Vital Signs Monitors

Operations Manual

Software Version 5.13 or above

L I F E S Y S T E M S

7320 CENTRAL AVENUE
SAVANNAH, GA 31406
800-841-1109
www.LifeSystemsonline.com

Foreword

Life Systems Inc. would like to thank you for your purchase of the Rosie series vital signs monitor.

Please read this manual carefully before using the monitor. Familiarize yourself with the features, methods of use, cautions and warnings, as well as any limitations of the monitor. This manual should be kept in a safe, convenient place for future reference.

This manual describes and supports all of the monitors in the Rosie series by discussing the fully configured model that includes NIBP, Pulse, Pulse Oximetry, Temperature, and printer. It may, therefore, present information that does not apply to your unit. The front and rear panel designs and connection ports may vary according to the parameters that have been built into your monitor.

 Life Systems Inc. maintains the right to modify the contents of this manual without prior notice. If you have any questions about the information presented in this manual or about other Life Systems products, please contact us at:

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1 Introduction

1.1 Purpose of Manual

This manual describes and supports all of the monitors in the Rosie II series by discussing the fully configured model that includes NIBP, Pulse, Pulse Oximetry, Temperature and a printer. It may, therefore, present information that does not apply to your unit(s). The front and rear panel designs and connection ports will vary according to the parameters that have been built into your monitor(s).

1.2 General Description

The Rosie II monitor is a portable, adult, pediatric and neonatal vital signs monitor. It non-invasively and automatically measures, systolic, mean and diastolic blood pressures, pulse rate, oxygen saturation (SpO_2), and temperature depending on the parameters incorporated into the specific model.

> Please Note: The Rosie monitor is designed for Single Patient Use only. Do not attempt to place the sensors on multiple patents, simultaneously.

The monitor incorporates large colored LEDs to display all current parameters, with each parameter having its own unique color to increase readability. A large LCD screen displays historical information, and is used to set up the operation of the unit. The monitor uses Colin's dynamic linear deflation blood pressure technology, and features a full array of alarm settings for each displayed parameter. Its memory holds up to 400 lines of information that can be viewed or printed in several print formats.

The monitor has been designed to operate on AC power (properly grounded hospital-grade outlet) or on a 6-volt internal battery.

The Rosie series offers several parameter combinations:

Model	Configuration
Rosie II-1	NIBP only
Rosie II-1P	NIBP with Printer
Rosie II-2	NIBP + Nellcor Pulse Oximetry
Rosie II-2P	NIBP + Nellcor Pulse Oximetry with Printer
Rosie II-3	NIBP + E-Temp
Rosie II-3P	NIBP + E-Temp with Printer
Rosie II-4	NIBP + Nellcor SpO_2 + E-Temp
Rosie II-4P	NIBP + Nellcor SpO_2 + E-Temp + Printer

1.3 Warranty

LIFE SYSTEMS INC. is committed to distributing the highest quality products by manufacturing devices that are equipped with unsurpassed speed, accuracy, reliability, quality, and comfort**.**

Every Rosie monitor purchased through Life Systems Inc. includes our "Gold-Standard" warranty. The monitor is warranted to be free from defects in material and workmanship for a period of three (5) years. The pulse oximeter, electronic predictive thermometer and printer, when purchased with the Rosie, are warranted for a period of three (3) years. Accessories and the rechargeable battery are warranted for a

period of ninety (90) days from date of purchase. If an extended warranty was purchased at time of sale, it will cover only the Life System components, not the pulse oximeter, electronic predictive thermometer or printer

1.4 Exclusions

This warranty does not extend to any warranted products (or parts thereof) that have been subject to misuse, neglect or accident; that have been damaged by causes external to the Warranty, including but not limited to failure of or faulty electrical power; that have been in violation of Life System's instructions; that have been affixed to any nonstandard accessory attachment; on which the serial number has been removed or made illegible; or that have been modified or improperly disassembled, serviced or reassembled by anyone other than Life System's, unless authorized by Life Systems.
Life Systems makes no warranty (a) with respect to any disposable products that are not warranted products, (b) with respect to any product purchased from a person other than Life Systems or a Life Systems Authorized distributor, or (c) with any respect to any product sold under a brand name other than Life Systems.

Life Systems will not be responsible for the effect of safety, reliability, and or performance of the product if: (a) assembly operations, extension, readjustments, modifications, or repairs are carried out by persons other than Life Systems or persons authorized by Life Systems to perform repair service on Life System's behalf; or (b) the electrical installation does not comply with the requirements of the applicable national and international standards, including requirements of the IEC; or (c) the Product is not used in accordance with Life System's instruction for use.

In the event of a defect in the product, Life Systems will be liable for injury or death of any actual person, or damage to property, to the extent, but only to the extent, that such liability is mandated under laws applicable to manufacturers in general and to manufacturers of the product category to which the product belongs.

1.5 Service Limitations

Maintenance and repair services performed by user personnel on the equipment covered in this manual apply only to products that are out of warranty. All warranty repairs should be performed only by qualified service technicians authorized by Life Systems. A comprehensive technical service manual for the Rosie containing specific information about operation, calibration, parts listing, and schematics can be obtained by contacting Life Systems Technical Service Department .

1.6 Returning the Unit

Prior to returning a unit for any reason, please:
Call Technical Services at 1(800) 841-1109 Ext. 105, for the most efficient and effective troubleshooting, you will need to have the unit in front of you and be knowledgeable of the problem in the unit is experiencing. If it is determined that the unit needs servicing, a Return Authorization (RA) number will be assigned and the Life Systems technician will instruct you on how to return the unit. * Life Systems *will not accept any package without a valid RA#*

1) Contact Technical Services ALWAYS
2) Send Back once Technical Services issues RA#

Ship to: Life Systems Inc
7320 Central Ave
Savannah, Ga. 31406

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Write "Attn: RA Number_____" (the number provided when you called) on the address label.

1.7 Shipping Procedures

Products shipped by Purchaser under this warranty shall be suitably packaged to protect the product. If Purchaser ships a product to Life Systems in unsuitable packaging, any physical damage present in the product on receipt by Life Systems (and not previously reported) will be presumed to have occurred in transit and will be the responsibility of the purchaser.

1.8 CSA & UL Recognition

This device has been certified by the Canadian Standards Association to comply with IEC 60601-1 with Amendments 1&2, IEC 60601-2-30, CSA C22.2 No 601.1-M90, CSA C22.2 No. 601.1S1-94 and UL Std. No. 2601-1 (2^{nd} edition) with accordance to Canadian and US standards. The CSA listing master contract number for this product is 216146.

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2 Physical Description

2.1 General Safety Information

Rosie II monitors should be operated in a location that is free from liquids (spillage), flammable chemicals or gases, vibration, shock (even during the transportation of the unit), and temperature, ventilation and humidity extremes. To avoid a possible accident, place the unit on a firm, flat base or mount it securely to a heavy-duty stand. Do not place items on top of the monitor and keep the cooling path free from obstructions while operating. Clean it with a soft damp cloth as directed in section 9.2; do not use solvents or other harsh chemicals. Do not autoclave. Refer to the Sec. 2.3 for other Warnings, Cautions and Important Information.

2.2 General Operating Precautions

- Arrange the power cord and cuff hose so that they do not create a hazard and are not moved during operation.
- Always follow approved technique when using each parameter. Refer to the section(s) in this manual pertaining to the parameter(s) included in your monitor.
- Always press front panel switches with a fingertip; not a fingernail or other pointed objects.

2.3 Warnings and Cautions of Use

Safety Symbols and Terms for Safety

Throughout this manual and on the actual products, safety symbols and terms are shown for safe and proper use of the products. The meanings of these symbols are shown below. Please familiarize yourself with these symbols before proceeding with this manual.

DANGER **DANGER** indicates an imminently hazardous situation which, if not avoided, may result in serious injury or death.

WARNING **WARNING** indicates a potentially hazardous situation which, if not avoided, may result in serious injury or death.

CAUTION **CAUTION** indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury.

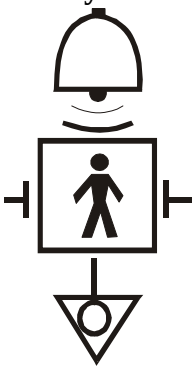
NOTE **NOTE** presents helpful information about the operation of the unit.

△ Indicates a warning, defined or described by its contents. Specific information or cautions are included within or nearby the symbol. In this case the symbol warns of the possibility of electrical shock.

⊘ Indicates a prohibited behavior. Specific instructions are included within or nearby the symbol, in this case, prohibiting disassembly.

● Indicates necessary action or gives instructional information. Specific instructions are included within or nearby the symbol, in this case, pulling the power cord by its connector.

Other Symbols



This mark indicates that an alarm is sounded. Once the alarm sounds, appropriate actions must be taken.

This mark indicates that these components meet Type BF electrical safety requirements for Difibrillation Proof applied parts.

This mark indicates the potential equalization terminal.

DANGER:

DO NOT USE THE ROSIE II MONITOR IN THE PRESENCE OF A FLAMMABLE ANESTHETIC MIXTURE WITH AIR OR WITH OXYGEN OR NITROUS OXIDE.

WARNING:

Only operate the equipment at the rated voltages and frequencies.

To ensure proper grounding, connect the monitor only to a properly grounded 3-wire hospital-grade receptacle. Do not use extension cords.

If any doubt exists as to the grounding connection, do not operate the unit from the AC power source; the monitor must be operated on the internal battery power.

Servicing other than that described in the Operation Manual should be performed by qualified service personnel only.

Accessory equipment connected to the analog and digital interfaces must be certified according to the respective IEC standards.

Do not modify this device without appropriate authorization.

This device can be damaged by energy discharged from a defibrillator. Please disconnect the SpO_2 and temperature probes from the monitor before defibrillator discharge.

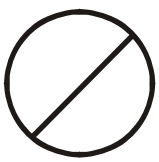
All wire-lead patient-connected transducer assemblies are subject to reading error, local heating, and possible damage from high-intensity sources or RF energy. Electro-surgical equipment's capacitively-coupled currents may seek alternate paths to ground through probe cables and associated instruments; patient burns may result. If possible, remove the probes from patient contact before activating the surgical unit or other RF source. Hazards can be reduced by selecting a temperature monitoring point which is remote from the expected RF current path to ground return pad. Appropriate probe selection and application must be determined then applied in the applicable manner.

Do not operate a cellular phone and/or radio trans-receiver in the presence of this monitor.

Only authorized personnel should attempt the operation of this unit.

Use only authorized accessories and options.

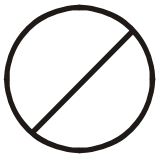
Read the Operation Manual before using this device.



Do not use this monitor in the presence of an MRI.

Inspect the monitor for safe operation before use.

WARNING:



Do not place items on top of the monitor.

Do not place heavy materials or this device on the AC power cord.

Do not connect the monitor to devices that do not meet medical safety standards.

Do not open the cover or disassemble.

If the monitor fails for any reason, turn OFF and unplug the AC cord.
Failures may include smoke or odor emission.

- Dropped units should be considered “failed” until they have been checked for proper operation.
- Units into which liquids have seeped should be considered “failed” until thoroughly dry and they have been checked for proper operation.

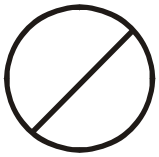
If the monitor fails as mentioned above:

1. Confirm that the AC plug is unplugged. (Do not pull on the cord. Unplug by holding and pulling the plug.)
2. Disconnect the monitor from the patient.
3. Place a "Do not use - Out of Order" sign onto the front of the monitor.
4. Contact the appropriate personnel according to your facility’s procedures or instructions.

CAUTION:

The unit should be installed in a location that provides:

- A level and stable surface for the unit to sit on.
- Space required for adequate airflow.
- Ambient temperature between 0-40 degrees Centigrade (32-104°F) and a humidity less than 75%.
- Appropriate grounding for the unit. If the AC wall plug does not supply ample ground potential, connect a grounding strap to the potential equalization conductor on the back of the unit, then to an appropriate ground.



The following locations are not suitable for installing the unit:

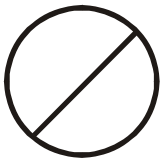
- Where direct sunlight is on the unit for an extended period of time. (Deterioration of the liquid crystal display will occur)
- Where the unit may be splashed with liquids.
- Where extreme shock and vibrations may damage the unit.
- Where gas and fire may be present.
- Where ambient temperature is below -10°C (14°F) or the humidity exceeds 95%.

If condensation is present on the unit, disconnect the monitor from AC power and dry the unit with a cloth. Condensation could lead to electric shock and other mechanical problems with the monitor.

Do not use a ball point pen or other sharp objects to push the switches. This could lead to mechanical problems.

WARNINGS and CAUTIONS During NIBP Monitoring: [redacted]

If the NIBP measurement is unsuccessful, or when there are doubts about the measurement values, assess the patient's condition immediately. Their condition may have deteriorated to the point where measurement limits are exceeded. Always verify that the cuff and cuff hoses are applied and/or attached appropriately and are not bent or blocked. If the display shows 0, the monitor's pressure may be 0 but if the cuff hose is blocked or bent there may be air remaining in the cuff. At this time, disconnect the hose from the cuff to ensure that blood flow is not restricted.



Do not apply the cuff to the same arm where IV or blood transfusions are being conducted.

Measurements are not possible for patients:

- With insufficient peripheral circulation, acute cases of low blood pressure, or low temperature.
- With a high frequency of arrhythmia.
- Using cardio/pulmonary pumps.

Accurate measurements may not be possible:

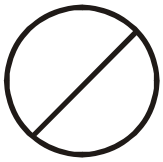
- When heart massage is conducted, when there are continuous external vibrations (CPR), or motion artifact due to patient movement.
- When improper cuff sizes are used.
- When the cuff position is above or below the heart level by 10 cm or more.
- When the patient moves or talks during a measurement.
- When the cuff is placed over thick clothing.
- When a rolled up sleeve is adding pressure on the arm.

Cuff placement and positioning should be checked at least every 8 hours for patients being continuously monitored. If any abnormality is found (such as redness or bruising of the skin), or if the cuff is poorly positioned, the cuff positioning and placement should be changed. If the cuff positioning is not changed, inflammation due to perspiration or internal hemorrhaging may occur.

WARNINGS and CAUTIONS During SpO_2 Monitoring:

If SpO_2 measurements do not register or when there are doubts about those measurements, please assess the patient's condition immediately. The patient's condition may have deteriorated to the point where measurement limits have been exceeded.

Applicable patient weight and measurement locations should be observed for each OxiMax® sensor. When the manufacturer's instructions are not observed, measurement errors could occur.



Do not use sensors with defective or damaged wire covering. This could lead to patient harm.

Avoid applying the sensor too tightly. Also, do not secure the sensor with tape. This could diminish blood flow and/or cause edema.

Reusable sensors have a limited useful life and using an old sensor may cause measurement errors. If the measurement values of an older sensor seem lower than a patient's conditions warrant, replace the sensor.

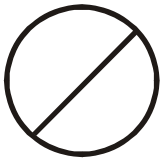
Measurements are not possible in the following cases:
- Insufficient peripheral circulation, acute cases of low blood pressure, and/or low temperature.
- When the patient is on a cardio/pulmonary pump.
- If the sensor is placed on the same limb as the NIBP cuff.

Accurate measurements may not be possible in the following cases:
- When heart massage is conducted or when there are weak continuous external vibrations (spasms, CPR, and/or venous pulsation).
- When the selection and application of an OxiMax sensor is not correct.
- Patients with carbon monoxide poisoning or who are heavy smokers (it is impossible to determine differences of functional disorder hemoglobin such as monoxide hemoglobin and metho-hemoglobin).
- When there are excessive reagent color elements within the arteries (indo-cyanine green, methylene blue, as well as others).
- Under the strong light of a surgical lamp or direct sunlight.
- When the patient is wearing black or bright red fingernail polish.

The unit may display meaningless measurement values when the sensor is not properly placed on the finger and/or when there are lighting changes at the light sensor section of the sensor.

Measurement sites should be checked at least every 2-3 hours and 8 hours respectively for Reusable and Disposable OxiMax sensors. If any abnormality is found, the measurement site must be changed. Without changing the site, inflammation and low temperature burns may occur.

WARNINGS and CAUTIONS During Temperature Monitoring:

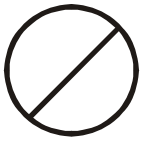


Do not use temperature probes with damaged wire coverings. Their use may lead to patient harm.

Use only IVAC® P850 Probe Covers for the E-Temp thermometer. The size, shape, and thermal characteristics of the probe cover can affect the temperature reading.

WARNINGS and CAUTIONS During Cleaning:

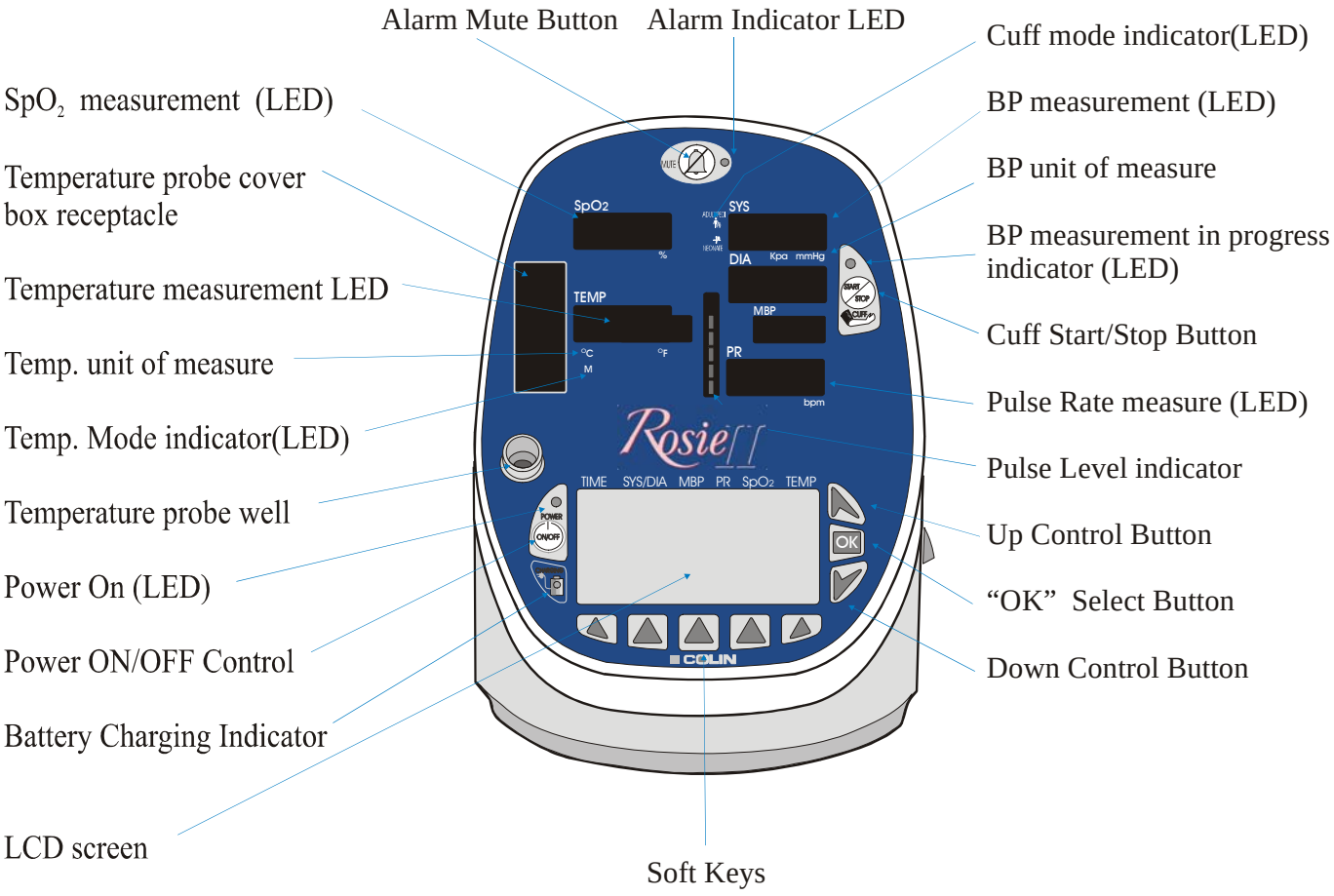
Always disconnect the monitor from the AC power source before cleaning the monitor with a wet or damp cloth.



