

SmartArm™
Non-Invasive Blood Pressure
Simulator

Operation Manual

Notices

The **SmartArm** is protected by U.S. Patent 5,027,641.

MAGNETIC MEDIA CAUTION: A strong magnetic field exists at the left rear of the **SmartArm** chassis. Please avoid placing magnetically-sensitive materials, such as computer diskettes, in this vicinity.

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Warranty

Clinical Dynamics Corporation ("Clinical Dynamics") warrants to the purchaser that the **SmartArm Non-Invasive Blood Pressure Simulator** shall be free from defects in material and workmanship for a period of one year from the date of purchase. Clinical Dynamics' sole obligation with respect to any such defect is limited to the repair with new or remanufactured parts, or at Clinical Dynamics' option, replacement of the **SmartArm**, or refund of the purchase price.

This warranty is made on the condition that prompt notification of a defect is given to Clinical Dynamics within the warranty period. Clinical Dynamics shall have the sole right to determine whether a defect exists.

This warranty extends to the original purchaser only. This warranty does not apply to a **SmartArm NIBP Simulator** that has been altered, subjected to misuse, negligence, unauthorized repair, or accident, or operated other than in accordance with the instructions.

This warranty represents the exclusive obligation of Clinical Dynamics and the exclusive remedy of the purchaser regarding defects in a **SmartArm NIBP Simulator**. *This warranty is given in lieu of any expressed or implied warranties, including the warranty of merchantability or fitness for a particular purpose, which warranties are disclaimed. No person is authorized to modify, in any manner, Clinical Dynamics' obligation described above.*

Clinical Dynamics shall not, in any case, be liable for special, incidental or consequential damages arising from breach of warranty, breach of contract, negligence or any other legal theory.

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Section 1. Introduction

General

The **SmartArm** Non-Invasive Blood Pressure (NIBP) Simulator has two patient simulation modes. The first BP Test mode is the Virtual Patient mode. Because there are patient induced artifacts, this mode is used to supply the monitor under test with the most stable and repeatable waveforms available.

The second BP Test mode is the Real (Clinical) Patient mode. This mode is designed to reproduce the oscillometric pressure pulses of a variety of actual patients. Patient data has been stored in the **SmartArm** allowing it to generate *physiologically correct* waveforms. The use of physiologically correct waveforms guarantees accurate testing of all oscillometric blood pressure monitors from any manufacturer now and in the future. The other distinguishing feature of the **SmartArm** is the use of a patented closed-loop pulse controller that ensures precision pulse amplitudes.

In addition to these accuracy-enhancing features, the **SmartArm** incorporates a high-resolution graphic display, internal battery, built-in cuff supports and a compact, lightweight enclosure. It also provides a leak testing mode, an overpressure testing mode and a digital manometer.

Intended Audience

This Operation Manual is intended for end users of the **SmartArm** NIBP Simulator. It contains installation and operation instructions, applications notes, performance limitations and routine performance verification procedures. *To achieve satisfactory results, it is imperative that the operator read this manual thoroughly before attempting to use the Simulator.*

Documentation Comments

Clinical Dynamics has attempted to present all information clearly and error-free as possible. However, if you detect any errors or omissions, or wish to suggest improvements to the manual, please complete the Documentation Comments form located at the back of this manual. Mail or fax the form to

Clinical Dynamics Corporation
Marketing Department
12 Beaumont Road
Wallingford, CT 06492

Fax: (203) 269-3402

Related Publications

The Operation Manual provides information for routine maintenance and calibration of the **SmartArm**. For major repair or parts replacement, please refer to the *SmartArm Non-Invasive Blood Pressure Simulator Service Manual*. The Service Manual is intended for qualified service personnel only.

Section 2. Product Description

Overview

The **SmartArm Non-Invasive Blood Pressure (NIBP) Simulator** is a state-of-the-art instrument designed to provide accurate, reliable and ergonomic performance. The following list presents some of the more salient features of the **SmartArm**.

- Standardized, scientific procedure for dynamically testing oscillometric or auscultatory NIBP monitors
- Precision pulse generation accuracy is achieved via patented closed-loop servo system.
- Virtual Patient patterns are included to eliminate patient induced errors. These patterns are included to maximize repeatability.
- Physiologically-correct clinical patient patterns guarantee valid testing of any manufacturer's oscillometric NIBP monitor, now and in the future
- Wide selection of clinically-relevant patient patterns allows NIBP monitors to be tested with controlled repeatable stimuli.
- Patient patterns were obtained from actual patients; their auscultatory and intra-arterial blood pressures displayed to provide absolute reference pressures.
- Works with both stepped and linear bleed, single or double tube NIBP monitors.
- High resolution, backlit LCD display provides an oscilloscope for viewing the patient "oscillometric envelope", cuff pressure waveforms and cuff pulse waveforms.

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Section 3. Physical Description

The **SmartArm Non-Invasive Blood Pressure (NIBP) Simulator** is a microprocessor controlled patient simulator housed in a compact (7.75 x 4.75 x 12.0 inch), portable (15 pounds with battery) aluminum case. Performance and technical specifications are listed below.

