SunTech Medical®
Brilliant Blood Pressure Solutions™

Cycle™
Stress BP

Cycle™ Users Manual

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Brilliant Blood Pressure Solutions™

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Safety and Effectiveness Considerations

Indications for Use

Consider the following safety and effectiveness issues prior to using the *Cycle* Stress Test Blood Pressure Monitor:

- Use *Cycle* only with adult patients, while they undergo a cardiac or exercise stress test under the supervision of a physician. Ensure that appropriate resuscitation equipment and personnel are available at all times during the procedure.
- This device is defibrillator protected with the exception of the pulse oximeter.
- The reliability of the device depends upon conformance with the operation and service instructions as detailed in this manual.

Cycle™ BP

is a non-invasive multi-parameter monitor measuring blood pressure and oxygen saturation for use in cardiac or exercise stress testing. It measures and displays an adult patient's systolic and diastolic blood pressure and the percent oxygen saturation of arterial blood.

User Responsibility

This product is designed to perform in conformity with the description contained in this operation manual and accompanying labels and inserts, when assembled, operated, maintained and repaired in accordance with the instructions provided.

The calibration of this product should be checked annually. A defective product should not be used. Parts that are broken, plainly worn, missing or incomplete, distorted or contaminated should be replaced immediately.

Should any repair or replacement become necessary, *SunTech Medical* recommends that service be performed at the nearest factory approved service center, details of which can be obtained by contacting *SunTech Medical* at the addresses listed in this document.

The user of the product shall have the sole responsibility for any malfunction which results from improper use, faulty maintenance, improper repair, damage or alteration by anyone other than *SunTech Medical* or their authorized service personnel.

Warnings and Contraindications

DO NOT USE THE MONITOR IF it has failed its diagnostic self test or if it displays a greater than zero pressure with no cuff attached or a value of saturation with no sensor attached. The values displayed by such a unit may be inaccurate.

DO NOT USE ON NEONATES, 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.

DO NOT ATTACH THE PULSE OXIMETER to the same limb as the CUFF or any other blood flow restrictor. Loss of monitoring can occur due to the hindering of pulse measurements.

DO NOT USE IN THE PRESENCE OF FLAMMABLE anesthetics; this could cause an explosion.

DO NOT IMMERSE the monitor in any fluid, place fluids on top of, or attempt to clean the unit with any liquid detergents or cleaning agents. This may cause an electrical hazard. Refer to Maintenance & Cleaning for instructions on cleaning. If any of these situations occur, please contact SunTech Medical.

DO NOT REMOVE UNIT COVERS.
Doing so may expose hazardous voltage and cause electrical shock. The monitor does not contain any user serviceable components. Refer to Maintenance & Cleaning for service instructions.

DO NOT MAKE REPAIRS YOURSELF: No repair should be undertaken or attempted by anyone not having been service trained by *SunTech Medical* or having a thorough understanding of the repair and operation of automatic blood pressure equipment. (Substitution of a component different from that supplied might result in measurement error).

DO NOT CONNECT the monitor to equipment that does not meet IEC 60601-1. When the monitor is attached to a patient, the monitor's RS-232 and USB connectors can only be connected to equipment that meets IEC 60601-1.

Precautions

Observe the patient carefully during the procedure. Ensure pressure compatibility to all patients. If any abnormality occurs, either in the unit or the patient, suspend the operation immediately and disconnect the cuff and pulse oximeter sensor from the patient.

Accuracy of any blood pressure recording or oxygen saturation measurement may be affected by the position of the subject, his or her physical condition and use outside of the operating instructions detailed in this manual. Interpretation of blood pressure and oxygen saturation measurements should be made only by a physician.

Safety and effectiveness in pregnant women, children under 13 years of age and neonates have not been established.

Adverse Reactions

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

Following the application 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 arm, 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.

Checking the Pulse Oximeter Placement

Use only pulse oximeter sensors supplied by SunTech Medical. Frequently check the application site of the pulse oximeter sensor to determine the positioning of the sensor and the circulation and skin sensitivity of the patient.

The following factors may affect the accuracy of pulse oximetry:

- Excessive ambient light
- Excessive motion
- Electrosurgical interference
- Moisture in the sensor
- Improperly attached sensor
- Incorrect sensor type
- Arterial catheters, blood pressure cuffs, infusion lines, etc.
- Poor pulse quality
- Venous pulsations
- Anemia or low hemoglobin concentrations
- Sensor not at heart level

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At a Glance

Viewing the Connector Panel

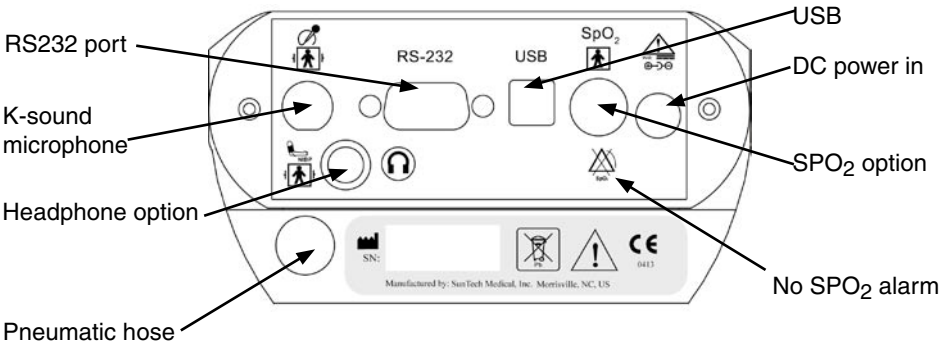

Figure 1: Connector Panel Connections

Connecting Cycle Options

After unpacking the monitor and connecting the cables, follow the steps in "Operation—Preparing the Patient." Connections are not interchangeable.

