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## 6.1 Calibration Introduction

The following procedures are provided to verify the proper operation of the **Passport 2** Monitor. Service Diagnostics provide the capabilities of diagnosing problems within the **Passport 2** hardware. A menu driven interface with the same "look and feel" as that of the **Passport 2** User Interface, is used to execute all tests.

**CAUTION:** Calibration is not to be performed while monitoring a patient.

## 6.2 Warning and Guidelines

In the event that the instrument covers are removed, observe these following warnings and general guidelines:

1. Do not short component leads together.
2. Perform all steps in the exact order given.
3. Use extreme care when reaching inside the opened instrument. Do not contact exposed metal parts which may become live.
4. Read through each step in the procedure so it is understood prior to beginning the step.

## 6.3 Test Equipment and Special Tools Required

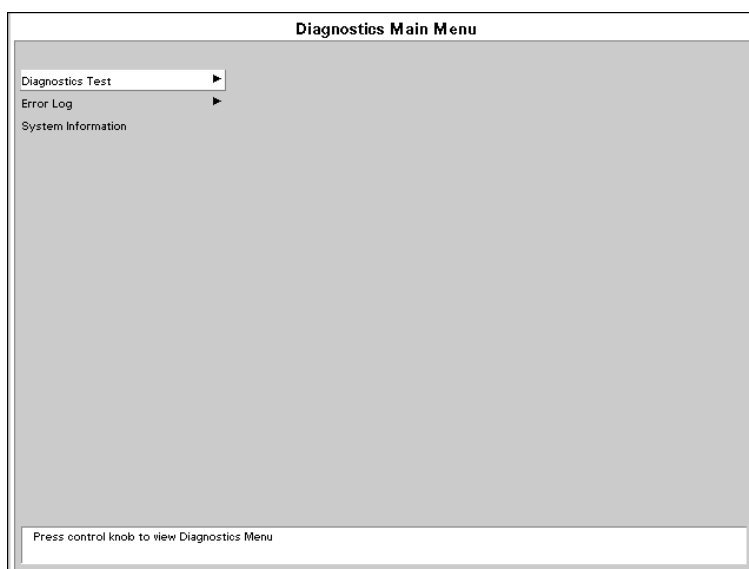
### 6.3.1 Description

- Digital Mercury manometer w/bulb and valve 0-500 mmHg - Netech Digimano - Accuracy 0.25% Full Range
- Test Chamber/Dummy Cuff - P/N 0138-00-0001-01 (700cc) or -03 (500cc)
- DVM
- Patient Simulator
- Digital Flow Meter
- Calibration Gas - P/N 0075-00-0033
- Calibration Gas Regulator - P/N 0119-00-0166
- Safety Analyzer - Dempsy Model or equivalent
- Flow Meter - Sierra Instruments or equivalent

## 6.4 Diagnostics

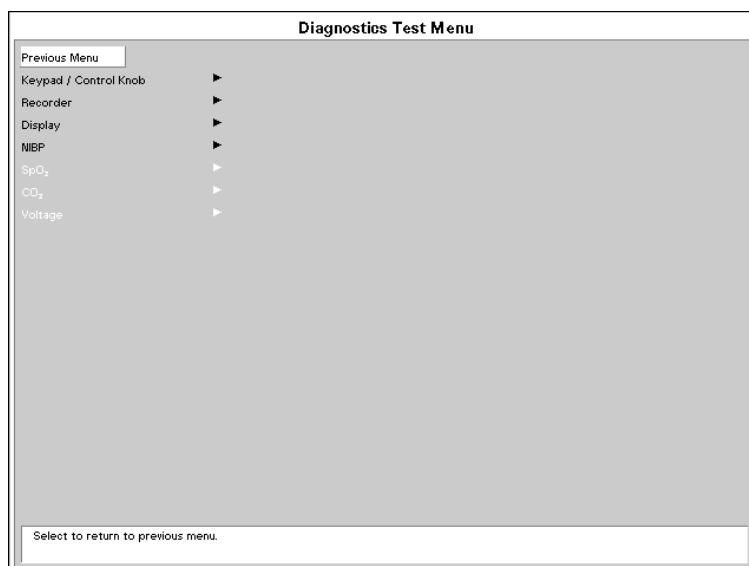
To enter the diagnostic mode:

1. Turn the power off.
2. Press and hold the **FREEZE** key and turn the unit on. The **Diagnostics Main Menu** will appear on screen. Release the **FREEZE** key.
3. Rotate the Control Knob to move the cursor up and down to the **Diagnostics Main Menu**. Pressing the control knob will select the desired test and open the second menu for testing.



**FIGURE 6-1**

### 6.4.1 Diagnostic Test Menu

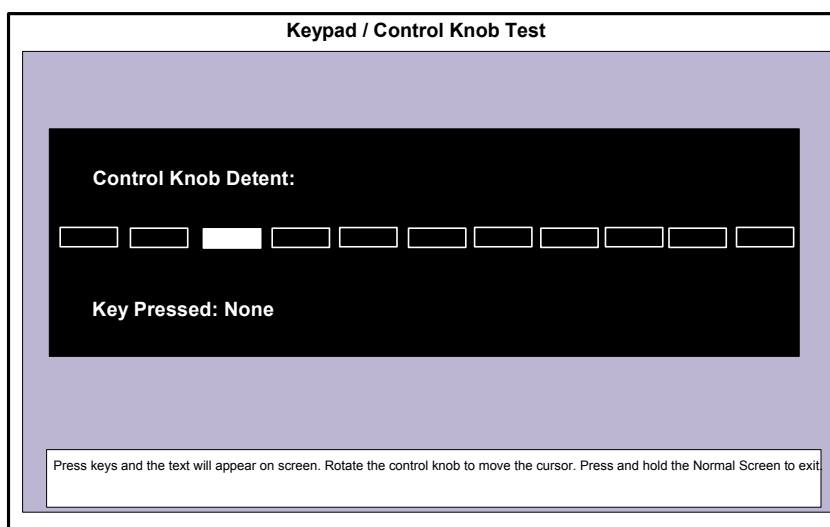


**FIGURE 6-2**

## 6.4.2 Keypad / Control Knob Test

When this menu is selected the unit will perform an echo test by displaying the name of the key that was pressed.