Technical Specifications

VIRTUAL PATIENT PATTERNS

In this mode the **SmartArm** functions like an arbitrary waveform generator with the cuff oscillation waveforms defined by CDC. Systolic, diastolic, mean blood pressure and pulse rate are given for each unique waveform. These values are displayed when the **SmartArm** is used in the virtual patient mode.

Virtual Patient Cuff Oscillation Definition

Amplitude: 2 mmHg

Rate: 30 bpm to 200 bpm in 5 bpm steps

Custom Oscillation Envelope Definition

Blood Pressure Range: Multiple envelopes are available a range of 60/30 to 225/185 mmHg

CLINICAL PATIENT PATTERNS

ADULT: Normal, Hypertensive, Hypotensive, Unstable/Artifact

PEDIATRIC: Normal

NEONATAL: Normal

(Unstable/Artifact patterns are useful for checking the trending capabilities of NIBP monitors.)

Note: Each pattern was acquired from an actual patient who simultaneously recording their arterial blood pressure. Each clinical pattern is accompanied by the correct systolic, diastolic, mean (MAP) blood pressure and pulse rate for that particular patient.

Pressure Adjust Range
Non-adjustable

Pulse Rate Adjust Range
Non-adjustable

PNEUMATIC PULSE GENERATOR

Pressure Pulse: 2 mmHg

Accuracy: +/- 1% of reading +/- 0.1 mmHg, maintained a patented closed-loop control system.

Open Loop Frequency Response: 0 - 60 Hz (-3 dB)

Transduction Technique: linear voice coil/pneumatic cylinder hybrid

PRESSURE TRANSDUCER

Pressure Range: 0 - 410 mmHg

Accuracy: +/- 0.1 mmHg, traceable to NIST (formerly NBS) pressure standard achieved via an EEPROM-based calibration table

Frequency Response: 0 - 500 Hz (wideband cuff pressure output)
0 - 5 Hz (normal cuff pressure output)
0 - 50 Hz (wideband cuff oscillation output)
0 - 12 Hz (normal cuff oscillation output)

Type: piezo-resistive strain gage with integral temperature compensation

DISPLAY

Type: Non-glare Film Super-Twisted Nematic (FSTN) LCD with Cold Cathode Fluorescence (CCFL) Backlight

Resolution: 320 x 240 (Horizontal x Vertical)

Dot Size: 0.33 mm

Dot Pitch: 0.37 mm

User Adjustments: CONTRAST (viewing angle)

Displayed Patient Data: Systolic BP, Diastolic BP, Mean BP, Pulse Rate, Cuff Oscillation Amplitude, Patient Pattern

Displayed

Test Waveforms: Cuff Oscillations and Cuff Pressure vs. Time
Oscillation Envelope (Oscillation Amplitude vs. Cuff Pressure)

Displayed Test Data: Instantaneous Cuff Pressure (Manometer), Peak Cuff Pressure, Inflation/Deflation Time and Rate, Total Elapsed NIBP Determination Time and Over-Pressure Setpoint

INTEGRATED "ARMS" (CUFF SUPPORTS)

Adult Cuff: 30 cm. circumference, 18.5 cm. width

Pediatric Cuff: 16 cm. circumference, 7.5 cm. width (Optional)

Neonatal: 10 cm. circumference, 4.5 cm. width

DIGITAL MANOMETER

Pressure Range: 0 - 410 mmHg

Accuracy: +/- 0.1 mmHg, traceable to NIST (formerly NBS) pressure standard achieved via an EEPROM-based calibration table

Operating Temperature (for specified accuracy):
0 - 50 degrees Centigrade

Proof Pressure: 1500 mmHg

INPUTS & OUTPUTS

Printer: Standard 25 pin PC parallel port, compatible with most "IBM PC style" printers.

Computer: Standard 9-pin "PC-AT" serial port, RS-232 serial interface.

BATTERY & AC ADAPTOR

Battery

Type: Rechargeable nickel cadmium

Voltage: 19.2 VDC, 1.5 Amp-Hour

Capacity: Approximately 150 simulated NIBP determinations

Charge Time: 12 Hours (from complete discharge)

External AC Adaptor

Type: Desktop switcher

Input: 110 - 240 VAC, 50-60 Hz, 53 Watts, 6 foot cord

Output: 24 VDC @ 2.2 Amps nominal, 6 foot cord

Weight: 16 ounces

PHYSICAL

Dimensions: 7.75" Wide x 4.75" High x 12.0" Deep

Weight: 8.5 pounds with battery

Case Material: Aluminum

Section 4. Functional Description

General

The SmartArm Non-Invasive Blood Pressure (NIBP) Simulator is a microprocessor controlled pneumatic signal generator and oscilloscope that allows dynamic functional testing of oscillometric blood pressure monitors. The SmartArm has the capability to create Virtual (idealized) patient blood pressure waveforms. Also included is the capability to recreate actual oscillometric pressure pulses recorded from a variety of actual patients. The use of such "live data" guarantees the ultimate validity of testing blood pressure monitors from a variety of manufacturers. In addition to its waveform simulation capabilities, the SmartArm incorporates a high-resolution graphic display which is used as an oscilloscope to view the cuff pressure and cuff pulse signals.

