



**Crystal Monitor[®] PSG Series
20-S, 20-B**

Preliminary
User's Guide



Telephone:(216) 791-6720 or Toll-free 1-877-CleveMed (1-877-253-8363)

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, 4th Floor
Cleveland, Ohio 44103

© Cleveland Medical Devices Inc. 1999-2006

LMA-06-007 Rev C
392-0016

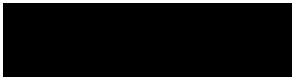
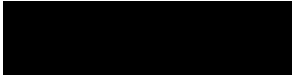


TABLE OF CONTENTS

Chapter 1: Introduction	5
Contraindications.....	5
Warnings	5
Minimum System Requirements	6
Intended Use	6
Package Contents and Warranty Information.....	7
General Device Description	9
Patient Unit.....	10
Memory Card.....	10
Computer Unit – Crystal Monitor 20-S only.....	11
Dongle – Crystal Monitor 20-B only.....	12
Crystal PSG.....	12
Chapter 3: Setting up the System.....	13
Setting Up the Crystal Monitor 20-S.....	13
Attaching the Device	13
Searching for Drivers	14
Specify the Driver Location	14
Confirm Installation	15
Completing the USB Driver Installation	15
Installing the COM Port Drivers	15
Searching for Drivers	16
Specifying the Driver Location	16
Confirming Installation.....	17
Completing the Installation	18
Installing the Crystal PSG Program.....	19
Windows Settings for Running Crystal PSG.....	19
Starting the Crystal PSG Program.....	19
Accessories, Operation and Care.....	20
Accessory Tips	20
Chapter 4: Crystal PSG Software.....	22
Chapter 5: Patient Management	23
Opening the Patient Database Browser	23
Database Operations	24
Removing a Patient.....	25
Closing the Patient Manager	25
Chapter 6: Creating a New Study	26
Using the New Study Wizard	26
Proceeding Through the New Study Wizard.....	27
Reviewing During Acquisition	30
Radio Frequency Channel	31
Chapter 7: Reviewing Data.....	32
Opening Saved Studies	32
Adding a Patient Study from a Memory Card	33
Review/Acquisition User Interface	37
Main Menu	37



Main Toolbar.....39

Acquisition Toolbar.....41

Keyboard Shortcuts41

Adjusting Individual Signals42

Staging Guide.....43

Scoring Guide.....43

Measuring Tool.....46

The Montage Editor47

Chapter 8: Report Generation.....49

 Editing and Creating a Report Template49

Chapter 9: Data Storage49

Chapter 10: Troubleshooting.....51



Chapter 1: Introduction

THE CRYSTAL MONITOR 20-S AND 20-B DEVICES COMPLY WITH PART 15 AND PART 95 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 UNDESIRE 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), 15.247, and Part 95. Such interference could be caused by the use of multiple Crystal Monitor systems operating in the same vicinity.

Warnings

Improper routing of leads may result in a choking hazard.

Do not use in conjunction with an external defibrillator.



Minimum System Requirements

Personal computer with 1 GHz or higher processor;
Microsoft® Windows NT 4/2000/XP (20-S);
Microsoft® Windows XP Service Pack 2 or higher (20-B);
192 MB of installed memory;
Minimum 500 MB free hard disk space (1 GB recommended);
CD-ROM Drive;
1024x768 or greater display resolution;
Mouse or other pointing device;
One USB port

The **Crystal Monitor 20-S Computer Unit** and **Crystal Monitor-B Bluetooth Dongle** communicates with your computer through a standard USB port.



Intended Use

The **Crystal Monitors** are 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.

© **Copyright 2006**

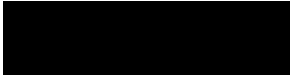
Cleveland Medical Devices Inc

This manual is copyrighted with all rights reserved. No part of this manual may be reproduced, transmitted, stored in a retrieval system, or translated into any language in any form by any means without the written permission of Cleveland Medical Devices Inc. Information in this manual is subject to change without notice. Cleveland Medical Devices Inc. assumes no responsibility for any errors, omissions, or inaccuracies. No part of the software described in this manual can be reproduced, transmitted, stored in a retrieval system, or translated into any language in any form by any means without the written permission of Cleveland Medical Devices Inc.

Energizer is a registered trademark of Eveready Battery Company Inc.

Duracell is a registered trademark of Procter & Gamble

Radioshack is a registered trademark of Radioshack Corporation



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.

Please check to make sure your kit has the required components to record the data:

Date of Purchase: _____

For the Crystal Monitor 20-S

- S/N: _____ (1) Patient Unit
- S/N: _____ (1) Computer Unit
- (1) Test Pack
- (1) Data Cable, USB
- (2) AA alkaline Ultra batteries
- Ver: _____ (1) Crystal PSG Software CD
- (1) User's Guide; this document

For the Crystal Monitor 20-B

- S/N: _____ (1) Patient Unit
- S/N: _____ (1) Bluetooth USB Dongle
- (1) Test Pack
- (2) AA alkaline Ultra batteries
- (1) SD Memory Card 1.0 GByte
- (1) USB Card Reader
- Ver: _____ (1) Crystal PSG Software CD
- (1) User's Guide; this document

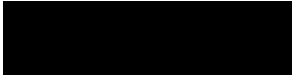
Bundled sensor package:

- (1) Respiratory effort package of 2 belts and 2 pairs of straps; P/N 116-0018
- (1) Nasal/oral cannula; P/N 502-0109
- (2) Gold cup electrodes, 10mm, 48"; P/N 116-0037
- (10) Button snap electrodes leads, female 1.5mm, 60"; P/N 116-0037
- (2) Button snap electrodes leads, female 1.5mm, 72"; P/N 116-0038
- (1) Pulse Oximeter Finger Sensor; P/N 501-0023
- (25) Adult flexi wraps; P/N 501-0024
- (1) Pulse Oximeter Interface; P/N 501-0028



Warranty: *The Crystal Monitor system carries a one (1) year warranty from the date of shipping the equipment. This warranty includes servicing and/or replacing any instrument or part thereof, except batteries and expendable supplies, returned to CleveMed factory for that purpose with transportation charges prepaid by CleveMed. Warranty does not apply if the device is damaged by accident, abuse, misuse, misapplication, or is modified without the written permission from CleveMed. Items not manufactured by CleveMed such as computers, cameras, etc., carry the original manufacturer's warranty.*

Extended Warranty is available and may be purchased at the time of the original purchase or at anytime up to thirty (30) days after the expiration of the original warranty. Please check with our sales office.



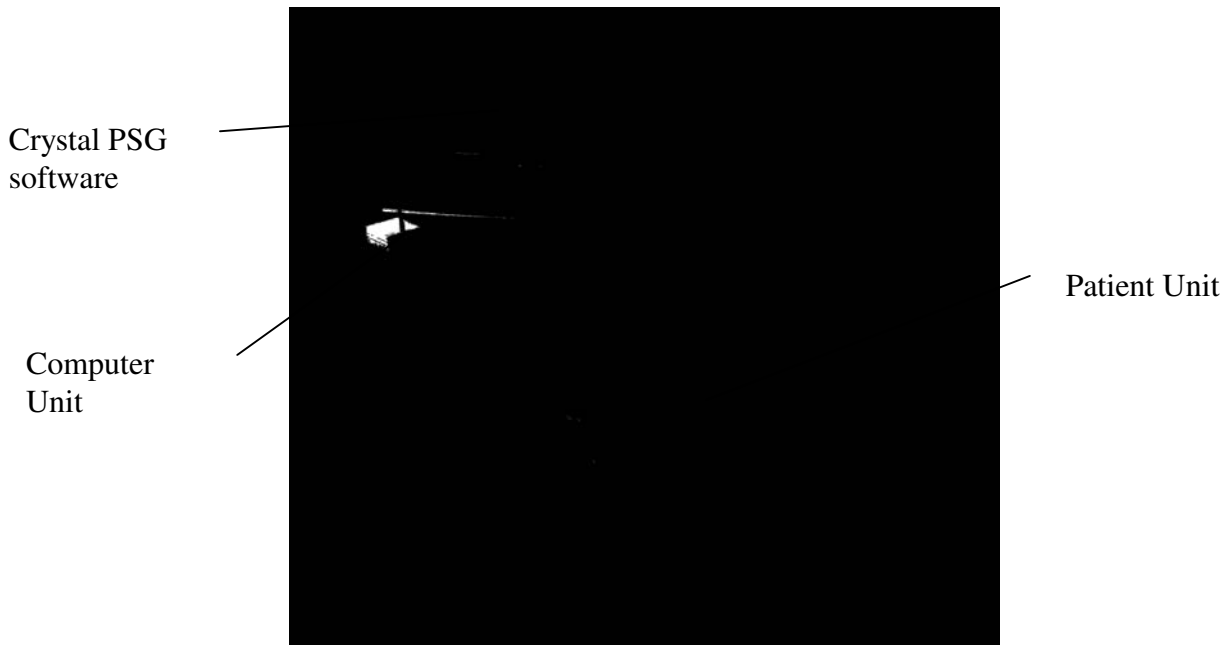
Chapter 2: About Crystal Monitor 20-S and 20-B

General Device Description

Crystal Monitors 20-S and 20-B are complete polysomnography systems capable of recording, displaying, scoring and analyzing fourteen physiological signals for attended or unattended sleep studies. The system is also capable of generating flexible, customizable reports for efficient interpretation and diagnosis.

Using wireless and miniaturization technologies, the Crystal Monitor offers sophisticated telemetry communication between the patient room and the monitoring room. This eliminates cables between the two rooms, which speeds installation of new labs or for expansion. Also, telemetry and small size is ideal for patient mobility and comfort.

The Crystal Monitor 20-S consists of two hardware components, the Patient Unit and the Computer Unit and a software component Crystal PSG. The Crystal Monitor 20-B consists of two hardware components, the Patient Unit and computer dongle and a software component Crystal PSG. The Patient Unit is worn by the person and is responsible for acquiring the physiological signals (14) from sensors on the body. The Patient Unit amplifies, samples, and digitizes the physiological signals and wirelessly transmits the data to the Computer Unit or dongle. The Computer Unit or dongle, connected to a USB port, receives the data and forwards it to the PC for display, review, and analysis.



Crystal Monitor 20-S system

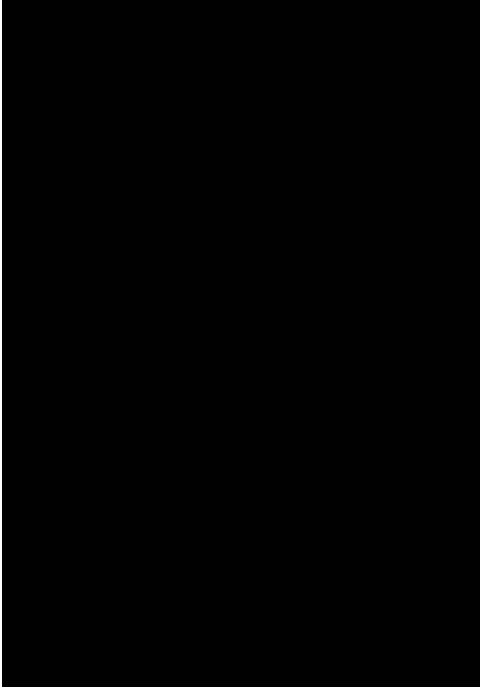


Patient Unit

The Patient Unit (Figure 2) can record up to 14 PSG channels (summarized below). The Patient Unit incorporates wireless technology. The Crystal Monitor 20-S is supplied with operation enabled in only one of two bands: The Industrial Scientific Medical 902 – 928 MHz (ISM) band or the WMTS 608-614 MHz band . The Crystal Monitor 20-B operates in the Industrial Scientific Medical 2.4 – 2.485 GHz (ISM) band. The Patient Unit is powered by two AA batteries for a minimum of 11 hours (Alkaline Ultra). The Patient Unit is turned on / off with a toggle switch located on the side of the enclosure. A green light indicates when the Unit is on. A flashing green light indicates low battery. When the light begins flashing there are approximately two hours of recording time left.

Crystal Monitor 20-S and 20-B channels:

- **C3-A2,**
- **O2-A1**
- **LEOG-A2,**
- **REOG-A1**
- **ECG**
- **Chin EMG,**
- **Leg EMG**
- **Airflow (pressure-based)**
- **Snore**
- **Body Position**
(supine, prone, left, right, upright)
- **Pulse Oximetry**
- **Abdominal Effort**
- **Thoracic Effort**
- **DC Auxiliary**



Memory Card

An SD memory card may be used to collect data within the patient unit. This provides for immediate backup during attended studies and allows the Crystal Monitor to be used for unattended studies. Multiple studies may be collected on a card before they are downloaded. However, for patient confidentiality no patient identification information is saved on the card. The technologist must identify studies by date and time. A 1 GB SD card will hold 60 hours of recording time. Any size or type of SD card is compatible with the Crystal Monitor.

A light by the SD card slot indicates the status of the card.

- Off – Memory card not inserted
- Green Solid – Memory card ready
- Green Blinking – Memory card working, data is recording
- Amber Solid – Memory card is full, locked or broken
- Amber Blinking – There is not enough disk space to record for 8 hours at start up. Data will be recorded until no disk space remains.



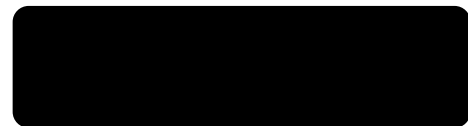
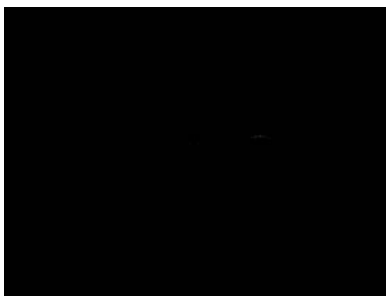
Computer Unit – Crystal Monitor 20-S only

The Computer Unit is a small receiver that plugs into the USB port of any PC. The Computer Unit is responsible for receiving the data from the Patient Unit and sending it to the PC. 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 accessible parts. Once plugged into the PC, the Computer Unit is automatically detected by the PC and waits for data from the Patient Unit.