Avoid using any solvents like thinners or benzene, as cleaning with these agents may cause damage to the monitor's exterior. See section 9.3 for cleaning instructions.

2.4 Front Panel Callouts:

This manual describes and supports all of the monitors in the Rosie series by discussing the fully configured model (2240P), which includes NIBP, Pulse, Pulse Oximetry, Temperature and Printer. It may, therefore, present information that does not apply to your unit. The front and rear panel designs and connection ports vary according to the parameters that have been built into your monitor.



2.5 Front Panel Description (clockwise from upper right):

Cuff Mode Indicator- A yellow LED light indicates the mode of operation for the NIBP parameter Adult/Pediatric, or Neonatal.

BP Measurement - Large YELLOW LED numbers show the current Systolic, Diastolic, and Mean blood pressures. The cuff pressure is shown in the mean blood pressure (MBP) window during the measurement cycle and final values appear follow deflation.

BP Unit of Measure Indicator- YELLOW LED light identifies the selected unit of measure of blood pressure values ("mmHg" or "kPa").

Cuff Measurement in Progress Indicator- When lit, this GREEN LED indicates that a blood pressure measurement cycle is in progress. There may be a slight delay (up to 30 seconds) between the indicator lighting and beginning of cuff inflation.

Cuff Start/Stop Button- When pressed, this button initiates cuff inflation or stops a blood pressure measurement cycle already in process and deflates the cuff.

Pulse Rate measurement – A RED LED number shows the current pulse rate in beats per minute (bpm).

Pulse Level Indicator- This eight segment LED bar indicates the strength of the pulse signal. The pulse strength determined from the SpO_2 is shown in red while that determined by the BP cuff is shown in green. The SpO_2 measurement is triggered by each pulse. The Blood Pressure pulse measurement is triggered by the cuff cycle and remains displayed on the monitor until the next cuff cycle.

"Up" Control Button- Moves the screen back in the Line-List memory, or increases the value of a number highlighted by the cursor in the LCD screen.

"OK" Select Button- Moves the cursor through the LCD screen when adjusting the setup.

"Down" Control Button- Moves the screen forward in the Line-List memory, or decreases the value of a number highlighted by the cursor in the LCD screen.

Soft Keys - Are used to control the operational settings of the monitor. Their function depends on the screen that appears in the LCD window. Refer to the Screen Description section of this manual for more information.

LCD Screen- A high-contrast backlit LCD screen used to set monitor variables, to input patient information and to access information from the line list. The backlight of the LCD automatically turns off after 5 minutes as the unit enters its sleep mode; Refer to Section 3-0.

Battery Charging Indicator- This light shows the status of the battery charge: It is lit only when the monitor is connected to AC power. A RED light signals the battery is charging. GREEN shows the battery is fully charged. Note: If the battery indicator is GREEN when the monitor is unplugged from AC power, it will turn RED when the unit is plugged in again. The charging cycle re-starts and the indicator will turn GREEN again in 4-6 hours. NOTE: Life Systems recommends that you continue to leave the unit plugged in even when the light has turned GREEN.

Power ON/OFF Button- Pressing this button turns the monitor ON and OFF. While the power is ON, pressing this button momentarily puts the monitor into "sleep mode". Pressing and holding the button for three seconds or more, turns the unit OFF and sounds an alarm at one second intervals until the unit turns off (approx 3 seconds)

Power ON LED- This GREEN LED will light when the power of the device is ON (even when the monitor is in the standby (or sleep) mode.

Temperature Probe Well- The temperature probe is inserted here when not in use. Withdrawing the probe initiates a temperature measurement, replacing it stops a measurement.

Temperature Mode Indicator- A GREEN LED indicates the monitor is in the "Monitoring" mode of measurement. When the LED is not lit, the monitor is in the "Predictive" mode.

Temperature Unit of Measure Indicator- A GREEN LED light indicates the unit of measure (^{o}C, or ^{o}F) selected for the temperature measurement.

Temperature Measurement - Large GREEN LED numbers show the current temperature measurement.

Temperature Probe Cover Box Receptacle- Insert the box of probe covers here. Use only "Rosie" approved Probe Covers.

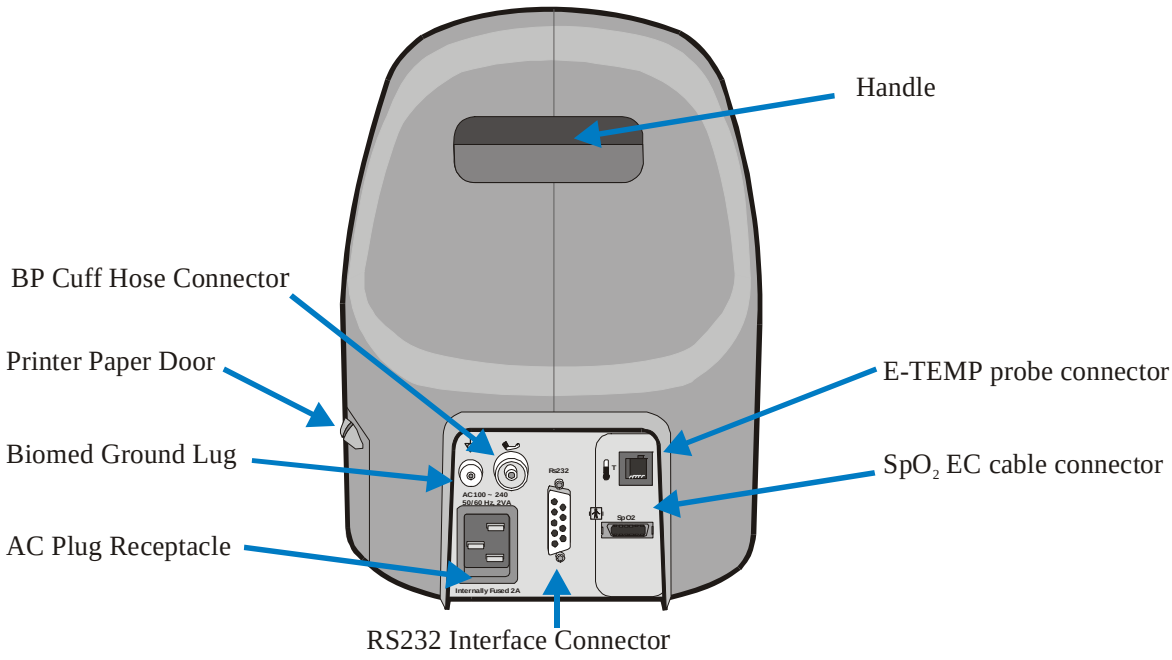
SpO_2 Measurement - RED LED numbers show the current Oxygen Saturation measurement (% saturation value).

Alarm Mute Button- Pushing this button silences an audible alarm for two minutes and activates the alarm indicator LED. If, after two minutes, the violating parameter is still outside acceptable limits the alarm will reactivate. To silence ALL alarms for two minutes (whether sounding or not), push and hold for at least three seconds.

Alarm Indicator - This light indicates the current status of the alarm function: No light/no alarms; a slow flashing light indicates that an alarm has sounded and has been silenced. A fast flashing light indicates all alarms have been silenced. The alarm will remain silenced for two minutes

This Manual describes and supports all of the monitors in the Rosie series by discussing the fully configured model that includes NIBP, Pulse, Pulse Oximetry, Temperature, and a printer, as well as the most current software revisions. It may, therefore, present information that does not apply to your unit. The front and rear panel designs and connection ports vary according to the parameters that have been built into your monitor.

Rear Panel Callouts:



2.6 Rear Panel Description- (clockwise from upper right)

Handle - Allows the user to move or carry the monitor. The handle area may feel warm, because it is also used as an exhaust port for the unit.

E-Temp Probe Connector- Configuration dependent, this port is used to connect the Alaris Turbo*Temp™ temperature probe cable. Push the cable connector of probe in until a positive latch is made.

SpO_2 EC Cable Connector- Configuration dependent, this port is used to connect the Doc-10 extension cable to the monitor. When connecting the Doc 10 extension cable you will have a positive lock on the cable when inserted correctly.

RS232 Interface Connector- Allows for RS232 or other communication interface with other systems.

AC Plug Receptacle- Standard inlet for AC cord plug.

Biomed Ground Lug- An additional ground point for "Biomed" or when external grounding is needed.

Printer Paper Door- Allows easy access to the paper roll compartment. Refer to Section 7.1 for more information.

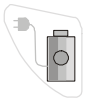
BP Cuff Connector- To connect the cuff hose, insert the connector *and rotate clock-wise to lock in place*.

Battery Cover (on the bottom of the unit, not shown)- Allows quick access to the battery compartment. It is secured with screws as access is intended for trained professionals only.

2.7 Recharging the Battery

The battery of the Rosie monitor recharges automatically any time the power cord is plugged into an appropriate AC power source. Recharging from a fully drained battery to a fully charged battery may take up to four hours.

The Battery Charging Indicator LED on the front of the monitor shows the charging status when the unit is plugged in: A RED light indicates the battery is charging. GREEN indicates battery power has reached at least 90% of capacity. A fully charged battery (greater than 90% of capacity) will generally last more than six hours at 15-minute "spot check" measurement frequencies. NOTE: Life Systems doesn't recommend that you let the battery discharge completely.



Battery Charging Indicator

Life Systems recommend that, when the monitor is stationary, it should be connected to an appropriate AC power supply to help ensure maximum battery power accessibility and life.

Refer to Section 9-1, and 9-2 for further information regarding battery removal and replacement.

Note: If the unit is stored or will not be used for an extended period of time, Life Systems recommends that the main battery be removed from the monitor.

Note: Always verify that the Battery Charging Indicator LED lights when the unit is connected into an AC outlet. A monitor that is plugged in but shows no Battery Charging light indicates a problem with the charging of the monitor. Refer to the troubleshooting section for assistance.

Note: The Rosie employs the "chimney effect" to cool the monitor: ambient air enters vents in the underside of the unit, passes over the internal components, cooling them, and rises to escape through vents in the handle. The handle will feel warm, especially during the battery charging cycle.

2.8 Installing the Rosie Monitor

Connect the monitor to a properly grounded 3-wire hospital grade AC power source.

Verify that the Battery Charging Indicator lights, allow the unit to fully charge before operating.

For Adult/Pediatric monitoring, attach the blood pressure cuff with the light blue cuff hose to the cuff hose connector on the back of the unit. Neonatal monitoring requires a neonatal blood pressure cuff identified by its pink cuff hose.

Select the appropriate sized BP cuff (sizes range from neonatal through large adult and thigh) and attach it to the cuff hose.

Connect the Doc10 SpO_2 extension cable to the SpO_2 Connector on the back of the monitor.

Select the appropriate SpO_2 sensor and attach it to the Doc10 extension cable.

Connect the appropriate E-Temp Probe (oral/rectal) by attaching the temperature probe cable to the E-Temp Probe Connector on the back of the monitor. Insert the probe into the probe well and place a new box of probe covers into the probe cover box receptacle.

If your Rosie monitor includes a built-in printer, load the paper by following the instructions in Section 7.1 “Loading Paper into the Printer.”

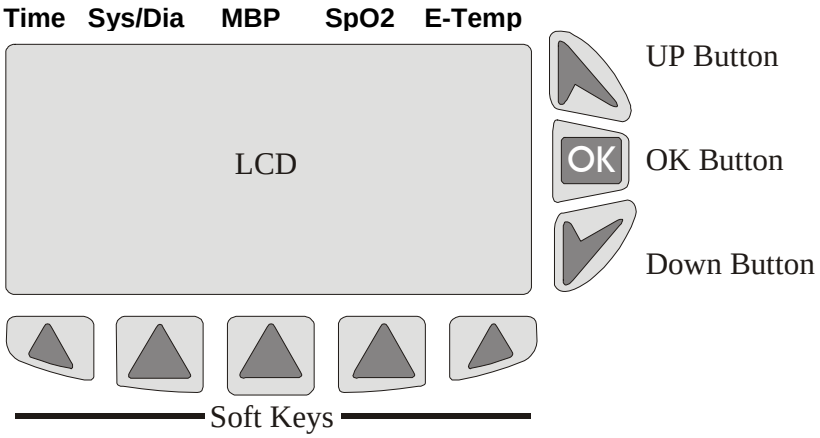
Press the “⏻ ” ON/OFF switch on the lower left hand corner of the front panel of the monitor.
The unit will initialize and perform a self-test. During this process “888” appears in all of the LED displays. As each parameter is initialized the displays change from “888” to “- - -” and the Line List (or Main Screen) appears on the LCD screen. Once this verification is complete for all parameters (about 10 seconds) the monitor is ready for use.

Note: Life Systems recommends that the user has a clear understanding of the Rosie Monitor, its intended use, warnings, precautions, and the other information found in this manual before using this device for patient monitoring.

3 LCD Screen Structure

The screens in the liquid crystal display (LCD) of the Rosie monitor have been designed so that all models use the same screen structure, regardless of the parameter configuration. This section describes each of those screens and the selections that are available for and through them. Selections are parameter-dependent – that is, you only see screens that apply to the parameters within your monitor.

The OK Button moves the cursor through the settings on the screen. The UP and Down Buttons increase or decrease the values highlighted by the cursor or toggle between two settings (Adult or Neonatal BP mode, for instance).



LCD screen, Buttons and Soft Keys

The Soft Keys select the functions you wish to view or revise. The two exceptions are PREV SCREEN (rejects any changes made and returns to the previous screen) and SAVE->MAIN (accepts, saves and initiates any changes and returns to the Line List or Main Screen.

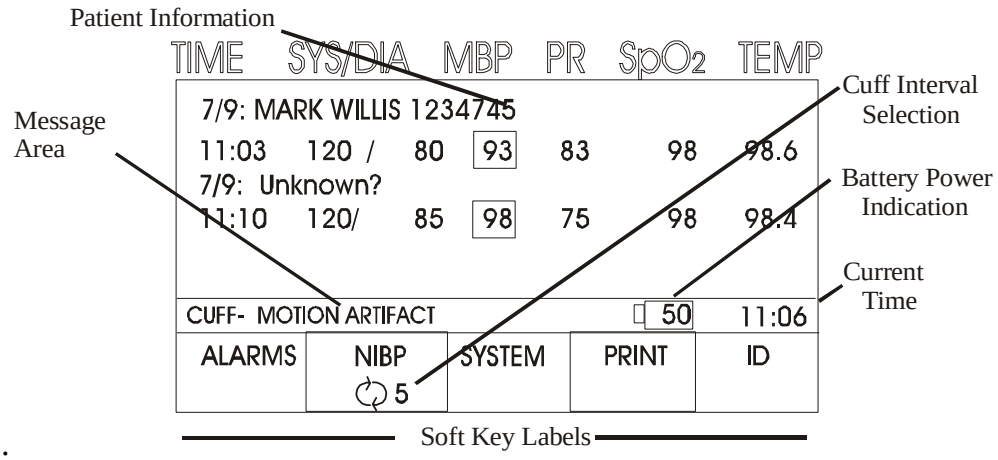
3.1 Line List Display or Main Screen

The Line List Display screen is the "main" screen of the monitor's LCD. It will appear once the initialization process of the monitor is complete. The labels on the housing across the top of the screen identify the columns of patient information presented, as shown in the illustration above.

The Line List Display on the next page is an example of the basic data presented. It shows the basic set-up selected for this monitor (ranges have been set for alarms, a cuff interval has been established), it shows the battery status (50% of capacity), it presents the vital signs values for the last two measurement cycles, and patient ID information.

If the monitor is "ON", not in "monitoring mode, but is not in use for five minutes, it enters a "sleep mode". In this mode all parameters are suspended in order to decrease power discharge (when on battery) and to speed charging (when plugged in). Pushing ANY button will power up the unit and begin the initialization process (see above) and parameters will be active in approximately 10 seconds.

While Sleep Mode is a default setting, if the Rosie Monitor is to remain on AC power, or you want it to just turn off, the unit can be set to bypass the Sleep Mode. The Biomedical/Technical Department must implement this setting.



Pressing the soft keys below the display will yield more information about that setting/set-up listed in the box above each key, and the screen will change accordingly.

Within the Line-List screen, if the UP or Down buttons are pressed the information on the display will change in steps ("page-turn"), while pushing and holding the buttons causes the Line-List information to scroll quickly. If the Down button is pressed the Line Listings scroll toward the most recent listing, while if the UP button is pressed, the Line Listing will scroll toward previous measurements.

NOTE: As you view any historical information, please refer to the date and time stamp of each measurement. If the user is reviewing historical information and the unit places a current listing to the memory, the view will remain where selected rather than automatically presenting the recent data. If the screen is left at an historical site for longer than 30 seconds and no buttons are pressed the screen will revert to current (the latest) information.

Within the Line List information, indications other than parameter measurements are also shown. In front of the SYS value, indications for Neonatal "N," or motion artifact "?" may be indicated. Motion artifact may also appear in front of the SpO_2 value. Any time a parameter has fallen outside of an alarm limit, that value will be placed in a box.

The Patient Name and ID information is entered through the use of the ID screens (see section 3.6). If no patient information is entered prior to a spot check measurement, the patient ID will be displayed as "ID: Unknown?"