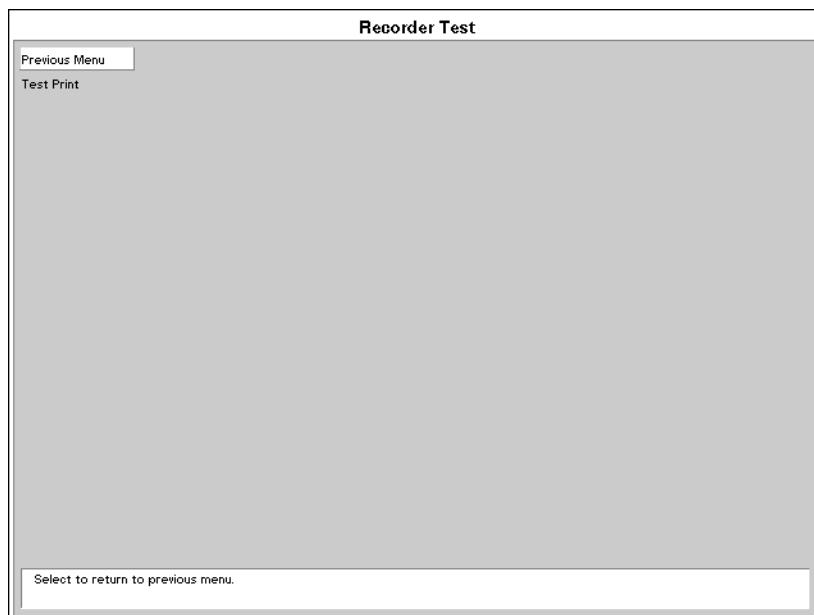
1. A blank key name will appear on screen
2. When a key is pressed the name of that key will be displayed in the key name window.
3. Exercise each key to verify proper operation.
4. A second window with blank boxes will be displayed on screen.
5. When rotating the control knob the blank boxes will illuminate with each active detent.
6. Press the **PRINT** key to print the test result on the local recorder.
7. Press the **NORMAL** key and hold to return to the Diagnostics Test Menu.



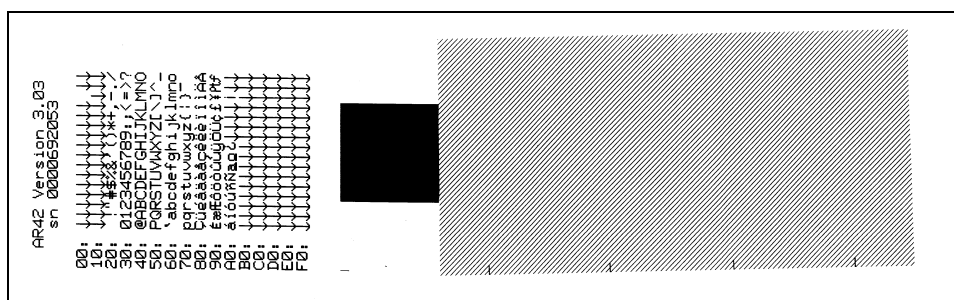
**FIGURE 6-3**

### 6.4.3 Recorder Test

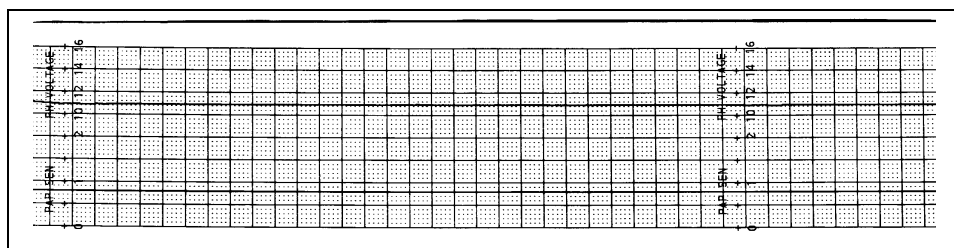
Select the Chart Grid ASCII Characters menu. The printer will print the Recorder Test pattern as shown in Figure 1 or Figure 2.



