Oscar Express Central Terminal User's Guide

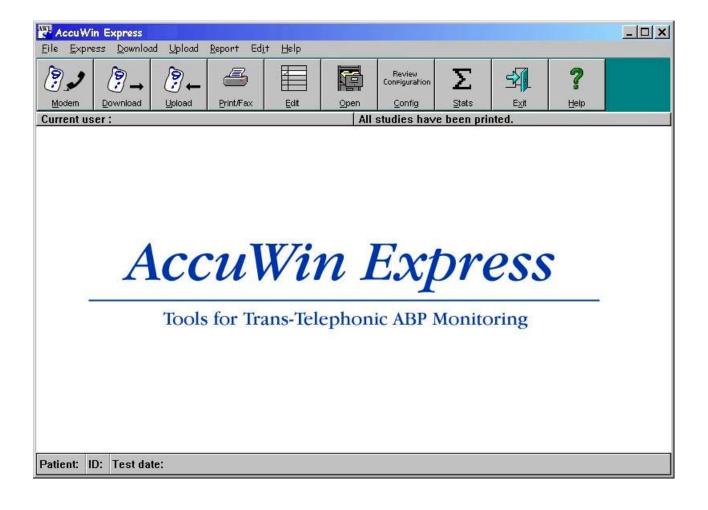




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Introduction to Ambulatory Blood Pressure Monitoring

The rationale for using ambulatory blood pressure monitoring (ABPM) is based upon the enormous variability of a person's blood pressure over time. A traditional view is that adverse effects of blood pressure (BP) on the circulatory system depend on the average level of pressure over time. However, scientific evidence and sound theoretical reasons support multiple measurements of BP as better predictors of pressure-related clinical outcomes than single measurements. "In every study in which Ambulatory Blood Pressure Monitoring has been compared with casual blood pressure measurements, ABP has proved superior in predicting either target organ damage, morbid events," or cardiovascular risk. 12,3

Casual blood pressure measurements taken in a doctor's office or clinic or by patients themselves are not representative of blood pressure readings throughout the 24-hour day. "Several clinical problems are better elucidated by ABPM than by casual readings. These include borderline hypertension with target organ involvement; "resistant" hypertension; episodic hypertension; "office" or "white coat" hypertension and evaluation of episodic hypotensive symptoms."

Ambulatory blood pressure monitoring provides an accepted clinical tool for collecting multiple BP measurements to better assist clinicians with diagnosis and management of hypertension. The data obtained from ambulatory blood pressure monitors is highly accurate and useful for managing a wide variety of hypertensive situations including:

- Borderline hypertension
- White coat hypertension
- Resistant hypertension
- Episodic hypertension and/or anxiety disorders
- Hypertension during pregnancy
- Childhood hypertension
- Efficacy of anti-hypertensive drug therapy on a 24 hour basis
- Changes in diet and daily routine designed to reduce hypertension
- Hypotensive symptoms
- Clinical trials of pharmaceutical agents, especially anti-hypertensive agents
- Nocturnal hypertension

Pickering, T. G. et al. "What is the role of ambulatory blood pressure monitoring in the management of hypertensive patients?" Hypertension 7.2 (1985): 171-77.

^{2.} Mansoor, G. A. and B. M. Massie. "Left ventricular hypertrophy: a potent cardiovascular risk factor and its relationship to office and ambulatory blood pressure." <u>Blood Press Monit.</u> 4 Suppl 1 (1999): S19-S22.

^{3.} White, W. B. "Ambulatory blood pressure as a predictor of target organ disease and outcome in the hypertensive patient." <u>Blood Press Monit.</u> 4.3-4 (1999): 181-84.

^{4.} National High Blood Pressure Education Program (NHBPEP) Working Group on Ambulatory Blood Pressure Monitoring. National High Blood Pressure Education Program (NHBPEP) Working Group report on ambulatory blood pressure monitoring. NIH publication; no. 90-3028, -21. 2002. Bethesda, MD., U.S. Dept. of Health and Human Services, National Institutes of Health, National Heart, Lung, and Blood Institute. 1990.

Introduction to the Oscar Express ABP Telemonitoring System

The Oscar Express Ambulatory Blood Pressure Telemonitoring System is designed to provide easy and effective ABP monitoring at remote sites managing the clinical process of data collection, while a central terminal manages the data handling and BP report generation. The Oscar Express system is made up of a central terminal, and multiple remote sites each operating one or more Oscar 2 monitors.

Using the Oscar 2 monitor and its modem capability, ABP data can be collected for a patient at a remote site and transmitted via modem over an analog phone line to the central terminal for data review. The central terminal handles the receipt and processing of data with the PC-based software package, AccuWin-Express. This software provides the central terminal an easy-to-use platform for reviewing and editing the ABP data to create a report that can be printed and sent, or faxed, to the remote site.

The modem capability of the Oscar 2 monitor also includes remote programmability by the central terminal. This allows the download of patient data *and* the upload of new study parameters to prepare the Oscar 2 for the next patient study—all in one quick transmission. This eliminates the time and cost of mailing or transporting an ABP monitor between sites for remote data collection and ABP report generation.

Note: Oscar Express is currently validated for use in North America and Europe. Other regional validations are ongoing.

Central Terminal and AccuWin-Express

The central terminal serves as the base for programming the Oscar 2 monitor for an ABP study, receiving all ABP data, storing and processing the data, and generating reports.

Requirements to serve as a central terminal include:

- A PC with Windows 98 or later, a CD-ROM drive, and at least 5 Megabytes of available hard drive space (A large patient database may require more hard drive space).
- An accessible analog phone line.
- An internal or external modem (AT compatible).

AccuWin-Express is the PC-based software tool provided to the central terminal for managing data handling and report generation. Like previous AccuWin-Pro software releases, AccuWin-Express is a powerful application allowing maximum flexibility in the configuration, analysis, and reporting of ABP studies. It adds the ability to program Oscar 2 monitors at multiple remote sites, receive data from multiple remote sites, as well as manage a database to easily configure remote site information, patient information, and patient studies.

AccuWin-Express also allows you to design and print clinical reports using either default or custom formats. When creating your own report formats, you can include any combination of the following data:

- Patient information
- Statistics of the ABP study—BP loads as well as maximum, minimum, and average BP values and standard deviations
- Clinical summary—includes patient history and clinical interpretation

Introduction to the Oscar Express ABP Telemonitoring System

- ABP study data
- Histograms of ABP study data and calculated variables
- Ambulatory blood pressure monitor configuration

Remote Sites

A remote site receives from the central terminal a fully initialized Remote Site Oscar 2 ABP system(s) and an initialized remote site modem kit. All that is needed for data transmission is a phone and an available analog phone line. The remote site manages the clinical process of data collection—issuing the monitor to patients, setting up the patients with the monitor, and making sure the Oscar 2 monitor is functioning correctly. When the patient returns the Oscar 2 monitor, the monitor is connected to the modem for data transfer to the central terminal. The central terminal retrieves the data from the Oscar 2 monitor and programs the monitor for the next patient study.

The Oscar 2 is a non-invasive oscillometric blood pressure monitor capable of measuring an adult patient's systolic and diastolic blood pressures. It is intended for use as an aid or adjunct to diagnosis and treatment.

AccuWin-Express is used to enable the Oscar 2 for Oscar Express modem communication. Once enabled, AccuWin-Express is the only software package that can communicate with the Oscar 2. This includes communication over analog telephone lines via modem and direct communication to the PC COM port. If you need direct Oscar 2-to-PC communication with previous versions of AccuWin-Pro, the Oscar Express option must be disabled. The Oscar Express option can only be disabled at the central terminal by AccuWin-Express with the monitor connected directly to the PC.

Operation

The Oscar 2 unit is worn by the patient either in a waist belt or shoulder strap and is connected to a cuff around the non-dominant upper arm. The cuff is inflated automatically at intervals that can be programmed during setup. Blood pressure is measured by the oscillometric method that senses pressure waves in the artery when occluded by pressure in the cuff. Measurement of the frequency of the pressure waves also allows heart rate to be measured. The Oscar 2 monitor can record up to 250 measurements.

Blood pressure measurements determined with this device are equivalent to those obtained by a trained observer using the cuff/stethoscope auscultation method, within the limits prescribed by the *American National Standard, Electronic or Automated Sphygmomanometers*. The Korotkoff sounds heard over the artery below the compression cuff vary in character as the pressure in the cuff is reduced from above systolic toward zero or atmospheric pressure. They are divided into phases. Phase 1 (K1) or systolic begins with the sudden appearance of a faint, clear tapping or thumping sound that gradually increases in intensity. Phase 5 (K5) or diastolic begins when silence develops, and is used to determine overall efficacy of the Oscar 2. To obtain results of the study, please send a written request to:

SunTech Medical 507 Airport Boulevard, Suite 117 Morrisville, NC 27560-8200 USA

Association for the Advancement of Medical Instrumentation. The National Standard of Electronic or Automated Sphygmomanometer. Arlington, VA: AAMI; 1996.

Specifications

Method of Measurement:	Oscillometry with step deflation.	
Blood Pressure Range:	25-260 mmHg (max inflate 280mmHg)	
Heart Rate Range:	40-200 bpm	
Accuracy:	±3 mmHg	
International Standards:	EN 60601-1, EN 60601-2-30, EN 60601-1-2 (EMC), EN 1060-1, EN 1060-3, "Non-Invasive Sphygmomanometers - General Requirements & Supplementary Requirements for Electro-Mechanical BP Measuring Systems", AAMI SP10 ES1 category C' (battery powered)	
Operating Conditions:	10°C (50°F) to 50°C (122°F) 20-95% RH non-condensing	
Power:	Two "AA" alkaline batteries or high capacity rechargeable batteries (NiMH)	
Calibration:	Minimally, once every year	
Safety Systems:	Maximum inflation pressure limited to 300 mmHg; Auto safety release valve for power failure. Maximum BP measurement time limited to less than 180 seconds.	
Size:	Approximately 120 x 80 x 32 mm	
Weight:	Approximately 280g (including batteries)	
Storage Conditions:	-20°c to 70°c, 15%-95% RH non- condensing	
Data Connector:	6 pin minidin: 1=PC-TXD (data from PC) 2= N/C 3= Ground 4= PC-RTS 5= PC-RXD (data to PC) 6= PC-DTR Max voltage on any pin = ±15V with respect to ground.	

Safety and Effectiveness

The following safety and effectiveness issues should be considered before using the Oscar 2 unit as part of the Oscar Express system:

This device is defibrillator protected.

Note: No precautions specific to the Oscar 2 are required during defibrillation, and defibrillation discharge has no effect on the Oscar 2.

- The monitor is intended for use following consultation and instruction by a physician.
- The reliability of the device is dependent upon conformance with the operation and service instructions, as detailed in this manual.
- This device has been designed for use on patients with normal sinus rhythms.
- The interpretation of blood pressure measurements should only be made by a physician. The
 accuracy of any blood pressure recording may be affected by the position of the subject, his or
 her physical condition, and use outside the operating instructions detailed in this manual.
- Safety and effectiveness on pregnant women and neonates have not been established.

