Oscar Express Remote Site User's Guide

Oscar 2
24-Hr ABP

SYS / DIA
120/80 mmHg

SunTech

SunTech Medical
The *motion-tolerant* BP company®

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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.[1,2,3]

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."[4]

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

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1. 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." Blood Press Monitor. 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." Blood Press Monit. 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.

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 that allows 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

- Tabulated 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 Oscar 2 ABP system(s), a modem, and a cable to connect the Oscar 2 monitor to the modem. All that is needed for data transmission is 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 with the Oscar 2 monitor, the monitor is connected to the modem for data transfer to the central terminal. The central terminal can retrieve the data from the Oscar 2 monitor, program the monitor for the next patient study, and format a clinical report of the collected data to be sent back to the remote site.

Setting up a Remote Site

Before a remote site can perform a patient ABP study, send data to a central terminal for report generation and receive a report back, the remote site must first set-up the modem, phone, phone line and Oscar 2 monitor.

When you receive a remote site package from your central terminal, open the contents and you should have each the following items:

- **Oscar Express monitor system.** A remote site may be issued more than one Oscar Express monitor system depending on the need and volume of each site. Each system will include an Oscar 2 monitor, ABP blood pressure cuff(s), monitor pouch, strap and belt. See *Products & Accessories* for a complete list of items.

- **Oscar Express remote site system.** Each remote site should receive a remote site system from the central terminal containing a fully Express initialized modem for Express and an Oscar 2 modem communication cable. See *Products & Accessories* for a complete list of items.

Your central terminal should have already set up your Oscar 2 monitor and programmed it for an ABP study, thus making it ready for an immediate patient study. To verify this, turn on the monitor by pressing the Start/Stop button (see *Oscar 2 at a Glance*). The display should show an **"OE"** on the left and a number on the right indicating how many currently stored BP readings are in the monitor, most likely 0 for zero. If this is the case, the monitor is ready for a patient study and an Oscar Express modem data transfer is not needed until the monitor has collected ABP data from a patient.

The **"OE"** indicates that the Oscar 2 monitor has been enabled for Oscar Express modem communication. If the display does not show an **"OE"**, you must contact your central terminal and arrange to have the monitor Oscar Express enabled. This can only be done at the central terminal with AccuWin-Express.

If the number of stored readings is 1 or more, it is suggested that your first modem data transfer is to load a new ABP program onto the Oscar 2 monitor which will erase all currently stored readings and prepare the monitor for the next patient.

Setting up a Remote Site

Modem connections

Whether your first Oscar Express modem data transfer with the central terminal is to program the Oscar 2 monitor with study parameters or to send patient ABP data and re-program for the next study, the proper connections need to be made in order to successfully perform a modem data transfer.

1. Plug Oscar 2 to modem cable into the 25-pin port on the back of the modem.

2. Connect the phone cord from the phone to the "phone" jack on back of modem. (*Optional if using voice option 1 with a separate dedicated phone line.* See **Voice communication options**).

3. Connect phone line cord from wall jack to "line" jack on back of modem. If you plan on using your fax line as the Express data line as well, a dual jack adapter is included to convert your wall jack into 2 jacks.

4. Connect modem power cable to the modem and plug into to wall outlet.

The modem is now connected. The final connection needed to perform a data transfer is to plug the serial data cable into the bottom of the Oscar 2 monitor. (See **Connecting the Oscar 2 monitor to the modem.**)

Setting up a Remote Site

Turn on the modem by depressing the On/Off button on the rear of the modem. Check that the power light on the front of the modem illuminates to ensure a proper connection. With a phone connected to the modem, (optional), you can pick up the phone and check that you hear a dial tone to ensure correct connections of the phone line.

Note: the Oscar Express system 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.

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 they 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 illustrated on the following pages 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.

