



User's Guide



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Intended Use

The BioRadio 150 is not FDA cleared to market. It is not intended for use in experimentation that involves human testing without specific IRB approval.

THIS DEVICE COMPLIES WITH PART 15 OF THE FCC RULES. OPERATION IS SUBJECT TO THE FOLLOWING TWO CONDITIONS: (1) THIS DEVICE MAY NOT CAUSE HARMFUL INTERFERENCE, AND (2) THIS DEVICE MUST ACCEPT ANY INTERFERENCE RECEIVED, INCLUDING INTERFERENCE THAT MAY CAUSE UNDESIRED OPERATION.

NOTE: THE MANUFACTURER IS NOT RESPONSIBLE FOR ANY RADIO OR TV INTERFERENCE CAUSED BY UNAUTHORIZED MODIFICATIONS TO THIS EQUIPMENT. SUCH MODIFICATIONS COULD VOID THE USER'S AUTHORITY TO OPERATE THE EQUIPMENT.

Contraindications

Interference may occur in the vicinity of equipment marked with the following symbol:



This device complies with CFR 47 – Part 15, 15.109(b), 15.249 and 15.247. Such interference could be caused by the use of multiple BioRadio 150 systems operating in the same vicinity. If you experience interference refer to chapter 3 for information on the radio link and how to reprogram the transmission frequency.

Warnings



Improper routing of leads may result in a choking hazard.



Do not use in conjunction with a defibrillator.



System Recommendations*

Windows XP Pro (32 bit), Windows Vista Business or Windows 7 Ultimate Intel Core 2 Duo 6300 1.86GHz CPU (or equivalent)
1GB (2GB for 64-bit systems) RAM
1024 X 768 or greater display resolution
One available USB 2.0 port
1GB or more available Hard Disk space
Microsoft compatible keyboard and mouse or other pointing device
Adobe Reader
Windows compatible inkjet or laser printer
CD-ROM Drive**

^{*} Product performance may vary based on your system configuration.

^{**}A CD-ROM Drive is not necessary if using the electronic delivery method of software installation.



Package Contents and Warranty Information

Cleveland Medical Devices Inc. thanks you for your recent product purchase. CleveMed offers phone technical support (9:00 AM - 5:00 PM EST) and warrants the BioRadio system (parts and labor) one year from the date of purchase. Technical support after the warranty period will be charged hourly. Contact CleveMed for hourly rates. For your benefit, we recommend that you record the pertinent details below. If necessary, this information will allow us to better serve your needs. We highly recommend that you staple a copy of the sales receipt to the blank pages in the back of this manual.

Please check to make sure your kit has the required components and records the requested data.

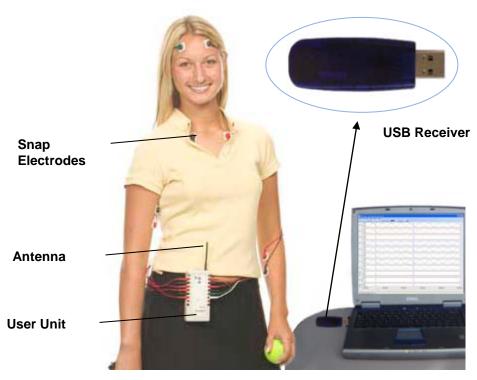
Date of Purchase:	
BioRadio S/N:	(1) BioRadio 150, P/N 502-0130
USB Receiver S/N:	(1) USB Receiver, P/N 502-0199-1
	(1)Mounting Strap, P/N 502-0107
	(2)AA Batteries, P/N 042-0111
	(1)Carrying Case, P/N 088-0009
	(1)BioCapture Software, P/N 360-0025
	(1) User's Guide, P/N 392-0028



Chapter 1: BioRadio 150 Hardware

General Device Description

The **BioRadio 150** is a wireless data acquisition system capable of recording, displaying, and analyzing physiological signals from users in real time. Using sophisticated wireless and miniaturization technologies, the BioRadio 150 provides physiological data acquisition that is untethered, thus allowing subjects to move freely while monitoring the physiological signals on the PC.



The BioRadio System

The BioRadio 150 consists of two hardware components: the BioRadio 150, or User Unit, and USB Receiver; and a software component: BioCapture Software. The User Unit is worn by the subject and is responsible for acquiring the physiological signals from sensors or surface electrodes attached on the body. The User Unit amplifies, samples, and digitizes the physiological signals and wirelessly transmits them to the USB Receiver. The USB Receiver connected to a USB port receives the data and forwards it to the PC for display and analysis. The BioCapture software displays and stores the data on the PC.



