CleveMed

Cleveland Medical Devices Inc.

Crystal Monitor ® PSG Series 20-S, 20-B

Preliminary

User's Guide

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TABLE OF CONTENTS

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 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), 15.247, and Part 95.
Such interference could be caused by the use of multiple Crystal Monitor systems operating in the same vicinity.

FCC RF Exposure requirements: The antenna(s) used for this transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

Warnings

Improper routing of leads may result in a chocking 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.

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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 PSG
software

Computer
Unit

Patient Unit

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
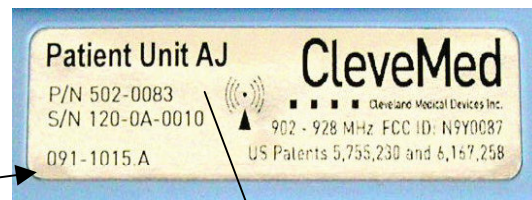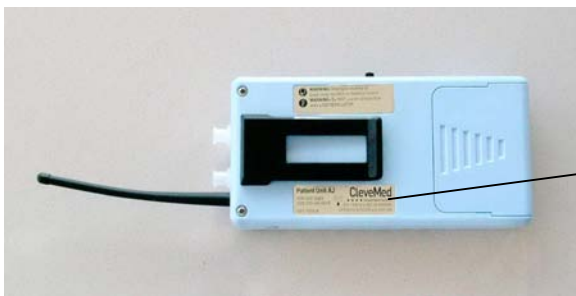   be recorded until no disk space remains.

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

Match the Patient Unit ID with the Computer Unit ID.

Computer Unit
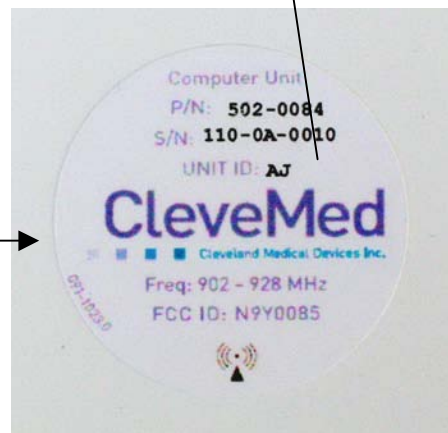
Dongle – Crystal Monitor 20-B only

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.**
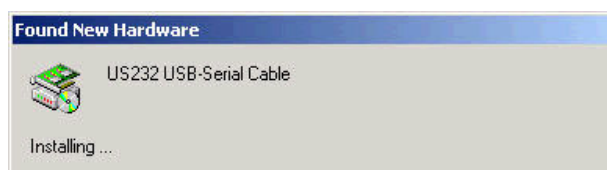
USB Driver Installation

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'
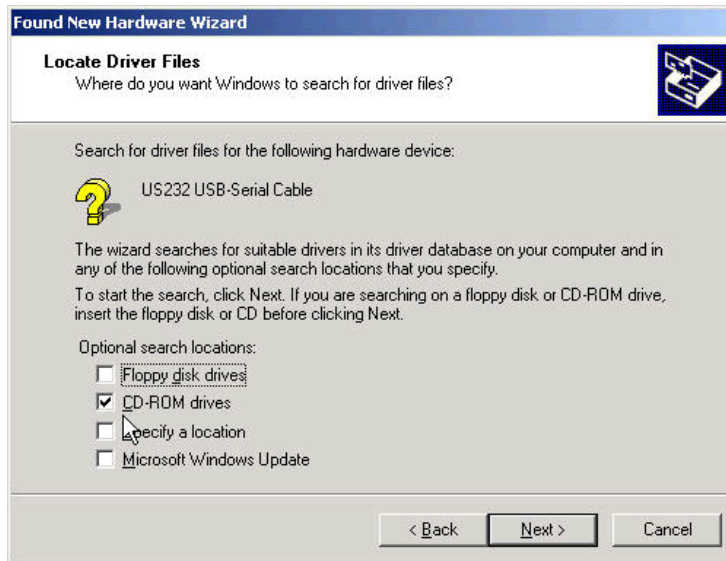
Confirm Installation