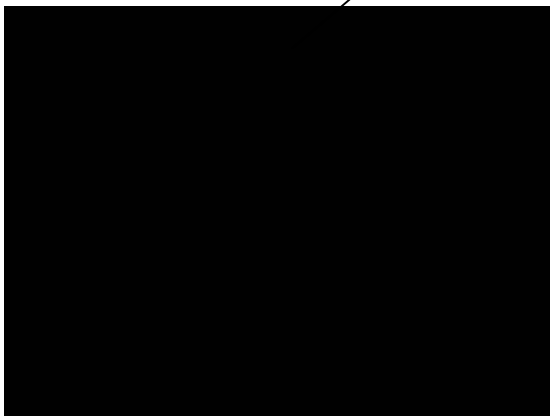
Patient Unit / Computer Unit match – Device ID

Proper operation of the system requires the Patient Unit and the Computer Unit to be matched (i.e. run at the same transmission frequency). Matching units can be identified easily through a Device ID number printed on the back of the units. The Device ID is a two letter ID such as AA. Users must check the Patient and Computer units for identical Device ID's before operation.

Patient Unit



Computer Unit





Dongle – Crystal Monitor 20-B only

The dongle is a small receiver that plugs into the USB port of any PC. The dongle is responsible for receiving the data from the Patient Unit and sending it to the PC. The dongle is powered from the PC and thus has no external power supply. Also, the dongle has no On/OFF switch or any other accessible parts. Once plugged into the PC, the dongle is automatically detected by the PC and waits for data from the Patient Unit.

Crystal PSG

Crystal PSG (Chapter 4) is a complete sleep acquisition, scoring and analysis software package for the Crystal Monitor 20-S and 20-B.

Installation and use of the software is described in later Chapters.



Chapter 3: Setting up the System

Setting Up the Crystal Monitor 20-S.

1. Plug the large end of the USB cable into your computer's USB port
2. Insert two AA Ultra-Alkaline batteries into the **Crystal Monitor 20-S Patient Unit**. The expected battery life under continuous use is 11 hours. **It is recommended to use Ultra-Alkaline batteries. Standard Alkaline or rechargeable batteries may not be able to power the device for a full night sleep study.**

USB Driver Installation

This will direct the user through the Crystal20 USB driver installation.

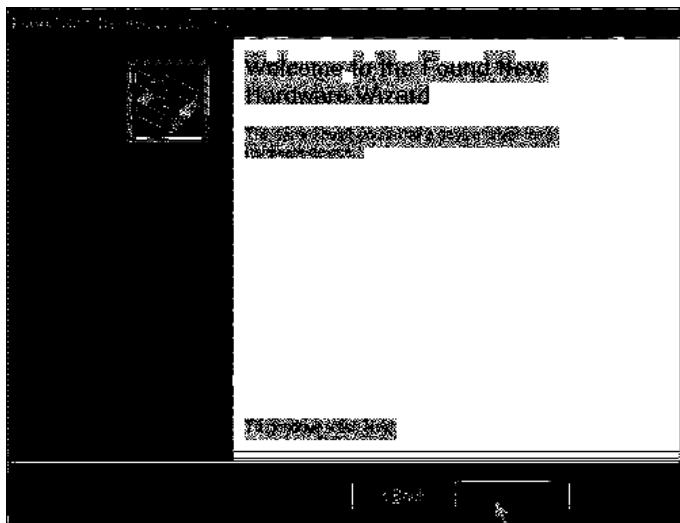
(Note: The Crystal Monitor 20-S requires a PC running Windows 2000, or XP with USB 1.1 capability.)

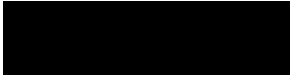
Attaching the Device

Plug the USB cable into any open USB port on the computer. Windows will detect the device and bring up a Found New Hardware window.



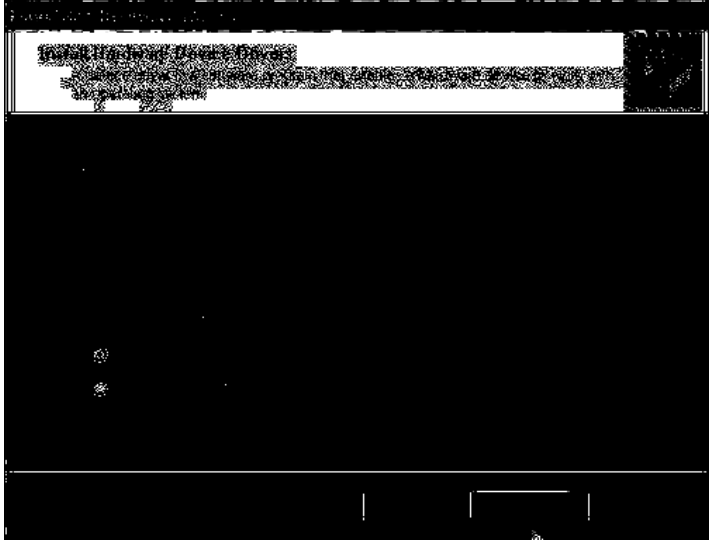
Once the device has been found, the Hardware Wizard page will appear. Click its 'Next' button to continue.





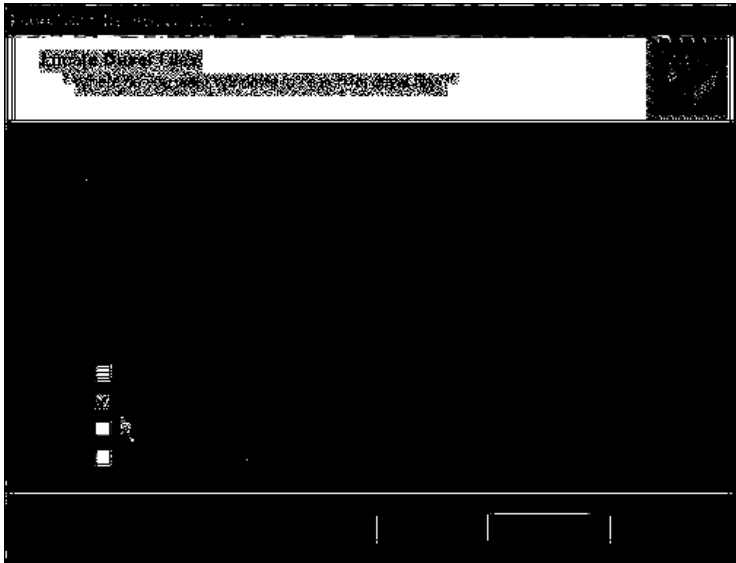
Searching for Drivers

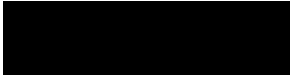
After clicking the 'Next' button, a page will appear allowing the user to choose the driver location method. Select the button marked "Search for a suitable driver for my device (recommended)" then click the 'Next' button.



Specify the Driver Location

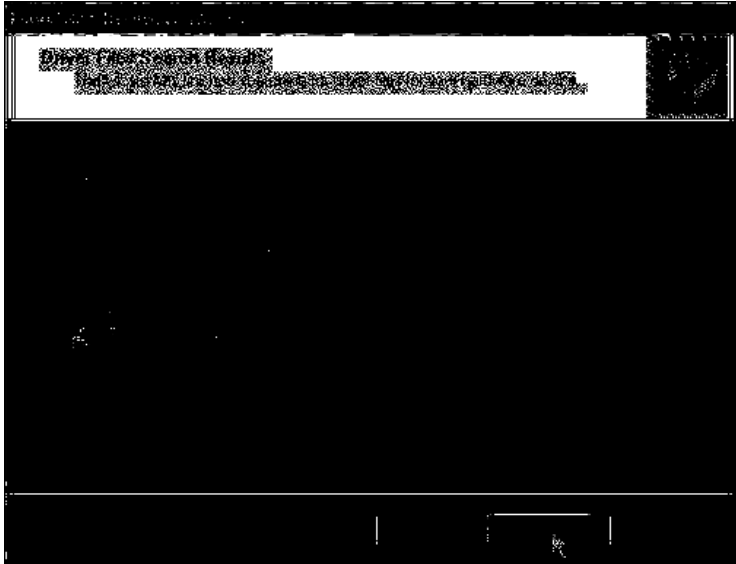
The next page in the Installation Wizard will ask the user where to search for the driver files. Select the CD-ROM drives checkbox then click the 'Next'





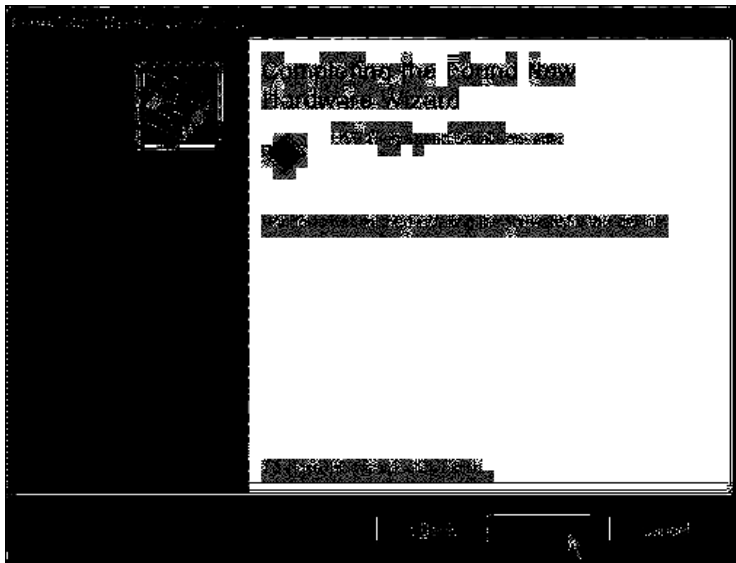
Confirm Installation

The Installation Wizard should locate the driver file "ftdibus.inf." Click the 'Next' button to confirm installation of this driver file.



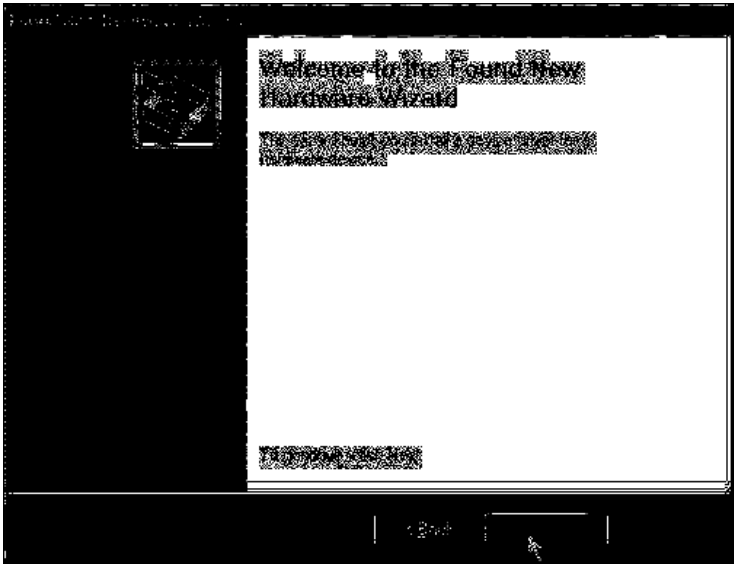
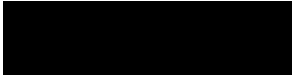
Completing the USB Driver Installation

Once Windows has copied the driver files from the CD-ROM to the system folder, a window will appear alerting the user that the installation is complete. Click the 'Finish' button to continue.



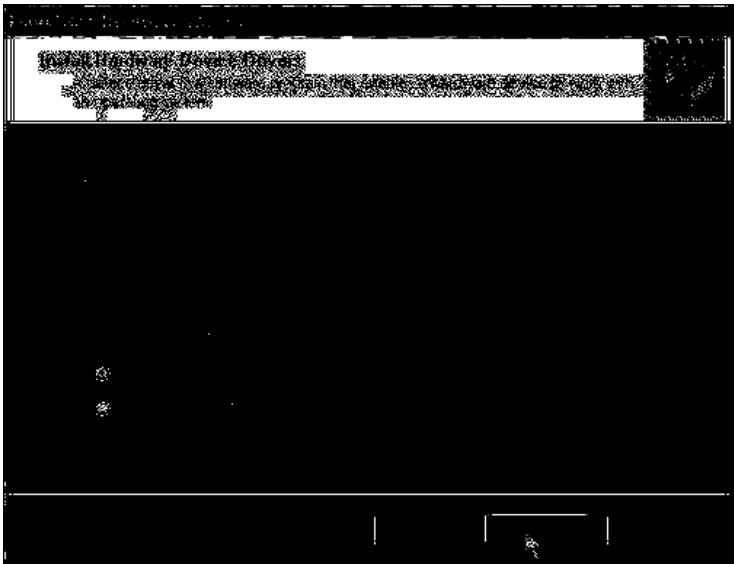
Installing the COM Port Drivers

When the USB drivers have been successfully installed, the Installation Wizard will again show the "New Hardware Found" page. Click the 'Next' button to continue.



