3.1.2 Test Report

Upon completion of the tests, the table of preventative maintenance test reports and the table of maintenance test reports in this chapter should be kept properly.

3.1.3 Preventative Maintenance

Below are preventative maintenance tests which need to be performed on the monitor. See the following sections for detailed maintenance procedures.

- Visual inspection
- NIBP test and calibration
- Microsteam and Sidestram CO_2 test and calibration
- AG test and calibration

3.1.4 Recommended Frequency

Check/Maintenance Item		Frequency
Preventative Maintenance Tests		
Visual inspection		1. When first installed or reinstalled.
NIBP test	Pressure check	1. If the user suspects that the measurement is incorrect.
	Leakage test	
	Calibration	2. Following any repairs or replacement of relevant module.
Sidestream and Microstream CO_2 tests	Leakage test	3.At least once a year is recommended.
	Performance test	
	Calibration	
AG tests	Leakage test	
	Performance test	
	Calibration	
Performance Tests		
ECG test and calibration	Performance test	1. If the user suspects that the measurement is incorrect.
	Calibration	2. Following any repairs or replacement of relevant module.
Resp performance test	/	3. At least once every two years.

SpO$_2$ test	/	Note: At least once a year is recommended for NIBP, CO$_2$ and AG.
NIBP test and calibration	Pressure check	
	Leakage test	
	Calibration	
Temp test	/	
IBP test and calibration	Performance test	
	Pressure calibration	
C.O. test	/	
Mainstream CO$_2$ test and calibration	/	
Sidestream and Microstream CO$_2$ tests and calibration	Leakage test	
	Performance test	
	Calibration	
AG tests	Leakage test	
	Performance test	
	Calibration	
ICG test	/	
BIS test	/	
RM test	/	
CCO/SvO$_2$ test	Interconnecting function	
	Output calibration	
Nurse call relay performance test	/	If the user suspects that the nurse call or analog output does not work well.
Analog output performance test	/	
Electrical Safety Tests		

Electrical safety tests	Refer to *A Electrical Safety Inspection.*	1. Following any repair or replacement 2. After the monitor drops. 3. At least once every two years.
Other Tests		
Power on test		1. When first installed or reinstalled. 2. Following any maintenance or the replacement of any main unit parts.
Touchscreen calibration	/	1. When the touchscreen appears abnormal. 2. After the touchscreen is replaced.
Recorder check	/	Following any repair or replacement of the recorder.
Network print test	/	1. When first installed. 2. Whenever the printer is serviced or replaced.
Battery check	Functionality test	1. When first installed. 2. Whenever a battery is replaced.
	Performance test	Once a year or if the battery run time reduced significantly.

3.2 Preventative Maintenance Procedures

3.2.1 Visual Inspection

Inspect the equipment for obvious signs of damage. The test is passed if the equipment has no obvious signs of damage. Follow these guidelines when inspecting the equipment:

- Carefully inspect the case, display screen, buttons and knob for obvious signs of damage.
- Inspect the SMR and parameter modules for obvious signs of damage.
- Inspect the power cord, wall-mount bracket and module accessories for obvious signs of damage
- Inspect all external connections for loose connectors, bent pins or frayed cables.
- Inspect all connectors on the equipment for loose connectors or bent pins.
- Make sure that safety labels and data plates on the equipment are clearly legible.
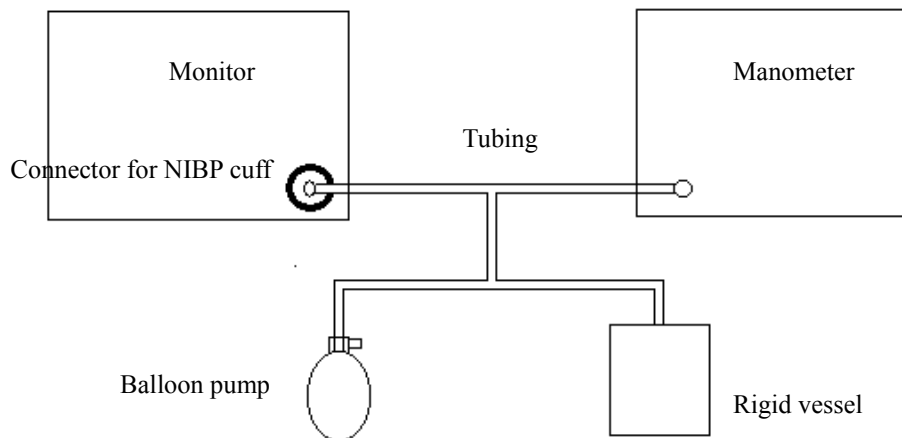
3.2.2 NIBP Tests and Calibration

