Opti-Amp USB

Optical Bio-Amplifier System
Manual Version 1.0

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Safety Instructions:

Complying with the following warnings and caution statements will ensure safe operation of the equipment as well as the safety of the users and patients. The following labels identify dangerous conditions and their possible effect. These symbols are used throughout the manuals:

WARNING:

This symbol identifies conditions or practices that may present danger to the patient and/or user.

CAUTION:

This symbol identifies conditions or practices that could result in damage to the equipment or in incorrect results.

WARNING:

When testing human subjects, an Isolation Transformer must be used:

Due to safety considerations, the system must be plugged into an Isolation Transformer in order to avoid the risk of electrical shock.

The computer and printer used with the system must be connected to the same Isolation Transformer.

Equipment that is not a part of the system and was not provided or approved by IHS must not be connected to the Isolation Transformer.

The Isolation Transformer must not be placed on the floor to prevent the accidental ingress of fluids.

WARNING:

Connect the power cable ONLY when the power switch is in the OFF position, failure to do so may damage the equipment.

Power cables shall be connected to electrical outlets approved by international standard IEC-60601. This is necessary for grounding reliability and proper isolation.

Connect all cables and verify all connections before turning on the power.

The System must be tested for leakage current by the biomedical engineering department of your institution.

The biomedical department of your institution must make sure that the leakage current test results comply with the requirements of your region.

The system must be tested thoroughly before connecting any patients.

Computers connected to a network need to be tested for leakage current while connected to the network, a network connection may affect total leakage current.

The System is not explosion proof and must not be used in presence of flammable gases or substances.

The system is not protected against defibrillators. Remove patient connections before defibrillation. If defibrillation occurs, retest the system for leakage current to ensure safety.

Hazardous electrical output may occur. This equipment is for use by qualified personnel only.

The operator must not touch any of the electrical cables and the patient at the same time.

Patient connections are not intended for direct cardiac contact, although they are electrically isolated.

WARNING:

Read and follow the instructions in the Hardware Installation manual when installing or transferring the system.

Dispose properly of batteries; follow the rules and regulations of your area, or institution, for proper disposal.

Do not clean ear canal unless you are a certified audiologist or physician trained in this procedure. Irreversible injury may result to patient if an unqualified person cleans the ear canal.

CAUTION:

Do not operate with damaged cords or plugs. Inspect all connection cords periodically for fraying or other damage.

The power supply provided with the Universal Smart Box is intended for use with that unit only; do not attempt to use this power supply with other equipment.

When connecting all cables, do not force the connection, damage to the hardware may occur.

Read and follow the instructions provided in the user manual to ensure safe and proper use of the equipment.

Ensure that the patient electrode leads are correctly attached and connected to the appropriate plug. Inverting the electrode connections may cause incorrect results and misdiagnosis.

Non-medical equipment that will be connected to all IHS devices must comply with the necessary standards for you area.

Turn off and disconnect all equipment all parts of the equipment when performing maintenance and cleaning.

Table of Contents

Introduction

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Welcome to the Intelligent Hearing Systems family of customers. Please be sure to read all the enclose documentation. Doing so will allow you to use the equipment safely. It will also allow you to maximize the benefits from this great investment.

Product Features

Opti-Amp USB is an accessible optical bio-amplifier system. Some of its features are:

- Up to eight programmable EEG or OAE channels
- Programmable Gain, High Pass Filters and Low Pass Filters
- Built in electrical noise notch filter customized for your power supply,

Opti-Amp USB works under the Windows© 98SE, ME, 2000 and XP operating systems. This manual assumes that you are familiar with the basic operation of these operating systems and their capabilities. Please refer to the operating system manuals when necessary.

Product Installation

To install the Opti-Amp USB, follow these steps:

1. Insert the installation CD into the computer's CD Drive
2. The Installation program will start automatically
3. Select the folder where you want the application installed and press the Start Button to proceed.
4. Once the software is installed, connect the hardware to the computer. Refer to page 3 for specific instruction on hardware connections.
5. Turn the power switch ON. The Switch can be found in the back of the box next to the power plug.
6. The computer will automatically detect the device and look for the device driver. If the operating system does not find the driver automatically, select the IHSUSB40.INF file from the software installation directory.

The system is now ready to use.

Customer Responsibility

The equipment, its components and included software shall perform reliably as long as it is operated and maintained in accordance with the instructions contained in the manuals, associated labels and inserts. A defective component must not be used. New IHS-manufactured parts should promptly replace broken, missing or worn parts. If you suspect a part of the equipment to be defective or if you need additional information, please contact IHS.

