# **4.0** *Calibration Procedure*

# 4.1 Introduction

The following procedures are provided to verify the proper operation of the **Spectrum**<sup>®</sup>/ **Spectrum OR**<sup>™</sup> Monitor. Service Diagnostics provide the capability of diagnosing problems within the **Spectrum**<sup>®</sup>/**Spectrum OR**<sup>™</sup> hardware. A menu driven interface similar to that of the **Spectrum**<sup>®</sup>/**Spectrum OR**<sup>™</sup> User Interface, is used to execute all tests.

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

## 4.2

# Warning and Guidelines

In the event that the instrument covers are removed, observe the 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 electrically active.
- 4. Read and understand each step of the procedure prior to beginning the step.

# 4.3 Test Equipment and Special Tools Required

- Digital Mercury manometer with bulb and valve 0-500 mmHg Netech Digimano -Accuracy 0.25% Full Range
- Test Chamber/ P/N 0138-00-0001-01 (700 cc) or -03 (500 cc) Dummy Cuff
- DVM
- Patient Simulator
- Digital Flow Meter
- Safety Analyzer Dempsy Model or equivalent
- BISx BIS Sensor Simulator P/N 0454-00-0060

# 4.4 Diagnostics

To enter the diagnostic mode:

- **1.** Turn the power OFF.
- Pressing and hold the FREEZE key (Spectrum<sup>®</sup>) or the SPIROMETRY key (Spectrum OR<sup>™</sup>) while powering ON the monitor. The Diagnostics Main Menu will appear on screen. Release the FREEZE key or the SPIROMETRY key.
- Rotate the Navigator<sup>™</sup> Knob to move the cursor within the **Diagnostics Main** Menu. Pressing the Navigator knob will select the desired test and open the second test menu.

Diagnostics Main Menu			
iagnostics Test 🕨			
rror Log 🕨 🕨			
ystem Information			
Press control knob to view Diagnostics Menu			

FIGURE 4-1 Diagnostics Main Menu

		Diagnostics Test Menu
Previous Menu		
Keypad / Control Knob	►	
Recorder	►	
Display	►	
NIBP	•	
Select to return to previou	s menu.	
1		

FIGURE 4-2 Diagnostics Test Menu

## 4.4.1 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 via the internal recorder.
- 7. Press the NORMAL key and hold to return to the Diagnostics Test Menu.

Keypad / Control Knob Test				
Control Knob Detent:				
Press keys and the text will appear on screen. Rotate the control knob to move the cursor. Press and hold the Normal Screen Key to exit.				

FIGURE 4-3 Keypad / Control Knob Test

## 4.4.2 Recorder Test

Select the Chart Grid ASCII Characters menu.

Recorder Test	
revious Menu	
est Print	
Select to return to previous menu.	

### FIGURE 4-4 Recorder Test Menu

The printer will print the Recorder Test pattern as shown in the figure below.

AR42       Verssion 3. 03         AR42       Verssion 3. 03         B81       With 1000         B81       With 1000         B81       Verssion 3. 03         B82       Verssion 3. 03         B81       Verssion 4.000         B82       Verssion 4.000         B83       Verssion 4.000         B84       Verssion 4.000         B84       Verssion 4.000         Verssion 4.000       Verssion 4.000	A
---	---

FIGURE 4-5 Recorder Test Strip

## 4.4.3 Display Tests

The display test offers the choice of a **Pixel Test** or a **Color Test**.

Display Tests
Previous Menu
Pixel Test
Color Test
Select to return to previous menu.
1

FIGURE 4-6 Display Tests Menu

## 4.4.4 Pixel Test

The pixel test will verify the proper operation the display. On screen one half of the screen will be illuminated, the second half will be black. Pressing the Navigator<sup>™</sup> knob will illuminate the second half of the screen, the first half will be black. Pressing the Navigator knob a third time will activate the **Display Test Menu** screen.