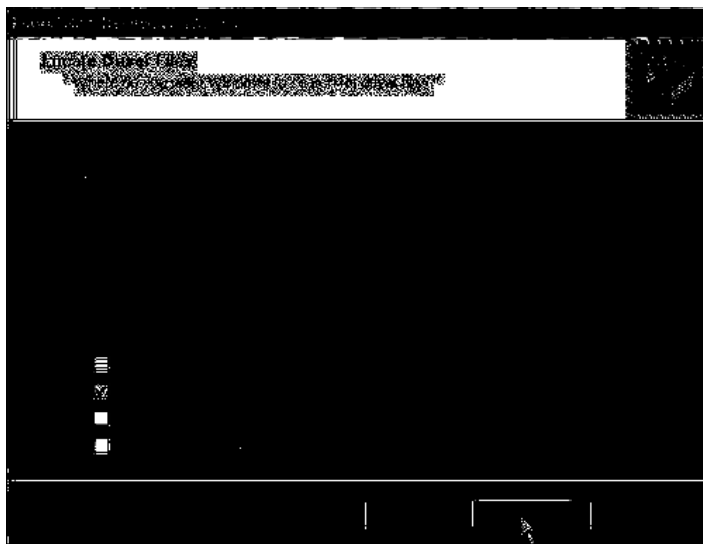
Searching for Drivers

Once again, the Installation Wizard will ask the user to specify the driver location method. Select the button marked “Search for a suitable driver for my device (recommended)” then click the ‘Next’ button.



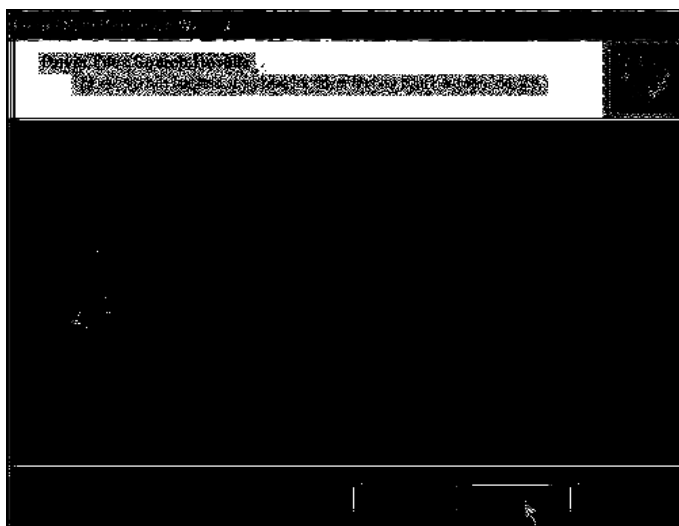
Specifying the Driver Location

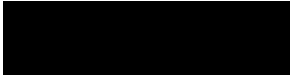
The next page in the Installation Wizard will ask the user where to search for the driver files. Select the ‘CD-ROM drives’ checkbox then click the ‘Next’ button.



Confirming Installation

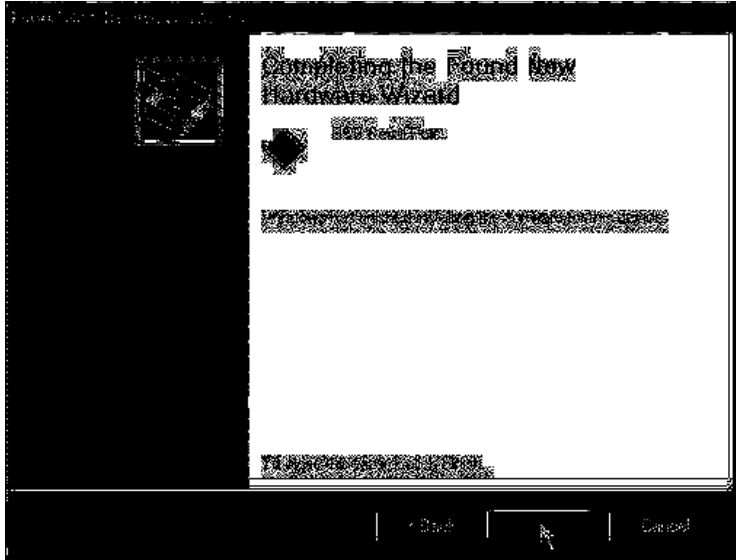
The Installation Wizard should locate the driver file "ftdiport.inf." Click the 'Next' button to confirm installation of this driver file.





Completing the Installation

Once Windows has copied the driver files from the CD-ROM to the system folder, a window will appear alerting the user that the installation is complete. Click the 'Finish' button to dismiss the Installation Wizard.



Setting Up the Crystal Monitor 20-B.

Insert two AA Ultra-Alkaline batteries into the **Crystal Monitor 20-B Patient Unit**. The expected battery life under continuous use is 11 hours. **It is recommended to use Ultra-Alkaline batteries. Standard Alkaline or rechargeable batteries may not be able to power the device for a full night sleep study.**

Bluetooth Installation

Crystal PSG for the Crystal 20-B is designed specifically for use with Windows XP (Service Pack 2). As part of your starter kit, you should have received a USB Bluetooth radio adapter like the one shown in the picture on the right. Windows XP SP-2 comes with Bluetooth drivers pre-installed, thus merely connecting the Bluetooth adapter will prepare the system for data collection from your Crystal 20-B unit.



USB Bluetooth adapter with antenna

Connecting the Bluetooth Adapter

Connect the Bluetooth adapter to your computer by inserting it into one of the available USB ports. (Consult your system's documentation if you cannot find a USB port).

Once inserted, a Bluetooth status icon will appear on in your system tray as illustrated in the picture below:



Your system is now ready to receive data from your Crystal Monitor 20-B unit. If you will be using multiple Crystal Monitor 20-B devices in the same area please refer to chapter 6 to ensure that data is acquired from the correct patient unit.

Troubleshooting

Some systems may have a different set of Bluetooth drivers already installed. This may or may not effect the installation process. If you do encounter a problem installing your system, please contact CleveMed for assistance. Often, some minor changes to how your computer discovers the USB Bluetooth adapter has to be changed, but due individual system differences, it is best to have a technical support representative walk you through the process.

Installing the Crystal PSG Program.

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

Windows Settings for Running Crystal PSG

1. Within Windows enter the Display Properties menu.
2. Select the screensaver tab and press the power button to open the Power Options Properties menu.
3. Set the power scheme so that the hard disk never turns off and the system never goes to system standby or hibernates.
4. Disable automatic virus scans and other programs that run automatically.
5. If you are collecting data on a laptop DO NOT close the lid during acquisition.

Starting the Crystal PSG Program



On the desktop click on **Crystal PSG** or,

1. Click on the **Start** Menu
2. Point to **Programs**
3. Point to the **CleveMed** folder
4. Point to the **Crystal PSG** folder
5. Click on **Crystal PSG**



Accessories, Operation and Care

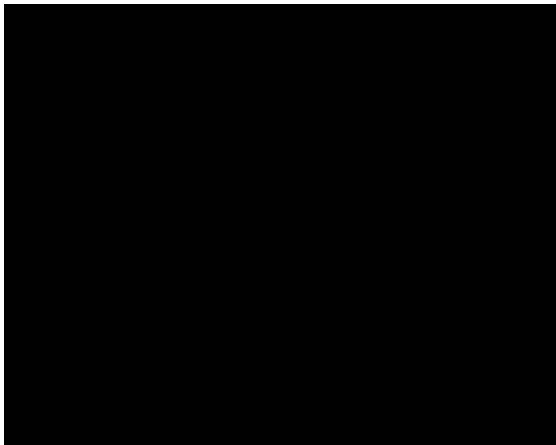
The recommended electrode placement follows the international 10-20 system for C3 and O2 placement. Reference electrodes (A1 and A2) are located on the mastoid process on each side of the head. In addition, several sensors typical to sleep studies are used, including two (2) respiratory effort belts, pulse Oximetry and a cannula to measure airflow.

Gold cup or snap style electrodes may be used with the Crystal Monitor. For the best recording results use a skin preparation cleanser and electrode paste or gel according to the manufacturers instructions. Check the impedance of the electrodes to ensure low and matched impedance between the electrodes.

Care should be taken to secure the lead wires to reduce the risk of a patient becoming entangled in the leads. After application; the leads can be gathered at the base of the head and secured similar to a ponytail using a Velcro wrap or other type of tie.

Accessory Tips

Cannula



Properly secure the cannula by wrapping the tubing behind the patient's ears. The cannula tubing should rest loosely below the patient's chin, do not over tighten the cannula.

When using an oral/nasal cannula instruct the patient to allow the oral prong to rest just inside their lips.

Before each new study visually inspect the air port connector between the cannula and the Crystal Monitor to ensure a secure connection. Condensation may occur in the cannula over night causing intermittent or no transmission of the airflow and

snore signal. You may wish to replace the cannula should this occur. Most cannulas are one-time use devices; please follow the manufacture's guidelines.

Pulse Oximeter

Before each new study visually inspect the connector between the pulse oximetry sensor and the Crystal Monitor to ensure a secure connection. Be sure to line up the red marks. Secure the sensor around the patients finger tip with a finger tape wrap. The sensor should be secured tight enough to maintain contact with the skin but should not impede blood flow.

Respiratory Effort Belts

Before each new study, visually inspect the connector between the respiratory effort belts and the Crystal Monitor to ensure a secure connection. The respiratory belts should fit snugly while maintaining patient comfort to ensure a good signal.



Body Position

A body position sensor is built into the Crystal Monitor patient unit. The patient unit should be clipped to the patient's waist band, pocket or respiratory effort belt. Insure that the front label faces away from the patient for correct left and right orientation.

Auxiliary DC Input

The auxiliary DC input accepts inputs ranging from +/- 2.5V. It may be used for sensors such as a thermocouple, body position sensor and temperature probe. Please contact CleveMed for a list of approved accessories or assistance in customizing a sensor for your needs.



Auxiliary DC Input

Battery Life

Ultra Alkaline AA batteries will last for at least 10 hours of continuous data acquisition. Lithium AA batteries will last at least 17 hours of continuous data acquisition. **Standard Alkaline or Rechargeable batteries are not recommended because they may not be able to power the device for a full night sleep study.**

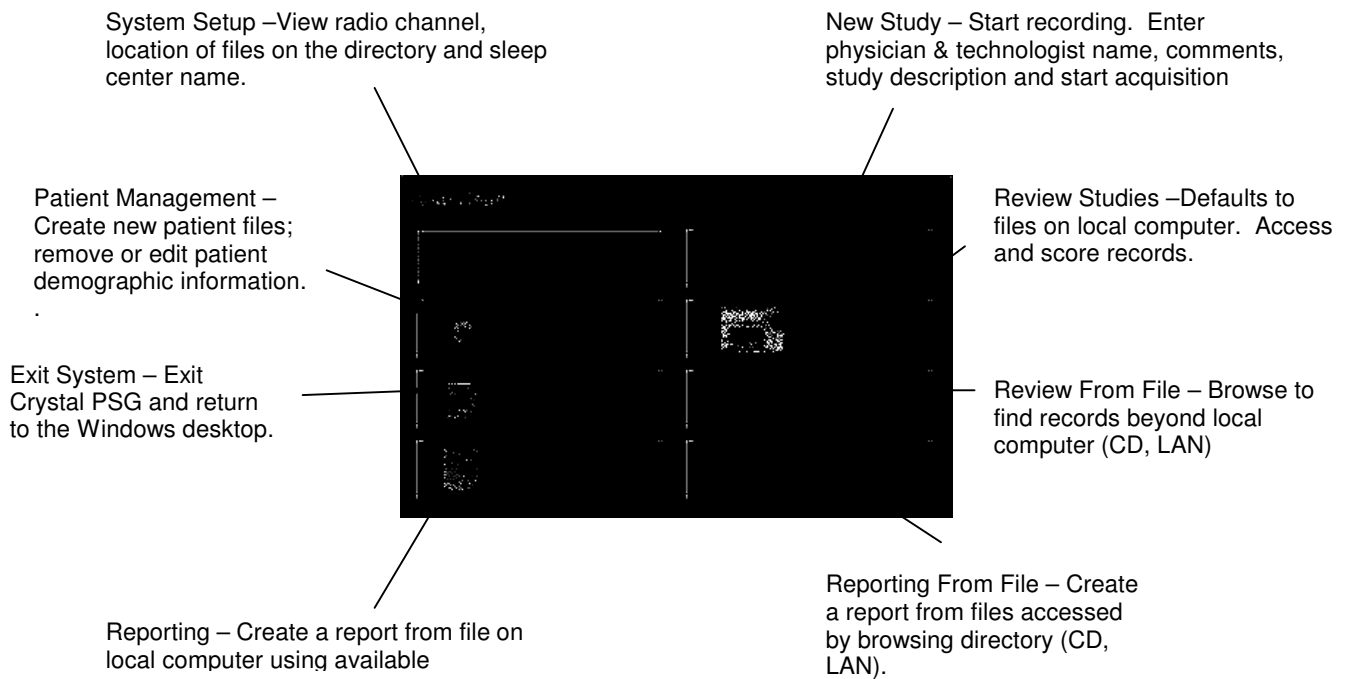
Battery Type	Test Conditions	Battery Life
AA Rechargeable Ni-Cd (1000 mAh)	no Memory	4 hours
Industrial Alkaline AA	no Memory	8 hours
Duracell® AA Rechargeable Ni-Mh (2100 mAh)	no Memory	8 hours
Radioshack® AA Rechargeable Ni-Mh (2000 mAh)	no Memory	11 hours
Duracell Ultra Alkaline AA	no Memory	12 hours
Energizer® e ² Lithium AA	no Memory	17 hours
Energizer e ² Titanium AA	SD Memory	4 hours
Industrial Alkaline AA	SD Memory	5 hours
Duracell Ultra Alkaline AA	SD Memory	10 hours
Energizer e ² Lithium AA	SD Memory	17 hours



Chapter 4: Crystal PSG Software

* **WARNING:** DO NOT OPEN OR TAMPER WITH ANY OF THE RAW DATA FILES SUCH AS THE HEADER FILE. TAMPERING WITH THESE FILES MAY CORRUPT PATIENT DATA AND THUS MAY LEAD TO IMPROPER DIAGNOSIS.