The responsibility of IHS is limited by the warranty as stated in the technical reference manual. Should the repair or replacement of the product become necessary after the end of the warranty period, the user must consult IHS before such repair or

replacement. If the product is in need of repair, do not use it until all repairs are completed, the unit is functioning properly and is appropriately tested. The owner of this product has sole responsibility for the following:

- Any malfunction resulting from improper use,
- Maintenance or repairs done by other than IHS,
- Any malfunction caused by parts that are damaged or modified by anyone other than IHS authorized personnel.

WARRANTY

Opti-Amp is manufactured by Intelligent Hearing Systems Corp. (IHS), Miami, FL and is sold under the warranty herein set forth. The warranty is extended only to the buyer purchasing the device from IHS or an authorized dealer-representative.

IHS warrants this product to be free from defects in workmanship and material under normal use and service and shall conform to its original specifications for a period of one (1) year from the date of delivery. The liability of IHS under this warranty is limited, at its sole discretion, to replacing, repairing or issuing credit (adjusted to reflect age and use of the product) for a system or portion thereof provided that (a) IHS is notified in writing within 30 days following the discovery of a defect by the buyer, (b) the defective device is returned to IHS, and (c) IHS's examination of the device shall disclose to its satisfaction that (i) the device has not been repaired or altered by anyone, (ii) any defect has not been caused by misuse, neglect or accident, and (iii) the device has not been used for other than normal use.

THIS WARRANTY IS EXPRESSLY IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, WHETHER STATUTORY OR OTHERWISE, INCLUDING AN IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. IN NO EVENT SHALL INTELLIGENT HEARING SYSTEMS CORP. BE LIABLE FOR ANY INCIDENTAL OR CONSEQUENTIAL DAMAGES RESULTING FROM THE USE OF THIS PRODUCT OR CAUSED BY ANY DEFECT, FAILURE, OR MALFUNCTION OF THE PRODUCT, WHETHER A CLAIM FOR SUCH DAMAGE IS BASED UPON WARRANTY, CONTRACT NEGLIGENCE OR OTHERWISE.

Hardware

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Parts and Accessories

The Opti-Amp optical bio-amplifier system includes the parts as outlined in the following list. If a part is damaged or missing, please contact Intelligent Hearing Systems immediately. Actual contents of the system depend on the configuration ordered. Systems with a single EEG channel will have a single channel transmitter box and a single channel fiber optic cable. Systems with more than one EEG channels will have one transmitter box for every two EEG channels. Systems with one or more OAE channels will include an OAE Probe per channel ordered. Pictured Items are not to scale.

Opti-Amp USB Box 	Opti-Amp Transmitter Box* 	OAE Probe* 
USB Cable 	Medical Power Cord 	Fiber Optic Cable* 

*These items are optional and depend on product configuration, see the packing list for actual included items.

Hardware Connections

The Hardware must be properly connected before you are able to use the system. Follow these instructions and refer to Figure 1 to connect the system:

1. Make sure that the Opti-Amp USB box power switch is in the OFF position **(2)**.
2. Connect the Medical Power cord **(E)** to the power receptacle found on the back of the box, next to the power switch **(1)**.
3. Connect the medical power cord plug **(F)** to the electrical outlet that you wish to use. An Isolation transformer is required for safety purposes specially when testing human subjects.

4. Connect the square end of the USB Cable(A) to the back of the USB connector of the Opti-Amp USB Box (6)
5. Connect the Flat end (B) to an available USB Port from the target computer.
6. If the system has EEG Channels, connect the round end of the fiber optic cable (C) to the corresponding connector inputs of the Opti-Amp USB box (4) and the square end (D) to the matching output of the Opti-Amp transmitter box. In two channel systems, Red corresponds to the Right channel and Blue corresponds to the Left channel.
7. If the system has OAE channels, connect the OAE probe(s) to the corresponding channel input (3).
8. Connect all other necessary cables to the channel outputs (4) for your particular implementation.

