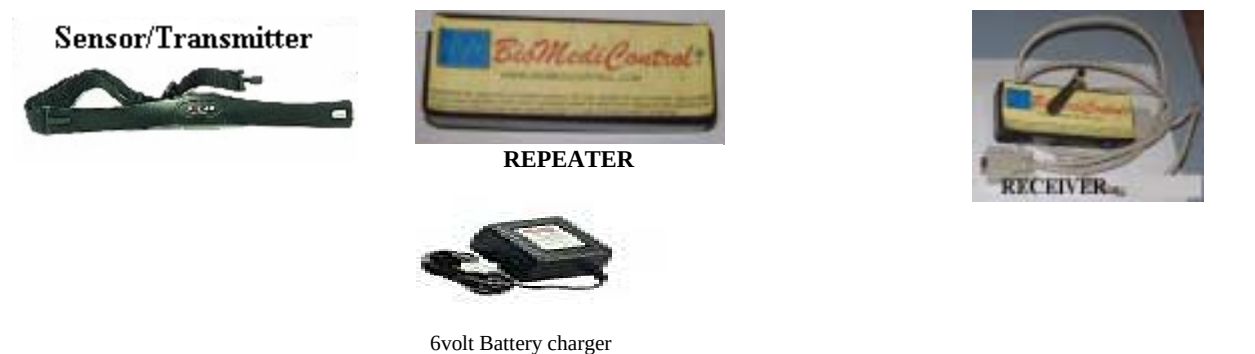


Operating instructions for **FOURCAST BioMediControl/SleepAnalyzer**™

A complete package must contain:

1. **Short-range monitor:** Sensor/Transmitter and chest strap (coded if this security option is included), and short range receiver or,
Long-range monitor: Sensor/Transmitter and chest strap (coded if this security option is included), repeater and 6volt battery charger, and long range receiver with external whip antenna.
Two 3.6Volt battery packs (RadioShack catalog number. 23-959) are required to power the repeater. The battery packs are included.
2. Computer software program FOURCAST on diskette or FOURCAST.zip downloaded from www.fourcast.net/biomed.htm



Before you can use this computer-powered wire(less) ultra-intelligent real-time monitor, user supplied computer equipment and related utility software must be installed as follows. Install a computer. Install a mouse if menu selections are to be made by using the mouse. Install a printer and standard 8.5"x11" paper if the printing features of the program are to be used. Install a modem and make arrangements for internet email services and telephone services, and install the related software if the Fax/Email and Telephone-Caller ID alarm features of the program are to be used. Plug the modem into a telephone wall receptacle. Turn on the computer and start the windows operating system. Install the software program winzip. The computer, mouse, printer, paper, modem, internet services, telephone wall receptacle, windows, and winzip are commonly, readily and easily available items, provided separately by the user. If winzip is unavailable an unzipped arrangement of the program files is available on floppy diskette or cd rom. To view the biomedical charts continuously, turn off the screen saver and screen power save options.

For short-range operation install the short-range receiver as follows

Select the short-range receiver. Insert the DB9 plug into the serial port of the computer (or Serial/USB or other appropriate adapter/connector). Place the receiver box at least one foot away from the computer or any other device that might interfere with its operation. Place the receiver within 3 feet of the sensor/transmitter. The maximum distance of 3 feet assumes optimal orientation and electromagnetic environmental conditions. Therefore, under many actual circumstances, a shorter distance will be necessary to insure proper operation.

The typical application is one in which the user is relatively stationary, such as when they are lying down and/or sleeping. In this case, the preferred location of the receiver is directly below the chest area, under the mattress, and centered between the sides of the bed on which the user is lying. Then, the user can roll on the bed and still remain within the operating range.

If the monitor is being used in a nursery or other multiple client facility, security is of paramount importance. Therefore, the beds or other monitoring stations should be well in excess of 3 feet apart. Furthermore, only coded sensor/transmitters should be used.