The Crystal Monitor utilizes a Windows® based user interface software called Crystal PSG. The key functions from the Main Menu include:





Chapter 5: Patient Management

The Patient Manager acts as an interface to the Patient Database, allowing the user to keep track of the patients involved in a series of studies. The Database Browser allows the user to add and remove patient records and to edit existing patient information.

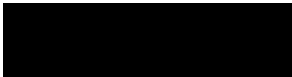
Opening the Patient Database Browser

The Patient Manager can be opened by:

-  Selecting  from the Main Menu.
-  Clicking the Add Patient  button in the New Study Wizard.

This will display the Patient Management window.

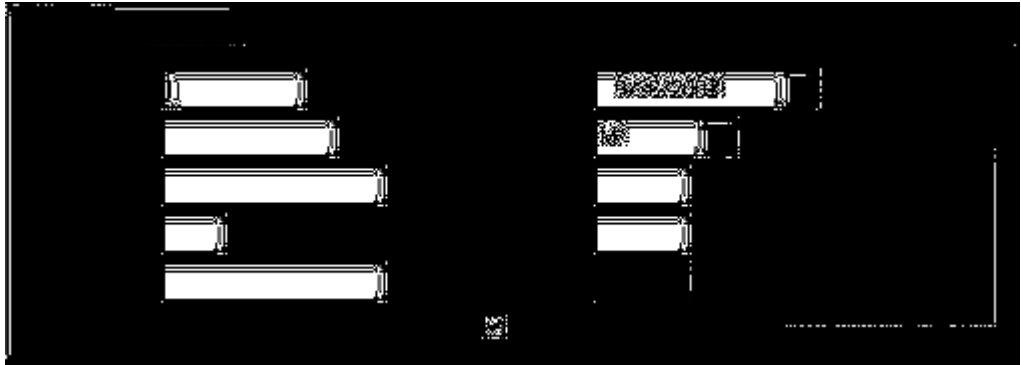




Database Operations

Adding/Editing Patients

To add a new patient to the system, click . A patient demographics field will be presented blank for you to enter the appropriate information. The Edit button will change to read **Lock** to indicate that the next time it is click that the record will be locked.




Once patient information has been entered, click .

You will be presented with the message:




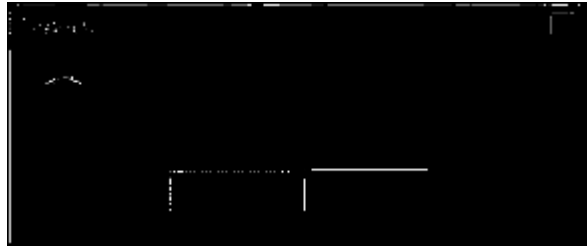
Click **Yes** and the new patient information has been entered into the system.

To edit existing patient information, select the patient you would like to edit, click  and follow the same instructions above for entering patient information.






Removing a Patient

A patient can be removed from the database by clicking  in the toolbar. Before removing, the software will prompt the user to be sure the patient should be removed.



Closing the Patient Manager

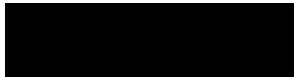
When finished, the user can close the Patient Database Browser by:

-  Clicking on the Close button  at the top-right of the window, or
-  Clicking on 

Upon closing the Patient Manager, a popup window will ask for confirmation of the changes made to the record.



To save the changes, click Yes. To discard the changes, click No.



Chapter 6: Creating a New Study

Using the New Study Wizard

The **New Study Wizard** allows the user to quickly and easily set up a new patient study. The simple interface helps the user attach identifying information to each study and organize patient information.

Note: Before starting acquisition, make sure that the **Crystal Monitor 20-S Computer Unit or Dongle (20-B)** is properly connected to your computer.

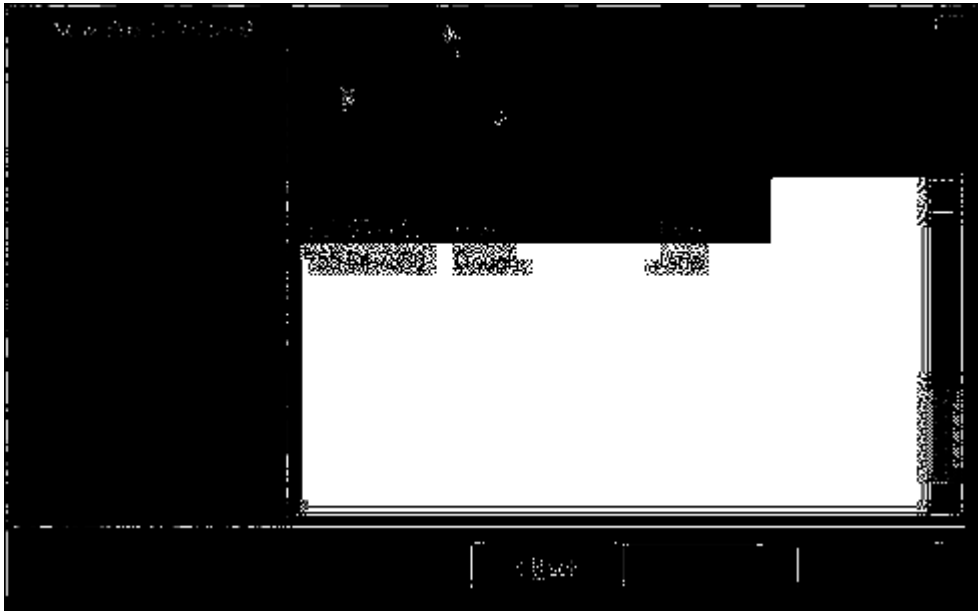
The **New Study Wizard** can be opened by:

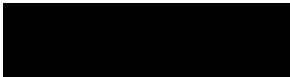


Clicking the **New Study** button on the **Main Navigator**.



This displays the **New Study Wizard**.

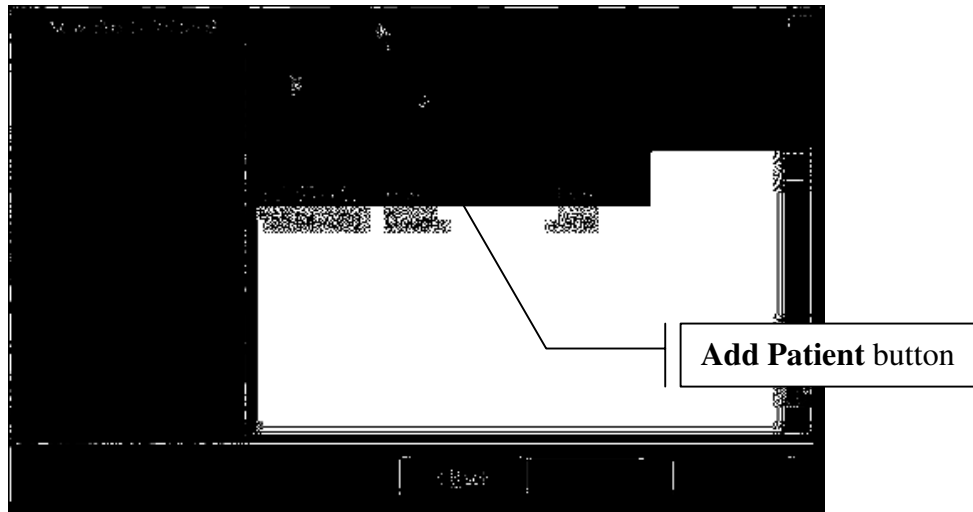




Proceeding Through the New Study Wizard

The first page of the **New Study Wizard** shows the **Patient List**. To use an existing patient:

- ☞ Select the patient in the **Patient List**.



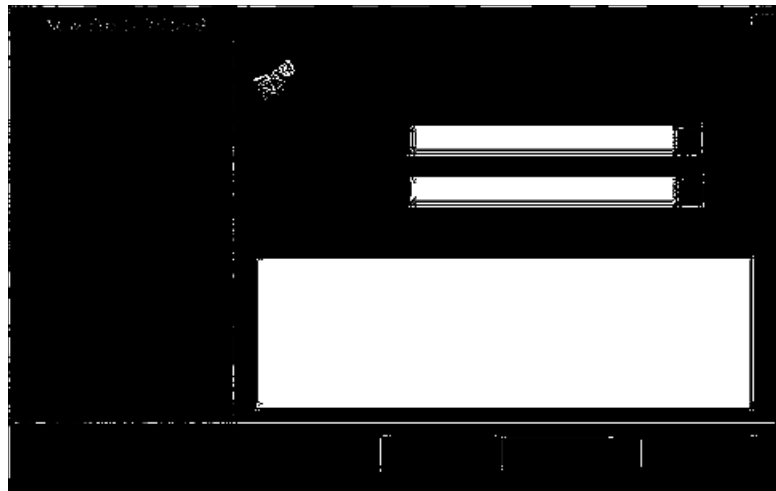
- ☞ To add a new patient Click the **Add Patient** button. This will open the **Patient Database Browser**.


For more information, see [Managing Patients](#).

When a patient has been selected, click the **Next** button.

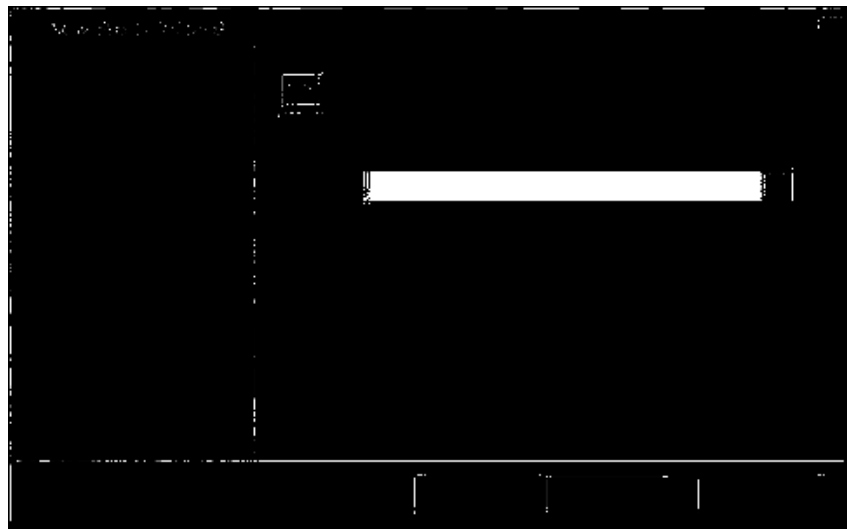


The second page of the **New Study Wizard** asks for the names of the **Physician** and **Technician** performing the study. This page also contains an optional **Comments** field for notes on this particular study.



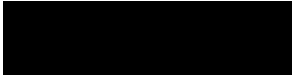
 To move on to the next page: Click the **Next** button.

The third page asks the user to add a brief description for the study. The description should identify the study.

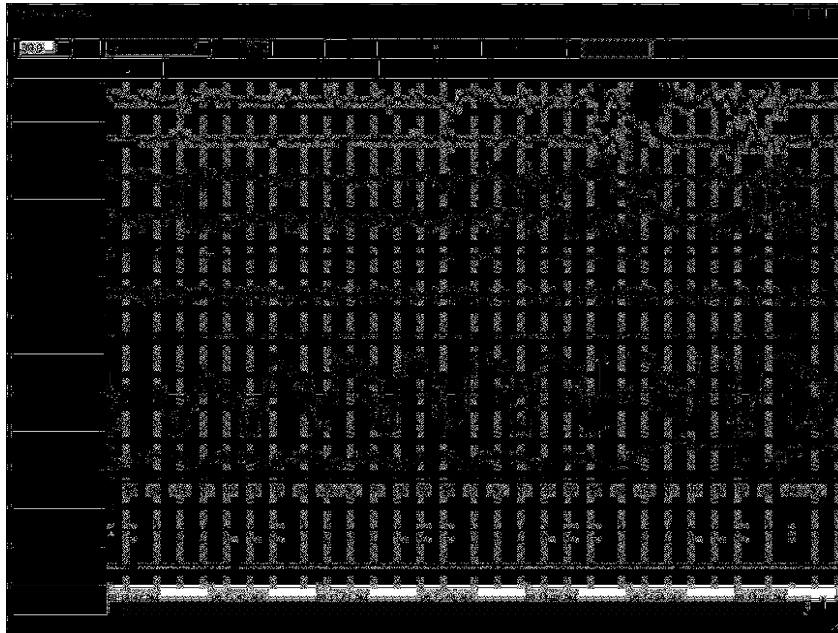


This is the last page in the **New Study Wizard**. To complete the **New Study Wizard** and to move on to **Data Acquisition**:

 Click the **Finish** button.



Acquisition will begin automatically and you should see live data begin to scroll across the screen.

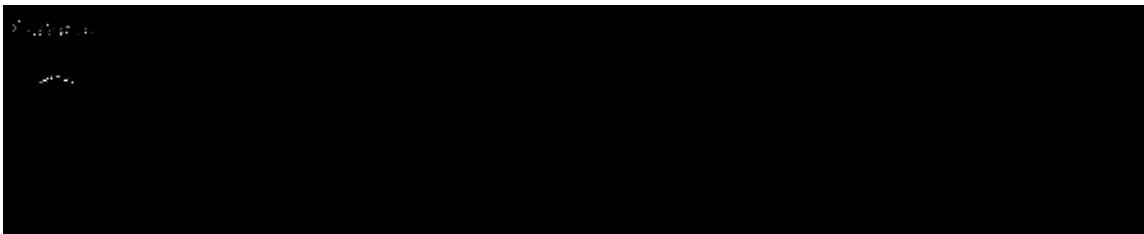


**Starting
(Crystal Monitor 20-B Only)**

Acquisition

After proceeding through the new study wizard as described above before acquisition begins the software will confirm which device it should record from.