In addition to its simulation and display capabilities, the SmartArm includes a precision digital manometer, a leak mode and an overpressure test mode. The net result is a comprehensive, objective test platform for calibration, quality control and periodic maintenance of NIBP monitors.

Oscillometric Blood Pressure Measurement Principles

Unlike auscultatory NIBP measurement which uses a stethoscope or microphone, the oscillometric method uses the amplitude of the pulse waves or oscillations in the cuff pressure to determine the patient's blood pressure. The cuff is inflated above the systolic pressure then deflated linearly or step-wise. The pressure and oscillometric pulses from a typical linear deflation are shown in Figure 4-1. Note that initially, when the cuff pressure is high, the pulse amplitude is small but as the cuff pressure decreases the pulse amplitude increases

then begins to decrease. During deflation, the amplitude of each cuff oscillation is measured and stored along with the cuff pressure at which that oscillation occurred. The oscillation amplitude is then plotted against the cuff pressure to produce the "oscillation envelope" curve, shown in Figure 4-2. The oscillation envelope is then used to determine the patient's blood pressure. It is widely accepted that the mean arterial pressure (MAP) occurs at the peak of the envelope where the cuff oscillation amplitudes were maximum. Unfortunately, there are no generally accepted formulas for determining the systolic and diastolic pressures. NIBP monitor manufacturers have developed unique, proprietary algorithms for estimating the systolic and diastolic pressures from the oscillation envelope.

Due to the unique algorithm of each NIBP monitor manufacturer and due to the variability of "physiologically correct" envelopes CDC provides the user with stable, repeatable Virtual Patient waveforms.

SmartArm Design Philosophy

For the purposes of simulating the most difficult NIBP measurements the SmartArm also includes the capability of recreating real patient *oscillometric envelopes*. Because the *oscillation envelope completely defines the blood pressure* the primary job of the SmartArm is to reproduce the envelope as accurately as possible. Because of the variety of systolic and diastolic determination algorithms, it is essential that SmartArm generate "physiologically correct" envelopes.

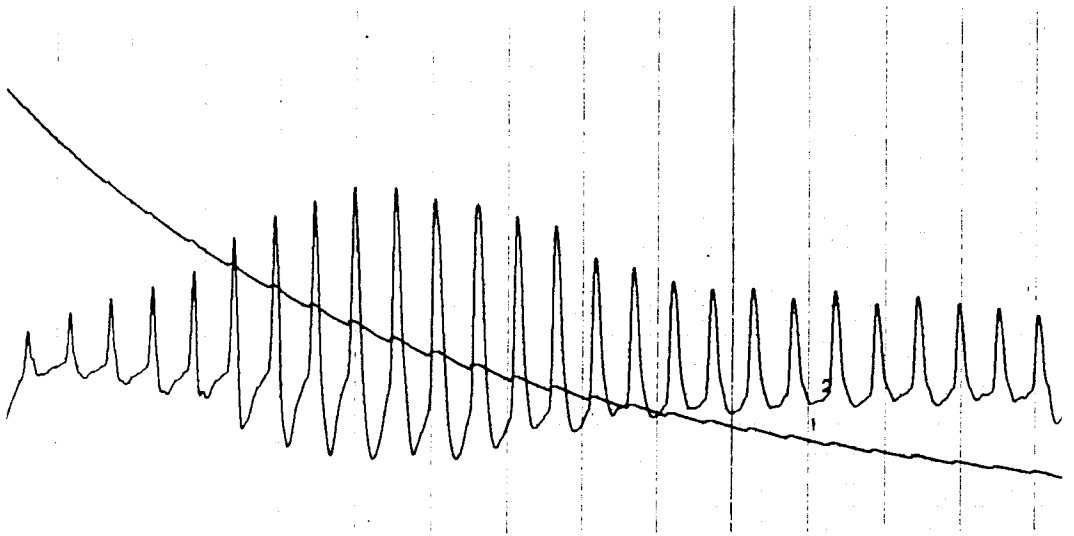


Figure 4-1. Cuff pressure waveform during a typical oscillometric blood pressure measurement.

