TeleDiagnostic Systems

Alpha400

Isolated USB EEG Amplifier
4 EEG Channels + 3 Aux Channels

Operation
Manual

A user's guide to the operation of the Alpha400 Isolated EEG amplifier.

Read Instruction Manual Before Use

The Alpha400 EEG Amplifier is electrically isolated from the line power and ground. However, if used within a hospital setting your facility may require that computers used with patient connected medical devices must also be isolated from line voltage according to UL medical safety standards. Consult with your biomedical department before use.

CAUTION

THIS DEVICE IS FOR SALE TO, OR ON THE ORDER OF, A LICENCED HEALTHCARE PROVIDER.

Per the 510K registration of The Alpha400 amplifier with the Food and Drug Administration as a medical device, US Federal Law restricts this device to sale by, or on order of, a licensed healthcare provider. The Alpha400 amplifier is intended for use only under the direct supervision of a licensed healthcare professional specifically trained in the application of EEG.

WARNING

Potential Explosion Hazard; Do not use in the presence of a flammable anesthetic mixture, or with Oxygen or Nitrous Oxide.

The metal enclosure chassis of the PC used with the Alpha400 amplifier must be placed outside the immediate patient/client vicinity (at least 10 feet), or the PC must be separately isolated and comply with EN60601-1-1 standards for medical system safety.

If reusable electrodes are used with the Alpha400 amplifier, these may present a potential risk of cross infection especially when used on abraded skin, unless they are restricted to a single patient or sterilized between patients.

The Alpha400 amplifier is not defibrillator proof, and is not intended for critical care patient monitoring or life support applications.

NOTICE

INSTALL SOFTWARE BEFORE CONNECTING THE Alpha400 AMPLIFIER TO YOUR COMPUTER.

The Alpha400 connects to a computer via a USB interface and requires software in order to operate. The Alpha400 is a "plug-and-play" device; and when you attach the Alpha400 to your computer for the first time it will be detected by Windows, and Windows will then attempt to locate and install the USB drivers required to support the amplifier. Please refer to the Software Installation section of this manual and follow the instructions for installing the Alpha400 software **BEFORE** connecting the Alpha400 to your computer for the first time.

If you have not already installed the Alpha400 software prior to connecting the amplifier to your computer, Windows will likely load a default USB driver that will NOT properly work with the Alpha400 amplifier and may prevent installation of the correct drivers. If this should happen, with the Alpha400 attached to your computer, you will need to go to the Device Manager and manually uninstall any driver that Windows has installed for the Alpha400. After uninstalling that driver you can then disconnect the Alpha400 amplifier and proceed to install the Alpha400 software according to the instructions in this manual.

USE, MAINTENANCE, AND CALIBRATION

INTENDED PURPOSE: EEG neurofeedback training.
EEG acquisition and recording for neurodiagnostic applications.
EEG acquisition and recording for research applications.

CONTRAINDICATIONS: none

The Alpha400 amplifier may be cleaned by wiping with a clean cloth.

No preventative inspections are required. Maintenance must be performed by qualified personnel.

The Alpha400 amplifier has been factory tested and calibrated to ensure the accuracy and frequency response of EEG measurements. The amplifier contains an integrated calibration function that allows the user to verify amplifier parameters.

The user of the Alpha400 amplifier must be familiar with the characteristics of EEG signals that are acquired and displayed by EEG systems. The user must be able to recognize artifacts and any anomalies in the EEG signals that may interfere with the effectiveness of the neurofeedback training or other EEG applications.

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Installation

Unpacking

The Alpha400 amplifier shipment will contain four items: The Alpha400 Amplifier, a USB cable, an Alpha400 Program CD, and this User's Manual. The optional electrode hook-up and supply kit may also be included if this option was ordered along with your amplifier.

Locate the packing slip. Carefully inspect all items for signs of any shipping damage. If any item appears to be damaged, please contact the EEG Spectrum customer service department immediately.