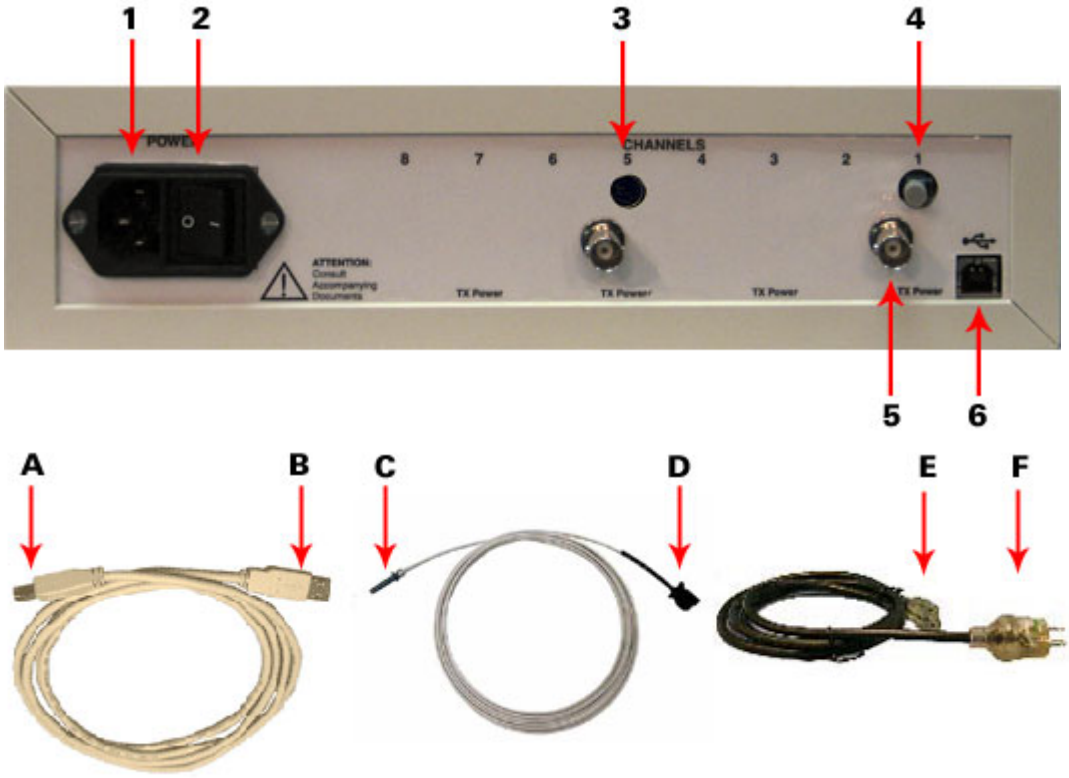

Figure 1 - Opti-Amp Connectors and Cables

Opti-Amp USB	
1	Power Input
2	Power Switch
3	OAE Probe Connector
4	Fiber Optic Receiver
5	BNC Output
6	USB Port

Cables	
A	USB Cable Square Connector
B	USB Cable Flat Connector
C	Fiber Optic Receiver End
D	Fiber Optic Transmitter End
E	Power Cord Connector
F	Power Cord Plug

Opti-Amp Transmitter Box

The Opti-Amp transmitter box houses the receptacles for the electrodes. Transmitters come in single or dual configurations. The transmitter converts Bio-Electrical Potential signals to light pulses to be transmitted via the optical cable(s) to the receiver board for optimal isolation and minimal electrical noise. The single channel transmitter has an additional switch that allows the user to reverse the electrodes, hence selecting the electrodes from which data is to be collected.

Batteries

The Opti-Amp transmitter uses two (2) 1.5-volt AA-size alkaline batteries. Be sure not to use rechargeable NiCADs or NiMH batteries, these batteries are of a lower voltage level and will not let the transmitter box work correctly.

Note: if you will not be using the Opti-Amp for a long time, take the batteries out of the Opti-Amp box, place them somewhere else cold and dry. As with any other battery-powered device, leaving the batteries inside for extended periods without use may cause the batteries to leak and damage the transmitter box. To take out the batteries, turn off the Opti-Amp by turning the rotary switch to the off position. Open the back of the Opti-Amp and take the batteries out from the batteries holder.

How to Test the Batteries

Test the batteries prior to and after patient data acquisition by rotating the switch to the "ON" position or one of the electrode impedance positions. When the switch is at the “ON” position, a beeping sound will indicate that the batteries need to be changed. When the switch is at one of the electrode impedance positions, the “Battery Check” light will not be lit or will be very dim and the batteries are to be replaced before another patient can be tested. If the batteries are still charged, the battery-check LED (Light Emitting Diode) will light up and stay bright when the rotary switch is set to any impedance checking position.

Battery Replacement Instructions

When replacing the Opti-Amp transmitter batteries, open the slot on the transmitter unit. Carefully remove both used batteries and replace with two new batteries. Make sure the batteries are connected with the correct polarity. The polarity is indicated on the battery container. After replacing the batteries, retest the batteries as previously described. For extended battery life, always make sure that the rotary switch on the transmitter unit is in the OFF position while not being used.