The monitor automatically adds/updates information into the Line-Listing memory:

- Upon the completion of a blood pressure measurement.
- Upon the violation of a set patient alarm limit.
- Upon the completion of an E-Temp measurement.
- At the user-selected memory intervals (see System Settings page 3-7)
- Upon receipt of first measurement following application of the SpO_2 sensor.

Data is saved (added to the Line List) at user-selected intervals or on completion of a blood pressure or temperature measurement. Parameters being measured concurrently will be saved to the Line List at the end of the longest-running measurement.

The maximum Line-List memory is 400 lines. Each memory listing presents patient ID, the date, current time, and the vital signs values. If the memory listing has 400 measurements stored and an additional measurement is made, the memory will automatically remove the oldest stored listing and add the current one.

The Line-Listing memory is automatically saved each time the unit is powered OFF. When the unit is powered back ON the entire Line-Listing will again be available.

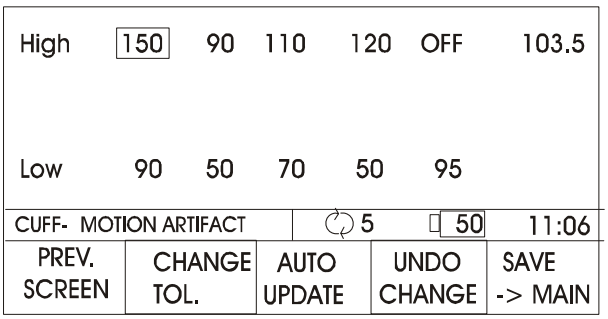
To clear all the data on a specific patient, Press the "ID" Soft Key from the Main Screen, Press the "Up" or "Down" button until the ID or the patient name appears on the screen, and then press the "View Pat." Soft Key. Verify that the selected patient is the appropriate patient you wish to delete from the listing, and push and hold the "Delete Pat." Soft Key. To clear the entire Line-List memory, enter the System Settings screen using the Soft Keys, move the cursor over the Line List Clear selection, then press and hold the "Delete" Soft Key for at least one full second. A "beep" sounds two times confirming the process.

3.2 Alarms Settings Screen

The Rosie monitors contain fully functional alarm parameters. High/low values can be set for Systolic, Mean, Diastolic, Pulse Rate, SpO_2, and Temperature (HI only). These alarms may be set manually for each use, or automatically as a protocol.

The alarms screen (shown below) is accessed by pressing the "Alarms" Soft Key from the Line-List screen. It allows the user to view the current alarm settings.

Alarms Screen



3.2.1 Setting the Alarm Limits

When you enter the Alarms Screen the cursor automatically appears over the Systolic High alarm limit. To move the cursor, press the "OK" Button until the cursor rests over the parameter value you want to change. To change the set value, press Up or Down .

The possible value ranges for each alarm limit are shown in the table below:

Parameter	Lower Limit Range (# of increments)	Upper Limit Range (# of increments)
Systolic (mmHg)	OFF, 20 ~ 160 (10)	50 ~ 240, OFF (10)
Mean (mmHg)	OFF, 20 ~ 120 (10)	50 ~ 200, OFF (10)
Diastolic (mmHg)	OFF, 20 ~ 120 (10)	40 ~ 180, OFF (10)
PR (bpm)	OFF, 30-295 (5)	35-300, OFF (5)
SpO_2 (%)	OFF, 50 ~ 99 (1)	51 ~ 100, OFF (1)
Body Temperature (^oF)		80.0 ~ 107.0, OFF (.1)

The alarm limits must retain their respective relationship – that is, the lower limit must remain below the upper limit. The values will change according to the unit of measure selected: a monitor set to show blood pressure in kPa will show alarm limits as a kPa range; temperature ranges will be shown in degrees F or degrees C in resolution of .1 degree.

3.2.2 Using Pre-Set Alarm Limits

The Rosie monitor can be set to store alarm protocols determined by your department. See section 3.2 to use this feature. To use the pre-determined alarm limits press the "Auto Update" Soft Key from the "Alarms Screen." The tolerances are normally generic tolerances selected by the appropriate personnel in the user's department. Refer to section 3.2.5 to learn how to set these tolerances.

Once the User uses the "Auto Update" to adjust the alarm limits, the new limits are displayed on the Alarm screen. At this time the user can agree with the values or make any modifications to the settings using the manual "Alarm" Soft Key. All active parameter alarm limit values can be adjusted using the tolerances found in the Auto Alarm Tolerance Screen. The new alarm limits will be shown on the screen and the user will be given the opportunity to adjust limits if required.

NOTE: In the Adult mode, the Rosie monitor will sound an alarm at a systolic pressure below 70 mmHg, even if a lower limit is set: Neither the feature nor the alarm can be overridden. The range remains adjustable for use in the Neonatal mode where lower limits can be set.

3.2.3 Removing Alarm Limit Changes

Pressing the “Undo Change” Soft Key erases any changes made and the alarms settings return to their previous values and status.

3.2.4 Saving Changes to the Alarm Limits

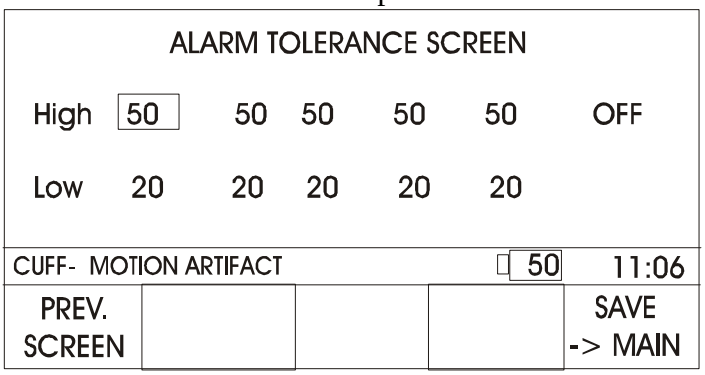
Pressing the “Save > Main” Soft Key, saves the changes, the new alarm limits are activated, and the LCD screen returns to the Line List Display.

Caution: When the measured value reaches or exceeds the high limit or falls below the low limit settings, its measurement LED display will flash. If the audible alarm has been set, the alarm will sound.

3.2.5 Changing the Auto Update Tolerances

To modify the pre-set alarm values, press the “CHANGE TOL.” Soft Key from the Alarms Screen and the display will change to the Auto Update Tolerance screen shown below.

Auto Update Tolerance Screen



The alarm tolerances have a range of 1 to 100% and OFF for the high alarm limits, and a range of 1 to 50% and OFF for the low alarm limits.

When the “Auto Update” Soft Key is pressed from the previous alarm screen, the current measurement value (patient’s baseline blood pressure) is multiplied against the High and Low alarm tolerances; the product of this multiplication is added to the current (baseline) value to set a high alarm limit value, and subtracted from the current value for the low alarm limit value.

Pressing the “Prev. Screen” Soft Key causes the screen to revert to the Alarms Screen and no changes are saved. Pressing the “Save to Main” Screen Soft Key saves the changes, activates the new limits, and returns the display to the Line List Display (Main Screen).

3.2.6 Audible Alarms

The Rosie monitors sound an alarm when set limits for Systolic, Mean, Diastolic, Pulse Rate, SpO_2, or Temperature are surpassed. The audible alarm is a high-pitched tone that sounds at one-second intervals until a new measurement is taken that falls within the alarm limits. The alarm volume is adjusted by modifying the settings through the System Setting screen (see section 3.4 on page3-7).

The Rosie monitor software allows clinicians 10 volume adjustments within a 15-decibel (db) range. Internal hardware adjustments allow this range to be positioned anywhere from a low of approximately 53 db (low) to a high of approximately 78db (very loud). The factory setting is in the lower part of the range – low to loud (55 – 70 db) – to suit most clinical needs. Moving the volume to the higher end of the overall range (moderate to very loud) requires adjusting an internal potentiometer. For details on accessing this hardware, please contact your Biomedical Department or Life Systems.

To silence the alarm, press the Alarm Mute button located on the top on the front panel of the monitor. The alarm will be silenced for two minutes during which the red Alarm Indicator light will flash slowly. Pressing and holding the Alarm Mute button for at least three seconds will silence the offending alarm as well as ALL other alarms for two minutes. When all alarms have been silenced, the Alarm Indicator LED will flash rapidly. If there are no alarms active, the LED will remain solid and no flashing will occur

If, for any reason, the monitor is unable to determine the final BP values during a measurement cycle, a caution code is displayed on the LCD display (for example, “NIBP: WEAK PULSE”), and the Unit “beeps” two times (alert before measurement retry) to announce a new measurement cycle is about to begin.

If the monitor incurs a critical error (such as loss of internal communication) the error code will be displayed in the LCD (“NIBP: TIMEOUT”) and an audible alarm will sound. This alarm will continue until silenced. Refer to section 10.6, “Error and Other Messages,” for more information.

3.2.7 Visual Alarms

When an alarm sounds, the LED value of the offending parameter will flash and a message will be shown in brackets on the LCD screen. The Alarm Mute Button has no effect on visual alarms, which will continue to sound until another measurement is taken and the result, once again, falls within the set alarm limits.

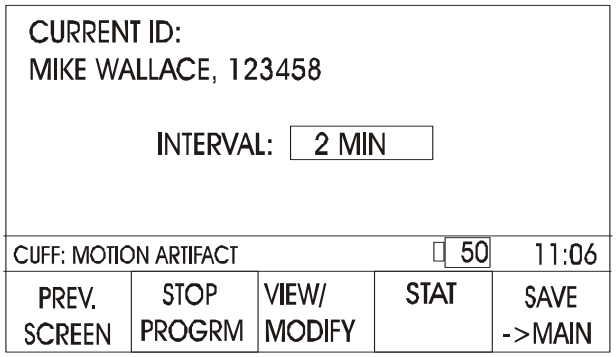
All alarms and messages are shown in the message area of the Line-List screen, with each alarm preceded by its offending parameter. Refer to section 3.3.

3.3 Cuff Interval Screen

The Cuff Interval Setting Screen is accessed by pressing the “Cuff” Soft Key under the Line-List screen. The monitor incorporates both static and dynamic cuff intervals. The static cuff intervals include 1, 2, 2.5, 3, 5, 10, 15, 20, 30, 60, 90, 120, and 180 minutes between cuff measurements. The dynamic timed interval programs (A, B, C, D, and E) are user-designed protocols. Programs A through D allow the user to set unit-specific protocols with up to five different cuff intervals. Program E is pre-set to a commonly used blood infusion protocol for training purposes, though it can be modified by following the steps on page 3-6.

Note: Resetting Factory Defaults (in the Service Screen Mode) erases all operator-designed dynamic cuff programs and resets program E to the factory pre-set blood infusion program.

Cuff Interval Screen

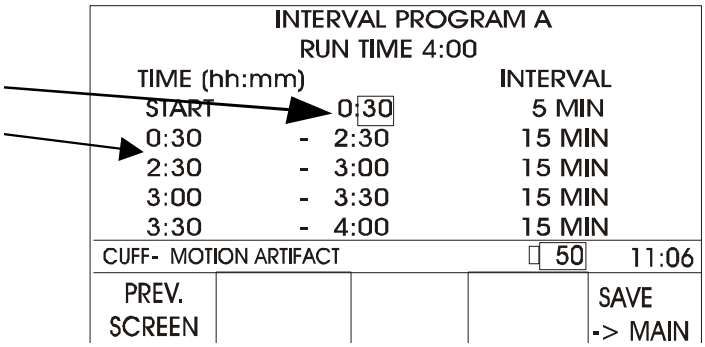


Pressing the "Cuff" Soft Key under the Line List (Main) screen brings up the Cuff Interval Screen on the LCD display. The currently selected cuff interval will appear in the window. Press the Up or Down Buttons to change the interval. To select one of the, user-designed dynamic timed interval programs (A, B, C, D, E), continue to press the Down button past the "1 min" interval. Press the "Save >Main" Soft Key to save the new input and return to the Line-Listing screen.

Pressing the "STAT" Soft Key from the Cuff Interval Screen, the screen will revert back to the Main (Line List) screen and continuous blood pressure measurements will be taken for five minutes, after which time the monitor will automatically revert to 5 minute cuff intervals.

Pressing the "STOP PROGRAM" Soft Key inactivates all interval settings and the cursor automatically moves over "OFF" as shown on the screen above.

To review and/or modify one of the user-designed cuff interval programs, select the desired program (A, B, C, D, E) then press the "View/Modify" Soft Key: the interval program will appear on the LCD screen as shown in the following example.



"Interval Program ": identifies the selected program, in this case, A.
"**Run Time hh:mm":** indicates the overall time period of the program. If the last period is left open-ended, through the user's selection of "—", the Run Time will also indicate this selection.

"From" Column: This column indicates the beginning time of each period. The values found in this column, are automatically linked to the ending time of the previous period.

"To" Column: This column indicates the end time of each period. The possible selections for this value are: "—" (this selection indicates that this period will continue for eternity), and 0:05 – 12:00 (a time selection, in five minute increments).

"Interval" Column: shows the cuff measurement interval selected for that time period. Any of the "manual selection cuff intervals" (ST,1, 2, 2.5, 3, 5, 10, 15, 20, 30, 60, 90, 120, 180 minutes) can be selected as long as they are shorter than the affected time span.

Each Interval Program allows up to five possible measurement periods that can be used. Two examples of Interval Programs are presented below:

Program: A	Run Time: --		Program: B	Run Time: --	
Start	-	1:00 5	Start	-	1:00 10
1:00	-	2:00 15	1:00	-	2:00 30
2:00	-	4:00 30	2:00	-	4:00 30
4:00	-	5:00 60	4:00	-	5:00 60
5:00	-	6:00 60	5:00	-	6:00 60

If an Interval program is in process when the user enters the screen, the cursor will identify the current point in time in that program. If there is no program running when entering the screen, the cursor will appear next to the first time frame.

Once a program has been set up or changes have been made to an existing program, pressing the "Save -> Main" Soft Key accepts, saves and implements the program and the LCD reverts to the Main (Line List) screen. Pressing the "Prev. Screen" Soft Key changes the screen back to the Cuff Interval screen without saving any changes.

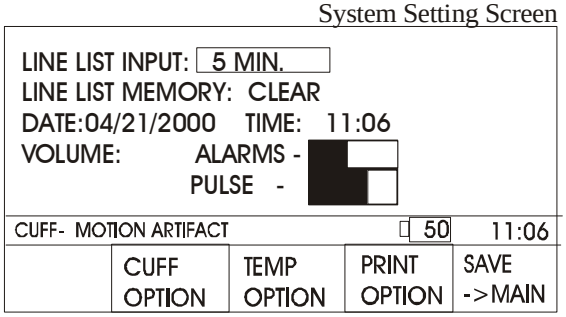
Program modifications cannot be made while an Interval Program is in process. If any attempt is made to modify the program while one is in progress, the program in process will stop. However, the monitor will allow you to revert to any of the standard cuff intervals or re-start a program in which modifications were made and saved.

While a cuff interval protocol is running, the letter (A, B, C, D or E) identifying that protocol and a number identifying the current cuff interval appears on the "MAIN" (Line List) screen under the word "Cuff": for example, "A-5" indicates program A running and a cuff interval of 5 minutes is in process.

3.4 System Settings Screen

Pressing the "System Setting" Soft Key from the Line List screen brings up the Systems Setting Screen that is used to make changes to the main system (Date, Time, Alarm volume, etc.). Press the "OK" button to move the cursor and the "Up" and "Down" keys to adjust the highlighted values. Using the Soft Keys under the screen gives access to the cuff, temperature, or print set-up screens as shown on next page.

System Setting Screen



Pressing "Save-> Main" saves the revisions and returns the LCD screen to the "Main" screen. "Line List Input:" is the rate at which the device stores patient information into the line list memory. While the Rosie monitor automatically stores data after each BP measurement and upon alarm activation, this option allows the user to store information at a rate not related those cycles. The possible selections are CUFF Only, 30 sec., 1, 2, 2.5, 5, 10, 20, 30, 60 minutes.

Activating "Line List Memory Clear" erases the entire line list. To activate this feature, move the cursor to select "Clear" then press and hold the "Delete" Soft key for three seconds: the monitor will "beep" three times while the button is being pressed and held.

NOTE: Data deleted from the Line List Memory **CANNOT** be retrieved.

The Date selection is arranged in the order of month, day, and year; the Time selection is in the 24-hour military time format. To set these data, use the "OK" Button to move the cursor to the intended data and use the "UP & Down" Buttons to change the values.

The selections for Volume allow the user to select the preferred volume for Alarms and Pulse sounds. If "OFF" is selected for the Pulse sound no pulse tone will be heard. Once again, use the "OK" Button to select the data set to be revised and the "Up and "Down" Buttons to change the Volume Settings. The selection for Pulse volume does not change the pitch of the pulse tone; its pitch is controlled by the SpO_2 value.

Pressing the "Save ->Main" Soft Key saves any changes and switches the display to the "MAIN" (Line List) screen.

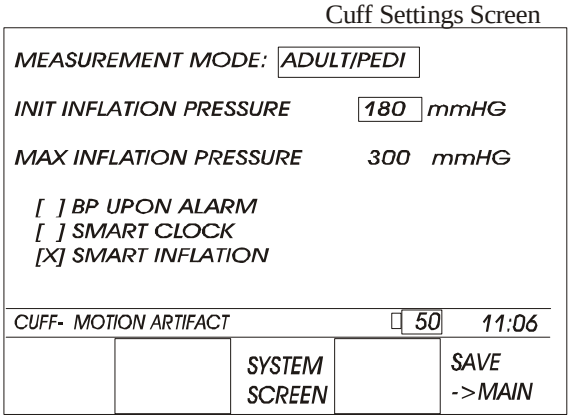
Pressing the "Cuff Options," "Temp Options," and "Print Options" Soft Keys access those respective displays to allow changes in those values.

3.4.1 Cuff Settings Screen

Access the Cuff Settings Screen by pressing the "Cuff Settings" Soft Key from the "System Settings Screen." (See next page).

MEASUREMENT MODE: Use the UP or Down buttons to select the appropriate blood pressure measurement mode (Adult/Pediatric or Neonate): Press OK to set the mode and move the cursor to the inflation pressure.

Cuff Settings Screen



INIT INFLATION PRESSURE: To select the desired inflation pressure for initial cuff inflation, use the UP or Down buttons to bring up the desired setting. The selections for inflation pressure vary between modes, and are as follows: Adult/Pediatric mode selections are 80 ~240 mmHg increments of 20; Neonatal mode selections are 80 ~140 in increments of 20. (Please see note on next page).

NOTE: BP Measurement Mode cannot be changed when a cuff interval has been set. To reset Measurement Mode, first turn off cuff intervals.