NIBP Accuracy Test

Tools required:

■ T-shape connector

■ Appropriate tubing

■ Balloon pump

■ Rigid Vessel with volume 500 ± 25 ml

■ Reference manometer (calibrated with accuracy equal to or better than 0.75 mmHg)

Follow this procedure to perform the test:

1. Connect the equipment as shown below.

2. Before inflation, check that the reading of the manometer should be 0. If not, open the valve of the balloon pump to let the whole airway open to the atmosphere. Close the valve of the balloon pump after the reading is 0.

3. Select [**Main Menu**]→ [**Maintenance >>**]→ [**NIBP Accuracy Test**].

4. Check the manometer values and the monitor values. Both should be 0mmHg.

5. Raise the pressure in the rigid vessel to 50 mmHg with the balloon pump. Then, wait for 10 seconds until the measured values become stable.

6. Compare the manometer values with the monitor values. The difference should be within ±3 mmHg. If it is beyond ±3 mmHg, calibrate the monitor by referring to *NIBP Calibration*.

7. Raise the pressure in the rigid vessel to 200 mmHg with the balloon pump. Then, wait for 10 seconds until the measured values become stable and repeat step 6.

NOTE

- **You can use an NIBP simulator to replace the balloon pump and the reference manometer to perform the test.**

- **You can use an appropriate cylinder and a cuff instead of the rigid vessel.**
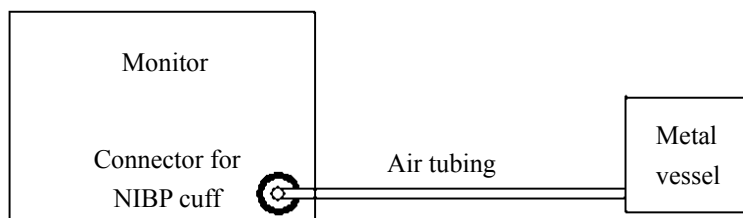
NIBP Leakage Test

NOTE

- **You should perform NIBP leakage test before any other NIBP concerned test and calibration.**

Tools required:

- An air tubing

- Metal container or vesselS

Follow this procedure to perform the test:

1. Set [**Patient Cat.**] to [**Adu**].

2. Connect a rigid metal container or vessel with a capacity of 500 ml ± 5% to the NIBP cuff connector of the monitor.

3. Select [**Main Menu**]→ [**Maintenance>>**]→ [**NIBP Leakage Test**]. The NIBP display shows [**Leakage Testing…**].

4. After about 20 seconds, the monitor will automatically deflate. This means the test is completed.

If no message is displayed in the NIBP parameter area, it indicates that the system has no leakage. If the message [**NIBP Pneumatic Leak**] is displayed, it indicates that the system may have a leakage. In this case, check if all connections are good and the cuff and tubing have no leakage. Perform the test again after making sure all connections are good and the cuff and tubing have no leakage.

You can either perform a manual leakage test:

1. Perform procedures 1 to 4 in the *NIBP Accuracy Test* section.

2. Raise the pressure in the rigid vessel to 250 mmHg with the balloon pump. Then, wait for 5 seconds to let the measured values becoming stable.

3. Record the current pressure value, and meanwhile use a time counter to count the time. Then, record the pressure value after 60s.

4. Compare the two pressure values and make sure the difference should not be greater than 6 mmHg.

NIBP Calibration

Tools required:

- T-shape connector
- Approprating tubing
- Balloon pump
- Metal Vessel with volume 500 ± 25 ml
- Reference manometer (calibrated with accuracy equal to or better than 0.75 mmHg)

Follow this procedure to perform a NIBP calibration:

1. Perform procedures 1 to 4 in the *NIBP Accuracy Test* section.

2. Select [**Main Menu**]→ [**Maintenance >>**]→ [**Factory Maintenance >>**]→ enter the required password→ [**Calibrate NIBP >>**].

3. Set [**NIBP Pressure**] to 150 mmHg in the [**NIBP Measurement Circuit**]. Raise the pump pressure to 150 mmHg. After the pressure value is stabilized, select the [**Calibrate**] button to start a calibration.