After inspecting for shipping damage, review the packing slip and assure that all items listed have been received. Check the serial number of each item that has a listed serial number to be sure it corresponds to the packing slip.

The setup and installation of the Alpha400 amplifier is extremely simple and straightforward. The next section will guide you through the process.

Software Installation

NOTICE: Do not attach the Alpha400 amplifier to your computer until AFTER you have completed the software installation process.

USB 2.0 support is required by the Alpha400 interface. Many systems produced prior to 2003 may require an update in their BIOS and/or hardware in order to provide USB 2.0 compatibility.

The Alpha400 amplifier is a precision EEG amplifier "front-end" acquisition system used to input EEG signals into a software application such as the EEGer software from EEG Spectrum. The Alpha400 is also provided with its own test application that may be used to verify the proper connection and operation of the amplifier. The following instructions will guide you through the installation onto your computer of the Alpha400 Test program, along with the drivers necessary to support the Alpha400 interface.

As of this time the Alpha400 Test Program has only been tested with Windows-XP Pro with Service Pack 2 installed, and with Windows Vista 32-bit. Before proceeding with the installation please close any applications that are currently running under Windows so that you are at the Windows desktop.

Locate the Alpha400 Test Program CD that was included with your amplifier and insert the CD into your CD drive. The installation program should then launch automatically and you will see the opening installation "Welcome" dialog. Click the "Next" button to proceed with the installation.

You will then see a series of dialogs, "Attention" message boxes, and RegSvr32 message boxes that will appear during the installation process. Continue to click either the "Next", or the "OK" button for each of these messages to proceed with the installation.

When the installation has finished, you will see the "Setup Complete" dialog.   Click the "Finish" button to complete the setup.

Alpha400 Driver Installation

Leave the installation CD in the CD drive following installation of the Alpha400 software.   When you are again at the Windows desktop you may then attach the USB cable from the Alpha400 amplifier to an available USB input on your computer.

As soon as this cable is plugged into your computer you should observe the USB indicator light up on the Alpha400 amplifier.   Windows will then automatically detect the attachment of the Alpha400 amplifier and you will see a message from Windows stating "New Hardware Found" and Windows will launch the "Found New Hardware Wizard".

The first message from the Found New Hardware Wizard will ask if you want to "Connect to Windows update to search for new software?"   Select the "No, not this time" option, and then click "Next".

At the next screen select the "Install software automatically" option, and then click "Next".   There will be two drivers installed during this process.   When the drivers have been installed, you will see the "Completing the found new hardware wizard" dialog. Click the "Finish" button to complete the installation of the Alpha400 drivers.

Files and Folders

The installation process will create an Alpha400 folder under your "Program Files" folder on your C: drive. (C:\Program Files\alpha400)   The main program files for the Alpha400 Test program will be installed into this folder. In addition, two INF files will be copied to the Windows folder, and two SYS files will be copied to the \Windows\System32 folder.   Copies of these files are also saved in the Alpha400 folder in case you need to reinstall the Alpha400 driver at sometime in the future.

The installation program will also create an Alpha400 Shortcut icon on your Windows desktop.   You can start up the Alpha400 Test program by double-clicking on this icon.

Initial Testing

After you have completed the installation of the Alpha400 Test program and the Alpha400 Drivers, you may double-click the Alpha400 icon on the Windows desktop to start the Alpha400 Test program.
The Alpha400 Test program will then start up and you will see the screen as shown in figure 1 below.

If you attempt to start the Alpha400 Test program, but the Alpha400 amplifier is not connected to the computer, you will receive the message: "USB Driver failed to open". If you receive this message, verify that the USB cable is connected from the Alpha400 amplifier to the computer, and that the USB light is lit on the Alpha400.

The Alpha400 amplifier obtains all of its power for operation directly from the USB cable. The USB interface portion of the amplifier remains powered on constantly as long as the USB cable is attached. This allows the amplifier to receive commands from the computer at any time. The Alpha400 amplifier also features a second fully isolated internal power supply to safely operate the amplifier portion of the circuitry. This section of the Alpha400 amplifier may be powered ON and OFF through software commands. This design allows the Alpha400 amplifier to be left continuously attached to the computer for convenience and powered ON and OFF as required for use. This design reduces the power consumption from the USB when not in use and extends the operating life of the amplifier.