Pressing the OK button moves the cursor to the "MAX INFLATION PRESSURE" function.

MAX INFLATION PRESSURE: To select the desired maximum inflation pressure for the cuff, use the UP or Down buttons to bring up the desired setting. The selections for maximum inflation pressure vary between modes. You can not set the maximum inflation pressure lower than the initial inflation pressure. If the unit is not able to read the blood pressure on the first try, it will automatically increase the amount of pressure and retry 2 more times. This feature allows you to control the maximum pressure it will inflate during the retries. This feature is ideal when working with pediatrics or the elderly. The default is 300mmHg for adults and 160mmHg for neonates. After you have selected the desired pressure, press the OK button move to the cursor to the "BP UPON ALARM" function.

BP UPON ALARM: BP upon alarm can be activated by pressing the "Up" or "Down" buttons. If set, the monitor will automatically take a blood pressure after an alarm. The default is set to off.

SMART CLOCK : When "Smart Clock" is selected, the monitor automatically adjusts the second and all subsequent cuff measurements taken on intervals to major points on the clock, making follow-up and charting easier. Two examples follow:

1. If a 15-minute interval has been set and the initial measurement is taken at 11:56, then next "normal" interval would be 12:11. Activating the Smart Clock feature initiates the second measurement at 12:00, then the next at 12:15, then 12:30, etc. (on the quarter hour marks of the clock).

2. If a 5-minute interval has been set and the initial measurement is taken at 11:13, then next "normal" interval would be 11:18. Activating the Smart Clock feature initiates the second measurement at 11:15, then the next at 11:20, then 11:25, etc. (on the five minute marks of the clock).

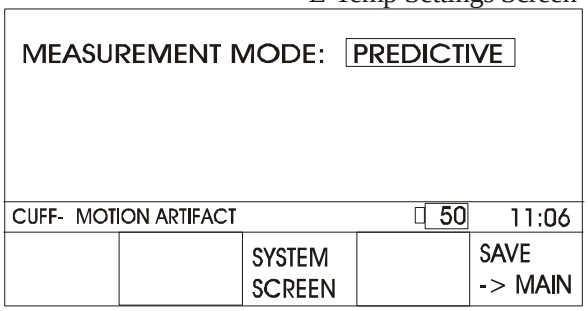
Pressing the "System Screen" Soft Key saves any changes made in the screen and the LCD reverts to the "System Settings Screen." Pressing the "Save->Main" Soft Key saves all changes and converts the CD screen to the Main or "Line List" screen.

SMART INFLATION: Smart Inflation can be disabled by pressing the "Up" or "Down" buttons. For a complete explanation of Smart Inflation, see section 4.2. The default is set to ON.

3.4.2 Temperature Configuration Screen

Pressing the "Temp Option" Soft Key from the System Setting Screen accesses the E-Temp Settings Screen (see next page):

E-Temp Settings Screen



Use the UP or Down buttons to select the "Predictive" or "Monitoring" temperature mode. The GREEN Temperature Mode LED light on the front of the monitor lights only when the Monitoring mode is selected. If the LED is not lit, the monitor is set in the E-Temp Predictive mode.

In the "Monitoring" mode, the Unit measures the patient's temperature continuously and displays the temperature constantly in large GREEN LED numbers. In the "Predictive" mode the monitor measures the patient's temperature for approximately 7 seconds, then displays the final temperature. Refer to section 5.4.1 for more information.

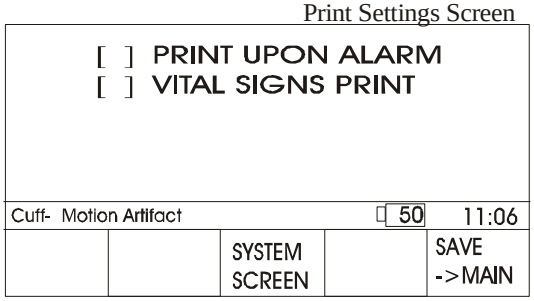
Pressing the "System Screen" Soft Key saves a change made in the screen and the LCD reverts to the "System Settings Screen." Pressing the "Save->Main" Soft Key saves a change and converts the LCD screen to the Main or "Line List" screen.

3.4.3 Print Configuration Screen

To have the Rosie monitor print a vital signs record automatically, press the "Print Options" Soft Key under the "System Settings Screen," and select the Vital Signs Print option. Each time a blood pressure, SpO_2, or temperature measurement is completed, the monitor will print the results. If measurements are simultaneous or immediately concurrent, the Unit will wait until the longest-running measurement is complete before printing, capturing all the data at one time. Note: All parameters must be disconnected/not in progress for the initiation of a vital sign print.

If you would prefer to have the unit print a Vital Signs Print upon a violation of the patient alarm limit settings, select the Print Upon Alarm option. Refer to Section 7.2 for an example of the vital signs record.

Print Settings Screen

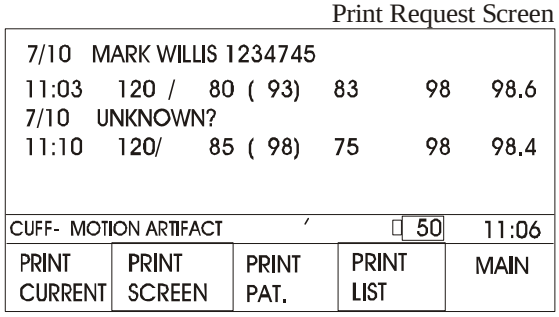


Pressing the "System Screen" Soft Key saves any changes made in the screen and the LCD reverts to the "System Settings Screen." Pressing the "Save->Main" Soft Key saves all changes and converts the LCD screen to the Main or "Line List" screen.

3.5 Print Request Screen

When the "Print" Soft Key is pressed from the "Line-Listing" or "Main" screen, the labels of the soft keys change on the screen to reflect the print request.

Print Request Screen



Pressing the "Current" Soft Key initiates a printout of the patient's current vital signs in a Vitals Print format. Refer to section 7.2 for an example of this printout.

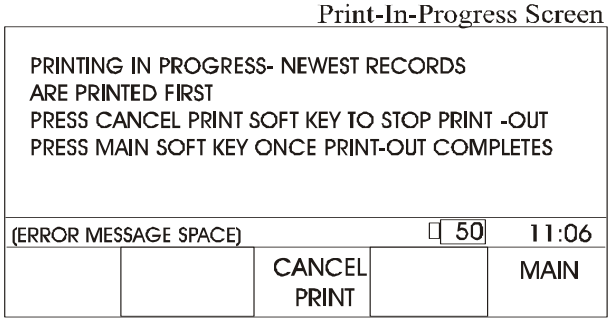
Pressing the "Print Screen" Soft Key initiates a line-list format printout of the vital signs that on the LCD screen at that time. Refer to Section 7.2 for an example of this printout.

Pressing the "Print Pat." Soft Key brings up the Patient ID screen (refer to section 3.6), where the user will be asked to select the patient ID to be printed. Once the appropriate ID has been selected, press the "View Patient" Soft Key to view the measurements. Press the "Print Pat." soft key to print the measurements. The information is printed in the order of current to oldest, in a line-list print format (Refer to Section 7.2 for an example of this printout). The information is printed.

Pressing the "Print List" soft key will initiate a printout of the entire line-list memory in the order of most current to oldest. The information is printed the line-list format (refer to Section 7.2).

As the Print Patient and Print List records are printed, a "Print in Progress" screen will appear (refer to Section 7.2.1). This screen allows the user to cancel the printing process once the desired records have been printed (press the "Cancel Print" Soft Key).

Print-In-Progress Screen

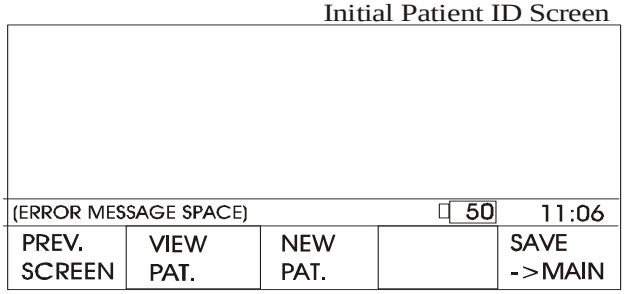


If the "Cancel Print" function is not used and the unit is allowed to continue printing until the print function is completed, the User must press the "Main" Soft Key to return the display to the Line-List screen.

3.6 Patient ID Screen

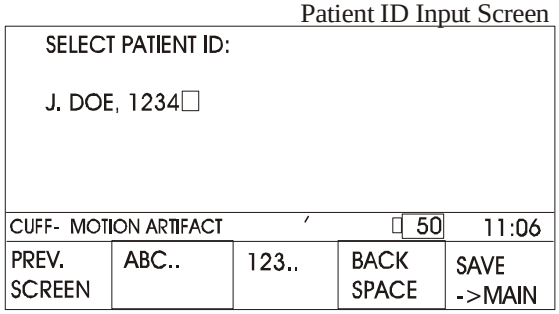
To enter patient ID information, press the "ID" soft key under the "Line List" screen and the Initial Patient ID screen will appear. If a measurement is started without entering a patient ID, the monitor will automatically identify the measurement as patient "Unknown?"

Initial Patient ID Screen



To enter a new patient ID, press the "New Pat." soft key in the Initial Patient ID Screen. The following Patient ID Input screen will appear:

Patient ID Input Screen



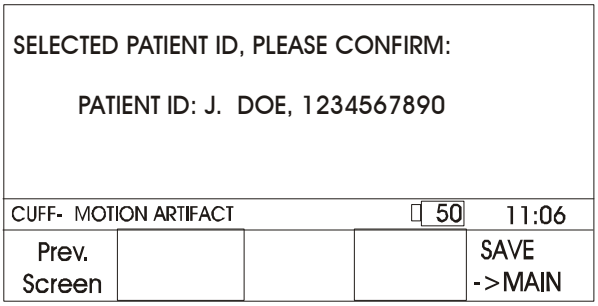
.

To enter letters, press the "ABC" Soft Key then use the UP or Down buttons to scroll through Alpha characters to select the desired letter. Press the "OK" button to accept that letter and move the cursor to the next space. The "123." Soft Key allows integration of numeric ID; select the numbers the same way as you did the letters

Pressing the “Back Space” Soft Key moves the cursor back one space clearing the last entry. Pressing the “Prev. Screen” Soft Key erases any new input and the LCD screen returns to the Patient Select screen.

Once the Patient ID input is complete, press the “Save->Main” soft key, and the Patient ID Confirmation screen will appear:

Patient ID Confirmation Screen



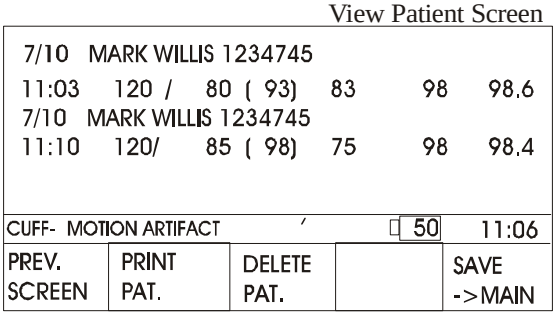
If the information is incomplete or incorrect, press the “Prev. Screen” Soft Key to return to the ID Input Screen and use the “Back Space” and “ABC” and “123” “Soft Keys” to make the desired revisions. Once the Patient ID information is complete and correct, press the “Save/Main” Soft Key to save the input and return to the “Main” Screen. This ID will be used to identify any measurements taken at this time.

Note: In order to ensure that all measurements appear under the same ID during “Spot Check” measurements, the following procedure must be used: First, place the SpO_2 probe onto the patient’s finger, then apply the BP cuff and initiate a measurement cycle. The E-Temp measurement can be taken any time during the cuff measurement cycle, and as soon as all measurements are complete, all the data will be ascribed to that patient.

To assign an existing Patient ID from the monitor’s memory to the next measurements, press the UP button to scroll through the existing patient identifications. Once the Patient ID has been located, press the “Save ->Main” soft key, and that identification will be used for the measurement, and the display will return to the Line-List screen.

To view historical patient measurement information, select the appropriate Patient ID as shown above, and press the “View Pat.” soft key. The following screen will appear allowing the user to view the four most recent measurements. The patient’s vital signs can be printed by pressing the “Print Pat.” Soft Key (refer to section 7.2). The patient ID and vital signs information can also be removed from the Line-List memory by pressing and holding the “Delete Pat.” soft key.

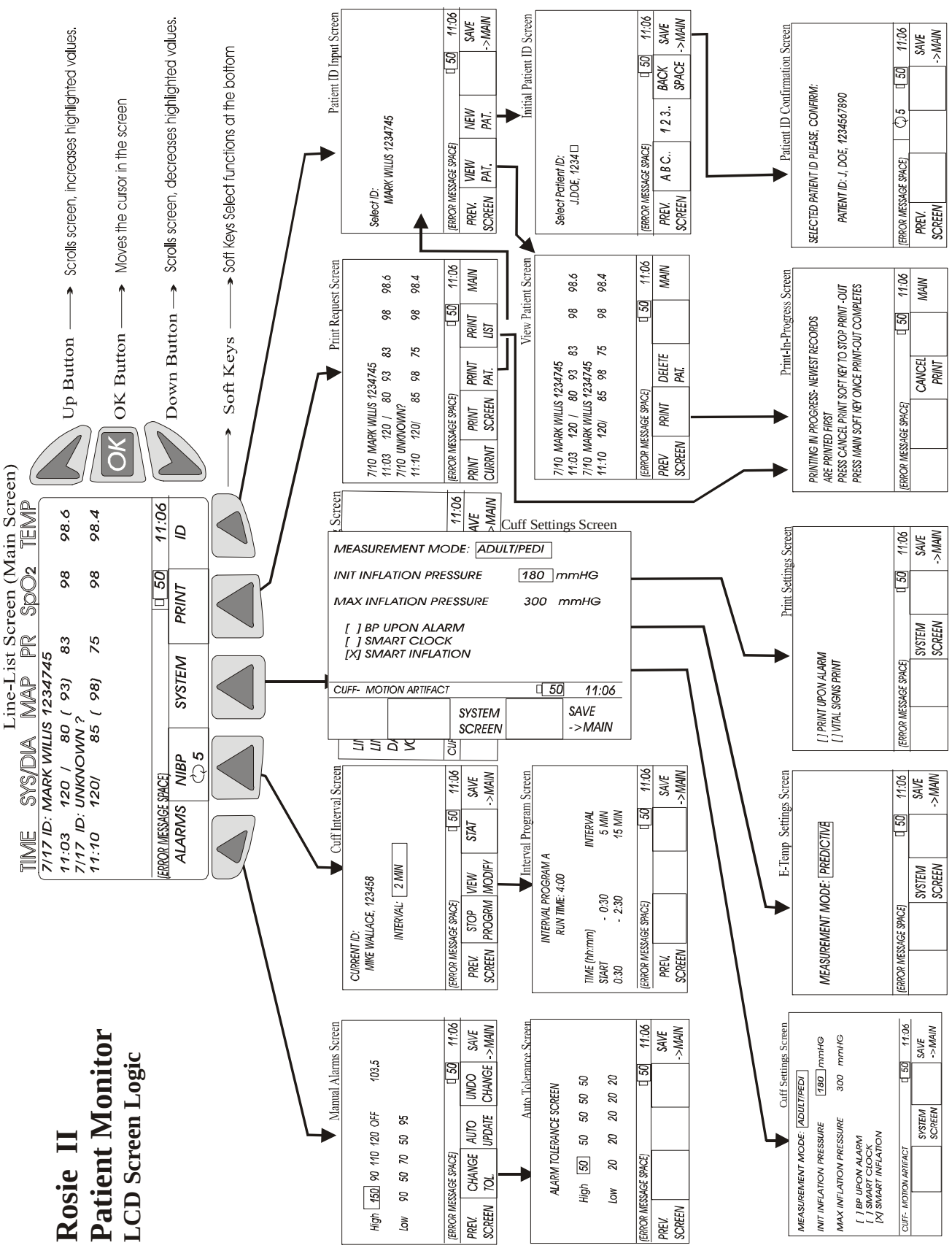
View Patient Screen



Caution: If cuff intervals or E-Temp Monitoring mode are in use, or if the SpO_2 sensor is connected to the same patient for longer than 5 min. the monitor assumes that all measurements taken during that time belong to the same patient and places those values in memory under that patient's ID.

If no cuff intervals are set and the SpO_2 sensor is <u>not</u> kept on the patient (or if no ID information has been entered), as additional measurements are taken, the monitor will assume the vital signs are for a new patient and the values will be placed under an "Unknown" patient ID label.

3.7 LCD Screen Structure Diagram



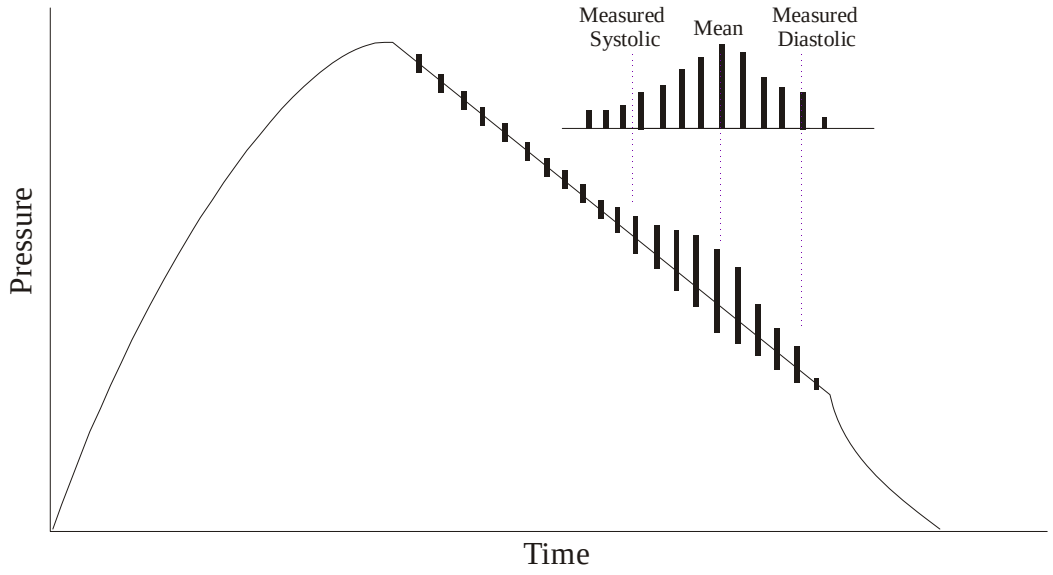
4 NIBP

4.1 Principles of the Oscillometric Technique

Oscillometry, or the oscillometric method, is a relatively simple, quick, reliable and comfortable, technique to measure blood pressure non-invasively, automatically. The fundamentals of the technique are easily explained.