Setting up a Remote Site

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 operator with the voice line and exchanges necessary information before performing a data transfer. When instructed by the central terminal operator, 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 during a data transfer.
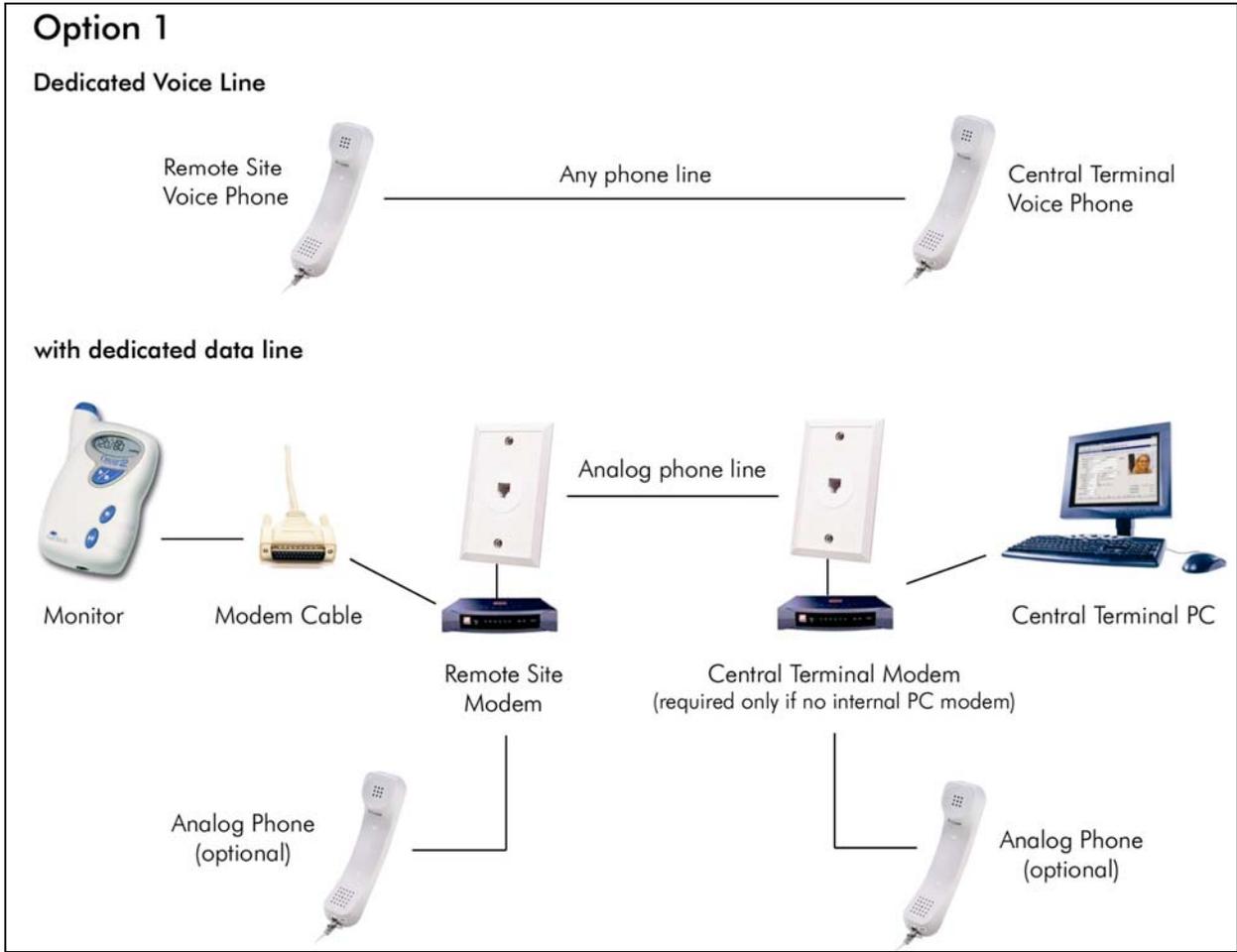
Fig. 1. Communication Setup Option 1

