3.4 Module Performance Tests

3.4.1 ECG Tests and Calibration

ECG Performance Test

Tool required:

■ Fluke Medsim 300B patient simulator recommended

Follow this procedure to perform the test:

1. Connect the patient simulator with the ECG module using an ECG cable.

2. Set the patient simulator as follows: ECG sinus rhythm, HR=80 bpm with the amplitude as 1mV.

3. Check the ECG waves are displayed correctly without noise and the displayed HR value is within 80 ± 1 bpm.

4. Disconnect each of the leads in turn and observe the corresponding lead off message displayed on the screen.

5. Set that the simulator outputs paced signals and set [**Paced**] to [**Yes**] on the monitor. Check the pace pulse marks on the monitor screen.

ECG Calibration

Tool required:

■ Vernier caliper

Follow this procedure to perform a calibration:

1. Select the ECG parameter window or waveform area→ [**Filter**]→ [**Diagnostic**].

2. Select [**Main Menu**]→ [**Maintenance>>**].

3. Select [**Calibrate ECG**]. A square wave appears on the screen and the message [**ECG Calibrating**] is displayed.

4. Compare the amplitude of the square wave with the wave scale. The difference should be within 5%.

5. After completing the calibration, select [**Stop Calibrating ECG**].

3.4.2 Resp Performance Test

Tool required:

■ Fluke Medsim 300B patient simulator recommended

Follow this procedure to perform the test:

1. Connect the patient simulator to the module using a non ESU-proof cable and set lead II as the respiration lead.

2. Configure the simulator as follows: lead II as the respiration lead, base impedance line as 1500 Ω; delta impedance as 0.5 Ω, respiration rate as 40 rpm.

3. Check the Resp wave is displayed without any distortion and the displayed Resp value is within 40 ± 2 rpm.

3.4.3 SpO$_2$ Test

Tool Required:

■ None.

Follow this procedure to perform the test:

1. Connect SpO$_2$ sensor to the SpO$_2$ connector of the monitor. Set [**Patient Cat.**] to [**Adu**] and [**PR Source**] to SpO$_2$ on the monitor.

2. Apply the Measure SpO$_2$ sensor to on your ring finger. (Assume that you stay healthy)

3. Check the Pleth wave and PR reading on the screen and make sure that the displayed SpO$_2$ is within 95% and 100%.

4. Remove the SpO$_2$ sensor from your finger and make sure that an alarm of SpO$_2$ Sensor Off is triggered.

NOTE

● **A functional tester cannot be used to assess the accuracy of a pulse oximeter monitor. However, it can be used to demonstrate that a particular pulse oximeter monitor reproduces a calibration curve that has been independently demonstrated to fulfill a particular accuracy specification.**

3.4.4 NIBP Tests

Refer to *3.2.2 NIBP Tests and Calibration*.

3.4.5 Temp Test

Tool required:

■ Resistance box (with accuracy above 0.1Ω)

Follow this procedure to perform the test:

1. Connect the two pins of any Temp connector of a module to the two ends of the resistance box using 2 wires.

2. Set the resistance box to 1354.9Ω (corresponding temperature is 37ºC).

3. Verify that the displayed value is within 37 ± 0.1ºC.

4. Repeat steps 1 to 3 and verify another temperature channel.

3.4.6 IBP Tests

IBP Performance Test

Tool required:

■ Medsim300B patient simulator, MPS450, or other equivalent device

■ Dedicated IBP adapter cable for test (P/N 009-002199-00 for Medsim 300B, P/N 009-002198-00 for MPS450)

Follow this procedure to perform the test:

1. Connect the patient simulator with the pressure module.

2. Make the patient simulator outputs 0 to an IBP channel.

3. Press the Zero Key on the module to make a zero calibration.

4. Configure the patient simulator as P (static) = 200 mmHg.

5. The displayed value should be within 200 ± 4 mmHg.

6. If the error is beyond ±4 mmHg, calibrate the pressure module. If the IBP module was calibrated with a dedicated reusable IBP sensor, check the calibration together with this IBP sensor.