An inflatable cuff is placed around a limb, usually the upper arm. When the cuff is inflated and the pressure in the cuff exceeds systolic blood pressure, blood ceases to flow through the (brachial) artery. Though the inflated cuff stops blood flow, each time the heart contracts, a very small pulse can be observed superimposed upon the cuff pressure signal. These small pulses are called oscillometric pulses.

Slowly relieving the pressure in the cuff allows the blood to penetrate further and further under the cuff, slightly increasing the amplitude of the pulses, until the cuff pressure eventually becomes equal to the systolic blood pressure, and blood can start to flow through the (brachial) artery. The increased surface area of the cuff that comes in contact with the blood as it passes under it, causes sudden, large increases in the amplitude of the oscillometric pulses.



As the pressure in the cuff continues to decrease, more cuff surface area is affected and the amplitude of the oscillometric pulses continue to increase until the cuff pressure reaches mean arterial blood pressure, and the amplitude of the oscillometric pulses peak. Then, as the cuff pressure decreases further, the oscillometric pulse amplitude decreases continuously until the cuff pressure reaches the diastolic blood pressure, and the amplitude of the oscillometric pulse drops off suddenly.

Rosie II applies an oscillometric technique that uses dynamic linear deflation to measure blood pressure. This technique adjusts the deflation rate according to the patient's heart rate ensuring consistent, accurate, patient-specific readings. Patient comfort is greatly enhanced because the pressure in the cuff is released constantly over the least amount of time necessary to assure accuracy.

Some measurement artifacts, such as exaggerated patient motion, arrhythmia, and hypovolemia make any blood pressure measurement impossible. However, the proprietary algorithms of the Rosie II will reject several types of artifacts to obtain an accurate measurement. However, in some instances, the artifact may be so severe that an accurate reading is simply not possible. In this situation, an alarm, when properly set, will notify of the clinician of the situation and the monitor will attempt another measurement cycle.

4.2 NIBP Parameter Settings

There are two setting menus that affect the function of the NIBP operation. The first is the Cuff Interval Setting screen, and the second is the CUFF setting screen within the System Settings.

4.2.1 Cuff Interval Screen

The cuff interval screen (refer to section 3.3, page 3-5) allows the clinician to select the appropriate cuff interval or interval program. The active cuff interval or program is displayed on the Line-Listing screen to the left of the current time.

Note: If an interval of 1 minute (Short-Term) is selected, after 12 measurements, the monitor will automatically change its interval measurement to 5 minutes.

To access the "Cuff Interval" screen, press the "Cuff" Soft Key from the "Line List" screen. Then choose one of the timed measurement intervals from a selection of STAT (continuous), 1, 2, 2.5, 3, 5, 10, 15, 20, 30, 45, 60, 90, 120, and 180 minutes. Pressing the "STOP" Soft Key can halt a cuff interval, already in progress. Once a value has been chosen, pressing the "Main" screen button saves that setting, the display returns to the Line-Listing (or Main) format, and the interval measurement begins.

Continuous measurements are initiated when "STAT" is selected in the "Cuff Interval" screen and the Start/Stop button is pressed.

To interrupt the measurement, press the Start/Stop button during the measurement. When the continuous measurements are interrupted in this manner, the word "STAT" in the CUFF soft key will appear reversed on the LCD screen and the measurements will cease.

Note: When "STAT" continuous measurements are specified, a rapid estimation of systolic blood pressure is displayed upon second and subsequent BP measurements. A single "beep" alerts the user of the displayed "Quick Estimated Systolic" value. On completing the measurement, two "beeps" sound and the actual BP values are displayed.

Caution: Five minutes after STAT measurements (Short-Term) have been initiated, the cuff interval will automatically revert to a 5-minute interval.

4.2.2 Cuff Settings Screen

The Cuff Setting Screen (refer to 3.4.1, page 3-9) allows the clinician to set up the overall parameters of the NIBP cuff measurements.

Cuff Mode: The user must select from the Adult/Pediatric or Neonatal mode to match the patient. If the Adult/Pediatric mode is selected, use the BLUE cuff hose and the appropriate size BP cuff. If Neonatal is selected, use the PINK cuff hose and a disposable neonate cuff of the correct size.

Initial Pressure: Setting the initial cuff inflation pressure allows the user to select a range inflation values from 120 mmHg to 220 mmHg in increments of 20 mmHg in the Adult/Pediatric mode, and 80 mmHg to 120 mmHg in increments of 20 mmHg in the Neonatal mode. Settings are saved when the monitor is turned off and become the default when the monitor is powered up.

BP Upon Alarm: When this alarm is activated, the monitor will automatically take a second blood pressure measurement upon an alarm limit violation to aid in verifying an alarm condition.

Smart Clock: By selecting the Smart Clock feature, the unit automatically "synchs" the second and subsequent cuff interval measurements with the major points on the clock, making trending of the information easier for the clinician; it can also ensure recent vital signs during the nurses' rounds.

4.2.3 Smart Inflation

Smart Inflation is set to ON when shipped from the factory. This selection will enable the monitor to automatically inflate the cuff to a required inflation pressure above arterial occlusion. The inflation pressure will customize itself to each patient's individual requirements. For example, monitors typically inflate to 180 mmHg and then deflate. In some patients, that can be very uncomfortable and they may even become agitated during test. Smart Inflation is monitoring for arterial occlusion during inflation, and stops when necessary, not to a preset pressure.

NOTE: It is important to understand that if a patient is moving, shacking or agitated during the blood pressure measurement, Smart Inflation might misinterpret the movement as a pulse. If it mistakes a pulse while inflating, it could potentially inflate to pressures over 180 mmHG. When you have patient that is unable to stay still, we recommend that you disable Smart Inflation. To disable Smart Inflation, first press the "SYSTEM" button then press the "CUFF OPTION" button. Move the curser to the "SMART INFLATION" choice, and un-check the "X". When Smart Inflation is disabled, the monitor will first inflate to the maximum pressure setting in the "INIT INFLATION PRESURE" setting. However, the monitor will also retry two more times at an increased pressure as normal. The default for INIT INFLATION PRESURE from the factory is 180 mmHG.

4.3 Applying of the Cuff

When applying the cuff to the patient there are many things that must be considered, especially size.

4.3.1 Adult/Pediatric Cuff Placement and Positioning

Proper cuff size and placement is essential to assure accurate blood pressure measurements.
The American Heart Association recommends cuff sizes should be at a length to width ratio of about 2:1, ensuring that if the bladder width is 40 percent the arm circumference, the bladder length will encircle 80 percent of the arm.
If the cuff is too small, the bladder width may be so small that the full cuff pressure is never applied to the artery (see figure C), and erroneously high-pressure reading results. If the cuff is too large, the extra width lengthens the time it takes for the blood to pass completely under the cuff, creating an erroneously low systolic measurement. In Figure D on page 4-4, the bladder width is adequate for the arm, and the full cuff pressure is applied to the brachial artery.

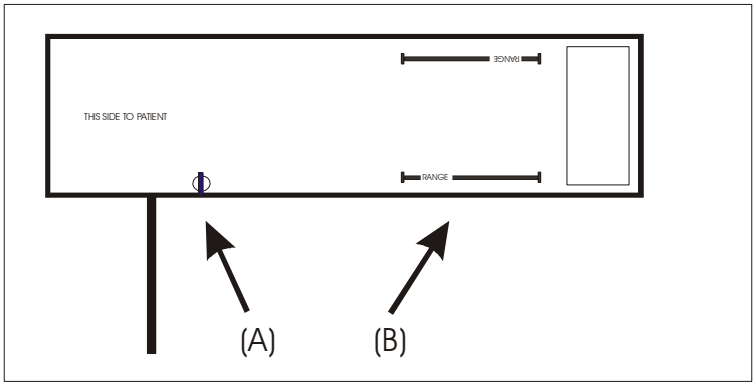
Cuffs for the thigh are available for large patients or those where neither arm is available for cuff placement. Blood pressure measured at the thigh is typically 20-30 mmHg higher than blood pressure measured at the upper arm.

The artery mark on the center of the cuff bladder (A in diagram, below) should be placed over the brachial artery. Make sure not to twist or kink the hose. The brachial artery is located on the inside of the upper arm -- it is NOT located directly above the location where the stethoscope is placed when manual measurements are taken.

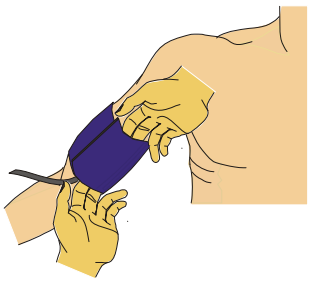
Note: Be aware of the actual location of the Brachial Artery. It is located on the inside of the upper arm.

The end of the cuff should fall inside the range marks clearly identified on the inside of the BP cuff (B in diagram below). If the end of the cuff does not fall within this range, increase or decrease the size of the cuff so that the new cuff fits correctly.

Note: Life Systems offers a wide range of blood pressure cuffs to meet your patient requirements; refer to the accessory portion of this manual for more information about cuffs.



Wrap the cuff snugly so that two fingers can be placed between the cuff and the arm (above and below the cuff).



If the cuff is wrapped too loosely, it cannot be inflated properly, there may be errors in measured values, and the patient is likely to be uncomfortable. It is best to wrap the cuff around a bare arm as clothing may cause errors in measured values.

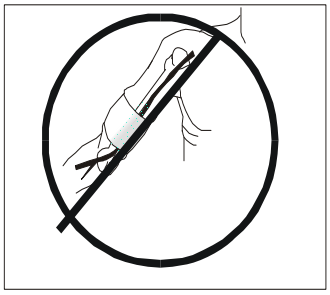


Figure C

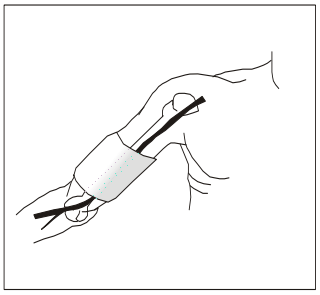


Figure D

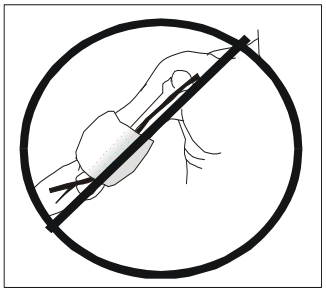
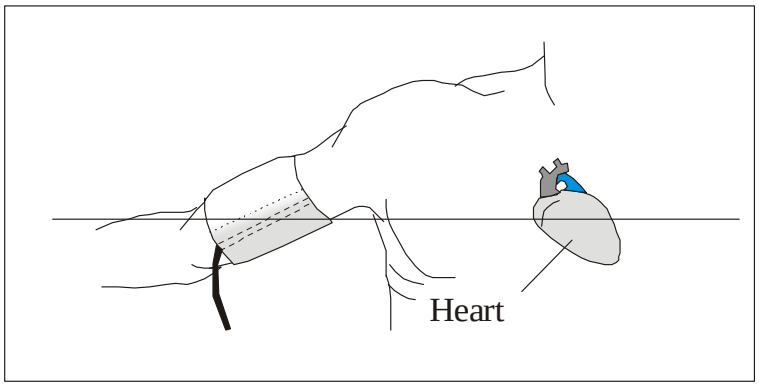


Figure E

Keep the cuffed part of the arm at the same level as the heart. The arm should also be resting on a level surface to reduce muscle tension that may cause an increase in blood pressure measurements.



Note: If the arm is above the level of the heart, the blood pressure measurement may be lower than the actual value: if the arm is below the heart level, the blood pressure may be higher than the actual value (due to the physical weight of the blood).

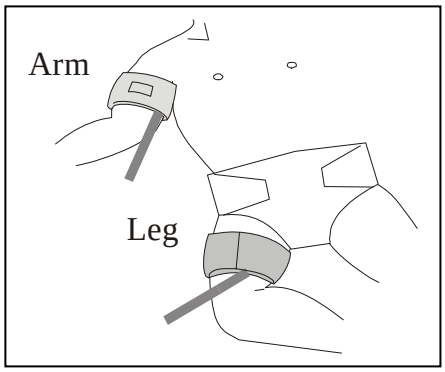
4.3.2 Neonatal Cuff Placement and Positioning

Note: Make sure the Neonatal measurement mode is selected in the Cuff Setting screen. Check the cuff site if long-term monitoring will be required. Check the patient's arm/thigh frequently for cuff site irritation.

Reliable measurements can be obtained by following the guidelines listed on the next page.

A. Be sure the disposable cuff is fully deflated before applying it to the neonate's arm or thigh.

B. Wrap the disposable cuff snugly to the arm or thigh.



C. Position the limb and cuff at heart level to avoid a pressure reading error due to hydrostatic pressure.

D. After applying the cuff, wait until the patient relaxes before initiating a measurement (the patient needs to be reasonably still to avoid motion artifact.

E. Check hose connections and cuff placements routinely for folds, kinks, cracks or any pressure being applied to the outside of the hose casings.

By pressing the CUFF START/STOP Button, the cuff is inflated to 120 mmHg in the Neonatal mode. Unless an initial cuff inflation pressure was pre-set in the "Cuff Option screen, the cuff will inflate to the 120 mmHg default.

WARNING:
Inaccurate measurements can occur if the neonate's systolic blood pressure is over 130 mmHg, due to the 150-155 mmHg maximum inflation pressure of the monitor in the neonate mode.

Inaccurate measurements can also occur during –

- External motion artifact as in patient movement, CPR, or bed movement.
- Serious episodes of shock, hypotension, or decreased body temperature.
- Frequent episodes of arrhythmia.

When the measurement has failed or if a measurement value is questionable, always verify the patient's blood pressure using another technique.

5 Electronic Predictive Temperature (E-Temp)

5.1 Principles of Electronic Predictive Temperature

Life Systems E-Temp temperature measurement technique is based on Alaris' Turbo*Temp™ predictive temperature technology that uses a temperature thermistor that changes it's output depending upon the temperature of the contacting tissue.

In the "Monitoring" mode, the monitor continuously updates and displays the temperature values as long as the temperature probe is in contact with the patient's.

In the "Predictive" mode, the monitor looks at the rate of change from a given starting temperature and, within 7 seconds, predicts and displays the final temperature, and sounds a tone signifying completion of measurement.

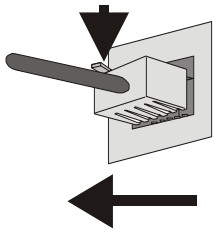
5.2 E-Temp Setting Screen

To select the temperature measurement mode ("Predictive" or "Monitoring"), press the "Systems" Soft Key from the "Line List" screen, then the "Temp Settings" Soft Key: See section 3.4.2 for setting instructions.

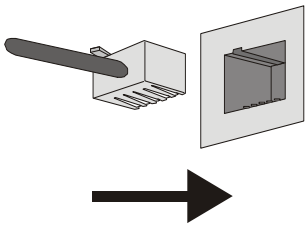
5.3 Connecting the Temperature Probe to the Unit

Connect the temperature probe cable to the temperature connector port on the back of the monitor. Insert the probe into the temperature probe well on the front of the monitor.

To remove the probe cable from the housing's connection, depress the connector's release and remove the probe.



Press to Insert Temperature Probe Connector



Press Connector's Release and Pull

5.4 Taking a Temperature

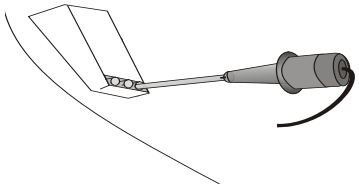
It is important to know what type of temperature measurement is required. The Rosie Monitor offers a fast predictive measurement as well as a continuous monitoring method.

Note: For oral temperature measurements, use the blue probe, and for rectal use the red probe.

5.4.1 Predictive Mode Measurements

A. Select “Predictive” in the Temperature Setting screen.

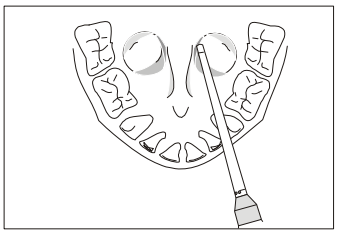
B. Insert the appropriate (oral or rectal) probe completely and firmly into the (appropriate) probe cover being sure the cover is on securely.

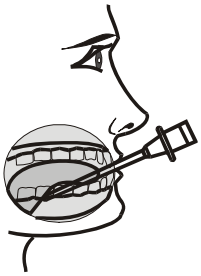


CAUTION: Failure to firmly install the probe cover may result in the probe cover becoming loose or disengaged during use. Be careful not to press the probe ejection button (where the cord exits the probe) during use.

C. Have the patient open their mouth slightly. Holding the probe loosely, place the probe tip into the sublingual pocket. Hold the probe during the entire temperature measurement process and keep the probe tip in contact with the tissue at all times. Do not allow the patient to reposition or hold the probe.

Oral



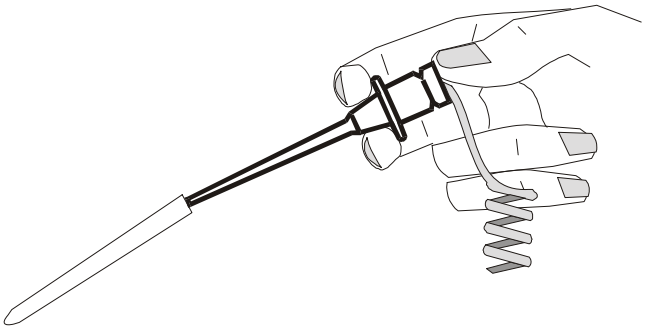


While the patient’s temperature is being taken, the E-Temp LED readout will show a moving pinwheel, indicating tissue contact. If tissue contact is broken, the pinwheel will stop moving until contact is reestablished. A beep will sound when the measurement is completed, and the display will show the temperature in large GREEN numbers. The value will remain on the screen for five minutes or until another temperature is initiated.

Note: A long delay from the time the probe is removed from the temperature probe well until it makes contact with the patient’s tissues, may cause a break in the measurement cycle, causing the monitor to switch from “Predictive” Mode to “Monitoring” Mode. If this occurs, eject the probe cover, insert the probe back into the temperature probe well, and begin the process again.

Note: If an unusually high or low temperature reading is obtained, confirm the reading using another temperature measuring device before beginning any treatment.

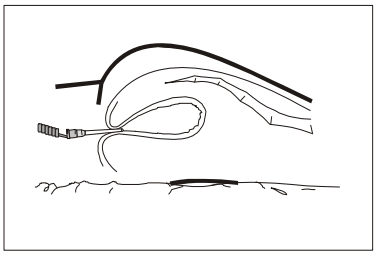
Once the measurement is completed, hold the probe as you would a syringe and press the probe eject button at the base of the probe to release the used cover into a waste container and return the probe into the probe well to prepare for the next measurement.



