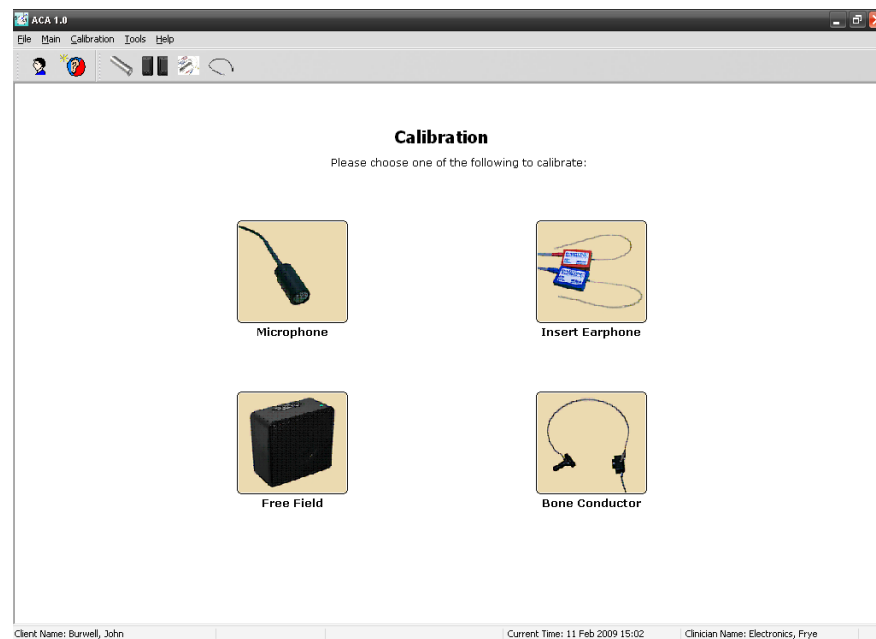
Chapter 2: Calibration

All transducers must be correctly calibrated before any assessment is to be performed in order to ensure that the stimulus and masking levels presented to the client are accurate and the resulting assessment results are reliable. The following transducers must be calibrated:

- Control Microphone (or microphone), *required for ACA assessments*
- Speaker/left (or free field), *required for ACA assessments*
- Insert Earphones, *required for CTE assessments*
- Bone Conductor, *required for CTE assessments*

It is recommended that these calibrations be performed once a year except the speaker calibrations which should be performed daily for best test results.

To access the Calibration window, press down the keys CTRL+SHIFT+ALT+K.



The Calibration window

2.1 Control Microphone Calibration

The control microphone calibration process involves obtaining the sensitivity of the microphone to input signals. It must be performed before free field calibration, because the control microphone is used during the free field calibration process.

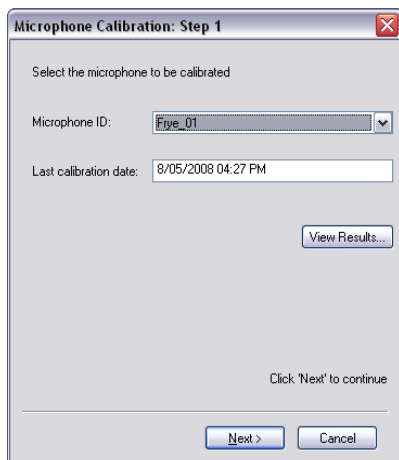
2.1.1 Opening the Calibration Wizard



Open the Calibration window by pressing **CTRL+SHIFT+ALT+K**.

In the Calibration window, open the Control Microphone Calibration Wizard by selecting the **Microphone** button.

You will be asked to key in an access code. Type "QWERTY" (caps sensitive). Once successful, the Microphone Calibration wizard will be displayed:



The Microphone Calibration Wizard

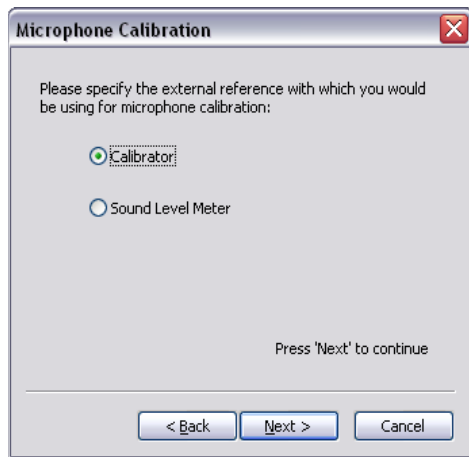
2.1.2 Step 1: Selecting the Control Microphone

By default, the existing control microphone is already selected. Click **Next** to proceed to the next step in the calibration process.

If you wish to add a new control microphone, see Section 2.1.7.

If you would like to view the current calibration table, click the **View Results** button. See Section 2.1.8 for details.

2.1.3 Step 2: Selecting the External Reference



If you are performing the calibration process with a sound level calibrator (recommended), select **Calibrator**.

If you do not have access to a sound level calibrator, you can perform the calibration with a sound level meter. Select this option if this is your calibration method.

Click **Next** after you have made your selection to proceed to the next step in the calibration process.

2.1.4 Step 3: Setting up the Equipment

Sound Level Calibrator Method

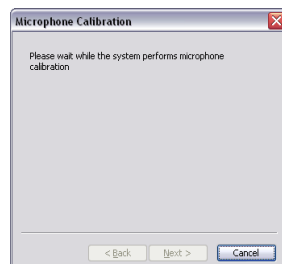
- Make sure that the control microphone is plugged into the Control Mic socket on the Stimulus Controller.
- Make sure the control microphone is correctly inserted into the sound level calibrator using the supplied adapter..
- Turn the calibrator on before proceeding.

Sound Level Meter Method

- Make sure the control microphone is plugged into the Control Mic socket on the Stimulus Controller.
- place the microphone of the sound level meter next to the HEARLab control microphone, with both microphones about 6 inches away from the loudspeaker grill.
- Set the sound level meter to measure the RMS dB SPL value using Fast time-constant with no weighting.
- Make sure the loudspeaker is connected to the Speaker Left socket on the Stimulus Controller.

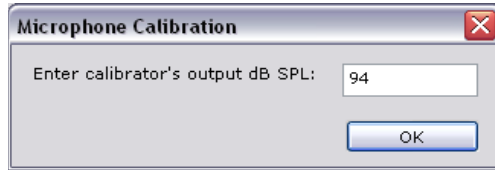
Click **Next** to proceed to the next step in the calibration process.

2.1.5 Step 4: Performing the calibration



Sound Level Calibrator Method

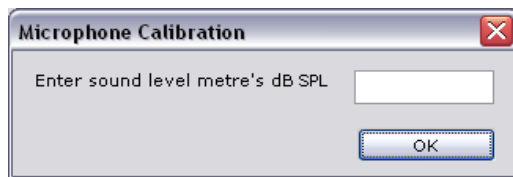
The control microphone will record and measure the signal coming from the calibration. This calibration process should take about three seconds. If the signal was successfully recorded, a window will appear and prompt you to enter the sound level calibrator's output dB SPL level:



Enter the level and click **OK** to return to the calibration wizard. Click **Next** to proceed to the next step.

Sound Level Meter Method

During the calibration process, a 1 kHz warble tone is presented through the free field speaker. If the signal was successfully recorded, a window will appear and prompt you to enter in the sound level meter's reading:



Enter the level and click **OK** to return to the calibration wizard. Click **Next** to proceed to the next step.

Unsuccessful Calibrations

If no signal was detected, you will be notified that the calibration was unsuccessful and prompted to try the calibration again.

Click **Yes** to try again (the wizard will return to Step 3), or **No** to cancel.

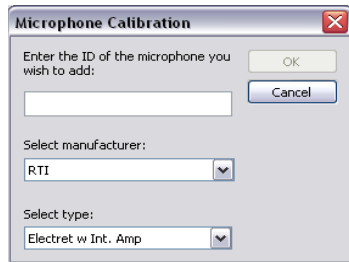
2.1.6 Step 5: Completing the Calibration

Type in any additional notes regarding the calibration (e.g. serial number of the calibrator or sound level meter used).

Click **Finish** to save the calibration and exit, or **Cancel** to discard the calibration and exit. Unsuccessful calibration results will not be able to be saved.

2.1.7 Adding a New Microphone

To add a new control microphone, open the Calibration Wizard (see Section 2.1.1) and select **Other...** from the **Microphone Serial No.** list. The Add New Microphone window will be displayed.



Enter the new microphone's ID and click **OK** to return to the wizard.

2.1.8 Viewing Current Calibration Results

To view the calibration tables current in use, open the Calibration Wizard (see Section 2.1.1) and click **View Results**. This will open the Calibration Record window. See Figure 2.1.8.