7. Make the patient simulator output 120/80 mmHg ART signal and 120/0 mmHg LV signal to the IBP channel and check that the IBP wave is displayed correctly.

8   Repeat the steps above for all the IBP channels.

IBP Pressure Calibration

Method 1

Tools required:

- Medsim300B patient simulator, MPS450, or other equivalent device

IBP adapter cable for test (P/N 009-002199-00 for Medsim 300B, P/N 009-002198-00 for MPS450)

Follow this procedure to perform the test:

1. Connect the patient simulator to the pressure connector on the module.

2. Set the patient simulator to 0 for the desired IBP channel.

3. Press the Zero Key on the module to make a zero calibration.

4. Configure the patient simulator as P (static) = 200 mmHg.

5. Select [**Main Menu**]→ [**Maintenance >>**]→[**User Maintenance >>**]→[**Cal**. **IBP Press. >>**]. In the [**Cal. IBP Press.**] menu, set the calibration value to 200 mmHg.

6. Select the [**Calibrate**] button next to the desired IBP channel to start a calibration.

7. If the calibration is completed successfully, the message [**Calibration Completed!**] will be displayed. Otherwise, a corresponding message will be displayed.

Method 2

Tools required:

- Standard sphygmomanometer
- Balloon pump
- Tubing
- T-shape connector

To perform a calibration:

1. Connect the 3-way stopcock, the sphygmomanometer and the balloon pump through a T-shape connector, as shown below.

2. Vent the transducer to the atmospheric pressure by turning on the 3-way stopcock to the air. Zero the transducer, and then open the stopcock to the sphygmomanometer.

3. Select [**Main Menu**]→[**Maintenance >>**]→[**User Maintenance >>**]→enter the required password → [**Cal**. **IBP Press. >>**] In the [**Cal. IBP Press.**] menu, set the calibration value to 200 mmHg.

4. Inflate using the balloon pump until the reading of sphygmomanometer approximates the preset calibration value.

Pressure transducer

3-way stopcock

T-shape connector

Pressure adapter cable

Sphygmomanometer

IBP Module
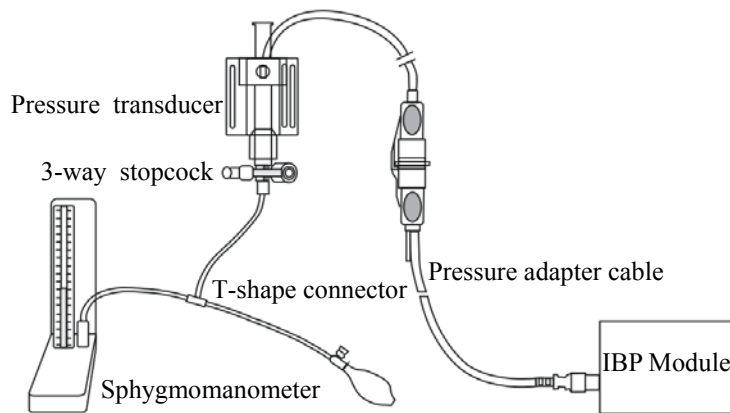
5. Adjust the calibration value in the [**Maintain IBP**] menu until it is equal to the reading of sphygmomanometer

6. Select the [**Calibrate**] button to start a calibration

7. The message [**Calibration Completed!**] is displayed after a successful calibration. If the calibration failed, the prompt [**Calibration Failed!**] will be displayed.

3.4.7 C.O. Test

Tools required:

■ Medsim300B Patient simulator, or MPS450, or equivalent equipment

■ C.O. adapter box (CI-3 module/cable, P/N: 3010-0289 for 300B, P/N: 5180500 for MPS450)

■ C.O. trunk cable (PN: 0010-21-42716)

Follow this procedure to perform the test:

1. Connect the patient simulator and the C.O. module using a C.O. trunk cable and a C.O. adapter box.

2. Set the blood temperature (BT) to 37ºC on the patient simulator and check the temperature value displayed on the monitor is 37 ± 0.2ºC.

3. On the patient monitor, set [**Auto IT**] to [**Off**], [**IT**] to 2ºC, and [**Comp. Const.**] to 0.595 in the [**C.O. Setup**] menu. Select [**C.O. Measure**] to enter the C.O. measurement window.