Before doing anything with the Alpha400 amplifier you need to first turn the main Power ON. Do this by clicking the POWER button on the Alpha400 Test program. You will observe that the button will light up when it has been clicked, and the POWER light will also light up on the Alpha400 Amplifier.

Figure 1: Alpha400 Test Program.
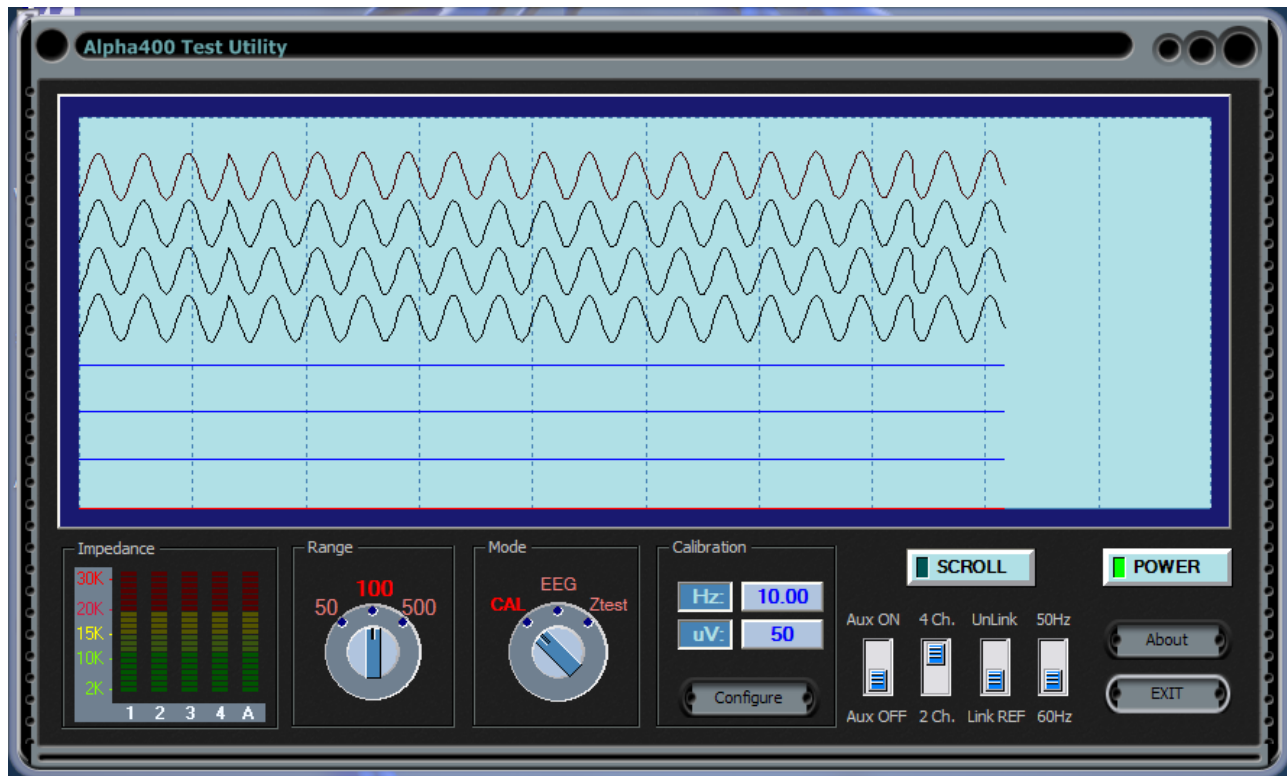
When you turn the Alpha400 POWER ON you will also notice that the CALIBRATE light will light up in addition to the POWER light on the Alpha400. This is because when the Alpha400 is turned on it powers up in CALIBRATE mode by default.