Headphone Option: Connection for headphones for manual BP measurement.		**SpO_2 Option:** For measurement of oxygen saturation.	SpO2
RS232: Serial (RS232) communications port for interfacing with stress systems.	**RS-232**	**Pneumatic Hose:** Connection for the patient cable's air hose.	NIBP
DC Power In: Defibrillator protected. A 9V DC input.	9Vdc	**K-sound Microphone:** Connection for the patient cable's microphone cable.	
USB: USB communications port for interfacing with stress systems.	**USB**	**No SpO_2 Alarm:** The monitor does not provide an alarm for a low SpO_2 condition	SpO₂

Looking at the Measurement View

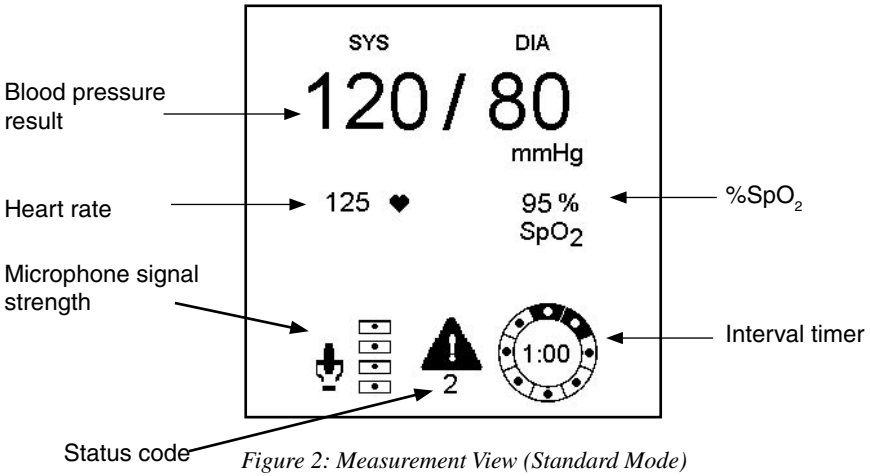

Figure 2: Measurement View (Standard Mode)

When power is applied to the *Cycle* monitor, a splash screen appears briefly. If the *Cycle* is attached to a stress system, the *Cycle* turns on and off along with the stress system.

The screen displays the following information while you take a measurement:

- *Blood Pressure Result*: After a measurement, displays the latest BP.
- *Cuff Pressure*: During a measurement, displays the pressure in the cuff.
- *Heart Rate:* Displays beats per minute.
- *Microphone Signal Strength:* Displays the strength of the microphone signal. During a measurement, the rhythmic display of signal corresponds to Korotkoff sounds.
- *Status Code:* Indicates a possible problem with the measurement. For a list of codes and their meanings, see "Advice and Troubleshooting."
- *Interval Timer:* When the Interval is set to MAN (Manual) on the Interval menu, displays how old the BP measurement is. At 5 minutes, measurement data is stored as history and the display clears. When set to a time, displays the number minutes and seconds since the beginning of the last reading.
- *%SpO_2*: Displays current percentage of oxygen saturation in arterial blood.

Using Cycle Buttons

Start/Stop: Initiates a measurement or terminates one in progress.

Menu: Displays menu options.

Advance: Helps you navigate through the screens. In Measurement View, pressing this button moves through the last reading and three memory readings. In Menu and System modes, pressing the **Advance** button allows you to move through the parameters of the configuration screens.

At a Glance, continued

Using the Memory Mode

Figure 3: Memory Mode

Viewing Measurement History

Cycle stores up to the previous three measurements. The most recent measurement appears as the first measurement. A measurement is stored in memory when either a new measurement is started or when the current one is 5 minutes old. When *Cycle* stores a new measurement to the history and if three readings are already stored, *Cycle* discards the oldest reading and adds the most recent one to history.

The following data displays when in Memory Mode:

- *Blood Pressure Result*: Displays blood pressure.
- *Heart Rate:* Displays beats per minute.
- *Status Code:* Displays code that indicates a possible problem with the reading. See "Advice and Troubleshooting."

1. Press **Advance**. The most recent reading appears.
2. Continue pressing **Advance** to move to the next reading.
3. To exit and return to Measurement view, press **Start/Stop** or **Menu**.

Preparing for a New Patient

Before every new patient test, you should clear a previous patient's readings from memory and prepare the monitor for the new patient.

1. From the Measurement View, press **Menu**.
2. From the Menu - End Test screen, press **Advance** to select the checkmark.
3. Press **Start/Stop** to save the setting and return to the Measurement view.

Note: Measurements are retained in memory until a new BP is taken.

Configuring the Monitor in Menu Mode

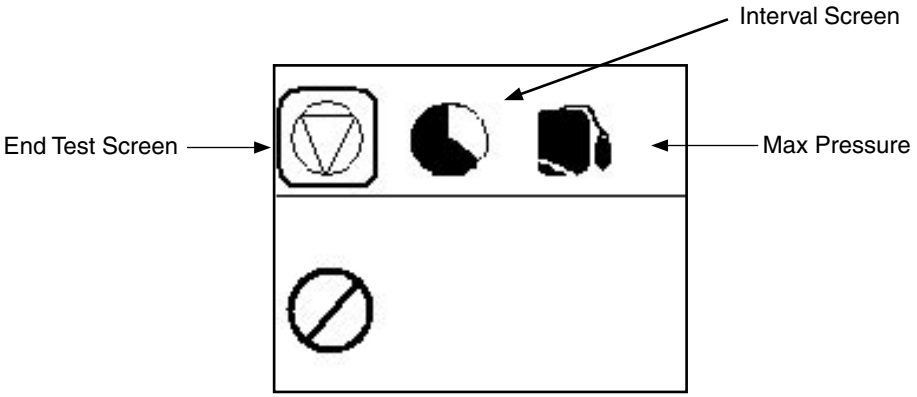

Figure 4: Menu Mode

Accessing the Menu Mode

1. From the Measurement view, press **Menu**. The Menu - End Test screen appears.
2. To move through the Menu mode screens, press **Menu**.
3. To exit Menu mode, save settings, and return to the standard Measurement view, press **Start/Stop**.

Ending a Measurement Test

You can end a measurement interval or clear the measurements for a new patient. The default is to continue the test (indicated with the circle/slash).

- To continue the test move to the next screen or return to the Measurement view.
- To end the test press **Advance** to select the check mark.

Setting Measurement Intervals

1. In the Interval screen, do one of the following:
   - To accept the current setting, move to the next screen or return to the Measurement view.
   - To set an interval, press **Advance** until the desired interval is displayed (1:30, 2:00, 3:00, 4:00, 5:00)
2. Press **Menu** to continue to the Max Pressure screen. Alternatively, press **Start/Stop** to save the settings and return to the Measurement view.

Setting the Maximum Cuff Pressure

You can set the maximum pressure to which the monitor will inflate. The default is 275 mmHg.

1. In the Max Pressure screen, press **Advance** to increase the value by 25 mmHg in the following order: 175, 200, 225, 250, 275. The values repeat.
2. Press **Start/Stop** or **Menu** to return to the Measurement view.