Setting up a Remote Site

<u>Set-up Option 2</u>

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 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.
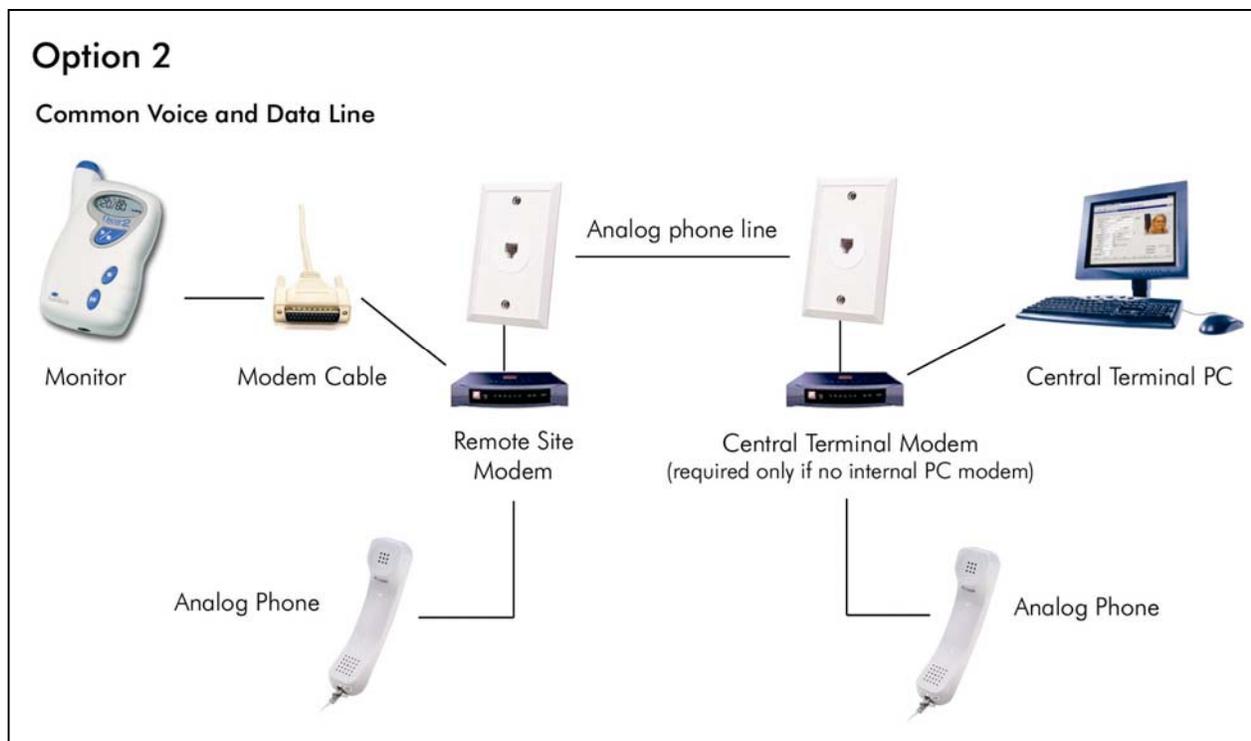
Introduction to the Oscar Express ABP Monitor: Oscar 2

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 monitor. This includes communication over analog telephone lines via modem and direct communication to the PC COM port. If Oscar 2-to-PC communication with AccuWin-Pro is required, the Oscar Express option must be disabled on the Oscar 2 monitor. 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 placed 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*.[1] 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, North Carolina 27560-8200

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

Introduction to the Oscar Express ABP Monitor: Oscar 2

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.

Introduction to the Oscar Express ABP Monitor: Oscar 2

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.

Introduction to the Oscar Express ABP Monitor: Oscar 2

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.

Introduction to the Oscar Express ABP Monitor: Oscar 2

Oscar 2 at a Glance

Systolic/Diastolic

START/STOP

Button reserved for future programmability

Express Button

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 OE 0	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.

Introduction to the Oscar Express ABP Monitor: Oscar 2

Pressure 160	Indicates the pressure in the cuff in mmHg during BP reading.
BP Reading SYS ☀ DIA $120/$ 80 mmHg	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 $20/$	Indicates what percentage of Express data transfer is complete

Preparing the Patient for Oscar 2 ABP Study

In order to accurately measure blood pressure during a 24 hour ambulatory blood pressure study, you must carefully and correctly prepare the patient.