5. Set patient category to [**Adu/Ped**] in the [**Overpressure Protection Circuit**], and raise the pressure to 330 mmHg. After the pressure value is stabilized, select [**Calibrate**] to start a calibration.

6. Set the patient category to [**Neo**] in the [**Overpressure Protection Circuit**], and raise the pressure to 165 mmHg. After the pressure value is stabilized, select [**Calibrate**] to start a calibration.

All calibration results are displayed in the [**Calibrate NIBP**] menu. If the calibration fails, check the test system for leakage and perform another calibration.

3.2.3 Sidestream and Microstream CO_2 Module Tests

Leakage test

Follow this procedure to perform the test:

1. Plug the module into the module rack.

2. Wait until CO_2 warmup is finished and then use your hand or other objects to completely block the gas inlet of the module or watertrap. The sidestream and microstream CO_2 modules will behave as follows:

   ◆ Sidestream: The alarm message [**CO$_2$ FilterLine Err**] is displayed on the screen after certain time. Block the gas inlet for another 30 s. If the alarm message does not disappear, it indicates that the module does not leak.

   ◆ Microstream: The alarm message [**CO$_2$ Purging**] is displayed on the screen after certain time. Block the gas inlet for another 30s. If alarm message [**CO$_2$ FilterLine Err**] is shown, it indicates that the module does not leak.
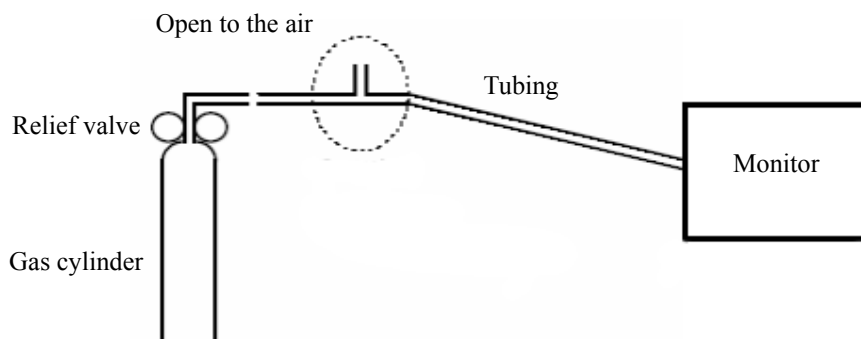
Accuracy Test

Tools required:

- A steel gas cylinder with $6\pm0.05\%$ CO_2 and balance gas N_2

- T-shape connector

- Tubing

Follow this procedure to perform the test:

1. Plug the module into the module rack.

2. Wait until the CO_2 module warmup is finished, and check the airway for leakage and perform a leakage test as well to make sure the airway has no leakage.

3. Enter [**User Maintenance**]→ [**Maintain CO$_2$ Purging**]→ [**Calibrate CO$_2$>>**].

4. Connect the test system as follows:

5. Open the relief valve to vent standard CO_2 and make sure that there is an excess gas flow through the T-shape connector to air..

6. Check the realtime CO_2 value is within $6.0\pm0.3\%$ in the [**Calibrate CO$_2$**] menu.

Calibration

Tools required:

■ A steel gas cylinder with 6±0.05% CO_2 and balance gas N_2

■ T-shape connector

■ Tubing

Follow this procedure to perform a calibration:

1. Make sure that the sidestream or microstream CO_2 module has been warmed up or started up.

2. Check the airway for leakage and perform a leakage test as well to make sure the airway has no leakage.

3. Select [**Main Menu**]→ [**Maintenance >>**]→ [**User Maintenance** >>]→ enter the required password→ [**Maintain CO$_2$ >>**]→ [**Calibrate CO$_2$ >>**].

4. In the [**Calibrate CO$_2$**] menu, select [**Zero**].

5. After the zero calibration is finished successfully, connect the equipment as follows:
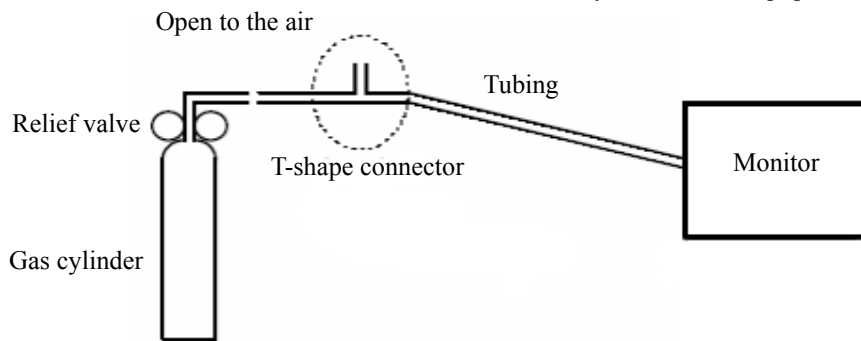
6. Open the relief valve to vent standard CO2 and make sure that there is an excess gas flow through the T-shape connector to air.