SunTech Medical Instruments, Inc. is responsible for the safety, reliability, and performance of its equipment under the following conditions:

- Assembly operations, extensions, re-adjustments, modifications, and repairs are carried out by SunTech authorized personnel.
- The electrical installation of the relevant room complies with all Local, State and Federal building and electrical codes.
- All equipment is used in accordance with instructions for its use.

Contact SunTech Medical Instruments for information before connecting any devices not mentioned in this Oscar Express Central Terminal User's Guide.

To ensure patient safety, use only parts and accessories manufactured or recommended by SunTech Medical Instruments.

Warnings and Contraindications

DO NOT—use in the presence of the flammable anesthetics; this could cause an explosion.

DO NOT—immerse the monitor in any fluid, place fluids on top, or attempt to clean the unit with any liquid detergents or cleaning agents. This may cause an electrical hazard. If accidental wetting occurs, please return to SunTech (See *Oscar Express and AccuWin Express Technical Assistance*).

DO NOT—remove unit covers. The monitor does not contain any user-serviceable components.

DO NOT—use the Oscar 2 monitor if it has failed its diagnostic self-test, or if it displays a greater-than-zero pressure with no cuff attached. The values displayed by such a unit may be inaccurate.

DO NOT—use on neonates or children, and patients known to be readily susceptible to bruising.

DO NOT—attach the cuff to a limb being used for IV infusions, as the cuff inflation can block the infusion, causing harm to the patient.

CAUTION—Substitution of a component different from that supplied may result in measurement error. Only personnel trained or authorized by SunTech Medical Instruments should undertake repairs.

CAUTION—If cuff fails to deflate within 3 minutes, instruct the patient on manual removal of cuff.

CAUTION—Check that operation of the unit does not result in prolonged impairment of the circulation of the patient.

WARNING—Ensure batteries are inserted with the correct polarity. Improper installation is a hazard.

WARNING—Oscar Express modem capability is designed for analog phone lines ONLY. Data transfers through office PBX or other digital phone systems are not expected to be compatible with the Express modem data transfer.

Precautions for Use

Ensure pressure compatibility to all patients. If any abnormality occurs in the monitor, suspend the operation immediately and disconnect it from the patient.

If the monitor has been used or stored outside its acceptable range (see *Specifications*), it may not meet performance specifications. If the cuff fails to deflate, the patient should be instructed on its proper and safe removal.

Adverse Reactions

Allergic exanthema (symptomatic eruption) in the area of the cuff may result, including the formation of urticaria (allergic reaction including raised edematous patches of skin or mucous membranes and intense itching) caused by the fabric material of the cuff.

Petechia (a minute reddish or purplish spot containing blood that appears in the skin) formation or Rumple-Leede phenomenon (multiple petechia) on the forearm following the application of the cuff, which may lead to Idiopathic thrombocytopenia (spontaneous persistent decrease in the number of platelets associated with hemorrhagic conditions) or phlebitis (inflammation of a vein) may be observed.

Oscar 2 at a Glance



Start/Stop Button	 TO POWER ON: When the monitor is off, press the Start/Stop button. TO POWER OFF: When the monitor is on but not taking a reading, press and hold the Start/Stop button until you hear five quick beeps. TO ABORT A MEASUREMENT: When the monitor is taking a reading and the cuff pressure is displayed, press the Start/Stop button. TO START THE PROGRAMMED ABP STUDY: When the time is flashing, press the Start/Stop button. TO START A SINGLE BP READING: When the time is displayed, press the Start/Stop button. 	
Express Button	Starts the modem data transmission from the remote site to the central terminal and can be programmed to automatically dial the central terminal.	
Oscar Express enabled	An Oscar 2 monitor displays an OE upon powering on to indicate the monitor has been enabled for Express modem data transfer. If the monitor has not been enabled for Express modem data transfer, it does not display the OE and will not communicate with the modem. Also displayed upon powering the monitor on is the number of BP readings currently stored. This number appears on the right of the LCD regardless of whether or not the monitor has been enabled for Oscar Express.	
Time 10:45	Indicates current time, when flashing, the monitor turns off in the next 20 seconds unless an ABP study is started or is in Express data transfer mode.	

Pressure 150	Indicates pressure in the cuff in mmHg during BP reading.	
	indicates pressure in the cult in mining during bill reading.	
SYS * DIA	Immediately after a BP reading, the display shows the results of the reading, blood pressure in mmHg followed by heart rate in beats per minute.	
Clock (-)	Denotes that a programmed ABP study is in progress.	
Sun 🌣	Denotes that the monitor is collecting readings according to the AWAKE program of the study.	
Moon)	Denotes that the monitor is collecting readings according to the ASLEEP program of the study.	
Battery + -	Indicates low battery voltage; BATTERIES NEED TO BE REPLACED.	
Printer =	Indicates the number of readings in memory.	
Percentage [][/	Indicates what percentage of Express data transfer is complete	

Preparing the Patient for Oscar 2 ABP Study

Central terminal operators who are issuing monitors from the central terminal directly to patients for ABP studies in addition to remote site studies should be familiar with the proper way to fit a monitor and cuff on a patient.

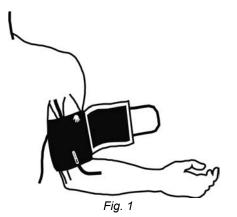
Fitting the Blood Pressure Cuff

After the Oscar 2 monitor has been programmed by the central terminal with AccuWin-Express, the patient can be fitted with the monitor and a blood pressure cuff.

For reliable data collection, it is important to select the proper size cuff for the patient's upper arm diameter. Without using the sleeve of the cuff, wrap the cuff around the patient's upper arm. Use the *Range Lines* on the inside of the cuff to measure the arm circumference. Ensure that this measurement is within the range of the cuff. If it is not, use another cuff size. IMPORTANT: using wrong cuff sizes will result in false and misleading measurements.

Patient Hook-up

- Insert the patient's arm through the sleeve as shown by the hand label (Fig. 1). Palpate the brachial artery. Slide the sleeve up the arm so the ARTERY MARKER is over the artery. Wrap cuff snugly around the arm (Fig. 2).
- Connect the hoses from the cuff and monitor by twisting the fittings together until you hear a snap.
 Drape the hose over the patient's shoulder, around the neck, across the opposite side of the body.
- 3. Insert the Oscar 2 into its pouch with the display showing through the window (Fig. 3). Attach the pouch to the patient using either the shoulder strap or belt, depending on the patient's preference (Fig. 4). Ensure the air hose from the unit to the cuff is not compressed, crimped or damaged.



4. To verify proper monitor operation, ensure that the monitor is on, and start a BP reading by pressing the Start/Stop button. The clock symbol should appear indicating the Oscar 2 is in the study mode. If problems occur, review the setup and fitting of the system or consult the *Troubleshooting* section in the remote site manual.

The patient and Oscar 2 ABP system are now ready for the ABP study.







Fig. 2 Fig. 3 Fig. 4

Preparing and Educating the Patient

Preparing your patient for the ABP study is the most important step to having a successful test. Review the following instructions with your patient.

- When the pressure in the cuff increases, the patient should avoid excess movement during measurements. Let the instrumented arm hang loosely, slightly away from the body. Avoid flexing the muscles or moving the hand and fingers of the instrumented arm.
- The patient can stop a measurement in progress by pressing the Start/Stop button.
- If programmed appropriately, the patient can start a measurement at any time the monitor is not taking one by pressing the Start/Stop button.
- It is important that the patient knows the proper position and fit of the cuff. The cuff should be positioned so that the ARTERY MARKER labeled on the cuff sleeve is directly over the brachial artery. Fit the cuff snugly around the upper arm.
- While sleeping, the patient should make sure that the hose is not crimped.
- The batteries can be replaced during a study without the data being lost or interrupting the monitor's program. Also, the monitor can be turned off without losing its data.
- Instruct the patient on how and when to fill out the patient diary.
- Ensure the patient knows how to care for the monitor. Keep it dry and do not drop it.
- If the monitor or cuff causes extreme pain or pain not normally associated with blood pressure measurement, the patient should remove the cuff and turn off the monitor.

Starting the Study

Before the patient leaves with the monitor and cuff correctly fitted, make sure that the clock symbol is displayed, indicating the monitor is in Study mode and operating correctly.

Finishing the Study

When the patient returns, remove the cuff, cuff anchor pad, monitor, and strap/belt. The BP data is stored on the monitor and is ready to be downloaded or transferred to the central terminal for report generation.

Before the central terminal can initialize Oscar 2 monitors for placement at remote sites, and receive, store, and process data from those remote sites, the central terminal operator must follow the directions below to install AccuWin-Express on a PC. Use the CD contained in the central terminal package. After installing AccuWin-Express, you can set up your computer, and configure the modem that came with the package or use an internal modem already provided on the PC.

Installing AccuWin-Express Software

Getting started is as simple as installing the software and using your computer to communicate directly with the Oscar 2 monitor for setup and remote site assignment.

AccuWin-Express Software Components

- Oscar Express Central Terminal User's Guide
- AccuWin-Express CD
- Oscar 2 PC serial interface data cable

Hardware Requirements

- PC-compatible computer with CD drive and at least 5MB available hard drive space.
- SVGA or compatible display adapter and monitor
- One available 9-pin serial port or USB port (requires optional USB adapter)

Software Requirement

Microsoft Windows® version 98 or later

To install the software

• If CD auto-play is enabled on your computer

Place the installation CD in your computer's CD drive, and follow the instructions on the dialog box that appears.

If auto-play is not enabled

- 1. Open Windows Explorer or Windows NT Explorer.
- 2. Click the CD drive icon.
- 3. Double-click the AUTORUN.EXE file.
- 4. Follow the instructions on the dialog box that appears.

Configuring your Computer for Communication

Before you can communicate with remote sites or with Oscar 2 devices directly, the central terminal operator must configure the PC ports for serial port direct monitor programming and for the modem communication. The configuration window appears automatically when you first launch AccuWin Express following installation. The configuration can be changed at any time.

To configure your computer

- 1. On the menu, select **Download**, and then select **Configure Port**.
- 2. On the Upload/Download Port Configuration dialog box, select the **Serial port** to which the PC-to-Oscar 2 cable is connected.
- 3. Select the **Modem port** for modem communication.
- 4. When finished, click **OK** to save your changes, or **Cancel** to close the dialog box without saving your changes.