Specifications

- Frequency Response: 1 Hz - 5,000 Hz (-6 dB)
- 60 Hz Notch Filter: On/Off (-12 dB)
- Input Impedance: 5 M-Ohms
- Noise: 0.6 Microvolt RMS (1 - 3,000 Hz)
- Output: Single Ended, Maximum Swing of +/- 10 volts
- Common Mode Rejection: > 113 dB at 1 kHz
  105 dB at 60 Hz (with notch filter off)
- Size: 19 cm x 10 cm x 4 cm (7.5" x 4.0" x 1.6")
- Weight: < 450 g (< 16 oz)

Software

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If the software is not already installed in your computer, follow the steps on page 1. The software is accessible from the Windows start menu under the programs > OptiAmp folder. You may also access the program by browsing to the installation directory.

Program Layout

Opti-Amp is a multipurpose Bio-Electrical Potentials (EEG, EMG) or OAE amplifier system that can be interfaced to any data acquisition hardware. A maximum of 8 channels may be added to the USB box assembly. The Opti-Amp software allows for easy setup of gain and filter settings for each channel independently. The program layout will change depending on the number of channels purchased with the Opti-Amp as seen on the following figures.

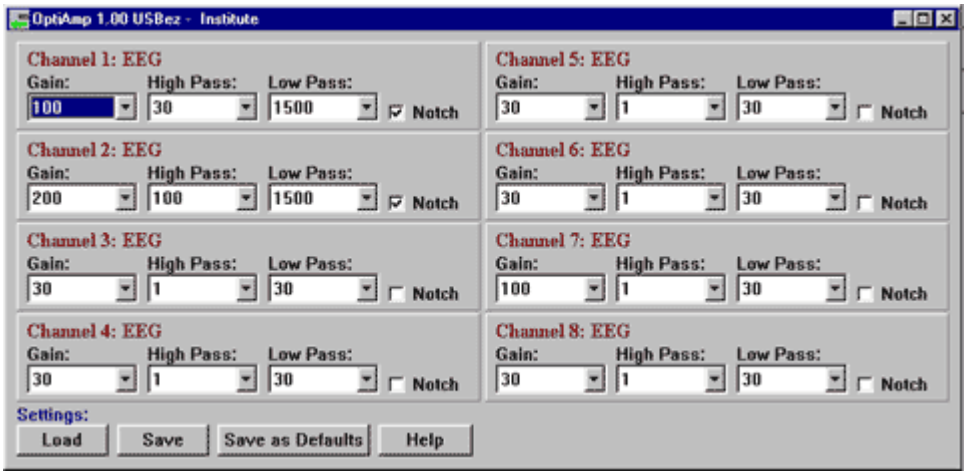

Figure 2 - Opti-Amp with Eight Channels

Figure 3 - Opti-Amp with Two Channels

EEG Channels

Each EEG channel will be labeled as such be the channel designation marker as shown in Figure 4. EEG channels contain settings for the Gain, High Pass filter and Low Pass filter. The Line Filter can be turned ON and OFF using the checkbox on the lower right hand corner. The built in line filter will be set to 50 or 60 Hz depending on the electrical supply in your area.

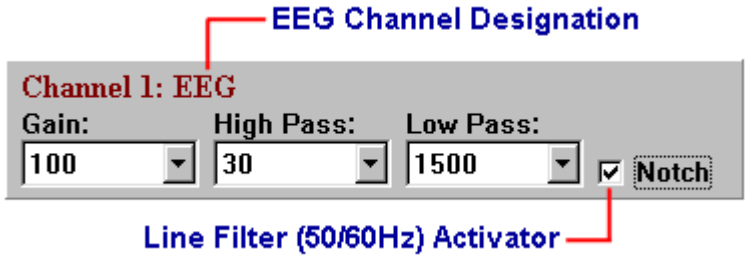

Figure 4 - EEG Channel Layout

EEG Channels Gain

The Opti-Amp USB provides eight (8) EEG Gain settings:

1	30k
2	50k
3	75k
4	100k
5	150k
6	200k
7	250k
8	300k

Listed Gains are the standard gains normally included in the device, actual gain values may vary if your system was special ordered. Refer to the drop down gain menus for actual again values that apply to your system. Gain settings may be custom made to any eight values between 5k and 500k

EEG Channels Filters

The Opti-Amp USB contains eight (8) Low Pass and eight (8) High Pass filter settings. The filter settings indicate the -6 dB amplitude frequency for a single pole RC filter.