7. In the [**Calibrate CO$_2$**] menu, enter the vented CO_2 concentration in the [**CO$_2$**] field.

8. In the [**Calibrate CO$_2$**] menu, the measured CO_2 concentration is displayed. After the measured CO_2 concentration becomes stable, select [**Calibrate CO$_2$**] to calibrate the CO_2 module.

If the calibration is finished successfully, the message [**Calibration Completed!**] is displayed in the [**Calibrate CO$_2$**] menu. If the calibration failed, the message [**Calibration Failed!**] is displayed. In this case, perform another calibration.

3.2.4 AG Tests

Leakage Test

1. Plug the AG module into the module rack.

2. Wait for a minute until the AG module warmup is finished and then use your hand or other objects to completely block the gas inlet of the AG module. An alarm message [**AC Airway Occluded**] will be displayed.

3. Block the gas inlet for another 60 seconds. Then select [**User Maintenance >>**] → [**Maintain AG >>**] → [**Calibrate AG >>**] and check that the current flow rate is less than 10 ml/min. If the alarm message does not disappear, it indicates that the module does not leak.

Accuracy Test

Tools required:

- Gas cylinder with a certain standard gas (such as $6 \pm 0.05\%$ CO_2, Bal N_2), or standard gas mixture. Gas concentration should meet the following requirements : $AA \geq 1.5\%$, $CO_2 \geq 1.5\%$, $N_2O \geq 40\%$, $O_2 \geq 40\%$, of which AA represents an anesthetic agent (Des, Sev, Enf, Iso, or Hal). $a/c \leq 0.01$ (a is the gas absolute concentration accuracy; c is the gas concentration)

- T-shape connector

- Appropriate tubing

1. Plug the AG module into the module rack.

2. Wait for at least 10 min and then perform a leakage test to make sure the airway has no leakage.

3. Check if the fan inside the AG module works correctly.

4. Connect the test system as follows:
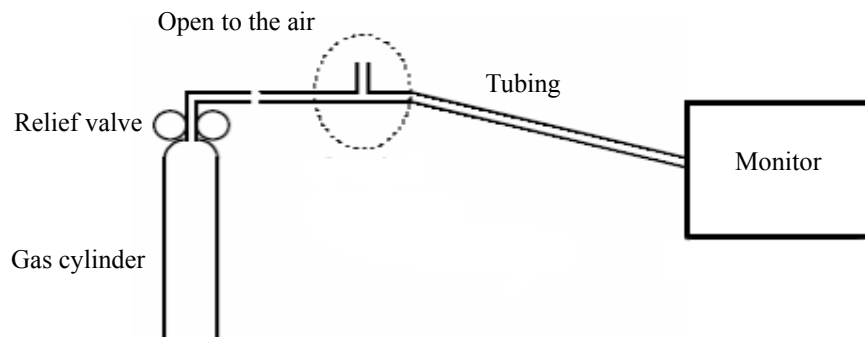
5. Adjust the relief valve and make sure the flowmeter reading is stable and within 10 and 50 L/min.

6. Check that the concentration of each composition meets the specification stated in the Operator's Manual.
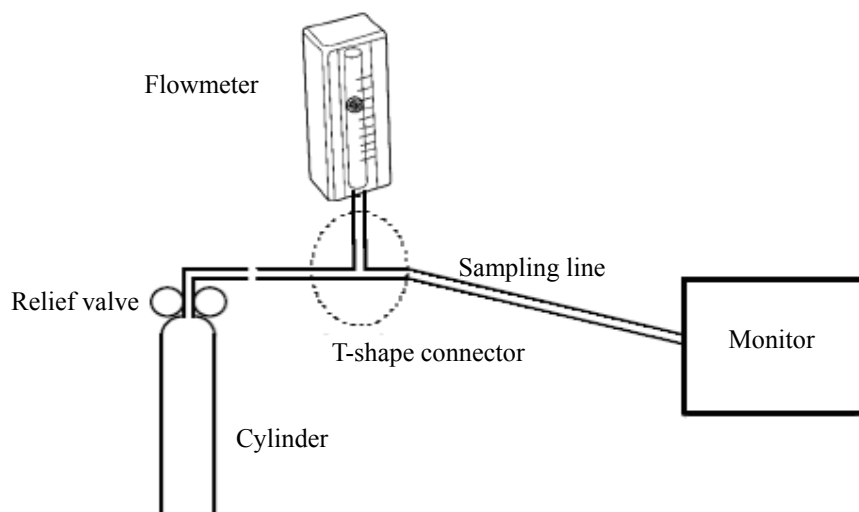
Calibration

