5.0 *Calibration Procedure*

5.1 Introduction

The following procedures are provided to verify the proper operation of the **Passport V** Monitor. Service Diagnostics provides the capability of diagnosing problems within the **Passport V** hardware. A menu driven interface, similar to that of the **Passport V** user interface, is used to execute all tests.

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

5.2 Warnings and Guidelines

If 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.

5.3 Test Equipment and Special Tools Required

- Digital/Mercury manometer with bulb and valve 0-500 mmHg Accuracy 0.25% Full Range
- Test Chamber/Dummy Cuff P/Ns 0138-00-0001-01 (700 cc), 0138-00-0001-03 (500 cc)
- Digital Voltmeter
- Patient Simulator
- Digital Flow Meter
- CO₂ Calibration Gas P/N 0075-00-0033-01
- Calibration Gas Regulator P/N 0119-00-0166
- GM Calibration Gas P/N 0075-00-0028
- Safety Analyzer-601 safety analyzer, Demsey Model 431, or equivalent

5.4 Services

To enter the Service mode:

- 1. Turn the power OFF.
- 2. Press and hold the **Mark Event** key while powering on the monitor. The Service Menu will appear on screen. Release the **Mark Event** key.
- **3.** Rotate the NavigatorTM Knob to move the cursor within the Service Menu. Pressing the NavigatorTM Knob will select the desired test and open the second test menu.



FIGURE 5-1 Service Menu

5.4.1 ECG Channels Check

The ECG signal may be inaccurate due to hardware or software problems. As a result, the ECG wave amplitude becomes greater or smaller. If so, the ECG module must be serviced.

Previous Menu Stop Channels Check ECG Size 1 cm/mV Print ECG		ECG Channels Check Menu	
EGG Size 1 cm/mV Print EGG	Previous Menu Stop Channels Cl	leck	
III 1 mV 1 mV 1 mV 1 mV 1 mV	ECG Size Print ECG	1 cm/mV	
1 mV	. 1 mV		
	1 mV		
	v 1 mV		
	elp		

FIGURE 5-2 ECG Channels Check Menu

- 1. Select the ECG Channels Check button in the Service Menu
- **2.** Use the NavigatorTM Knob to select the Start Channels Check button and activate the test. A square wave should appear on the screen.
- **3.** Compare the amplitude of the square wave with the wave scale. The difference should be within 5%.

5.4.2 NIBP Maintenance

The NIBP Maintenance offers the choice of NIBP Accuracy Test, NIBP Leakage Test, and Calibrate NIBP.

	NIBP Maintenance Menu
Previous Menu	
Patient Size NIBP Accuracy Test NIBP Leakage Test	Adult
Calibrate NIBP	•
Help	

FIGURE 5-3 NIBP Maintenance Menu

5.4.2.1 NIBP Accuracy Test

- 1. Connect the equipment as shown in FIGURE 5-4.
- 2. Select NIBP Accuracy Test using the NavigatorTM Knob to activate the test.
- 3. Using the manometer's bulb valve, raise the pressure in the test chamber to 300mmHg.
- **4.** Compare the pressure displayed on the screen with the pressure viewed on the manometer. The difference between readings should not be greater than +/-3 mmHg.

NOTE: An NIBP simulator can be used to replace the reference manometer with the bulb valve to perform the test.

Specifications: 0 to 300 mmHg +/- 3 mmHg



FIGURE 5-4 NIBP Accuracy Test

5.4.2.2 NIBP Leakage Test

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. Select NIBP Leakage Test using the NavigatorTM Knob to activate the test.
- 3. The chamber is inflating. At the same time, the "NIBP Leakage Test" button changes to "Stop Leakage Test", and the real-time pressure and the message "Leakage Testing..." appears in the prompt message area.
- 4. When the leakage test is completed, the button "Stop Leakage Test" changes back to "NIBP Leakage Test." If any leakage is detected, the message "NIBP Pneumatic Leak" appears.

5.4.2.3 NIBP Calibration

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

- 1. Connect the equipment as shown in FIGURE 5-4.
- 2. Use the NavigatorTM Knob to select Calibrate NIBP.
- **3.** Select Inflate to activate the calibration. At the same time, the Inflate button changes to Accept.
- 4. Select Reference Pressure to set the calibration reference pressure.