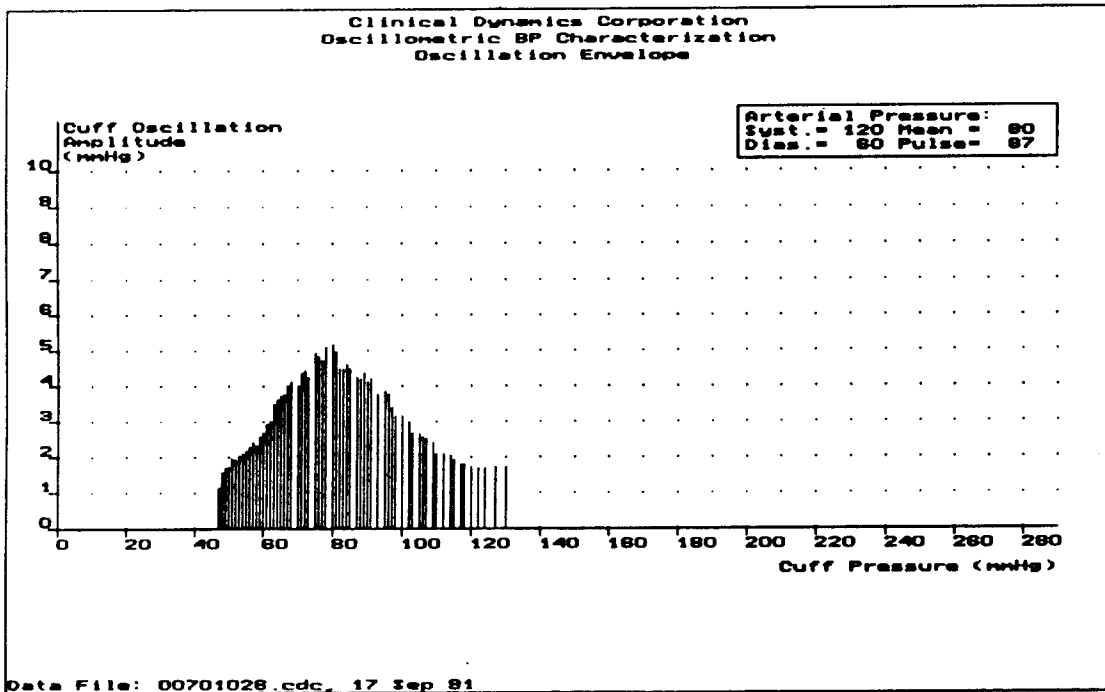


Figure 4-2. The Oscillation Envelope derived from a typical oscillometric blood pressure measurement.

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Section 5. Installation and Operati

Contents Checklist

- 1 SmartArm NIBP Simulator
- 1 External Power Supply (110-240 V, 50-60 Hz, worldwide input)
- 1 Power Cord, 6 foot
- 1 DINAMAP adaptor (threaded fittings)
- 1 LUER adaptor
- 1 HP adaptor (nickel-plated fittings)
- 1 PROPAQ / MARQUETTE adaptor (O-ring)
- 1 IVAC adaptor (hose & electrical connector)
- 1 BAUM / IVAC adaptor (5/32" ID hose & barb)
- 1 Self leak-test hose (plugged at distal end)
- 1 Inflation Bulb with "T" fitting
- Note: Adult and Neonatal Cuff Supports are built-in
- 1 Operation Manual
- 1 Service Manual

Initial Power-Up Sequence

1. Connect the External Power Supply to a suitable AC power source using the Power Cord.
2. Connect the Power Supply output plug to the DC Voltage jack located at the rear of the right panel of the SmartArm. The green LED will illuminate to indicate the presence of power from the External Power Supply.
3. Press the red POWER switch to power-up the SmartArm.
4. Adjust the CONTRAST control for the desired backlighting and optimum contrast. This control is located on the right panel, under the overhang of the front panel.

5. The screen momentarily displays its power-up message indicating the firmware (software) version in use. This version number is needed for any telephone technical support.
6. The next power-up screen is the Self-Test Diagnostics. Upon entering this screen, the SmartArm executes a self-test sequence which checks each of the major hardware subsystems and posts the results of each test.
7. After the final test, it enters an "un-zeroed" digital manometer mode wherein the pressure at the Pressure Port is displayed in 0.1 mmHg units with a temperature-dependent offset. If the SmartArm is functioning correctly, the offset should be between 100 and 110 and the display should not fluctuate more than +/- 3 digits.
8. Press any "F" key to auto-zero the pressure transducer. NOTE: ENSURE THAT THE Pressure Port IS AT ZERO PRESSURE BEFORE PERFORMING THE AUTO-ZERO. If the SmartArm determines that the Pressure Port is not at zero, a "Failed" message will be posted. Simply disconnect the pressure port and press any "F" key to repeat the transducer auto-zero.
9. After a successful auto-zero, the manometer will display 0 and it will display the Pressure Port pressure in mmHg units. At this point the static calibration of the SmartArm manometer may be checked by applying a known pressure to the Pressure Port and comparing the manometer reading to the known pressure. After completing the pressure transducer auto-zero, press any "F" key to proceed to exit the Self-Test Diagnostics mode.

10. The SmartArm is now at the **Primary Display Screen**. The initial Virtual Pattern BP envelope is displayed.

Connecting to the Blood Pressure Monitor

1. Select the appropriate Adaptor Block using the following table as a guideline:

Blood Pressure Monitor Adaptor Block

| | |
|------------------------|-------------------|
| ● Critikon DINAMAP | DINAMAP |
| ● CAS Medical | LUER |
| ● DataScope | LUER |
| ● Hewlett-Packard | HP |
| ● IVAC | IVAC |
| ● Marquette | PROPAQ / MARQUETT |
| ● MDE Escort | LUER |
| ● Colin | LUER |
| ● Protocol Propaq | PROPAQ / MARQUETT |
| ● SpaceLabs | LUER or BAUM |
| ● Air-Shields | LUER |
| Athena Neonate Monitor | |

If none of the above adaptor blocks appear to match your tubing/cuff interface and if your cuff has a standard "Baum-style" 5/32" ID rubber hose, you use the BAUM adaptor block. If you have questions regarding selection of the adaptor block, please contact:

Technical Support
 Clinical Dynamics Corp.
 12 Beaumont Road
 Wallingford, CT 06492
 Phone: (203) 269-0090

Fax: (203) 269-34

2. Disconnect the blood pressure monitor cuff from the hose. (As if you were going to replace the cuff.) In the case of a dual-lumen hose, only one of the hoses should be disconnected.