If you now see the POWER and CALIBRATE lights are lit up on the Alpha400, you can then click the SCROLL button on the Alpha400 Test program. You will then begin to see a calibration signal scrolling across the screen in real time and you will see that the ONLINE light has lit up on the Alpha400 amplifier.

CONGRATULATIONS! Your Alpha400 Amplifier is now installed and operational on your computer. You can now explore the other options that are available in the Alpha400 Test program to demonstrate the various functions and features of the Alpha400 Amplifier.

Range Control

The availability of an analog range control is a unique and valuable feature of the Alpha400 amplifier that will be discussed in detail in a later section. By clicking on the Range knob you can select the full-scale input range of the Alpha400 amplifier as either 50, 100, or 500 microvolts peak-to-peak.

Mode Control

With the Mode knob you can put the Alpha400 amplifier into Calibration, EEG, or Impedance Test modes. When in CAL mode an internal calibration signal is fed directly into the inputs of the Alpha400 amplifiers. In EEG mode the electrode jacks are connected to the amplifier inputs. When the Ztest mode is selected the Impedance Bar-Graph LED displays will be activated and the impedance of the electrodes at each input jack will be displayed on the LEDs. Note that SCROLL must be enabled for the impedance test to function.

Calibration

In the Calibration section of the Alpha400 screen the frequency and amplitude settings of the Alpha400 calibrator are displayed. When first powered ON, the amplifier will default to settings of 10.00 Hz and 50 microvolts peak-to-peak. To adjust the settings of the Alpha400 calibrator, click the Configure button and the Alpha400 Calibration Configuration dialog will appear as shown in figure 2 below.

Figure 2: Calibration Configuration Dialog
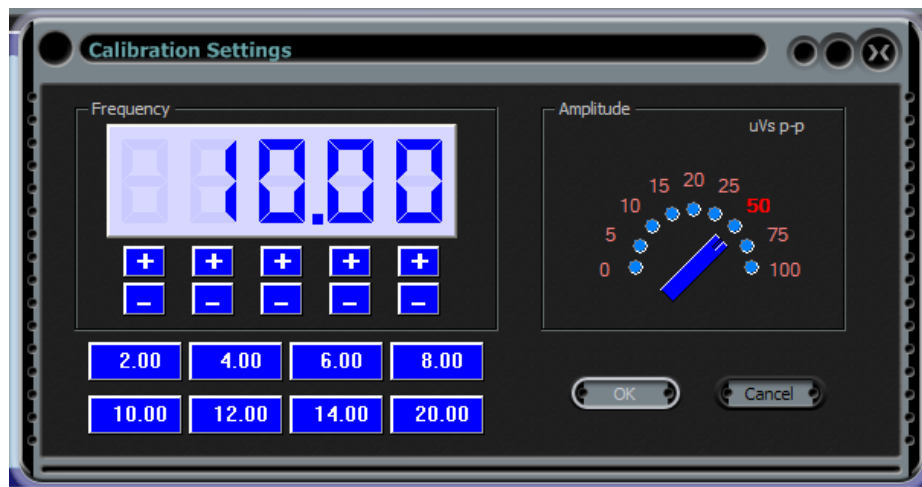
With this configuration dialog you can set the frequency and amplitude of the Alpha400 calibrator. The frequency is adjusted by clicking the "+" and "-" buttons under each digit position to either increase or decrease the frequency value. Alternatively, one of the preset frequency buttons may be clicked to select a preset frequency in the range from 2.00 up to 20.00 Hz.   The calibrator is capable of generating any frequency from 0.01 Hz up to 999.99 Hz.

The Amplitude switch is used to select the desired amplitude in microvolts peak-to-peak of the calibration signal in the range from 0 up to 100 microvolts. The 0 microvolt position may be used to perform a noise test of the Alpha400 amplifier channels.