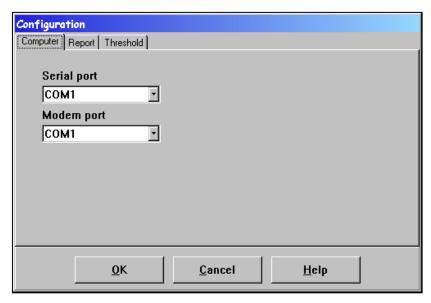


Fig. 5. Configure the port

Default Passcode

To provide data security, a 4-digit passcode is used by AccuWin-Express to access information in an Oscar 2 monitor when being used in an Oscar Express modem transfer. The passcode assignments are automatically tracked by AccuWin-Express so memorizing the passcode is not required. Central terminal users can also choose to not use passcodes, if preferred, by selecting the checkbox in Fig. 6.

The 4-digit default passcode entered will be used on all Oscar 2 monitors set-up by the central terminal unless otherwise specified. See *Customization and Configuration* for more information about using and changing security passcode settings. Following installation, when first running AccuWin-Express, the software will prompt the central terminal for a default passcode.

Default passcode entry
Enter a default 4-digit passcode to be used by AccuWin-Express when initializing an Oscar Express monitor.
Default passcode (4- digit number): 1234
OR
Do not use passcodes. (Any Express software can talk to monitors you program)
<u>O</u> K <u>H</u> elp

Fig. 6. Default passcode entry

Default Auto-dial number

The central terminal can program each Oscar 2 monitor sent to a remote site with an auto-dial number. This allows the remote site user to simply press a single button and the phone number to the central terminal will automatically be dialed. AccuWin-Express will prompt for the default auto-dial number on the initial run following installation.

Note: It is important to remember that each remote site may have different dialing requirements to reach the central terminal and will have to meet the exact dialing sequence the remote site phone requires. For example, some remote sites may need to dial an area code for long distance or dial 9 to reach an outside line. For that reason, different auto-dial numbers can be stored with each remote site's information. See *Configuring and Customizing AccuWin-Express* for more information on setting and changing auto-dial numbers.

However, a default number can be entered to be used if a remote site-specific auto-dial number is not selected. For example, if most of the remote sites will be local calls without needing to reach an outside line, simply enter the central terminal phone number.

Default callback number entry				
Enter a default auto-dial call back number	er.			
This should be the exact number seqund	e dialed most often wh	nen a remote site calls t	he central terminal.	
Default callback number:	9,1(800)555-1212			
1 7 0		11-1		
	<u>0</u> K	<u>H</u> elp		

Fig. 7. Default Autodial callback number entry

Auto-dial entry examples

Type of call	Auto-dial entry
Local call	555-1234
Long distance	1-212-555-1234
9 to reach outside line, long distance	9, 1-212-555-1234

Connecting the Oscar 2 Monitor to Your Computer

The first step in setting up an Oscar 2 monitor for uploading and downloading studies at a remote site is to connect it to the central terminal computer. To avoid electrical shock, make sure that the power to the PC is off.



Connect the PC interface cable to the monitor connection at the bottom of the unit.

Connect the other end of the PC interface cable to the 9-pin serial port on the back of the computer that was selected when configuring your computer for communication.

Setting up Your Central Terminal Modem

External Modem

If using the SunTech endorsed ZOOM V.92 External modem, refer to the Quick Start guide for the 56K External Modem provided in your modem kit for proper installation. Be sure to note which COM port you install the modem into. This information is needed to complete installation of AccuWin-Express.

Internal Modem

If using an internal modem that is already installed on your PC, please refer to your system properties device manager to identify the COM port assigned to your modem. A phone line splitter may be required if the central terminal PC internal modem does not have a voice phone jack.

Voice communication options

When preparing to do a modem data transfer with the remote site, the central terminal operator needs to communicate with the remote site to:

- Identify which remote site is about to send data
- Identify the remote user you are speaking to
- Identify the patient for the data about to be sent
- Determine if the Oscar 2 monitor is to be programmed for a new patient study and what parameters are needed
- Ensure that the data transfer was successful after completion

You can use one of two remote site setups to do this. Option 1 is **highly recommended**, as it minimizes the chance of ambient background noise interfering with the modem communication. However, if the remote site only has one phone line, Option 2 will work. Regardless of the method used, data communication begins with a person-to-person call to the central terminal.

Set-up Option 1 (recommended)

This option requires a second phone line separate from the analog phone line being used by the modem. This second phone line is a dedicated voice line and *can* be part of a PBX office or other digital phone systems. The required analog phone line connected to the modem is for data only.

The remote site makes a person-to-person call to the central terminal with the voice line and exchanges necessary information before performing a data transfer. When instructed by the central terminal user, the remote site starts the modem data transfer over the dedicated data line. The remote site user does not need to pick up the data line phone connected to the modem at any time.

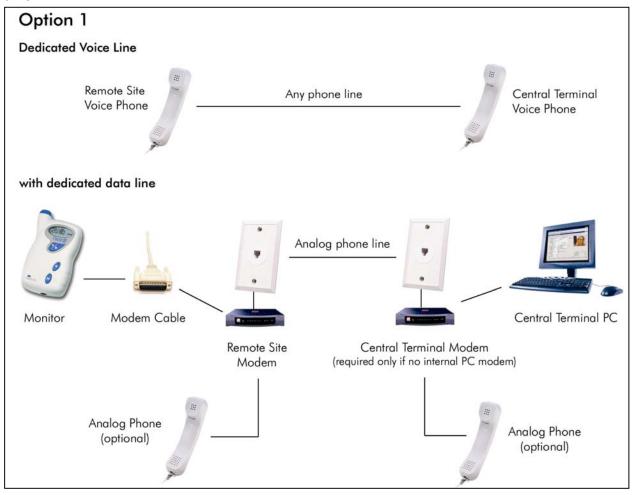


Fig. 8. Communication Setup Option 1

Set-up Option 2

This option should be used if only one phone line is available at the remote site. In this set-up, the same line is used for both voice and data communication.

The remote site makes a person-to-person call to the central terminal with the phone connected to the modem and begins with voice communication. The remote site and central terminal exchange necessary information to perform the data transfer. When instructed by the central terminal, the remote site begins the data transfer over the same phone line. Once modem communication is complete, the modem releases the line for voice communication again. The transfer can be completed as a person-to-person call between the remote site and the central terminal ensuring that there were no errors.

Note: Background noise can interfere with the data communication. If the phone has a mute button, it can be used to minimize ambient noise from interfering with the data transfer.

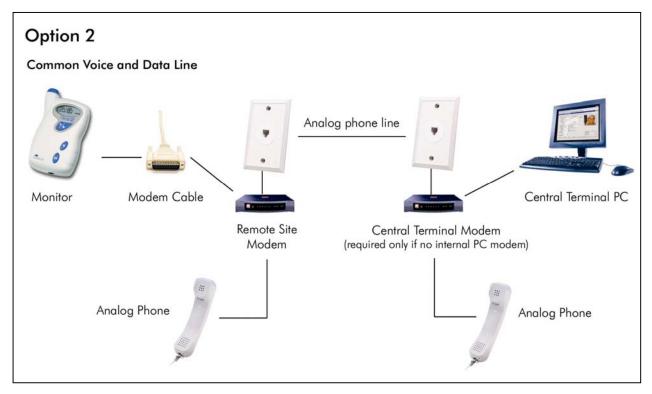


Fig. 9. Communication Setup Option 2

AccuWin-Express provides an interface to manage the central terminal. It has the flexibility to manage multiple remote sites as needed and the simplicity to retrieve the important test data.

AccuWin-Express Basics

The menu bar provides you with access to all functions of the software, whereas the toolbar provides easy access to frequently used functions.

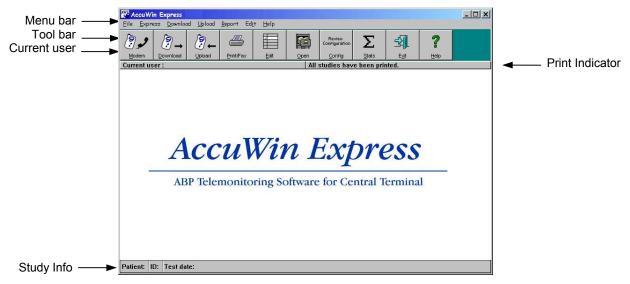


Fig. 10. AccuWin-Express menu and toolbar

The toolbar functions are described as follows:

- Modem Perform a modem data transfer with a remote site for download, upload, or both
- Download Download data directly from an Oscar 2 connected directly to the PC
- Upload Set-up an Oscar 2 connected directly to the PC and upload patient study parameters
- Print/Fax Print or fax a patient study report
- Edit Open BP data table of current study for viewing and editing
- Open Open a patient study
- **Config** Review or edit monitor configuration
- Stats Review summary of BP statistics for selected study
- Exit Exit AccuWin-Express
- Help Go to online help for AccuWin-Express

Study Info displays the patient name, ID, and data the currently viewed study was performed.

Current user indicates which user is currently logged in, so the software can record user actions and when they are performed.

Print indicator notifies the central terminal of how many studies still need to have reports printed or faxed.

Preparing an Oscar 2 for a Remote Site

Before a central terminal can issue Oscar 2 monitors to remote sites for Express ABP data modem transfer studies, the central terminal operator must create remote sites, and then set-up the monitors for each remote site. Each Oscar 2 monitor needs to be enabled for Oscar Express communication, assigned to a remote site, and programmed for the first study. The first step is to create the remote site(s).

Creating a Remote Site

The central terminal operator needs to create a remote site for each different site that will be performing patient ABP data collection studies. After installing AccuWin-Express, there will automatically be one remote site created, called "local". This *local* remote site is actually for the central terminal to store its own collected data and to track monitors in-house. For instance, if a central terminal is going to issue Oscar 2 monitors directly to patients for data collection, this *local* remote site is where any ABP data that is retrieved from an Oscar 2 directly connected to the central terminal PC should be saved. This *local* remote site can also be where Oscar 2 monitors are assigned to while they are in the central terminal's inventory and not at a remote site. The remote site information for the *local* site can be edited to contain the appropriate information for your central terminal.

To create or add a remote site

- 1. On the menu, select **Express** and then **Add Remote Site**. The Remote Site Information dialog box is displayed (Fig. 11).
- 2. Complete the fields for the site you want to add. Some of these fields are described as follows:
 - Name enter a name that will help you identify the remote site.
 - **Company** full name of the remote site company.
 - **Time zone** time zone of remote site. This field is required, so AccuWin-Express can make time adjustments when programming the Oscar 2 monitor.
 - Contacts remote site users.
 - **Site Passcode** Numeric passcodes auto-assigned on all Oscar 2 monitors for that remote site.
 - Auto-Dial Number auto-dial number specific to all Oscar 2 monitors for that remote site. Include area codes if needed and the number needed for an outside line, such as
 - Default Study Protocol used if you want to set default study parameters specific to that remote site.
- 3. When you have completed the fields, click **OK** to save the new record, or **Cancel** to close the dialog box without saving.

Note: If the **Edit** checkbox is selected, the information can be edited. If you clear the checkbox, the record cannot be edited.