System Specifications

SYSTEM SPECIFICATIONS			
Transmission Range:	100 feet line of sight*		
RF Band:	2.4-2.484 GHz ISM Band		

USER UNIT (BIORADIO)		
Dimensions:	5.25"x 2.5" x 1.1" (not including antenna)	
Weight:	210 grams (7.4 oz.) with batteries	
	8 configurable channels	
	(external sensors)	
Number of Input Channels:	4 embedded channels: accelerometer, pulse oximetry, pressure based airflow and DC auxiliary input	
Input Range:	± 750 μV to ± 2V (configurable)	
Resolution:	8, 12, 16 bits, configurable	
Noise:	< 2 μV peak-to-peak (0.5 Hz - 100 Hz)	
Sampling Rate:	128-960 samples per second per channel (configurable)	
CMRR:	90 dB	
Power Source:	2 AA alkaline batteries	
Battery Life:	8 hours continuous use	
Input Impedance:	> 20 MΩ at 10 Hz	
Filter Input Bandwidth:	0.5 Hz - 250 Hz (-3 dB attenuation)	

USB RECEIVER			
Dimensions:	2.7" x 0.9" x 0.3"		
Weight:	0.3 oz.		
Power Supply:	USB powered from the computer		

^{*} Transmission distance varies based on the operating frequency and the building architecture.



User Unit

The BioRadio has a total of 15 acquisition channels. It acquires data from up to 8 programmable differential input channels typically used for recording biopotentials such as ECG (electrocardiography), EEG (electroencephalography), or EMG (electromyography). In addition there are several transducers embedded into the system including a dual-axis accelerometer which is also used to calculate the orientation of the BioRadio, a differential pressure based airflow sensor, and a pulse oximetry processing board. The BioRadio incorporates wireless technology in the 2.4GHz band. The BioRadio is powered by two AA batteries which provide a minimum of 8 hours of use. The BioRadio is turned ON/OFF with a toggle switch located on the side of the enclosure. A green light indicates when the Unit is on.

Channel Input Types

The types of physiological signals that can be recorded require surface electrodes or transducers placed on various locations of the body and can be further divided into four categories:

Category 1: Eight (8) configurable biopotential signals

Category 2: 1 oxygen saturation sensor (SpO2)

Category 3: 1 airflow sensor (differential)

Category 4: 1 auxiliary DC input
Category 5: Dual axis accelerometry

The first category of input channels, biopotentials, require the use of surface electrodes such as snap-type electrodes or gold cup electrodes that attach to the body on one end and plug directly into the BioRadio on the other end. The signals that can be recorded include, but are not limited to, the Electroencephalogram (EEG), Electromyogram (EMG) and Electrocardiogram (ECG). The image on page 5 illustrates an example of 4 biopotential signals connected to the BioRadio: 2 EMG (arms), 1 ECG (chest), and 1 EEG (head). The user has the capability to configure the BioRadio 150 data acquisition hardware to best capture the various physiological inputs, such as AC/DC coupling, input ranges, sampling frequencies, and resolution (see Chapter 3). While these inputs are typically used for biopotentials recordings, they can also be used as general purpose inputs for wireless data acquisition with a maximum input range of +/- 2 volts.

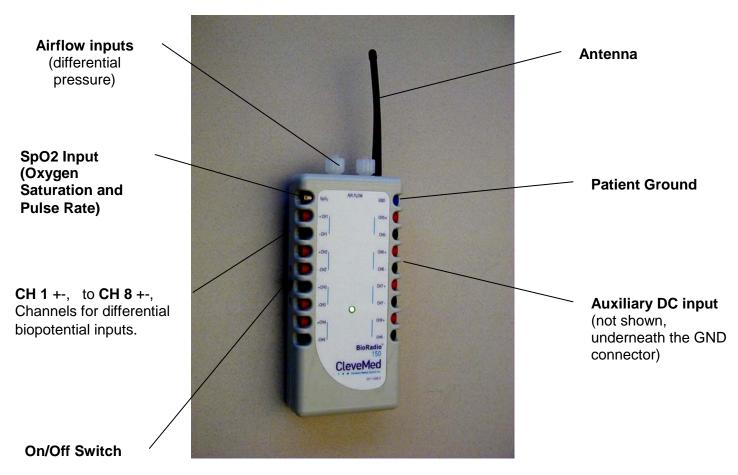
The second category, the blood oxygen saturation sensor (SpO2), is specific to the BioRadio 150 system. This requires an additional accessory that attaches to the finger and records blood oxygen saturation and pulse rate.