**FIGURE 6-4**



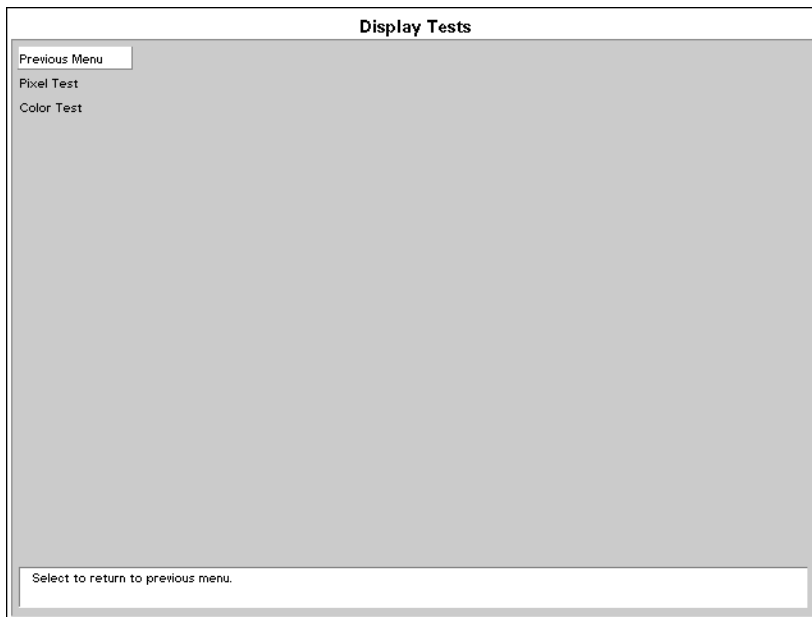
**FIGURE 6-5** AR-42 Test Strip



**FIGURE 6-6** XE-50 Test Strip

### 6.4.4 Display Tests

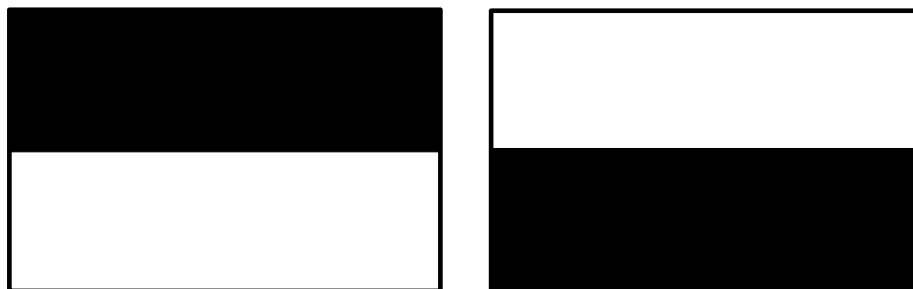
The display test offers the choice of a Pixel test or a Color test. The color tests will only be available on units with a color display.



**FIGURE 6-7**

### 6.4.5 Pixel Test

The pixel test will verify the proper operation the display. On screen one half of the screen will be illuminated while the second half is off. Pressing the control knob will illuminate the second half of the screen while the first half is turned off. Pressing the control knob a third time will activate the display test menu screen.

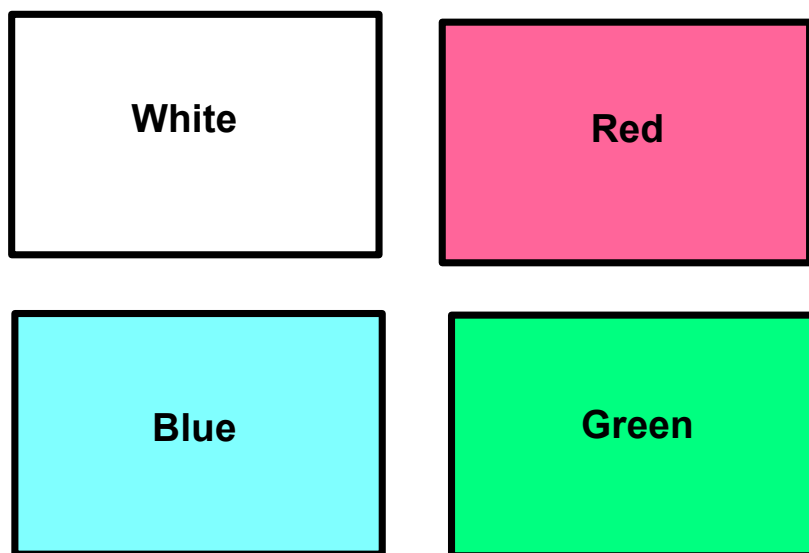


**FIGURE 6-8**

### 6.4.6

#### Color Test

The color test will verify the four basic colors of the display. Press the control knob to view the selected color screens in full illumination. The colors are Red, Blue, Green and White.



**FIGURE 6-9**

## 6.4.7 NIBP Tests

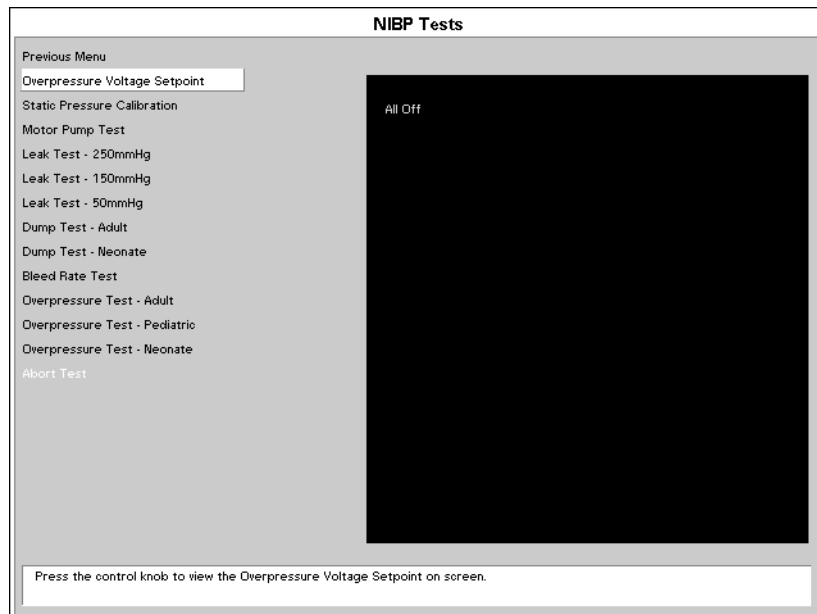
The following tests requires an approved 700 cc Test Chamber P/N 0138-00-0001-01 or 500 cc Test Chamber P/N 0138-00-0001-03 to ensure proper test results.

### 6.4.7.1 Overpressure Voltage Test

**A.** Specification with P/N 0997-00-0501 only.

The purpose of this test is to verify the Zero Point of the Over Pressure Transducer is set to  $0.100 \pm 0.010$  volts.