3. Connect the cuff to the short side of the appropriate adaptor block and the tubing to the other short side of the adaptor block. Ensure that an airtight seal is achieved.
4. Assuming you are using an adult cuff, wrap the cuff around the SmartArm cuff support just as you would wrap it around a patient's arm. For best results, squeeze excess air from the cuff.
5. Insert one of the male Luer connectors on the Pneumatic Hose into the female Luer on the long side of the selected adaptor block. Connect the other end of the Pneumatic Hose to the Pressure Port on the right panel of the SmartArm.
6. Please refer to Figure 5-1 for an illustration of the proper connection between the SmartArm and the NIBP monitor to be tested.

CONFIGURATION: Oscillometric

1. The SmartArm default setting is the DINAMAP configuration. Leave the simulator in this mode for use with Oscillometric NIBP monitors.

Auscultatory

1. From the **Primary Display Screen**, press the **CONFIG** key. Press the **MONITOR** key to select the IVAC monitor. The **MONITOR** key toggles between the DINAMAP and IVAC NIBP monitor settings (displayed in top left section).
2. Press the **REM** key to select RS-232 port control. **ON** selects serial remote control. **OFF** selects serial automatic data-logging with compatible monitors.
3. After your selection is complete, press the **RETURN** key to return to the **Setup Screen**. The NIBP monitor configuration selected will be displayed on the pressure portion of the **Primary Display Screen**.

MODE

After its power-up sequence, the **SmartArm** enters its initial Virtual Patient Envelope display mode. At this point the user has the option of selecting the desired test **MODE** or selecting a different patient or hearing rate. Pressing **MODE** will allow the user to select the desired test type.

Leak Test

This test allows the user to evaluate the system under test for leaks and to determine the source of these leaks. This mode provides a storage oscilloscope display of pressure versus time. The pressure scale is 0 to 450 mmHg with each pixel representing 3mmHg. The time scale is 0 to 60 seconds with three pixels representing 1 second.

The Leak Test mode is used to determine the rate of leakage of the pneumatic system. If this rate exceeds the manufacturers specifications the Leak Test mode may then be used to determine the source of those leaks. By performing the test while using a clamp to isolate portions of the pneumatic circuit the user can isolate the leaky component.

LEAK TEST AUTO

1. From the **Primary Display Screen**, press the **MODE** key.
2. Select **LEAK TEST** and place the monitor in the calibration or service mode (check all connections).
3. Press the **INFLATE** key to start the Leak Test.
4. After the pressure stabilizes, the Leak Test will begin automatically and last 60 seconds.
5. When in Leak Test mode, the top of the display has digital readouts labelled "Start Pressure", "Pressure Drop", "Timer" and "Manometer." At the end of sixty seconds the "Pressure Drop" and "Timer"

LEAK TEST MANUAL

5. displays will freeze and display the pressure drop and the leak rate in mmHg per minute. This should be within specifications for the NIBP monitor.
6. While this test is running, you can check the Static Calibration of your NIBP monitor.
7. Compare the SmartArm manometer in the upper right corner to the pressure on the NIBP monitor.
8. To check the monitor at 100mmHg, press the **CAL 100** key. Testing at 100mmHg is recommended by many NIBP monitor manufacturers.
9. Press the **MODE** key after the leak test and static calibration test are completed to return to the **Primary Display Screen**.
1. Select **LEAK TEST** and place the monitor in the calibration or service mode (check all connections)
2. Press the **AUTO** key, this toggles between the auto and manual inflation mode.
3. Use the inflation bulb or the NIBP monitor's internal pump to pressurize the pneumatic circuit to the desired test pressure.
4. When the pressure has settled, press the **START** key to begin the Leak Test.
5. When in Leak Test mode, the top of the display has digital readouts labelled "Start Pressure", "Pressure Drop", "Timer" and "Manometer." At the end of sixty seconds the "Pressure Drop" and "Timer" displays will freeze and display the pressure drop and the leak rate in mmHg per minute.

6. Press the **MODE** key after the Leak Test and Static Calibration Test are completed to return to the **Primary Display Screen**.

Digital Manometer

NOTE: In the Leak Test mode the user also has available a precise (0.1 mmHg) digital manometer. The pressure is displayed in the upper right hand corner of the SmartArm screen.

The bottom section of the display in Leak Test mode describes the "F" key function. **ZERO** resets the electrical zero on the pressure transducer.

Temporarily remove the input from the pressure monitor and press **ZERO**. To exit Leak Test mode press **MODE**. To continue testing monitor press **MODE** one more time.

OVER-P AUTO

1. From the **Primary Display Screen**, press the **MODE** key.
2. Select the **OVER-P TEST** and place the NIBP monitor in the calibration or the service mode.
3. Check all connections.
4. Press the **INFLATE** key. The over pressure test will determine whether the over pressure valve is releasing at the correct pressure (consult the NIBP monitor's Service Manual for relief valve specifications).
5. At the over pressure point, the monitor should release the pressure. The display will indicate the over pressure point and the pressure waveform will be displayed. On some monitors the pressure will not drop to zero but just below the set point. In this case set point pressure can be read from the screen.