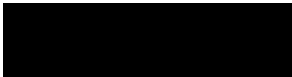
The acquisition/review window will appear revealing a blank page soon followed by a confirmation window:



The device named in parentheses was the last Crystal Monitor 20-B device used by your computer. Each Crystal Monitor 20-B device is labeled with a two letter code, which can be found on the back of the patient unit. The device name used in the message above came from a device with the letter code "AB". When prompted with this message, you should confirm that the device named in parentheses matches the one connected to your patient. If the device named in this message is the device you would like to use, click <Yes> and you can skip the next section of the text.

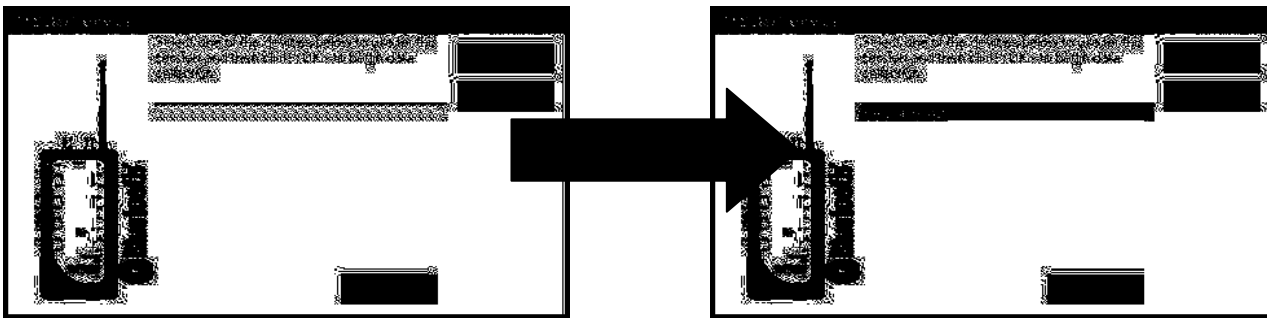
Selecting a Different Crystal Monitor 20-B Unit

If the named device is not the one you would like to collect data from, and then click <No> when prompted with the initial confirmation window and a device selection form should appear
Cleveland Medical Devices Inc.



and after about 10 seconds a list of available Crystal Monitor 20-B units in your area should appear.

Cleveland Proprietary Information



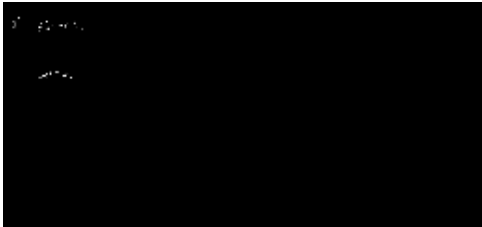
Not

e: if no devices appear, ensure your Crystal Monitor 20-B unit is in range, has fresh batteries and is turned on, and then click <Search Again>.

Once you find the device you would like to connect in the list, highlight it by clicking its entry in the list and click <OK>.

Connecting to the device

Sometimes when you try to connect to your preferred device, it may be out of range, turned off, or perhaps its batteries have expired. When this happens, you will not be able to start data collection until it becomes available. If you answered yes to the device

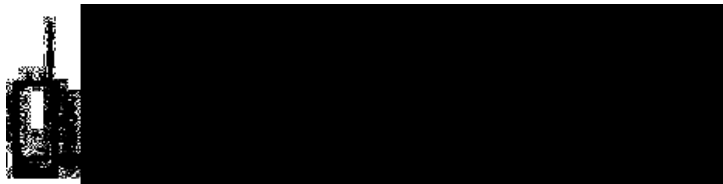


confirmation dialog that appears at the start of acquisition and the device for some reason is unavailable, you will be prompted with the message shown at the right. Clicking <Yes> will allow you to browse for a Crystal Monitor 20-B unit. You can use this window to help troubleshoot the system by periodically clicking the <Search Again> button as you bring the unit closer, or turn the device on/ replace batteries.

(Note: It does take some time (10-15sec) for the system to resolve the name of the device, so you may want to click the <Search Again> button a few times after turning the unit back on)

Starting Acquisition

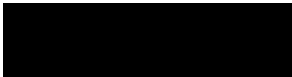
Once you have successfully selected the Crystal 20-B unit you would like to collect data from, a countdown window indicating that acquisition will commence in 5 seconds will appear:



During acquisition the device ID of the patient unit can be verified in the lower left corner of the acquisition screen.

Reviewing During Acquisition

During acquisition, you can review the collected data by clicking the . This will suspend live update of the screen and allow you to use the navigation controls to page back through the data, add scores, enter staging, etc. See Chapter 7 for more information about the review capabilities.



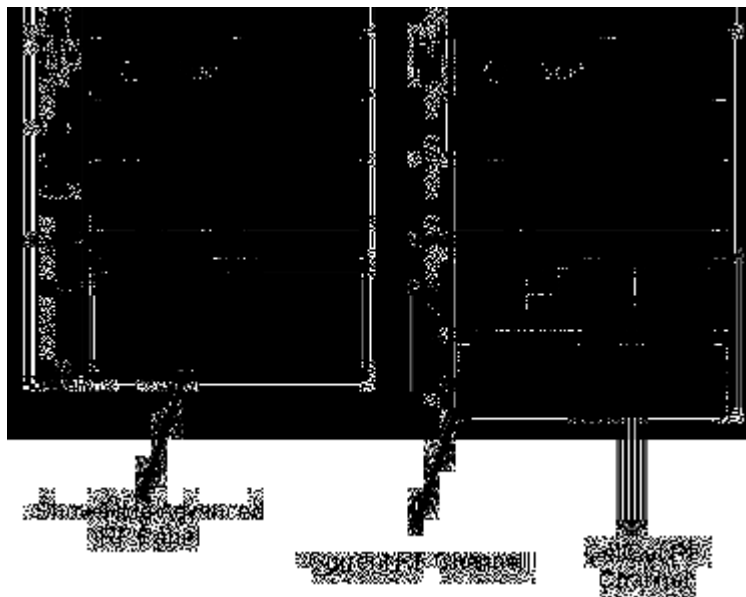
Radio Frequency Channel (Crystal Monitor 20-S only)

While collecting data with the Crystal Monitor 20-S the user may change the radio frequency (RF) channel that the device is using to transmit data.

For most applications the user can leave the software in the default mode where the device will automatically change channels when interference occurs. The user can manually change channels by selecting the switch RF channel button from the acquisition toolbar.



Advanced users may wish to manually select an RF channel. This feature will be most useful in environments where the frequency spectrum is known to be busy. On the patient summary panel the Advanced RF Panel can be displayed. The Get button will display the current RF channel. The Set button will reset the RF channel to the channel number currently displayed.





Chapter 7: Reviewing Data

Opening Saved Studies

Once a data file has been recorded, it can be reviewed. During the review, it can be scored or the display settings can be changed, just as during the recording.

To review a previously recorded study:



Click the **Review Studies** button on the **Main Menu**



This displays the **Open Study...** dialog window, where you select the study you wish to review.



The top portion of the **Open Study...** window displays a list of all studies in the system. Studies can be arranged in order by **Patient ID**, **Last Name**, **First Name**, **Study Description** or **Test Date** by clicking on the appropriate column title. A brief summary of the highlighted study is found on the lower half of the screen, detailing the date and time of the study, the associated physician, attending technician, and a brief description of the study.



To open a study for review:

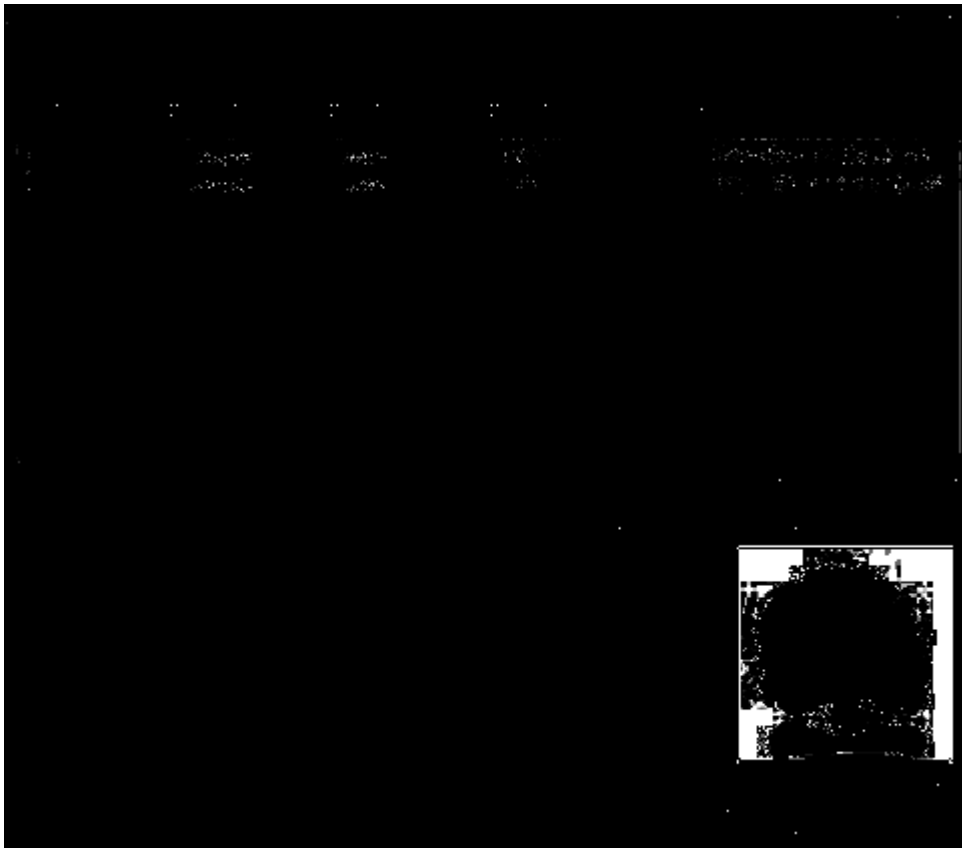
- Select the study you wish to review, then
- Click the **OK** button on the bottom of the window.

Click the **Cancel** button to dismiss the window without opening a study.

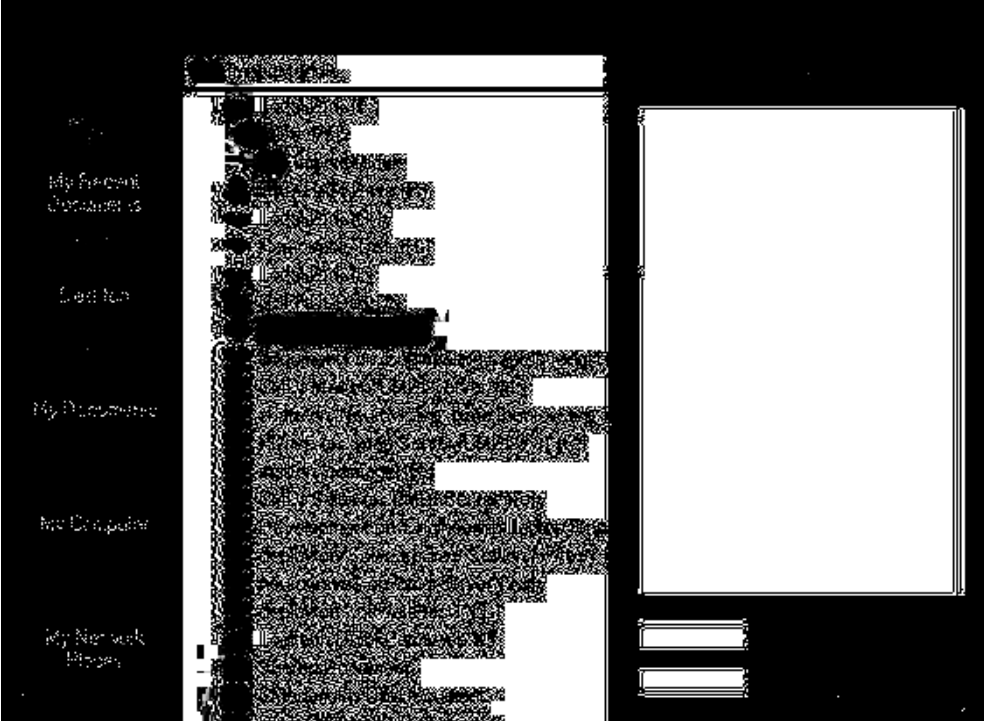
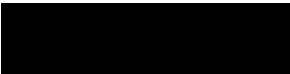
Adding a Patient Study from a Memory Card

After inserting an SD card in the card reader,

Click the Review Studies button on the Main Menu

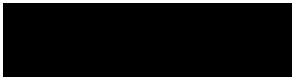


Click  to open a browsing window



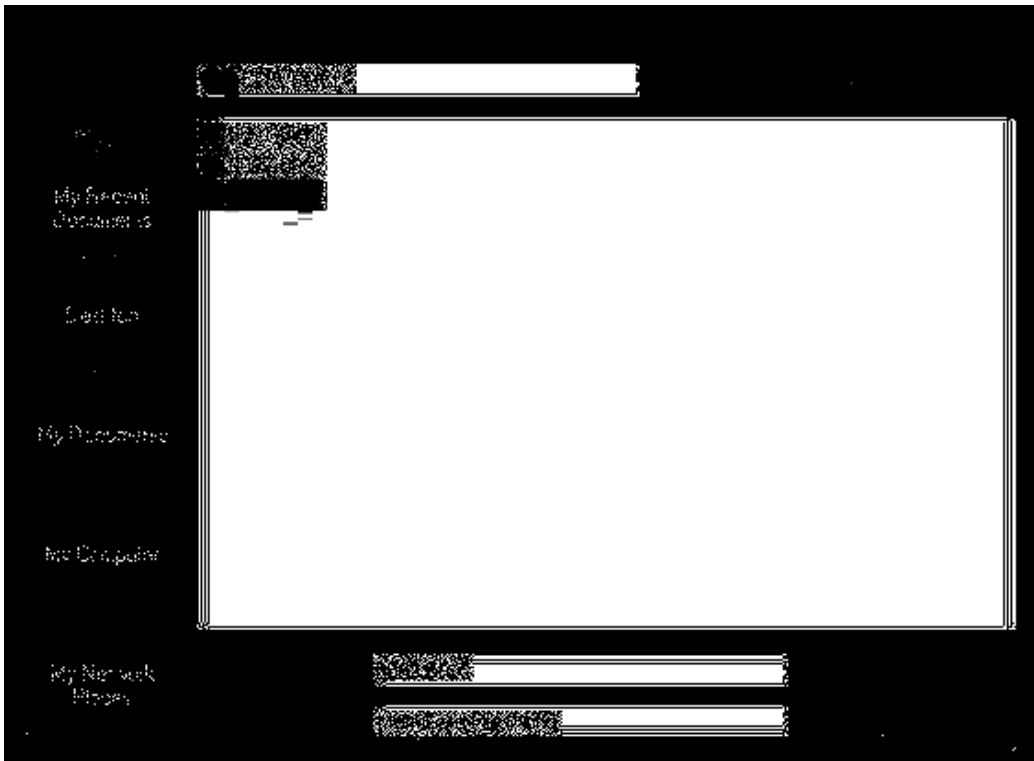
Select the removable disk that refers to your SD card. The drive name will vary depending on the computer used and the number drives available.