1. Verify on screen that the Overpressure zero point is  $0.100 \text{ volts} \pm 0.010$ .

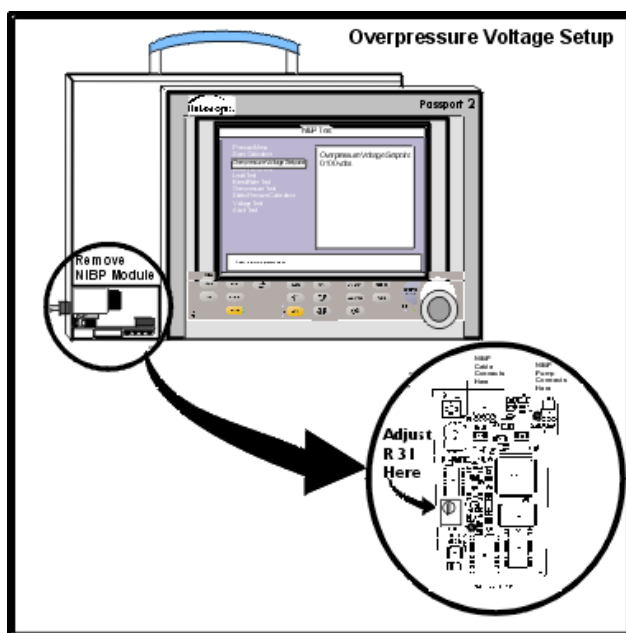


**FIGURE 6-10**

2. If the Overpressure zero point is out of specification follow the following procedure:
  - a. Turn Unit off. Remove the eight screws that secure the front and rear housing together. Separate the front and rear housing. Disconnect the interconnect cable from the TFT/display board and remove the ground strap.
  - b. Place the front housing to the side for future use.
  - c. Remove the NIBP Pump assembly and bracket from the Main Assembly by removing the two screws and placing the NIBP pump to the side.
  - d. Remove the Rectus fitting from the left side of the monitor with a 0.25 hex nut driver.
  - e. Remove the NIBP Cable assembly from the J1 connector of the NIBP module.
  - f. Slide NIBP Module from the rear of the unit.
  - g. Reattach the NIBP Cable to connector of the NIBP module J1 and place it on a protective surface.
  - h. Reattach the Front Housing Assembly via the Interconnect cable. Repower unit and enter NIBP Diagnostics.



- i. Select down to NIBP Overpressure Voltage. Adjust potentiometer R 31 on the NIBP Module and verify on screen the Overpressure Voltage is 0.100 volts.

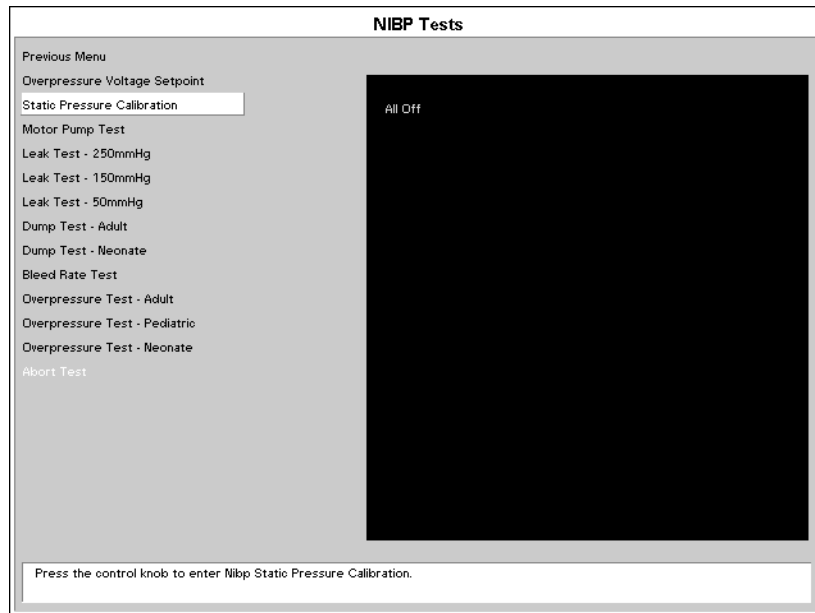


**FIGURE 6-11**

- j. Reassemble unit and verify proper operation.
- B.** Specification with P/N 0670-00-0730/0670-00-0746-01
- No manual adjustment is required. The voltage setpoint is controlled by software. If "Check Calibration/Cuff Overpressure" appears on the screen in message area, replace the NIBP module accordingly.
- C.** Specification: .030 to .170 volts

### 6.4.7.2 Static Pressure Calibration

The purpose of this test is to verify the pressure transducer sensitivity for optimal accuracy.



**FIGURE 6-12**

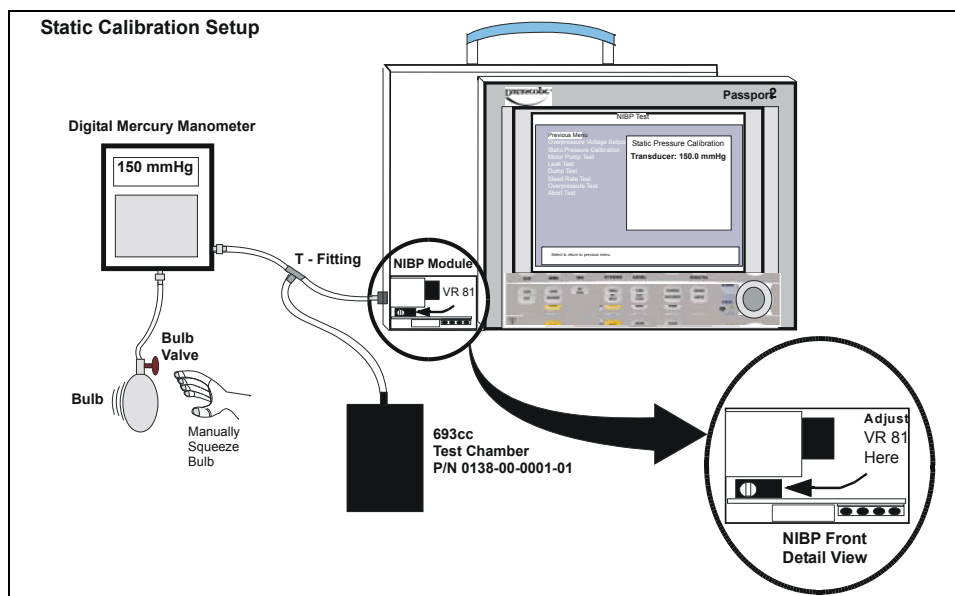
1. Connect the dummy cuff / test chamber to the side panel fitting.
2. Rotate the control knob to highlight the static pressure calibration. Once the static pressure calibration test is highlighted press the control knob to activate the test.
3. Using a bulb and valve manually inflate the chamber to 150mmHg. (150mmHg is the middle of the specified range)
4. Verify the pressure displayed on screen matches the pressure viewed on a Digital Mercury Manometer.