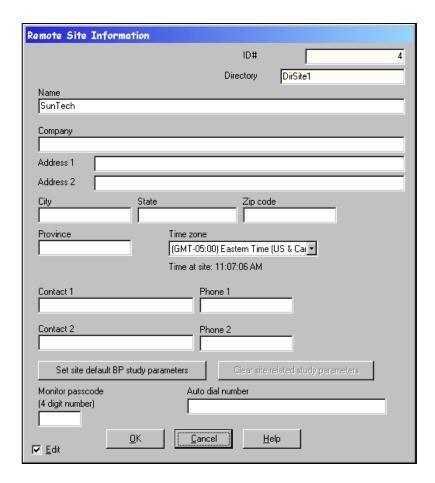


Fig. 11. Remote Site Information dialog box

Monitor Set-up/Upload

The next step in setting up an Oscar 2 monitor for the Oscar Express system is to enable it for modem communication and assign it to a remote site, or your local site. Monitor set-up programs the Oscar 2 with a study protocol for an ABP study and assigns the monitor serial number to a specific remote site for tracking purposes. The numeric passcode and auto-dial number for the remote site can also be programmed into the monitor, depending on your passcode and auto-dial settings (See *Configuring and Customizing AccuWin-Express*).

Note: Make sure the monitor to be set up is connected to the correct computer COM port with the provided cable.

To set-up an Oscar 2 monitor for Express

- 1. On the toolbar, select **Express**, then **Setup**, and then **Monitor**; or click **Upload** on the tool bar.
- 2. The system auto-detects the Oscar 2's serial number.
- From the Assigned remote site drop-down list, select the remote site to assign the monitor to, or click New Site to create a new remote site.
- 4. Under **Monitor study parameters**, do one of the following:
 - Select **Default study parameters** to auto-set with global study parameters or default remote site study parameters, depending on whether they have been set for the chosen remote site.



Fig.12. Monitor Set-up/Upload

• Select **Custom study parameters** to go to the Oscar 2 Upload Parameters dialog box (See *Configuring and Customizing AccuWin Express*). This allows custom study parameters to be loaded on the monitor.

An optional setting that can be displayed in this window is the **Enable modem communication** checkbox. This setting allows the central terminal to enable and disable Oscar Express capability for an Oscar 2 monitor. Disabling a monitor for Express allows it to communicate directly with a PC running a previous version of AccuWin-Pro and is done by leaving this checkbox empty. However, the monitor will no longer be able to communicate with a modem. The option to display this checkbox is set in the AccuWin-Express set-up options. (See *Configuring and Customizing AccuWin Express*). It is recommended that the central terminal not routinely display this checkbox at monitor set-up to prevent accidentally disabling a monitor intended for Express modem data transfer.

5. Click **OK**. The Oscar 2 is ready to be sent to a remote site for immediate use; the study protocol has been loaded.

Note: Once the study parameters are uploaded to the Oscar 2, all previously stored data is erased and the monitor AUTOMATICALLY SHUTS OFF.

Retrieving Data from an Oscar 2

You can retrieve data from a remote site via the modem and phone line, or with the monitor connect directly to the computer.

Retrieving data from an Oscar 2 at a remote site via modem

- 1. The central terminal operator answers the call and asks for necessary information as to which remote site is calling and what action(s) is to be performed.
- 2. For any modem data transfer, the central terminal operator must first open AccuWin-Express.
- 3. Once the program is launched, click **Modem** on the toolbar. The Express Modem Transfer dialog box appears (Fig. 13).

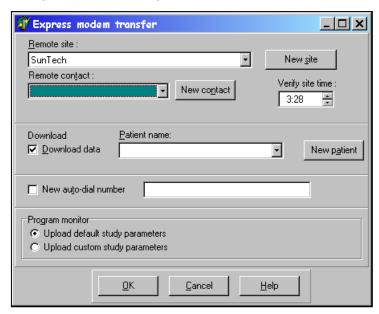


Fig.13. Modem transfer dialog box

4. Select the appropriate site from the **Remote site** drop-down list, or click **New site** to add a site.

You can create a new remote site if necessary, but you should seldom, if ever, need to. Each remote site should be created before a monitor is assigned and sent to that remote site.

You can record the name of the remote site user in the **remote contact** box for record keeping purposes.

- Ask which patient the data is for. Select a patient from the **Patient name** drop-down list, or click **New patient** to add a patient.
- 6. **Verify** site **time** at the remote site matches the display automated by time zone.
- 7. If the remote site does not want to download data for a patient, but wants to change **or** verify the study parameters programmed on the Oscar 2 monitor by uploading new study parameters, clear the **Download data** checkbox.
- 8. If the central terminal wants to change the programmed auto-dial number on the Oscar 2 monitor, enter the new number in the **New auto-dial Numbers per remote site**.
 - **Note**: AccuWin-Express options must be set to display the **New auto-dial number** option or can be set to not display the option (See Configuring and Customizing AccuWin-Express).
- 9. Under **Program monitor**, you can select **Upload default study parameters** or **Upload custom study parameters**.

Uploading new study parameters erases any data already on the Oscar 2. You can also set the AccuWin-Express options to display the option to **not upload new study parameters** and also to not allow custom study parameters or not to allow uploading a new set of parameters (See *Configuring and Customizing AccuWin-Express*).

Note about uploading default study parameters: If default parameters have been set for the remote site, those default parameters are automatically programmed into the Oscar 2 monitor. If default parameters have not been set for that remote site, the Oscar 2 automatically uses the global default BP study parameters set in Configuring and Customizing AccuWin-Express.

 Click **OK**. The Patient Information dialog box is displayed (Fig. 14). Confirm that this is the correct patient.

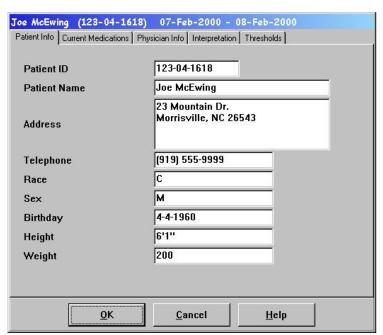


Fig. 14. Patient information dialog box

11. Click **OK**. If you are programming the Oscar 2 with **custom study parameters**, the Upload Parameters window opens. Set the parameters, and click **OK**.

A message window alerts you to check that the Oscar 2 monitor at the remote site is turned on and **not** in Study mode (time should be flashing).

If the monitor is in study mode, have the remote site user turn the monitor off by holding the Start button down until it beeps five times, and then turn the monitor on again. The remote site user also needs to make sure the monitor is connected to the modem and the modem is powered on.

12. Click **OK**.

The final window instructs you to ask the remote site user to press and hold the **Express** button until it "chirps" (beeps three times rapidly). Data transfer from the remote site begins.

- 13. Do one of the following:
 - For voice communication option 1:The central terminal phone connected to the data line rings indicating that the remote site is trying to establish modem communication. Click OK. AccuWin-Express answers the line and automatically starts data communication.
 - For voice communication option 2:

With the same phone line being used for voice and data, when you hear a touch-tone dialing sequence, click **OK** to automatically begin the data transfer.

Ambient noise can interfere with data communication. Avoid speaking into or near the phone mouthpiece or placing the mouthpiece down abruptly. This may increase data transmission time or cause time out errors, but it does not affect the integrity of transmitted data.

A small window displays the transmission progress. When data transmission has been successfully completed, the modem data transfer ends, and you can resume the person-to-person call.

14. After a successful transmission, verify that the remote site user disconnects the Oscar 2 from the modem and has made sure the Oscar 2 monitor **is off**. If the Oscar 2 is stored away while left powered on, a study automatically begins in 5 minutes and the monitor must be reprogrammed before issued to a patient.

If the transmission was unsuccessful, notify the remote site user to attempt another transmission before ending the call.

Direct Download of BP Data from the Oscar 2

For Oscar 2 monitors issued by the central terminal to patients in-house, or monitors that have been returned from a remote site with data to be downloaded, the central terminal can download ABP data directly from the Oscar 2 to the PC. Any data received from a monitor connected directly to the PC can be stored in any remote site.

Before you download the data directly from the monitor, make sure:

- You disconnect the unit from the patient before connecting the ABP unit to your PC or any piece of hardware (to avoid electric shock).
- You remove the ABP unit from the pouch.
- The Oscar 2 is connected to the computer via the serial port with appropriate cable. (See Connecting the Oscar 2 Monitor to Your Computer).
- The Oscar 2 is not in Study mode, (time flashing).

To download BP data directly from the Oscar 2

1. On the menu, select **Download** and then **Direct Download**, or select **Download** on the toolbar. The Site and patient selection dialog box is displayed (Fig. 15).



Fig.15. Site and patient selection dialog box

- 2. Select a site from the **Remote site** drop-down list. This is probably the **local** (central terminal) site, but the data could be stored in any remote site. A **New site** can also be added.
- 3. Select a patient from the **Patient name** drop-down list, or click **New patient** to add a patient.
- 4. Click **OK**. The Patient Information window opens. Confirm that this is the correct patient, and click **OK**.

- 5. After completion, a dialog box prompts you for patient demographic information. You can accept the default values or enter a new name and ID number.
- 6. Click **OK** to save the data.

Configuring and Customizing AccuWin-Express

A central terminal operator can set AccuWin-Express options to customize the features you want to use. For instance, you might want to determine how to use security passcodes, set the central terminal auto-dial phone number options, set global study parameters for programming the monitors, and program other user settings.

On the menu, select **Express**, and then **Setup**, and then **Options**. The Express options dialog box is displayed (Fig. 16).

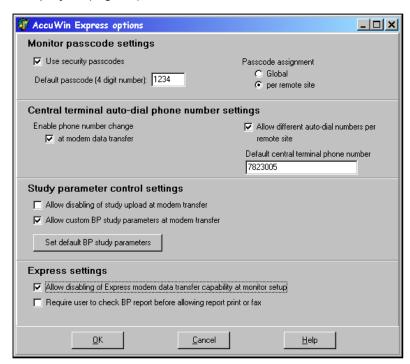


Fig. 16. Express options

Monitor Passcode Settings – Central terminal users can choose to use a numeric passcode to prevent other central terminals from having access to their data and generating reports for their remote sites. If the central terminal decides to use security passcodes, a 4-digit passcode is put on each Oscar 2 monitor when it is set-up for remote site assignment. Each time a remote site initiates a modem data transfer, AccuWin-Express recognizes the monitor serial number and

automatically provides the passcode to allow data transfer. If the passcode is not recognized, the Oscar 2 monitor does not allow the data transfer.

The central terminal has two choices for managing passcodes. You can choose a global passcode for every Oscar 2 monitor sent to remote sites, or you can choose a different passcode for each remote site, so only Oscar 2 monitors at one remote site have the same passcode.

Global passcode assignment -- To use a global passcode, select **Global** and enter the passcode (a 4-digit number) in the **Default passcode** field. Even if you decide to use different passcodes for each remote site, you still need to enter a default passcode in case you forget to set the remote site passcode.