Select the "CLEVEMED" folder

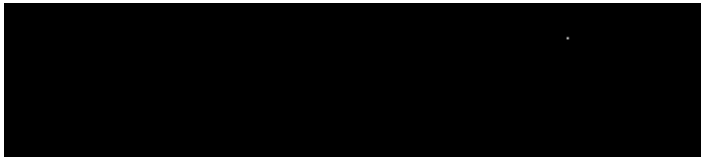
From "Files of type" Select "Mem Card File (*.brx)"



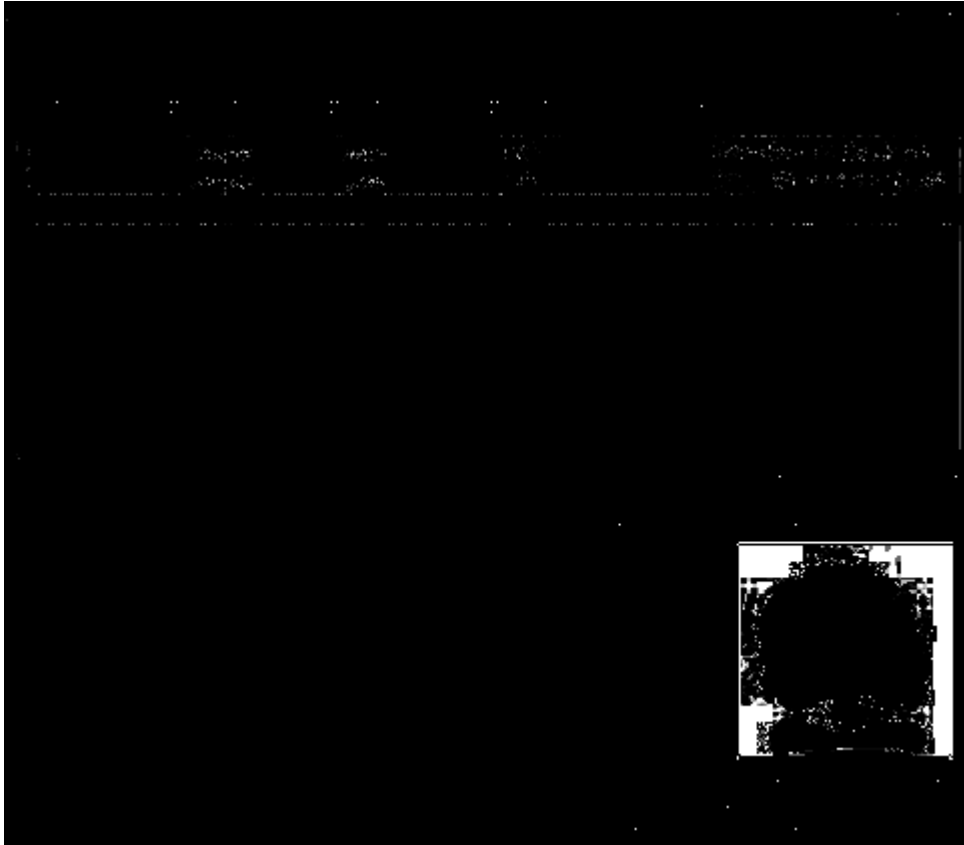
Select the file you wish to import and Click <Open>

The New Study Wizard will appear and you should follow the steps you normally would to start a new study (see Proceeding Through the New Study Wizard)

After you click <Finish>, a progress window will appear showing the import process



After the import progress window closes, a new entry will appear in the list of studies.

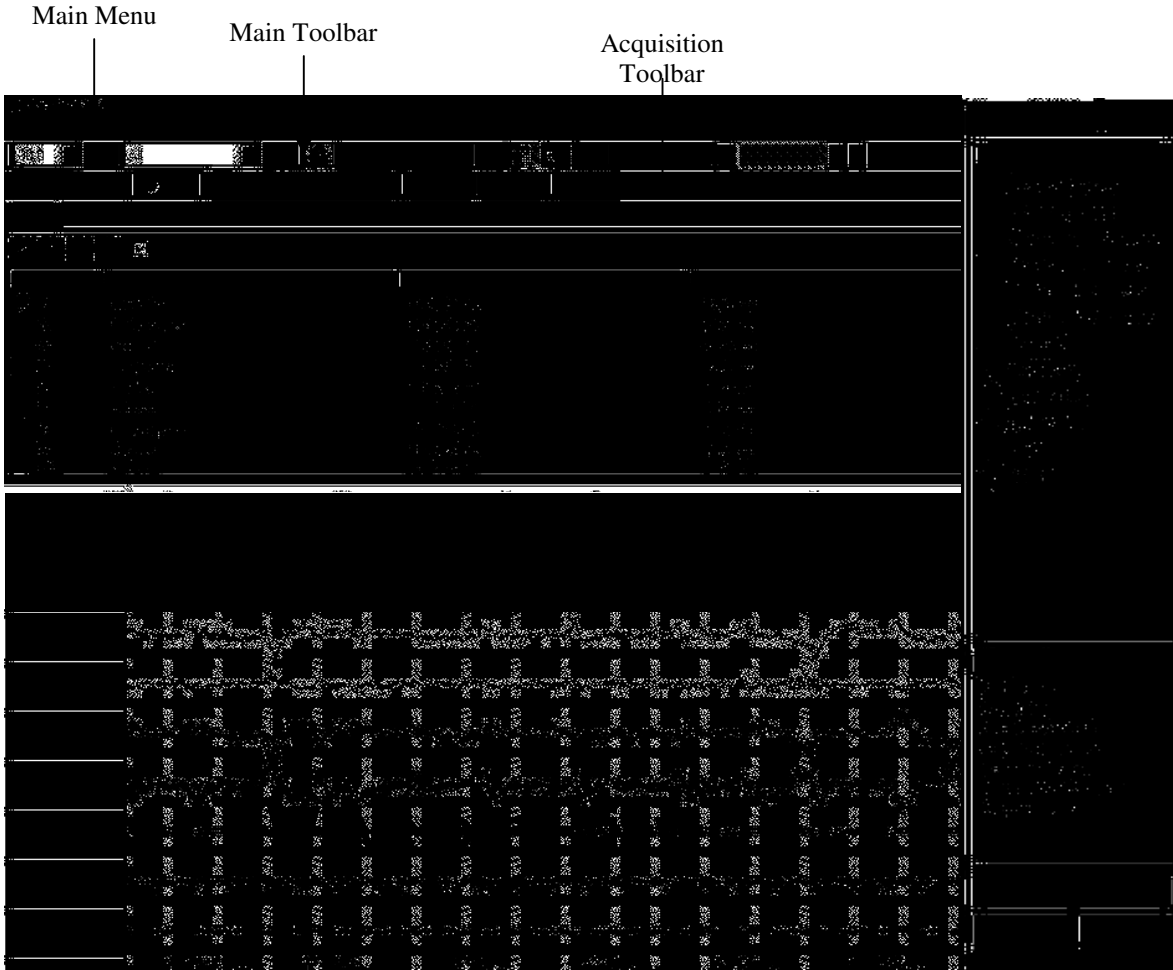


To review the study select the newly added study and click <OK>.

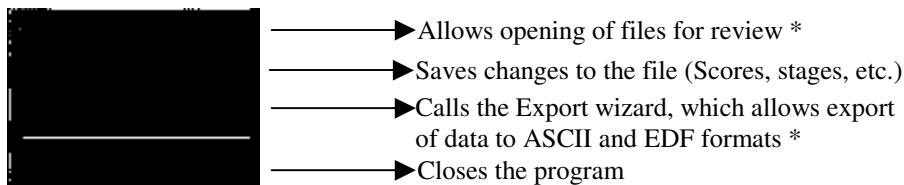


Review/Acquisition User Interface

The same user interface is used for both acquisition and review in order to facilitate quick and simple study collection, review, and scoring. The layout is annotated in the figure below.

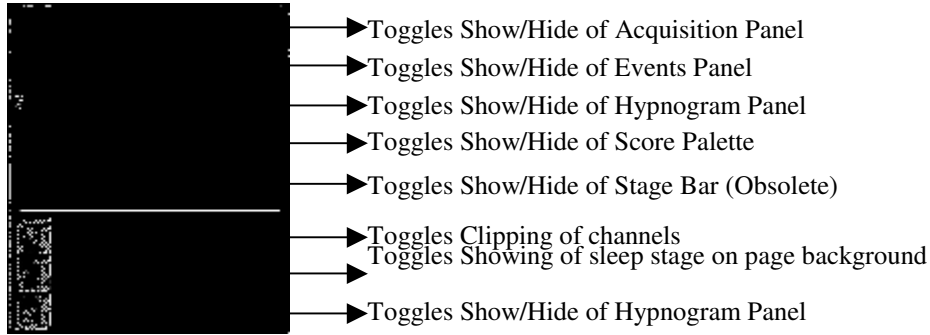


The **Main Menu** bar contains the **File, View, Tools, and Help** menus. These menus provide a convenient way of accessing information controlling various aspects of the acquisition module. The **File Menu** has the following commands:

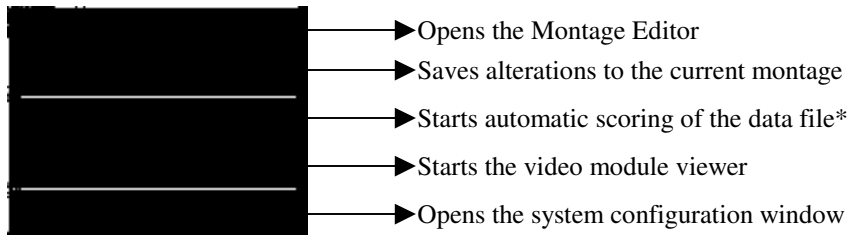


***Note: opening of files for review is not available during acquisition**

The **View Menu** has the following commands that allow you to configure the display of the application.



The **Tools Menu** has the following commands:



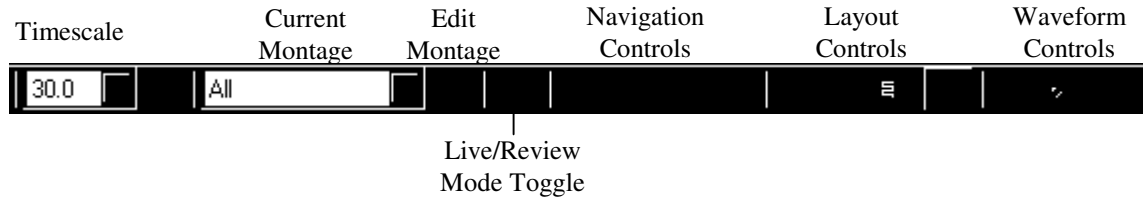
***Note: automatic scoring is a review function not available during acquisition**

The **Help Menu** provides access to an online manual and contains software version information.

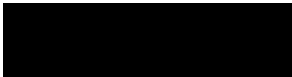








Main Toolbar

The main toolbar in Crystal PSG provides quick and convenient access to the major functions of the system, some of which were outlined above.



Main Controls	
Timescale:	Allows the user to change the page size of the display graph; the traces should expand with decreasing time and compress with increasing time.
Current Montage:	Allows the user to select a different layout setting. The layout dictates how and what array of waveforms to display.
Edit Montage:	Allows the user to add, edit or remove waveform display configurations.
Live/Review Mode Toggle:	Toggles live updating of the review display. When "Locked" the navigation buttons are disabled, and the screen will be updated once a second with the newly acquired data.
Navigation Controls	
Begin Keyboard shortcut: <Home>	Moves the display to the beginning of the data file.
Previous Page Keyboard shortcut <PgUp>	Moves to display back one page (page size dictated by the Timescale setting).
Next Page Keyboard shortcut <PgDn>	Moves to display forward one page (page size dictated by the Timescale setting).
End Keyboard shortcut <End>	Moves the display to the end of the data file.