4Ch / 2Ch

The Alpha400 amplifier can operate with either 2 or 4 of its EEG channels active.   When in 2-channel mode only the 'A' and 'B' input jacks are active; the 'C' and 'D' input jacks are inactive and the amplifier will output a flat line for those two channels.

Link / Unlink

In 'Link" mode the 'Ref 1' and 'Ref 2' reference input jacks are internally connected together. This allows for easy use of the Alpha400 amplifier in monopolar linked ear recording. In the 'Unlink' mode the 'Ref 1' jack serves as the input reference to active electrode inputs 'A' and 'C', and the 'Ref 2' jack serves as the input reference to active electrode inputs 'B' and 'D'.

Before exiting from the Alpha400 Test program be sure to stop the SCROLL mode, and to turn the POWER OFF.

Alpha400 Features

Electrode Inputs

All devices designed to detect EEG signals use a special type of amplifier input known as an Instrumentation Amplifier. An instrumentation amplifier is designed to detect minute signals in the presence of very large amounts of noise. Instrumentation amplifiers require two input signals in order to work, the idea being that the small signals of interest will be different at the two inputs, but the noise signal (or, common mode signal) will be the same at the two inputs. The instrumentation amplifier works by subtracting the two signals from each other. In this way the common mode signal (the noise) is cancelled out, and the signal of interest remains.

There are basically two approaches for selecting the two signal sources that will be input to the instrumentation amplifier for EEG recording. In the first method both of the signal sources are placed onto the head over areas that are generating active EEG signals. For example, one electrode might be placed at the C3 location, and one electrode at the O1 location. In this case the output from the instrumentation amplifier would be the difference between C3 and O1, in other words, C3 signal minus O1 signal. This type of configuration where both electrodes are placed over active EEG locations is called a bipolar input.

Bipolar electrode inputs are commonly used in clinical EEG recording. When a large number of bipolar inputs are recorded simultaneously they have the advantage of being able to provide information that allows the precise localization of abnormal waveforms that are observed in the EEG. Bi-polar inputs have one big disadvantage however, and that is that any EEG waveforms that are the same at both electrode locations will also be canceled out along with the noise. In neurofeedback applications where an individual is attempting to learn to produce a certain type of EEG pattern, the cancellation of EEG components that are the same at two electrode sites is a very undesirable situation.

The alternative approach to providing two inputs to the instrumentation amplifier is to place one electrode over an active EEG site, and the other on a neutral site that will have the same common mode signal but not have any EEG signal. Typically the earlobes are selected as the neutral electrode site as they have almost identical common mode signals as the active EEG electrodes, but they have almost no observable EEG signal. The ear electrodes are referred to as the "A" electrodes (for Aural), with A1 being the left ear and A2 being the right ear. For example, we might put one electrode over O1 and the other over A2. In this case the output from the instrumentation amplifier will be O1 minus A2. Since A2 has the same common mode signal as O2, but has no active EEG signal, the final output will just be the EEG activity occurring at the O1 site. This type of electrode input configuration is called a monopolar input (also sometimes called a Referential Input). The use of a monopolar input avoids the undesirable effect of canceling out EEG signals of interest, and provides a much greater accuracy of the true EEG amplitude.

There are a couple of potential difficulties that can be associated with the use of the A1 and A2 ear electrodes. One is that it can tend to be a little more difficult to obtain low impedance values on the ears than it is on the scalp. Since the ear electrodes are used as reference for all of the active EEG channels, a bad ear electrode can result in observing noise and artifact on all of the channels. The second issue is that the ear electrodes can sometimes be prone to picking up EKG artifact. One common technique that is often used to reduce these potential sources of ear electrode problems is to link the two ear electrodes together. By linking the two ears together there is a better chance of being able to have low impedance. Also, since the EKG artifact is of opposite polarity at the two ears, linking the ears together tends to cancel out the EKG artifact.

Often special jumper wires or "Y" electrodes are used to achieve linked ears. For convenience the Ref 1 and Ref 2 Alpha400 inputs may be easily linked together internally inside the Alpha400 amplifier under software control for maximum convenience in performing linked-ear monopolar recording.