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System Setup

Compatible Stress Systems

You can set up the *Cycle* to work directly with your stress system. This means your stress system can prompt the *Cycle* to take a BP measurement while you are performing a stress test. In addition, on some systems, the measurement from the *Cycle* will be transferred to your stress system to be displayed on screen and printed on any reports.

The following stress systems are compatible with the *Cycle*.

For more information on ordering the proper cables for your stress system, see Accessories and Consumables.

- AT10
- AT60
- Cardio-Card
- CardioDirect
- Cardiofax ECG9320
- CardioSys
- Case (GE)
- Case12
- Case 15
- Case 16
- Case 8000
- Centra
- CH2000
- CS-200
- Custom
- Formula
- Mac 5000
- Mac-VU-Stress
- Max-1
- Medilog Stress
- Q3000
- Q4000
- Q4500
- Q5000
- QRS Card
- Q Stress
- Quest
- Stress Vue
- X-Scribe II

See www.SunTechMed.com/interfacenotes.htm for a complete list of compatible systems. Here, you can download instructions on setting up your particular stress system.

To test the setup, you will need to hook up a patient and take a measurement. It is not possible to use an oscillometric blood pressure simulator because the *Cycle* uses auscultation to measure BP.

Accessing the System Menu

Use the System menu to access the following screens:

- Contrast
- Communication
- Deflate Rate
- Calibration Check

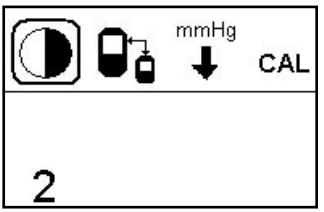

Figure 5: System Menu: Contrast

1. From the Measurement view press **Menu** and **Advance** simultaneously for 3 seconds until the Contrast screen appears.
2. To move to the next screen, press **Menu**.
3. To scroll through the available selections for each screen, press **Advance**.
4. To save System Menu changes and return to the Measurement view, press **Start/Stop.**

Using the System Menu—Contrast Screen

Use this screen to set the monitor display's contrast.

1. Press **Advance** to scroll through settings from 1 to 10, with 1 being the lightest and 10 being the darkest. The default setting of 5 provides optimum contrast for an environment with normal office lighting.
2. To save your selection and display the Communication Screen, press **Menu**.

Using the System Menu—Communication Screen

Use this screen to set up *Cycle* to communicate with the stress system to which it is connected. Simply choose the model of stress system. The default stress system setting is *Custom* with the *SunTech* protocol.

1. Press **Advance** to scroll through an alphabetical list of available stress systems.
2. To choose a stress system not on the list, press **Advance** until Custom: appears. Press **Menu** to access a list of available protocols. To scroll through the list of protocols, press **Advance** again.
3. To save your selection and display the Deflate Rate Screen, press **Menu**.

The following are the custom protocols available on *Cycle.*

- Biosound
- Bosch
- Bosotron
- Cambridge Heart
- Ergoline
- Marquette
- Nihon Koden
- Quinton
- Reynolds
- Stresslink
- SunTech

Using the System Menu—Deflate Rate Screen

Use this screen to set the deflate rate for the monitor.

1. Press **Advance** to toggle to the selections of either AUTO (the monitor chooses the optimum deflate rate based on the patient's heart rate) or 3 mmHg/sec (used primarily to perform manual measurement comparisons). The default setting is *AUTO*.
2. To save your selection and display the Calibration Check Screen, press **Menu**.

Using the System Menu—Calibration Check Screen

Use this screen to check the monitor's pressure calibration. When you display this screen, the valves close.

1. Verify that the cuff pressure on the display is within 2 mmHg of your calibrated reference manometer through a range of pressures from 0–250 mmHg.
2. Press **Menu** to return to Measurement view.

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Operation

Preparing Your Patient — Overview

To accurately measure blood pressure during a stress test, carefully and correctly prepare your patient.

1. Choose the appropriate cuff size.
2. Insert the microphone into the cuff.
3. Place the cuff on the patient's arm.
4. Attach the cuff and microphone to the patient cable.
5. Use the wrist strap to secure the cables to the patient and away from the ergometer pedals.

Conducting the Stress Test — Overview

After correctly preparing your patient for the study, you can begin the stress test.

1. Take 1-2 BP measurements with the patient seated or standing still before starting the stress test.
2. Advise and support your patient to get accurate BP measurements.
3. End study.

See the following pages for details on each of the above steps. Accurate blood pressure readings depend on correctly hooking up the microphone, cuff and *Cycle* monitor, and instructing the patient on the proper arm position during a blood pressure reading. The *Cycle* monitor should be set up before preparing your patient.

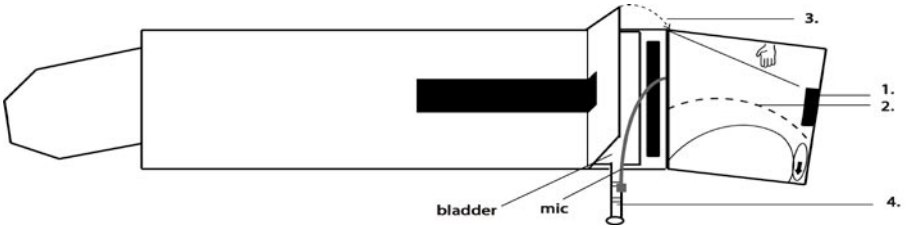
Preparing the Patient

To accurately measure blood pressure during a stress test, carefully and correctly prepare your patient.

1. Choose the appropriate cuff size.
   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's circumference. Ensure that this measurement is within the range of the cuff. If it is not, use another cuff size.
   Caution: Using a cuff that is the wrong size will result in false and misleading measurements.

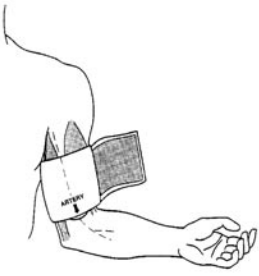
2. Insert the microphone into the cuff.
   When you receive the *Orbit-K* cuff, the microphone should already be properly inserted. If you need to replace the mic, follow these simple steps:

Figure 6:
Orbit-K™ BP Cuff



- First, locate the sensor marker flap on the cuff sleeve and slide the microphone into the sensor flap (Fig. 6 step 1). Do not squeeze the microphone when inserting into the cuff.
- Next, thread the microphone cable through the cuff sleeve (Fig. 6 step 2).
- Then, close the Velcro flap over the cable (Fig. 6, step 3) and secure the microphone cable to the cuff hose (Fig. 6, step 4).

