CleveMed

Cleveland Medical Devices Inc.

User's Guide
for
BioRadio 150

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 Bioradio 150 User's Guide

CleveMed Proprietary Information

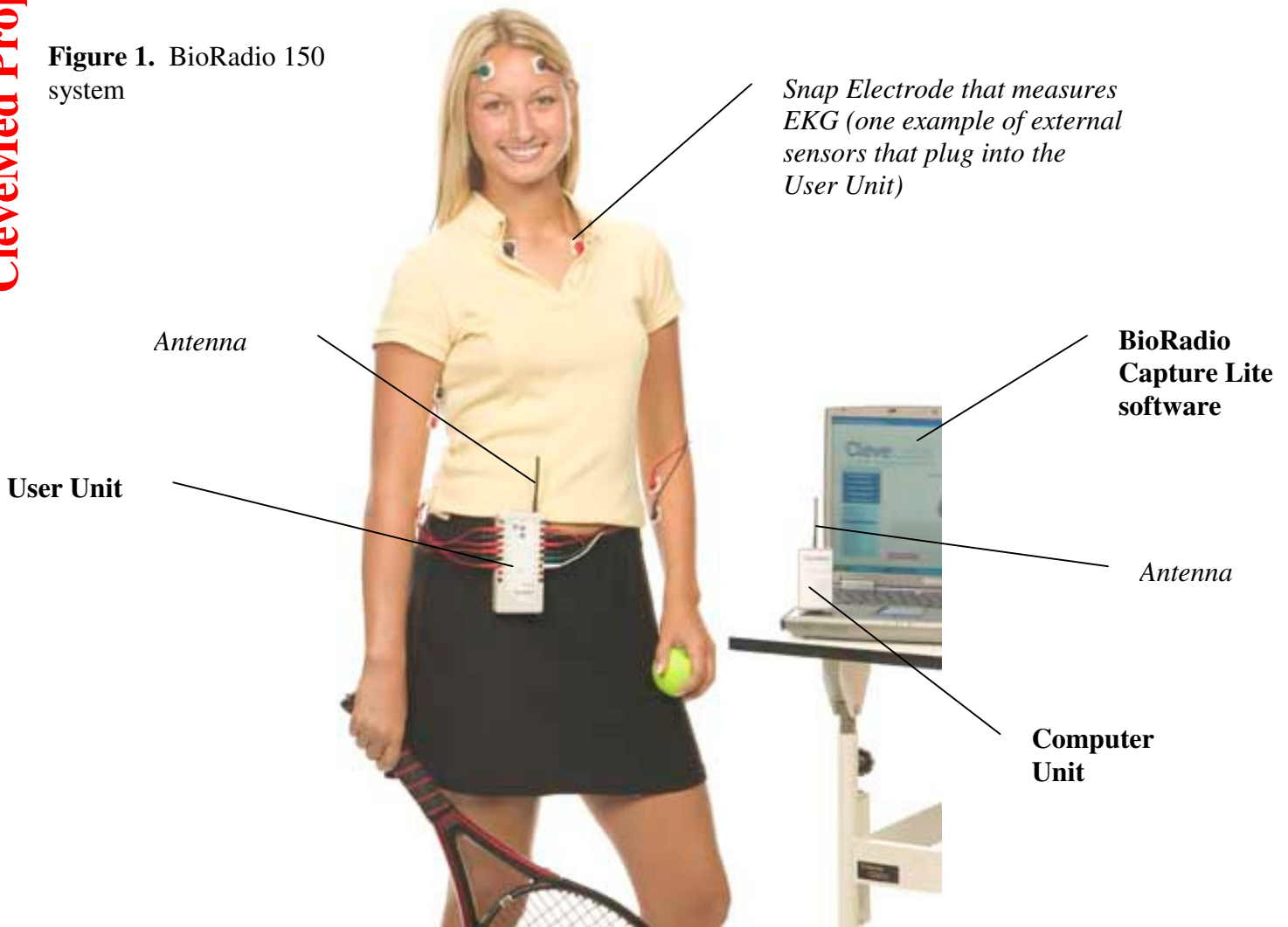|	
Telephone:	**(216) 791-6720 or Toll-free 1-877-CleveMed (1-877-253-8363)**
	9:00 a.m. - 5:00 p.m. EST **Monday - Friday**
Fax:	**(216) 791-6739**
E-Mail:	**Customer Support: support@CleveMed.com** **Sales: sales@CleveMed.com**
Web:	**http://www.CleveMed.com**
Mailing Address:	**Cleveland Medical Devices Inc.** **4415 Euclid Avenue, Fourth Floor** **Cleveland, Ohio 44103**

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Chapter 1: About BioRadio 150

General Device Description:

BioRadio 150 (Figure 1) is a wireless data acquisition system capable of recording multiple 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 the users to move freely while monitoring their own physiological signals on the PC. The BioRadio 150 system can be standalone or may accompany a number of application programs that are developed by CleveMed for specific research and education applications (if purchased with the BioRadio 150, details of the application software will be described separately).