	LOW PASS		HIGH PASS
1	30	1	1
2	100	2	10
3	300	3	30
4	500	4	50
5	1000	5	100
6	1500	6	150
7	3000	7	300
8	5000	8	500

Listed filters are the standard filters normally included in the device, actual filter values may vary if your system was special ordered. Refer to the drop down filter menus for actual filter values that apply to your system. Filter settings may be custom made to any 16 values between 0.5 Hz and 10 kHz.

OAE Channels

Each OAE channel will be labeled as such be the channel designation marker as shown in Figure 4. OAE channels contain settings for the Gains. The TrOAE Filter can be turned ON and OFF using the checkbox on the lower right hand corner.

Figure 5 - OAE Channel Layout

OAE Channels Gain

The Opti-Amp USB provides eight (8) OAE Gain settings:

1	100
2	300
3	500
4	1000
5	2000
6	4000
7	8000
8	10000

Listed Gains are the standard gains normally included in the device, actual gain values may vary if your system was special ordered. Refer to the drop down gain menus for actual again values that apply to your system. Gain settings may be custom made to any eight values up to 10000.

TrOAE Filters

The use of filters detriments the acquisition of DPOAE data, however, active filters are necessary for the acquisition of TrOAE data. Checking the TrOAE Filter activator will bring online the active filters. The active filter has a range of 450 Hz to 5 kHz. Make sure you deactivate this option when acquiring DPOAE recordings.

Program Settings

All settings of the program may be saved to a file and retrieved for a later use. They may also be set as default settings, so that those settings are loaded upon start-up.

- Save current settings use the Save button
- Load previously saved settings using the Load button
- Make the settings default with the Save as Default button

Opti-Amp settings files have the .SET file extension and should preferably be saved to the Settings_OptiAmp directory from the installation directory.

EEG Electrode Configurations

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Before acquiring data, make sure that the optical cable(s) are properly connected to the receiver and transmitter units and all electrodes are properly connected to the transmitter unit. Also, make sure the output of the Opti-Amp USB Box, for the corresponding channel, is properly connected to your averaging system. Check to see that the power switch on the transmitter box is set to the ON position.

Example of Electrode Placement (ABR)

The electrodes should be placed according to the following diagrams, once in place, impedance check is necessary for proper for testing. The electrode leads are connected to the electrode plugs located on the top cover of the transmitter box. Electrodes should ONLY be connected to the Transmitter Box. Do not connect electrodes to any other plug or alter the circuit to connect electrodes directly to another position.

One Channel Opti-Amp (Figure 2):

Right mastoid electrode:	connects to RED plug on Transmitter Box
Left mastoid electrode:	connects to BLUE plug on Transmitter Box
High forehead electrode:	connects to BLACK plug on Transmitter Box

NOTE: Remember to set the left/right switch to the appropriate ear.

Two Channel Opti-Amp - testing right/left ear only (Figures 3A and 3B):

Test ear mastoid electrode:	connects to RED plug on Transmitter Box
Other ear mastoid electrode:	connects to BLACK plug on Transmitter Box
High forehead electrode:	connects to BLUE plug on Transmitter Box

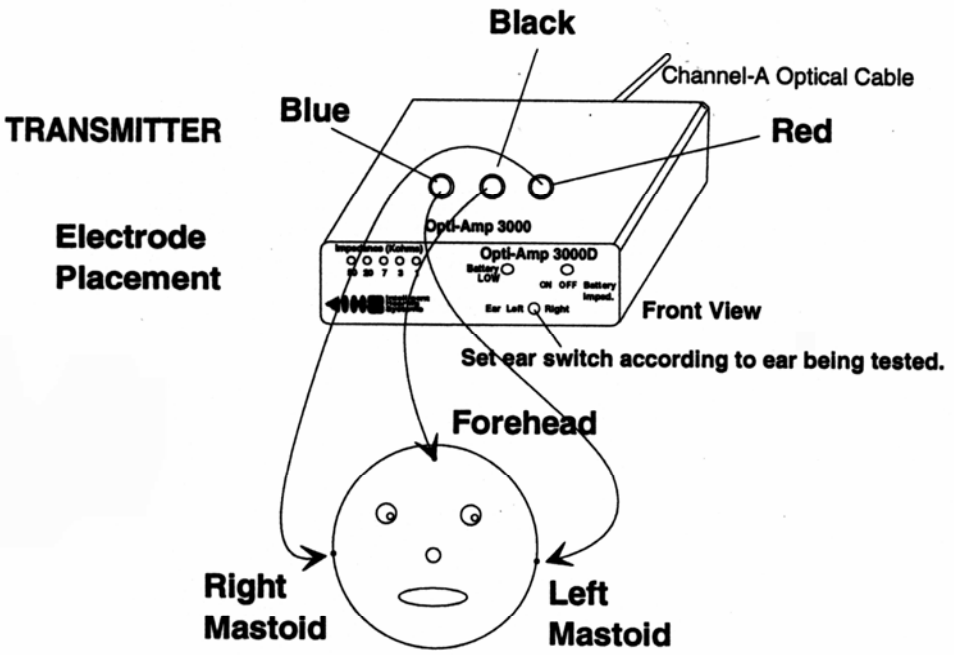
NOTE: Remember to connect electrode leads to the appropriate site on the Opti-Amp transmitter box:

- Side A when testing right ear (Figure 3A)
- Side B when testing left ear (Figure 3B)

Two Channel Opti-Amp - testing both ears (Figure 4):

Test ear mastoid electrode:	connects to RED plug - side A on Transmitter Box
Other ear mastoid electrode:	connects to RED plug - side B on Transmitter Box
Low forehead electrode:	connects to BLACK plug on Transmitter Box
High forehead electrode:	connects to BLUE plugs via Y-adaptor on Transmitter

Electrode Configuration for 1 Channel Differential Opti-Amp Transmitter

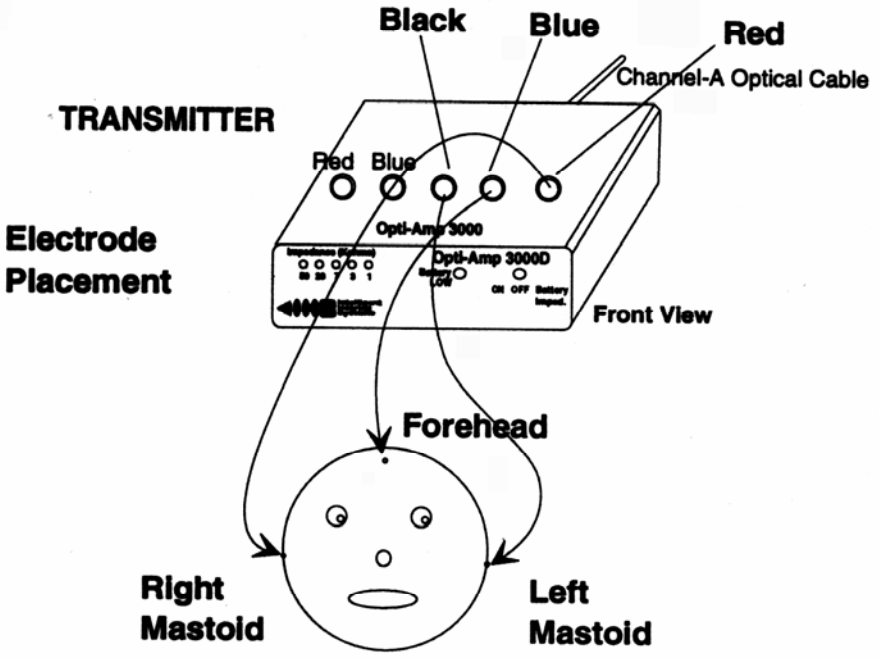


RED - Right Ear (Negative when testing right ear / Ground when left ear)
BLUE - Left Ear (Negative when testing left ear / Ground when right ear)
BLACK - Forehead (Positive electrode)

CAUTION - CONNECT TO PATIENT'S RIGHT AND LEFT MASTOIDS! OPPOSITE FROM YOUR RIGHT & LEFT WHEN LOOKING AT PATIENT FACE TO FACE.

Figure 2

Electrode Configuration for 2 Channel Differential Opti-Amp Transmitter (Testing Right Ear Only)