FIGURE 4-7 Pixel Test Menu

## 4.4.5 Color Test

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



FIGURE 4-8 Color Test

# 4.4.6 NIBP Tests

The **NIBP Test** offers the choice of Overpressure Voltage Setpoint, Static Pressure Calibration, Motor Pump Test, Leak Tests, Bleed Rate Test, and Overpressure Tests. The tests mentioned above require 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.



FIGURE 4-9 NIBP Tests Menu

## 4.4.6.1 Over Pressure Voltage Set Point

No manual adjustment is required. The voltage set point is controlled by software. If **Check Calibration/Cuff Overpresssure** appears in message area of the screen, replace the NIBP module accordingly.

Specifications: .030 to .170 volts

## 4.4.6.2 Static Pressure Calibration

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

		NIBP Tests
Previous Menu		
Overpressure Voltage Setpoint		
Static Pressure Calibration		All Off
Motor Pump Test		
Leak Test - 250mmHg		
Leak Test - 150mmHg		
Leak Test - 50mmHg		
Dump Test - Adult		
Dump Test - Neonate		
Bleed Rate Test		
Overpressure Test - Adult		
Overpressure Test - Pediatric		
Overpressure Test - Neonate		
Abort Test		
Press the control knob to enter Nibp	) Static Pressure Ca	libration.

FIGURE 4-10 NIBP Tests Menu

- 1. Connect the dummy cuff / test chamber to the side panel fitting.
- 2. Use the Navigator<sup>™</sup> knob to select Static Pressure Calibration and activate the test.
- **3.** Use a bulb and valve to manually inflate the chamber to 150 mmHg. (150 mmHg is the middle of the specified range)
- **4.** Verify the pressure displayed on screen matches the pressure viewed on a Digital Mercury Manometer.

#### Specifications: 0 to 300 mmHg +/- 3 mmHg

If the readings do not match, proceed with the following steps:

- **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.
- Locate R81 on the NIBP Module. Turn unit on and enter the Diagnostic Mode as stated in section 4.4. 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 4-11.

### Specifications 150 mmHg +/- .1%

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

Specifications 30 mmHg,100 mmHg, 150 mmHg, 190 mmHg and 250 mmHg. +/-3 mmHg



FIGURE 4-11 Static Calibration screen

# 4.4.6.3Motor Pump Test

The purpose of this test is to determine if the output of the pump is adequate.

		NIBP Tests	
Previous Menu			
Overpressure Voltage Setpoint			
Static Pressure Calibration		All Off	
Motor Pump Test			
Leak Test - 250mmHg			
Leak Test - 150mmHg			
Leak Test - 50mmHg			
Dump Test - Adult			
Dump Test - Neonate			
Bleed Rate Test			
Overpressure Test - Adult			
Overpressure Test - Pediatric			
Overpressure Test - Neonate			
Abort Test			
Press the control knob to activate the	ne Motor Pump Test		

FIGURE 4-12 Motor Pump Test

- 1. Connect the dummy cuff / test chamber to the side panel fitting.
- 2. Select the Motor Pump Test using the Navigator<sup>™</sup> control knob to activate the test.
- **3.** Target pressure of 300 mmHg will be displayed on the screen. The time required to pump to 300 mmHg will also be displayed on screen.

SpecificationsPump to 300 mmHg in < 35.0 seconds. - 500 cc test<br/>chamberSpecifications:Pump to 300 mmHg in < 49.0 seconds - 700 cc test<br/>chamber

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

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

		NIBP Tests
Previous Menu		
Overpressure Voltage Setpoint		
Static Pressure Calibration		All Off
Motor Pump Test		
Leak Test - 250mmHg		
Leak Test - 150mmHg		
Leak Test - 50mmHg		
Dump Test - Adult		
Dump Test - Neonate		
Bleed Rate Test		
Overpressure Test - Adult		
Overpressure Test - Pediatric		
Overpressure Test - Neonate		
Abort Test		
Press the control knob to activate the	Leak Test	

FIGURE 4-13 Leak Test

- 1. Connect the dummy cuff / test chamber to the side panel fitting.
- 2. Select the Leak Test using the Navigator<sup>™</sup> knob to activate the test.
- **3.** The chamber inflates to 250, 150 or 50 mmHg of pressure. After ten (10) 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 time period.