Remote site passcode assignment – To assign a different passcode for each remote site, select **per remote site passcode assignment**. Then enter the passcode for each remote on the Remote Site Information dialog box (See Fig. 11).

To make security easy and reliable, tracking the monitor passcodes is completely automated by AccuWin-Express. If you decide to change the assigned passcode(s) at any time, AccuWin-Express automatically tracks which Oscar 2 monitors have the new passcode and which monitors still use an older passcode. To update a monitor with a new passcode, the monitor must be directly connected to the central terminal PC and re-assigned to the corresponding remote site. Note that only central terminal (AccuWin-Express) users know this passcode, and it is not revealed to the remote sites.

Auto-dial number settings – Remote site users can initiate the data transfer by pressing the **Express** button, which automatically dials the central terminal number programmed into it by the central terminal user. Since remote sites have different dialing requirements, such as dialing 9 for an outside line or area code for long distance, the auto-dial number programmed into the Oscar 2 can vary for each remote site. However, you can set a default auto-dial number for the most frequent setting.

You can also choose whether or not to allow phone number changes at modem data transfer. When the **Enable phone number change at modem transfer** checkbox is selected, the auto-dial number on the Oscar 2 unit that is calling in can have the number changed. You might need this capability if the Oscar 2 is programmed with the wrong auto-dial number, or if the phone number of the central terminal changes.

Note: if the wrong auto-dial number is programmed into an Oscar 2, the remote site can still manually dial the central terminal to start modem data transfer.

Study parameter control settings – This feature allows the central terminal to set the default BP study parameters to be programmed on the Oscar 2 monitor. If different default parameters are needed for different remote sites, those can be set, as well, on the Remote site information dialog box (See Fig. 36).

To set the default study parameters

1. Click **Set default BP study parameters** to display the Upload parameters dialog box (Fig. 17).

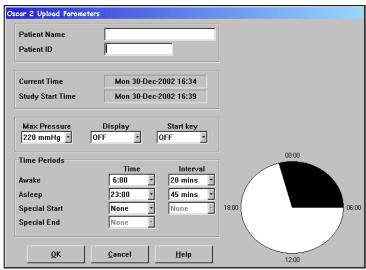


Fig. 17. Upload Parameters dialog box

2. Select the appropriate upload parameters, and click **OK**. Since these are the default parameter settings, **Patient Name** and **Patient ID** are left blank. In the above example, the test parameters are adjustable in the following ranges:

Patient name and ID For reporting and referencing data, left blank

when setting default parameters.

Max Pressure: 120 to 260 mmHg,

Time Periods: Up to 3, with automatic retry function,

Display: ON allows the patient to view the results,

Start key: ON allows patient to start readings,

Time Intervals: 5, 10, 15, 30, 45, 60, and 90 minute intervals,

3. When you have finished, click **OK** to save your settings, or click **Cancel** to close the dialog box without saving your settings.

Allow disabling of study protocol at modem transfer

You can also select whether you want the option to disable study upload during a modem transfer with a remote site. You might want to do this if a remote site will download collected study data to the central terminal and keep that data on the monitor. If the **Allow disabling of study protocol at modem transfer** checkbox is selected, the option of **Do not upload new study parameters** is available in the Modem transfer dialog box (See Fig. 13).

Allow custom BP study parameters at modem transfer

The **Allow custom BP study parameters at modem transfer** option allows central terminal users to program custom study parameters that differ from the global default BP study parameters and the remote site default BP study parameters. If selected, **Upload custom study parameters** is a choice in the Modem transfer dialog box (See Fig. 13).

Express Settings – Other settings allow you to enable and disable the Express modem capability at the Monitor Set up/Upload dialog box. If this checkbox is left cleared, which is the default setting, all Oscar 2 monitors are automatically Express-enabled when set up and the option to enable/disable Express modem communication does not appear in the Monitor Setup/Upload dialog box (See Fig. 12).

The final option allows you to set whether a "check" is required before printing or faxing a study report. The central terminal user manager or supervisor can use this to require a check of an edited study before AccuWin-Express will allow printing or faxing of the report.

Working with an Ambulatory Blood Pressure Study

Viewing an Ambulatory Blood Pressure Study

Each study in a patient file contains data that can be displayed on the graph in one of two ways. It also contains the complete ABP data table and provides access to the patient and physician information.

To view a patient's data

Use this feature to select a patient's data. You can then edit, print, or fax a report detailing the results.

1. On the menu, select **File**, and then **Open Data**, or from the toolbar, select **Open**. The **Select Study** dialog box appears (Fig. 18).

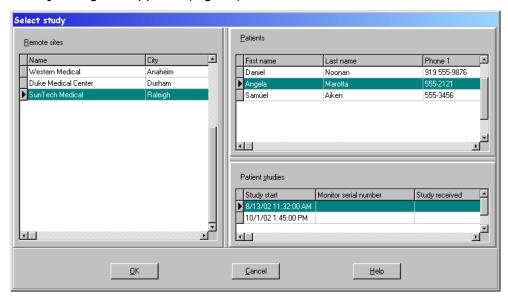


Fig.18. Select study dialog box

You can sort the **Remote site** list, the **Patients list**, or **the Patient studies** list by any column in the list by clicking the column heading. Click the heading again to reverse the sort order. You can also configure any of the three lists to customize the columns displayed by right-clicking in the list (See *Configuring Lists*).

- 2. Select the site associated with the patient on the **Remote site** list.
- 3. Select the patient whose BP data you want to retrieve on the **Patient** field.
- 4. Select a patient study from the **Patient studies** list.

Working with an Ambulatory Blood Pressure Study

Note about "to be printed" flags

You may notice red circular flags that appear next to a remote site, a patient and a study. These flags alert you that this study has been received from a remote site and has yet to be printed/faxed. Each time a study is received by AccuWin-Express and saved into a remote site, a flag appears next to the corresponding remote site, corresponding patient, and corresponding study. The flags appear until a report has been printed or faxed for that study. Note that a flag next to a remote site can indicate that more then one study needs to be printed or faxed.

5. When you have made your selection, select **OK**, or click **Cancel** to close the dialog box without selecting a patient.

If you click **OK**, a graphical representation of the patient's data is displayed in the data display area as shown in figure below.

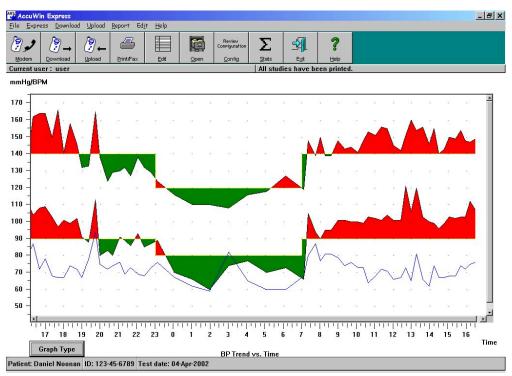


Fig.19. Patient data graph

You can move the mouse left and right to see specific data for any point in time during the study at the top of the window. The scale from left to right represents time (x axis). The scale from top to bottom represents blood pressure in mmHg (y axis) Click and drag the pointer along the x and y axes to adjust the view.

You can also click **Graph Type** to change the view from a line graph to a bar graph. The Line graph shows pulse pressure, the difference between diastolic and systolic pressure for each reading.

You can now edit the BP data, or print or fax a report.

Working with an Ambulatory Blood Pressure Study

Editing an Ambulatory Blood Pressure Study

On the menu select **Edit**, and then select **BP Data**, or on the tool bar select **Edit**. If you are not already in a patient study, you are prompted to select one. A tabular listing of each BP reading in the patient's study data appears.

Because the ambulatory blood pressure monitor collects blood pressure readings while the patient is going about daily activities, some readings can be disrupted by excessive patient movement or for other technical reasons. All readings taken by the blood pressure monitor have **Test Codes** and **Quality Codes**, which

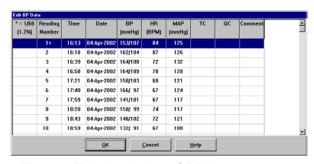


Fig. 20. Tabular listing of BP data

indicate the reliability of the particular BP reading (See *Troubleshooting* an explanation of these codes).

When the ambulatory blood pressure monitor data is downloaded to the PC, all of the readings that have suspect **Test Codes** are "tagged" either with an asterisk (*) or, in rare instances, with an exclamation point (!). Tagged records are omitted from the statistics and are printed in a separate part of the report.

Note: ! indicates a permanent tag. This item cannot be "untagged," and will not be included in the statistics.

A tagged reading does not necessarily mean the reading is invalid. If you are confident that a particular BP reading that is automatically tagged by the ambulatory blood pressure monitor is invalid; leave the reading tagged. If you are confident that a tagged reading looks reasonable, you can "untag" the reading. Or, if the reading is not tagged, but in your opinion should be, you can tag it.

How do you decide to tag or untag a BP Reading?

First, ask yourself, "Is the BP reading physiologically possible?"

Sometimes, you obtain BP readings that are not physiologically feasible. Generally, these BP readings have *Quality Codes* associated with them that can help in your editing decision.

To help determine if the BP reading is feasible, review the readings immediately before and after the reading in question. If a patient diary is available, look at the activities listed for the reading in question for a sudden change in activity or a symptomatic event. Sometimes a quality code can be initiated if a patient makes a significant change in activity, such as changing from sitting quietly to standing and yelling. In this case, you would expect a significant change in the BP. If that were the case and the reading were tagged, you would probably want to untag the BP reading.

Working with an Ambulatory Blood Pressure Study

Some Test Codes signal a high probability that the reading is invalid. Test Code 2, which means erratic oscillometric signal, usually indicates arm movement. For example, if you have a TC=2 reading that appears to be in line with the readings above and below it, you might want to untag the reading. Quick arm movement during cuff deflation can generate the code but not affect the BP.

The key to data editing is to review the BP readings above and below the questionable BP reading and correlate the information with the diary. Use your judgment to decide if a BP reading looks valid. Many BP researchers leave all suspect data in the valid data (except for zero readings), because many times the suspect readings average themselves out, (some are high and some are low) and do not end up significantly influencing the final report.

To tag erroneous data for omission

- 1. Select the row in question by clicking the far-left column for that row. The row is highlighted and tagged.
- 2. To untag the data, click the far-left column in the selected row again. The asterisk disappears.
- 3. When you have finished editing the BP data, click **OK** to save your changes, or click **Cancel** to close the dialog box without making changes. Remember, all of the editing changes you make are saved if you click **OK**.

Patient Diary Comments

You can use the **Comments** column on the far-right of the table, to keep track of patient activity during a BP reading. While activity is only one of the many factors that can affect blood pressure, it can be helpful in understanding a BP reading within the context of the rest of the study.

To enter a comment

- 1. Click the far-right cell under the **Comments** column for the reading for which you want to add a comment
- 2. Enter a comment in the cell.
- 3. Press Enter.