**Specification: 0 to 300mmHg +/- 3mmHg**

If the readings do not match follow the following procedure.

1. Turn unit off.
2. Remove the eight screws from the rear of the unit and separate the front and rear housing.
3. Remove the NIBP Pump assembly and bracket from the Main Assembly. Be sure to reattach NIBP pump cable to module before next step.
4. Locate R81 on the NIBP Module. Turn unit on and enter the Diagnostics as stated in section 6.4. Reenter the diagnostics menu and select the Static Pressure Calibration menu.
5. Manually inflate the chamber to 150mmHg.

6. Adjust R81 potentiometer and verify the linearity accordingly. See figure below.



**FIGURE 6-13**

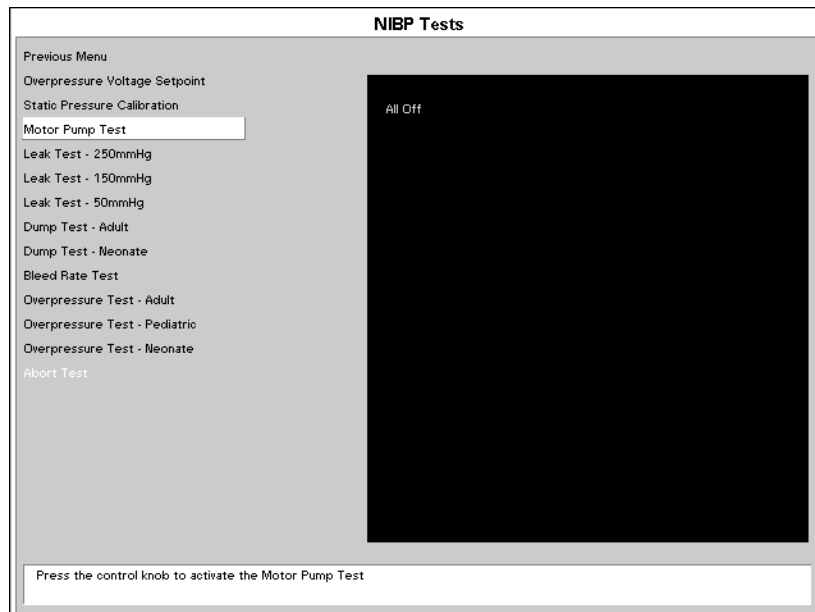
Specification: = 150mmHg +/- 0.1%

7. Reassemble unit and verify the following static pressure points to ensure proper calibration.

**Specification: 30 mmHg, 100 mmHg, 150 mmHg, 190 mmHg and 250 mmHg. +/-3 mmHg.**

### 6.4.7.3 Motor Pump Test

1. Connect the dummy cuff / test chamber to the side panel fitting.
2. Rotate the control knob to highlight the motor pump test. Once the motor pump test is highlighted press the control knob to activate the test.
3. On screen the target pressure of 300mmHg will be view on screen. The time required to pump to 300mmHg will be viewed on screen.



**FIGURE 6-14**

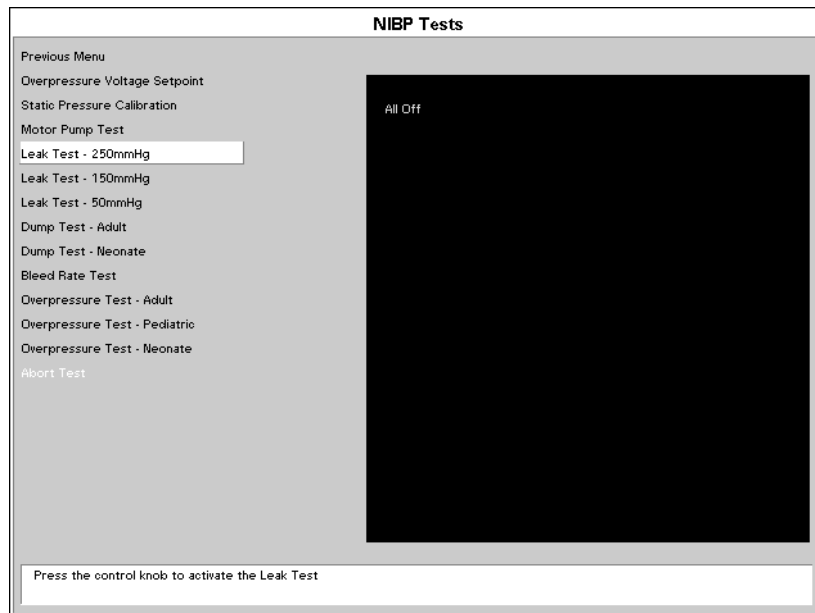
**Specification: Pump to 300mmHg in < 35.0 seconds. – 500cc test chamber**

**Specification: Pump to 300mmHg in < 49.0 seconds – 700cc test chamber**

#### 6.4.7.4 Leak Test (250mmHg, 150mmHg, 50mmHg)

The purpose of the leak test is to verify the leak rate of the pneumatic components.

1. Connect the dummy cuff / test chamber to the side panel fitting.
2. Rotate the control knob to highlight the leak test. Once the leak test is highlighted press the control knob to activate the test.
3. The chamber will inflated to 250, 150 or 50 mmHg of pressure. After ten seconds the pressure on screen the pressure is released. During this ten second period the monitor will determine the leak rate and display the total drop in pressure for that period.