Figure 1. BioRadio 150 system

Snap Electrode that measures EKG (one example of external sensors that plug into the User Unit)

Antenna

BioRadio Capture Lite software

User Unit

Antenna

Computer Unit

Cleveland Medical Devices, Inc.
4415 Euclid Avenue, Cleveland, Ohio 4415 , tel: 1-877-clevemed, www.clevemed.com

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BioRadio 150 consists of two hardware components (User Unit and Computer Unit) and a software component (BioRadio Capture Lite). The User Unit is carried by the person (on the belt) and is responsible for acquiring the physiological signals from sensors attached on the body. The User Unit processes the physiological signals and wirelessly transmits it to the Computer Unit using CleveMed's proprietary telemetry protocol. The Computer Unit receives the data from the User Unit and forwards it to a PC. The BioRadio Capture Lite software displays and stores the data on the PC.

User Unit (Figure 2): The User Unit has a total of 12 acquisition channels. It acquires data from up to 11 external physiological sensors (placed on the User's body) and from one internal sensor that measures motion or position of the User Unit itself. The User Unit incorporates state-of-the-art wireless technology in the Industrial Scientific Medical 902 – 926 MHz (ISM) band. The User Unit is battery powered (2 AA) that lasts for at least 12 hours continuous use. The User Unit is turned on / off with a toggle switch located on the side of the enclosure.

11 external sensors: The eleven external sensors can be placed on various locations on the body to sense various types of physiological signals. The eleven external sensors can be further divided into four categories of sensors:

Category 1: 8 biopotential signals such as Electroencephalogram (EEG), Electromyogram (EMG) and Electrocardiogram (ECG). Figure 1 illustrates an example where 4 bioptential signals are connected to the User Unit: 2 EMG (arms), 1 ECG (chest), 1 EEG (head).
Category 2: 1 oxygen saturation sensor (SpO2).
Category 3: 1 airflow sensor (differential).
Category 4: 1 auxiliary DC input.

The first category of sensors, biopotential sensors, are off-the-shelf electrodes such as snap-type electrodes or gold cup electrodes that attach to the body on one end and plug directly into the User Unit on the other end (Figure 1). The second category, oxygen saturation sensor, is specific to the BioRadio 150 system and wraps on the User's index. The airflow sensor uses off-the-shelf nasal cannula that can monitor the User's breathing. The last category of external sensors, Auxiliary DC, can be used to hookup to other monitors such as blood pressure monitors capable of producing an analog output voltage (0-2 V).