Tools required:

■ Gas cylinder with a certain standard gas (such as $6 \pm 0.05\%$ CO_2, Bal N_2), or standard gas mixture. Gas concentration should meet the following requirements: AA $\geq 1.5\%$, $CO_2 \geq 1.5\%$, $N_2O \geq 40\%$, $O_2 \geq 40\%$, of which AA represents an anesthetic agent (Des, Sev, Enf, Iso, or Hal). $a/c \leq 0.01$ (a is the gas absolute concentration accuracy; c is the gas concentration)

■ T-shape connector

■ Appropriate tubing

Follow this procedure to perform the pressure calibration:

1. Select [**Main Menu**]→ [**Maintenance >>**]→ [**User Maintenance** >>]→ enter the required password→ [**Calibrate AG >>**] to access the [**Calibrate AG**] menu.

2. Check the airway and make sure that there are no occlusions or leaks.

   ◆ Vent the sampling tubing to the air and check if the [**Current FlowRate**] and [**Set FlowRate**] are approximately the same. If the deviation is great, it indicates that there is an occlusion in the tubing. Check the tubing for an occlusion.

   ◆ Check the airway and make sure that the airway has no leakage.

3. Connect the test system as follows:

4. Open the relief valve and vent a certain standard gas or gas mixture. Then adjust the relief valve and make sure   the flowmeter reading is stable and within 10 and 50 L/min.

5. In the [**Calibrate AG**] menu, the concentration and flowrate of each measured gas are displayed.

   ◆ If the difference between the measured gas concentration and the actual one is t very small, a calibration is not needed.

   ◆ If the difference is great, a calibration should be performed. Select [**Calibrate >>**] to enter the calibrate menu.
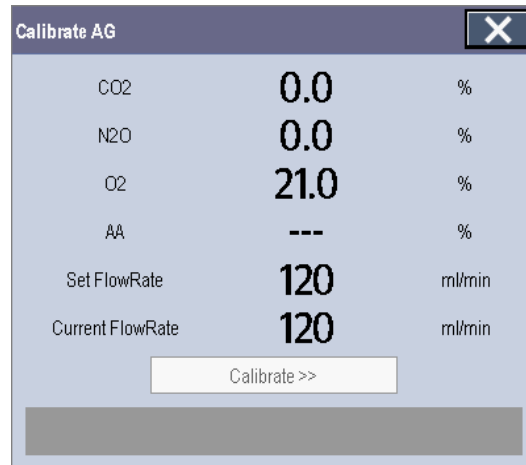
6. Enter the vented gas concentration. If you use only one gas for calibration, set other gases' concentration to 0.

7. Select [**Start**] to start calibration.

8. If the calibration is finished successfully, the message [**Calibration Completed!**] is displayed. If the calibration failed, the message [**Calibration Failed!**] is displayed. In this case, perform another calibration.

⚠CAUTION

● **Calibrate the O_2 module, If it has been transported for long distance.**

3.2.5 Preventative maintenance test report

Customer name		
Customer address		
Servicing person		
Servicing company		
Equipment under test (EUT)		
Model of EUT		
SN of EUT		
Hardware version		
Software version		
Test equipment	Model/No.	Effective date of calibration

Test items	Test records	Test results(Yes/No)
Visual inspection		
The case, display screen, buttons, knob, SMR, modules, power cord, wall-mount bracket and accessories have no obvious signs of damage.		Yes No
The external connecting cables are not frayed and the connector pins are not loose and bent.		Yes No
The external connectors are not loose or their pins are not bent.		Yes No
The safety labels and data plate are clearly legible.		Yes No
NIBP test		
The difference is within ±3 mm when 0, 50 or 200 mmHg is set for NIBP accuracy test.		Yes No
There is no leakage with NIBP, or the manual leakage test result does not exceed 6mmHg/min.		Yes No
Sidestream CO_2 test		