NOTE: The reference pressure can be set from 240 mmHg to 260 mmHg. The default pressure is 250 mmHg and the input step is 1 mmHg.

- 5. When the pressure viewed on the manometer matches the reference pressure, select Accept to accept the calibrated result. The measured pressure will replace the reference pressure to complete the calibration.
- NOTE: If the calibration is successful, the calibration time will be displayed in the format of year, month, day, hour, and minute. Otherwise, the calibration time is displayed as dashes.

NOTE: During the calibration process, pressing the Deflate button will abort the calibration. However, if the calibration has already been accepted, it cannot be aborted.

5.4.3 IBP Calibration

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

- 1. Connect the patient simulator to the pressure connector P1(P2) on the module.
- **2.** Set the pressure on the simulator to 0.
- 3. Press the P1(P2) Zero Key on the module to start a zero calibration.
- Select P1(P2) Calibrate Pressure to set the calibration reference pressure. The default pressure is 200 mmHg.

NOTE: The Calibration Pressure is adjustable from 80 mmHg to 300 mmHg at 2 mmHg intervals.

- 5. Adjust the simulator to match the calibration reference pressure.
- 6. Select P1(P2) Calibrate to calibrate the pressure module.

	Calibr	ate IBP Menu
Previous Menu		
P1 Zero	200 mmHa	150 /1491 05/06/2009 15:25
P1 Calibrate	200 mining	Sensor Off. Cannot Zero!
P2 Zero		
P2 Calibration Pressure P2 Calibrate	200 mmHg	200 (200) 05/06/2008 15:35

FIGURE 5-5 Calibrate IBP Menu

5.4.4 CO_2 Calibration

It is recommended that, in order to provide accuracy verification of the CO_2 , calibration is performed once a year or whenever CO_2 readings appear suspicious. The date of the last successful calibration appears on the Calibration CO_2 Menu.

The CO₂ module must be warmed up before calibration.

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

- **1.** Use the NavigatorTM Knob to select Calibrate CO₂.
- 2. Connect the gas cylinder with the tubing using a T- connector. Check the airway and make sure there are no leaks.
- **3.** Select Zero on the Calibrate CO_2 Menu (only for Sidestream CO_2).

NOTE: A zero (optional) is recommended before calibration. If zeroing fails, the message CO₂ Zeroing Failed appears. Otherwise, no message will appear.

- 4. Adjust the concentration of the standard gas to 5%.
- NOTE: The concentration of the standard gas used to calibrate the Sidestream CO_2 module can be adjusted from 3% to 7% at 1% intervals. For the Microstream CO_2 module, it can be adjusted from 4.0% to 6.0% at 0.1% intervals.
- **5.** Make sure the CO₂ tubing is vented before flowing the gas. CO₂ readings will appear during the calibration.
- NOTE: If the Sidestream CO₂ module is used, the Calibrate CO₂ Menu will show the measured CO₂ concentration, atmospheric pressure, and sensor temperature. If the Microstream CO₂ module is used, the Calibrate CO₂ Menu will show the measured CO₂ concentration and atmospheric pressure.
- 6. After the measured CO₂ concentration becomes stable, select Calibrate to calibrate the CO₂ module. Continue to steadily flow gas until a calibration message appears at the bottom of the calibration tile.
- If the calibration is successful, the message "Calibration Completed Successfully" appears. Otherwise, the message "Calibration Failure" appears. If so, another calibration is required.