Editing Sleep Times

The sleep times are downloaded automatically from the ambulatory blood pressure monitor into AccuWin-Express as programmed before the ABP study. However, you can edit the sleep times later if you want. The sleep time is determined by setting the time when the patient went to sleep, and the time at which the patient awoke. The clock is displayed in Military Time, i.e., 12:00 is noon, 18:00 is 6:00 p.m., and 00:00 is midnight.

Working with an Ambulatory Blood Pressure Study

To edit sleep times

- On the menu, select Edit, and then select Sleep Times.
 If you are not already in a patient study, you are prompted to select one.
 Select the name of the patient whose sleep times you want to edit.
- 2. On the Sleep Period dialog box, you can select times within 30-minute intervals. If the patient did not sleep during the study, you can select **0:00** for both times.



Fig.21. Sleep times dialog box

3. When you have finished selecting the sleep times, click **OK** to save your selections, or click **Cancel** to close the dialog box without saving your selections.

Editing Blood Pressure Thresholds

You can use this feature to select the systolic and diastolic thresholds that AccuWin-Express uses when calculating the Blood Pressure Load. The default, recommended thresholds for calculating Blood Pressure Load are 140/90 for awake periods and 120/80 for sleep periods. These are the defaults that are used when you select the **Factory Defaults** button.

To edit blood pressure thresholds

- On the menu, select Edit, then Thresholds to display the Thresholds dialog box (Fig. 22).
 - If you are not already in a patient study, you are prompted to select one.
- 2. Select the value(s) you want to modify and enter the new threshold value(s).
- When you have finished setting the BP thresholds, select **OK** to save your changes, or select **Cancel** to close the dialog box without saving your changes.

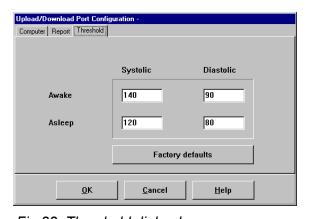


Fig.22. Threshold dialog box

Working with an Ambulatory Blood Pressure Study

IMPORTANT NOTE:

When printing a report or viewing statistics, the BP Load is calculated using the BP Threshold values that are currently set in AccuWin-Express. For example, if you download data for a patient and then print a report, the current BP thresholds are used to calculate and print the BP Load for that patient. If, at a later date, the BP threshold settings are changed, the BP Loads are calculated using the current BP thresholds. Therefore, the BP Load may be different. This method was chosen based on the assumption that all data, at any time, should be viewed using the currently accepted values for BP thresholds, regardless of what the accepted thresholds may have been in the past or will be in the future.

Viewing BP Statistics

You can review the statistics about a patient study, such as BP Load, count number, systolic and diastolic blood pressure averages, and heart rate averages during the awake and asleep times, as well as over the entire study. AccuWin-Express provides these calculations to simplify the tracking of a patient's progress and the analysis needed to assist in formulating a diagnosis.

To view statistics for a patient study

 On the menu, select Report and then View Statistics, or Stats on the toolbar.
 If you are not already in a patient study, you are prompted to select one.

The Statistics dialog box gives you the average BP readings and BP Load calculations for the awake, asleep, and overall time periods. It also displays the total number of BP readings used to calculate the statistics.

2. Click **OK** to close the Statistics dialog box.

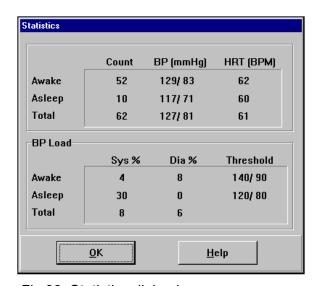


Fig.23. Statistics dialog box

Creating Reports

In order to document the study and its findings, you can create and customize a report. It can contain everything that you have edited and reviewed in the study or be a simple statistical clinical summary of the study.

Configuring and Customizing a Report

Once you have created a report, you can edit it to show the data you want. In addition, you can delete reports that you no longer need. You can also set up report formats and name them, so that you can select and use them later for new reports. You can give your report a title, such as your company name, which will print on the report. On the graph tab, you can select the kind of graph you want to represent the data in the report.

To customize and configure a report

- Select Report on the menu, and then select Configure Report. The Report configuration dialog box appears.
- You can select either Edit Report or Add Report.

When you first **Select Configure Report**, no report formats are shown. You must first create a report format or as many report formats as you need. If you are editing a report format that was already added, select the report you want to configure from the drop-down list, and then click **Edit Report**. Or you can select **Delete Report** to delete a previously created report format.

3. On the **Pages** tab, you can select which pages you want to include in the report.

Only pages that are selected are printed. In Figure on the left, all pages are selected to print. The blank field above the checkboxes is for entering the report format name. You could give the format similar to the one in the figure the name of "Full" or "Complete." If only the BP Summary Page is selected to print, you could call the report "Summary."



Fig. 24. Report configuration dialog box

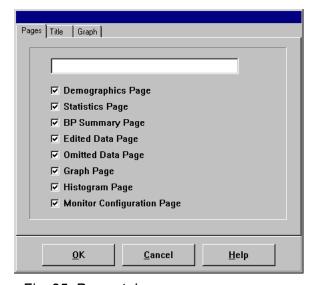
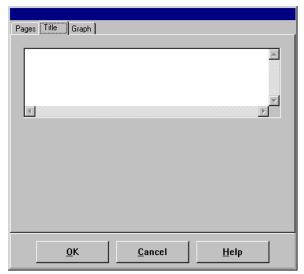


Fig. 25. Pages tab

Creating Reports

4. Use the **Title** tab to put a custom title at the top of each page of the report. To add a title to the report format, type the title in the text field. The title could include information such as the central terminal name, physician name, or study name. You can also create multiple report formats with a different title for each remote site containing the remote site name.



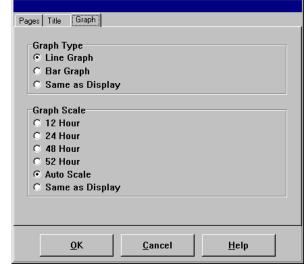


Fig. 26. Title Tab

Fig. 27. Graph tab

- 5. Select the **Graph** tab, and then select the type of graph and time duration to represent the data.
- 6. When you have completed all three tabs, click **OK** to return to the first dialog box.
- 7. Click **OK** to save the report.

Previewing a Report

You can preview a report before printing it by scrolling through each page on your screen. You can make the view larger or smaller for easier review or to fit more information on the screen. When you're ready, you can print or fax the report.

Note: If the **Check before print** option is selected in the AccuWin-Express options (See Fig. 16), the report must be checked before it can be printed or faxed.

Creating Reports

To preview and print the report once it has been configured

- On the menu, select **Report**, and then **Print Preview**. If you are not already in a study, you are prompted to select one
- 2. You can do any of the following:
 - To print the report, click Print.
 - To select printing options, click Setup.
 - To go to the next or previous page or the report, click **Next** or **Prev**.
 - To change the format of the report, click Format.
 - To change the size of the view, select a percentage from the drop-down list.

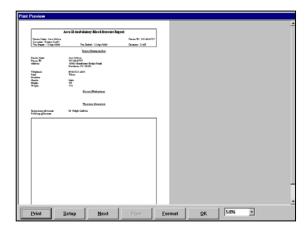


Fig. 28. Sample report page

3. When you have finished previewing the report, click **OK** to close the Preview window.

To check a report before printing

Depending on the AccuWin-Express settings chosen in set-up options, you might need to check a report before printing or faxing the configured report. To do this, from the menu select **Express** and then **Check study** to automatically record the time and day it was checked. You are also prompted to log in again, so the program can record who checked the report. If the study has already been checked, the **Check study** checkbox is selected, when you select **Express** on the menu.

Printing and Faxing Reports

Once you have edited and formatted a report, and had it "checked" if required, you can send the report to a printer or fax the report to the remote site.

To print or fax a report

1. On the menu, select Report and then Print, or on the toolbar select Print/Fax. If you are not already in a patient study, you are prompted to select one.

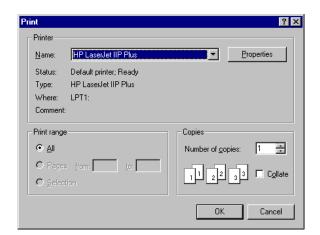


Fig. 29. Printer configuration dialog box

2. Select a printer or fax program from the **Name** drop-down list, and click **OK**.

Viewable Database Lists

To help manage your data, you can view lists of remote sites, patients, studies, or monitors, and sort these lists in different ways. You can select which information to include on these lists and arrange the information in ways that best suit your needs. From these lists, you can also select and edit records. You can click any column heading to sort the list by that heading. Click the heading again to reverse the sort order. You may also print the list you have created.

To view a list of remote sites

- 1. On the menu, select Express, and then View.
- 2. Select Remote Sites.



Fig. 30. Remote Sites list

- 3. You can do any of the following:
 - Click Configure Display to rearrange the display.
 - Click Filter to filter the list.
 - Select Show all sites to return to the full list (after filtering).
 - Click Edit to edit remote site information.
 - Click New to add a remote site.
 - Click Close to close the Remote Sites list.
 - Click **Monitors** to review a list of monitors assigned to the selected remote site.
 - Right-click for a menu to Print the list, Configure Display, or Edit.

To view a list of patients

- 1. On the menu, select **Express**, and then **View**.
- 2. Select Patients.

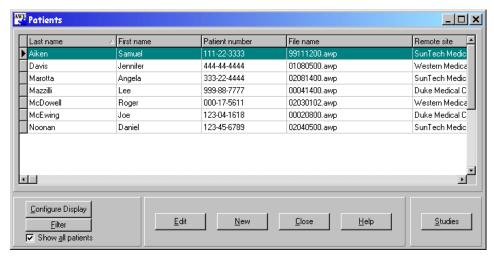


Fig. 31. Patient list

- 3. You can do any of the following:
- Click Configure Display to rearrange the display.
- Click Filter to filter the list.
- Select **Show all patients** to return to the full list (after filtering).
- Click **Edit** to edit patient information.
- Click New to add a new patient.
- Click Close to close the Patient list.
- Click **Studies** to review a list of studies for the selected patient.
- Right-click for a menu to **Print** the list, **Configure Display**, or **Edit**.

To view a list of patient studies

- 1. On the menu, select **Express**, and then **View**.
- 2. Select Studies.

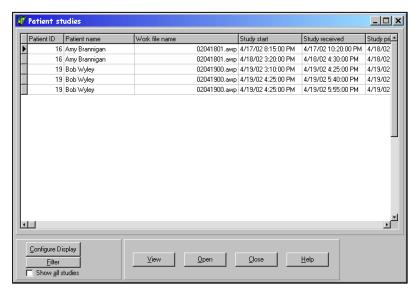


Fig. 32. Patient Studies list

- 3. You can do any of the following:
 - Click Configure Display to rearrange the display.
 - Click Filter to filter the list.
 - Select **Show all studies** to return to the full list (after filtering).
 - Click View to view information for a patient study.
 - Click Close to close the Patient list.
 - Right-click for a menu to Print the list, Configure Display, or View.