Block the gas inlet of the module or watertrap. The sidestream CO_2 flowrate is slower than 10ml/min and an alarm of CO_2 Filterline Err is given. It indicates that there is no leakage.		Yes	No
The displayed CO_2 value is within $6\pm0.05\%$.		Yes	No
Microstream CO_2 test			
Block the gas inlet of the module or watertrap. An alarm of CO_2 Filterline Err is given. It indicates that there is no leakage.		Yes	No
The displayed CO_2 value is within $6\pm0.05\%$.		Yes	No
AG test			
When AG flowrate is slower than 10ml/min, an alarm of AG Airway Occluded is given. It indicates that there is no leakage.		Yes	No
The fan inside the AG module works properly.		Yes	No
The measurement accuracy of CO_2, N_2O, O_2 and AA (AA represents an anaesthetic agent) meets the product specifications in the Operator's Manual.		Yes	No

3.3 Power On Test

This test is to verify that the patient monitor can power up correctly. The test is passed if the patient monitor starts up by following this procedure:

1. Insert two batteries in the battery chamber and connect the patient monitor to the AC mains, the AC mains LED and battery LED light.

2. Press the power on/off switch to switch on the patient monitor. The operating status LED lights up, and the technical and physiological alarm lamps light blue and red respectively.

3. After the start-up screens are displayed, the system sounds a beep indicating the self test on alarm sounds is passed. At the same time, the alarm lamp turns from yellow to red, and then turns off together with the technical alarm lamp. This indicates that the self test on alarm lamps is passed.

4. The patient monitor enters the main screen and start-up is finished.

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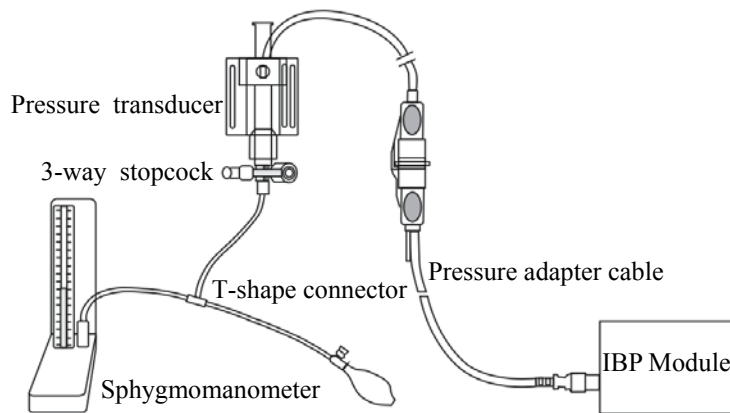
5. Adjust the calibration value in the [**Maintain IBP**] menu until it is equal to the reading of sphygmomanometer

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
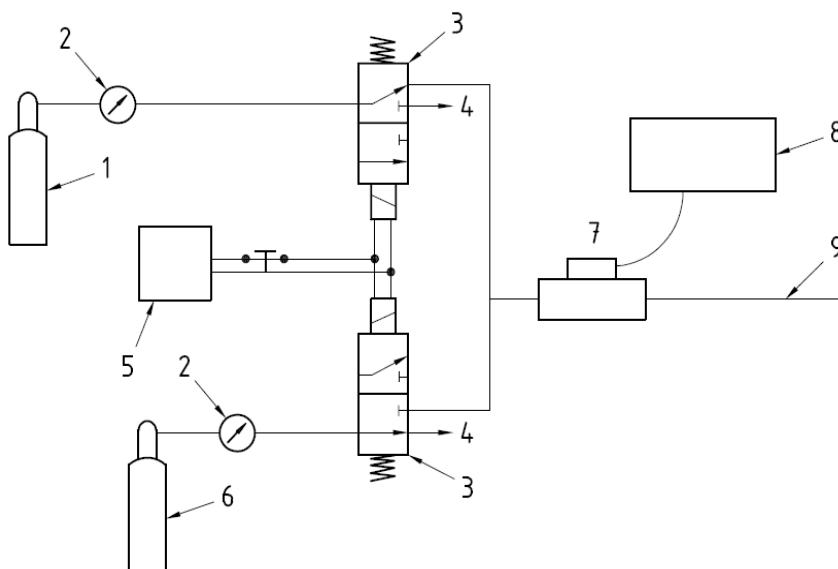
In the figure above,