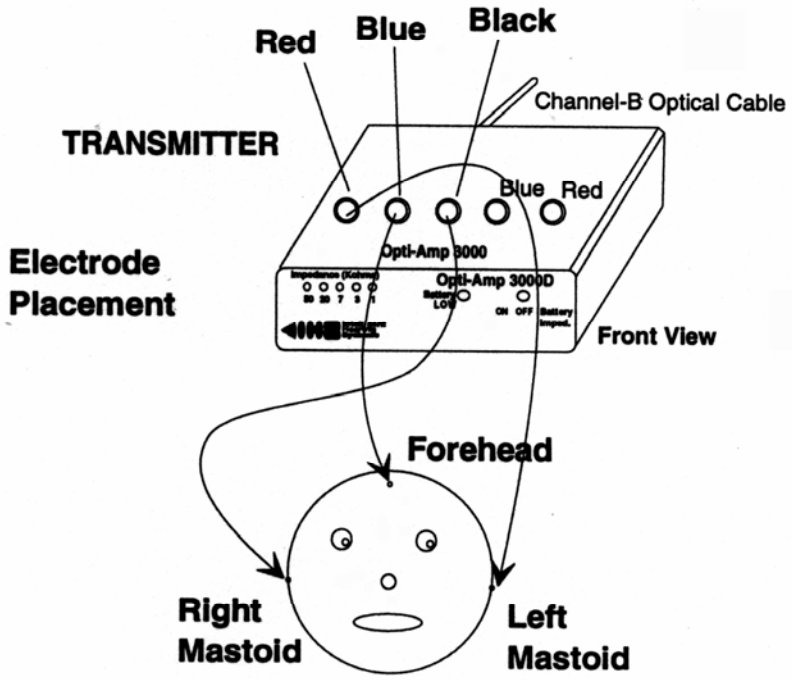


RED - Test Ear (Negative Electrode)
BLUE - Forehead (Positive Electrode)
BLACK - Other Ear or Forehead (Ground Electrode)

CAUTION - CONNECT TO PATIENT'S RIGHT AND LEFT MASTOIDS! OPPOSITE FROM YOUR RIGHT & LEFT WHEN LOOKING AT PATIENT FACE TO FACE.

Figure 3-A

Electrode Configuration for 2 Channel Differential Opti-Amp Transmitter (Testing Left Ear Only)

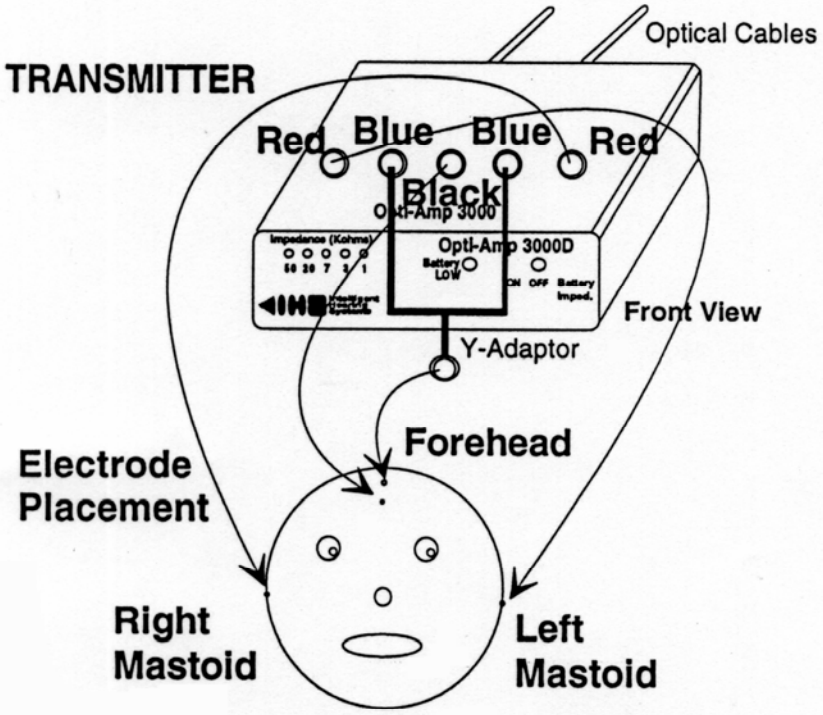


RED - Test Ear (Negative Electrode)
BLUE - Forehead (Positive Electrode)
BLACK - Other Ear or Forehead (Ground Electrode)

CAUTION - CONNECT TO PATIENT'S RIGHT AND LEFT MASTOIDS! OPPOSITE FROM YOUR RIGHT & LEFT WHEN LOOKING AT PATIENT FACE TO FACE.

Figure 3-B

Electrode Configuration for 2 Channel Differential Opti-Amp Transmitter (Testing Both Ears)



RED - Test Ear (Negative Electrode)
BLUE - Forehead (Positive Electrode)
BLACK - Other Ear or Forehead (Ground Electrode)

CAUTION - CONNECT TO PATIENT'S RIGHT AND LEFT MASTOIDS! OPPOSITE FROM YOUR RIGHT & LEFT WHEN LOOKING AT PATIENT FACE TO FACE.

Figure 4

Programming

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External Controls

The Opti-Amp parameters can also be controlled from another application using the Windows Clipboard to send and receive information. To enable this option, select the "Enable External Program Control" check box on the lower right side of the Opti-Amp dialog box. If you wish this option activated the next time you run the Opti-Amp software, save the current settings as the Default settings.