4. Select [**Start**] in the C.O. measurement window to start C.O. measurements.

5. On the patient simulator, set C.O. to 5L/min and wait for 3 to 10 seconds.

6. Verify that the C.O. value displayed on the monitor is 5±0.25L/min.

3.4.8 Mainstream CO_2 Tests

NOTE

- **Select [Main Menu]→[Maintenance >>]→ [User Maintenance >>]→enter the required password→[Maintain CO_2], make sure that the setting of [Barometric Pressure] is correct before performing mainstream CO_2 tests.**

Tools required:

- A steel gas cylinder with $6\pm0.05\%$ CO_2
- A steel gas cylinder with compressed air or N_2 (with standard concentration)
- Two 3-way valves (power supply controlled)
- Flowmeter
- Power supply
- Tube

Follow this procedure to perform the test:

1. Wait until CO_2 warmup is finished and then select [**Start Zero Cal.**]from [**CO_2 Setup**] menu to start a zero calibration. If the zero calibration fails, the prompt message [**CO_2 Zero Failed**] is displayed. Otherwise, the baseline of waveform recovers to zero.

2. Set [**Apnea Delay**] to 10 s in the [**Adjust CO_2 Limits**] menu.

3. Blow to the CO_2 sensor to generate a CO_2 waveform and then place the sensor in the air. Check if the alarm message [**CO_2 Apnea**] is displayed on the screen.

4. Connect the test system as follows
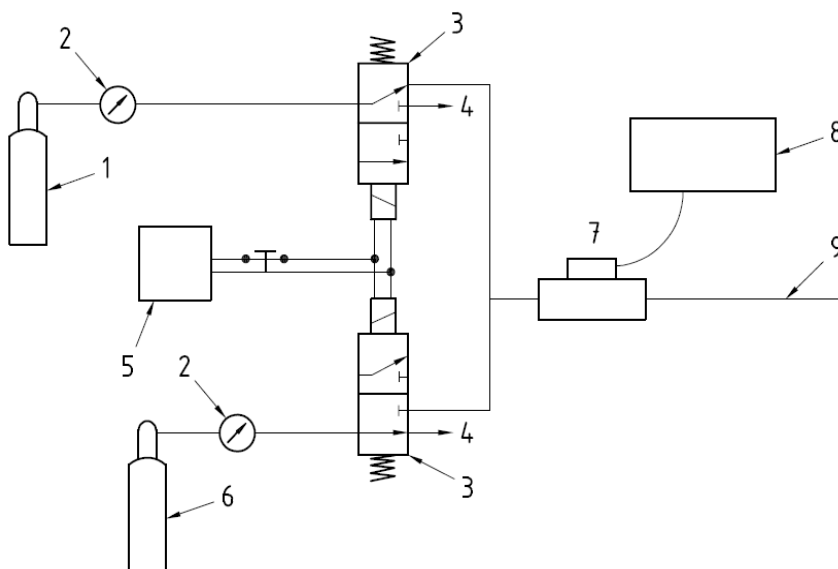
In the figure above,

1	A steel gas cylinder with $6\pm0.05\%$ CO_2
2	Flowmeter
3	3-way valve (power supply controlled)
4	Open to air
5	Power supply (controlling two 3-way valves)
6	Compressed air or N_2 with standard concentration
7	Mainstream CO_2 sensor
8	Patient monitor
9	Tube (preventing back flow)

5   Adjust the power supply and turn on/off 3-way valves to ensure that that only one cylinder is connected to the Mainstream CO_2 sensor via the 3-way valves at one time and the flowmeter reading is stable and within 2 and 5L/min.

6   Switch between the two cylinders to connect Mainstream CO_2 sensor at an intervals of 6 to 10s and check if the displayed CO_2 value is within $6.0\pm0.3\%$.

3.4.9 Sidestream and Microstream CO$_2$ Module Tests

See section *3.2.3 Sidestream and Microstream CO$_2$ Module Tests.*

3.4.10 AG Tests

See section *3.2.4 AG Tests.*