1 Internal Sensor: The internal position sensor can be used to sense the position or movement of the User Unit; therefore the internal sensor can be used to detect the movement of the USER provided the User wears the User Unit (as shown in Figure 1).
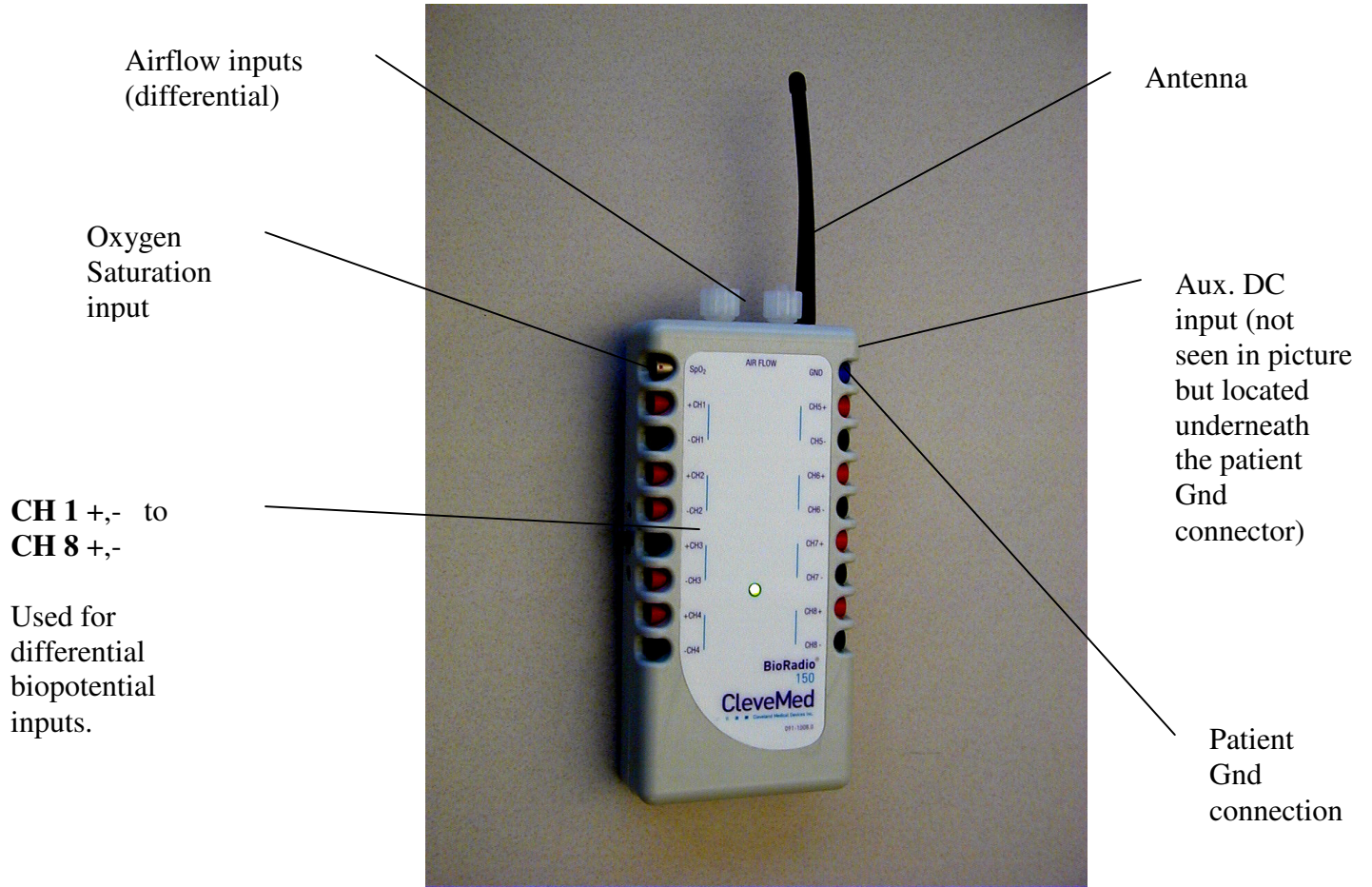
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Airflow inputs
(differential)

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Oxygen
Saturation
input

Aux. DC
input (not
seen in picture
but located
underneath
the patient
Gnd
connector)

CH 1 +,-   to
CH 8 +,-

Used for
differential
biopotential
inputs.

Patient
Gnd
connection

Figure 2. The BioRadio 150 User unit.

Computer Unit (Figure 3): The Computer Unit is a smaller device that plugs into the USB port of any PC. As mentioned earlier, the Computer Unit is responsible for receiving the data from the User Unit, demodulates it and sends it to the PC. Similar to the User Unit, the Computer Unit contains a radio transceiver that operates in the 900 MHz ISM band. The Computer unit is powered from the PC and thus has no external power supply. Also, the Computer Unit has no On/OFF switch or any other user accessible parts. Once plugged into the PC, the Computer Unit is automatically detected by the PC and awaits for data from the User Unit.
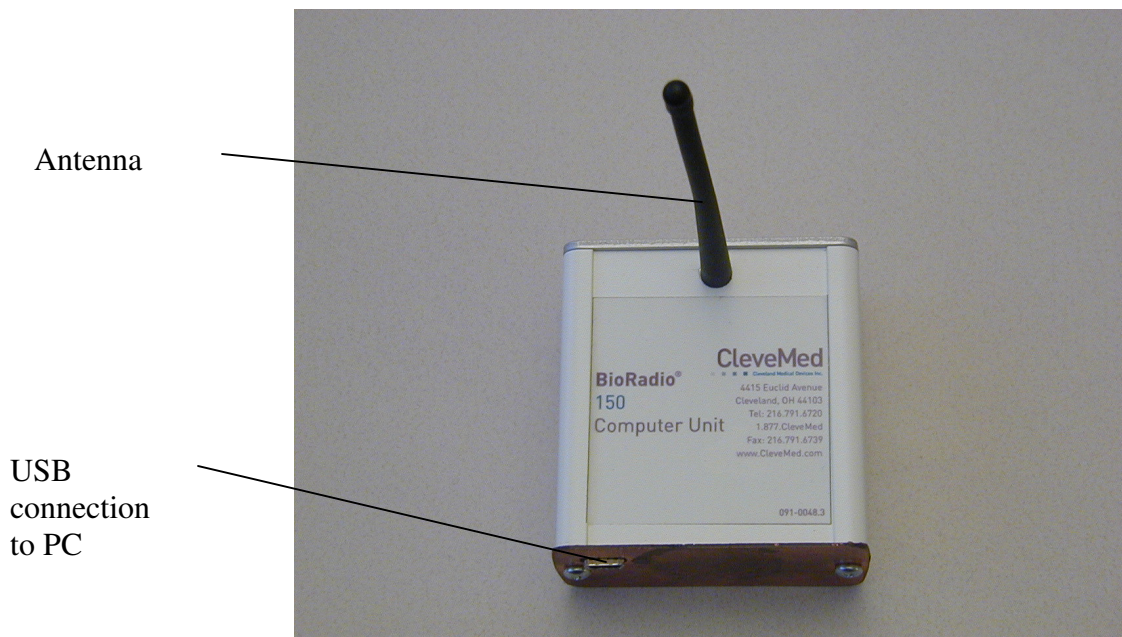
Antenna