Figure 7:
Cuff Placement



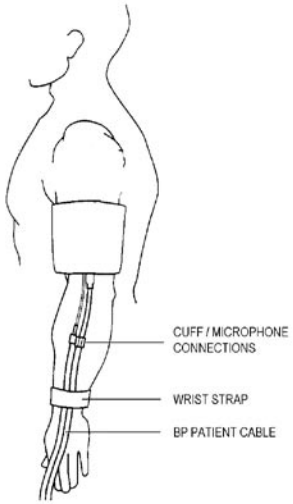
3. Place the cuff on the patient's arm.
   Locate the sensor marker on the *Orbit-K* cuff. Palpate the brachial artery (which lies between the biceps and triceps on the medial side of the upper arm). Slide the patient's arm through the sleeve as indicated by the label. Slide the cuff onto the arm with the sensor marker over the brachial artery. See Fig 7.

Operation, continued

4. Connect the air hose and microphone to the patient cable. Pay close attention to the microphone's connector and cable when attaching.

5. Wrap the cuff around the arm and secure. Use the wrist strap to secure the cables to the patient.

Figure 8:
Cables & Wrist Strap



Conducting the Stress Test

After your patient is properly prepared, take measurements by pressing **START/STOP** or using your stress system if properly interfaced (see "Compatible Stress Systems"). You can stop a measurement in process by pressing **START/STOP**.

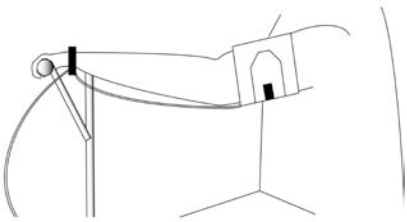
1. **Take 1–2 BP measurements with the patient seated or standing still.** With the patient sitting or standing still, take a measurement by pressing the **START/STOP** button or by using your stress system. As the measurement is being taken, you can estimate the patient's BP by watching the display of the cuff pressure and microphone signal. You should see K-sounds just as you would hear them if taking a manual BP with a stethoscope. Once you take a reliable measurement with *Cycle*, you can proceed with the stress test. If, after two attempts, you are unable to get an accurate measurement with the *Cycle*, see "Advice & Troubleshooting."

2. **Advise and support your patient to get accurate BP measurements during the stress test.** If a status code appears, consult the "Advice & Troubleshooting" section of this manual to get a valid measurement.

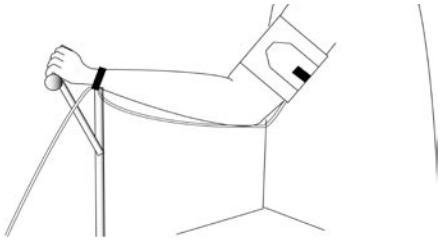
If there is significant noise as a measurement is being taken or if you are unable to get a reliable measurement, try the following:

- If the patient is holding onto the handlebars for support, advise the patient to lightly grip the bar. Alternatively, ask the patient to turn his/her hand over so that the palm is facing upward.
- Help your patient relax his/her arm when a measurement is taken (see Fig. 9)
- Instead of the patient gripping the bar for support, hold your patient's shoulder and forearm to support him/her during a measurement.

Figure 9: Limitations to Arm Movement During Stress Test



This is ***acceptable*** arm position during a BP reading. (Straightened Arm)



This is ***unacceptable*** arm position during a BP reading. (Bent Arm)

Operation, continued

Types of Measurement Readings

Cycle enables you to take measurement readings in the following ways:

- Manual measurement readings, where you press **Start/Stop** each time you want to take a reading.
- Interval measurements, where you specify a time interval at which *Cycle* takes the readings.
- Readings initiated by a connected stress system.

Setting Up Interval Measurements

You can configure *Cycle* to take readings at set intervals.

1. From Measurement view press **Menu**.
2. From the Menu - End Test screen, press **Menu** to continue to the Interval screen.
3. In the Interval screen, do one of the following:
   - To accept the current settings, press **Start/Stop**.
   - To set an interval, press **Advance** until the desired interval is displayed, and press **Start/Stop**. Pressing **Start/Stop** saves the settings and returns to the Measurement view.

Taking Interval Measurements

1. To start the interval reading, from Measurement view, press **Start/Stop**.
   Cycle takes the readings at the intervals you specified in the Interval screen.
   The Interval Timer counts up to the end of the interval, at which time the next measurement is started.
2. To stop the *reading* during an interval, press **Start/Stop**.
   This does not affect the Interval Timer; it continues to count up to the end of the interval as usual and a new reading will be started at the end of the interval.
3. To stop the *interval* measurement, press **Menu** to display the End Test screen, press **Advance** to select the checkmark, and press **Start/Stop** to save the setting and return to the Measurement view.

Taking Measurements via a Stress System

By connecting your stress system to the *Cycle* monitor the stress system can remotely request that measurements be taken. A stress system can initiate a request during interval measurements, although it is NOT recommended.

1. Connect the stress system's interface cable to the Connector Panel on the bottom of the *Cycle* monitor. (Visit www.SunTechMed.com to find interface notes online specific to your requirements.) Select your stress system from the System menu - Communication screen. The stress system can now remotely initiate BP measurements by the Cycle monitor.
2. To stop a measurement in progress, press the Stop option on the stress system.

   Note: You can also press the **Start/Stop** button on the Cycle monitor to end the measurement.

Resetting the Monitor

You can reset all monitor and system settings configured in the Menu and System modes to their default settings. Press **Menu** and **Advance** at the same time for at least 6 seconds. The long duration prevents accidental resets.

Note: The System Mode - Contrast screen appears 3 seconds after you press the Menu and Advance buttons. Continue to hold down both buttons. After 6 seconds the screen goes blank briefly to indicate that the monitor has been reset.

Using the Headphone Option

Use the headphone option to listen to the sounds that are picked up by the microphone in the cuff. These sounds are similar to those heard when taking a manual BP. Simply plug in the headphones to the phono jack on the *Cycle*. Use the cuff pressure displayed on the Measurement screen to approximate pressure.

Using the Pulse Oximetry, SpO_2 Option

Use the pulse oximetry option to measure the oxygen saturation of arterial blood. Simply plug in the sensor/module cable to the SpO_2 receptacle on the bottom panel of the *Cycle* and attach the sensor to your patient. After a few seconds, a measurement appears on the main measurement screen. The SpO_2 value is updated once per second. For a list of available sensors please see the Accessories and Consumables section. You can replace the sensor by unplugging it from the module and plugging in the new sensor.