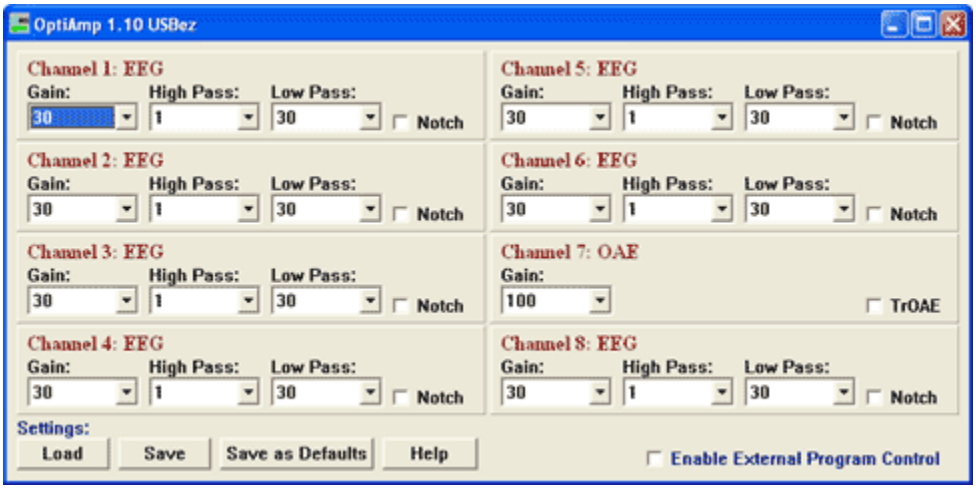

Figure 6 - Opti-Amp Main Screen

Available Instructions

Instruction:	Purpose:
OPTIAMP-CHx-GAIN=n	Programs Channel x Gain to option n
OPTIAMP-CHx-HP=n	Programs Channel x to High Pass option n
OPTIAMP-CHx-LP=n	Programs Channel x to Low Pass option n
OPTIAMP-CHx-SWITCH=ON	Programs Channel x Line Filter On (EEG) or TrOAE Filter On (OAE)
OPTIAMP-CHx-SWITCH=OFF	Programs Channel x Line Filter Off (EEG) or TrOAE Filter Off (OAE)
OPTIAMP-SAVE	Saves the current settings as default.
OPTIAMP-CLOSE	Closes the Opti-Application

Example Program:
(The exact syntax may vary depending on the language you are using.)

```
WinExec('OptiAmp.Exe');  // Use this or similar instruction to run the Opti-Amp software
ClipBoard.AsText:='OPTIAMP-CH1-GAIN=3'; // Sets Channel 1 gain to 3rd option
Delay(1000); // Use a delay to wait for OptiAmp to respond to your instruction
TempStr:=ClipBoard.AsText; // Read the confirmation from OptiAmp
If TempStr='OK-OPTIAMP-CH1-GAIN=3' then ShowMessage('OK!');
```

An OK statement followed by the instruction sent, indicates that the Opti-Amp Software accepted and programmed the instruction. An ERROR statement indicates that the Opti-Amp software did not understand a portion of your instruction.

The simplest way to test the communications module is to run Notepad and type in some instructions. Position the Opti-Amp software and the Notepad window in such a way that you can see both program windows at the same time on your computer screen. Type an Opti-Amp instruction in Notepad, highlight the instruction and press [Control] + [C] to copy the text to the Clipboard. You should see the appropriate value change on the Opti-Amp dialog window. Now if you press [Control] + [V], you will see the confirmation statement (i.e. "OK-Instruction") appear on the Notepad.

Programming Tips

It is important not to lock out the Windows Clipboard by continuously reading or writing to the Clipboard. This will not allow other applications to write or read from the Clipboard. A delay or interrupt method may be used in order to allow the Opti-Amp application time to read and write to the Clipboard.

It is also important to read the format of the data currently on the clipboard. If another application places graphical data on the clipboard, reading it as a text may cause your application to crash.

The Opti-Amp program allows you to save the current settings as defaults. The next time you run the Opti-Amp program, all the default settings will be loaded and the Opti-Amp hardware programmed accordingly. The only way to make sure that all the settings are set as your application desires is to program all the settings each time you run your application. If someone changes the settings and saves them as the default settings, your application will not know if those values have been changed or not. Unless you are sure that no one can modify your settings, you should not assume that the loaded default values are the ones you want to use.

For additional information about controlling Opti-Amp from another application, contact Intelligent Hearing Systems.