**FIGURE 6-15**

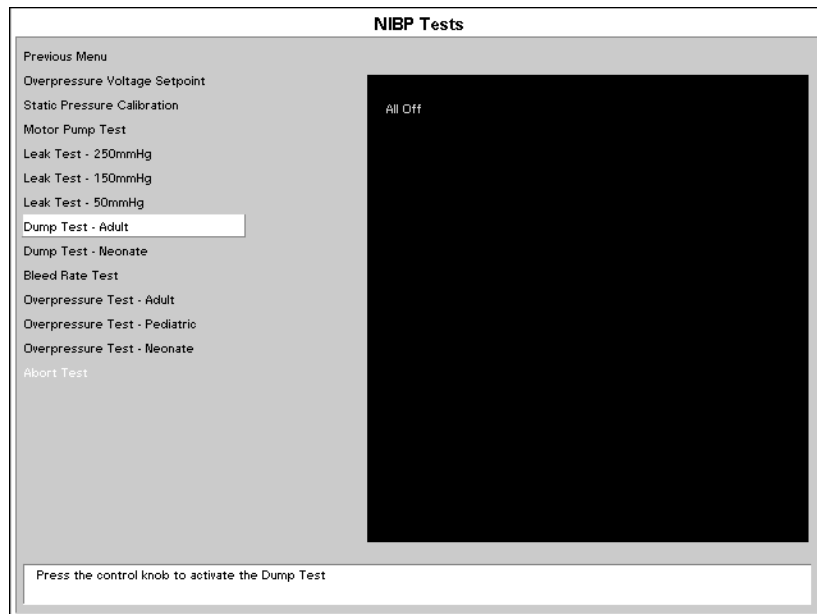
**Specification: Leak rate should not exceed 10 mmHg / 10 seconds for the target values of 250, 150 and 50 mmHg. – 500 cc test chamber**

**Specification: Leak rate should not exceed 10 mmHg / 14 seconds for the target values of 250, 150 and 50 mmHg. – 700 cc test chamber**

### 6.4.7.5 Dump Test (Adult, Neonate)

The purpose of this test is to verify the valve that control the and dump rate is functioning properly.

1. Connect the dummy cuff / test chamber to the side panel fitting.
2. Rotate the control knob to highlight the dump test. Once the dump test is highlighted press the control knob to activate the test.
3. The chamber will inflate to 270mmHg of pressure (Adult) 170mmHg (Neonate). The dump valve will start to deflate at 260 (Adult) 150 (Neonate) after 10 seconds (Adult) 5 seconds (Neonate) the unit will dump the pressure to approximately 15mmHg (Adult) 5mmHg (Neonate). On screen the result of the test will be viewed.



**FIGURE 6-16**

**Specification: Dump Rate – 260 to 15mmHg / 10sec or less – Adult – 500cc test chamber**

**Dump Rate – 150 to 5mmHg / 5sec or less - Neonate – 500cc test chamber**

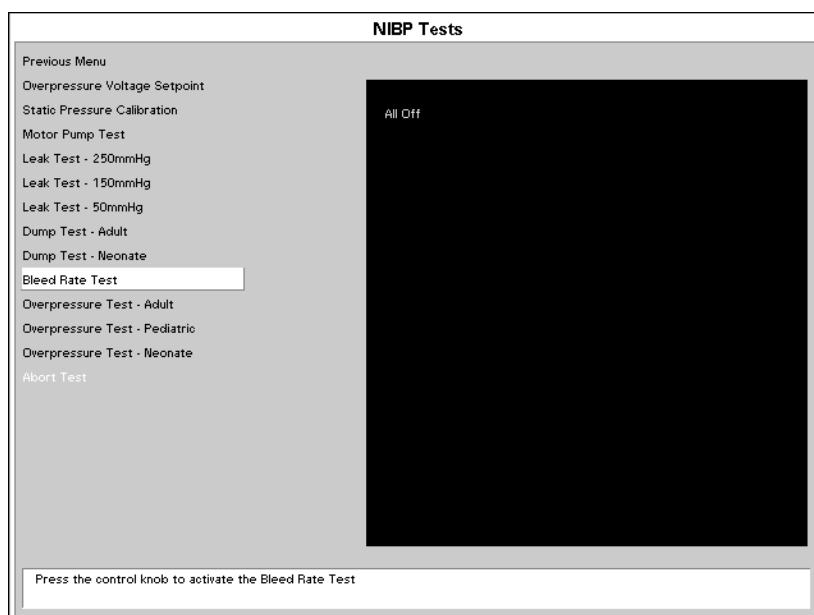
**Specification: Dump Rate – 260 to 15mmHg / 14sec or less – Adult – 700cc test chamber**

**Dump Rate – 150 to 5mmHg / 7sec or less - Neonate – 700cc test chamber**

### 6.4.7.6 Bleed Rate Test

The purpose of this test is to verify the valves that control the bleed rate is functioning properly.

1. Connect the dummy cuff / test chamber to the side panel fitting.
2. Rotate the control knob to highlight the bleed rate. Once the bleed rate test is highlighted press the control knob to activate the test.
3. The chamber will inflate to 220mmHg of pressure. The bleed rate valve will open and deflate the pressure for 10 seconds. On screen the result of the test will be viewed.



**FIGURE 6-17**

**Specification: Bleed Rate = 6.0mmHg / sec  $\pm$  20% - 500cc test chamber**

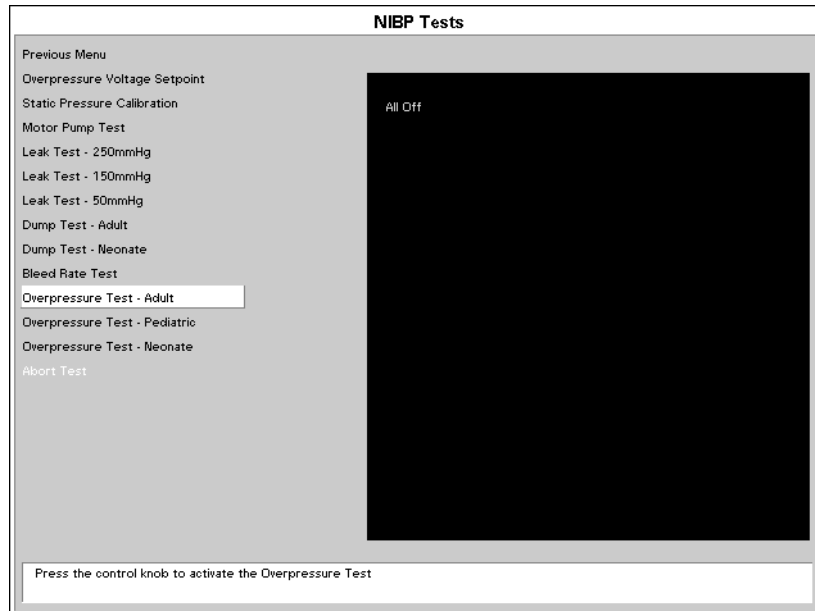
**Specification: Bleed Rate = 6.0mmHg / sec  $\pm$  20% - 700cc test chamber**

### 6.4.7.7 Overpressure Test (Adult, Pediatric, Neonate)

The purpose of this test is to verify the hardware overpressure sensor is functioning properly.