The airflow sensor uses an off-the-shelf cannula to monitor the User's breathing using a differential pressure sensor.

An auxiliary DC input can be used to connect other monitors, such as blood pressure monitors, capable of producing an analog output voltage (0-1.7 V).



Finally, the unit integrates a dual axis accelerometer. This sensor provides both raw acceleration data (provided in DAQ counts, not calibrated acceleration) and also a position channel to indicate the orientation of the unit based on the accelerometer data.



The BioRadio 150 User Unit.



USB Receiver

The USB Receiver plugs into the computer USB port. The USB Receiver is responsible for receiving the data from the User Unit and sending it to the PC. The USB Receiver is powered from the PC and thus has no external power supply. Also, the USB Receiver has no ON/OFF switch or any other user accessible parts. Once plugged into the PC, the USB Receiver is automatically detected by the PC and waits for data from the User Unit.

User Unit / USB Receiver match - Device ID

The User Unit is assigned or "matched" to the specific USB Receiver it is shipped with. It will not communicate with any other USB Receiver. A Device ID printed on each Unit will help the user ensure a "match" between the User Unit and the USB Receiver. The Device ID on the USB Receiver is a two letter ID (such as AA). The Device ID on a "matched" User Unit consists of the same two letters (AA).



The BioRadio 150 USB Receiver



Chapter 2: Setting Up the BioRadio 150 System

Installing the BioCapture Software Program

- 1. Insert the BioCapture installation CD-ROM into your computer's CD-ROM drive.
- 2. The installation should automatically start. If it doesn't, browse to "My Computer", "BioCapture", then double-click on the SETUP.exe file.
- 3. Follow the on-screen prompts to install the software.

Optimizing System Performance Through Windows Settings

The BioRadio system requires some adjustments to the USB serial port driver to optimize system performance. This procedure outlines how to make the changes. The changes will allow the software to more consistently find the USB Receiver, which is connected to the computer over the USB port.

Step 1: Connecting the USB Receiver

Insert the USB Receiver into a USB port on your computer.

Step 2: Open the Computer Management window

To open the device manager, right-click on the "My Computer" icon on the desktop or in the start menu (This depends on whether your system is setup for "classic" view or not). Select "Manage." The Computer Management console should appear.



Step 3: Open the Device Manager

From the left hand pane of the Computer Management console, select "Device Manager" and the right hand pane should show a list of device categories.





Step 4: Select the "Ports" device group

From the device list, select the "Ports (COM & LPT)" device group and click on the + sign, expanding it to reveal all ports. Note the "USB Serial Port" listed there.

Step 5: Get USB Serial Port properties

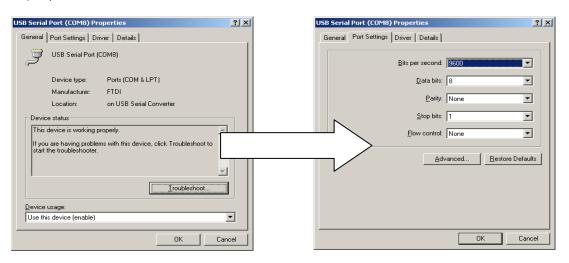
Right-click on the device named "USB Serial Port (COMX)", where X is a system assigned port number. Select Properties from the menu and the properties window for the selected port should appear.



Step 6: Advanced Properties

Select "Port Settings" from the tabs shown at the top of the properties window and look for the

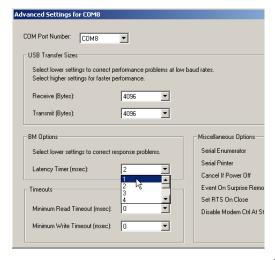
"Advanced" button. Click "Advanced" and the "Advanced Settings for COMX" window should appear. Look for "BM Options" about mid-page and notice the "Latency Timer (msec)" option.



Step 7: Select "Latency Timer" Value

To enable the appropriate response for your new BioRadio, select a "Latency Timer" value of 1ms.

NOTE: This process may need to be completed more than once, as the latency timer is specific to the COM port the device is connected to.