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.*

3.4.11 ICG Test

Tool required:

- ICG simulator (BZ-4575)
- BioZ Dx patient cable (PN: 040-000543-00）
- BioZ Dx lead wire (PN: 040-000544-00)

1. Connect the ICG simulator and the patient monitor using ICG patient cable and lead wire.

2. Select **[ICG setup]**→ [**Patient Demographics >>**] and then input parameter values as follows:

Height	180 cm	CVP	6 mmHg
Weight	75 kg	PAmean	8 mmHg
PAWP	10 mmHg		

3. Switch on the simulator and set as follows: HR=60±1 bpm, VI=61±4/1000s, TFC=32±2/kOhms. Then, start ICG monitoring.

4. After the measurement becomes stable and check that the measured results are as follows: HR=60±2 bpm, VI=61±4/1000s, TFC=32±2/kOhms.

5. Set on the simulator as follows: HR=70±1 bpm, VI=48±4 /1000s, TFC=32±2 / kOhms, and then start ICG monitoring. After the measurement becomes stable and check that the measured results are as follows: HR=70±2 bpm, VI=48±4 /1000s, TFC=32±2 / kOhms.

3.4.12 BIS Test

You can choose either of the following methods to perform the test:

Method 1:

Tools required:

- BIS cable (PN: 6800-30-50761）
- BIS sensor (PN: 0010-10-42672)

1. Connect the BIS sensor to a healthy, wide-awake adult as directed in the Operator's Manual.

2. Check the EEG wave and BIS numerics displayed on the screen and make sure the BIS value is within 80-100.

Method 2:

Tools required:

- BIS simulator (with flexible cable)

- BIS cable (PN: 6800-30-50761）

1. Connect the BIS sensor with the BIS simulator and select [**BIS Setup**]→ [**BIS Sensor Check**] to perform a cyclic impedance check.

2. After the cyclic impedance check is finished, check that the result for each electrode is pass.

3. Check the EEG wave and BIS numeric displayed on the screen.

3.4.13 RM Test

Tool required:

- Gas source

- Ventilator (calibrated)

- Adult artificial lung （PN: 040-000744-00）

- RM connector (PN: 6800-20-50328）

- Adult/pediatric flow sensor (PN: 0010-30-42678)
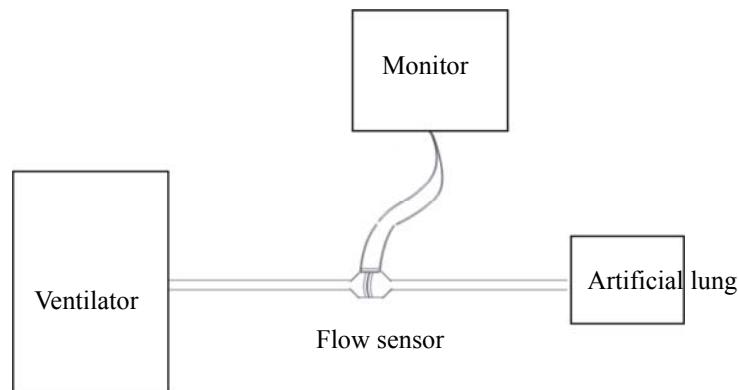
Follow this procedure to perform the test:

1. Connect the equipment as shown above. Make sure that the blue sensing tube on the flow sensor is connected with the artificial lung.

2. Set [**Patient Cat.**] to [**Adu**]. In the [**RM Setup**] menu, select [**Sensor Type**] according to the used sensor and set [**Ventilation Mode**] to [**Mechanical**].

3. Enter the [**RM Setup**] menu and select [**Calibrate** >>]. Input the constant marked on the sensor and calibrate the flow sensor.

4. Configure the ventilator as follows: TV=500 ml, RR =20 rpm, I:E=1:2.

5. Select [**Respiratory Loop**] in the [**RM Setup**] menu. Verify that the displayed TV is within 500±50ml and RR is within 20±1rpm.

3.4.14 CCO/SvO$_2$ Tests

Interconnecting Function

Tools required:

■ CCO/SvO$_2$ cable (PN: 115-004083-00)

1. Connect and set the patient monitor and Vigilance monitor per the procedures in the Operator's Manual.
2. Set the Vigilance monitor to Demo mode.
3. Check that the CCO/SvO$_2$ numerics displayed on the patient monitor and Vigilance monitor are consistent.