For long-range operation install the long-range receiver as follows

Select the long-range receiver. Insert the DB9 plug into the serial port of the computer (or Serial/USB or other appropriate adapter/connector). Place the receiver box at least one foot away from the computer or any other device that might interfere with its operation. Select one of the eight (2x2x2=8) available frequency channels by setting the 3 position dip switches marked "2", "3" & "4" on the repeater box and make the identical selection on the receiver box. The original settings are "all off." The channel may be changed in the event that there is interference from another transmitter operating within the range of the receiver. Plug the 6volt battery charger into a 120V wall receptacle, and into the charging jack of the repeater. If the repeater is turned off, its batteries will start charging, and will not be over charged. When fully charged, new batteries can operate the repeater for more than one day before discharging. However, to insure proper operation and to protect the batteries from damage due to over-discharge, it is important that the batteries be recharged once per day. The repeater can be turned on and used while the batteries are being charged. Therefore, recharging is conveniently accomplished while the user is stationary, resting or asleep, usually during a midday rest period or over night. The repeater is to be turned off when not in use. If the repeater will not be in use for an extended period of time, the batteries should be removed to prevent over discharge due to small but prolonged leakage.

Use the switches marked "1" on the repeater and the receiver to turn them on. Place the repeater within 3 feet of the sensor/transmitter. The maximum distance of 3 feet assumes optimal orientation and electromagnetic environmental conditions. Therefore, under many actual circumstances, a shorter distance will be necessary to insure proper operation. If the battery is charged, then the charger may be unplugged from the repeater.

The receiver is provided with an external whip antenna. The repeater is provided with an internal loop antenna for which the specified operating distance is a maximum of 400 feet. The user of the sensor/transmitter and the repeater, moving together may travel away from the receiver, but no farther than 400 feet. This maximum distance of 400 feet is based on an assumption of optimal antennae orientation and electromagnetic environmental conditions. Therefore, under many actual circumstances, a shorter distance will be necessary to insure proper operation.

If an external whip antenna is installed on the repeater, the range of operation can be extended to 1000 feet. In that case, the user of the sensor/transmitter and the repeater, moving together may travel away from the receiver, but no farther than 1000 feet. The maximum distance of 1000 feet is based on an assumption of optimal antennae orientation and electromagnetic environmental conditions. Therefore, under many actual circumstances, a shorter distance will be necessary to insure proper operation.

The typical application is one in which the user of the sensor/transmitter seeks mobility in and around a house. The preferred location for the repeater is on a waist belt or in a shirt pocket. As an example, consider a square, one level, and 5000 square foot house. The maximum distance that could be required is 100 feet. If the house

is built on two levels, the maximum distance required is 50 feet. Such a house is very large and well above average in size. Therefore, the operating range of the repeater is expected to meet and exceed most if not all such needs. If the user chooses to travel outside the house, then the actual range is limited to whatever the prevailing conditions (interference, metal sidings and walls containing electrical wires, etc.) will allow. If the battery in the repeater discharges, the user and the repeater must return together to the location of the charger, where the charger must be plugged into the charging jack of the repeater. A moment or two may be required to add enough charge to the battery for normal operation to resume.

If the user wishes to travel by car, away from the immediate neighborhood of their home, they may still be monitored. A portable computer connected to a wireless phone may be placed in the car and powered by the car battery to insure continuous operation. The user may then park the car and move about in the vicinity of the car, in and out of nearby buildings, within a range limited by whatever the prevailing conditions (interference, metal sidings and walls containing electrical wires, etc.) will allow. Once again, if the battery in the repeater discharges, the user and the repeater must return together to the location of the charger, where the charger must be plugged into the charging jack of the repeater.

The typical application is one in which at certain times, the user is relatively stationary, such as when they are lying down and/or sleeping. In this case, the preferred location of the repeater is directly below the chest area, under the mattress, and centered between the sides of the bed on which the user is lying. Then, the user can roll on the bed and still remain within the operating range. The battery inside the repeater may discharge during the period when the user is asleep. Therefore, the preferred location of the charger is near the bed in which the user lies down to sleep, and plugged into the repeater. When the user awakes and is ready to travel away from the bed, the charger is unplugged from the repeater. The user can then travel with the repeater as described above.