Chapter 3: BioCapture Software

The BioCapture software allows the user to collect, display, save and analyze physiological data collected from the BioRadio. The intuitive design provides access to hardware configuration, data collection, review and analysis.

Typically Recorded Signals

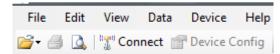
The BioCapture system is capable of recording any combination of physiological signals. The following is a list of physiological signals that can be recorded along with the supplies necessary for recording.

Physiological Signal	Supplies Necessary
ECG or Electrocardiogram: electrical	snap electrode leads, cloth snap
activity of the heart	electrodes, skin prep
EMG or Electromyogram: electrical activity	snap electrode leads, cloth snap
of the muscle	electrodes, skin prep
EEG of Electroencephalogram: electrical	gold cup electrodes, conductive paste, skin
activity of the brain	prep
EOG or Electro-oculogram: electrical	snap electrode leads, cloth snap
activity of the eye	electrodes, skin prep
Blood Pressure	Blood Pressure Cuff, Transducer Interface
	Cable
Step or Jump Force	Force Plate, Transducer Interface Cable
Grip Strength	Hand Dynamometer, Transducer Interface
	Cable
Pressure Based Airflow	Nasal/Oral Airflow Cannula
Temperature Based Airflow	Nasal/Oral Thermocouple
Chest or Abdominal Respiratory Effort	Respiratory Effort Belt
Lung or Airflow Volume	Spirometer, Transducer Interface Cable
Blood Oxygen Saturation (SpO2)	Pulse Oximeter Sensor
Heart Rate	Pulse Oximeter Sensor

For additional information regarding these signals or how to purchase the supplies necessary, please contact your sales representative at sales@clevemed.com.



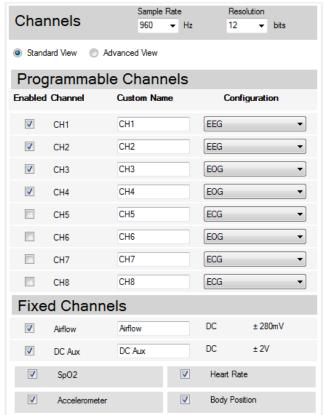
Configuring your BioRadio



Configuration of your BioRadio is performed through the Configuration Window, accessible from the tool bar or device menu. First, click the "Connect" button along the top tool bar. Once the software has located your device, the "Device Config" option becomes available. When selected, a window will open providing two channel configuration options: Standard and Advanced.

Standard Configuration

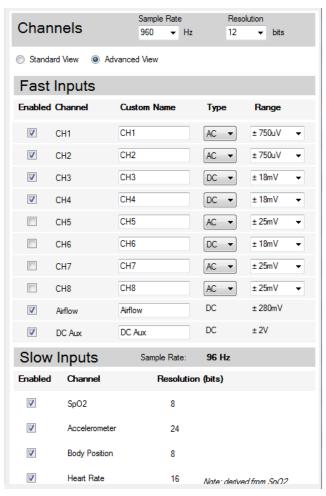
When configuring your BioRadio in the Standard View, first select the number of channels you will be using by clicking the box next to the channel label. If desired, the name of the channel can be changed in the Custom Name field to represent the signal you will be recording, such as Respiration or ECG. Each channel should have a unique name. The Standard Configuration provides pre-set configurations for specific physiological signals, such as ECG, EMG, EEG, EOG, GSR and SkinTemp. Selecting one of these options from the drop down menu will automatically set the optimal configuration parameters for that signal as well as the filter settings.





Advanced Configuration

When configuring the BioRadio in the Advanced View, select the number of channels you will be using by clicking the box to the left of the channel label. If desired, the name of the channel can be changed in the Custom Name field to represent the signal you will be recording, such as Respiration or ECG. Each channel should have a unique name. Next, the coupling type and input range need to be set to be appropriate for the signal beina In the Type field, select measured. either AC (Alternating Current) or DC (Direct Current). The input range is selected from the available drop down menu.



Configuration Name and Description

You have the option of entering and storing a configuration name and description to your saved session file for later review. To utilize this feature enter the name and description of your choice into their respective textboxes. Then, click the "Program Device" button located at the bottom of the Configuration Window. Once the Configuration Window closes navigate to the File menu and select "Save Session". Enter a filename and click "Save". To recall the session, make sure your device is connected then navigate to the Open menu and select "Session". Select the file from the list in the Open window and click Open. To review the name and description, open the Configuration Window.