USB
connection
to PC

Figure 3. BioRadio 150 Computer Unit

BioRadio Capture Lite:

BioRadio Capture Lite is a basic data acquisition and display software offered with BioRadio 150 (Figure 4). The program has a sub-menu on the right-hand side of the screen that provides information about the device and the data as well as allows the user to select basic functionality. Under the Control sub-menu (Figure 4) the software allows the user to Start and Stop acquisition, change display update rate, and to Save the data. The Device sub-menu displays the name of the device that is connected to the PC (BioRadio 150) and the COM port name used for the connection. Additionally, the Device sub-menu allows the user to change the sampling rate (100 Hz to 960 Hz per channel) and change the transmission frequency from channels 1 through 85. The Signal sub-menu provides feedback to the User regarding the fidelity of the acquired signal (good packets is a measure of error free signal received from the User Unit, Bad packets is a measure of received but corrupted packets, Dropped packets is a measure of data lost due to interference. As mentioned earlier, specific application software maybe purchased.
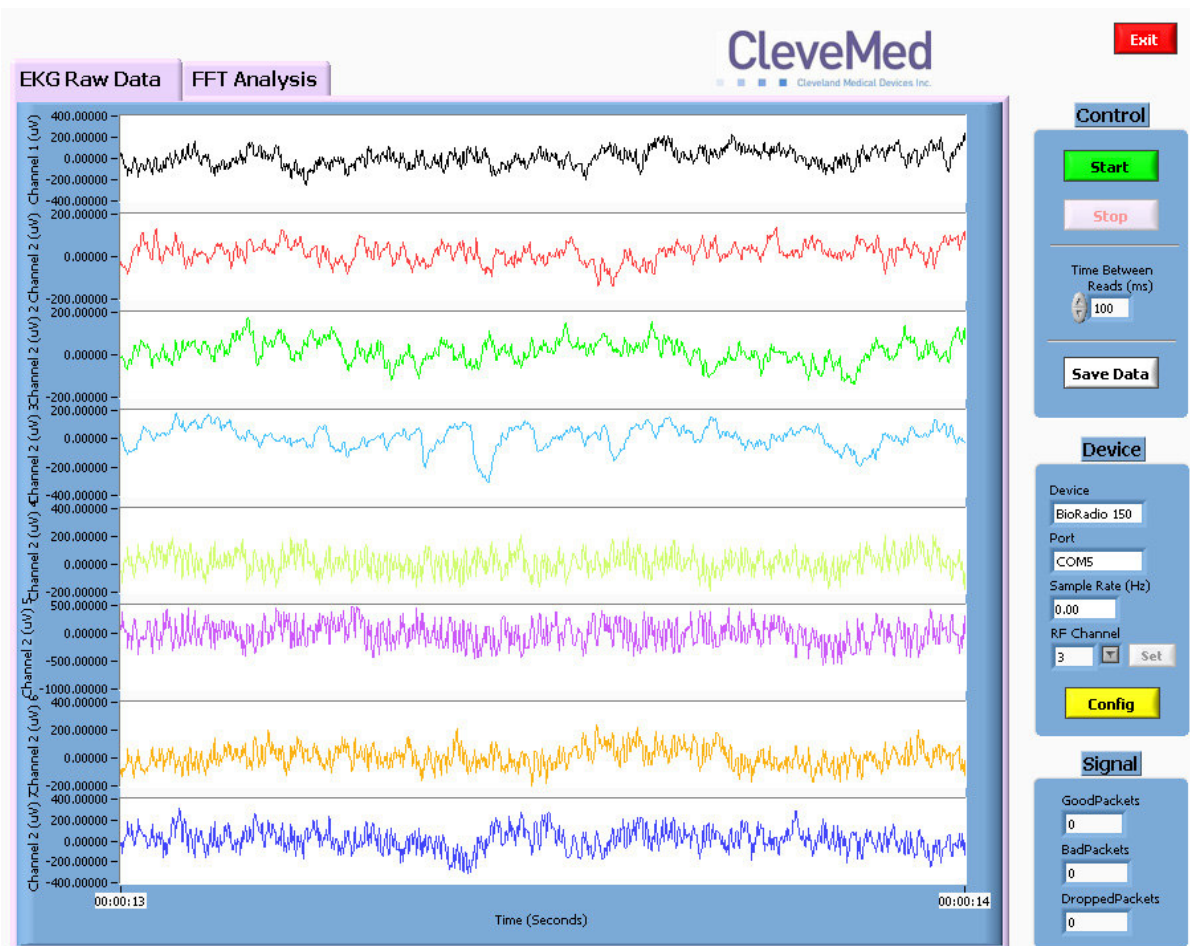