OVER-P MANUAL

6. Press the **MODE** key after the **OVER-P TEST** is complete to return to the **Primary Display Screen**.
1. Select the **OVER-P TEST** and place the NIBP monitor in the calibration or the service mode.
2. Press the **AUTO** key, this toggles between the auto and manual modes.
3. Use the inflation bulb or the NIBP monitor's internal pump to pressurize the pneumatic circuit until the over pressure valve opens.
4. At the over pressure point, the monitor should release the pressure. The display will indicate the over pressure point and the pressure waveform will be displayed. On some monitors the pressure will not drop to zero but just below the set point. In this case set point pressure can be read from the screen.
5. Press the **MODE** key after the **OVER-P TEST** is complete to return to the **Primary Display Screen**.

PULSE

In the pulse mode the user can see the actual pulses on the cuff. These pulses are displayed on the screen. The amplitude of the pulses is 1 mmHg per major vertical division. Three cascaded traces will be displayed. The **SIM:On/SIM:Off** key turns the pulses from the SmartArm on or off. The **TRIGGER** button restarts this test. The pressure on the cuff is displayed in the upper right hand corner of the screen. To exit this test, press **MODE**. To continue testing press **MODE** again.

SETUP

With the **SmartArm** in the **Primary Display Screen**, the user has the option of selecting another patient and/or changing the HR (heart rate). To do this press the **SETUP** key. If the user then presses the **PATIENT** key a list of patients and their Systolic/Diastolic and (mean) pressures is available. Press **UP** or **DOWN**. Then press **SELECT** to choose the desired patient. The **SmartArm** will return to the **Primary Display Screen** and display the pressure envelope for the selected patient.

To change Heartrate on the selected patient, press **SETUP**, then press the **HR** key. The HR box at the top of the screen will blink and display the current Heartrate. Use the **UP** and **DOWN** keys to scroll between 30 and 200 Beats Per Minute (5 BPM increments). If the user presses the **UP** or **DOWN** key once the HR will increment or decrement 5 BPM. Holding the key will initiate a rapid scrolling through the entire range of rates. Press **ENTER** to select the desired HR. Press **RETURN** to exit this mode. The user is now in the **Primary Display Screen**.

BP TEST

1. From the **Primary Display Screen**, press the **MOI** key (IVAC adaptor needs electrical connection).
2. Select **BP TEST** and check all connections.
3. Press the **SEQ:OFF** key. The display will read **AUTO SEQ:1**. Continue to press the **AUTO SEQ** key to select the amount of cycles per pressure (1-10 consecutive tests per pressure available).
4. After the last test, the simulator will increment to the next pressure for continued testing.

BP TEST

5. Start the NIBP monitor, after the test is complete, compare the readings of the monitor with the value from the **SmartArm**. To establish consistent **BP TEST** readings, as least 3 cycles are recommended.
6. Press the **SCROLL** key to see cuff inflation and pulses generated by the **SmartArm**.
7. Press the **MODE** key when viewing is complete to return to the **Primary Display Screen**.

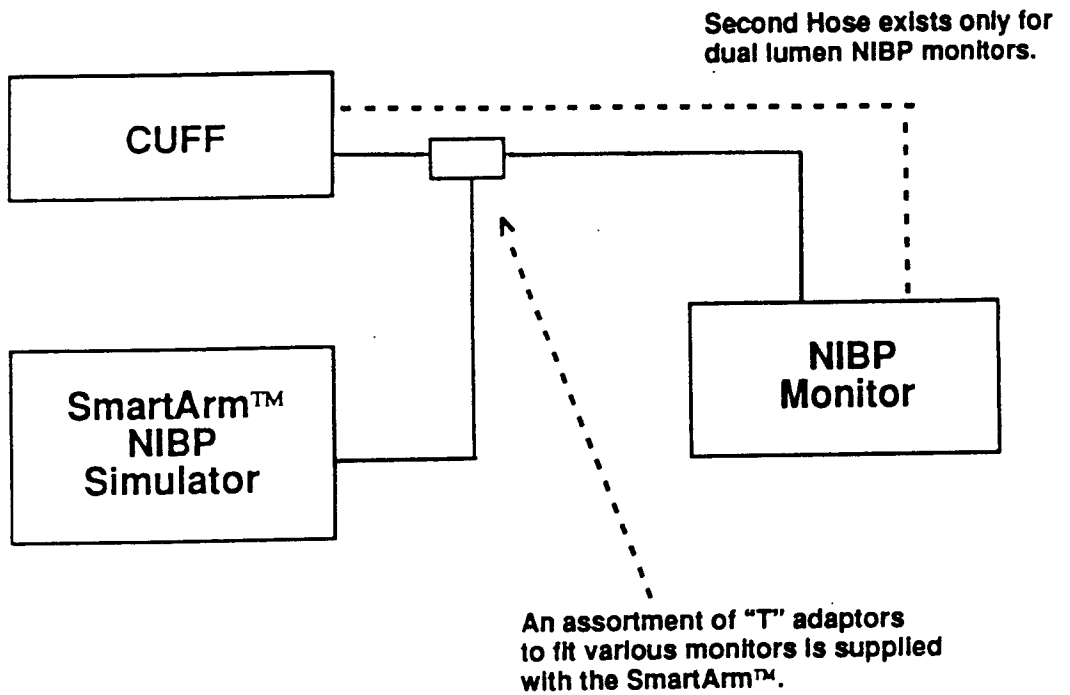


Figure 5-1. Pneumatic connection between the SmartArm and the NIBP Monitor.