Configuring Sample Rate and Resolution

The channels on your BioRadio can be set to various sampling rates from 128 to 960 samples per second. The resolution can also be configured to 4, 8, 12 or 16 bits.





Choose a sampling rate and bit resolution appropriate for your application. For example, an EEG signal can be captured with 256 samples per second at 12 bit resolution whereas an EMG signal would need to be captured with a higher sampling rate of 960 Hz. All channels are sampled simultaneously at the set sampling rate. Likewise, the resolution, the number of data bits used in recording each sample, is a common setting for all fast inputs.

Configuring Fixed Inputs

Your BioRadio is equipped with built in transducers for providing additional preprogrammed channels: a differential pressure sensor for measuring airflow, a dual axis accelerometer, body position, heart rate, and SpO₂. These inputs are sampled at 1/10th the rate of the eight programmable inputs. To program your BioRadio to collect data from these inputs, click the box to the left of the signal name.

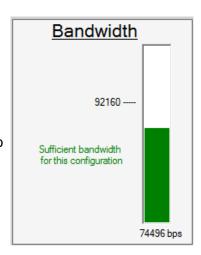
Accelerometer data is made up of two values: X and Y coordinates. Both values are displayed when the Accelerometer is enabled and each is recorded independently when data is saved to file.

Body Position is calculated for a subject wearing the BioRadio positioned on the chest facing upward and outward. The position is recorded numerically as a value between 0 and 4, where each number indicates a position:

- 0: Supine
- 1: Right side
- 2: Left side
- 3: Prone
- 4: Upright

Bandwidth Indicator

When finished entering the configuration, ensure that the indicator on the left states that there is enough bandwidth to transmit the information you have selected. If there is not enough bandwidth, the indicator will turn red. In this instance, lessen the amount of data being transmitted. Some options are lowering the sampling rate, lowering the resolution or de-selecting a channel.



Programming the Configuration

To finish, click the "Program Device" button at the bottom of the screen. The main window will now appear with the channels displayed for the selected configuration.

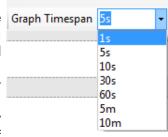
Collecting Data

Once the device configuration is complete, click the green arrow in the tool bar to start data acquisition. Clicking the blue square will stop data acquisition.





During both real time data collection and data review, the Graph Timespan window size can be adjusted using the Graph Timespan option in the tool bar. In data review, window sizes from one second to ten minutes can be selected from the drop down menu. During data collection, available ranges are one to sixty seconds. When the Graph Timespan is set to 1 or 5 seconds, the x-axis will be displayed in increments of milliseconds. Any other timespan selection will display the x-axis in increments of



seconds. Additionally, you can also collect data with the x-axis set to either elapsed time or real time display using the Time Scale option in the View menu.

Event Markers

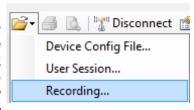
If you would like to indicate an event that occurred within your dataset, a feature called Event Markers has been added to BioCapture. Any Event Markers you would like to create are entirely customizable. This feature can be accessed by selecting Edit → Event Markers in the main menu bar before the start of acquisition. After opening the Event Markers box, 'Press a key' flashes. Press a key you would like to use to indicate an event during data collection. Once you select the key, you will be prompted to enter the name of the event, as well as a color to correspond with that event. You must choose a unique key, event name, and color for each event you add. Once you have selected your desired key, name, and color, click "Add." You will see your selection appear in the list below. Once you are done adding new events, press "OK." Failure to click "Add" / "OK" will prevent your new events from being added/saved. During data acquisition, you can press the appropriate key to indicate the event you specified. Upon navigating away from acquisition you will be asked if you would like to save your session. Click 'Yes' if you would like your event markers saved. It is important to note that you can only review the events if you are recording data (see Recording Data). You also have the option of exporting event markers with your data (see Exporting Data).

Recording Data

To record data, click the record icon (red dot) in the tool bar. A window will appear prompting you to enter a file name and location. BioCapture recording files have the extension .bcr. Once a name and location have been selected, data will be scrolling on the screen and the red dot icon will be outlined, indicating that data is being recorded. To stop recording, click the record icon and the outline will disappear. To stop data collection, click the stop icon (blue square).