Figure 4. BioRadio Capture Lite software

Minimum System Requirements

Personal computer with Pentium III™ 500 MHz or higher processor (or equivalent);
Microsoft® Windows 98/NT 4/2000/XP;
64 MB of installed memory;
Minimum 500 MB free hard disk space (1 GB recommended);
CD-ROM Drive;
SVGA 256-color or higher resolution video adapter;
Mouse or other pointing device;
One free USB port

The Computer Unit communicates with your computer through a standard USB port.

Intended Use

The Bioradio 150 is intended for monitoring and recording of physiological signals to aid in research and/or diagnostic purposes.

This device is not intended for use as life support equipment such as vital signs monitoring in intensive care units.

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:

$$(((\cdot)))$$

This device complies with CFR 47 – Part 15, 15.109(b) and 15.249.
Such interference could be caused by the use of multiple BioRadio 150 units operating in the same vicinity. If you purchase multiple units please notify Cleveland Medical Devices Inc. at the time you place your order so that each of your units may be programmed to different frequencies.

Warnings

Improper routing of leads may result in a chocking hazard.
Do not use in conjunction with a defibrillator

Package Contents and Warranty Information

Cleveland Medical Devices Inc. thanks you for your recent product purchase. 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 record the requested data:

S/N: _____ ❒ User Unit
S/N: _____ ❒ Computer Unit
                            ❒ USB data cable (3 feet)
                            ❒ Sensors packet: Snap-On electrodes (45), Snap-On leads (6), EEG leads (5)
                            ❒ Two AA alkaline batteries
Ver: _____ ❒ BioRadio ® Capture Lite Installation Software (1 CD)
                            ❒ User's Guide, this document

Date of Purchase: _____

Chapter 2: Setting Up the BioRadio 150

Installing the BioRadio Capture Lite Program

1. Insert the BioRadio Capture Lite installation CD-ROM into your computer's CD-ROM drive
2. Double-click on the BioRadio Capture Lite Installer program
3. Follow the on-screen prompts to install the Software
4. Once the software has been installed, start the BioRadio Capture Lite Software

Starting the BioRadio Capture Lite Program

- Click on the **Start** Menu
- Point to **Programs**
- Point to the **BioRadio Capture Lite** folder
- Click on **BioRadio Capture Lite**

The software is ready to be used. When the hardware hookup is done, you can start data acquisition by pressing the Start button.

Installing the BioRadio 150 Hardware

1. Remove User Unit and Computer Unit from Starter Kit case.
2. Insert 2 AA batteries in the User Unit. Turn on the BioRadio 150 to make sure the green LED lights indicating that the device has not been damaged during shipping. Turn off.
3. Attach sensor(s) to the body. Many sensors can be used with the BioRadio 150. The starter kit comes with EEG and EKG types of sensors. Final choice of the sensors depends on the User's application.
4. Plug in the sensor lead wire into one of the User Unit ports (check chapter 1 – User Unit) and turn the device ON. The green LED should come on. If the LED is flashing then the batteries are not new and need replacement.
5. Plug the large end of the USB data cable into your computer's USB port. Plug the small end of the USB cable into the Computer unit.
6. The system is ready for use.