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Section 6. Serial Communication

Introduction

Remote control of the SmartArm is possible via an RS-232 serial port. Physically, this port is a 9 pin female "D-shell" connector located on the right panel of the SmartArm. The serial port operates with the following communications parameters:

Baud Rate: 600 bps
Data Bits: 8
Stop Bits: 1
Parity: none

This serial port is configured as a "DCE" allowing direct connection (i.e., using a *standard* rather than a null modem cable) to the serial port on IBM-compatible computers. Handshake control signals (CTS, RTS, etc.) are ignored.

Communication between the SmartArm and the Host device consists of two categories:

- 1) Command messages sent by the Host to the SmartArm
- 2) Test Result messages sent by the SmartArm to the Host

Command messages (from the Host) consist of four (4) fields:

- 1) the preamble: [S][A]
- 2) the command byte: a single *upper-case* letter (described below)
- 3) the data bytes: 0 or more bytes (command dependent)
- 4) the termination byte: <CR> (i.e., Hexadecimal 0D, ASCII carriage return control code)

Test Result messages are automatically sent by the SmartArm after the completion of a test in the LEAKTST, BP TEST and OVER-P modes. Test Result messages consist of four (4) fields:

- 1) the preamble: [S][A]
- 2) the mode identifier byte: an ASCII digit indicating the SmartArm test mode and thus specifying the format of the test data that follows. (described below)
- 3) the data bytes: a string of ASCII digits containing the test result data; the format is test mode dependent (described below)
- 4) the termination byte: <CR>

In order to facilitate Host operation via a "dumb terminal" a computer running communications software (e.g. PROCOMM PLUS or Crosstalk), most messages are comprised exclusively of ASCII printable characters. The only message that uses binary characters is the Define Custom Patient command that sends a 301 byte array to the SmartArm. A checksum is not used because it will not, in general, be printable and it is awkward to generate and transmit checksums with an ASCII terminal. Message integrity checking is achieved via a structured message format and limit tests for all transmitted data.

Before developing a software communications driver for use in your SmartArm application, it is recommended that the developers familiarize themselves with the communication protocol using a dumb terminal or a PC operating as a dumb terminal.

Command and Test Result Summary

Host Command Format:

```
[S][A][command byte][data bytes]<CR>
```

The possible Host Commands are listed below and are described in detail on the following pages:

| Command Byte | Command |
|---------------------|--|
| A | Lock Keypad |
| B | Set Mode |
| C | Set Patient (i.e., Set Blood Pressure) |
| D | Set Pulse Rate |
| E | Set Systolic/Diastolic |

SmartArm Test Results Format:

```
[S][A][mode identifier byte][data bytes]<CR>
```

The possible SmartArm Test Results messages are listed below and are described in detail on the following pages:

| Mode Identifier Byte | Test Results from |
|-----------------------------|--------------------------|
| 2 | BPTest Mode |
| 4 | LeakTest Mode |
| 5 | Over-P Mode |

Lock Keypad

The Lock Keypad command locks and unlocks the SmartArm front panel keypad.

Command Byte: A

Command Format:

[S] [A] [A] [L] <CR>

where

L is the data byte, a single ASCII digit indicating lock or unlock operation. Valid digits for L are:

0 (Hex 30) = Unlock the keypad

1 (Hex 31) = Lock the keypad

If L is an invalid digit, the Lock Keypad command will be ignored.

Set Mode

The Set Mode command switches the SmartArm into the desired operating mode.

Command Byte: B

Command Format:

[S] [A] [B] [M] <CR>

where

M is the data byte, a single ASCII digit indicating desired operating mode. Valid digits for M are:

1 (Hex 31) = Envelope / Setup Mode

2 (Hex 32) = BPTest Mode

3 (Hex 33) = Pulse Mode

4 (Hex 34) = LeakTest Mode

5 (Hex 35) = Over-P Mode

Set Patient

The Set Patient command selects the patient type used by the SmartArm during a blood pressure simulation. This command selects one of four patient groups:

1. Virtual Adult
2. Virtual Neonatal
3. Real Adult
4. Real Neonatal

In addition, the Set Patient command selects a particular patient, and thus a particular blood pressure setting, from within the patient group.

Command Byte: C

Command Format:

[S] [A] [C] [G] [P] <CR>

where

G is a single ASCII digit specifying the patient group.