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

# 4.4.6.5 Dump Test (Adult, Neonate)

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

		NIBP Tests	
Previous Menu			
Overpressure Voltage Setpoint			
Static Pressure Calibration		All Off	
Motor Pump Test			
Leak Test - 250mmHg			
Leak Test - 150mmHg			
Leak Test - 50mmHg			
Dump Test - Adult			
Dump Test - Neonate			
Bleed Rate Test			
Overpressure Test - Adult			
Overpressure Test - Pediatric			
Overpressure Test - Neonate			
Abort Test			
Press the control knob to activate the	e Dump Test		
P			

FIGURE 4-14 Dump Test

- 1. Connect the dummy cuff / test chamber to the side panel fitting.
- **2.** Select **Dump Test** using the Navigator<sup>™</sup> knob to activate the test.
- **3.** (Adult) or 5 seconds (Neonate) the unit will dump the pressure to approximately 15 mmHg (adult) or 5 mmHg (Neonate). The result of the test will be displayed on the screen.

	ADULT	
The chamber will inflate to:	270 mmHg	170 mmHg
The dump valve will start to deflate at:	260 mmHg	150 mmHg
After 10 seconds:	15 mmHg	5 mmHg
Specifications:	Dump Rate – 260 to 15mmHg / 10sec o less – Adult – 500cc test chamber Dump Rate – 150 to 5mmHg / 5sec or less - Neonate – 500cc test chamber	
Specifications:	Dump Rate – 260 to 15mmHg / 14sec or less – Adult – 700cc test chamber	
	Dump Rate – 1 less - Neonate	50 to 5mmHg / 7sec or
	icss incondic	

# 4.4.6.6 Bleed Rate Test

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

		NIBP Tests
Previous Menu		
Overpressure Voltage Setpoint		
Static Pressure Calibration		All Off
Motor Pump Test		
Leak Test - 250mmHg		
Leak Test - 150mmHg		
Leak Test - 50mmHg		
Dump Test - Adult		
Dump Test - Neonate		
Bleed Rate Test		
Overpressure Test - Adult		
Overpressure Test - Pediatric		
Overpressure Test - Neonate		
Abort Test		
Press the control knob to activate t	he Bleed Rate Test	

FIGURE 4-15 Bleed Rate Test

- 1. Connect the dummy cuff / test chamber to the side panel fitting.
- 2. Select the **Bleed Rate** using the Navigator<sup>™</sup> knob to activate the test.
- **3.** The chamber will inflate to 220 mmHg of pressure. The bleed rate valve will open and deflate the pressure for 10 seconds. The result of the test will be displayed on the screen.

Specifications:	Bleed Rate = 6.0mmHg / sec ± 20% - 500cc test chamber
Specifications:	Bleed Rate = 6.0mmHg / sec ± 20% - 700cc test chamber

# 4.4.6.7 Overpressure Test (Adult, Pediatric, Neonate)

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

		NIBP Tests
Previous Menu		
Overpressure Voltage Setpoint		
Static Pressure Calibration		All Off
Motor Pump Test		
Leak Test - 250mmHg		
Leak Test - 150mmHg		
Leak Test - 50mmHg		
Dump Test - Adult		
Dump Test - Neonate		
Bleed Rate Test		
Overpressure Test - Adult		
Overpressure Test - Pediatric		
Overpressure Test - Neonate		
Abort Test		
Press the control knob to activate the	Overpressure Tes	st

FIGURE 4-16 Overpressure Test

- 1. Connect the dummy cuff / test chamber to the side panel fitting.
- 2. Select **Overpressure Test** using the Navigator<sup>™</sup> knob to activate the test.