Fitting the 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.**

Introduction to the Oscar Express ABP Monitor: Oscar 2

<u>Patient Hook-up</u>

1. Insert the patient's arm through the sleeve as shown by the hand label (Fig. 3). 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. 4).

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. 5). Attach the pouch to the patient using either the shoulder strap or belt, depending on the patient's preference (Fig. 6). 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.
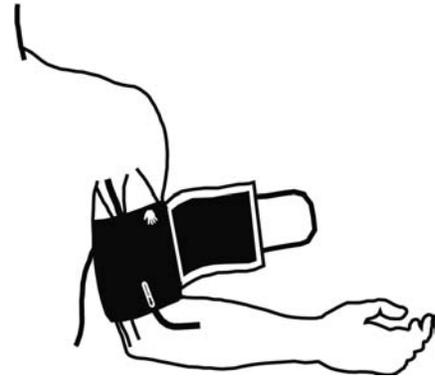
The patient and Oscar 2 ABP system are now ready for the ABP study.

Fig. 3

Fig. 4

Fig. 5

Fig. 6

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Introduction to the Oscar Express ABP Monitor: Oscar 2

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 shows up on the display, indicating that the monitor is in Study mode and operating correctly.

Finishing the Study

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

Oscar Express Data Transfer with Central Terminal

If patient data is stored on the Oscar 2 monitor and needs to be sent to the central terminal, or if the central terminal needs to program the Oscar 2 with a study protocol, or both, an Oscar Express data transfer with the central terminal is necessary to perform these tasks.

When ABP data is sent, the central terminal receives the data and saves it in a patient file in the appropriate remote site. Before the modem communication completes, the central terminal also programs the Oscar 2 monitor, clearing out any saved BP data and preparing it for the next patient study.

Connecting the Oscar 2 Monitor to the Modem

Before performing a data transmission to the central terminal, make sure:

- You disconnect the Oscar 2 unit from the patient before connecting to the modem or any piece of hardware (to avoid electric shock).

- You remove the Oscar 2 unit from the pouch.

- The Oscar 2 is connected to the modem with appropriate cable.

- The modem is powered on.

- The Oscar 2 is powered on and not in Study mode. (Time should be flashing). To take the monitor out of study mode, turn the monitor off and then power the monitor back on.

The first step in performing a data transfer is to call a central terminal operator to identify your remote site, indicate you have patient data to download, the patient name and/or ID, and whether you wish to upload to the Oscar2 to program a new study and what those parameters should be. If needed, a data transfer can be an upload only.

Depending on which option you use for the voice communication set-up, follow the appropriate steps for performing the Oscar Express data transfer.

Option 1 – Separate modem data and voice lines:

Step 1. Contact the central terminal
Use a separate voice line, this can be your regular office phone, to call the central terminal operator and tell them you would like to perform an Oscar Express data transfer.

Step 2. Preparing for modem data transfer
The central terminal will ask for your remote site identification and what type of transfer is desired (download, upload or both). If there is BP data on the Oscar 2 to download, you will need to provide the appropriate patient information. If you wish to also have the Oscar 2 programmed for a new study, you may need to indicate the parameters to set.

The central terminal should instruct you to make sure you:
- Have the Oscar 2 connected to the modem with the modem cable

- Have the modem turned on (power light illuminated)
- Have the Oscar 2 turned on and OUT of study mode (time flashing on display)

Step 3. Starting the data transfer
The central terminal operator will indicate when to begin the data transfer. To do this, press and hold the Express button (►►) until you hear three rapid beeps or a "chirp".

The Oscar2 will then automatically dial the central terminal data transfer line and the data transfer will begin. During the data transfer through the modem, the Oscar 2 will display a percentage to indicate the progress of the transfer. Meanwhile, the central terminal operator can communicate to you the status of the data transfer over the voice line.