HEARLab ACA only stores the current calibration record. If you would like to keep a permanent copy of calibration records, use the **Save As...** button to store the record as a text file. The **Print** button can also be used for creating a hard copy of the record.

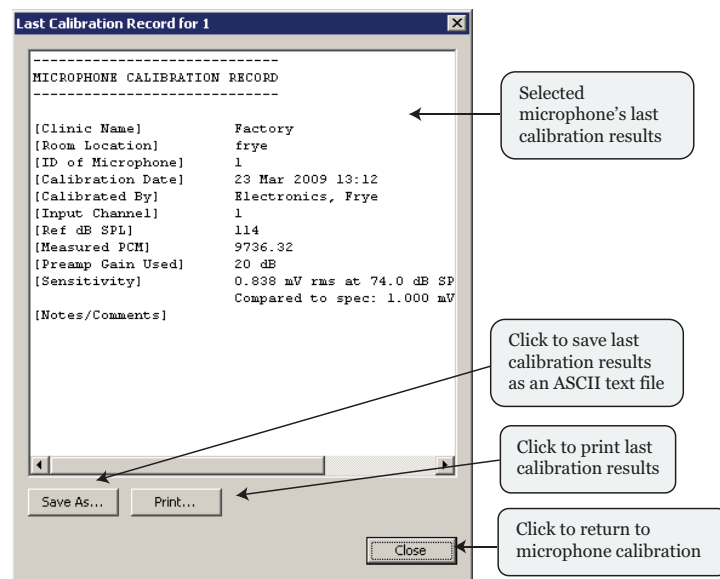
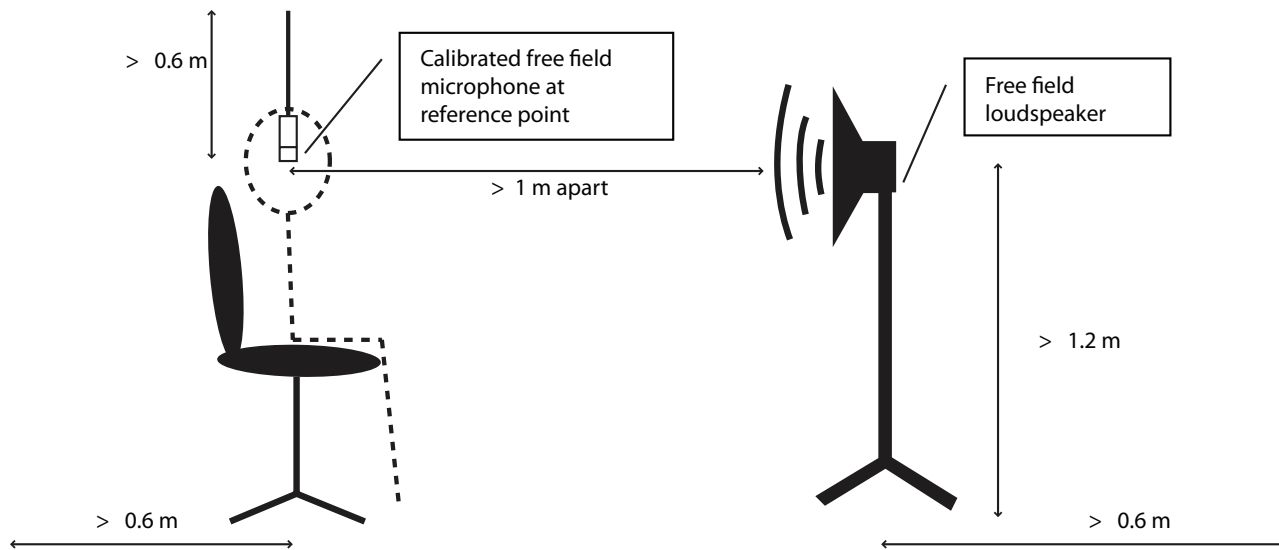


Figure 2.1.8: Calibration Record window

2.2 Free Field Calibration

The free field calibration process involves obtaining the frequency response of the free field environment (room acoustics + loudspeaker frequency response) and equalising the complex signals that are to be presented in that environment.

To set up the room for free field calibration, set up as you would for an ACA assessment. Place the control microphone at the approximate location where the patient's head is likely to be situated.



Typical room setup for free field calibration

2.2.1 Opening the Calibration Wizard



Open the Calibration window by pressing **CTRL+SHIFT+ALT+K**.

In the Calibration window, open the Control Microphone Calibration Wizard by selecting the **Free Field** button. See Figure 2.2.2.

2.2.2 Step 1: Selecting the Loudspeaker Position

To specify the loudspeaker position in the room, use the **Loudspeaker Position** list. The last calibrated position is selected by default. See Figure 2.2.2.

To view the current calibration table, click the **View Results...** button. See Section 2.2.9 for details.

Click **Next** to proceed to the next step in the Calibration Wizard.

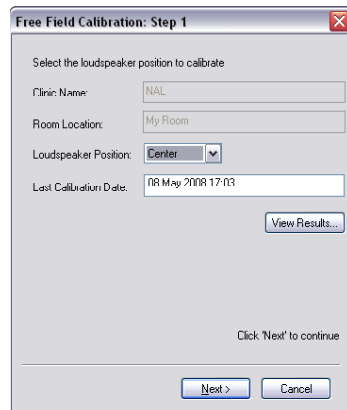


Figure 2.2.2: Free Field Calibration Wizard

2.2.3 Step 2: Selecting the Loudspeaker

Select the loudspeaker to be calibrated using the **LoudspeakerID** list. The existing loudspeaker will be selected by default. See Figure 2.2.3.

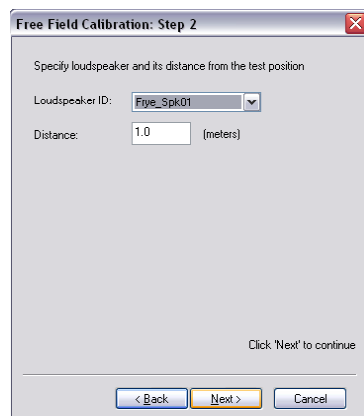


Figure 2.2.3: Loudspeaker Selection

Specify the distance between the loudspeaker and the test position.

Click **Next** to proceed to the next step in the Calibration Wizard.

2.2.4 Step 3: Selecting the Calibration Method

The control microphone is a standard accessory for HEARLab. The "Automatic" calibration method uses this microphone and should be selected for most calibrations. See Figure 2.2.4.

- The control microphone should be automatically selected for use in the calibration process. If necessary, use the list provided to specify the microphone.

- If an external amplifier will be used, select **External amplifier to be used**.
- If you would like to perform the calibration manually with a sound level meter, see Section XXX.

Click **Next** to proceed to the next step in the Calibration Wizard.

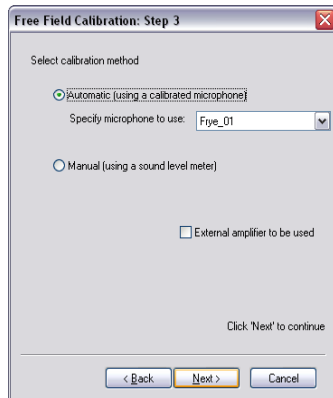


Figure 2.2.4: Calibration Method selection

2.2.5 Step 4: Positioning the Speaker

Make sure the loudspeaker is positioned as shown in the picture.

Click **Next** to proceed with calibration.

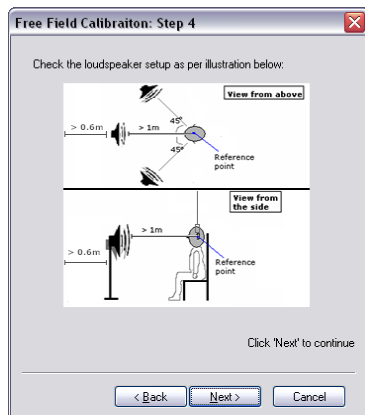


Figure 2.2.5: Speaker positioning

2.2.6 Step 5: Setting up the Equipment

- Make sure the control microphone is plugged into the Control Mic socket of the Stimulus Controller and properly placed at the test position.
- Make sure the loudspeaker is plugged into the Left Speaker socket of the Stimulus Controller.

Click **Next** to proceed to the next step in the Calibration Wizard.

2.2.7: Step 6: Performing the Calibration

During the calibration process, a series of warble tones (125-8000 Hz in 1/3 octave intervals) will be presented through the loudspeaker. The control microphone will measure and record these signals to obtain the frequency response of the free field environment. See Figure 2.2.7.