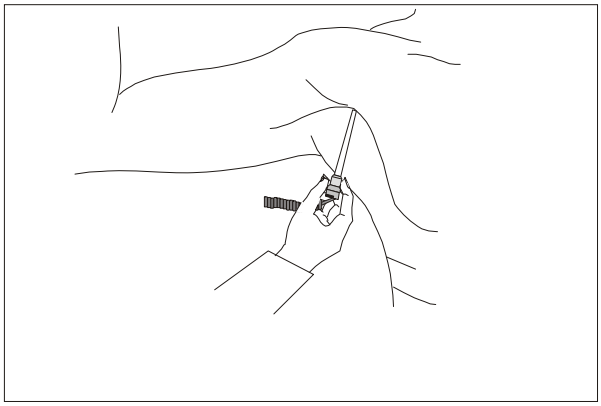
Note: If the probe tip temperature is higher than 92 ^{o}F (33.3 ^{o}C) when taken out of the temperature probe well, the monitor will be unable to quickly predict the patient's temperature. Instead, it will automatically go into the Monitoring Mode ("M") will appear below the E-Temp indication on the screen) which may require 3 minutes or longer. The monitor will not beep at a final temperature; it will continue to monitor the patient's temperature until the probe is returned to the temperature probe well.

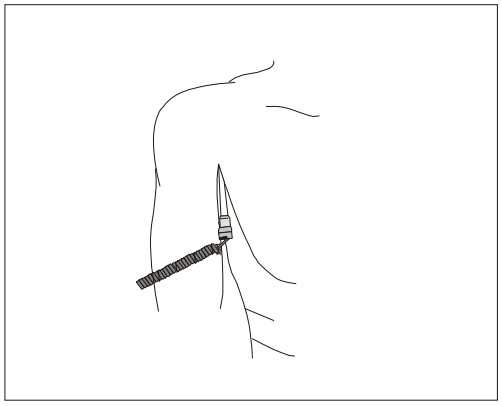
To take a rectal temperature, use the optional red thermometer probe. Install a disposable cover as described for oral use and insert the probe into the patient's rectum. To insure proper tissue contact, angle the probe slightly after insertion as shown in the accompanying illustration. Recommended insertion depth is ½" to ¾ " for adults and ¼" to ½" for children. A lubricant may be used if desired. The measurement will proceed similarly to the oral measurement, and the final reading will replace the pinwheel pattern in the LED window.

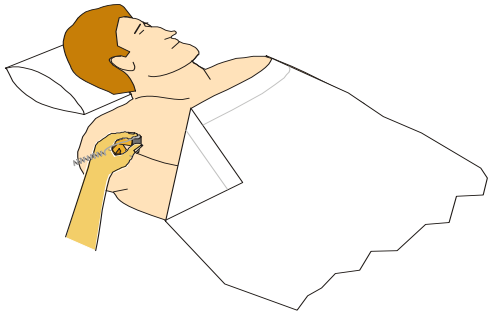
Rectal



For axillary temperature measurements, remove probe from temperature probe well and attach probe cover. Place the probe in the patient's axilla, making sure the tip of the probe is in contact with the skin and positioned as close as possible to the axillary artery and with the patient's arm held close to their side. Leave the probe in place according to the timeframe set by your facility's protocol for taking an axillary temperature.







Once the patient's temperature is taken, remove the probe, eject probe cover, and return the probe to the probe well.

5.4.2 Monitoring Temperature

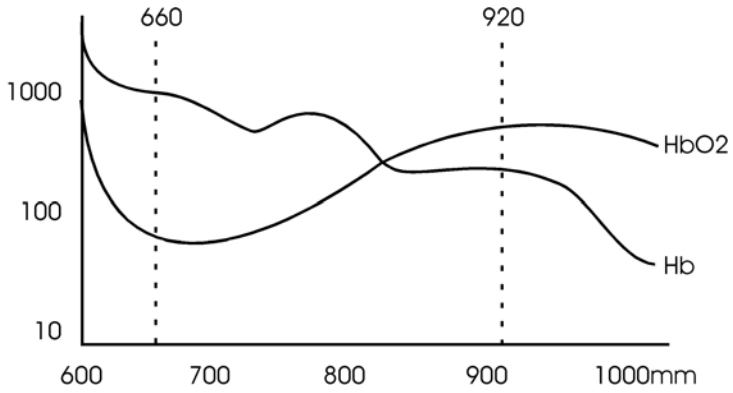
Select "Monitor" in the E-Temp Setting screen (See section 3.4.2).

Remove the oral probe from the probe well, and attach a probe cover. Have the patient open mouth slightly. Holding the probe loosely, place the probe tip into the sublingual pocket. Hold the probe during the entire temperature measurement process and keep the probe tip in contact either the tissue at all times. Observe the display until the value stops changing (3-5 minutes), indicating the final temperature. Unlike in "Predictive" Mode, there is no audible signal (beep) to indicate a final temperature reading.

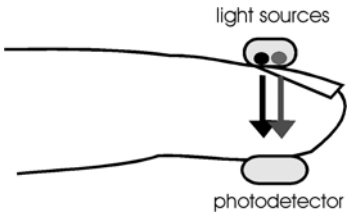
6 Pulse Oximetry (SpO_2)

6.1 Principles of Pulse Oximetry

Pulse Oximetry provides continuous non-invasive information about the percent of oxygen that is combined with the hemoglobin in the patient's blood, also referred to as oxygen saturation. In combination with the hemoglobin value, the SpO_2 provides valuable information about arterial oxygen content in the blood.



Pulse oximeters utilize two light-emitting diode "LEDs" of given wavelength-- a red light at approximately 660nm and an infrared light at approximately 920nm. A photo detector is placed opposite to these LEDs, across the vascular bed. The difference in the intensity of transmitted versus detected light at each wavelength is caused by the absorption of light by oxygenated and deoxygenated hemoglobin within the vascular bed. The determination of arterial hemoglobin oxygen saturation is automatically computed from the relative amounts of light transmitted to the photo detector.

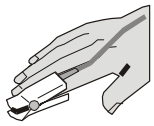


Pulse Oximetry uses the two-wavelength technology to determine functional oxygen saturation. Functional saturation is the ratio of oxygenated hemoglobin over that of total possible hemoglobin available for oxygen transport. The formula for that equation is as follows:

$$SpO_2\ (\%) = 100 \times [Hb02 / (Hb02 + Hb)]$$

6.2 Probe Selection

The monitor uses Nellcor® OxiMax® sensors. Only Nellcor, OxiMax sensors are recommended for use with the Press-Mate Prodigy monitor. It is important to select the appropriate sensor for use with each patient to obtain accurate measurement results. Please select one of the following OxiMax sensors available from Nellcor:



Dura-Sensor® DS-100A. This reusable sensor should be applied to adults weighing over 40 kg.

MAX-A®. This disposable adhesive sensor should be applied to adults weighing over 30 kg.

MAX-AL®. This disposable adhesive sensor is the same as the MAX-A OxiMax sensor, however it has a longer, 36" cable.

MAX-P®. This disposable adhesive sensor should be applied to pediatric patients weighing from 10 -50 kg.

MAX-I®. This disposable adhesive sensor should be applied to infants weighing from 3-20 kg.

MAX-N®. This disposable adhesive sensor should be applied to neonates weighing less than 3 kg. Use on the leg or arm. This sensor may also be used on the forearm of an adult weighing over 40 kg.

MAX-R®. This disposable adhesive nasal sensor should be applied to adult patients weighing more than 50 kg.

MAX-FAST®. This disposable adhesive forehead sensor should be applied to patients weighing more than 40 kg.

Dura-Y® D-YS. This reusable multisite sensor can be applied to patients weighing more than 1 kg. If used with the D-YSE ear clip, the sensor can only be used on patient's weighing more than 30 kg.

Warning- Carefully read the directions for use provided with Nellcor sensors for complete description, instructions, warnings, cautions and specifications.

Caution- Use of any sensor other than the above designated OxiMax sensors, is not allowed. Such sensors may not operate normally and could lead to patient injury.

- If reusable sensors are used, the monitoring site must be checked at least once every four hours as directed.
- The Nasal OxiMax sensor cannot be reused.
- Other disposable sensors may be reused only on the same patient, and as long as the adhesive properties of the tape is not depleted.

Note: Please contact Life Systems about any accessories for use with the above mentioned sensors.

6.3 OxiMax Sensor Accuracy Specification

Sensor Models	SpO_2 Range 70%-100%
OXIMAX Sensor Models Single Patient Use	
MAX-A, *MAX-AL*	+/- 2
MAX-N[t]* (Adult)	+/- 2
MAX-N[t]* (Neonate)	+/- 3
MAX-P*	+/- 2
MAX-I*	+/- 2
MAX-FAST	+/- 2
MAX-R[‡]	+/- 3.5
OxiCliq Sensor Models Single Patient Use	
OxiCliq A	+/- 2.5
OxiCliq P	+/- 2.5
OxiCliq N[t] (Adult)	+/- 2.5
OxiCliq N[t] (Neonate)	+/- 3.5
OxiCliq I	+/- 2.5
Reusable Sensor Models	
D-YS (Infant to Adult)	+/- 3
D-YS (Neonate)	+/- 4
D-YS & D-YSE	+/- 3.5
D-YS & D-YSPD	+/- 3.5
DS-100A	+/- 3
OXI-A/N (Adult)	+/- 3
OXI-A/N (Neonate)	+/- 4
OXI-P/I	+/- 3

Accuracy Specification: Accuracy specifications are based on controlled hypoxia studies with healthy, non-smoking adult volunteers over the specified saturation SpO_2 range. Pulse oximeter SpO_2 readings were compared to SaO_2 values of drawn blood samples measured by hemoximetry. All accuracies are expressed as +/-"X"digits. This variation equals +/-one standard deviation (+/- 1 SD), which encompasses 68% of the population.

Neonatal Accuracy: When sensors are used on neonatal subjects as recommended, the specified accuracy range is increased by +/- 1 digit as compared to adult usage, to account for the theoretical effect on oximeter measurements of fetal hemoglobin in neonatal blood. For example, MAX-N accuracy on neonates is +/- 3 digits, rather than +/-2.

Oxygen saturation accuracy can be affected by certain environmental and patient physiological conditions, as discussed in the operator's manual of the monitor.

Use only Nellcor sensors with this device.

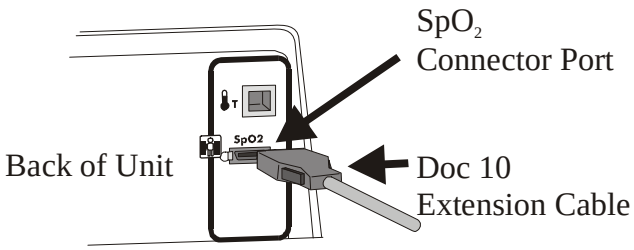
* The accuracy specification under motion conditions is +/- 3. For a definition of motion, contact Nellcor Technical Services or your local Nellcor representative.

[t] The MAX-N and the OxiCliq N were tested on patients > 40kg.

[‡] The accuracy specification has been determined between saturations of 80%-100%.

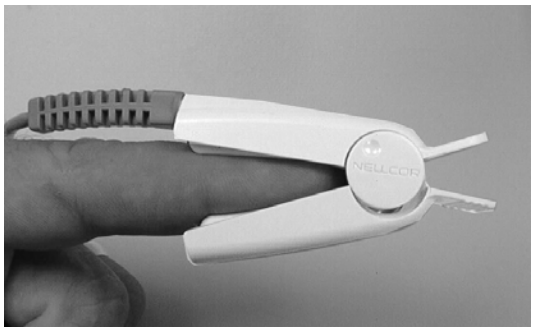
6.4 Connecting the SpO_2 Probe Cable to the Unit

Plug the extension cable into the SpO_2 connector on the rear panel of the unit and press firmly to lock it in place.



6.5 Applying the Probe Attachment

The Dura-Sensor 100A probe is for adult patients whose weight is more than 40kg.
Put the DS-100A on the forefinger, placing the finger far enough into the sensor that the nail comes in contact with the back.



Make sure that the clamping strength of the probe is not so tight that perfusion is affected.

CAUTION:

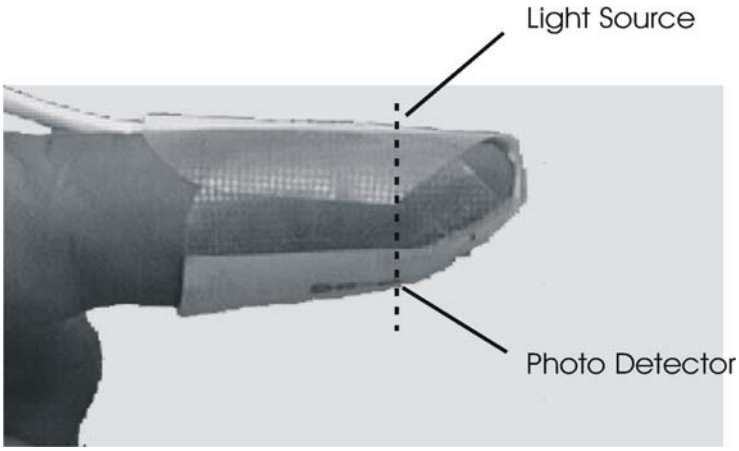
- Dura-Sensor S-100A is only for adult (more than 40Kg) fingers. This probe is only for use on the finger.
- The DS-100A is for spot check measurements only. If the probe is be used for an extended time, relocate the sensor to a different finger every 2-3 hours.
- If the finger is put into the probe too far, the tip of the finger may be compressed and may cause necrosis.
- Never use surgical tape to secure the probe in place.
- Be alert to low thermal burns on peripheral circulation disorder patients who are monitored continuously for extended periods.

6.6 Applying Disposable OxiMax Sensors

Please read the instructions attached to the OxiMax before using.

Remove the protective film on the adhesive surface of the probe. (If the OxiMax is used on the finger make sure the wire is located over the nail.)

Wrap the sensor over the finger so that the light source and the photo detector are in the same line, ensuring accurate readings are obtained.



CAUTION

- Apply to a clean, dry site.
- Avoid applying additional tape over the sensor to reduce the risk of venous pulsation and inaccurate saturation measurements as well as the potential for pressure damage at the site. Applying tape over the cable, however, may help prevent the sensor from becoming dislodged.
- Check sensor site and circulation distal to the sensor at least every 8 hours and change the sensor site as required.
- Remove the sensor carefully from the patient for use on another site.
- OxiMax sensors may be reused on the same patient if the adhesive tape attaches without slipping. Replace the sensor when its adhesive quality is depleted.

7 Printer Operation

7.1 Loading Paper into the Printer

The Rosie series monitors use an automatic paper loading system. If your unit has a printer, follow the instructions listed below to load the paper:

Verify the appropriate paper roll orientation. Only one side of the paper is printable. Use your fingernail to rub the paper; if the paper marks, the correct side is up.

1. Tear a straight line off the end of the roll to make insertion of paper easier (See Figure A).
2. Press the Power ON/OFF " ⏻ " switch, turning the power ON.
3. Open the monitor's paper door on the right side of the monitor and insert the thermal recorder paper so that the end comes from the back over the top of the roll (See Figure B).
4. Pull the paper's leading edge out 6 - 10 inches and loop it back into the printer just under the black roller. As the paper is placed just under the printer roller, the printer will automatically grab and feed the paper (See Figure C).
5. Once the paper passes the outer edge of the case, close the paper door and select a print format: The resulting printout will remove any remaining loop in the paper.

Figure A

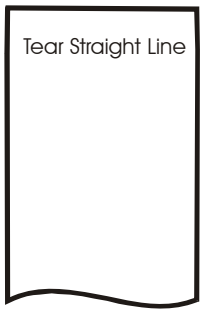


Figure B

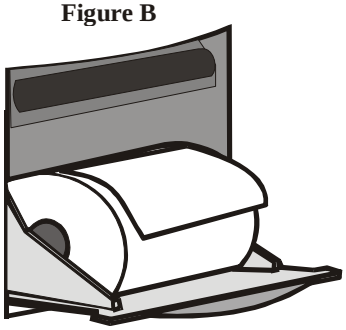


Figure C

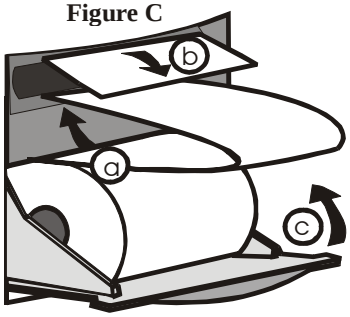
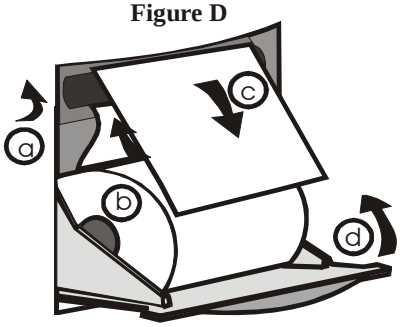


Figure D



7.2 Print Formats

7.2.1 Line List Format

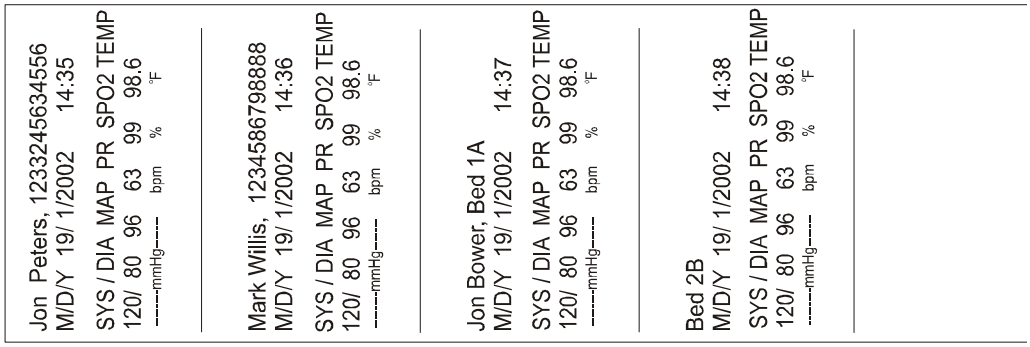
The Rosie monitor with printer will print the line list format when the “Print Patient” soft key is pressed in the “View Patient” screen and when the “Print List” soft key is pressed in the “Print” screen (refer to section 3.4).

The printed record includes the Current Date, Patient’s Name, Patient’s ID number, and vital signs information. This printout is delayed until the completion of the blood pressure measurement to allow for completion of other parameter measures that may be running concurrently. Any values causing alarm signals are shown within a box as shown below.