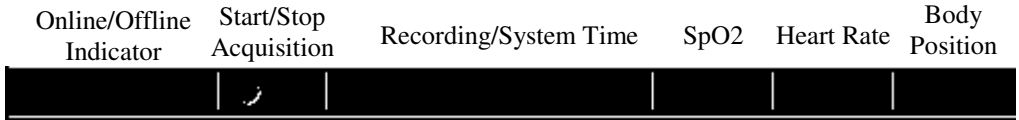


Layout Controls	
 Acquisition Panel	Toggles Show/Hide of Acquisition Panel
 Events Panel	Toggles Show/Hide of Events Panel
 Hypnogram Panel	Toggles Show/Hide of Hypnogram Panel
 Score Palette	Toggles Show/Hide of Score Palette
Waveform Controls	
 Scoring:	Allows the user to highlight and label specific portions of the display.
 Measure:	Allows the user to magnify a small portion of the graph and obtain statistical data/measurement information from that portion.



Acquisition Toolbar

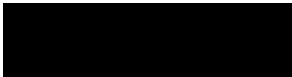
The acquisition toolbar provides control over system data acquisition as well as status information.



Offline/Online indicator	Shows the state of the Crystal Monitor transmitter (whether it is on or off or out of range).
Start/Stop Acquisition	Controls start and stop of acquisition
Recording/System Time	Clicking this label toggles between showing time of day or elapsed recording time.
SpO2 Heart Rate and Body Position	Real-time indicators of live acquisition data

Keyboard Shortcuts

- Select Next Trace (Above): <Up Arrow>
- Select Next Trace (Below): <Down Arrow>
- Increase Trace Gain: <Shift> + <Up Arrow>
- Decrease Trace Gain: <Shift> + <Down Arrow>
- Move Trace Up (offset): <Ctrl> + <Up Arrow>
- Move Trace Down (offset): <Ctrl> + <Down Arrow>
- Beginning of Recording: <Home>
- End of Recording: <End>
- Page Forward: <Page Down>
- Page Back: <Page Up>
- Scroll through the study: <Right Arrow> or <Left Arrow>
- Speed of Scrolling: <Right Arrow> or <Left Arrow>
- Increase Event Length: <Shift> + Left Mouse
- Decrease Event Length: <Shift> + Right Mouse



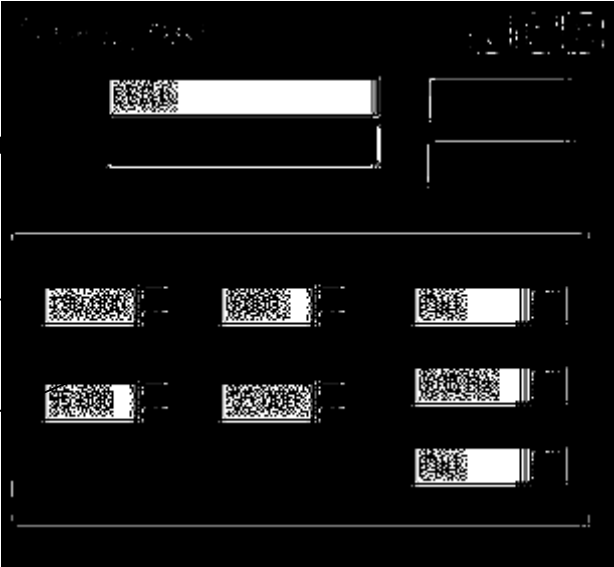
Adjusting Individual Signals

To make changes to each signal double left click on the name of the channel you would like to adjust. A new window will open.

Color – Can change display color of individual channels

Range – Increase value to decrease signal amplitude

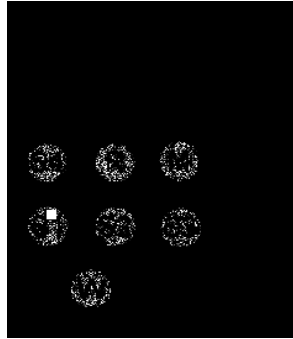
Offset – adjusts the position of the signal





Staging Guide

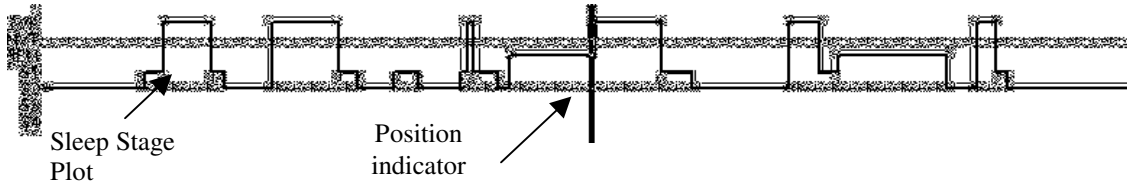
- 0: Wake
- 1: Stage 1
- 2: Stage 2
- 3: Stage 3
- 4: Stage 4
- 5: REM
- 6: Movement



At any time during review, the user may stage the current page by using the numeric keypad, or numeric keys according to the following definitions:

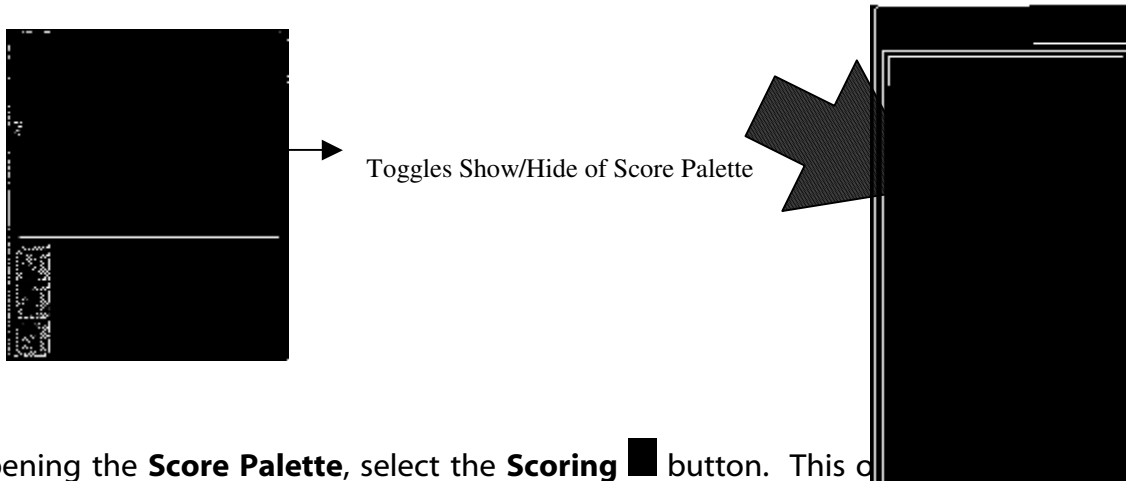
For convenience, the system is set to automatically page forward to the next epoch (30sec), each time a new stage is entered.

As part of the review window, a hypnogram view is provided that will show a 20 minute window of the sleep architecture. The value of the current epoch is shown according to the y-axis of this plot and a highlighting bar indicates the position of the current page within the plot.



Scoring Guide

To begin scoring, you must first open the **Score Palette** window. To do this, open the **View** option at the top of the screen and select **Score Palette**. You may need to expand your screen window to view the entire page.



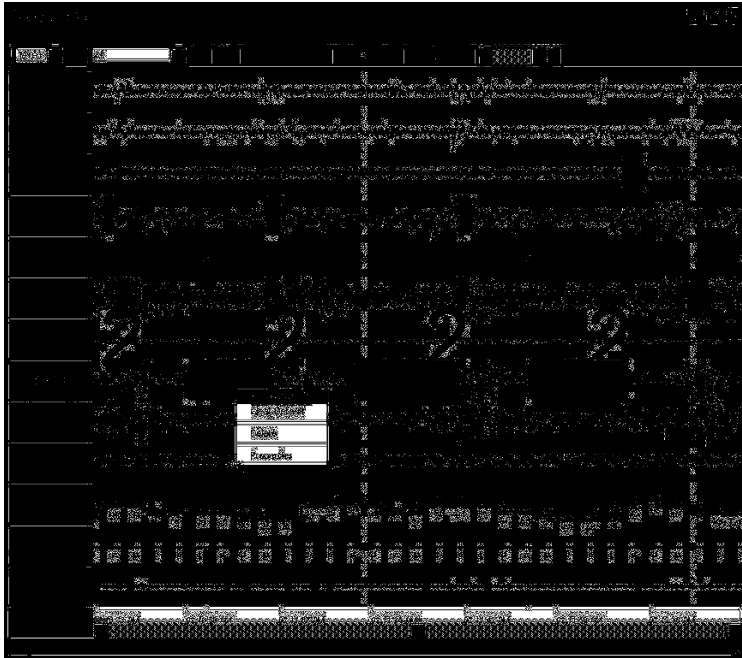
After opening the **Score Palette**, select the **Scoring** button. This allows you to mark and label any section of the chart. Once the **Scoring** button has been selected, you may choose any event on the right side of the screen.





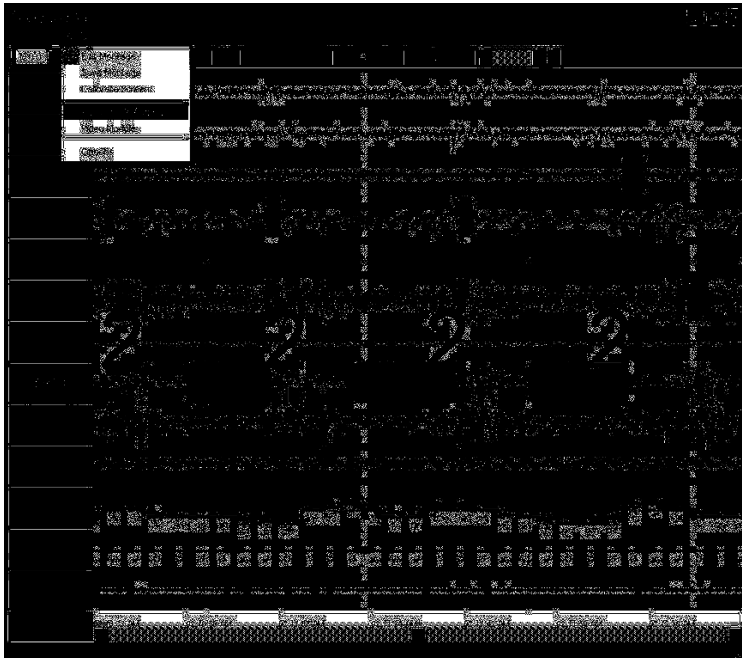
Marking Events

The colored boxes show events commonly seen in patients being assessed for sleep disorders. If a particular color is selected, the color and label will appear on any section you choose. To mark (or score) a certain area, highlight the area with your left mouse cursor and drag it over the length of the event. For faster scoring of repeated events, just click the same channel again without dragging.



A default event can be set for each channel. Place an event on a channel. With the event selected right mouse click and select Set as Default from the menu.

The duration of events can be adjusted by holding the shift key and using the right and left mouse buttons. The left mouse button will lengthen the duration and the right mouse button will shorten the duration.




Auto-Scoring

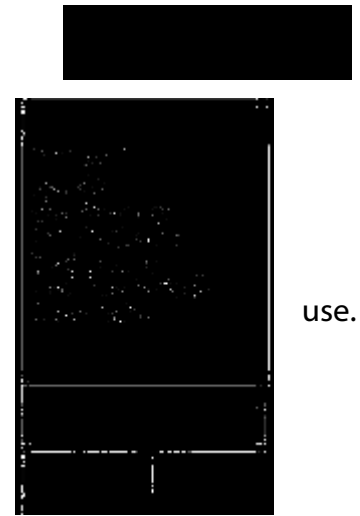
Previously recorded studies can be autoscored by selecting Tools and Re-scan file (autoscore). Auto-scoring will score events such as arousals, apneas, hypopneas and desaturations. Auto staging is not available in Crystal PSG.

Auto-scoring a file will not delete any manually entered scores. On the events list auto-scores will be marked so manual and auto-scores can be easily differentiated.

Adding Comments and Bio-cals


To add a comment to a certain area, select the **Comment**  button. Then, in the bottom window, you can select a specific pre-labeled comment (such as Leg Movement or Eye Blink). If desired, you may enter your own comment in the space provided. If you click the **Add** button, it will be permanently added to the comments box for future use. If you do not click **Add**, then it will be used once. To remove a saved comment, highlight it in the list and click **Remove**.