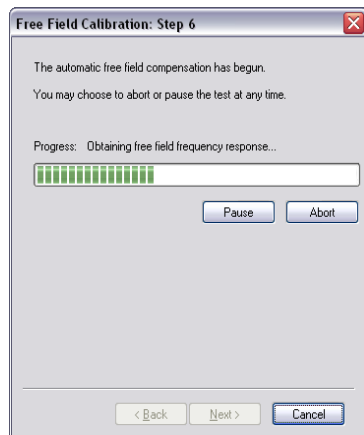


Figure 2.2.7: Automatic calibration in progress

- You may pause or abort the calibration process at any time, but during the calibration process, the **Back** and **Next** buttons on the wizard will be disabled. They will be enabled again when the calibration process has completed.
- If the system could not obtain a signal, or finds that the obtained frequency response exceeds ± 8 dB of the reference frequency but is still within ± 11 dB of it, a warning message will be displayed on-screen and you will be prompted to restart the automatic calibration process or to continue.
- After the first frequency sweep, the system will make automatic level adjustments as the second frequency sweep is presented in order to produce a (near) flat frequency response. The signals will again be recorded and measured by the microphone.
- Upon the completion of the second frequency sweep, the filtered (filter generated from obtained frequency response) ACA stimuli will be presented and recorded.

If the measured frequency response of the field exceeds ± 10 dB, or if the adjusted frequency response still exceeds IEC 645-2 tolerances, you will be notified and asked whether or not you wish to retry the calibration. You may wish to view the preliminary calibration results before making the decision. If you choose to retry, the calibration process will be repeated, and all previous adjustments will be discarded.

You may wish to adjust the room setup (e.g. moving furniture around, moving the loudspeaker and test position further away from the walls) to improve the frequency response of the sound field.

Click **Next** to proceed to the next step of the Calibration Wizard.

2.2.8 Step 7: Completing the Calibration

Type in any additional notes regarding the calibration (e.g. sound level meter used, name of the operators performing the calibration). See Figure 2.2.8.

Click **Finish** to save the calibration and exit, or **Cancel** to discard the calibration and exit. Unsuccessful calibration results will not be able to be saved.



Figure 2.2.8: Completing the Calibration Wizard

2.2.9 Viewing Current Calibration Results

To view the existing calibration tables for the specified loudspeaker position, open the Calibration Wizard (see Section 2.2.1), select the loudspeaker position, and click View Results. A window will open with the calibration results. See Figure 2.2.9.

HEARLab ACA only stores the current calibration record. If you would like to keep a permanent copy of calibration records, use the **Save As...** button to store the record as a txt file. The **Print** button can also be used for creating a hard copy of the record.

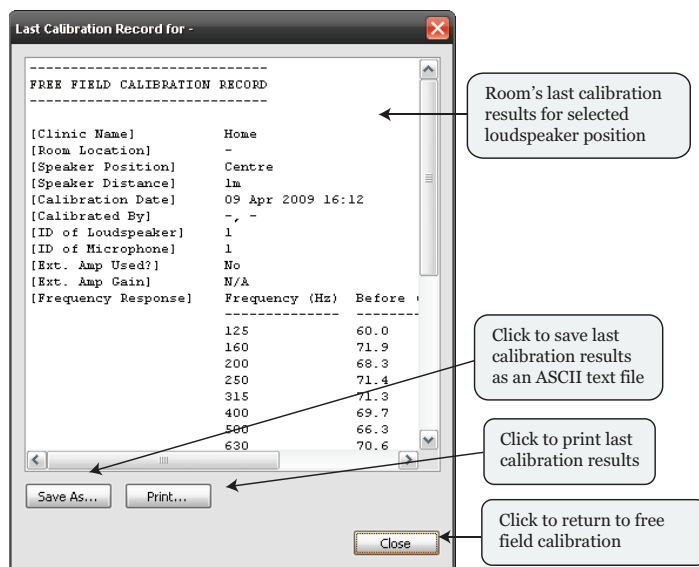


Figure 2.2.9: Viewing current calibration results

2.2.10 Adding a New Loudspeaker

To add a new loudspeaker, open the Calibration Wizard (see Section 2.2.1), select the loudspeaker position (see Section 2.2.2). In Step 2 of the Calibration Wizard, use the Loudspeaker ID list to select **Other**. This will open the Add New Loudspeaker window. See Figure 2.2.10.

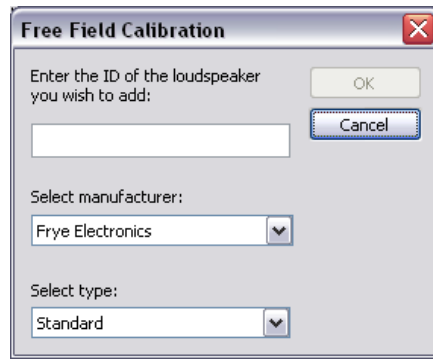


Figure 2.2.10: Adding a new loudspeaker

Type the ID of the new loudspeaker and click **OK** to return to the Calibration Wizard.

2.2.11 Using a Sound Level Meter (Manual Calibration)

It is possible to calibrate the sound field manually with a sound level meter instead of using the automatic calibration process with the control microphone. This method requires two people: one to operate the HEARLab controls and one to make sound level meter readings. The objective of the procedure is to adjust the levels at each frequency until the SLM reading gives the indicated Target dB SPL level.

1. Open the Calibration Wizard (see Section 2.2.1) and follow it to Step 3: Selecting the Calibration Method.
2. Select **Manual (using a sound level meter)**.
3. Make sure that the free field speaker is plugged into the **Free Field Speaker** socket of the SC
4. Position the sound level meter operator with the meter at the test position.
5. Set the SLM to measure RMS dB SPL with Fast time-constant and no weighting. Depending on the microphone used with the SLM, point the microphone towards the sound source or point it downwards.
6. Click through the Calibration Wizard until you reach Step 6: Free Field Calibration. See Figure 2.2.11.

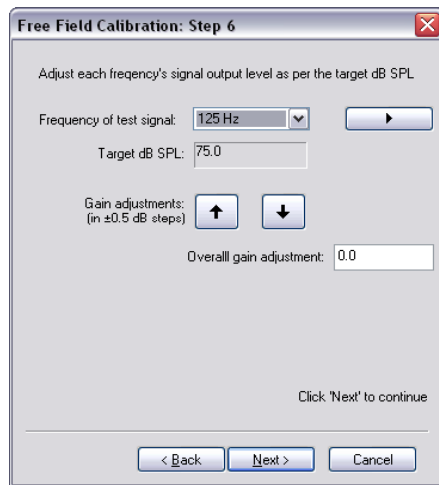





Figure 2.2.11: Manual calibration

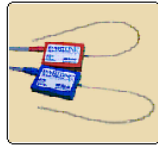
7. Select the frequency by using the **Frequency of the test signal** list. The frequencies to be presented are: **125 Hz, 250 Hz, 500 Hz, 1 kHz, 1.5 kHz, 2 kHz, 3 kHz, 4 kHz, and 8kHz.**
8. Click the  button to present the signal. While the signal is being presented, the operator with the SLM should measure the signal level. If the reading is not within ± 0.5 dB of the target level, adjust the presentation level using the  button to increase the level, or the  button to decrease the level. Adjustments are in **0.5 dB** steps.
Alternatively, you can input gain adjustments in the **Overall gain adjustment** text box, and use the ENTER key to apply the specified gain.
9. Repeat steps 7 and 8 until all frequencies have been presented, measured, and adjusted accordingly.

2.3 Insert Earphone Calibration

The insert earphone calibration process involves obtaining the frequency response of the insert earphones and adjusting the output levels to compensate for that response. The additional equipment required for insert earphone calibration is:

- 2cc acoustic coupler (IEC 126) OR an occluded-ear simulator (IEC 711)
- Artificial ear
- Sound level meter

2.3.1 Opening the Calibration Wizard



Open the Calibration window by pressing **CTRL+SHIFT+ALT+K**.

In the Calibration window, open the Insert Earphone Calibration Wizard by selecting the **Insert Earphone** button.

You will be asked to key in an access code. Type "QWERTY" (caps sensitive). Once successful, the Insert Earphone Calibration wizard will be displayed. See Figure 2.3.1.