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.
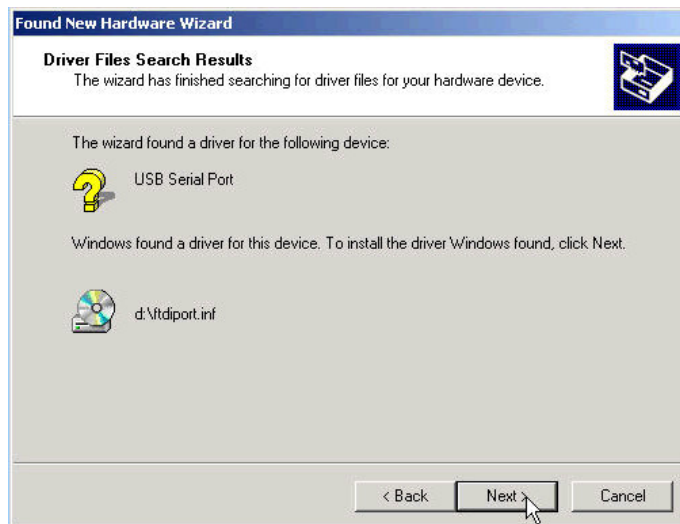

Specifying the Driver Location

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.
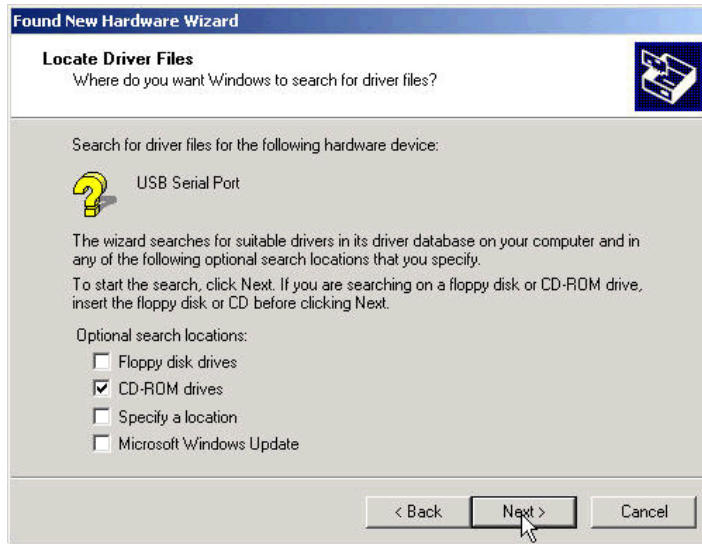
Confirming Installation

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.
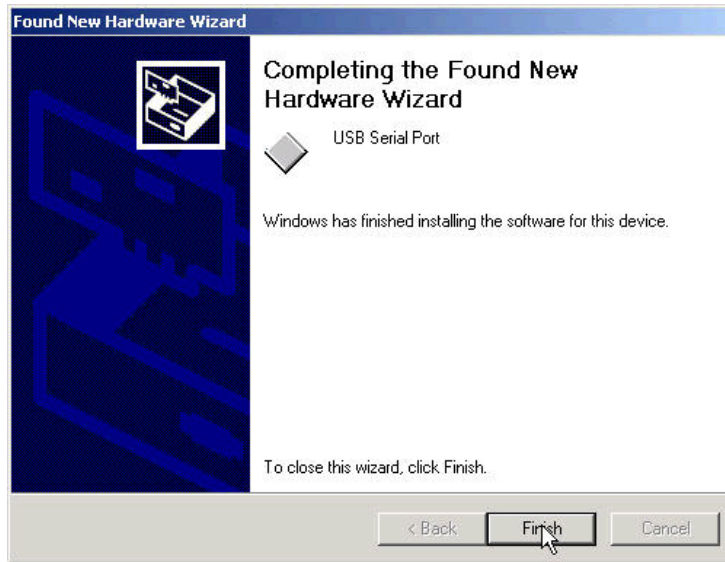
Setting Up the Crystal Monitor 20-B.

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.
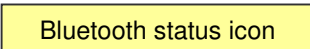

USB Bluetooth adapter with antenna

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:

Bluetooth status icon

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 form 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:
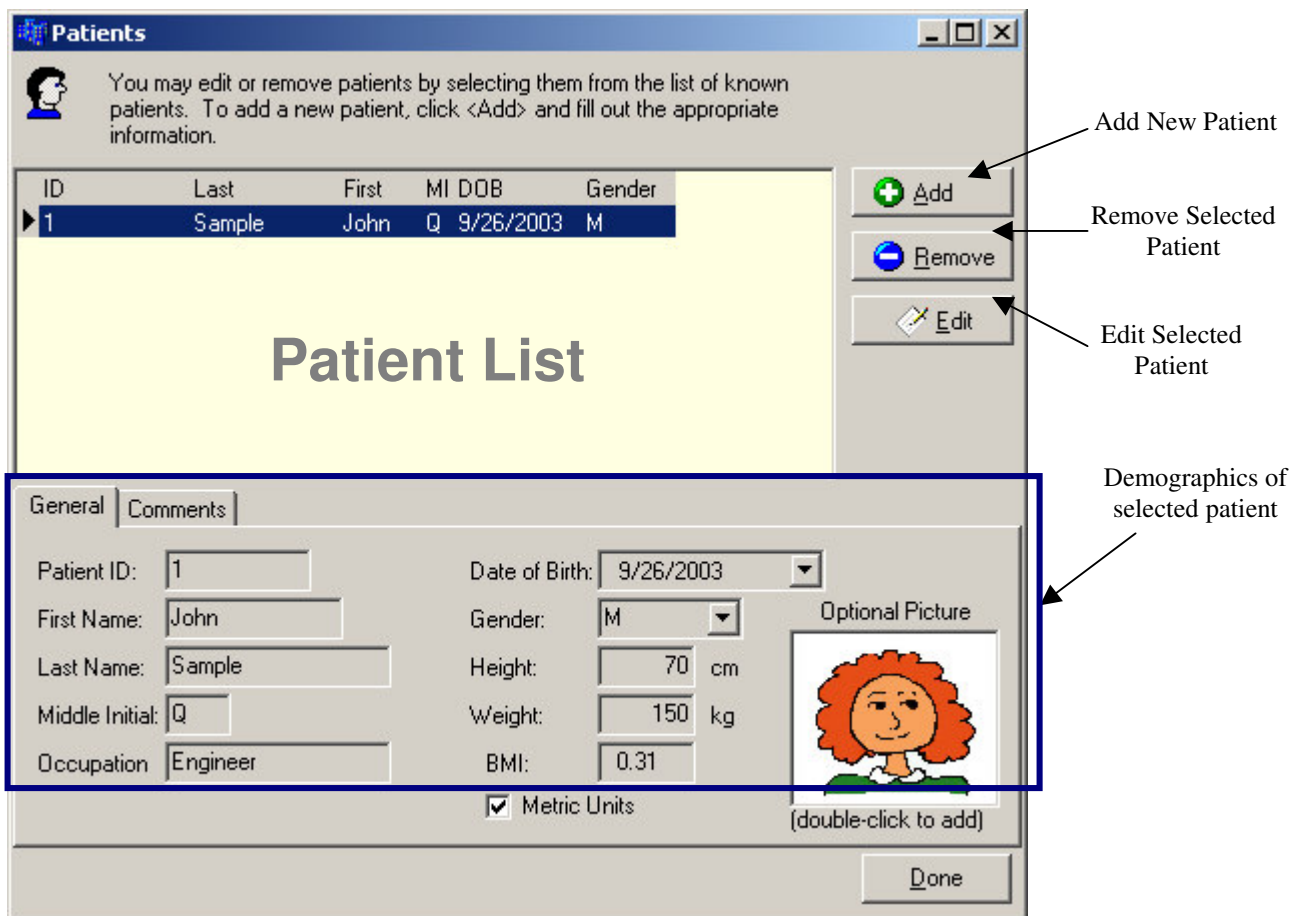
System Setup –View radio channel, location of files on the directory and sleep center name.

New Study – Start recording. Enter physician & technologist name, comments, study description and start acquisition

Patient Management – Create new patient files; remove or edit patient demographic information. .

Review Studies –Defaults to files on local computer. Access and score records.

Exit System – Exit Crystal PSG and return to the Windows desktop.

Review From File – Browse to find records beyond local computer (CD, LAN)

Reporting – Create a report from file on local computer using available

Reporting From File – Create a report from files accessed by browsing directory (CD, LAN).

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 [Patient Management] from the Main Menu.

🖱 Clicking the Add Patient 🗿 button in the New Study Wizard.