To perform 2-channel bipolar recording, simply put the Alpha400 amplifier into 2-channel mode and select the Unlink reference configuration. The 'Ch. A' jack and the 'Ref 1' jack are now the two bipolar inputs for channel 1, and the 'Ch. B' jack and the 'Ref 2' jack are now the two bipolar inputs for channel 2.

Impedance Test

Impedance testing is an essential and important part of EEG recording. After the electrodes have been attached to your subject and connected to the Alpha400 amplifier, the Alpha400 amplifier may be put into impedance test mode. The impedance of the four active EEG electrodes and of the linked A1 and A2 electrodes will then be displayed. The range of impedance values is from 1 K-ohm up to 100 K-ohms. It is generally accepted that electrode impedance should be less than 10 K-ohms. With proper electrode attachment procedures it should be possible to routinely achieve impedance values less than 5 K-ohms.

Some users may be puzzled by why they sometimes observe electrode impedance readings that are ranging in the 20 K-ohm range, or even higher, and yet the Alpha400 EEG signals look good on the screen. This is a common misconception about why we strive to get low impedance value readings. The very high quality input amplifiers of the Alpha400 are capable of recording a clean EEG signal with impedance values that may be very high. The primary point of concern is not that the absolute value of the impedance reading is low, but more importantly that the impedance reading between the active and reference electrodes are matched.

In order for the instrumentation amplifier to accurately eliminate the common mode signal, it is of crucial importance that the common mode signal be as close as possible to identical at both of the inputs. So, for example, if the impedance of one electrode was 20K and the other was 5K the resulting EEG signal would be much noisier than if the impedance of both electrodes was exactly 20K. Of course, low impedance electrodes are preferable to high impedance electrodes, but you should keep in mind that in striving to achieve low impedance electrodes we are not only looking for the low impedance, but just as importantly this also assures that there is minimal impedance difference between the electrodes.

Calibration

Calibration of your EEG amplifier systems and validation of the performance of filters used for detecting EEG bands should be an integral part of any neurofeedback operation. Especially in research applications this is of utmost importance.

Many labs routinely record a segment of calibration signal of a known frequency and amplitude at the beginning and ending of every single recording. Other labs simply perform a general calibration of their systems on some periodic schedule such as once a week. The exact calibration protocol will vary depending on the users and types of applications, but some form of routine calibration procedure should be an essential part of any program that is utilizing EEG recording.

The Alpha400 amplifier features an integrated DDS (direct digital synthesizer) calibration circuit. This synthesized calibration generator provides an extremely accurate frequency source of plus/minus .005 Hz (five-thousandths of a hertz).   The frequency of the Alpha400 calibration signal may be adjusted over the range of 0.01 Hz up to 999.99 Hz.

There are nine available amplitude settings for the Alpha400 calibration signal. They are 0, 5, 10, 15, 20, 25, 50, 75, and 100 microvolts peak-to-peak.   The 0 amplitude setting may be used to verify the amplifier channel noise levels.

Analog Gain Control

There is in general somewhat of a misunderstanding about the significance of the bits of resolution of the analog-to-digital (A2D) converter used in EEG recording systems. The bits of resolution are a measure of how finely the A2D converter slices and digitizes the signal that it is recording. A2D converters can be 8 bits, 12 bits, 16 bits, 24 bits, or even as high 32 bits. It is much more meaningful to consider what is the resolution of the EEG signal that ultimately gets recorded, rather than what is the full scale span of the A2D converter that is used.

An analogy will be helpful in understanding this concept. Most everyone is familiar with digital cameras these days. And most understand the difference between an optical zoom, and a digital zoom.   Inside the digital camera there is a sensor array that actually records the photographic image. With an optical zoom the lens of the camera is adjusted to provide magnification of the visual field so that farther-away objects will fill up the entire image sensor array. With a digital zoom a small portion of the image sensor array is expanded. As most of use know from experience, if you apply too much digital zoom you will end up with an image that looks pixilated. This effect never occurs when you use a true optical zoom.