CAUTION: Inspect the sensor application site at least every 6 to 8 hours to ensure correct sensor alignment and skin integrity. Patient sensitivity may vary due to medical status or skin condition. Discontinue use of adhesive tape strips if the patient exhibits an allergic reaction to the adhesive material.

Operation, continued

Preparing the Patient for Pulse Oximetry - Finger Application

Proper sensor placement is critical for good performance. If the sensor is not positioned properly, light may bypass the tissue and result in pulse oximetry inaccuracies.

CAUTION: Some nail polish colors (particularly dark shades) or artificial nails may reduce light transmissions and affect pulse oximetry accuracy. Remove any nail polish or artificial nails before using the sensors.

1. Insert a finger (preferably the index, middle, or ring finger) into the Adult Articulated Finger Clip (Figure 11) until the end of the finger reaches the finger stop. Keep the fingernail facing the sensor top (as shown in Figure 11). Ensure that long fingernails are not interfering with proper finger position.
2. For the best results when using the sensor for data collection, secure the sensor cable independently from the sensor with medical tape, preferably around the base of the fingers. Make sure that the tape securing the cable does not restrict the blood flow. The thumb is not recommended for use with the Adult Articulated Finger Clip Sensor.

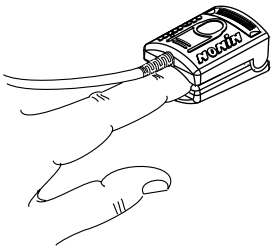


Figure 11: Finger clip sensor

Preparing the Patient for Pulse Oximetry - Ear Clip Application

Figure 12: Ear clip sensor

To Attach the Ear Clip Sensor:

1. Rub the ear lobe vigorously for at least 5 seconds.
2. Apply the Ear Clip Sensor to the lobe of the ear (Figure 12). Ensure that the Ear Clip Sensor is positioned so the light emitter and light detector are completely covered by the earlobe.

Note: If the sensor is not positioned properly, light may bypass the tissue and result in SpO_2 inaccuracies.

Proper sensor placement is critical for good performance.

Preparing the Patient for Pulse Oximetry - Forehead Application

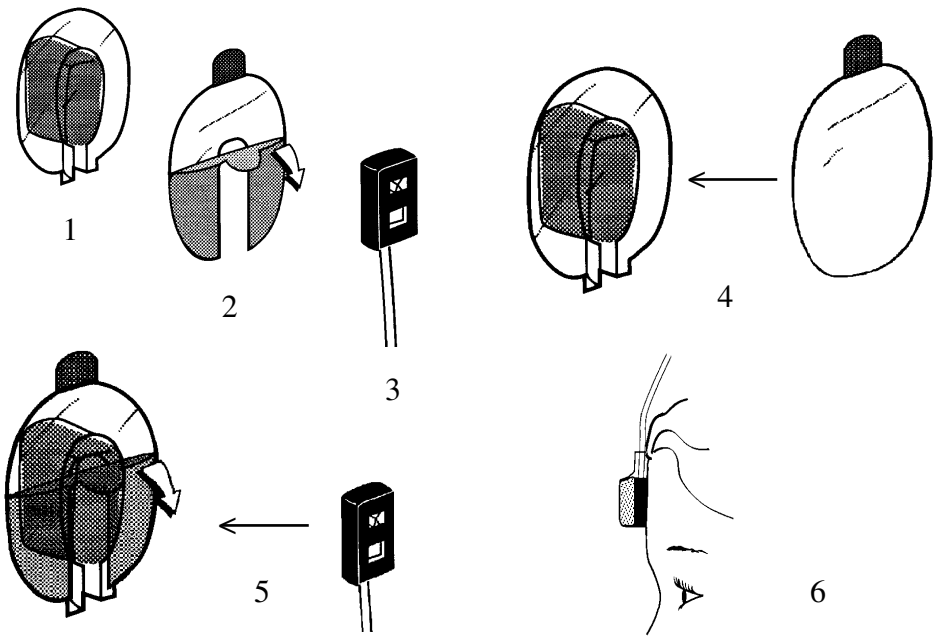
Designed for use on well-vascularized skin surfaces of patients weighing greater than 30 kilograms. The application site will usually be the forehead.

Note:
Reflectance Sensors generally do not perform as well as sensors located on the fingers or toes. They are not recommended for applications where the best possible SpO_2 accuracy is important.

To Attach the Reflectance Sensor:

1. Clean the patient's skin with an alcohol wipe before applying the Reflectance Sensor.
2. Remove the backing from one side of the double-back tape, and apply it to the flange of the Reflectance Sensor Holder (Figure 4).
3. Remove the backing from the other side of the tape.
4. Press the Reflectance Sensor into the foam with the sensor window facing out (Figure 5).
5. Attach the sensor holder and the sensor to the patient (Figure 6). Use additional medical tape to secure the sensor and the cable to the patient to avoid pulling or tipping the sensor.

Note: If the sensor is not positioned properly, light may bypass the tissue and result in SpO_2 inaccuracies. Proper sensor placement is critical for good performance.



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Advice and Troubleshooting

Quality and Status Messages

In some situations, *Cycle* may experience difficulties obtaining a BP measurement. In these cases, a status code and icon appear on the screen between the microphone signal and the time counter. In most cases, *Cycle* will be able to determine and display the blood pressure on the screen. You may use your judgement to verify the validity of this measurement. The status code provides you with an indication of the cause of the difficulty, and the table on the subsequent pages describes steps that you can take to eliminate or minimize the problem. If the *Cycle* displays a reading of 0/0 or --/--, then the monitor was unable to obtain a valid measurement. You can use the solutions in the table to correct the problem so a measurement can be obtained.

It may not be possible to reliably measure BP noninvasively due to different physiologies, such as large circumference arms and conditions such as the following:

- A blocked brachial artery
- An occluded subclavian artery
- Atrial fibrillation
- Ectopic heart beats
- Non-working grafts on dialysis patients
- Decrements in blood flow due to stroke or other condition

Getting BP results to appear on the stress system

1. Review the setup of the *Cycle* and stress system by going through the instructions listed for your model at the SunTech Web site: http://www.SunTechMed.com/. See the FAQ section for further details.
2. Start a test on the stress system and initiate a BP measurement. If the interface is set up correctly, measurements can be started from the stress system (see stress system's user manual) and also displayed on the screen of the stress system.

NOTE: For some stress systems, BPs accompanied by status codes will not be displayed on the stress system. In addition, some measurements may take longer than 50–60 seconds, and some stress systems may report this as faulty communication with *Cycle*. In either of these cases, type in the BP that is displayed on *Cycle* if it is a valid measurement.