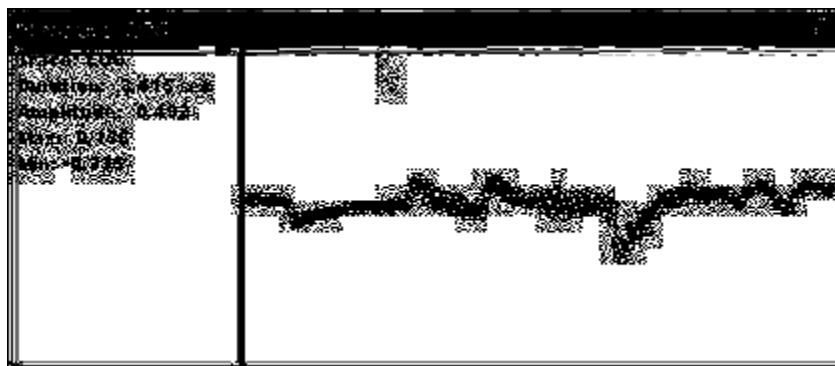
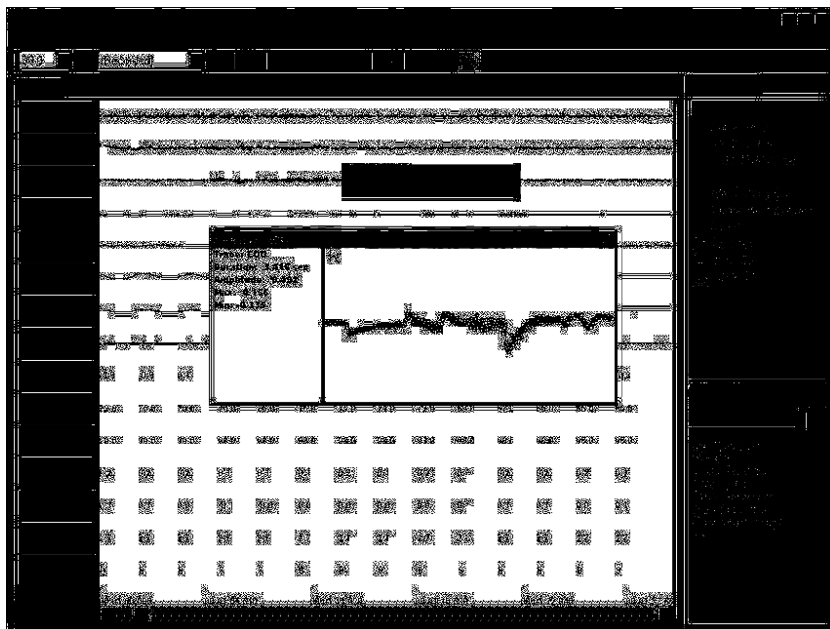
To put the comment in a certain area on the trace, choose a comment, then, highlight the area with the cursor.





Measuring Tool

To obtain more detailed information about the waveforms, choose the **Measuring  Tool**. Then highlight the desired section of the graph. A new window will appear in the middle of the screen with an enlarged view of the highlighted section and statistical data on the left side of the new screen.



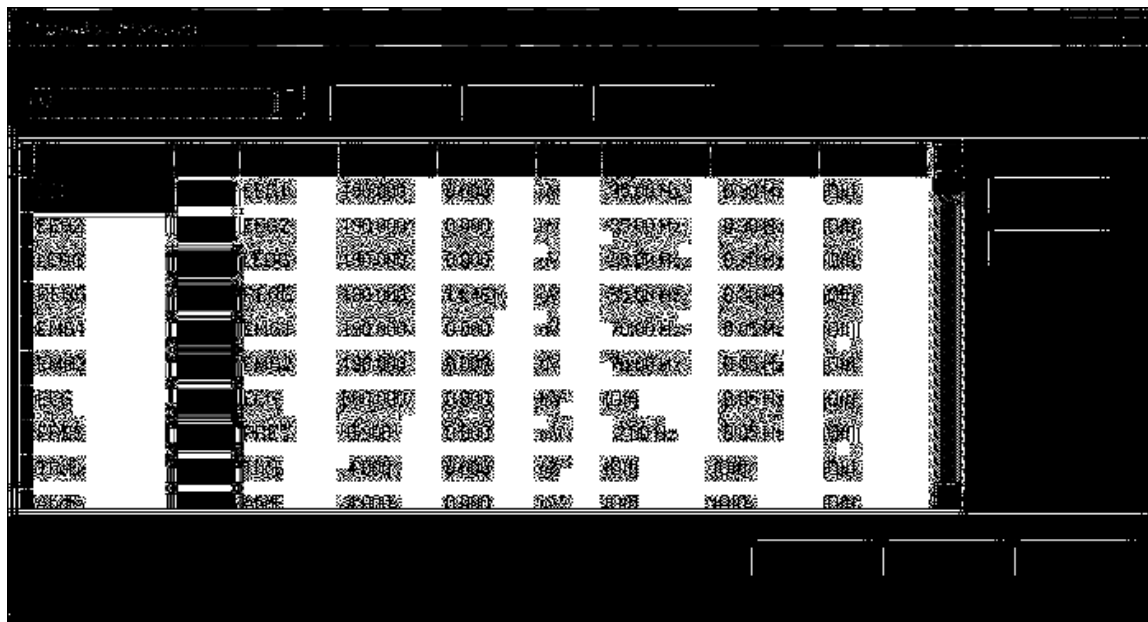
The statistical data shows the following:

- **Trace:** which specific channel the highlighted section is taken from
- **Duration:** the duration of the highlighted section
- **Amplitude:** the maximum peak-to-peak amplitude of the highlighted section
- **Max:** the maximum value in the highlighted section
- **Min:** the minimum value in the highlighted section



The Montage Editor

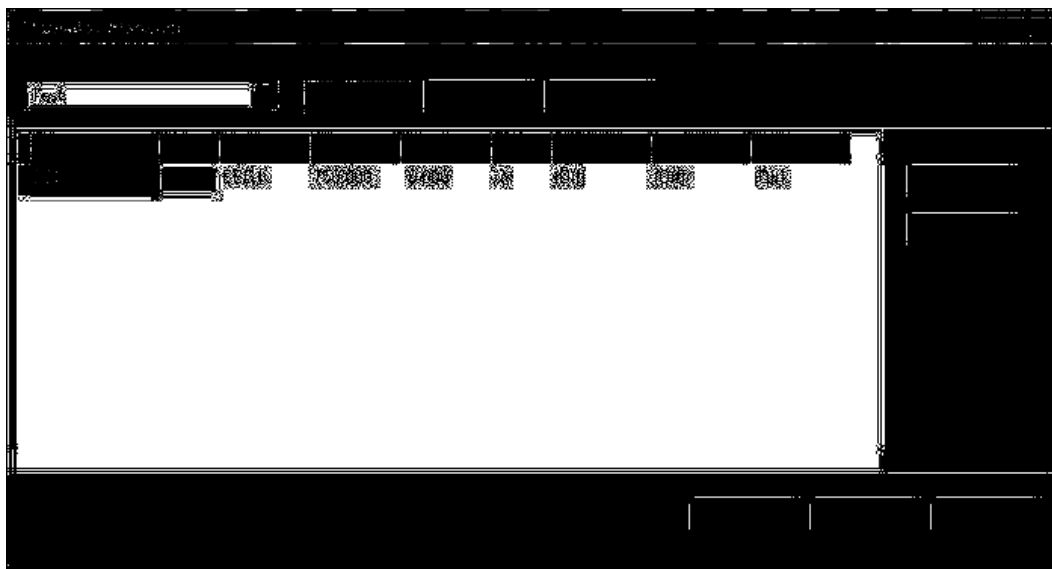
Click the **Montage Editor**  button. A new window should appear.



This screen enables you to add/remove channels, change the color of certain channels on the acquisition screen, change the limits of the input, and add low/high pass filters.

- The **Name** box allows you to name the channel. You may edit/change this name as you see fit.
- The **Color** box changes the color of that channel's trace when it appears in the waveform view.
- The **Input** box represents the actual channel from the transmitting device that you would like to record under this name. These channels are marked appropriately on the device.
- The **Range** and **Offset** boxes allow you to set the upper and lower limits on the trace. The range is equivalent to sensitivity settings on other machines. To enlarge the graph, set smaller limits. To compress the graph, set larger limits.
- The **Units** box allows you to set the value of one unit.
- The **Low Pass**, **High Pass**, and **Notch** boxes allow you to filter the input.

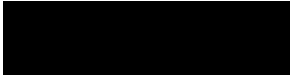
If you would like to make a personalized display configuration, you can click **New**. You will be asked to enter a **Display Configuration** name. After you enter a name, click **OK**. A blank display configuration window will appear.




To add a new recording channel, click **Add**. A new channel will appear. You can manipulate the settings according to preference. Notice the blue highlighting around the right end of the channel toolbar. This indicates the channel you are currently modifying. To remove a specific channel click on that channel, highlight it, and click the **Remove** button. After you have completed your personalized display configuration, click the **Save** button.

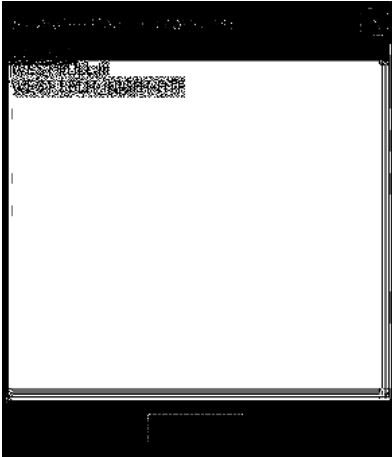
To modify an existing configuration without overwriting the original, you may use the **Copy** button. Choose an existing configuration, then click the **Copy** button. You will be asked to enter a **Display Configuration** name. Enter a unique name and click **OK**. You will be able to modify existing parameters, delete or add channels, and rename existing channels. Once you have finished, click the **Save** button. All of the new modifications will be saved under the new name.

To exit this screen, press **OK**.



Chapter 8: Report Generation

To generate a report, from the Main Menu select  Select & open a study according to the same process used for scoring.



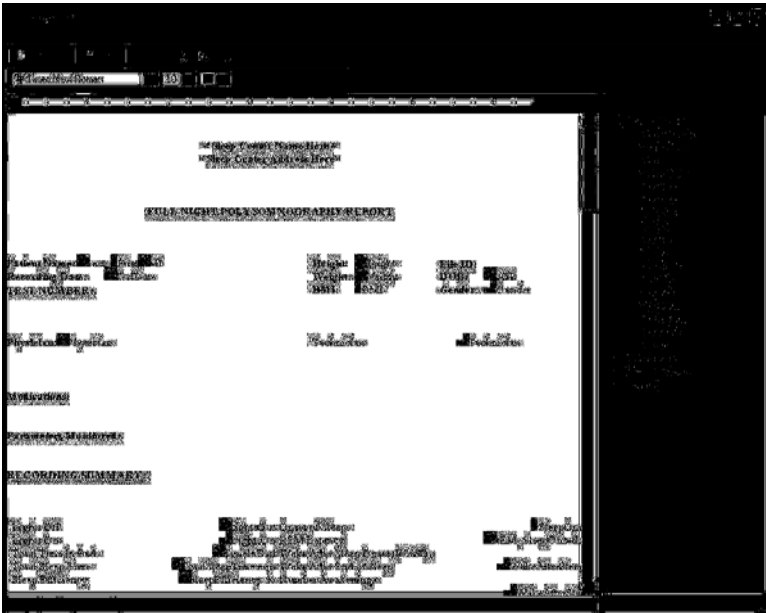
Select a template from the list in order to generate a report according to a standard format. The report may take up to a few minutes to generate depending on the length of the study and the number of events marked.

Crystal PSG is preconfigured with a few report templates that your lab can customize. CleveMed is also able to assist you in creating your own personalized report templates.

Editing and Creating a Report Template



After generating a report, select the view menu to toggle between "Edit Report" and "Edit Template". In edit report mode, the generated report for a particular patient may be edited. This is used for entering physician notes or scores for tests that are not part of the PSG test. In edit template mode, new templates can be created and edited.



In edit template mode, a list of calculated and drop in merge fields is shown on the right side of the screen. Text can be written including merge fields when the report is viewed in report mode the merge fields will be completed with the data for the selected patient. Please contact CleveMed for further assistance with creating custom report templates.

Chapter 9: Data Storage

The default software settings store patient data files in C:\CleveMed\CrystalPSG. Each recorded study creates two files a header file (*.psg) and a data file (*.psd). The header and data files are both named by the date and



time that the file was collected. For example, the files 2005-05-18-23-45-25.psg and 2005-05-18-23-45-25.psd were created for a study recorded on May 18 2005 starting at 11:45:25 PM. **It is important to not open and edit these files as they may become corrupt or the patient data may be displayed incorrectly leading to a misdiagnosis.**

Note: There is no patient demographic information available in either file. The patient name, ID and other personal information is not included to comply with HIPAA (Health Insurance Portability and Accountability Act) in the event of sharing data with other labs or CleveMed.

Before archiving data, it is suggested that a log including the patient ID number, name, study date, and study time is created. A spreadsheet program, such as Microsoft Excel, could be used to make the log. To make data retrieval easier, create a folder named for each patient and copy the appropriate .psg and .psd files into the folder. Then the folder can be archived.



Chapter 10: Troubleshooting

If your **Crystal Monitor** is not performing properly, use this troubleshooting chart for quick solutions to common problems. If the problem persists, call Cleveland Medical Devices Customer Support at 1-877-CLEVEMED.

Symptom:	Possible Cause:	Solution:
1. No data is being displayed	a. Receiver unplugged from PC	a. Re-connect to USB port.
	b. Patient Unit power switch off	b. Turn power back on (Patient Unit)
	c. Patient Unit batteries are exhausted	c. Replace batteries
2. Signal image breaking up periodically	Dropped packets (poor wireless signal)	a. Position Computer Unit and Patient Unit closer together. Recommended distance is 100 feet (20-S) or 50 feet (20-B) direct (line of sight)
		b. Move large metal objects away from the area.
		c. Contact CleveMed for instructions on performing a frequency spectrum survey to determine good recording channels for your environment.
3. Signal image cut off	Amplitude of data exceeding visible range	Adjust scale control
4. Signals difficult to visualize	Channel color selected does not contrast well with screen background chosen	Change channel color
5. Signals are noisy	a. Electrode impedance is too high or miss matched	a. Check the impedance on the patient electrodes and replace electrodes with high impedance
	b. Display settings are not correct	b. Adjust the filter settings on the channels that are noisy
	c. System failure	c. Please contact customer support for further assistance.
6. Computer freezes up or display appears choppy	a. PC needs a faster processor	a. Run Crystal Monitor PSG on a Pentium III™ 500 MHz or higher system.
	b. Timescale is too large to display the requested number of data points	b. Change the timescale to a smaller value.
7. No receiver found	a. No power to the receiver	a. Check that the USB cable is not damaged, is properly connected to the Computer Unit



		and to the computer
	b. Drivers are not installed	b. See Chapter 3 Setting up the System.