This will display the Patient Management window.
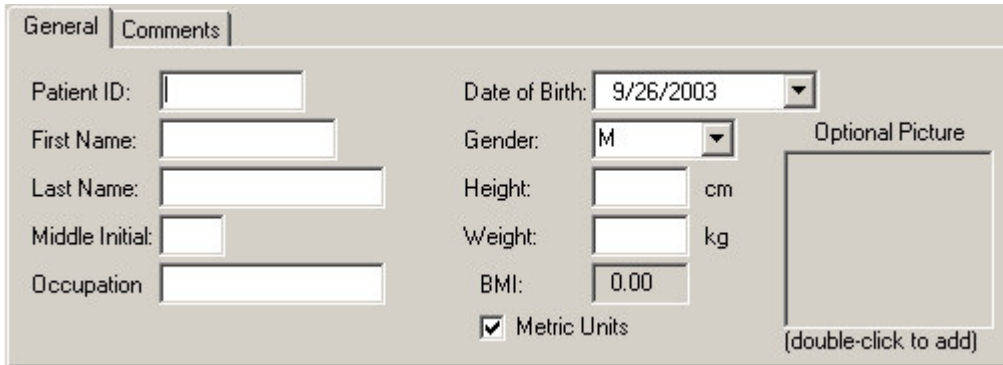
Database Operations

Adding/Editing Patients

To add a new patient to the system, click [⊕ Add]
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 [✎ Lock]

You will be presented with the message:
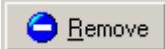
Click **Yes** and the new patient information has been entered into the system.

To edit existing patient information, select the patient you would like to edit, click

[✎ Edit] and follow the same instructions above for entering patient information.

Removing a Patient

A patient can be removed from the database by clicking [🔵 Remove] n the toolbar. Before removing, the software will prompt the user to be sure the patient should be removed.
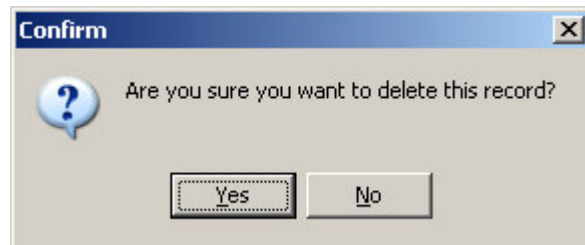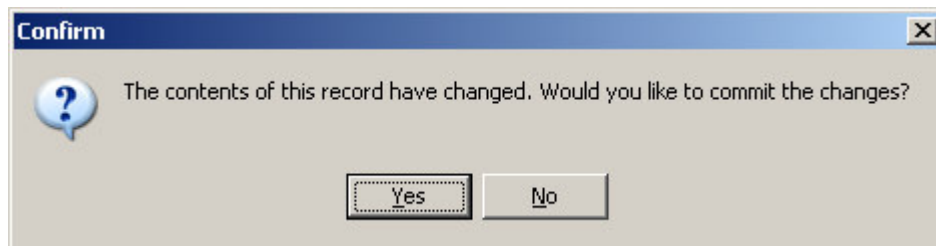

Closing the Patient Manager

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 [Done]

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

To save the changes, click <u>Y</u>es. To discard the changes, click <u>N</u>o.

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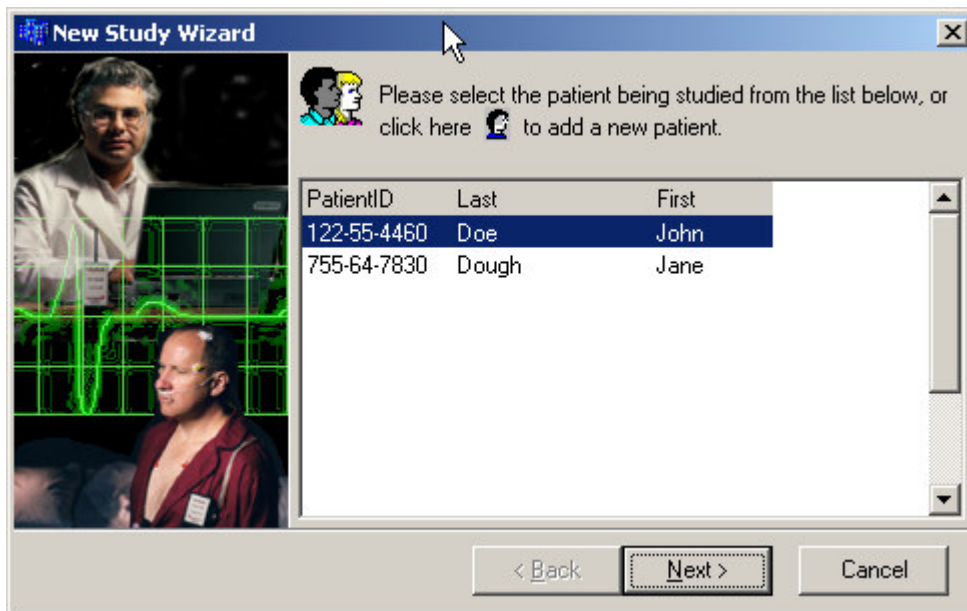
The **New Study Wizard** can be opened by:

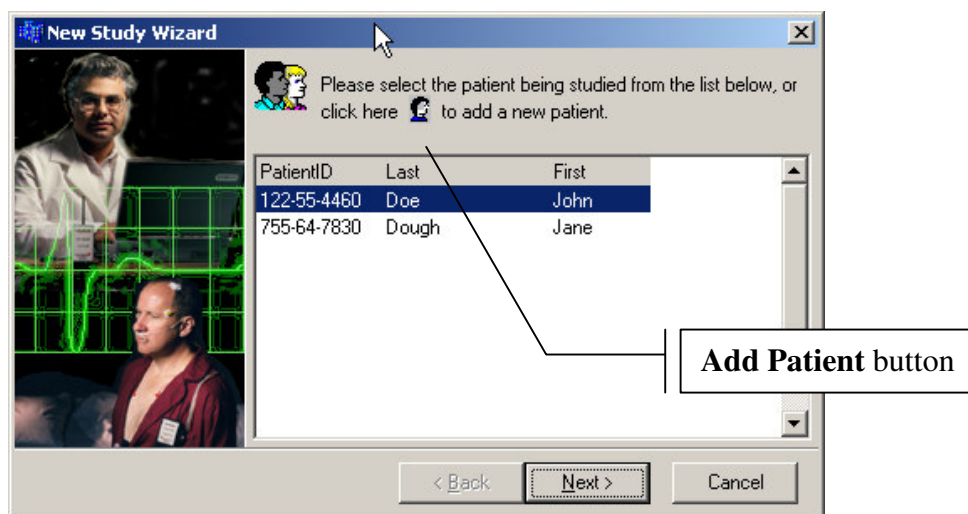🖱️   Clicking the **New Study** button on the **Main Navigator**.

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:
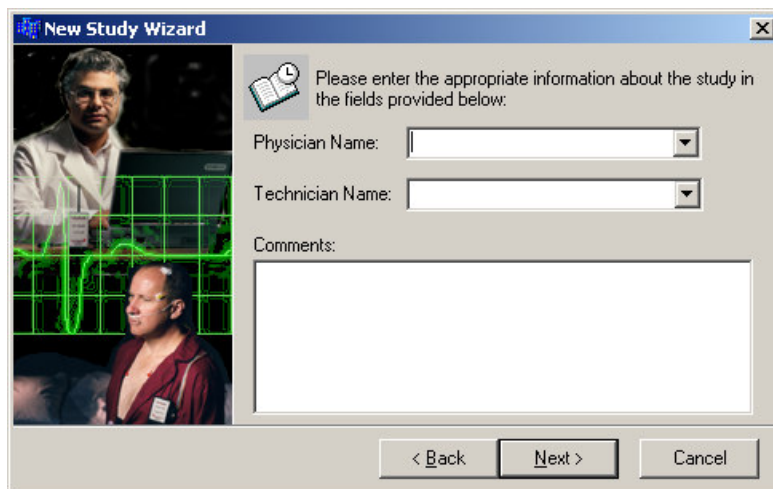
Select the patient in the **Patient List**.

Add Patient button

To add a new patient Click the **Add Patient** but ... 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.
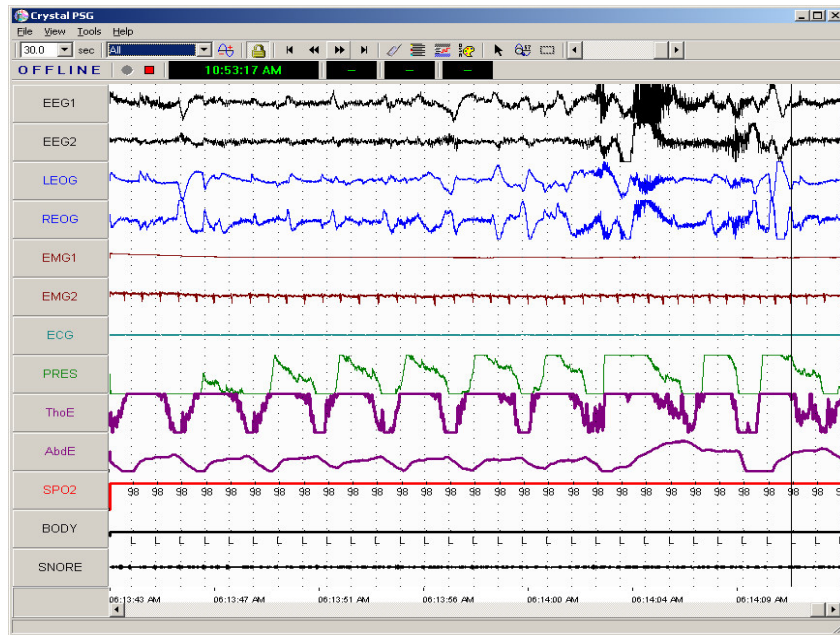