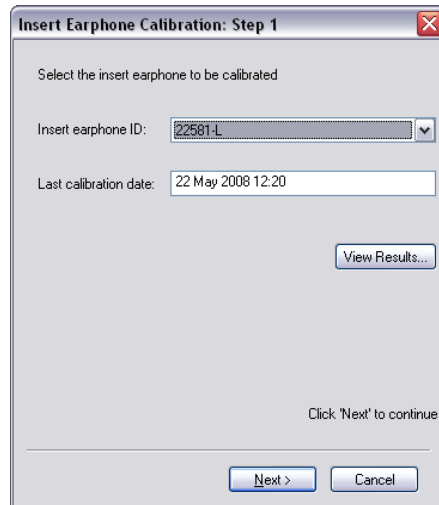


Figure 2.3.1: Insert Earphone Selection

2.3.2 Step 1: Selecting the Insert Earphone

Select the earphone to calibration by using the **Insert earphone ID** list. The last calibrated insert earphone is selected by default.

If you would like to add a new insert earphone, see Section 2.3.7.

If you would like to view current calibration results, click the **View Results** button. See Section 2.3.8 for details.

Click **Next** to proceed to the next step in the Calibration Wizard.

2.3.3 Step 2: Selecting the Output Channel

Use the **Output Channel** list to select whether you are calibrating the left insert earphone or the right insert earphone. See Figure 2.3.3.

Click **Next** to proceed to the next step in the Calibration Wizard.



Figure 2.3.3: Insert earphone output channel selection

2.3.4 Step 3: Specifying the Coupler

This step selects the type of coupler used in the calibration process. This step is very important because it selects the RETSPL values that are used in HL to SPL conversion calculations. **Selecting the wrong coupler will lead to incorrect calibration corrections.** See Figure 2.3.4.

If you are using a 2-cc coupler for the calibration, select **Acoustic Coupler** and input the Coupler ID.

If you are using an **Occluded Ear Simulator**, choose that selection and input the OES ID.

Click **Next** to proceed to the next step in the Calibration Wizard.

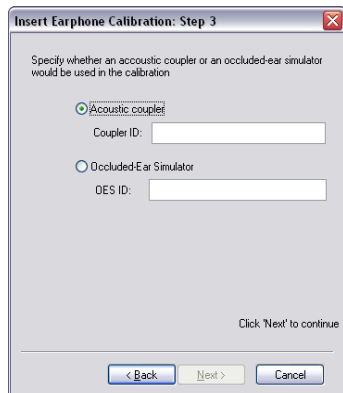


Figure 2.3.4: Specifying the coupler

2.3.5 Step 4: Setting up the Equipment

- Make sure the insert earphone is connected to the Insert Left or Insert Right socket on the back of the Stimulus Controller.
- Make sure the insert earphone is connected properly to the coupler or ear simulator.




- Insert the sound level meter microphone into the coupler or ear simulator.
- Set the sound level meter to measure RMS dB SPL with fast time constant and no weighting.

Click **Next** proceed to the next step in the Calibration Wizard.

2.3.5 Step 5: Performing the Calibration

During the calibration process, a series of pure tones are presented through the insert earphone. Measure the output level using the sound level meter. The objective of the procedure is to adjust the levels at each presentation frequency until the SLM reading matches the indicated Target dB SPL level.

The frequencies to be presented are: 500Hz, 1 kHz, 1.5 kHz, 2 kHz, 3 kHz, 4 kHz.

1. Use the **Frequency of test signal** list to select the frequency to present.
2. Click  to present the signal. Use the SLM to measure the signal level. If the reading is not within ± 0.5 dB of the target level, adjust the presentation level using the  or  buttons. Adjustments are in **0.5 dB** steps.

Alternatively, you can type the adjustment into the **Overall gain adjustment** box and hit ENTER.

3. Repeat this procedure until all frequencies have been presented, measured, and adjusted accordingly.

In cases where the sensitivity of the insert earphone output exceeds manufacturer's specifications by ± 6 dB, or if the frequency response exceeds ± 10 dB, you will be notified and asked whether or not you would like to retry the calibration. You may wish to view the preliminary results before making a decision. Should you choose to retry the calibration, all previous adjustments would be discarded.

Click Next to proceed to the next step in the Calibration Wizard.

2.3.6 Step 6: Completing the Calibration

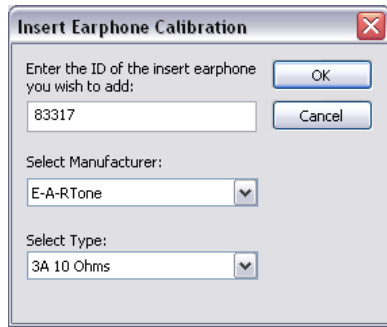
Enter any additional notes regarding the calibration (e.g. sound level meter used, name of the operators performing the calibration, artificial ear used).

Click **Finish** to save the results and exit, or **Cancel** to discard the results and exit.

2.3.7 Adding a New Insert Earphone

To add a new insert earphone, open the Insert Earphone Calibration Wizard by following the instructions found in Section 2.3.1.

In the **Insert Earphone ID** box, select Other. This will open the Add New Insert Earphone window. See Figure 2.3.7.



Insert Earphone Calibration

Enter the ID of the insert earphone you wish to add:

83317

Select Manufacturer:

E-A-RTone

Select Type:

3A 10 Ohms

OK Cancel

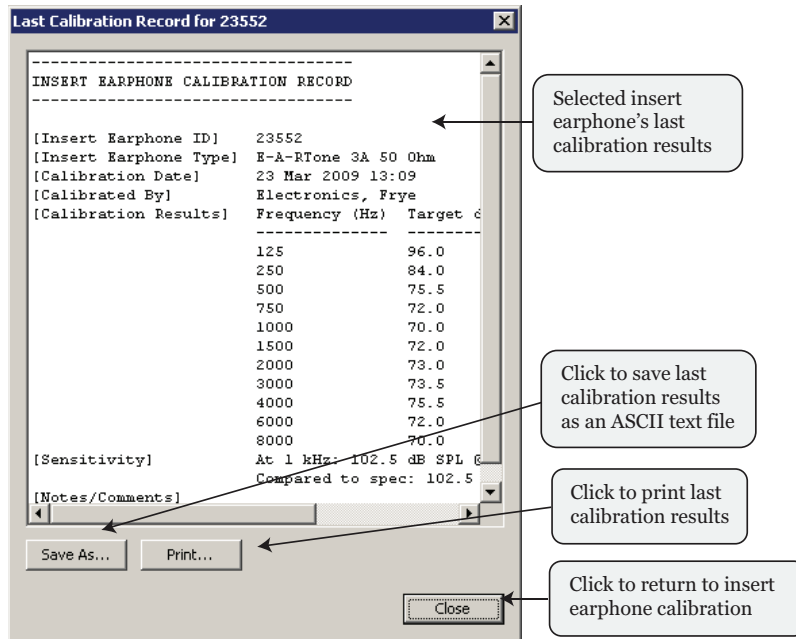
Figure 2.3.7: Adding an Insert Earphone

Enter the ID of the new insert earphone, select the manufacturer and the type of the insert earphone, then click **OK** to return to the wizard.

2.3.8 Viewing Current Calibration Results

To view the current calibration tables, follow the instructions in Section 2.3.1 to open the Insert Earphone Calibration Wizard and click **View Results**. A window will appear, displaying the results (dB adjustments to obtain target dB SPL level). See Figure 2.3.8.

HEARLab ACA only stores the current calibration record. If you would like to keep a permanent copy of calibration records, use the **Save As...** button to store the record as a txt file. The **Print** button can also be used for creating a hard copy of the record.



Last Calibration Record for 23552

INSERT EARPHONE CALIBRATION RECORD

[Insert Earphone ID] 23552
[Insert Earphone Type] E-A-RTone 3A 50 Ohm
[Calibration Date] 23 Mar 2009 13:09
[Calibrated By] Electronics, Frye
[Calibration Results]

Frequency (Hz)	Target d
125	96.0
250	84.0
500	75.5
750	72.0
1000	70.0
1500	72.0
2000	73.0
3000	73.5
4000	75.5
6000	72.0
8000	70.0

[Sensitivity] At 1 kHz: 102.5 dB SPL 6
Compared to spec: 102.5

[Notes/Comments]

Save As... Print... Close

Selected insert earphone's last calibration results

Click to save last calibration results as an ASCII text file

Click to print last calibration results

Click to return to insert earphone calibration

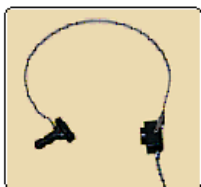
Figure 2.3.8: Calibration Record

2.4 Bone Conductor Calibration

The bone conductor calibration process involves obtaining the frequency response of the bone conductor and adjusting the output levels to compensate for that response. The additional equipment required for bone conductor calibration are:

- A calibrated artificial mastoid
- A sound level meter

2.4.1 Opening the Calibration Wizard



Open the Calibration window by pressing **CTRL+SHIFT+ALT+K**.