## 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

- NOTE: For Spectrum only, due to safety conditions, the unit must be reset after each Overpressure Test (with software G.10 or lower.)
- 3. Press the print key to send the test result to the local printer.

# 4.4.7 Error Log

Refer to section 4.4 to enter the Diagnostic Main Menu.

	Diagnostics Main Menu
Diagnostics Test	•
Error Log	<u>▶</u>
System Information	
Press control knob to view Diag	inostics Menu
1	

### FIGURE 4-17 Error Log

## 4.4.7.1 Error Log in Memory

	Error Log
Previous Menu	Errors Logged in EMS
Error Log 🔶	11/14/02 17:09:00 BOARD:UNDTYPE:Informational
Dump Printer	rrottip.oxx , line 272
	Communications Failure
	11/11/02 12:09:00 BOARD IND TYPE informational
Clear	rrovtip.cxx , line 272
	ARG1: 0x00000000 ARG2: 0x00000000 Communications Failure
	11/14/02 17:09:00 BOARD:UNDTYPE:Informational regitin over line 272
	ARG1: 0x00000000 ARG2: 0x00000000
	Communications Failure
	rrovtip.oxx , line 272
	ARG1: 0x00000000 ARG2: 0x00000000 Communications Failure
	11/14/02 17:09:00 BOARD:UNDTYPE:Informational regiting over line 272
	ARG1: 0x00000000 ARG2: 0x00000000
	Communications Failure
	11/14/02 17:09:00 BOARD:UNDTYPE:Informational
	rrovtip.cxx , line 272 ARG1: 0x0000000 ARG2: 0x0000000
	Communications Failure
	V
Select to return to previous menu.	
1	

#### FIGURE 4-18 Error Log in Memory

- 1. Select **Error Log** using the Navigator<sup>™</sup> knob.
- **2.** Errors logged in the memory will appear on screen. A maximum of 30 entries will appear with the most recent errors at the beginning of the log. Each error is time stamped and dated.
- 3. Use the Navigator Knob to move the cursor within the list of errors.
- 4. To clear all data from the error log, use the Navigator knob to select Clear.

# 4.5 Microstream<sup>®</sup> $CO_2$ Calibration

In order to provide accuracy verification of the Microstream CO2, calibration is required every 4000 operating hours or once a year, whichever comes first. In addition, to achieve the most accurate CO2 readings possible, it is advised that the first calibration be performed after 1200 operating hours. The date of the last successful calibration appears on the **CO<sub>2</sub> Calibration Menu**.

	CO₂ Menu
Normal Scree	n
Calibrate 🕨	
Scale	40 mmHg
Grid	Off
Color	
Select to re	eturn to normal screen.
1	

FIGURE 4-19 CO<sub>2</sub> Menu

# NOTE: For maximum accuracy during calibration, a 20 minute warm-up time is recommended.

- Connect the tubing that comes with the calibration gas to the gas canister and to the FilterLine<sup>®</sup>. Use calibration gas, (P/N 0075-00-0033-01) and a Microstream FilterLine. Attach the gas / tubing assembly to the CO<sub>2</sub> input port on the Spectrum<sup>®</sup>/Spectrum OR<sup>™</sup>.
- 2. Select the CO<sub>2</sub> Parameter Tile using the Navigator<sup>™</sup> Knob.
- Select the CO<sub>2</sub> Menu. The same menu can be accessed by using the Parameters Menu and selecting CO<sub>2</sub>.
- **4.** Select **Calibrate** and press the button on the gas canister to begin releasing the gas mixture.
- NOTE: Auto zero occurs at the start of the CO<sub>2</sub> monitoring session and periodically throughout the monitoring session. Auto zero will last approximately 15 seconds.
- 5. Select Start from the Calibration Menu. Once the Start option has been selected, no CO<sub>2</sub> waveform data will be displayed.
- 6. The message Calibrating, continue to apply 5% CO<sub>2</sub> will appear in the Calibration Menu.