Step 4. Completing communication with Central Terminal
When the data transfer is complete, the Oscar 2 display will indicate 100% and will automatically turn off. The unit is now ready for the next patient study if an upload was performed.

WARNING!: Do not store the Oscar 2 unit without batteries, otherwise the set clock time will be lost. You can replace with new batteries immediately prior to fitting next patient. If there were any problems with the transfer, the central terminal operator will indicate this and a data transfer can be repeated. After a successful transfer, the modem automatically disconnects the data line and the voice call can also be ended.

Oscar Express Data Transfer with Central Terminal

Option 2 – Common modem data and voice line:

Step 1. Contact the central terminal
Using the analog phone connected to the modem, manually dial the central terminal operator and tell them you would like to perform an Oscar Express data transfer.

Step 2. Preparing for modem data transfer
The central terminal will ask for your remote site identification and what type of transfer is desired (download, upload or both). If there is BP data on the Oscar 2 to download, you will need to provide the appropriate patient information. If you wish to also have the Oscar 2 programmed for a new study, you may need to indicate the parameters to set.

The central terminal should instruct you to make sure you:
- Have the Oscar 2 connected to the modem with the modem cable
- Have the modem turned on (power light illuminated)
- Have the Oscar 2 turned on and OUT of study mode (time flashing on display)

Step 3. Starting the data transfer
The central terminal operator will indicate when to begin the data transfer. To do this, press and hold the Express button (►►) until you hear three rapid beeps or a "chirp". The Oscar2 will then automatically begin the data transfer process.

Warning: Any background noise during the data transfer can interfere with the modem transmission. If the remote site phone has a "mute" button, it should be used to minimize background noise from interfering with the data transfer.

During the data transfer through the modem, the Oscar 2 will display a percentage to indicate the progress of the transfer. You will have to wait until the data transfer is complete until you can once again use the line to communicate directly with the central terminal operator.

Step 4. Completing communication with Central Terminal
When the data transfer is complete, the Oscar 2 display will indicate 100% and will automatically turn off. The modem communication on the line should end (beeping stops) and the phone line is again available for voice communication. The unit is now ready for the next patient study if an upload was performed. If there was a problem with the transfer, the central terminal operator will indicate this and a data transfer can be repeated.

Warning: Do not store the Oscar 2 unit without batteries, otherwise the set clock time will be lost. You can replace with new batteries immediately prior to fitting next patient. If there were any problems with the transfer, the central terminal operator will indicate this and a data transfer can be repeated. After the central terminal operator confirms a successful transfer, the voice call can be ended.

Overview of AccuWin-Express Report Symbols

After performing a data transmission with the central terminal, the data is saved on a PC at the central terminal. Using AccuWin-Express, the central terminal can review and edit the data to create a custom clinical report for your patient. This report may be printed out and mailed or faxed to you. The following table explains some of the symbols that may appear in a typical report.

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

Issue	Solution
Modem doesn't power on	Check power cord connection.
	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 phone line (voice option 2)	Check phone line connections from wall jack to modem.
	Check phone line connection from phone to modem.
Auto-dial does not work or dials wrong number.	Use phone to manually dial central terminal.
	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, re-assigning 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. The central terminal may have to enable this in the Express > Settings > Options window.
Modem data transfer fails.	Check phone line connections between modem and wall jack.
	Check cable connections between the modem and the Oscar 2 unit.
	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.

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

For assistance with Oscar Express modem data transfers, please contact your central terminal. For detailed assistance on your Oscar 2 monitor, please refer to this **Oscar Express Remote Site 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
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 or medical grade 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.
Remote Site User's Manual	80-0031-00	1
External V.92 modem	98-0060-00*	1
Oscar 2 Modem Cable	91-0067-00	1
2-Way Phone Line Splitter	64-0086-00	1

* Modem shipped with Modem Kit 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
Tel: 1.800.421.8626 or 1.919. 654.2300
Fax: 1.919.654.2301

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.

Part #80-0031-00
Rev A