To view a list of monitors

- 1. On the menu, select Express, and then View.
- 2. Select Monitors.

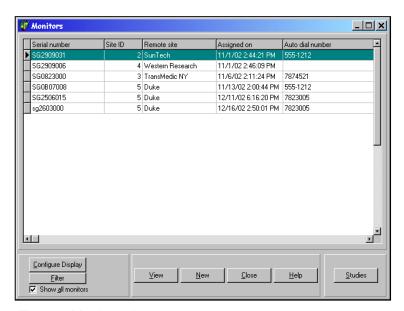


Fig. 33. Monitors list

- 3. You can do any of the following:
 - Click Configure Display to rearrange the display.
 - Click Filter to filter the list.
 - Select **Show all monitors** to return to the full list (after filtering).
 - Click View to view monitor information.
 - Click New to add a monitor.
 - Click Close to close the Monitors list.
 - Click Studies to review a list of studies for the selected monitor.
 - Right-click for a menu to Print the list, Configure Display, or View.

Configuring Lists

You can configure lists to select which columns are displayed on the lists and in what order. This applies to any of the four lists—Remote Sites, Patients, Studies, and Monitors. You can also change the column titles to help customize your database.

To configure a list

- 1. On the menu, select **Express**, and then **View**.
- 2. Select Remote Site, Patients, Studies, or Monitors.
- 3. On the list, click **Configure Display**. The Column selection dialog box appears.

Note: Configuring the display can also be done on the Select Study dialog window, (Fig. 18), by right-clicking in the list on the list you want to configure.

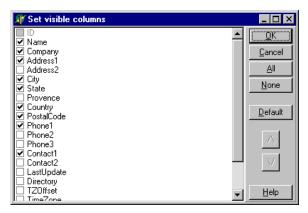


Fig.34. Column selection dialog box

- 4. You can do any of the following:
 - Select the checkbox(es) for each category that you want to on the list.
 - To change the order of the columns as they appear on the list, select a category and use the up and down arrows to move the category up or down the list.
 - To change the name of a category, double-click the category name. Then, in the Change identifier dialog box, type the new name and click **OK**.
 - On the Patient and Studies lists, you can click Custom text and Custom number to create custom fields.
- 5. Once you have finished making configuration changes, click **OK** to save your changes, or click **Cancel** to close the dialog box without saving your changes.

Note: If after changing the configuration you want to restore the defaults, click Default.

Filtering Lists

You can use the lists to find certain records. If a list includes many records, you can filter by certain conditions to list only those records that meet those conditions.

To filter a list

- 1. On the menu, select **Express**, and then **View**.
- 2. Select Remote Site, Patients, Studies, or Monitors.
- 3. Click **Filter**. The Filter Conditions dialog box appears.



Fig. 35. Filter Conditions dialog box

- 4. Select a Column name to filter, an Operator, and a Value.
- 5. You can do any of the following:
 - Select Case sensitive to make the condition values specific to upper or lower case text.
 - Click **Delete** to remove a condition that you set.
 - Click Suppress the filter to clear all items in the condition list and turn off the filter.
 - Click Cancel to close the dialog box without saving your changes.
 - Click Add to list to add the condition you just created to the condition(s) window.
- 6. Repeat steps 3-5 to add other conditions to the list.
- 7. When you have finished adding conditions, click **Apply the filter** and the list appears showing only the items meeting all of conditions you set.

Editing Database Information

Certain information, such as a remote site address, or a patient's last name might periodically change and need to be updated. AccuWin-Express lets you edit the information fields for remote sites and patient information.

To edit remote site information

On the Remote Site list, you can select a remote site and click **Edit** to edit or update information about a remote site.

1. On the menu, select **Express** and then **View**.

- 2. Select Remote Sites.
- 3. Select the remote site for which you want to edit data, and click **Edit**. The Remote Site Information dialog box appears. The **Edit** checkbox in the bottom left corner must be selected to allow the information to be edited.

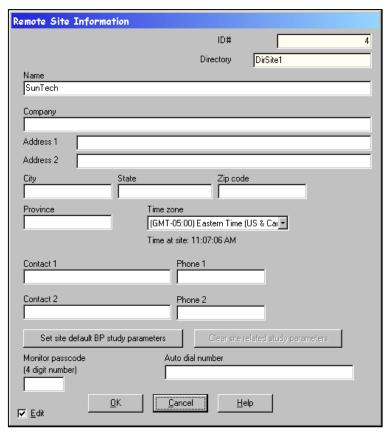


Fig. 36. Remote site information dialog box

- 4. Edit the fields as necessary.
- 5. Click **OK** to save your changes, or **Cancel** to close the dialog box without saving your changes.

To edit patient data

If a patient's basic demographic information has changed, you can update that information.

- 1. On the menu select **Edit** and then **Patient Data**, or on the task bar click **Edit** and then **Patient Data**. If no file is opened you are prompted to identify a patient and test date.
- 2. To confirm your selection of patient and test data, click **OK**. The patient data dialog box appears.

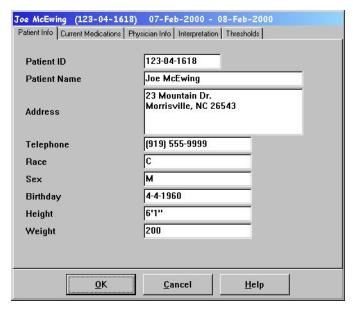


Fig. 37. Patient data dialog box

3. Select the tab for the information that you want to edit or add.

Within this function you can add or make changes to:

- Patient Info
- Current Medications
- Physician Information
- Interpretation
- Thresholds
- Current Medications
- Physician Information
- Patient Info
- Interpretation

Note: When the physician has had a chance to review the final AccuWin-Express report, select the **Interpretation** tab to enter the evaluation and diagnosis of the patient based on the information gathered during the BP recording session.

- 4. Edit the data as necessary.
- 5. Click **OK** to save your changes, or click **Cancel** to close the dialog box without saving your changes.

Audit log

AccuWin-Express automatically keeps a log of user actions at the central terminal intended to help with tracking central terminal activity. A simple text file is continually updated with the dates and times of user actions, user names, types of actions, related remote sites and patient numbers, and study numbers if relevant. To view, open the file **audit** in the Log directory (\AWExpress\Log for normal installation). It is strongly recommended that this file be opened as Read Only to prevent corruption or permanent loss of recorded activity.

File Maintenance

When you download BP data, it is saved to a file in the AccuWin-Express data directory, so that you can retrieve it later. AccuWin-Express provides several functions to maintain these BP data files. These include deleting, importing, and copying files. It is recommended that the central terminal operator periodically make a backup copy of the data directory as a precaution in case of accidental data deletion.

Deleting Data Files

You can use this feature to delete one or more patient data files or an entire remote site. Each patient file contains all the BP data for that patient, therefore deleting a patient file deletes ALL BP study data for that patient. Deleting a remote site deletes ALL BP study data for ALL patients within that remote site.

To delete a patient data file

- 1. On the menu, select File, then Delete Data, and then Patient Data.
- 2. In the File Selection dialog box, select the BP data files to delete.

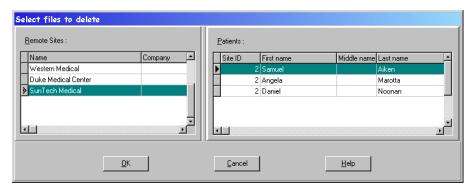


Fig. 38. File selection dialog box

3. When you have selected the names of the patient(s) you want to delete, click **OK**.

A **Delete Verification** dialog box prompts you for each data file to be deleted. You can choose for a file be deleted or skipped, or you can choose for all selected files to be deleted with no further prompting. Click **Cancel** to close the dialog box without deleting patient data.

To delete a remote site

1. On the menu, select File, then Delete Data, and then Remote Site.

File Maintenance

2. On the Remote site selection dialog box, select the remote site to delete.

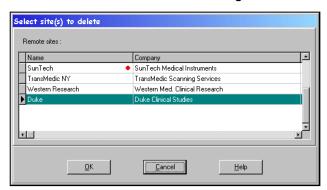


Fig. 39. Remote site selection dialog box

- 3. When you have selected the remote site to delete, click **OK**.
- 4. A **Delete Verification** dialog box prompts you to select the data files to be deleted. A remote site can only be deleted if you agree to delete all patient study files stored within the remote site. Click **Cancel** to close the dialog box without deleting any data.

Moving Data Files

You can move patients out of one remote site and into another, if necessary.

To move patient data files

- 1. Select File from the menu, and then Move Data.
- 2. Select the **Remote Site** to move patient files into, click **OK**
- 3. Select the patient(s) you want to move. Click **OK**.

Copying Data Files

You might need to copy a patient's BP data file to disc or to a different directory. These BP data files can not only be read by AccuWin-Express, but they can also be opened by any previous version of AccuWin-Pro.

To copy a patient's data file to other disks or directories

- 1. Select **File** from the menu, and then **Copy Data**.
- 2. Select a Remote Site and a Patient, and click OK
- 3. To select an item(s), click a patient name(s). Click the patient name again to clear a selection.
- 4. When you have selected the patient file(s) you want to copy, click **OK**.

File Maintenance

- 5. Select the disk drive or directory to copy to.
- 6. When you have selected the destination drive and directory, click **OK**. A message confirms that the file was copied.

Note: You cannot copy BP data files into other AccuWin-Express remote site folders.

Importing Data Files

A central terminal may have previous AccuWin-Pro files for patients they may want to import into the AccuWin-Express database. **Note:** AccuWin-Express will not allow Import of files for existing patients already in a remote site.

To import a patient's data file into AccuWin-Express

- 1. Select **File** from the menu, and then **Import**.
- 2. Select a Remote Site, and click OK
- 3. Select the patient data file for which you want to import data, and click **OK**.

Exporting Data Files

You can export data in an alternate format, for example, if you need to merge the data with a database.

To export a patient file

- 1. Select **File** from the menu, and then **Export**.
- 2. If you don't already have a study opened, select a Remote Site, Patient, and a study.
- 3. Select either ASCII or GDT tab.
 - To configure this function for ASCII output:

Delimeters allow you to choose a character to separate field items in the database.

Export allows you to choose exactly which information to export.

To configure for GDT output:

GDT is a standard format for sharing computer medical records; a summary can be exported from this selection.