1. Connect the dummy cuff / test chamber to the side panel fitting.
2. Rotate the control knob to highlight the specified overpressure test. Once the overpressure test is highlighted press the control knob to activate the test.

**NOTE:** Due to safety conditions the unit must be reset after each Overpressure Size as been tested.



**FIGURE 6-18**

#### Software Trip points

**Specifications: Adult < or = 300 mmHg**

**Pediatric < or = 200 mmHg**  
**Neonate < or = 150.0 mmHg**

#### Hardware Trip points

**Specifications: Adult < or = 330 mmHg**

**Pediatric < or = 220 mmHg**  
**Neonate < or = 165 mmHg**

3. Press the **PRINT** key to record the test result on the local printer.



## 6.5 Verification

### 6.5.1 Initial Set-up

- 1.** Using a patient simulator, connect the ECG, IBP1, IBP2 and temperature cables to the left side connector panel. Set the ECG simulator for 60 bpm, 1mv QRS signal.
- 2.** Set up the Passport 2 as follows:
  - Patient Menu - Adult mode (patient size)
  - Monitor Setup -
    - a.** Display Setup - 3 Waveforms / 6 Waveforms (12Leads)
    - b.** ECG Speed - 25 mm/sec
    - c.** IBP Speed - 25mm/sec (optional)
    - d.** Respiration / Gas Speed - 12.5 mm/sec
  - Print Setup -
    - a.** Waveform 1 - ECG 1
    - b.** Waveform 2 - ECG 2
    - c.** Select Printer - Local
  - Parameters -
    - a.** ECG
      - ECG 1 - II
      - ECG 2 - I
      - ECG 3 - III
      - ECG 1 through 6 Size - 1cm/mV
    - (12 Lead) Page 1
      - ECG 1 - I
      - ECG 2 - II
      - ECG 3 - III
      - ECG 4 - AVR
      - ECG 5 - AVL
      - ECG 6 - AVF
    - (12 Lead) Page 2
      - ECG 1 - V1
      - ECG 2 - V2
      - ECG 3 - V3
      - ECG 4 - V4
      - ECG 5 - V5
      - ECG 6 - V6

**b. NIBP**

Set Start Pressure - 180 mmHg  
Interval - 5 minutes  
IBP1 - Scale 0 to 160mmHg  
IBP2 - Scale 0 to 80mmHg

**c. SpO<sub>2</sub>**

Averaging mode - 2  
Sensor Off Audio - off

**d. CO<sub>2</sub> - (optional)**

Apnea Delay - 30  
Scale 40 mmHg

**e. Respiration -**

Resp lead - II  
Apnea Delay - 30  
Resp source - Auto  
Scale - 3

**f. Gases - (optional)**

Select agent - Auto  
O<sub>2</sub> scale - 100%  
N<sub>2</sub>O Scale - 10%

## 6.5.2 ECG Tests

### 6.5.2.1 Initialization

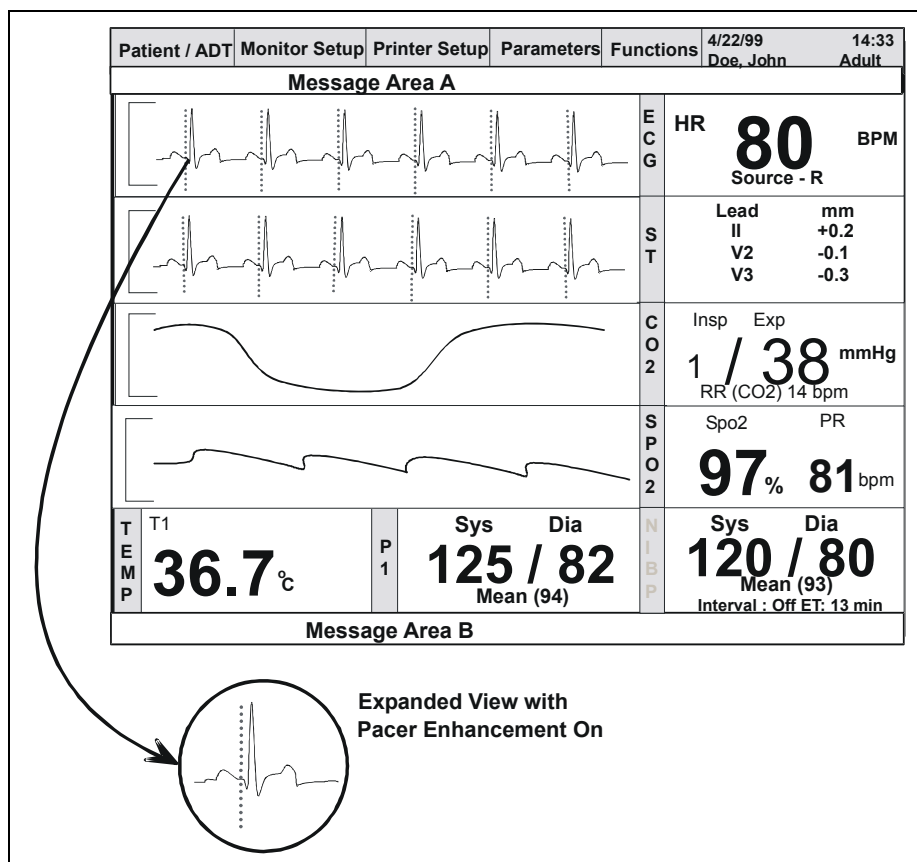
1. Observe that the trace display sweeps across the waveform 1 screen in five seconds. There should be five complete ECG cycles. The same display and timing should be seen in the Waveform 2 screen.
2. Check the following sweep speeds for the appropriate displays:  
12.5 mm/sec – 10 second sweep/window.