In the Calibration window, open the Bone Conductor Calibration Wizard by selecting the **Bone Conductor** button.

You will be asked to key in an access code. Type "QWERTY" (caps sensitive). Once successful, the Bone Conductor Calibration wizard will be displayed. See Figure 2.4.1.

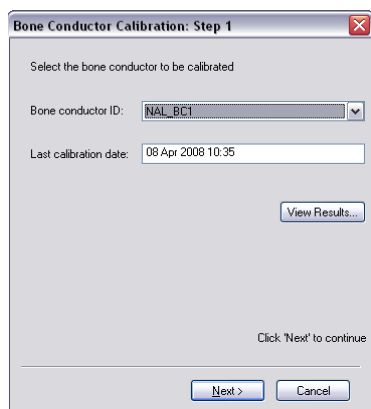


Figure 2.4.1: Bone Conductor Calibration Wizard

2.4.2 Step 1: Selecting the Bone Conductor

The bone conductor should automatically be selected in the **Bone Conductor ID** list.

If you would like to add a new bone vibrator, see Section 2.4.7.

If you would like to view current calibration results, click the **View Results** button. See Section 2.4.8 for details.

Click **Next** to proceed to the next step in the Calibration Wizard.

2.4.3 Step 2: Setting up the Equipment

The instructions for connecting the bone conductor and the sound level meter to the artificial mastoid will be displayed.

- Make sure the bone conductor is connected to the Bone jack on the Stimulus controller.
- Make sure the bone conductor and the sound level meter are connected correctly to the artificial mastoid.
- Set the SLM to measure dB SPL with fast time setting and no weighting.

Click **Next** to proceed to the next step in the Calibration Wizard.

2.4.4 Step 3: Inputting Mastoid Corrections

Type the Artificial Mastoid ID into the box and input the correction figures from the mastoid's calibration results for each of the listed frequency. See Figure 2.4.4.

Click **Next** to proceed to the next step in the Calibration Wizard.

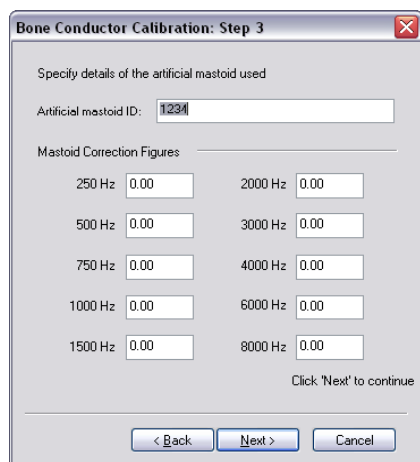



Figure 2.4.4: Artificial Mastoid Corrections

2.4.5 Step 4: Performing the Calibration

During the bone conductor calibration process, a series of pure tones are presented through the bone conductor and measured using a sound level meter. The objective of the procedure is to adjust the levels at each presentation frequency until the SLM reading reaches the indicated Target dB SPL level. The frequencies to be presented are: 500Hz, 1 kHz, 1.5 kHz, 2 kHz, 3 kHz, 4 kHz. See Figure 2.4.5.

1. Select the frequency of the pure tone to present using the **Frequency of test signal** list.
2. Click the  button to present the signal.
3. Check the SLM. If the reading is not within ± 0.5 dB of the target level,

adjust the presentation level using the   buttons. Adjustments are in 0.5 dB steps.

Alternatively, enter the gain adjustments in the **Overall gain adjustment** box and use the ENTER key.

4. Repeat this procedure until all frequencies have been presented, measured, and adjusted accordingly.

In cases where the frequency response of the bone conductor exceeds ± 10 dB, you will be notified and asked whether or not you wish to retry the calibration. You may wish to view the preliminary results before making a decision. Should you choose to retry the calibration, all previous adjustments would be discarded.

5. Click **Next** to proceed to the next step in the Calibration Wizard.

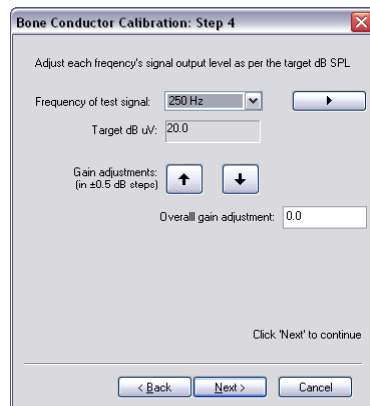


Figure 2.4.5: Performing the calibration

2.4.6 Step 5: Completing the Calibration

Enter any additional notes regarding the calibration (e.g. sound level meter used, name of the operators performing the calibration). See Figure 2.4.6.

Click **Finish** to save the results and exit, or **Cancel** to discard the results and exit.

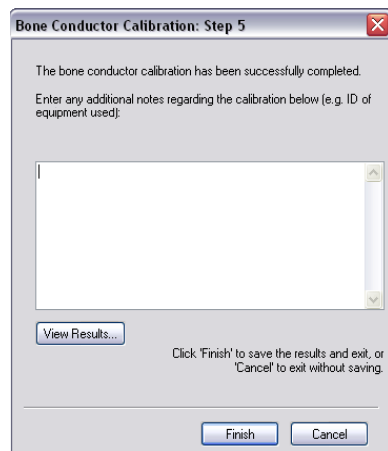


Figure 2.4.6: Completing the calibration

2.4.7 Adding a Bone Conductor

To add a new bone conductor, follow the steps in Section 2.4.1 to open the Bone Conductor Calibration Wizard and select **Other...** in the **Bone Conductor ID** box. This will open the Add New Bone Conductor window. See Figure 2.4.7.

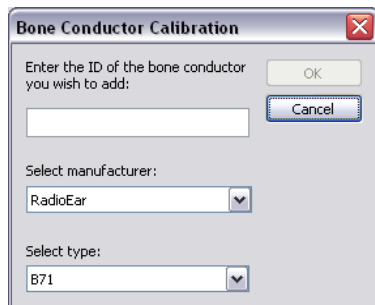
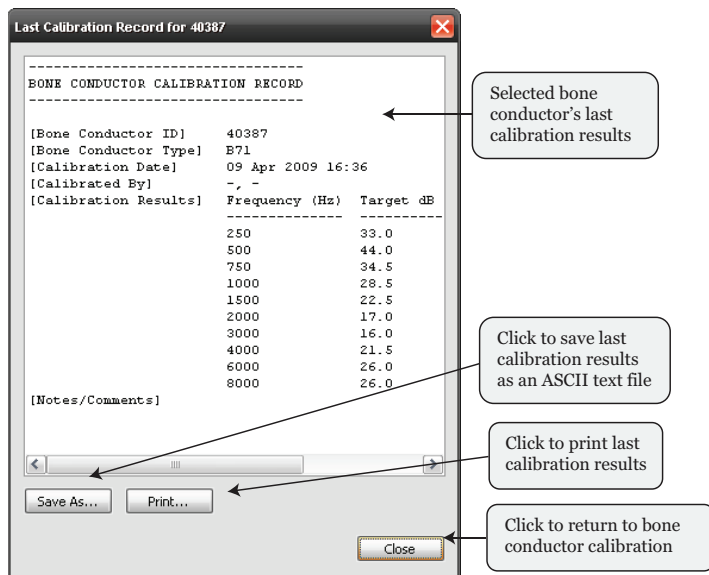
A screenshot of the 'Bone Conductor Calibration' dialog box. It has a title bar with a close button. Inside, there's a text input field for 'Enter the ID of the bone conductor you wish to add:' with 'OK' and 'Cancel' buttons to its right. Below that is a 'Select manufacturer:' dropdown menu with 'RadioEar' selected. At the bottom is a 'Select type:' dropdown menu with 'B71' selected.

Figure 2.4.7: Adding a new bone conductor

Enter the ID, manufacturer, and type of the new bone conductor and click **OK** to return to the wizard.

2.4.8 Viewing Current Calibration Results

To view the current calibration results of the bone conductor, open the Bone Conductor Calibration Wizard as described in Section 2.4.1 and click **View Results**. A window will open displaying the results (dB adjustments to obtain target dB SPL level).

A screenshot of the 'Last Calibration Record for 40387' window. It displays a table of calibration results. Callout boxes point to various features: 'Selected bone conductor's last calibration results' points to the table; 'Click to save last calibration results as an ASCII text file' points to the 'Save As...' button; 'Click to print last calibration results' points to the 'Print...' button; and 'Click to return to bone conductor calibration' points to the 'Close' button. The table has columns for 'Frequency (Hz)' and 'Target dB'.