Reviewing Data

To review data, open a recording file by selecting Open → Recording from the File menu or the File Open icon in the tool bar. Navigate to your saved recording file and click open. BioCapture will read the recording file and display the recording in the main window. In order to easily review events that were added during data collection, select View



→ Event Navigator. This window lists all recorded events during data acquisition. If you double click on a specific event, the BioCapture review window automatically adjusts to take you to the selected event within the data.



Data Display

Whether you are viewing real time data or reviewing saved data, various display options are available by right-clicking the plot area to show the graph context menu.

Filters

You can apply various filters to your signal according to your application. When using a preset configuration from the Standard View of the configuration window, a filter may have been automatically been applied to your signal. To add, modify, or remove a filter, select Custom Filters option from the menu.





The custom filter dialog offers four types of filters: <u>Lowpass</u>: allows low frequencies to pass through <u>Highpass</u>: allows high frequencies to pass through <u>BandPass</u>: allows signals within a certain frequency band pass through by combining a high and low pass filter

<u>Bandstop</u>: prevents certain bands from passing through

Once the type of filter is selected, one of five filter designs can be chosen:

Elliptic: equiripple behavior in both the passband and the stopband

Bessel: linear filter with a maximally flat group delay, or maximally linear phase response

Butterworth: has a frequency response as flat as possible in the passband

Chebyshev: a steeper roll-off and more passband or stopband ripple

Inverse Chebyshev: flatter in the passband than the Butterworth

Depending on your chosen filter type and design, other input fields are enabled to set that filter's specific settings, such as order and cutoff.

There is also an option named Notch Filter. This can be accessed by right clicking in the graph display or in the menu bar by clicking on the Notch Filter icon. The Notch Filter allows all frequencies except those centered in a stop band around a specific frequency to pass. There are two specific frequencies provided for the notch filter: 50 Hz and 60 Hz.

Grid Lines

You can enable or disable Grid Lines on a plot by selecting the Grid Lines option from the graph context menu.

Plot Colors

The Plot Line Color and Plot Area Color options allow you to select a color for the graph line and graph background color.



Y-axis

By default, each plot is displayed with a fixed y-axis range based on the configuration selected in the Device Configuration window. You have the option of either manually modifying the y-axis to your own range or specifying an auto-scale method. To modify the y-axis range right-click on the plot area to bring up the graph context menu.

The Y-axis submenu provides 3 options:

1. Set Min/Max

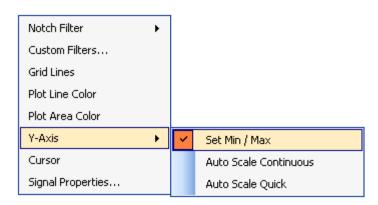
Selecting this option will bring up a window allowing you to specify the minimum and maximum values for the y axis.

2. Auto-scale Continuous

This option will configure the graph to automatically scale the y-axis to fit the data currently being charted. As new data is added to the graph, the y-axis will be continuously modified to fit the data. Caution: this option is processor-intensive, and may cause performance degradation on slower PCs if used on several channels concurrently.

3. Auto-scale Quick

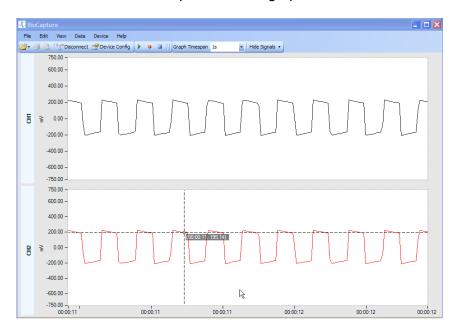
This option will scale the y-axis to fit the data which has already been plotted to the graph. The y-axis is not continuously modified as additional data is plotted.





Cursor

Selecting the Cursor option will cause the plot cursor to appear. You can drag the cursor along the plot line to see values at specific points along the graph. The cursor is most useful when reviewing data since the data is still. In real time the cursor will quickly disappear to the left as more data is plotted to the graph.



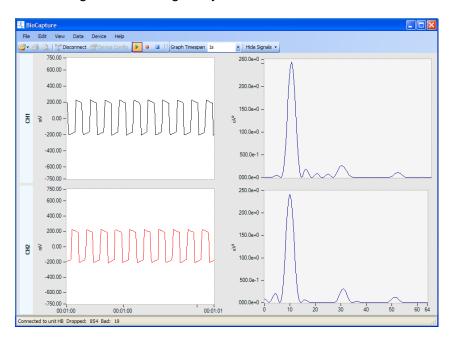
Signal Properties

The signal properties option will bring up a window where additional signal properties can be configured. From this dialog, you can specify a gain and offset to be applied to the signal. You can also set a new units label that will be applied to the graph.