Installing the sensor/transmitter

Place the wireless Sensor/Transmitter and chest strap around the chest of the human body so that the plastic part is at the front on the chest and the strap is at the back of the chest. The logo must be in a central upright position. Adjust the strap for a firm but comfortable fit. Use water to moisten the two grooved areas (left and right of center) that are in contact with the skin of the user. The Sensor/Transmitter will automatically sense a voltage pulse each time the heart beats, and transmit a signal to the short range receiver, or to the repeater which will transmit the signal to the long range receiver.

Installing and starting the computer program

1. Installing from the internet: Create a new folder on your computer and name it FOURCAST. Download FOURCAST.zip from www.fourcast.net/biomed.htm and save it in the FOURCAST folder. Click on FOURCAST.zip in the FOURCAST folder to install the program.
2. Installing from a diskette. Run the SETUP.EXE program on the diskette to install FOURCAST in the FOURCAST folder.
3. Execute the program FOURCAST.EXE to obtain the initial screen and operating menus.

Computer program customization

Click on the main menu item CUSTOMIZE, and customize the program features by making the following menu selections (or accept the suggested default selections):

- a) BioMediControl.
- b) Enter the names and/or labels that you wish to appear as a legend on all charts and text associated with the chart data.
- c) Select the electronic sensor/transmitter used to measure the biomedical data that are to be monitored. The default selection is the provided wireless heart rate sensor. If pulse oximetry or other biomedical data monitoring is selected the sensor must be purchased separately.
- d) Select the age and sex of the person to be monitored. The program will automatically assign upper and lower limits considered to be normal for the age and sex category. These assigned values apply to a person who is at rest. For oxygen saturation, the default range is 94% to 100% for all human beings. The upper and lower limits may be edited separately by opening the file in which the above selection is stored. The program gives you instructions for doing that. Later, during this customization session, the program will display the contents of that file to allow you to edit the upper and lower heart rate limits. If the user will be moving around continuously while wearing the monitor, select WALK ABOUT to set a lower limit but no upper limit for heart rate. This will avoid triggering false alarms. The alarm will still be triggered if there is a very sudden change in heart rate of more than the default value of three standard deviations (item f below).
- e) Select Yes, to turn on the automatic Print/Fax/Email alarm, otherwise No.

- f) Specify the maximum number of standard deviations within which normal conditions are considered to exist.
- g) Select the criterion for activating the automatic alarm. The default selection “t” sets the criterion to the length of time for which an abnormal condition exists. Selection “n” sets the criterion to the number of times that consecutive data values fall outside the range specified for normal conditions.
- h) If the time criterion “t” is selected (see g above), then select the threshold time for which an abnormal condition must exist before the print/fax/email and telephone caller-ID alarms are initiated. If the number criterion “n” is selected (see g above), then select the number of consecutive times that the range specified for normal conditions is exceeded before the print/fax/email and telephone caller-ID alarm are initiated.
- i) Select the viewing time, from 1 to 10 seconds per chart, between when the charts are to be updated. Data are collected as they occur, possibly at shorter intervals, and held in memory for periodic updating of the charts.
- j) Select the time length, in minutes, of historical data to be displayed on each chart (limited only by the ability of the computer to store data). The default sampling interval of 1 may be increased, in which case data are grouped and averaged as necessary so as to span the history that is requested. It may be necessary to display more data than actually requested so as to make each group equal in size.
- k) **If you are an expert professional**, specify the shortest window length, longest window length, and increment to optimize the model that will analyze the data, otherwise accept the default value.
- l) **If you are an expert professional**, specify the differencing and antithetic times series analysis options to optimize the model that will analyze the data, otherwise accept the default value.
- m) Select the communications protocol used for reading data from the automatic measuring sensors that collect data to be monitored. These include the identification number of the serial communications port, the communicating speed or baud rate in bits per second, the data byte size in bits per byte, and the number of start and stop bits. Select the telephone number that the computer will dial, the email message, and the communications protocol, in case the telephone-caller ID alarm is initiated. **WARNING!** Cell phone email messaging systems are non-standard and vary depending on the phone service provider. It is not possible to program the computer for all variations that might exist. For that reason, the email message may not appear on the target phone. Therefore, you must not rely on the email message for any purpose. Instead, make sure that the target phone subscribes to caller ID and that it is turned on. The caller ID phone number displayed on the target phone will identify your computer as having made the call.
WARNING! The monitor uses the computer's modem to execute the fax and telephone alarms. The monitor can be used on a computer that is also being used by other applications. However, there must be no sharing of the same modem. For example if the computer is being used to browse the internet via a single modem, the monitor's fax and telephone alarms will not function because the modem will already be in use. In that case, a separate modem or other means of internet connection must be used.
- n) In the case of certain measuring sensors, the names are automatically supplied by the program, in accordance with the type of sensor. For example, in the case for a heart rate sensor, the name defaults to PULSEbpm. In the case of a pulse oximeter, the names default to SPO2% and PULSEbpm. The names may be edited.
- o) The program automatically supplies a run description that appears as a legend on all charts and text associated with the chart data. For example if BioMediControl was selected, the run description will default to “FOURCAST BioMediControl.” The run description may be edited.