Frequency (Hz)	Target dB
250	33.0
500	44.0
750	34.5
1000	28.5
1500	22.5
2000	17.0
3000	16.0
4000	21.5
6000	26.0
8000	26.0

Figure 2.4.8: Calibration Record

HEARLab ACA only stores the current calibration record. If you would like to keep a permanent copy of calibration records, use the **Save As...** button to store the record as a text file. The **Print** button can also be used for creating a hard copy of the record.

Chapter 3: Repair

This chapter describes how to disassemble the Stimulus Controller (SC) and Electrode Processor (EP) for the purpose of repair. The SC and EP should only be opened by an experienced technician authorized by Frye Electronics or one of its distributors. Opening the EP or SC may void its warranty. Check with the factory (service@frye.com) for more details.

3.1 Stimulus Controller

3.1.1 Removing the Case

1. Turn the unit off. Remove the power plug from the power line jack.
2. Note where all cables are plugged in and then unplug all cables from the rear panel of the instrument.
3. Remove the four screws in the bottom plastic cover holding the bottom and top plastic covers together.
4. Separate the two covers. Lay them to one side, storing the hardware in a safe place for later use.
5. If desired, the two main boards of the SC can now be tested, as they are easily reached from the top and bottom of the instrument.

3.1.2 Removing the Circuit Boards

1. Remove the 6 #6 screws from the rear panel. Remove the two screws that hold the heat sink to the side panel.
2. Slide the circuit boards toward the rear of the instrument. Disconnect the two power entry connections from the rear panel power entry module. Disconnect the secondary power cable at the connector on the top of the upper circuit board. Completely slide the boards from the chassis.
3. Separate the two boards from each other by disconnecting the interboard cable at one of the connectors. The cable can be removed from the connector by pulling up on the plastic retainer and moving it away from the circuit board surface about 1/8 inch (3 mm).

To separate the two boards, they will need to be removed from the rear panel. This is done by removing the plastic nuts that hold them there. There are ten nuts on the upper board and 3 on the lower board. Store them for later use.

4. Store the circuit boards in static free containers while they are out of the instrument.

3.1.3 Removing the Power Supply

1. Remove the two connectors from the primary and secondary connector terminals. Fold the cardboard voltage shield out of the way.
2. Use a screwdriver and remove the #6 screws on the top of the supply holding the power supply in position. Store the screws in a safe place.

3.1.4 Replacing the Power Supply

1. Make sure that the primary leads to and from the front panel mounted power switch are dressed between the chassis side and the side power supply mounting standoffs. Make sure that the secondary power leads are out of the way. Place the power supply so that the secondary end is closer to the front panel.
2. Use the four #6 screws and fasten the supply into position.
3. Reconnect the two connectors to the primary and secondary connectors. Reposition the cardboard voltage shield.

3.1.5 Installing the Circuit Boards

1. Use the connector nuts and fasten the boards to the rear panel. Do not over tighten the plastic nuts.
2. Connect the interboard cable to the two circuit boards.
3. Slide the boards into the chassis, being careful to engage them in the card guides made to hold them. Make sure the fiberboard voltage shield is in place while moving the board assembly past it. The lower board has a short card guide near the front panel. Make sure that the board fits into it.
4. Slide the rear panel toward the front, but reconnect the power leads to the rear panel power entry module before sliding the panel all the way in.
5. Replace the #6 screws in the rear panel and the heat sink.
6. Connect the secondary power cable to the upper circuit board connector.

3.1.6 Assembling the Case

1. Place the upper and lower parts of the case over the chassis. Note that the bottom part has holes for retaining screws.
2. Fasten the system together using the four case screws.

3.2 The Electrode Processor

The electrode processor (EP) is a plastic case that is snapped together and uses no retaining hardware. But disassembly and reassembly goes much more smoothly if a certain sequence of operations is followed.

3.2.1 Disassembling the EP

1. Unplug the electrode and firewire cables from the unit.
2. Using a standard size screwdriver or pocket knife blade, insert the blade into the slot on the bottom half opposite to the firewire connector.
3. Gently pry the two sides of the top panel away from the bottom panel.
4. When the sides are free, gently slide the lower panel away from the top assembly, sliding the panel in the end grooves.
5. When the panel is removed, the two circuit boards can slide out of the case.

3.2.2 Separating the Boards

1. The interboard cable connectors work the same way as the ones in the SC unit. Gently pry the plastic ring on the connector away from the board surface about 3 mm to release the cable.
2. Store the boards in a static free container.

3.2.3 Replacing the Boards

1. Reconnect the interboard connection cable.
2. Note that the upper board has connectors for the electrodes. Position the assembly so that the firewire connector will line up with the hole placed for it in the panel, and the electrode connectors will line up with the holes provided for them.
3. Slide the two boards into their respective slots.

3.2.4 Reassembling the Case

1. Position the lower panel that was removed before so that the end slots line up with and engage the slots made for them.
2. Slide the panel into place and gently force the sides apart to mate the top with the bottom panel grooves.

Chapter 4: Circuit Descriptions

4.1 Stimulus Controller

4.1.1 Power Supply

The Stimulus Controller (SC) incorporates a medical grade main AC to 12VDC power supply that is supplied line power through a slow blow, .5 ampere fuse and a front panel mounted on/off switch. The power supply has built in short circuit protection. A 4Amp fuse has been added in series with the secondary circuit. This is followed by an on/off switch, UR401, operated by over and under voltage detectors. Working with U401 and U402, R401, R402 sets the over voltage at 16.2 V while R403 and R404 sets the under voltage at 10.6V. A number of linear regulators are employed to provide 9V, 5V, 3.3V as well as separate supplies for analog and digital circuits. U408 provides -5V for part of the analog circuits.

4.1.2 USB Hub

Both the SC and Electrode Processor (EP) are designed as USB devices for control and communication by the PC. U101 provides the 2 ports needed.

4.1.3 Communication and Control

The SC employs a Texas Instrument controller, U104, for USB audio streaming and control. U103 contains the firmware that defines the activities of the controller. The PC can control the audio input and output paths with a defined set of commands that are sent to the controller. The commands are executed by setting up a set of control signals with a number of buffers. U107 and U108 configure the output paths. U109 and U110 configure the input paths.

4.1.4 Switch inputs

Up to 3 switches (normally open) can be connected to the SC via 5 pin DIN socket. Logic H is available on Pin 1 as switch common. Pins 4, 2 and 5 are the normally open contacts. These switches are debounced and latched with U106. The later can be read and cleared by the PC.

4.1.5 External Control

Relay UR205 provide a normally open contact for external control, for example, turning reward on or off. The PC controls the relay via the controller by sending a specific command.

4.1.6 Microphone Inputs

There are two channels for recordings. The LINE IN Channel has a choice of 3 inputs. Each channel has three amplifiers. The first stage has a gain of 4dB or 24 dB. The second amplifier provides a 2 pole low cut @ 50 Hz as well as a 20dB gain. The third amplifier provides a 2 pole high cut @ 16 kHz as well as another 20dB gain. The last 2 stages can be selected or bypassed giving a selectable gain range of 60dB.

4.1.7 Amplifiers and filters

Each of the microphone channels has three amplifiers. The first stage has a gain of 4dB or 24 dB. The second amplifier provides a 2 pole low cut @ 50 Hz as well as a 20dB gain. The third amplifier provides a 2 pole high cut @ 16 kHz as well as another 20dB gain. The last 2 stages can be selected or bypassed giving a selectable gain range of 60dB.

4.1.8 Audio Codec

The microphone signals are connected to the AC97 Audio Codec, U201. It handles analog to digital and digital to analog signal conversions, data formatting and audio streaming interfaces.

The Codec includes input mixer which is employed to accept inputs from two auxiliary inputs. Note that each input is connected to both the Left and Right channels of the mixer. This facilitates selection of any of the inputs to be fed to either Left or Right output channels. As well as local playback, the PC can acquire the signal by selecting input and set the gain for the ADC for audio data stream-in.

The Codec converts audio stream-out to analog signals. These signals are available as LINE_OUT, HP_OUT and MONO_OUT. There are separate volume controls for each output.

4.1.9 Volume Control

The main audio outputs are taken from LINE_OUT pins. U202 is a digital stereo volume control with fine steps of 0.5dB and a range of +32dB to -90dB. Its gain is set with a 16 bit word clocked in by the controller in response to PC command.

4.1.10 Power Amplifiers

A pair of power amplifiers is included in the SC, U203 and U205, to drive free field loudspeakers to moderate levels or low impedance transducers such as headphones, insert phones and bone conductors. These amplifiers have a fixed gain of 26 dB. Their output can be attenuated by 40dB with relay switches, UR201 and UR202. They are intended to be used when acoustic stimulus is low.