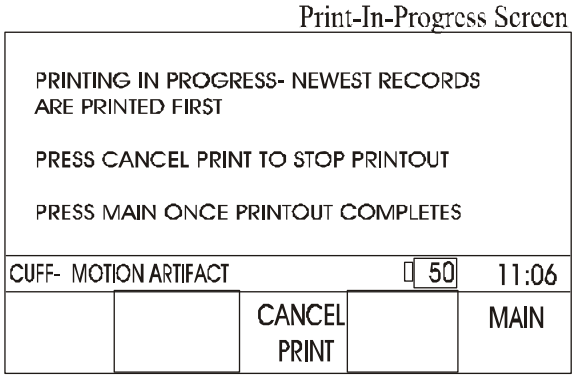
If the LCD indicates “motion” with a “?” mark next to the cuff reading or SpO_2 reading, this same indication will appear next to their corresponding values on the printout.

If the LCD indicates the monitor is in the Neonatal mode (see section 4.3.2), the notation “N” will appear next to the printed SYS value.

Below is an example of the line list printout:



Once this print is initiated, the records are printed from the most current to the oldest. To stop the printer, press the “Cancel Print” Soft Key on the “Print in Progress” screen as shown below:



Once this print is finished, the “Main” soft key must be pressed to return the screen to the Line List screen.

7.2.2 Vital Signs Format

The Rosie monitor with printer can be set to print out vital sign automatically after each measurement ("Print Options" screen, section 3.4.3). This print format is also used, when the "Print Upon Alarm" selection has been made ("Print Options" screen, section 3.4.3) and a patient alarm occurs generating the alarm condition.

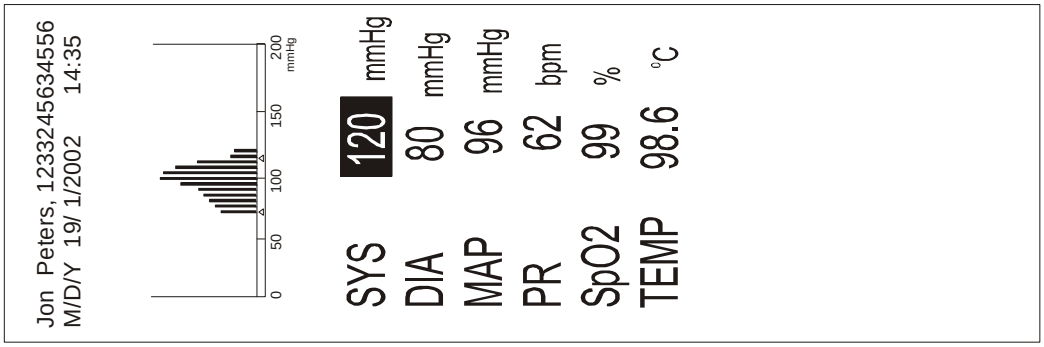
If the "Current" Soft Key is pressed in the "Print" screen (see section 3.4) a printed record will be made of the last measurement taken and stored in memory.

The printed record includes the Current Date, Patient's Name, Patient's ID number, and vital signs information. This printout is delayed until the completion of the blood pressure measurement to allow for completion of other parameter measures that may be running concurrently. Any values causing alarm signals are shown within a box as shown below.

If the LCD indicates "motion" with a "?" mark next to the cuff reading or SpO_2 reading, this same indication will appear next to their corresponding values on the printout.

If the BP Mode is set to neonatal, the indication of "N" will appear next to the SYS printed value.

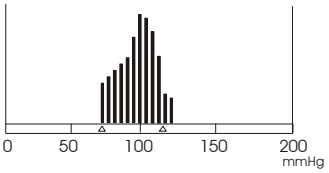
Below is an example of the vital signs print:



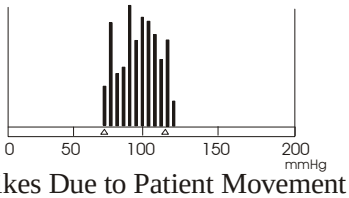
Tearing off the Printout- For best results, the operator should pull the strip UP and TOWARD or UP and AWAY from themselves--.

7.3 Using the Printed Oscillometric Profile

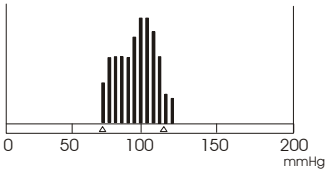
When a vital signs printout is recorded, the printout includes the oscillometric profile. A Normal oscillometric profile is a bell shaped curve and variances from this shape indicate possible problems with the measurement's accuracy:



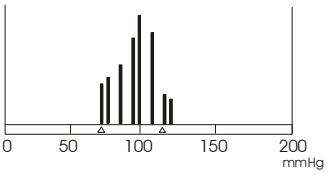
Normal



Spikes Due to Patient Movement



Plateau due to Patient Movement



Missing Oscillations Due to Arrhythmia or Patient Movement

8 Rosie Troubleshooting

8.1 Troubleshooting Guide

Warning-
Should the monitor fail for any reason, follow the procedures below immediately.

1. Check the patient's condition.
2. Read this "Troubleshooting" section to search for the problem and possible solutions.
3. If the problem remains unsolved:
   a. Remove the cuff and or probe from the patient.
   b. Turn the power OFF and, if plugged into an AC source, unplug the monitor.
   c. Indicate with a sign "Out of Order, Do not use."
   d. Contact the appropriate personnel for service.

When the unit does not operate properly, please check the following troubleshooting guidelines before consulting Life Systems Technical Service Dept at 800-841-1109. This Guide has been written in an order from most common to least common problem.

8.2 Problems with the Monitor *(Verify against Error Messages for further information)*

Cannot turn power ON to the monitor, Display is blank	
Cause	Solution
Cord is unplugged or loose Cord. Or damaged:	Check the power input cord connections. Verify AC power through AC *When this problem occurs, the user will not see the charging LED lit.*
Battery is discharged:	Plug the monitor into a hospital-grade AC power outlet and recharge the battery for at least 10 minutes. Then turn ON again.
Internal AC Fuse is bad:	The AC/DC converter has auto-resetting fuses that can be reset by removing AC power for 30 sec.
Battery Fuse is bad:	If the unit operates on AC power, but will not function on battery power, the 5A fuse on the battery may be blown. Remove battery from bottom of unit, check fuse.
Technicians only:	
Internal AC Fuse is bad:	The AC/DC converter has auto-resetting fuses that can be reset by removing AC power for 30 sec. IF the problem still exists, open left side *(printer)* of monitor and check and replace defective fuse on the AC input connector. 250V 2A
Sheet Switch is defective:	Before replacing, check if sheet switch connector (bottom) is connected to main board appropriately. Verify pin 2 is pulled low as the power button is pressed, if it is pulled low the sheet switch is OK.
AC/DC Power supply is	Disconnect the DC power supply wires from the main board, with AC applied, 7-defective: 8V DC should be found, if not, replace power supply.
Main Board is defective:	Replace the main board.

Cannot turn ON power to the monitor, Displays comes on, and Power cycles	
Cause	Solution
Battery is defective:	Allow battery to Charge for a period of 10 minutes. Then turn ON again. Verify battery voltage is above 6.0 V as power cycles.
Technicians only:	
Main Board is defective:	Replace with known good board.

The unit overheats	
Cause	Solution
The unit will normally get warm as it charges a fully depleted battery. It will normally start to cool down after 2 hours of charging.	
Airflow to the Monitor is impeded:	Move the monitor or remove objects that are too close to it.
Technicians only:	
Battery is defective:	If after charging for several hours the unit remains hot, especially the battery on the bottom of the unit, replace the battery.

Battery Power does not last	
Cause	Solution
The unit has been designed to provide a minimum of 4 hours of battery power with spot check measurements taken every 15 minutes. Life Systems *recommends the battery be replaced at least once a year to maintain sufficient battery power.*	
Technicians only:	
Battery is defective:	Replace Battery
Main Board is defective:	Replace Main Board. The main board determines the remaining battery power and if the AD converter has failed the board can notify the user of a depleted battery with sufficient power still exists.

Monitor does not respond to button press	
Cause	Solution
Verify that the unit is not functioning, clinicians sometimes call trying to operate the unit in a manner that the device was not intended to operate.	
Technicians only:	
Sheet Switch connector	Reconnect Sheet Switch connector to main board and verify appropriate Connection
Sheet Switch is defective:	Verify the appropriate, pins are pulled low as the buttons are pressed, if not, replace sheet switch.
Main board is defective:	Replace the main board.

Unit forgets settings and continuously says "Factory Defaults"	
Cause	Solution
The message "SYS-Factory Defaults" are only shown on the screen the first time the unit is powered up after the Factory Defaults have been initiated. If the unit senses the saved memory has become corrupt, the unit will initiate a Factory Default.	
Technicians only:	
Clock Battery Defective	Replace Clock battery
Main Board is defective:	Verify Solder of U2, U3, U18 and other components. Replace main board.

Display is not complete or missing segments	
Cause	Solution
Model # Wrong	Verify selection of Model configuration in the Service Menu
Technicians only:	
VR1 setting	Adjust VR1 so that contrast of LCD is acceptable
LCD Defective	Replace LCD
LED Defective	Replace LED or main board as required
Main Board is defective:	Replace main board

Display shows Garbage while unit off and charging	
Cause	Solution
Technicians only:	
LCD Defective	Replace LCD

Speaker Volume is not appropriate	
Cause	Solution
Settings of Volume In System Screen:	Verify user selects the appropriate volume selections in the SYSTEM configuration screen.
Technicians only:	
VR2 settings:	Adjust VR2 on the top of the main board, so that the volume becomes acceptable.
Speaker defective or disconnected:	Check connections to speaker or replace speaker.
Main Board is defective:	Replace main board

8.3 Problems with Printer

Paper Jams	
Cause	Solution
If a paper jam occurs: turn off unit, remove AC power, lift up the platen release lever on the left side of the printer, and slowly pull on the paper to remove it from the printer.	
Incorrect width paper:	Verify that the paper is Colin paper, users have a tendency to use whatever paper they find, if too wide or narrow paper is used, the printer can jam.
Paper inserted wrong:	If the paper is inserted into printer at a harsh angle to the front or back, the printer can jam.
Technicians only:	
Alignment of printer:	Verify that the printer bracket is placed up against the paper door spindles. Once the bracket is in the appropriate position, tighten the two screws on the bottom of the unit to retain the bracket position.

Printer Does Not Print	
Cause	Solution
A paper Jam Occurred:	Turn off unit, remove AC power, lift up the platen release lever on the left side of the printer, and slowly pull on the paper to remove it from the printer. As power is again turned on, the printer will reset, allowing printing to continue.
Model # Wrong	Verify selection of Model configuration in the Service Menu
Incorrect paper:	Verify that the paper is Colin paper, users have a tendency to use whatever paper they find. Verify paper comes off the roll in the back of the paper door.
Non-Thermal paper:	If the paper is not thermal paper, it will not print. Touch the paper with an alcohol wipe, and the paper ink should come to the surface, if no ink appears, get the appropriate paper.
Technicians only:	
Cable disconnect:	Verify the interface cables connecting the printer are connected on both ends firmly.
Printer Defective:	Replace printer
Main Board Defective:	Replace Main Board

8.4 Problems with NIBP (Verify against Error Messages for further information)

LED's don't change from "888" to "- - -"	
Cause	Solution
Incorrect Model setting	Have BioMed/Technician reset the correct Model Number in the Service Mode.

Cuff does not inflate	
Cause	Solution
Faulty cuff hose connection:	Check all connections and check hoses for damage or leaks.
Leak in the cuff:	Check and replace if faulty.
Cuff Mode selection:	If the Mode selection in the Cuff Configuration Screen is inappropriate for the patient's cuff being used, the unit will not inflate the cuff, and alarm.
Cuff Hose kinked:	Verify the cuff hose is not kinked or occluded.
Technicians only:	
Sheet Switch is defective:	Verify that the Cuff LED is lit as the Cuff Start/Stop button is pressed.
Module hose is disconnected or defective:	Connect internal hose, or replace.
Module cable has become disconnected:	Check connections of NIBP module cable.
Module is defective:	Replace NIBP module.
Main Board is defective:	If any of the DC power lines to the NIBP module are not present, replace the main board.

NIBP Initializing Message shown	
Cause	Solution
Loss of communication:	Cycle power OFF, wait ten seconds, and then power back ON and see if message clears.
Technicians only:	
Module cable has become disconnected:	Check connections of NIBP module cable.
Module is defective:	Replace NIBP module.
Main Board is defective:	If any of the DC voltages to the NIBP module are not present, replace the main board.

Abnormal readings	
Cause	Solution
If the machine feels that the NIBP measurement could have been influenced by motion, vibrations, or arrhythmia, a "?" is placed to the left of the measurement values shown on the LCD.	
Vibrations such as shivering, Arrhythmia or noises including bodily contact or motion, or Cardiac massage during a measurement:	Please assess the patient's condition, then start the measurement again.
Cuff placement or positioning:	Verify the appropriate cuff is selected for the patient. Apply the cuff as specified in the Operations Manual.
To verify a suspect measurement value, initiate another measurement, placing your stethoscope under the cuff and watching the cuff pressure shown in the MAP display. The clinician's measured values fall normally within 5 mmHg of the monitor's displayed values at the measurements completion.	
Technicians only:	
Extreme leak in unit or cuff:	Verify location of leak. Replace defective connectors, hoses, or modules as needed to correct leak. Use the appropriate Service Mode tests to locate leaks.
NIBP Module is defective:	Replace NIBP module.

Unreliable NIBP readings	
Cause	Solution
Cuff Placement and Positioning:	Verify appropriate cuff placement and positioning as indicated in Operation Manual
Cuff/limb is not at Heart Level:	Verify and place cuff/limb at patient's heart level.
Unstable blood pressure:	Verify patient for reciprocal pulsations or respiratory alterations.
Patient Movement or Anxiousness:	Check for patient movement or anxious state (nervous movements).

8.5 Problems with E-Temp (Verify against Error Messages for further information)

No temperature measurement	
Cause	Solution
Model # Wrong	Verify selection of Model configuration in the Service Menu
Disconnected probe or cable:	Connect probe or change, if defective.
Probe out of well on power-up:	Insert probe into probe well, try measurement again.
Defective Probe:	If "Temp- Probe Disconnected" message is shown, this normally indicates a defective probe. Replace probe, and place new probe into, and out, and back into probe well to reset message.
Technicians only:	
Temp Cable disconnected:	If unit was dropped or disassembled, verify the cables are connected to the temperature module.
Main Board is defective:	Replace main board.

"Temp- Internal Error" shown	
Cause	Solution
Defective Probe:	If this message is shown, this normally indicates a defective probe. Replace probe, and place new probe into, and out, and back into probe well to reset message.
Technicians only:	
Temp Cable disconnected:	If unit was dropped or disassembled, verify the cables are connected to the temperature module.
Main Board is defective:	Replace main board.

Temperature reading unreasonable	
Cause	Solution
Normally if one of the problems is the cause the user will also notice, slow temperature measurement times as well as the tissue contact "pinwheel" interrupting its spin.	
Patient's mouth was open:	Ask patient to keep mouth closed during measurement.
Improper probe placement:	Verify placement of probe as shown in the manual. Unlike slower temperature measurement techniques, this fast measurement requires the user to make sure the probe is placed directly against the sublingual artery in the back, center of the tongue.

Parameter LED's don't change from "888" to "- - -"	
Cause	Solution
Incorrect Model setting	Have BioMed/Technician reset the correct Model Number in the Service Mode.

8.6 Problems with Pulse Oximetry *(Verify against Error Messages for further information)*

Measurements are not displayed	
Cause	Solution: Address each condition according to facility protocol
Model # Wrong	Verify selection of Model configuration in the Service Menu
Perfusion has reduced:	Verify appropriate perfusion of sensor site.
Strong ambient light:	Drape the sensor site to shield it from light source.
Probe or Cable are defective:	Replace and retest.
Technicians only:	
SpO_2 Interface cable is defective:	Replace cable and retest
SpO_2 Module is defective:	Replace SpO_2 module
Main Board is defective:	Replace Main Board

Unable to measure	
Cause	Solution
Assess patient condition:	Patient may have peripheral circulatory dysfunction caused by shock, hypotension or arterial infarction of the probe area.
Sensor Type:	The unit is designed to work with Nellcor OXIMAX sensors only.
Sensor placement:	Verify appropriate positioning and placement of sensor.
Sensor is too tight:	Loosen sensor on site.
Sensor on same arm as Cuff:	Move sensor to the other arm.
Sensor placed on same arm as I-V or A-line:	Choose another sensor site.

Readings are unreliable	
Cause	Solution: (Address each condition according to facility protocol)
Other pulsations exist:	Blood alterations other than normal, including cardiac massage, external noise, vein pulsations, and convulsions may cause fault in readings.
Probe applications:	Verify appropriate probe selection and placement for patient.
Carbon-Monoxide:	This pulse oximeter has no capability to identify hemoglobin such as carbon-monoxy hemoglobin or methemoglobin, which cause functional damage. Therefore, faulty readings may result when measuring Carbon-Monoxide intoxicated patients, or patients who are heavy smokers. Consult Blood Gas.
Reagent Chromocyte:	Readings may have been influenced by the presence of reagent chromocytes such as indosian-green and methyene-blue (when heavily concentrated in the artery). Check patient condition, and past procedures.
Ambient Light:	Shield the sensor from the light.

No SpO_2 measurement	
Cause	Solution: (Address each condition according to facility protocol)
Perfusion has declined:	Verify appropriate perfusion of sensor site.
Strong ambient light:	Drape the sensor site to shield it from light source.
Probe or Cable is defective:	Replace and retest.

SpO_2 Internal Error	
Cause	Solution: (Address each condition according to facility protocol)
SpO_2 Probe or Cable is defective:	Replace and retest. Contact Life Systems Technical Support

8.7 Errors and Other Messages Shown in Message Window

Monitor Related Messages		
Message Shown	Description	Action Required
"SYSM: BATTERY LOW"	Battery is below 20% power capacity.	Connect monitor to suitable AC power outlet.
"SYSM: BATTERY EMPTY"	Battery is empty	Connect unit to suitable AC outlet before monitor turns off.
"SYSM: INTERNAL FAILURE"	Monitor failure.	Contact Life Systems Technical Services.
"SYSM: CHECK CLOCK"	RTC potential problem	Reset Time through System Setting Screen.
"SYSM: BATTERY NEAR EMPTY"	Battery below 10%	Charge battery
"SYSM: BATTERY TEMPERATURE"	Internal Temperature > 50^{o} C	Cool down unit, Replacement battery is needed.
"SYSM: FACTORY DEFAULTS"	System returned to factory default settings	None if user selected factory defaults. If monitor shows this indication frequently replace main board.
"SYSM: FAILURE xxxx"	ROM Check Sum error	Replace Main Board

Printer Related Messages		
Message Shown	Description	Action Required
"PRNT: CHECK PRINTER"	Printer platen UP	Lower printer platen
"PRNT: PAPER EMPTY"	Printer paper empty.	Insert a full roll of printer paper.
"PRNT: INTERNAL ERROR"	Printer Failure.	Remove any obstacles from printer, including paper jams, reset power. Replace main board or printer as required.