Starting the monitor

Select the main menu item COMMUNICATIONS (MONITOR). Select the type or types of charts to be plotted from:

- 0-History only
- 1-History & standard deviations
- 2-Special cause
- 3-Common cause
- 4-History & special cause
- 5-History & common cause
- 6-Special cause & common cause

where selection 2 through 6 include standard deviations.

Select one of the following:

- c – to create new charts. Data from the last session will be copied to a backup file.
- s – to resume updating of already existing charts from the last session.

r – to restore the charts from the backup files, and resume updating of the restored charts.

Start the monitor and select "c" to create a new chart. A 'start communications' window will flash on the screen to indicate that the serial port is being opened for incoming data. This may occur more than once until the receiver is detected. After about 5-10 seconds, with no signal from the transmitter, the following message will appear: *"Searching for transmission code. Count= 1 Data value= xxx Code= xxx.."* If there is no signal from the sensor/transmitter (*Code = 2*), such as when it is not installed, the heart rate (*Data value*) has no meaning. After the sensor/transmitter is installed and transmission begins, the monitor will search for a unique transmission code associated with the particular sensor/transmitter. If the sensor/transmitter is not coded, the transmission *Code = 0* will be displayed. If the sensor/transmitter is coded, the actual transmission code will be displayed. The transmission code must appear five times consecutively before it is accepted. Once the code is established, only data associated with that code are accepted by the computer. All other data are rejected. Each time the sensor/transmitter is installed it will randomly select one of twenty-eight possible codes. The position of the sensor/transmitter may be adjusted for comfort. However, if the sensor/transmitter is removed from the chest for more than about ten seconds and replaced on the chest, the code will change and the monitor must be restarted.

In the case of the long-range monitor, make sure that the transmission code detected by the computer is for the correct sensor/transmitter and no other sensor/transmitter that could be in use within the transmission range of the receiver. Do this by starting the monitor while the user is close to the receiver, and is wearing the sensor/transmitter. This will give the wearer of the sensor/transmitter priority in the event that there is another transmitter operating within the range of the receiver.

Continuous updating of the charts

The program automatically opens the serial port of the computer, reads the data at the port and displays the data on the screen. After approximately ten data values, the program creates the first set of charts. Then, the program continuously reads the sensor data arriving at the serial port and updates the charts. A new plot is made at each update. If the charts do not appear, stop then restart the monitor. If the charts still do not appear, stop & exit the program, restart the program then restart the monitor. To freeze a screen so as to view or focus on one chart and the summary data displayed below the chart, click on the maximize icon () for the window which contains the chart. To unfreeze the screen click on the restore icon.

WARNING! The program relies on the windows operating system which, at times, has been observed to cease operation for no known reason. The user must check the computer screen periodically to verify that the charts are being updated, especially at least once per day when the operating system updates the date calendar.