A mono output channel is provided via U206.

4.1.11 Output selectors

The audio outputs can be routed to a number of output sockets that are labeled in accordance with their intended transducers. Included also is the ability to connect the audio signal to an external amplifier and routing the latter's output to the FREE FIELD loudspeakers connected to the SC.

4.1.12 Socket for EP

Either left or right HP_OUT can be selected as STIM OUT for connection to the EP. Included in the EP connection are the USB data pair and a +9VDC power supply.

4.2 Electrode Processor Unit

4.2.1 Connectors and Cables for electrodes

The electrode connectors and cables as pictured are designed to work with commercially available single use sensor pads. Amplifier circuit components are built into the Reference and Active electrode connectors. The Reference and Active connector cables are active as pre-amplifier circuits are located within the connector body so that the signal cables are driven by low impedance amplifiers to reduce pick up of unwanted signals. These circuits also provide a differential signal gain of 121 between the Reference and Active contacts when the EP is operating in scalp signal acquisition mode.

These circuits include switches that enable software to measure resistance between Reference and Ground and between Active and Ground.

4.2.2 Amplifier and filter

There are 3 channels implemented in EP. Following the differential amplifier, a further amplification of 9.182 is applied to the signal with an amplifier filter circuit built around U209 for ch1. The filter is a 2 pole Butterworth low pass with 3dB frequency of 4 kHz. Following the filter, there is another buffer U210 to drive the ADC as recommended by the circuit manufacturer. Note that ch2 and ch3 uses the same reference electrode signal to obtain differential signals between the reference and respective active electrodes. U208 buffers the mid rail supply voltage for these filters.

4.2.3 Analog to Digital Converters

U120 and U121 are 2 channel analog to digital converters. In impedance mode, the reference signal is fed into U120's left channel input. In acquisition mode, this channel is used for recording the stimulus input. ADC transfers data to the controller with the I2S Serial Audio Interface. On board firmware configures the ADC to operate in slave mode sampling at 16 bit @ 16 kS/s. The -3dB low frequency response would be 0.33 Hz nominally.

4.2.4 Optical isolators and isolated power

Electrode signal pick up and processing circuits are referred to as patient contact circuits. High isolation of these circuits is required for medical devices. Medical grade optical isolators, U110 to U116 are used to provide the required isolation of patient contact circuits from the rest of the hardware. U105 is a medical grade DC to DC converter. Its output powers the patient circuits.

4.2.5 Stimulus Input

To provide definite time relationship between stimulus and response, the stimulus input signal is recorded in parallel with the response signals. Isolation between it source and patient contact circuits are provide by the optically isolated amplifier U119. This signal is also employed for measuring impedance between electrodes. In impedance mode this signal is routed to the ground electrode. The amount of signal pick up by the reference and active electrodes are used to calculate the resistances between the ground and these electrodes.

4.2.6 Communication and control

The controller, U102, use firmware that is stored in EPROM U101. The controller contains hardware USB interface and audio interface for the ADCs. It communicates with the PC via a USB hub that is located in the HEARLab SC. With the firmware, response acquisition is implemented as USB microphone devices. Control of EP circuits is implemented via USB HID protocol. A specific command set is defined by the firmware for specific controls.

Chapter 5: Two-Room Setup

The chapter describes how to set up the HEARLab System in a two-room setup with the patient in a sound proof room and the operator in a separate control room. See Figure 5.1.

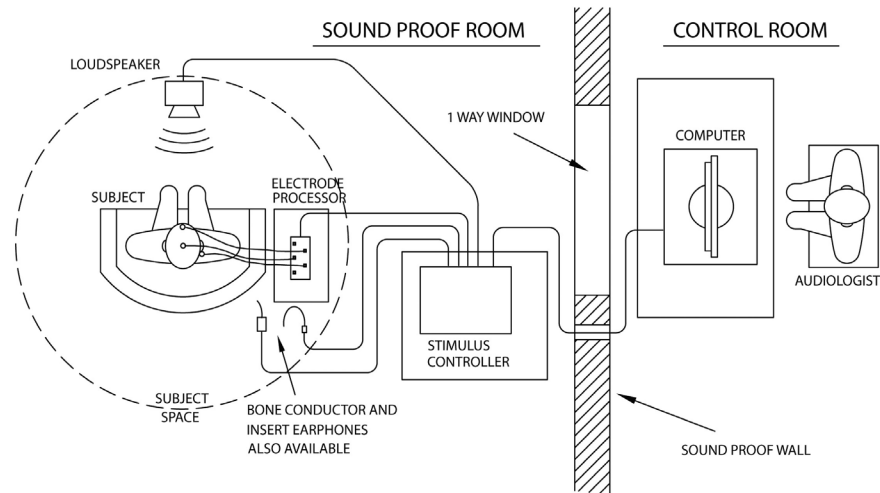


Figure 5.1: HEARLab ACA Two-Room Setup

The basic requirements described in the Operator's Manual for the one room setup apply. However, it may be useful to employ an external power amplifier and a monitor loudspeaker.

5.1 External power amplifier

If the distance between the loudspeaker and the nominal subject's head possible is going to be more than 1.2 meters (4 feet), an external power amplifier driving a higher power loudspeaker may be required.

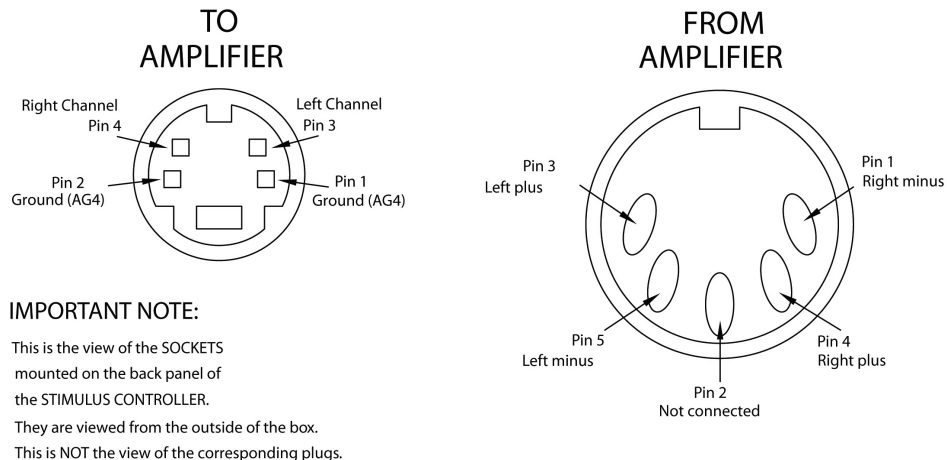
Two sockets located at the back of the Stimulus Controller labeled "To Amplifier" and "From Amplifier" are provided to facilitate such a setup.

5.1.1 Configuring the Software for a Two-Room System

Refer section 3.9.2 of this manual to set up the software to automatically employ the external loudspeaker during calibration and during testing.

5.1.2 Diagram of Amplifier Connections

Signal assignments for these sockets are defined in the following diagrams. Cables with the correct plugs may be obtained from authorized suppliers.



5.2 Monitor loudspeaker

For 2 room setup, a monitor loudspeaker may be employed to allow the tester in the control/observation room to acoustically monitor the test space, including the acoustic stimulus, subject and distracter's voices.

- The socket labeled “Monitor Speaker” at the back of the Stimulus Controller is provided for cabling.
- The software allows the tester to adjust the volume of the monitor speaker to suit.

Chapter 6: Safety

The HEARLab system complies with:

- IEC 60601-1 and AS/NZS3200.1.0 Medical electrical equipment - Part 1.0: General requirements for basic safety and essential performance.
- IEC 60601-1-2, collateral standard for Electromagnetic compatibility requirements
- Australian Therapeutic Goods Administration, Class 1 (Rule 4.1)
- European Medical Device Directive, Class 1 (Rule 12)
- U.S. FDA, Class 2
- ISO 13485: 2003

6.1 Safety Classification for IEC 60601-1

Type of protection against electrical shock: Class 1

Degree of protection against electrical shock: Type BF

Mode of operation: Continuous

Degree of protection against the ingress of water: Ordinary

The HEARLab System does not require sterilization.




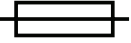

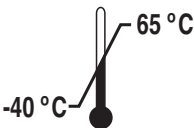
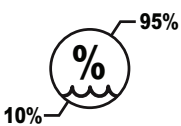
Warning: The HEARLab System is not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.