Calibr	ate CO2
Previous Menu	
CO2 5%	
Zero	
Calibrate	
CO2 0.00%	
Atmospheric Pressure 755	5mmHg
Sensor Temperature 3	3°C
Help	

FIGURE 5-6 Sidestream CO₂ Calibrate Menu

	Calibrate	CO2	
Previous Me	าบ		
C O 2	5.0%		
Calibrate			
CO2		0.00%	
At mospher i c	Pressure	755mmHg	
		<u> </u>	
help			

FIGURE 5-7 Microstream CO₂ Calibrate Menu

5.4.5 Gas Calibration

It is recommended that to maintain accuracy of the Gas Module 3, calibration is required once a year or whenever gas readings appear suspicious.

```
NOTE: Single gas calibration is intended for 5%CO<sub>2</sub> or 55%O<sub>2</sub> or
33%N<sub>2</sub>O or 2%Des only. For mixed gas calibration, 5% CO<sub>2</sub>,
55%O<sub>2</sub>, 33% N<sub>2</sub>O and 2% Des are calibrated
simultaneously.
```

```
NOTE: The Gas Module 3 must fully warm up before performing a gas calibration. For maximum accuracy, a warm-up time of 10 minutes is recommended.
```

- 1. Use the NavigatorTM Knob to select Calibrate Gas.
- 2. Connect the gas bottle and the tubing using a T-connector as shown in FIGURE 5-8.
- 3. Check the airway and make sure that there is no occlusion or leakage.
- **4.** Press the Gas Selection button to select the type of calibration gas.
- 5. Select Start to activate a calibration. At the start of the calibration, the message "Zeroing..." will be displayed for each of the gas labels as the Gas Module zeros the gas channels. After zeroing is successful, the Gas Module will request the calibration gas as indicated in the next step.
- NOTE: After the calibration is started, the module will begin zeroing, sampling, and calibrating automatically.
- NOTE: If the Gas Module fails zeroing, a zeroing error will be displayed and the previous calibration data will be restored. If so, repeat the calibration procedure from step 1. If problems persist, contact Customer Support.

- 6. The message "Feed Calibration Gas" will be displayed. At this time, vent the desired standard gas or gas mixture to the tubing opening the gas valve. Gas values will appear in the window as the Gas Module samples the calibration gas.
- 7. When the calibration is completed, the message "Feed Calibration Gas" will disappear and the message "Complete" will be displayed next to each value that was successfully measured. If at least one gas was successfully measured, the Accept menu choice will become available. If the values are acceptable, select Accept. To cancel the calibration and restore the previous calibration data, select Abort.
- NOTE: When the Accept menu choice is selected, the message "Calibration Completed Successfully" and "Disconnect Calibration Gas" will be displayed. To avoid premature emptying of the gas bottle, always remove the regulator at the end of the procedure.
- NOTE: For Gas Module 3, if any input data is corrupt or if there are any other errors, a Calibration Error message will appear after the Accept button is selected. The Gas Module 3 will not accept span calibration with errors in any channel.



FIGURE 5-8 Gas Calibration



FIGURE 5-9 Calibration

5.4.6 Monitor Log



FIGURE 5-10 Monitor Log Menu

- 1. Select the Monitor Log using the NavigatorTM Knob to enter the Monitor Log Menu.
- 2. Errors log will appear on screen. Each error is time stamped and dated.
- **3.** Use the NavigatorTM Knob to move the cursor within the list of errors.
- **4.** To clear all data from the error log, use the NavigatorTM Knob to select Clear.

5.5 Verification

5.5.1 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 bpms, 1mv QRS signal.
- 2. Set up the Patient Menu for Adult (Patient Size) as follows:
- A. Monitor Setup
 - 1. Display Setup 3 Waveforms
 - 2. ECG Speed 25 mm/sec
 - 3. IBP Speed 25 mm/sec (optional)
 - **4.** Respiration / Gas Speed 12.5 mm/sec
- B. Print Setup
 - 1. Waveform 1 ECG 1
 - 2. Waveform 2 ECG 2
 - 3. Select Printer Local
- C. Parameters
 - 1.ECG
 - **a.** ECG 1 II
 - **b.** ECG 2 I
 - **c.** ECG 3 III
 - d. ECG 1 thru 6 Size 1 cm/mV
 - e. ECG 1 I
 - **f.** ECG 2 II
 - **g.** ECG 3 III
 - h. ECG 4 AVR
 - **i.** ECG 5 AVL
 - i. ECG 6 AVF
 - **k.** ECG 7 V
 - **2.** NIBP
 - a. Set Start Pressure 180 mmHg
 - Interval 5 minutes
 - **b.** IBP1 Scale 0 to 160 mmHg
 - c. IBP2 Scale 0 to 80 mmHg
 - **3.** SpO_2
 - **a.** Averaging mode 2
 - **b.** Sensor Off Audio off
 - 4. CO₂ (optional)
 - **a.** Apnea Delay 60
 - **b.** Scale 40 mmHg