- NOTE: If no gas is being delivered, or the mixture does not contain 5% CO<sub>2</sub>, the message "Calibration error. Caused by no gas or wrong gas concentration" will appear. Obtain a new gas canister and return step 1.
- 7. When the proper gas mixture is applied, the message Calibrating, continue to apply 5% CO<sub>2</sub> will appear in the Calibration Menu window. When the calibration is complete, the message will change to Calculating, calibration gas can be removed. Release the button, on the canister, and remove the connector.
- 8. After a moment, the message will change to **Calibration Completed Successfully**. The date and time of the successful calibration will appear in the **Calibration Menu**.
- **9.** Use the Navigator<sup>™</sup> Knob to select **Previous Menu**.
- **10.** Use the Navigator Knob to select **Normal Screen** and return to the monitor's normal display screen.
- 11. When the Spectrum<sup>®</sup>/Spectrum OR<sup>™</sup> has detected valid breaths, data will display for the CO<sub>2</sub>, Inspired CO<sub>2</sub> and Respiratory Rate.
- 12. The CO<sub>2</sub> respiration waveform and data will automatically replace the ECG respiration waveform and data on the display. If respiration wave or data is not displayed, use the **Display Setup Menu** to select **RESP** or **CO<sub>2</sub>** to be displayed as desired.
- **13.** The CO<sub>2</sub> waveform scale can be changed by accessing the **CO<sub>2</sub> Menu**.
- NOTE: Microstream<sup>®</sup> CO<sub>2</sub> waste and CO<sub>2</sub> FilterLine<sup>®</sup> should be treated as biohazardous waste.

# 4.6 Verification

# 4.6.1 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 bpms, 1mv QRS signal.
- 2. Set up the Patient Menu for Adult (Patient Size) as follows:

Α.	Monitor Setup	1. 2. 3. 4. 5.	Display Setup – 3 Waveforms ECG Speed – 25 mm/sec IBP Speed – 25 mm/sec (optional) Respiration / Gas Speed – 12.5 mm/sec EEG Speed – 25 mm/sec
В.	Print Setup	1. 2. 3.	Waveform 1 – ECG 1 Waveform 2 – ECG 2 Select Printer – Local
с.	Parameters	1.	ECG: a. ECG 1 - II b. ECG 2 - 1 c. ECG 3 - III d. ECG 1 thru 6 Size - 1 cm/mV (12 Lead) Page 1 e. ECG 1 - 1 f. ECG 2 - II g. ECG 3 - III h. ECG 4 - AVR i. ECG 5 - AVL j. ECG 6 - AVF (12 Lead) Page 2 k. ECG 1 - V1 l. ECG 2 - V2 m. ECG 3 - V3 n. ECG 4 - V4 o. ECG 5 - V5 p. ECG 6 - V6

NOTE: 12 Lead applies to Spectrum only.

D. NIBP

- Set Start Pressure 180 mmHg Interval – 5 minutes
  - **2.** IBP1 Scale 0 to 160 mmHg
  - **3.** IBP2 Scale 0 to 80 mmHg
  - 4. SpO<sub>2</sub>
    - **a.** Averaging mode 2
    - **b.** Sensor Off Audio off

#### 5. CO<sub>2</sub> (optional)

- **a.** Apnea Delay 60
- **b.** Scale 40 mmHg

### 6. Respiration

- a. Resp lead II
- **b.** Apnea Delay 60
- c. Resp source Auto
- **d.** Scale 3

#### 7. Gases (optional)

- a. Select agent Auto
- **b.** O<sub>2</sub> scale 100%
- **c.** N<sub>2</sub>0 Scale 10%

#### 8. Spirometry Verification (optional)

- **a.** Select display loops pressure volume
- b. Paw Scale 0-40
- c. Volume scale 0- 900
- d. Flow Scale -40 -+40

### 9. BISx Verification (optional)

- a. Expand view no
- **b.** EEG setup menu -25uV to +25uV
- c. Sensor Check
  - Pass or Fail
  - High impedance
  - Noise
  - Lead off