Signal Frequency Analysis

When acquiring live data or reviewing a recording, a power spectrum graph can be displayed by double-clicking on the signal plot to be analyzed. In the figure below, two 10 Hz square wave signals are being analyzed.



There is also a Toggle Power Spectrum tool built into BioCapture. This can be accessed by clicking on the icon located in the menu bar. The Toggle Power Spectrum tool adds or removes power spectra for all plots simultaneously.

Saving/Recalling Sessions

You have the option to save your data display selections and use them at a later time. To utilize this feature, customize the data display window to your specifications. For instance adjust the filters, change the plot color and enable the grid lines. Navigate to the File menu and select "Save Session". Enter a filename and click "Save". To recall the session, make sure your device is connected then navigate to the Open menu and select "Session". Select the file from the list in the Open window and click Open. Your customized display options will be visible.

Exporting Data

You can export recording data to a comma-delimited spreadsheet (.csv) file. To do this, open a saved recording. Then click Data→ Export to display the export data dialog. From this dialog you can select the channels to be exported and then select a destination file for your exported data. In addition to selecting which channels you would like to export, you can also select whether or not you want to include a column for real time, elapsed time, or both. Furthermore, you are given the option of exporting events that have been indicated during data collection. When exported, the events are indicated by a "1" when they occur. Otherwise, the event is indicated by a "0." Note: You may see



a default value of 9999999 within your data. The software automatically assigns this value during the times data acquisition is lost. If you see an SPO2 value of 127 and a heart rate value of 511 in your data file then the sensor was not attached to the subject's finger.

Software Development Kit

CleveMed provides a software development kit (SDK) free of charge with the purchase of your BioCapture system. The SDK includes drivers for LabView and Matlab providing the ability to create custom software applications using the BioRadio. The user can control BioRadio communications and acquisition and collect acquired data in real time. Also included in the SDK is example code demonstrating how to utilize the Virtual Instruments (VIs) and M-files in a program to acquire, plot and process the BioRadio Data. These drivers can be downloaded from the CleveMed website at: http://www.clevemed.com/BioCapture/sdk.shtml.



Chapter 4: BioRadio 150 Trouble Shooting

BioRadio 150 Hardware Light Codes

The green LED located on the front of the BioRadio will begin to flash when the batteries are running low, indicating that they need to be replaced.

Frequently Asked Questions

Symptom: The BioRadio device will not connect or a data acquisition device is not found.

Solution A: Ensure that the green LED on the front of the BioRadio illuminates when the device is turned on. If it is not, the batteries need to be replaced.

Solution B: Make sure the USB Receiver is recognized by your PC. Check your device manager to ensure that a USB serial port exists and is enabled.

Solution C: Disable any modems and Bluetooth devices, as these peripherals may compete for communication priority with your PC.

Solution D: Check to make sure the BioRadio user unit is at least three feet from the computer unit connected to the PC.

Solution E: Other wireless technologies may have cross talked with your User Unit, in such a manner that affects how your User Unit is recognized by the USB Receiver. Contact CleveMed technical support.

Symptom: The data in the BioCapture software shows a flat signal and/or indicates a high number of dropped packets.

Solution A: Check to make sure the BioRadio user unit is at least three feet from the USB Receiver connected to the PC.

Solution B: Change the latency timer setting of the USB serial port. See "Optimizing System Performance Through Windows Settings" in Chapter 2 of this document.

Symptom: The Test Pack does not output a 10Hz 150uV (300uV peak to peak) square wave in the BioCapture software.

Solution A: Make sure the GND and SpO₂ inputs are plugged in.

Solution B: Contact CleveMed technical support.

Symptom: There is no green light when the BioRadio User Unit is turned ON

Solution A: Replace the batteries.

Solution B: Contact CleveMed technical support.

Symptom: The data, in BioCapture, resembles a lot of noise.

Solution A: Make sure you have your GND input plugged in and is well positioned and secured on the body.

Solution B: Move your User Unit away from your PC. PCs are a source of substantial electromagnetic interference (EMI).



Keyboard Shortcuts

AutoScale all graphs Ctrl-A

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