This is the last page in the **New Study Wizard**. To complete the **New Study Wizard** and to move on to **Data Acquisition**:

🖱   Click the **Finish** button.

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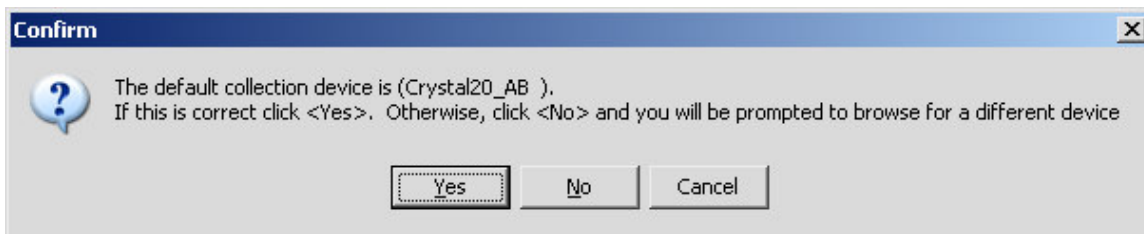

Starting   Acquisition
(Crystal Monitor 20-B Only)

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

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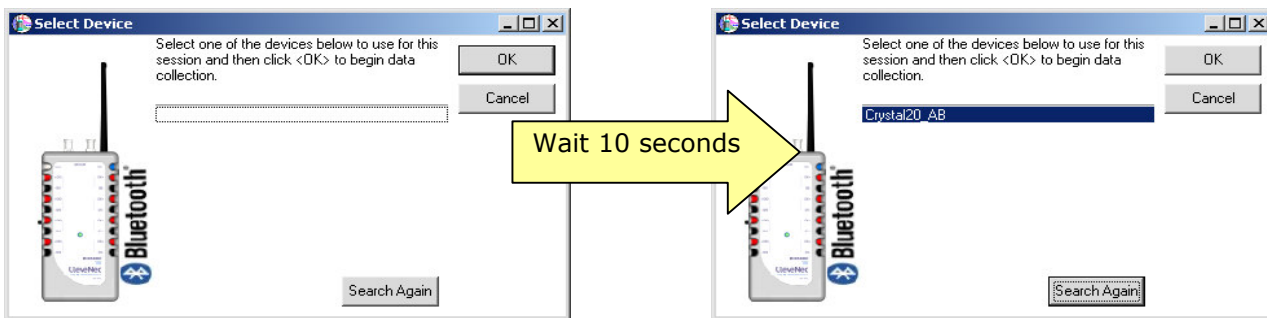

Note: if no devices appear, ensure your Crystal Monitor 20-B unit is in range, has fresh batteries and is turned on, and then click <Search Again>.

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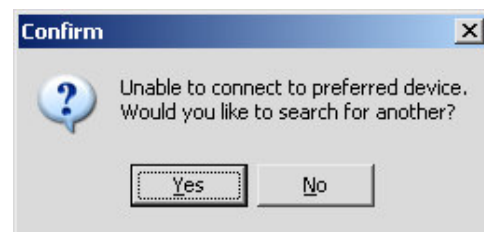
(Note: It does take some time (10-15sec) for the system to resolve the name of the device, so you may want to click the <Search Again> button a few times after turning the unit back on)

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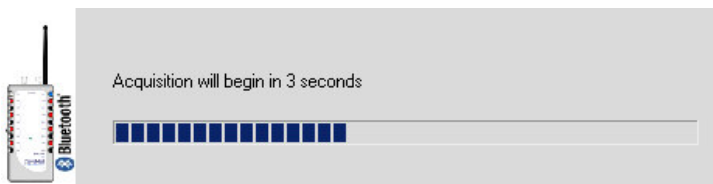
During acquisition the device ID of the patient unit can be verified in the lower left corner of the acquisition screen.

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.