## 4.6.2 ECG Tests

## 4.6.2.1 Initialization

- Observe that the trace display sweeps across the waveform 1 screen in five (5) seconds. There should be five (5) complete ECG cycles. The same display and timing should be seen on the Waveform 2 screen.
- Check the following sweep speeds for the appropriate displays: 12.5 mm/sec – 10 second sweep/window

### 4.6.2.2 Leads OFF

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

### 4.6.2.3 Pacer Detect

- 1. Set the Pacer Enhancement feature to 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 4-20 Pacer Setup Menu

### Heart Rate

- 1. Set the ECG simulator to ECG QRS Waveform. Set the rate to 251 bpm.
- 2. Verify the Rate display is 251 ± 5 bpm.
- **3.** Decrease the rate to 30 bpm and allow signal to stabilize. Verify that the rate display is 30 bpm ± 3 bpm.

### Alarms

- 1. Set the simulator to 1mv ECG QRS signal, rate set to 60 bpm
- 2. Set to Print on Alarm, install paper in the recorder, and set the Low HR alarm to 50 bpm, and High alarm to 120 bpm.
- **3.** Increase the HR to 125 and verify the following:
  - **a.** The high alarm violates with an audio tone and red LED on keypad.
  - **b.** The recorder is initiated and prints the ECG strip displaying the ECG information.
  - c. Verify the overall width of the grid is  $40 \text{ mm} \pm 2 \text{ cm}$ .
  - d. Mute the alarm by pressing the MUTE ALL key.
  - e. Verify that the **Mute Alarm** message is displayed in the Message Area "A" and the alarm is silent.
- **4.** Press the **MARK EVENT** key. Press the **TREND** key and examine the trend data. The high HR rate should be red (LCD) indicating the High HR was violated.

## 4.6.3 IBP 1, IBP 2, IBP 3 and IBP 4 (Optional) Verification

- 1. Set the simulator to **O** mmHg for both IBP 1 and IBP2.
- 2. Press the ZERO ALL key. Verify the systolic, diastolic and mean values display as 0  $\pm$  1 mm /Hg.
- 3. Apply 50,150, and 300 mmHg and verify that Sys/ Dia /Mean parameters agree.
- **4.** Apply a 120/80/mmHg signal into IBP 1 and 3 apply a 60 / 20/ mmHg signal into IBP 2 and 4 and verify that the correct waveforms are displayed on the screen.

### 4.6.4 Temperature Verification

### 400 Series Probe

- 1. Set the Simulator to 37° C. Connect to the monitor using a 400 series probe.
- **2.** Verify the temperature is  $37^\circ \pm 2^\circ C$ .

### 700 Series Probe

1. Repeat same test for 700 series probe.

4.6.5	SpO <sub>2</sub> Verification
	1. Set the display waveform 4 as <b>Pleth</b> . Set the HR source to <b>Auto</b> .
	2. Verify that the SpO <sub>2</sub> message is displaying <b>SpO<sub>2</sub> No Sensor</b> in Message area "B".
	<ol> <li>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.</li> </ol>
	<b>4.</b> Apply sensor to finger.
	<ol> <li>Verify SpO<sub>2</sub> displays the pleth waveform, and the SpO<sub>2</sub> indicates a valid reading. Verify the HR source is SpO<sub>2</sub> and a beep tone is present.</li> </ol>
4.6.6	NIBP Verification
	<ol> <li>Connect the Adult cuff connector to the NIBP hose. Attach the NIBP hose to the Cuff connection the left side on the monitor.</li> </ol>
	2. Apply cuff and press the START key.
	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.
4.6.7	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.
	<b>5.</b> Remove one of the batteries and verify the unit still operates. Verify the second battery operates, if installed alone.
4.6.8	Battery Back-up Verification
	1. Select Monitor Setup menu
	2. Select Advanced Setup
	3. Set Date and Time
	4. Select Save Current settings
	5. Select Normal Screen
	6. Verify correct Date and Time is displayed
	7. Power unit OFF
	8. Remove AC power cord and 12V (11.1V Li) batteries if installed
	9. After 2 minutes plug unit back in, reinstall batteries, and power ON
	10. Verify that correct Date and Time is retained
4.6.9	CO <sub>2</sub> Operation Verification
	<ol> <li>Connect the FilterLine<sup>®</sup> Short Term assembly to the input port of the CO<sub>2</sub> connector on the left side of the monitor.</li> </ol>

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 are displayed on the screen.