- 5. Respiration
- **a.** Resp lead II
- **b.** Apnea Delay 60
- c. Resp source Auto
- **d.** Scale 3
- 6. Gases (optional)
- a. Select agent Auto
- **b.** O₂ scale 100%
- **c.** Agent scale- 10%

5.5.2 ECG

5.5.2.1 Initialization

- Observe that the trace display sweeps across the waveform 1 screen in six (6) seconds. There should be six (6) complete ECG cycles. The same display and timing should be seen on the Waveform 2 screen.
- **2.** Check the following sweep speeds for the appropriate displays: 12.5 mm/sec 12 second sweep/window

5.5.2.2 Leads OFF

- 1. 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.

5.5.2.3 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 (white line) is displayed before the R wave of the QRS signal.

Heart Rate

- 1. Set the ECG simulator to ECG QRS Waveform. Set the rate to 250 bpm.
- 2. Verify the Rate display is 250 ± 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 local printer, 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 local printer 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. Silence the alarm by pressing the Silence All key.
 - e. Verify that the Silence Alarm message is displayed in the Message Area "A" and the alarm is silent.
- **4.** Press the **Mark Event** key. Press the **Trends** key and examine the trend data. The high HR rate should be red (LCD) indicating the High HR was violated.

5.5.2.4 Performance Test

Tool required: Patient simulator

- 1. Connect the patient simulator to the ECG/Resp connector on the module.
- 2. Set HR output to 80 bpm in the ECG simulator.
- 3. The displayed HR value should be 80 \pm 1 bpm for 3- and 5-lead ECG monitoring.

5.5.3 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 values display as 0 \pm 1 mm/Hg.
- 3. Apply 50,150, and 300 mmHg and verify that Sys/ Dia /Mean parameters match.
- **4.** Apply a 120/80/mmHg signal into IBP 1 and apply a 60 / 20/ mmHg signal into IBP 2 and verify that the correct waveforms are displayed on the screen.

5.5.4 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 $37^{\circ} \pm 0.1^{\circ}$ C.

5.5.5 SpO₂ Verification

- **1.** Connect the patient simulator to the SpO_2 connector on the monitor.
- **2.** Select the model and the manufacturer of the SpO₂ module under test, and then configure the patient simulator as follows: SpO₂ 96%; PR 80 bpm.
- The displayed SpO₂ and PR values should be within the following ranges: DPM, Masimo, and Nellcor SpO₂: 96% ± 2% PR (bpm):80 ± 3
- Verify that SpO₂ displays the pleth waveform, and the SpO₂ indicates a valid reading. Verify the HR source is SpO₂ and a beep tone is present.

CAUTION: A functional tester cannot be used to assess the accuracy of the pulse oximeter probe or a pulse oximeter monitor.

5.5.6 NIBP Verification

1. Connect the Adult cuff connector to the NIBP hose. Attach the NIBP hose to the Cuff connection on the left side of the monitor.

- 2. Apply cuff and press the Start key.
- **3.** Verify the pump motor starts pumping and inflating 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.

5.5.7 Battery Operation Verification

- 1. Remove the batteries if they are installed in the unit.
- 2. Verify that the unit functions properly, powered via line cord.
- 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 that the unit operation is not interrupted.
- **5.** Remove one of the batteries and verify the unit still operates. Verify the second battery operates, if installed alone.

5.5.8 CO₂ Operation Verification

- 1. Connect the FilterLine[®] Short Term assembly to the input port of the CO₂ 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 ETCO₂, Inspired CO₂ and respiration readings are displayed on the screen.

5.5.9 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:
 - 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 μ A under normal operating conditions Less than 300 μ A under a single fault condition for 120 VAC and less than 500 μ A under a single fault condition for 230 VAC

Patient Leakage

 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 50 μA under a single fault condition.