4. Click OK

Overview of AccuWin-Express Report Symbols

Symbol Explanation

- t Indicates a reading was taken in the Office Test Mode.
- + Indicates that the reading was initiated by pressing the Oscar 2 "Start" key. You or the patient can override the pre-programmed protocol at any time and initiate a reading if you have programmed the Oscar 2 monitor to do so.
- Indicates that the pressure to which the cuff inflated in the dynamic inflation mode may have been too low to obtain an accurate systolic reading. If programmed to do so, the Oscar 2, initiates a retry reading and inflates to the maximum pressure four minutes later to obtain a second reading. Readings marked with a symbol are automatically edited from the AccuWin Pro report. Compare the "tagged" BP reading marked with a to the BP readings above and below it. If the "tagged" reading seems to be reasonable, "untag" it; if it does not seem reasonable, leave it tagged.
- r Indicates that this reading was a Retry reading. Retries are extra readings that are automatically obtained 4 minutes after a questionable reading is obtained by the Oscar.

Troubleshooting

The following sections address issues and situations that the central terminal or remote site may encounter when conducting an ABP study or an attempted Express modem data transfer. The table below covers issues when using AccuWin-Express for a modem data transfer while the overview of quality and test codes describes issues specific to the Oscar 2 monitor itself. The accompanying solutions will help guide you through solving these problems.

Oscar Express modem data transfer troubleshooting

Oscar Express modem data transfer troubleshooting			
Issue	Solution		
Madam dasan't navyar an	Check power cord connection.		
Modem doesn't power on	Check power button on rear of modem is depressed.		
Oscar 2 monitor doesn't power on (LCD always blank)	Replace batteries.		
No dial tone on combined data/voice	Check phone line connections from wall jack to modem.		
phone line (voice option 2)	Check phone line connection from phone to modem		
	Use phone to manually dial central terminal.		
Auto-dial does not work or dials wrong number.	Central terminal should check the remote site information window for correct auto-dial number settings.		
	If the Oscar 2 unit is at the central terminal, reassigning the monitor to the remote site with the corrected auto-dial number in the remote site information window will re-program the monitor correctly.		
	To change the auto-dial number on an Oscar 2 unit at a remote site, the central terminal must enter the correct number in the Modem Data Transfer window. You may have to enable this in the AccuWin-Express options.		
	Check phone line connections between modem and wall jack.		
	Check adapter and cable connections between the modem and the Oscar 2 unit.		
Modem data transfer fails.	Check that the Oscar 2 unit is Express capable. (Displays OE when turned on).		
	If using voice communication option 2, background noise can interfere with the modem data transfer. Using a mute button and minimizing background noise will help alleviate this problem.		
	Disable call waiting if applicable.		

Troubleshooting

Overview of Quality and Test Codes

The columns labeled **Test Code** and **Quality Code** are used extensively in your data editing decisions. These codes indicate various technical attributes of the BP reading that you should take into consideration when making a decision to "tag" or "untag" a BP reading. It is possible to have both a **Test Code and a Quality Code** on the same BP reading.

Remember, Test and Quality Codes do not automatically indicate that a reading is invalid; they only serve as guides to help you edit data.

Oscar 2 test code definitions

Test Code	Description in AccuWin Pro	Solution
1	Weak or no oscillometric signal	Check position of cuff, tighten cuff.
2	Artifact/Erratic Oscillometric Signal	Remain still during BP reading.
3	Exceeded retry count (4 inflate attempts)	Remain still during BP reading.
4	Exceeded Measurement time	Check air hose connections and make certain cuff is tight.
85	Reading Aborted (blocked values or pneumatics)	Check air hose connections and make certain air tubing is not crimped.
86	Reading Aborted (user abort)	Push START/STOP button to restart reading.
87	Reading Aborted (inflate time-out out or air leak)	Check air hose and cuff.
88	Reading Aborted (safety time-out)	Retry reading, push START/STOP button. If problems persist return unit for servicing.
89	Reading Aborted (cuff over-pressure)	Check for blocked or kinked air hose.
90	Service Required (power supply out- of-range or other hardware problem)	Replace batteries. If problem persists, return for servicing.
91	Service Required (safety override fitted or auto-zero out-of-range)	Retry by pushing START/STOP button. If problems persist return unit for servicing.
97	Service Required Transducer out-of- range	Return for servicing
98	Service Required (A/D out-of-range)	Return for servicing
99	Service Required (EEPROM calibration data CRC failure)	Unit needs to be recalibrated. Return for servicing.

Troubleshooting

Oscar 2 Quality Code definitions

Quality Code	Description
TC	This QC indicates that a Test Code occurred that would indicate that this reading is suspect. Refer to the table above for detailed definitions of Test Codes.
LOH	Dynamic pressure too low. Pressure to which cuff inflated in the dynamic inflation mode may have been too low to obtain an accurate systolic reading. The reading will be automatically omitted from the report.

Oscar Express and AccuWin-Express Technical Assistance

From the AccuWin–Express toolbar buttons, you can select the Help function for a quick, on-line reference guide. For more detailed assistance, please refer to this **Oscar Express Central Terminal User's Guide** or contact your nearest SunTech service center.

USA, Canadian and Latin American Headquarters and Service

507 Airport Boulevard, Suite 117 Morrisville, NC 27560-8200 USA Toll free USA and Canada: 800.421.8626

Phone: 919.654.2300 Fax: 919.654.2301 www.suntechmed.com

European and Far East Headquarters and Service

Oakfield Industrial Estate Stanton Harcourt Road Eynsham, Oxfordshire OX29 4TS (44) 1.865.884.234

In the event you are unable to rectify the error and need assistance, please call our service department: in the US, 1.800.421.8626, and 919.654.2300, or in the UK 01865.884234.

Maintaining and Cleaning the Oscar 2

After use, it is important to perform preventative maintenance to ensure the safe and efficient operation of the monitor.

Cleaning After Use

The Oscar 2 unit is not sterilizable. DO NOT immerse the monitor in any fluid, or attempt to clean with liquid detergents, cleaning agents, or solvents. Use a soft, damp cloth to remove dirt and dust from the monitor. If the unit does become immersed in water, do not use; contact the SunTech service department.

You can use a mild disinfectant solution such as Cidex to clean the cuff, strap, belt, and pouch. Or, you can also wash these items in a washing machine. Make sure that you either remove the bladder from the cuff or use a cuff plug (part #97-0021-00) to keep the inside of the bladder dry. Wash these items using warm water and a mild detergent; if needed, hang to dry.

Maintenance After Use

Visually inspect cables, pneumatic hoses, and the monitor case for cracks, fraying, or kinks. DO NOT use the monitor if it shows any signs of damage. Contact the SunTech service department.

Annual Maintenance

It is recommended that you check the accuracy of the Oscar 2 once a year. If necessary, an authorized service center can recalibrate the pressure transducers in the monitor.

To check calibration

The Oscar 2 must first be placed into the proper mode.

- 1. Remove and then replace one of the two "AA" batteries.
- 2. While the LCD is displaying dashes, press and hold down the START/STOP key.
 - The unit displays the software version.
 - The unit displays the battery voltage.
 - You hear a click as the valves are closed.
 - You will now see "0 mmHg" displayed.
 - The calibration of the unit can now be checked against a calibrated mercury column.
- 3. Place a "T" tube (part #98-0030-00) between the hose from the monitor and the cuff.
- 4. Wrap the cuff around a suitably sized can or bottle. This acts as the reservoir for the unit.
- 5. Attach the third end of the "T" tube into a mercury column, which gives you access to the bulb and a reference.

Maintaining and Cleaning the Oscar 2

- 6. Using the bulb of the mercury column, inflate the cuff to 250 mmHg. Once the pressure has stabilized at this level, the LCD should match the mercury column by ±2.0 mmHg.
- 7. Check the unit against the column every 50 mmHg from 250 to 50 mmHg and the unit should be within ±2.0 mmHg. If not, the unit needs to be returned to the service department for recalibration or repair.

The Oscar 2 does not contain any user serviceable internal parts and should only be opened by an authorized service representative. To return for service, send to your nearest SunTech office listed under *Limited Warranty*.

Products and Accessories

Contents of Oscar Express central terminal system (99-0028-00)

Description	Item number	Qty.
AccuWin-Express software CD	27-0039-A1	1
Oscar 2 PC Interface Cable	91-0056-00	1
Central Terminal User's Manual	80-0030-00	1
Remote Site User's Manual	80-0031-00	1
Oscar Express Quick Guide	82-0034-00	1
2-Way Phone Line Splitter	64-0086-00	1

Contents of Oscar Express monitor system (99-0028-01, 99-0028-02)

Description	Item number	Qty. Basic	Qty. PowerPack
Oscar 2 ABP monitor	97-0012-01	1	1
Orbit ABP cuff - Small Adult	98-0063-01	0	1
Orbit ABP cuff - Adult	98-0063-02	1	1
Orbit ABP cuff - Large Adult	98-0063-03	0	1
Oscar 2 Pouch	98-0032-00	1	1
Oscar 2 Strap	98-0036-00	1	1
Oscar 2 Belt	98-0037-00	1	1
Patient Diaries	82-0019-00	10	250
AA, Alkaline Batteries (4)	17-0004-00	1	1
AA, NiMH Rechargeable Batteries (4)	17-0005-00	0	1
Battery Charger	17-0007-00	0	1
Oscar Express Quick Guide	82-0034-00	1	1

Contents of Oscar Express remote site system (99-0028-05)

Description	Item number	Qty.
External V.92 modem	98-0060-00*	1
Oscar 2 Modem Cable	91-0067-00	1
Remote Site User's Manual	80-0031-00	1
2-Way Phone Line Splitter	64-0086-00	1

^{*} Modem shipped with Remote Site system is fully initialized for Express modem communication. A stand alone 98-0060-00 modem is not initialized.

Limited Warranty

OSCAR 2 Ambulatory BP Monitor

SunTech Medical provides to the original purchaser the following limited warranty from the date of invoice.

Blood pressure serialized monitor

24 months

Accessories, i.e., patient hoses, interface cables, and cuff

90 days

SunTech Medical warrants each instrument to be free from defects in material and workmanship. Liability under this warranty covers servicing of the instruments when returned from the customer's facility prepaid to the prospective factory depending on location. SunTech Medical will repair any component(s) or part(s) that it finds to be defective during the period of this limited warranty. Should a defect become apparent, the original purchaser should notify SunTech Medical of the suspected defect. The instrument should be carefully packaged and shipped prepaid to:

SunTech Medical 507 Airport Boulevard, Suite 117 Morrisville, NC 27560-8200, USA Toll free (US): 800.421.8626

Phone: 919.654.2300 Fax: 919.654.2301

SunTech Medical, Ltd. Europe Oakfield Industrial Estate Stanton Harcourt Road Eynsham, Oxfordshire OX29 4TS England

Tel: 44.1865.884234 Fax: 44.1865.884235

The instrument will be repaired in the shortest possible time and returned prepaid by the same shipping method as received by the factory.

This limited warranty is void if the instrument has been damaged by accident, misuse, negligence, act of God, or serviced by any person not authorized by SunTech Medical.

This limited warranty contains the entire obligation of SunTech Medical and no other warranties expressed, implied, or statutory are given. No representative or employee of SunTech Medical is authorized to assume any further liability or grant any further warranties except as set herein.