## 4.6.10 Cardiac Output Verification

### Setup

- Access the Installation Menu by pressing and holding the DISCHARGE key (Spectrum<sup>®</sup>) or the TRENDS key (Spectrum OR<sup>™</sup>) while powering ON the monitor.
- 2. Select Enable EPM and change to Yes.
- 3. Select the weight units to kgs.
- 4. Select the height units to cms.
- 5. Save the current settings and turn unit OFF.

### Operation

- 1. Turn the Spectrum<sup>®</sup>/Spectrum OR<sup>™</sup> monitor on.
- **2.** Set the Patient Size to Adult.
- 3. Press the CO button on the Spectrum<sup>®</sup>/Spectrum OR<sup>™</sup> monitor to bring up the Cardiac Output menu.
- **4.** Select the CO Setup menu. Select the Injectate Temp sensor to **Inline**. Optional Set the Patient Size (72.0 in) and Weight (200 lbs) accordingly.
- Connect the Cardiac Output cable P/N 0012-00-1447-01 (P3) to the Spectrum<sup>®</sup>/ Spectrum OR<sup>™</sup>.
- 6. Connect the appropriate connectors (P1- temp and P2- catheter) to the simulator (Netech Cardiac Output Microsim). Turn on the simulator.
- 7. Set the Cardiac Output rate to 5 liters/min.
- 8. Set the blood temperature to 38° C (98.6°F).
- 9. Set the injectate temperature to 20°C. Press the Previous Menu key.
- Wait for "Inject When Ready" on screen. Verify that the Spectrum<sup>®</sup>/Spectrum OR<sup>™</sup> monitor displays 38.0 +/-0.2°C (98.6+/-.2°F) for blood temperature (Tblood) in the Temp tile.
- 11. When the Spectrum<sup>®</sup>/Spectrum OR<sup>™</sup> displays the prompt Inject When Ready select the Start CO on screen. Press the up arrow button on the simulator.
- 12. Verify the **Spectrum**<sup>®</sup>/**Spectrum OR**<sup>™</sup> displays 5.0 +/-0.5 L/min for Cardiac Output (CO) and 2.5 +/-0.5 L/min/m<sup>2</sup> for Cardiac Index (CI) in the CO tile.
- **13.** Repeat the above steps three times and verify no deviations occur.

## 4.6.11 BISx Verification

### Setup

1. Connect the BISx sensor simulator to the BISx module via the patient interface cable.

- 2. Enter the BISx Sensor Test menu by pressing the **BIS** key and selecting sensor check from the **BIS** menu.
- **3.** Allow the sensor to test the impedance of each electrode for approximately 15 to 20 seconds.
- **4.** Verify on screen the following values.
  - **a.** Electrode #1 = 4 6 k ohms
  - **b.** Electrode #2 = 8 17 k ohms
  - **c.** Electrode #4 = 3 5 k ohms
  - **d.** Electrode #3 = 2 4 k ohms
- NOTE: Do not bend BISx Sensor Simulator. Bending could result in damage to the components and could compromise the functionality of this tool.

## 4.6.12 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:
  - Case Grounded: Normal polarity Normal polarity with open neutral
  - Case ungrounded: Normal polarity
     Normal polarity with open neutral Reverse polarity

Specifications: Verify the current reading of the test is less than 100 µA 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

## 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.

Specifications: Verify the current readings of the test are below 50µA under a single fault condition. (Including 12 Lead for Spectrum only)