Status codes and solutions

Status code	Description	Solution
1	Weak or missing K-sounds.	If the patient is static or still: 1. Check HR is within 10 beats of stress system's displayed HR. 2. Take another BP and watch for K-sounds. 3. Reposition cuff so that the mic is over the brachial artery and try again. 4. Reconnect the patient cable to the cuff and microphone and try again. 5. If possible, place the cuff on the opposite arm and try again. 6. Check that the microphone is flat (not bent) and undamaged. 7. Replace the microphone. If the patient is exercising: 1. Check HR is within 10 beats of the stress system's displayed HR. 2. Take another BP and watch for K-sounds. 3. Advise patients to relax arms (if their hand is gripping a bar for support), turn the hand over so that the back of the hand is leaning over the bar for support, or drop the arm by the side as you support them by holding the shoulder and forearm, and take another measurement.
2	Arm movement or noise.	If the patient is static or still: 1. Reposition the cuff so that the mic is over the brachial artery and try again. 2. Reconnect the patient cable to the cuff and microphone and try again. 3. If possible, place the cuff on the opposite arm and try again. If the patient is exercising: 1. Ensure the patient is not moving their upper body excessively. 2. Advise patients to relax arms (if their hand is gripping a bar for support), turn the hand over so that the back of the hand is leaning over the bar for support, or drop the arm by the side as you support them by holding the shoulder and forearm. and take another measurement. 3. Instruct your patient to drop his arm by his side while a BP reading is in progress (avoid excessive bending of the arm).

Advice and Troubleshooting, continued

Status code	Description	Solution
3	Irregular pulse or noise.	If the patient is static or still: 1. Reposition the cuff so that the mic is over the brachial artery and try again. 2. Reconnect the patient cable to the cuff and microphone and try again. 3. If possible, place the cuff on the opposite arm and try again. If the patient is exercising: 1. Ensure the patient is not moving their upper body excessively. 2. Advise patients to relax arms (if their hand is gripping a bar for support), turn the hand over so that the back of the hand is leaning over the bar for support, or drop the arm by the side as you support them by holding the shoulder and forearm. and take another measurement. 3. Instruct your patient to drop his arm by his side while a BP reading is in progress (avoid excessive bending of the arm).
4	Projected systolic value. The systolic value reported is very close to the maximum pressure to which the cuff was inflated.	1. Check that the max pressure is set high enough. 2. If there are doubts about the systolic BP, take another measurement. The monitor will inflate the cuff to the maximum pressure (set in the Menu Mode - Max Pressure screen) for the next reading.
5	Air leak. The monitor will terminate a BP reading if the target inflation is not reached in 60 seconds.	1. Check that the patient cable is properly connected to the monitor and cuff. 2. Readjust or tighten the cuff to fit properly around the patient's arm. 3. Check that the cuff or patient cable is not leaking on inflation.
6	Cuff overpressure. The monitor will terminate a BP reading if the air hose or BP cuff has reached an unreasonably high pressure.	1. Check that the patient cable is not being pinched or blocked. 2. Instruct your patient to drop his arm by his side while a BP reading is in progress (avoid excessive bending of the arm).
7	Internal measurement delayed. Measurement was delayed to give the arm time to re-vascularize.	1. Scheduled automatic reading was not taken because the minimum time between automatic readings had not elapsed. The next reading will be taken as scheduled. 2. If this status occurs frequently, increase the measurement interval (set in the Menu Mode - Interval Screen).

Status code	Description	Solution
8	Deflation too slow.	If using 3mmHg/sec deflate, switch to AUTO.
9	Restricted flow status.	1. Instruct patient not to bend arm until deflation is complete. 2. Contact the SunTech Service Dept. or an authorized service agent, if this status code occurs repeatedly.
10	Projected diastolic value.	If there are doubts about the diastolic BP take another measurement.
20	BP measurement error.	1. Repeat the measurement. 2. Contact the SunTech Service Dept. or an authorized service agent, if this status code occurs repeatedly.
100	BP hardware error.	1. Repeat the measurement. 2. Contact the SunTech Service Dept. or an authorized service agent, if this status code occurs repeatedly.
Any 5-Digit Code	System Error.	1. Press MENU button to clear. Press ADVANCE button to mute the alarm. 2. Contact the SunTech Service Dept. or an authorized service agent, if this status code occurs repeatedly.

System Errors

A System Error (any 5-digit status code) indicates a possible problem with the monitor's hardware or software. When this error occurs, the alarm will sound continuously. This alarm can be muted by pressing the Advance button. Pressing the Menu button will clear the alarm, and the monitor will rerun its internal tests. If the error occurs repeatedly, please contact the SunTech Service Department or an authorized service agent.

To test the System Error alarm function, press the Start/Stop key when you connect power to the monitor. System Error "11111" should appear on the screen and the alarm should sound. Pressing the Advance button will mute the alarm. Pressing the Menu button will end the test; the monitor will complete its power-up sequence and display the Measurement view.

Note: If System Error code "12054" occurs, the monitor will reset all user parameters to their factory default values when clearing the problem. These defaults are: Interval = Manual; Max Pressure = 275 mmHg; Contrast = 5; Communication = Custom (protocol = SunTech); Deflate Rate = Auto.

Advice and Troubleshooting, continued

EMC Statement

This equipment has been tested and found to comply with the limits for medical devices to IEC60601-1-2: 2001. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. This equipment should not be used adjacent to or stacked with other equipment. If adjacent or stacked is necessary, this equipment should be observed to verify normal operation in the configuration in which it will be used. However, even if used properly, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving device.
- Increase the separation between the equipment.
- Connect the equipment into an outlet on a circuit different from that to which the other device(s) are connected.
- Consult the manufacturer or field service technician for help.

Use only SunTech-approved cables and accessories with this monitor. Use of unauthorized cables or accessories may result in increased emissions or decreased immunity. Portable and mobile RF communications equipment can affect Medical Electrical Equipment.