Progressive alarm systems

Under normal conditions, defined as data points falling between the upper and lower control limits, the color of the charts is white. If at any time a data point falls above the upper control limit or below the lower control limit, an abnormal condition exists, and there is an alarm as follows. A single breach of the control limits results in a sound alarm and a blue screen, and the breaching point is marked with the number of the observation for reference. If the condition returns to normal, the sound stops and the screen returns to white. Two consecutive breaches will sound the alarm and turn the screen yellow for caution. Three breaches will sound the alarm and turn the screen red to signal danger. The home user is alerted or an attending observer such as a friend or family member is alerted to give assistance. By adding external speakers, a mother can hear the computer sound alarm from anywhere in the house, and respond to her baby. In an institution, a professional caregiver is alerted to investigate a biological condition. Once again if the condition returns to normal, by itself or due to intervention, the sound alarm stops and the screen returns to white. If the screen remains red for a period of time longer than the period specified in the computer program customization menu item h above, the program will continue the sound and color graphics alarms. However, it will also initiate the Print/Fax/Email alarm, dial and send a telephone alert, and a caller ID to the telephone number specified in the computer program customization menu item m above. This permits a professional caregiver to read the charts from anywhere in the world. Through existing local area networking methods, a computer located at a central station can display the screen of any one of several bedside computers where the program is running and charting the data.

If the data transmission code changes and therefore cannot be verified, the data are ignored. If verifiable data ceases to arrive at the serial port due to a disconnect, a low battery condition in the sensor/transmitter or in the repeater or if either the sensor/transmitter or repeater is out of range, the sound alarm, red color alarm and telephone caller-ID alarm are initiated. A screen message "NO SIGNAL" will appear.

Stopping the monitor

Minimize the window containing the chart so as to see the STOP icon. The monitor is stopped by clicking on the STOP icon, then selecting YES to print all charts or NO otherwise, then selecting YES to terminate the monitor.

NOTICE

The products to which these instructions apply are recommended for the non-invasive measurement of biological vital signs. They display data on a computer screen and a printer, and will alarm when values fall outside a predetermined user specified range. They are not suggested or recommended for use in connection with any illness or health defect whatsoever. No medical interpretation or diagnosis is performed and no treatment or action whatsoever, medical or otherwise, is suggested or recommended. They will not prevent, treat or cure any illness. Users are responsible for the proper operation of their computer and other hardware at all times. In case of illness consult a physician.

DISCLAIMER

The manufacturer of this product is continually striving to improve the quality and function of its products and services; for this reason, it reserves the right to make changes without notice. Specifications are based on representative lot samples. Values may vary from lot to lot and are not guaranteed. The manufacturer makes no guarantee, warranty, or representation regarding the suitability or legality of any product or service for use in a specific application. No device, product or service is intended for use in applications of a critical nature where the safety of life or property is at risk. The user assumes full liability for the use of the device, product or service in such applications. Under no circumstances will the manufacturer be responsible for losses arising from the use or failure of any device, product or service in any application, other than the repair, replacement, or refund limited to the original device, product or service purchase price. Some devices are patented. Under no circumstances shall any user be conveyed any license or right to use or ownership of these patents.

RADIO FREQUENCY

The long-range monitor described in this product contains a RF module that has been previously tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment on and off, the user is encouraged to try to correct the interference by one or more of the following measures:

Reorient or relocate the receiving antenna.

Increase the separation between the equipment and the receiver.

Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

Consult the dealer or an experienced radio/TV technician for help.

This equipment has been certified to comply with the limits for a Class B computing device, pursuant to FCC Rules. In order to maintain compliance with FCC regulations, shielded cables must be used with this equipment. Operation with non-approved equipment or unshielded cables is likely to result in interference to radio and TV reception. The user is cautioned that changes and modifications made to the equipment without the approval of the manufacturer could void the user's authority to operate this equipment.

Model Number: FOURCAST



Tested To Comply
With FCC Standards

FOR HOME OR OFFICE USE

FCC ID: QU8FOURCAST

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.