The HEARLab ACA software is indicated for use in the recording and analysis of human electro-physiological data as an aid in the assessment of hearing and hearing-related functions. The data is obtained with electrodes attached to the scalp of the subject to detect the presence or absence of electro-physiological signals that may be evoked in response to auditory stimulus. These electro-physiological signals being monitored are not intended to indicate signals vital to life or health or state of well being of the patient.

Note that for conformance to IEC 60601-1 Type BF patient isolation requirements the HEARLab System must be setup in accordance with instructions in the Operator's Manual.

It should be noted that it is the user responsibility to ensure that conformance to IEC 60601-1 Type BF patient isolation requirements are maintained when patient connected equipment or accessories not supplied by Frye Electronics are used with or in conjunction with the HEARLab System.

6.2 Meaning of Symbols

Symbol	Meaning
	Read the accompanying documents. Please read the Operator's Manual before operating HEARLab.
	Patient applied parts of HEARLab are type BF.
	CE signifies compliance with the European union's Medical Devices Directive 93/42/EEC.
	Replace fuses only with the same type and rating (1.0A, 250 V time delay)
	Keep dry. The HEARLab System should not be exposed to water or other fluids.
	The shipping/storage temperature of the HEARLab System is -40 to 65 degrees Celsius (-40 to 158 degrees Fahrenheit).
	The shipping/storage humidity of the HEARLab System is 10 to 95% relative humidity (non-condensing).

6.3 Electromagnetic Compatibility

6.3.1 Cables and Peripherals

Warning: The use of accessories, transducers and cables other than those listed in the table below may result in increased emissions or decreased immunity of the HearLAB System.

Cable	Maximum Length (m)
Control mic	4
Speech mic	2.5
Distractor headphones	1
TDH Headphones	2
Insert earphones	2.5
Electrode 1	1.5
Reference electrode	1.5
Ground electrode	1.5
Bone vibrator	2
Electrode processor	3
USB	2
Speaker	3
Monitor speaker	2

Peripherals		
Description	Manufacturer	Model/Part Number
Personal computer including keyboard, mouse and monitor	*	*
Speech mic		
Insert earphones	Eartone	3A
Headphones	Telephonics	TDH39P
Distractor headphones		
Control mic	Frye Electronics, Inc	Refmic
Bone vibrator	Radioear	B71
Speaker	Frye Electronics, Inc	034-2261-00
Active electrode	Frye Electronics, Inc	061-2192-00
Reference electrode	Frye Electronics, Inc	061-3192-00
Ground electrode	Frye Electronics, Inc	061-1192-00

* The personal computer must comply with the relevant EMC requirements for information technology equipment.

6.3.2 Electromagnetic Emissions Declaration

Guidance and manufacturer's declaration – electromagnetic emissions		
The HEARLab System is intended for use in the electromagnetic environment specified below. The customer or the user of the HEARLab System should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The HEARLab System 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. The HEARLab System is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
RF emissions CISPR 11	Class A	
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Warning: The HEARLab System should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, The HEARLab System should be observed to verify normal operation in the configuration in which it will be used.

6.3.3 Justifications of Lower Immunity Levels

Electrostatic discharge

The instrument is inherently sensitive to high voltage discharges. These discharges are approximately 10,000,000,000 times the amplitude of the measured signals. Although instrument performance may be affected, no data is recorded that adversely affects the outcome of the test when interrupted by such an electrical event. Further, no adverse harm comes to the patient from the application of these discharges

Radiated RF immunity

Exposure to radiated RF may cause disturbances of the active EEG trace. These disturbances will not affect the long term averages of the data. Further, if the interfering signal has an amplitude that introduces a signal that exceeds the dynamic range of the system, the epoch which was under recording when the interference occurred is automatically marked as invalid and discarded.

Electrical Fast Transient Burst

Electrical fast transients may cause interruption of the ACA software. The interruption of the program does not adversely affect the data or the patient.

Conducted RF Immunity


Exposure to conducted RF on the power line and cables may cause disturbances of the active EEG trace or speaker output. These disturbances will not affect the long term averages of the data. Further, if the interfering signal has an amplitude that introduces a signal that exceeds the dynamic range of the system, the epoch which was under recording when the interference occurred is automatically marked as invalid and discarded.

Any sounds issuing from the loudspeaker that are not synchronous with the computer driven stimulus are ignored by the averaging system.

6.3.4 Electromagnetic Immunity

Guidance and manufacturer's declaration – electromagnetic immunity			
The HEARLab System is intended for use in the electromagnetic environment specified below. The customer or the user of the HEARLab System should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment—guidance
Electrostatic discharge (ESD) IEC 61000-4-2	+/- 6 kV contact +/- 8 kV air	+/- 6 kV contact +/- 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	+/- 2 kV for power supply lines +/- 1 kV for input/output lines	+/- 2 kV for power supply lines +/- 1kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	+/- 1 kV differential mode +/- 2 kV common mode	+/- 1 kV differential mode +/- 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.

<p>Voltage dips, short interruptions and voltage variations on power supply input lines</p> <p>IEC 61000-4-11</p>	<p><5% U_t (>95% dip in U_t) for 0.5 cycle</p> <p>40% U_t (60% dip in U_t) for 5 cycles</p> <p>70% U_t (30% dip in U_t) for 25 cycles</p> <p><5% U_t (>95% dip in U_t) for 5 sec</p>	<p><5% U_t (>95% dip in U_t) for 0.5 cycle</p> <p>40% U_t (60% dip in U_t) for 5 cycles</p> <p>70% U_t (30% dip in U_t) for 25 cycles</p> <p><5% U_t (>95% dip in U_t) for 5 sec</p>	<p>Mains power quality should be that of a typical commercial or hospital environment. If the user requires continued operation during power mains interruptions, it is recommended that the HEAR-Lab System be powered from an uninterruptible power supply.</p>
<p>Power frequency (50/60 Hz)</p> <p>Magnetic field</p> <p>IEC 61000-4-8</p>	<p>3 A/m</p>	<p>3 A/m</p>	<p>Power frequency magnetic fields should be at levels characteristic of a typical commercial or hospital environment.</p>
<p>Note U_t is the a.c. mains voltage prior to application of the test level.</p>			

Guidance and manufacturer's declaration – electromagnetic immunity			
The HEARLab System is intended for use in the electromagnetic environment specified below. The customer or the user of the HEARLab System should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 Vrms 3 V/m	<p>Portable and mobile RF communications equipment should be used no closer to any part of the HEARLab System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> $d = 1.2 \sqrt{P}$ $d = 1.2 \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = 2.3 \sqrt{P} \quad 800 \text{ MHz to } 2.5 \text{ GHz}$ <p>Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters as determined by an electromagnetic site survey,^a should be less than the compliance level in each frequency range.^b</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> <div style="text-align: center;">  </div>

Note 1 At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the HEARLab System is used exceeds the applicable RF compliance level above, the FP35 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the HEARLab System.

^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m

Recommended separation distances between portable and mobile RF communications equipment and the HEARLab System			
The HEARLab System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the HEARLab System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the HEARLab System as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
<p>For transmitters rated at a maximum output power not listed above, the recommended distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.</p> <p>NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.</p> <p>NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			

Chapter 7: Schematic Drawings

Page	Name	Part #	Drawing #
1	SC Upper - Digital Control	061-0190-02	999-3028-00 (1)
2	SC Upper - Signal Processing	061-0190-02	999-3028-00 (2)
3	SC Upper - Power Distribution	061-0190-02	999-3028-00 (3)
4	SC Lower - Digital Control	061-0191-02	999-3029-00 (1)
5	SC Lower - Codec & Ext Control Relay	061-0191-02	999-3029-00 (2)
6	SC Lower - Analog Signal Amplifiers & Filters	061-0191-02	999-3029-00 (3)
7	SC Lower - Power Supplies	061-0191-02	999-3029-00 (4)
8	Stimulus Controller Block Diagram	N/A	999-3036-00
9	Electrode Processor - Digital Control	061-0194-01	999-3030-00 (1)
10	Electrode Processor - Electrode Signal Processing	061-0194-01	999-3030-00 (2)
11	Electrode Processor Block Diagram	N/A	999-3035-00
12	Active Electrode (ACTELEC)	061-2192-00	999-3031-00
13	Ground Electrode (GNDELEC)	061-1192-00	999-3032-00
14	Reference Electrode (REFELEC)	061-3192-00	999-3033-00
15	Primary Wiring H1000	N/A	999-3034-00
16	Impedance Test Fixture	061-0194-00	999-3016-00

Note: Raw circuit boards are marked with part number prefix “060-”. The part number prefix changes to “061-” for assembled boards.