<table>
<tr><th colspan="3">Guidance and manufacturer's declaration – electromagnetic emissions</th></tr>
<tr><td colspan="3">The Cycle BP Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the Cycle BP Monitor should assure that it is used in such an environment.</td></tr>
<tr><th>Emissions test</th><th>Compliance</th><th>Electromagnetic environment – guidance</th></tr>
<tr><td>RF emissions
CISPR 11</td><td>Group 1</td><td>The Cycle BP Monitor uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</td></tr>
<tr><td>RF emissions
CISPR 11</td><td>Class B</td><td rowspan="3">The Cycle BP Monitor is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td></tr>
<tr><td>Harmonic emissions
IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuations/
flicker emissions IEC
61000-3-3</td><td>Complies</td></tr>
</table>

Guidance and manufacturer's declaration – electromagnetic immunity			
The Cycle BP Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the Cycle BP Monitor should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Cycle BP Monitor requires continued operation during power mains interruptions, it is recommended that the Cycle BP Monitor be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

In the event of power loss to the monitor, all user settings are saved. The monitor will power-up with the same settings as prior to the power loss.

Advice and Troubleshooting, continued

Guidance and manufacturer's declaration—electromagnetic immunity

The Cycle BP Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the Cycle BP Monitor should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the Cycle BP Monitor, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	$d = [\frac{3.5}{V_1}] \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = [\frac{3.5}{E_1}] \sqrt{P}$ 80 MHz to 800 MHz $d = [\frac{7}{E_1}] \sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1—At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2—These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Cycle BP Monitor is used exceeds the applicable RF compliance level above, the Cycle BP Monitor should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Cycle BP Monitor.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the Cycle BP Monitor

The Cycle BP Monitor is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Cycle BP Monitor can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Cycle BP Monitor as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = [\frac{3.5}{V_1}]\sqrt{P}$	**80 MHz to 800 MHz** $d = [\frac{3.5}{E_1}]\sqrt{P}$	**800 MHz to 2.5 GHz** $d = [\frac{7}{E_1}]\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1—At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2—These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Advice and Troubleshooting, continued

Frequently Asked Questions (FAQs)

Q. How do I set up the *Cycle* monitor to work with my stress system?
A. Choose your system from the list. See "Compatible Stress Systems." Set the communication protocol in the System Menu - Communication screen. If your stress system is not listed use the Custom setting or please contact SunTech Medical.

Q. The *Cycle* displays a status message. What does it mean, and what do I do?
A. See the "Advice & Troubleshooting" section for details on the status message and solution.

Q. How do I clean the cuff after a stress test?
A. You can do any of the following:

- Remove the bladder and microphone from the cuff and machine wash the cuff.
- Remove the microphone, connect a cuff plug (part #97-0021-00) to the bladder connector and machine wash the cuff and bladder together.
- Use a medical grade disinfectant such as Cidex on the cuff.

Then Air dry.

Q. The *Cycle* monitor returns results of 0/0 or --/-- after blood pressure measurements. What do I need to do to get a BP reading?
A. Similar to taking BP measurements on a patient manually with a stethoscope and sphygmomanometer, there are certain noisy conditions where the *Cycle* cannot accurately measure blood pressure. When the *Cycle* encounters these situations, it returns a reading of 0/0 or --/--. Follow steps 1 and 2 in Conducting the Stress Test to provide the best conditions to obtain a measurement. If a status message is displayed, see the “Advice and Troubleshooting” section for details on correcting any problems.

Q. I cannot clearly see the *Cycle* display. How do I fix this?
A. By adjusting the contrast, which you can adjust the contrast from the System Menu--Contrast screen.

Preventative Maintenance

The monitor performs system and software checks during normal operation. If there are any problems, a status code appears in place of the measurement screen. Pressing the Menu button allows the monitor to attempt to clear the error. If the error recurs, contact SunTech Medical.

Inspect cables and pneumatic hoses for cracks, fraying or kinks and the microphone for signs of bending. DO NOT use the power supply or monitor if there are any signs of damage.

The monitor does not contain any user serviceable parts and should only be opened by an authorized service representative. DO NOT remove covers or break the warranty seal as this will void the manufacturer's warranty.

Pulse Oximeter

CAUTIONS: Do not immerse the sensor in liquid. Do not use caustic or abrasive cleaning agents on the sensors.

Calibrating the Monitor

It is recommended that the monitor's calibration be checked annually. Use the Calibration Check screen in the System menu. Connect your calibrated reference manometer with a bulb to the pneumatic connector using a T-connector, *SunTech* part # 98-0030-00.

Verify that the Cuff Pressure on the Display is within ±2 mmHg of the pressure value on your calibrated reference manometer through a range of pressures from 0–250 mmHg. If not, contact *SunTech* about calibration.

Cleaning the Monitor

Before cleaning, disconnect the power supply from the monitor. The monitor is not sterilizable. DO NOT immerse the monitor in any fluid or attempt to clean with any liquid detergents, cleaning agents, or solvents. Remove dirt and dust from the monitor by wiping with a soft, damp cloth.

Cleaning the Cuffs

Use a medical grade disinfectant on the cuff sleeve and inside of the cuff between patients. Periodically, remove the bladder and microphone, machine wash the shell of the cuff in cold water and line dry.

Cleaning the SpO_2 Sensors

Finger Clip

Clean the sensor with a soft cloth dampened with a mild detergent or isopropyl alcohol. Ensure that all tape residues are removed. Do not pour or spray any liquids onto the sensor. Allow the sensor to dry thoroughly before reusing. Do not open the case of the adult finger clip sensor more than 90° or the case may be damaged. Figure 13 shows the appropriate opening of the case for cleaning.

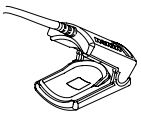

Figure13: Opening finger clip sensor

Ear Clip

Clean the sensor with a soft cloth dampened with a mild detergent or isopropyl alcohol. Ensure that all tape residue is removed. Do not pour or spray any liquids onto the sensor. Allow the sensor to dry thoroughly before reusing. Do not immerse the sensors in liquid. Do not use caustic or abrasive cleaning agents on the sensors.

Forehead

Clean the sensor with a soft cloth dampened with a mild detergent or isopropyl alcohol. Ensure that all tape residue is removed. Do not pour or spray any liquids onto the sensor. Allow the sensor to dry thoroughly before reusing. Do not immerse the sensors in liquid. Do not use caustic or abrasive cleaning agents on the sensors.

Maintenance and Cleaning, continued

Disposal

This symbol indicates the monitor contains materials (such as electrical components) which are hazardous. Please return to SunTech Medical for disposal.