### 6.5.2.2 Leads OFF

1. Disconnect one lead at a time RA, RL, LL, LA, and C from the simulator and observe that the message "Lead OFF" appears on the display.
2. Set the ECG simulator to Short Leads. Verify the resolution does not exceed one pixel resolution.

### 6.5.2.3 Pacer Detect

1. Set the Pacer Enhancement feature "on" in the ECG Setup menu.
2. Set the ECG simulator to Ventricular Pacer.
3. Verify the pacer pulse (yellow line) is displayed before the R wave of the QRS signal.



**FIGURE 6-19**

### 6.5.2.4 Heart Rate

1. Set the ECG simulator to ECG QRS waveform. Set the rate to 251 bpm.
2. Verify the Rate display is  $251 \pm 5$  bpm.
3. Decrease the rate to 30 bpm and allow signal to stabilize. Verify that the rate display is  $30 \text{ bpm} \pm 3 \text{ bpm}$ .

### 6.5.2.5 Alarms

1. Set the simulator to 1mv ECG QRS signal, rate set to 60 bpm.
2. Set the **Passport 2** to Print on Alarm, install paper in the recorder, and set the Low HR alarm to 50 bpm, and Hi alarm to 120 bpm.
3. Increase the HR to 125 and verify the following:
  - The high alarm violates with an audio tone and red led active on keypad
  - The recorder is initiated and prints the ECG strip showing the ECG information
4. Measure the Grid and verify the overall width of 40 mm  $\pm$  2 cm.
5. Mute the alarm by pressing the **MUTE ALL** key.
6. Verify that the mute alarms message is displayed in the Message Area "A" and the alarm is silent.
7. Press the **MARK EVENT** key. Press the **TREND** key and examine the trend data. The high HR rate should be red (LCD) or normal brightness (EL) indicating the High HR was violated.

### 6.5.3 IBP 1 and IBP 2 Verification

1. Set the simulator to 0 mmHg for both IBP 1 and IBP2.
2. Press the **ZERO ALL** key. Verify the Systolic, diastolic and mean displays "0"  $\pm$  1 mmHg.
3. Apply 50, 150, and 300 mmHg and verify that the following parameters Sys/ Dia / Mean agree.
4. Apply a 120/80/mmHg signal into IBP 1 and a 60 / 20/ mmHg signal into IBP 2 and verify the correct waveforms are displayed in the window.

### 6.5.4 Temperature Verification

1. Set the Simulator to 37° C 400 series probe
2. Verify the temperature is 37°  $\pm$  0.3°
3. Repeat same test for 700 series probe.

### 6.5.5 SpO<sub>2</sub> Verification

1. Set the **Passport 2** to display waveform 4 as pleth. Set the HR source to Auto.
2. Verify that the SpO<sub>2</sub> message is displaying SpO<sub>2</sub> No Sensor in Message area "B".
3. Connect the SpO<sub>2</sub> sensor to the Panel connector. Verify the SpO<sub>2</sub> message changes to Sensor off or SpO<sub>2</sub> initializing.
4. Apply sensor to finger.
5. Verify window 4 displays the pleth waveform, and the SpO<sub>2</sub> indicates a valid reading. Verify the HR is from SpO<sub>2</sub> and a beep tone is present.

### 6.5.6 NIBP Verification

1. Connect the Adult cuff connector to the NIBP hose. Attach the NIBP hose to the Cuff connection the left side on the monitor.
2. Apply cuff and press the start key on the **Passport 2**.
3. Verify the pump motor starts to pump and inflates the cuff to 180 mmHg (Adult). The cuff will begin to deflate and obtain a blood pressure reading of Sys/ Dia/ Mean in about 20 to 30 seconds after peak pressure is obtained.
4. Verify the reading on screen.

### 6.5.7 Battery Operation Verification

1. If batteries are installed in the unit, remove them.
2. Verify the unit functions on Line power correctly.
3. Install the two batteries in the appropriate slots located on the left side of the monitor.
4. Remove the line cord from the unit. Verify the unit operation is not interrupted.
5. Remove one of the batteries and verify the unit still operates. Verify the second battery operates in the same manner by reinstalling the first battery and removing the second battery.

### 6.5.8 CO<sub>2</sub> Operation Verification

1. Connect the Filterline Short Term assembly to the input port of the CO<sub>2</sub> connector on the left side of the monitor.
2. Attach a can of Calibration Gas P/N 0075-00-0033-01 to the Filterline Short Term assembly. Feed gas into monitor and verify the ETCO<sub>2</sub>, Inspired CO<sub>2</sub> and respiration readings occur on the screen.

### 6.5.9 Leakage Current Tests

1. Plug the line cord of the unit into the safety analyzer. Connect the case ground lead of the analyzer to the equipotential lug of the monitor on the rear of the monitor.
2. Perform the tests under the following conditions:

**a.** Case Grounded:

Normal polarity  
Normal polarity with open neutral

**b.** Case ungrounded:

Normal polarity  
Normal polarity with open neutral  
Reverse polarity

Specs: Verify the current reading of the test is less than 100  $\mu$ A under normal operating conditions.

Less than 300  $\mu$ A under a single fault condition for 120 VAC and less than 500  $\mu$ A under a single fault condition for 230 VAC.

### 6.5.9.1 Patient Leakage

- 1.** Lead to ground: Sink Current Patient circuit (Test V Model 431 Dempsey; patient leakage with line voltage on leads).
- 2.** Connect the ground wire from the safety analyzer to the equipotential lug of the monitor.
- 3.** Connect the ECG cable from the Analyzer to the monitor.
- 4.** On the safety analyzer depress the "Apply 115 VAC" button and note the reading.
- 5.** Repeat the test for normal and open ground polarity combinations.

Specs: Verify the current readings of the test are below 50uA under a single fault condition.

**NOTE:** Including 12 Lead.