Valid digits for G are:

0 (Hex 30) = Real Neonatal patients

1 (Hex 31) = Real Adult patients

2 (Hex 32) = Virtual Neonatal patients

3 (Hex 33) = Virtual Adult patients

P is a single ASCII digit indicating the particular patient within the patient group. Each patient has an associated blood pressure setting and default pulse rate. The blood pressure and pulse rate settings are listed below in

following format: Systolic/Diastolic (Mean Arterial), HR
Pulse Rate. Valid digits for P are patient group dependent
as specified below:

Real Neonatal

0 (Hex 30) = 68/ 33 (48), HR = 150

Real Adult

0 (Hex 30) = 120/ 60 (80), HR = 90

1 (Hex 31) = 112/ 74 (90), HR = 80

2 (Hex 32) = 127/ 55 (79), HR = 65

Virtual Neonatal

0 (Hex 30) = 31/ 13 (19), HR = 120

1 (Hex 31) = 55/ 29 (42), HR = 120

2 (Hex 32) = 190/160 (170), HR = 120

Virtual Adult

0 (Hex 30) = 60/ 30 (40), HR = 70

1 (Hex 31) = 80/ 48 (58), HR = 70

2 (Hex 32) = 100/ 65 (77), HR = 70

3 (Hex 33) = 120/ 80 (95), HR = 70

4 (Hex 34) = 150/ 95 (114), HR = 70

5 (Hex 35) = 200/140 (167), HR = 70

6 (Hex 36) = 255/185 (220), HR = 70

Set Pulse Rate

The Set Pulse Rate command selects the pulse rate used by the SmartArm during a blood pressure simulation.

Command Byte: D

Command Format:

[S] [A] [D] [PPP] <CR>

where

PPP is a string of 3 ASCII digits denoting the desired pulse rate in bpm. Note that 3 digits are always required, that is, for pulse rate less than 100, either a leading or trailing ASCII space (hex 20) must be inserted.

Set Systolic/Diastolic

The Set Systolic/Diastolic command independently sets the systolic and diastolic pressures used by the SmartArm during a blood pressure simulation.

Command Byte: E

Command Format:

[S] [A] [E] [SSS] [DDD] <CR>

where

SSS is a string of 3 ASCII digits denoting the desired systolic pressure in mmHg and DDD is a string of 3 ASCII digits denoting the desired diastolic pressure in mmHg. Note that 3 digits are always required; that is, for pressures less than 100, either a leading or trailing ASCII space (hex 20) or a leading "0" (hex 30) must be inserted. Also note the following restrictions on the systolic pressure, diastolic pressure and pulse pressure (pulse pressure = systolic - diastolic):

$67 \text{ mmHg} \leq \text{systolic pressure} \leq 200 \text{ mmHg}$

$42 \text{ mmHg} \leq \text{diastolic pressure} \leq 175 \text{ mmHg}$

$25 \text{ mmHg} \leq \text{pulse pressure} \leq 100 \text{ mmHg}$

Attempts to set a parameter outside these ranges will result in the violating parameter being set to the exceeded limit.

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BPTest Mode Test Results

In the BPTest mode, whenever the SmartArm determines a blood pressure simulation has been completed, it automatically transmits the BPTest Mode Test Results message.

Mode Identifier Byte: 2

Test Results Format:

[S] [A] [2] [SSS] [DDD] [MMM] [PPP] [A] < C

where

SSS is a string of 3 ASCII digits denoting the target systolic blood pressure in mmHg.

DDD is a string of 3 ASCII digits denoting the target diastolic blood pressure in mmHg.

MMM is a string of 3 ASCII digits denoting the target mean arterial pressure (MAP) in mmHg.

PPP is a string of 3 ASCII digits denoting the target pulse rate in bpm.

A is a single ASCII digit denoting the oscillation amplitude setting in mmHg.

LeakTest Mode Test Results

In the LeakTest mode, whenever the leaktest timer has reached the desired elapsed time (nominally 60 seconds), SmartArm automatically transmits the LeakTest Mode Test Results message.

Mode Identifier Byte: 4

Test Results Format:

[S] [A] [4] [SSS] [DDD] <CR>

where

SSS is a string of 3 ASCII digits denoting the leak start pressure in mmHg.

DDD is a string of 3 ASCII digits denoting the leak test pressure drop in mmHg.

Over-P Mode Test Results

In the Over-P mode, whenever the over-pressure setpoint been detected, the SmartArm automatically transmits the Over-P Mode Test Results message.

Mode Identifier Byte: 5

Test Results Format:

[S] [A] [5] [SSS] <CR>

where

SSS is a string of 3 ASCII digits denoting the over pressure setpoint in mmHg.

Section 7. Parallel Printing

The SmartArm provides standard parallel printing for simulation test results only.

Upon power up, the SmartArm will print a document header. Please refer to figure 7-1. After each successful completed NIBP simulation, the SmartArm will print the simulator settings and a space for results to be recorded manually.

The SmartArm can communicate with a NIBP monitor that provides RS232 serial output.

SmartArm RS232 pinout:

Pin 2: RX

Pin 3: TX

Pin 4: DTR

Pin 5: GND

Pin 6: DSR

PLEASE NOTE: Contact the NIBP monitor manufacturer to have the correct communication protocols provided.

SmartArm NIBP Simulator Test Report

NIBP Monitor Model: _____

Serial Number: _____

Location: _____

Date: _____ Time: _____

| Test# | Patient | Pressures | HR | Amp |
|-------|---------|-----------|-------|-------|
| ===== | ===== | ===== | ===== | ===== |

Figure 7-1. SmartArm NIBP Simulator Test Report.