The same phenomenon occurs with the digitization of an EEG signal. The A2D converter in the EEG amplifier is like the image sensor that we are going to impress the EEG signal onto.

Let's imagine that we have an A2D converter that has 24 bits of resolution. This sound impressive. But, suppose that the input range to that A2D converter is fixed, and let's say that it provides a range of 200 millivolts.   Well, what happens when we are recording an EEG signal that is only averaging at about 50 microvolts? What happens is that we end up digitizing the EEG signal with only a very small range of the 24 bits or resolution that our A2D converter has available. In fact, we would only be using about the lower 12 bits of the A2D converter to digitize our EEG signal.

Now let's imagine that we have an A2D converter that has 16 bits of resolution, but in front of our A2D converter we have an analog gain control so that we can boost up the amplitude of our EEG signal to the point where those same 50 microvolts now use the entire available range of the A2D converter.   In this case, even though we are now using a 16 bit A2D converter instead of a 24 bit A2D converter, that same EEG will now be digitized with a resolution that is about 16 times greater.

In fact, the Alpha400 amplifier does use a 16 bit A2D converter. But, in conjunction with this the Alpha400 also provides a selectable analog gain control with input ranges of 50, 100, and 500 microvolts. This design strategy provides for a significantly higher quality digitized EEG.

Alpha400 Amplifier

Specifications

Channels: 4 EEG channels + 3 Auxiliary channels (0 to +2.0 volts dc)

Input Impedance: > 5 Meg Ohms differential at the electrode jacks
                           > 100 Gig Ohms at the amplifier inputs

CMR: > 100 dB

Noise: < 1.0 uV p-p referred to input

Preamp Gain: Software Selectable: 50, 100, 500 microvolts p-p full scale

Anti-Alias Filter: 4th Order Butterworth at 55Hz

Bandpass: 0.5 Hz to 55 Hz

Notch Filter: > 50dB rejection at 60Hz / 50Hz or Notch OFF

Impedance Test: An electrode test command is sent under software control to produce a simultaneous
                           test of all electrodes.

Calibration: An internal calibration system is based on a crystal controlled DDS (direct digital
                           synthesizer) with amplitude adjustment.   Under software control, the calibrator can
                           generate any frequency from 000.01 Hz up to 999.99 Hz with an accuracy of +/-
                           .002 Hz.   Amplitudes from 0 up to 100 microvolts may be selected.

A2D Resolution: 16 bits

Sample Rate: 256 samples/sec.

Aux Inputs: The Alpha400 amplifier provides three AUX input channels. Inputs to these
                           channels must be isolated from the patient. Input voltage is: 0.0VDC to 2.50VDC.

Computer Interface: Isolated USB

Power: All Alpha400 power is derived directly from the USB cable.

Isolation: Medical grade digital isolation per UL 1577 Component Recognition Program.
                           Each isolator is fully tested with 3000V rms for 1 second, and 2500V rms for 1
                           minute.   Internal isolated dc-dc converter rated at 6000 VAC isolation.

Warranty / Service

Warranty

The warranty for your Alpha400 amplifier is simple:

The Alpha400 amplifier is warranted against any failure due to defective materials, components, or workmanship for the life of the amplifier (see warranty for details).

Warranty coverage does not include failure due to breakage, or normal wear of the electrode input jacks, the USB connector, or the AUX input connector. Warranty coverage does not include shipping.

Other than that, if your Alpha400 amplifier ever fails during its life due to workmanship, or the failure of any internal electronic components, it will be repaired or replaced at no charge.

If you feel that your Alpha400 amplifier requires repair under the terms of this warranty, you must first contact TeleDiagnostic Systems at (408) 845-9000 to obtain a return authorization. With this authorization, you may then ship your Alpha400 amplifier for repair to:

TeleDiagnostic Systems
3080 Olcott, Suite 100c
Santa Clara, CA 95054