E-Temp Related Messages		
Message Shown	Description	Action Required
"TEMP: PROBE FAILURE"	Defective E-Temp Probe.	Cycle power of unit ON and OFF; if failure continues, replace probe.
"TEMP: PROBE DISCONNECT"	E-Temp Probe is disconnected or defective.	Check connections and hose, replace if necessary.
"TEMP: INTERNAL ERROR"	E-Temp Module Failure.	Contact Life Systems Technical Services.

NIBP Related Messages		
Message Shown	Description	Action Required
“NIBP: CHECK FOR LEAKS”	Pressure in cuff did not reach specified value within 30 sec. (within 10 sec. for neonatal modes).	Check cuff and hose connections for air leaks.
“NIBP: CHECK CUFF/PATIENT”	Pressure dropped to 10 mmHg without completing a measurement.	Check cuff position and placement; verify no patient movement occurred.
“NIBP: MOTION ARTIFACT”	Air was not discharged for 15 sec. because of patient movement.	Check for patient movement or presence of arrhythmia.
“NIBP: RE-INFLATION”	Cuff pressure did not exceed arterial occlusion and cuff will inflate again.	Automatic re-inflation of cuff pressure; no action required.
“NIBP: IRREGULAR PULSE”	Abnormal oscillometric waveform.	Check for patient movement or presence of arrhythmia.
“NIBP: WEAK PULSE”	Impossible to measure BP because of arrhythmia, patient movement, or the pulse signal was too weak; a measurement retry will occur.	Check for patient movement or presence of arrhythmia. Verify appropriate cuff is used and applied correctly.
“NIBP: TIMEOUT”	Measurement took over 160 seconds or more than 160 heartbeats measured during cuff deflation.	Check for extreme patient movement or obstruction of air discharge.
“NIBP: OVERPRESSURE”	Cuff pressure rose above 325 mmHg.	Check cuff placement or kink in cuff or cuff hose
“NIBP: CHECK CUFF SIZE”	Neonatal cuff used in Adult Mode.	Verify and correct measurement mode and cuff/hose selections.
“NIBP: INITIALIZING”	Possible NIBP Module problem found.	System is trying to verify problem. No user action required
“NIBP: INTERNAL FAILURE”	NIBP Module Failure.	Contact Life Systems Technical Services.
“NIBP: PROGRAM IN PROGRESS”	NIBP: Interval program is running.	User will get this message if they are attempting to change from Neonate to Adult while a interval program is running. Stop interval program, then change modes.

SPO_2 Related Messages		
Message Shown	Description	Action Required
"SPO2: NO SENSOR"	Loss of Probe Signal.	Verify attachment of sensor to extension cable (EC-8) and to patient finger.
"SPO2: NO SIGNAL"	Patient perfusion too weak.	Check placement of sensor and if polish is on finger. Remove polish and reapply sensor.
"SPO2: MOTION ARTIFACT"	Patient movement too strong.	Check placement of sensor.
"SPO2: INTERNAL FAILURE"	SpO_2 Module Failure.	Contact Life Systems Technical Services.

8.8 Rosie Error Log Codes

I. General Service Log Format –

A. General Overview

The Rosie stores all warning/fatal alarms into its service log. The service log allows up to 99 entries within its buffer. If more than 99 entries are present, the buffer will wrap, thus overwriting the oldest entries with new entries as they occur.

B. Format:

Time- Module – Error Code – *Addition (if applicable)

Char. Length: 8 4 2-4 (0-7)

Example: 12/12/00SPO2TIME

*Note: Any information sent from the modules explaining the error will be added in this area. It is up to the user to read the appropriate module specification to understand what the additional info references.

C. Format Definitions:

Note: When a module sends over an error code that is not defined by the Rosie, it will store that error for troubleshooting purposes, though the user must consult the respective module specification document to translate the error.

Time format:	Modules:	Error Code	Def:
MM/DD/YY	SYSM-	M2	Warning – Battery near empty
		M3	Fatal – Battery Empty
		M5	Warning – Run Time Clock Error
		M10	Fatal – RAM/ROM error
		M11	Warning – Factory Defaults reset

	M13	Fatal – System Overheat
	M14	Fatal - System Overheat
NIBP-	TIME	Warning – Comm. Timeout
	E09	Warning – M2600 E09 error
	E08	Warning – M2600 E08 error
	E07	Warning – M2600 E07 error
	NR3	Warning – No read after 3 tries
	(other)	Warning – (check M2600 spec.)
SPO2-	TIME	Warning – Comm. Timeout
	S03	Warning – No Sensor Detected
	S04	Warning – Monitoring No Signal
	(other)	Warning – (check SpO2 spec)
TEMP-	TIME	Warning – Comm. Timeout
	TA6	Warning – Probe Failure
	TA7	Warning – Probe Disconnect
	(other)	Warning – (check Temp spec)
PRNT-	P02	Warning – Plat is up
	P03	Warning – Paper empty
	(other)	Warning – (check Printer spec)

P00 Warning – Communication Timeout

9 General Maintenance

This manual describes and supports all of the monitors in the Rosie series by discussing the fully configured model (model 2240P) that includes NIBP, Pulse, Pulse Oximetry, temperature, and printer. It may, therefore, present information that does not apply to your monitor.

9.1 Battery Care and Replacement

The battery of the monitor may be recharged at any time by connecting the monitor's power cord to a properly grounded 3-wire hospital grade AC power source. The battery indicator on the front of the monitor will light indicating the charging state of the battery. The battery may require up to four to six hours to bring the charge from a completely discharged state to above 90% of capacity.

As the unit charges and the battery's power increases, the charge indicator shows the status of the battery charge whenever the unit is plugged into AC power. A RED light signals a battery charge below 90% and a GREEN light indicates the battery is fully charged and ready to use. When the monitor is ON, and AC is removed, the Battery Indicator located in the lower right quadrant of the "Line List" or Main Screen on the LCD also indicates current battery power levels.
NOTE: If the battery is fully charged, and the unit is unplugged and plugged back into AC power, the charging cycle starts over again and the light turns to RED. This is normal.

Life Systems recommends that when the monitor is stationary, it be connected to an appropriate AC power supply to help ensure maximum battery power accessibility and life.

The battery is accessible from the bottom of the unit and should only be replaced by qualified personnel. Life Systems recommends this battery be replaced once every two years to guarantee optimum battery life. Replaced batteries should be disposed of in a manner acceptable by local and national recommendations.

9.2 Internal Fuse Replacement

The monitor is protected by three fuses. Two of the fuses are located (internal to the monitor) on the line and neutral of the AC Inlet and should only be inspected and replaced by qualified personnel with 250V 2A fast acting fuses. The third fuse is a 5 A fast acting fuse located on the internal battery harness.

9.3 Cleaning

9.3.1 Monitors

The exterior of the monitor should be wiped clean with a cloth slightly dampened with mild soap* and water solution or ammoniated window cleaner. Do not apply large amounts of liquid. The monitor front panel should be cleaned carefully to prevent scratches to the displays. Dust and dirt particles can be blown off or brushed off using a soft brush. Fingerprints and stains may be removed by using a liquid lens cleaner and soft cloth.

- Do **not** immerse the device.
- Do **not** clean with abrasive cleaning agents, isopropyl alcohol or other solvents.

9.3.2 Pulse Oximetry Sensors and Cables

Use a cloth slightly dampened with a mild soap and water solution or other acceptable solution* to clean the sensor surface before and after each patient use. Then wipe the sensor with a soft dry cloth to ensure all detergent residues have been removed.

*Acceptable Cleaners:

Dishwashing detergents, i.e., Ivory, Joy (Procter and Gamble Corp.); Palmolive (Colgate-Palmolive Corp.).

Chlorine bleach (5.25%; 0.75 cup/gal.)

Germicidal detergents, i.e., Hi-Tor Plus (Huntington Corp.)

9.3.3 Reusable Cuffs

Neonatal cuffs and all other disposable cuffs are supplied for single patient use and should be discarded if they become soiled. For all other cuffs:

Remove the bladder from the cuff. All parts of the cuff and bladder can be cleaned with an alcohol wipe or a damp cloth, or they may be disinfected with an EPA registered low level disinfectant wipe/spray**. Care should be exercised to ensure that no fluid enters the cuff hose at any time. If immersion is necessary, insert cuff hose caps into the ends. Should water enter the cuff hose, the hose may be dried by passing air through it. A more thorough hand washing of the cuff will enhance the service life. After removing the bladder, hand wash the cuff in warm, soapy water; then rinse thoroughly. Allow the cuff to air dry, and then reinsert the bladder. If machine washing, be sure that the hook and loop fasteners are engaged so that the hooks do not collect lint or other fibers. If ironing or pressing the cuff, ensure that the temperature does not exceed 325^{o}F (162^{o}C).

The cuff may be sterilized by exposure to EtO.*** Since the cuff is used as an external accessory only, the desired sterility assurance level (SAL) of 10^{-3} should be achieved. Due to variations in hospital sterilizing technique, precise instructions cannot be given; however, maximum exposure and aeration times should be employed. Care should be taken to allow ventilation of EtO residuals prior to use of the cuff. Acceptable methods for determining sterilizer effectiveness should be used, such as biological indicators. For further information regarding sterilization procedures with your unit, contact the sterilizer manufacturer.

**i.e., Virahol®, Veridien Corporation, St. Petersburg, FL.

9.3.4 Temperature Probes and Cables

Caution: Observe the following precautions when cleaning and sterilizing probes, as improper handling easily damages them.

Avoid contact with strong, aromatic, chlorinated, keytone, ether or ester solvents. Prolonged immersion in alcohol or mild organic solvents, detergent solutions or highly alkaline solutions cause the vinyl cable covers to lose flexibility.

During cleaning or sterilization, probes should be handled gently. When wiping clean, hold the probe at the sensing tip and wipe the probe and lead wire toward the plug. Excessive pressure can stretch the covering and break the internal wires, destroying the probe. Continued flexing of lead wires during use and cleaning can also break the internal wires. Failure from this cause is not covered by the warranty. Disinfection: Probes may be disinfected and sanitized by washing with 3% hydrogen peroxide or an EPA registered disinfectant containing isopropanol (i.e., Veridien Corporation's Virahol®). Dakin's solution (sodium hypochlorite in neutral buffer) is also suitable. Brief immersion of the probe in detergent solutions is not harmful, and is recommended before disinfection if soiled material is noted on the probe. Activated dialdehyde solutions are also effective. Probe plugs should not be immersed.

Sterilization: Ethylene oxide (EtO***) sterilization is the preferred method. After sterilization, probes must be safely and thoroughly ventilated before handling.

Storage and Handling: Handle all probes and cables with care. When not in use, probes and leads should be formed into loose loops. If wires are stretched or wrapped tightly around instrument cases, stresses sufficient to cause mechanical failure may occur. Store probes at temperature below 50°C, preferably at room temperature.

***Recommended EtO cycle:

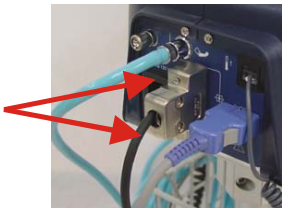
Temperature	Humidity	Gas Concentration	Exposure	Aeration Cycle
$125^{o}F \pm 5^{o}F$	50%	650 mg/liter	2 hrs	24hrs

Rosie II

Barcode Scanner Instructions

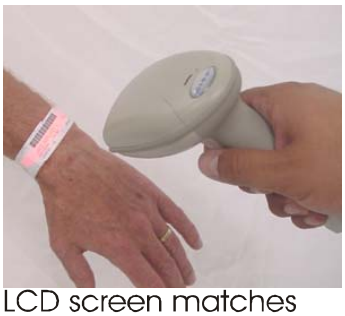
Mounting and integrating the scanner:

Connect the bar code scanner interface cable to the back of the Rosie Monitor on the IO connector. Secure the cable in place by tightening the top and bottom retaining screws in the connector.



Attach the scanner's mounting arm to the Rosie stand just below the unit so that the scanner is held to one side of the unit. Tighten the arm's mount by tightening the two allen bolts with the appropriate wrench.

Attach the enclosed "Reset Bar Code Reader" label to the scanner's mounting arm for easy access when needed. This label can be used to reset the scanner when it appears the scanner is no longer reading the patient's bar code correctly.



Scanning a patient's ID:

At this point you can use the scanner to read the patient's Identification bar code. Turn the unit on: once the Self-Test is complete, simply pull the scanner's trigger and, with the scanner approximately six (6) inches from the patient's wrist, aim the red scanning light at the patient's bar code. As the unit "Beeps", the ID code is recorded into the monitor's memory. Verify that the ID displayed on the monitor's LCD screen matches that on the patient's wrist, then press the "Save->Main" soft key. Now you can begin measuring the patient's vitals signs which will be recorded into memory identified by the patient's ID.

If the scanner will not read the patient's ID, slowly move the scanner away from the bar code, starting at a distance of 3 inches, moving away to a distance of 12 inches. If the scanner still does not read the bar code, verify that the bar code is not damaged, then scan the "Reset Bar Code Reader" bar code presented below, and try again.

Scan for John Doe Demonstration ID:

Demo- John Doe-ABCD24680-

Scan to Reset Bar Code Reader:

Scanner Reset

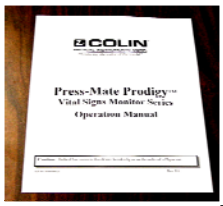
11 Supplies and Accessories

11.1 Ordering Information

Contact Life Systems Customer Service Department for information, part numbers, and pricing of the following accessories:

Power Cord

Printer Paper



Operation Manual

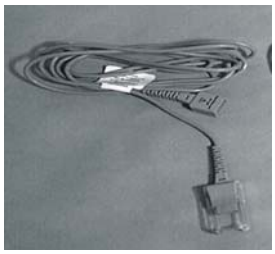
Disposable Cuffs

Reusable Cuffs

Cuff Hose

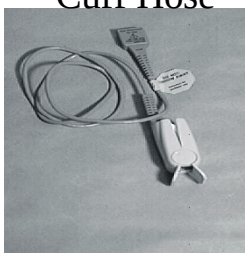
Probe Covers

Neonatal Cuff Hose



Doc 10 Extension

Service Manual



DS100 A Finger Probe

Patient ID Bar Code Scanner

12 Rosie Specifications

12.1 Monitor and Display Specifications

Monitor:

Protection Type:	Class I / Internal Power device
Dimension:	240 (W) x 238 (H) x 250 (D) mm
Weight:	Approx. 8.5 lbs (including internal battery)
Power Supply:	AC 100 V ~ 120 V, 220V ~ 240V, 50/60 Hz
Power Consumption:	Max 180VA/AC; Max 40W/Battery
Internal Battery:	6V 5Ah Sealed Tin-Acid Battery Charge Time: Full in 4 hours
Battery Usage Life:	6 hours with cuff interval taken once every 15 min.

This device is rated for Continuous Operation as per IEC 601-1, clause 5.6 regulations.

Environment-
Operation:

Temperature	32~104F (0~40C)
Humidity	30~85% (non-condensing)
Atmospheric Pressure	700-1060hPa

Shipping and Storage

Temperature	-4 ~ 140F (-20~60C)
Humidity	10~95% (non-condensing)
Atmospheric Pressure	500~1060hPa

This device is rated as Drip-Proof as per IEC 601-1, clause 5.3 regulations.

Display-

Type:	backlit monocolor LCD, and LED
Size:	3” (H) x 4.5” (W)
Resolution:	240 x 128 dots

Configuration-

Rosie II-1	NIBP only
Rosie II-1P	NIBP with Printer
Rosie II-2	NIBP + Nellcor Pulse Oximetry
Rosie II-2P	NIBP + Nellcor Pulse Oximetry with Printer
Rosie II-3	NIBP + E-Temp
Rosie II-3P	NIBP + E-Temp with Printer
Rosie II-4	NIBP + Nellcor SpO_2 + E-Temp
Rosie II-4P	NIBP + Nellcor SpO_2 + E-Temp + Printer

12.2 NIBP Specifications

Measurement Method:	Oscillometric		
Deflation Method:	Dynamic Linear Deflation		
Pressure Detection:	Semiconductor Pressure Sensor		
Inflation Method:	DC Rolling Diaphragm Pump		
Pressure Display Range:	0 ~ 300 mmHg		
Pressure Accuracy:	± 1 %, less than ± 3 mmHg		
Pulse Accuracy:	± 2 %, or ± 2 bpm		
Measurement Accuracy:	Meets or exceeds AAMI SP-10		
Measurement Range:		Adult/Pediatric Mode	Neonate Mode
	Systolic	60 – 250 mmHg	40 – 120 mmHg
	MAP	45 – 235 mmHg	30 – 100 mmHg
	Diastolic	40 – 200 mmHg	20 – 90 mmHg
	Pulse	40 – 200 bpm	40 – 240 bpm
Shock Protection:	Type BF (Defibrillator Protected)		

12.3 SpO_2 Specifications

Method:	2 wave length pulse wave type
SpO_2 Display Range:	0 ~ 100%
SpO_2 Accuracy:	Refer to Sensor Manual of each sensor D-25 Disposable sensor (adult) 70 ~ 100% +/- 2 digits 0 ~ 69% Unspecified N-25 Disposable sensor (NEO) 70 ~ 100% +/- 3 digits% Other ranges - no accuracy statement
PR Display Range:	20 ~ 250 bpm
PR Accuracy:	+/- 3 bpm
Shock Protection:	Type BF (Defibrillator Protected)

12.4 E-Temp Specifications

Method:	Turbo*Temp™ Electronic Predictive Thermometer
Probe Types:	Oral - # 2887A; Rectal - #2888A
Modes:	Predictive- Measurement complete within 7 seconds of tissue contact Monitoring- Continuous temperature measurement
Display Resol:	+/-0.1 ^{o}C or +/- 0.2 ^{o}F
Display Range:	Predictive Mode 35.0 ~ 41.1 ^{o}C; 95 ~ 106 ^{o}F Monitoring Mode 26.7 ~ 42.2 ^{o}C; 80 ~ 107.9 ^{o}F
Accuracy:	(When tested with the thermometer in the Monitoring Mode and using the oral probe (Alaris PN 2887A) in a calibrated water bath); +/-0.1 ^{o}C or +/- 0.2 ^{o}F
Scale:	Selectable from ^{o}C to ^{o}F
Protection Type:	Type BF (Defibrillator Protected)

12.5 Recorder Specifications

Method:	Thermal Array Recorder
Resolution:	8 dots/mm
Paper Width:	58mm (54mm printable)

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