For service inquiries, please contact:

SunTech Medical, Inc.
507 Airport Boulevard, Suite 117
Morrisville, NC 27560 USA
USA
Tel: (1) 919 654-2300
Fax (1) 919 654-2301

or

SunTech Medical, Ltd.
Oakfield Industrial Estate
Stanton Harcourt Road
Eynsham, Oxfordshire OX29 4TS England
Tel: (44) 1865 884234
Fax: (44) 1865 884235

Accessories and Consumables

Part #	Description	Special Instructions
19-0012-00	Power Supply	
91-0086-00	Patient Cable, 3m	
91-0086-01	Patient Cable, 2m	
98-0006-00	K-sound Microphone, 14	For Small Adult, Adult, and Adult Plus Cuffs
98-0006-01	K-sound Microphone, 18	For Large Adult Cuffs
98-0062-01	Orbit-K Small Adult Cuff	Includes microphone. Range: 18–27 cm
98-0062-02	Orbit-K Adult Cuff	Includes microphone. Range: 25–35 cm
98-0062-05	Orbit-K Adult Plus Cuff	Includes microphone. Range: 27–40 cm
98-0062-03	Orbit-K Large Adult Cuff	Includes microphone. Range: 32–44 cm
98-0008-00	Pole/Rail Clamp & Screws	
98-0083-01	Headphone Upgrade	Requires monitor be sent to SunTech for upgrade
98-0003-00	Wrist Strap	
98-0030-00	T-tube kit	For calibration check
80-0035-00	Cycle User's Manual	English
80-0036-00	Cycle Service Manual	English
27-0071-A1	Cycle CD	Includes translated manuals
98-0087-00	Xpod® SpO_2 kit, Adult Finger Clip	Includes Xpod® and Adult Finger Clip Sensor
98-0087-01	Xpod® SpO_2 kit, Ear clip	Includes Xpod® and Ear Clip Sensor
98-0087-02	Xpod® SpO_2 kit, Reflectance	Includes Xpod® and Reflectance Sensor
91-0087-05	Xpod® pulse oximeter	
52-0003-00	Purelight® Adult Finger Clip Sensor	
52-0002-00	Purelight® Ear Clip Sensor	
52-0001-00	Purelight® Reflectance Sensor	
44-0011-00	Reflectance Sensor Holders	
99-0027-11	Additional One-year Warranty	Extended Warranty – 1 year
99-0027-12	Second-Year Added Warranty	Extended Warranty – 1 year
99-0027-13	Third-Year Added Warranty	Extended Warranty – 1 year
99-0027-14	Three Year Extended Warranty	Extended Warranty - 3 years (purchased at one time)

Accessories and Consumables, continued

RS232 Interface Cables

Stress system	RS-232
Burdick Quest	91-0013-00
Cambridge Heart CH2000 (v2.0.3 and up)	91-0065-00
Esaote Formula	91-0048-00
Marquette Case 12 or 15	91-0012-00
Marquette Case 16	91-0013-00
Marquette Centra	91-0012-00/91-0013-00
Marquette Case 8000	91-0013-00
GE-Marquette Case	91-0013-00
Marquette/Sensormedics Max 1	91-0010-00
Marquette Mac-VU-Stress	91-0010-00
Marquette-Hellige CardioSys	91-0013-00
Marquette MAC 5000	91-0010-00
Mortara X-Scribe II	91-0013-00
Nasiff Associates Cardio-Card	91-0013-00
Nihon-Koden Cardiofax ECG-9320	91-0061-00
PBI QRS Card / Oxford Medilog Stress	91-0013-00
Philips Stress Vue	91-0013-00
Quinton Q4500	91-0019-00
Quinton Q5000	91-0020-00
Quinton Q Stress	91-0013-00
Reynolds CardioDirect 12-S	91-0013-00
Schiller AT10, AT60 or CS-200	91-0035-00
Welch Allyn CardioPerfect Workstation	91-0013-00

Specifications

Blood Pressure Measurement:	Auscultatory for use during all static and active phases of the ergometric stress test. **The device is designed to function in the presence of a normal ECG sinus rhythm.** Diastolic pressures correlate to K-5 Korotkoff sound.
Range:	Pressure: Dia: 20–150 mmHg Sys: 50–250 mmH Heart Rate: 40 – 200 BPM (beats per minute)
Accuracy:	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.
Pulse Oximetry Accuracy:	70–100% ± 2 digits (± 1 Standard Deviation)
Conditions for Use:	Operating, 10°C (50°F) to 40°C (104°F), less than 95% RH non-condensing. Storage, -20°C (-4°F) to 50°C (122°F), less than 95% RH non-condensing. The system might not meet its performance specifications if used or stored outside the specified temperature and humidity ranges listed above.
Power:	External power supply, use only SunTech part number 19-0012-00. Input: 100-240 VAC @ 50-60 Hz. Output : 9VDC @ 5A IEC 320 type input connector.
Calibration:	Verify the accuracy of cuff-pressure transducers/indicators annually.
Safety Systems:	Independent hardware over-pressure circuit and redundant software overpressure algorithm to limit cuff pressure to less than 300 mmHg (+20/-10 mmHg). Independent hardware timing circuit and redundant software timer algorithm to limit the duration of a blood pressure cycle to less than 180 seconds.
Dimensions:	Width = 4.8 inches Depth = 6.0 inches Height (front) = 1.6 inches, Height (rear) = 2.5 inches
Standards:	UL60601-1, CAN/CSA C22.2 601-1 IEC 60601-1, IEC 60601-1-2 (EMC), IEC 60601-1-4, IEC 60601-2-30, IEC60601-2-49, ISO 9919 Meets “Non-Invasive Sphygmomanometers - General Requirements & Supplementary Requirements For Electro-Mechanical BP Measuring Systems” EN 1060-1, EN 1060-3
Classification:	Equipment Classification: Class II; Mode of Operation: Continuous.
Warranty:	2 year standard warranty

Cycle BP Monitor

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

All serialized monitors	24 months
Orbit-K BP Cuff(s)	6 months
Accessories, i.e. patient cables, disposables	90 days

SunTech Medical, Inc. warrants each instrument to be free from defects in material and workmanship. Liability under this warranty covers servicing of the instrument when returned from the customer's facility within the United States prepaid to the factory. SunTech Medical, Inc. 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 first notify SunTech Medical, Inc. of the suspected defect. The instrument should be carefully packaged and shipped prepaid to:

SunTech Medical, Inc.
Service Department
507 Airport Boulevard, Suite 117
Morrisville, NC 27560 USA
Tel: 919.654.2300
Fax: 919.654.2301

Or

SunTech Medical, Ltd.
Service Department
Oakfield Industrial Estate
Stanton Harcourt Road
Eynsham, Oxfordshire OX29 4TS
England
Tel: +44 (0) 1865 884 234
Fax: + 44 (0) 1865 884 235

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, Inc.

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