Output Performance

Tools required:

■ Oscillograph (Recommanded model: Agilent DSO5052A)
■ CCO/SvO$_2$ cable (PN: 115-004083-00)

1. Connect the signal output end of the connecting cables of the CCO/SvO$_2$ module to the oscillograph.
2. Make the monitor to perform an ECG calibration. Check that the ECG waves displayed on the oscillograph are consistent with the ECG calibration waves displayed on the monitor screen.
3. Select [**CCO Setup**]→ [**Signal Output Setup >>**] and then select [**Simulated High Value**] from the pop-up menu. Check that the amplitude of electrical level at the signal output port of MAP, CVP and SpO$_2$ are 5±0.25V, 5±0.25V and 10±0.5V respectively.

3.5 Nurse Call Relay Performance Test

Tools required:

- Oscilloscope

1. Connect the nurse call cable to the Nurse Call Connector of the patient monitor.

2. Enter [**Demo**] mode. Then, select [**Main Menu**]→ [**Maintenance >>**]→ [**User Maintenance >>**]→ enter the required password→ [**Others >>**]**.**

3. In the [**Others >>**] menu, select [**Nurse Call Setup >>**] and then in the [**Nurse Call Setup**] menu, select all optional [**Alm Lev**] and [**Alm Cat.**], and set **[Contact Type]** to **[Normally Open]**

4. In [**Nurse Call Setup >>**] menu, set [**Signal Type**] to [**Pulse**]. Make the monitor to generate an alarm and check that the oscillograph displays positive pulses of 1s width when there is an alarm.

5. In [**Nurse Call Setup >>**] setup menu, set [**Signal Type**] to [**Continuous**].Make the monitor to generate an alarm and check that the oscillograph outputs continuous high level when there is an alarm.

3.6 Analog Output Performance Test

Tool required:

- Medsim300B patient simulator, or MPS450, or equivalent equipments
- Oscillograph

Connect the patient simulator to the monitor using an ECG or IBP cable and connect the oscillograph to the Auxiliary Output Connector of the patient monitor. Verify that the waves displayed on the oscillograph are identical with those displayed on the monitor.

3.7 Electrical Safety Test

See *A Electrical Safety Inspection* for electrical safety tests.

3.8 Touchscreen Calibration

Tools required:

■   None.

1.   Select the [**Cal. Screen**] QuickKey or select [**Main Menu**]→ [**Maintenance >>**]→ [**User Maintenance >>**]→ enter the required password→ [**Cal. Touchscreen**].

2.   The ⊕ symbol will appear at different positions of the screen.

3.   Select, in turn, the central point of the ⊕ symbol.

4.   After the calibration is completed, the message [**Screen Calibration Completed!**] is displayed. Select [**Ok**] to confirm the completion of the calibration.

3.9 Recorder Check

Tools required:

■   None.

1.   Print ECG waveforms. The recorder should print correctly and the printout should be clear.

2.   Set the recorder to some problems such as out of paper, etc. the patient monitor should give corresponding prompt messages. After the problem is removed, the recorder should be able to work correctly.

3.   Switch automatic alarm recording for each parameter ON and then set each parameter's limit outside set alarm limits. Corresponding alarm recordings should be triggered when parameter alarms occur.
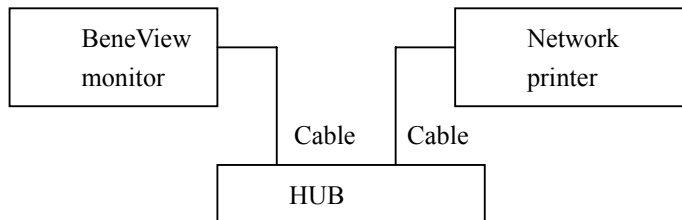
3.10 Network Print Test

Note

- **HP LaserJet 1505n or 2035n laser printer is recommended for BeneView series of patient monitors.**

Tools required:

- Hub and network cable

3.10.1 Equipment Connection and Setup

1 Connect the patient monitor and network printer to a HUB using common network cables as follows:

```
┌──────────────┐                 ┌──────────────┐
│  BeneView    │                 │  Network     │
│  monitor     │                 │  printer     │
└──────────────┘                 └──────────────┘
              Cable         Cable
            ┌────────────────────┐
            │       HUB          │
            └────────────────────┘
```

2 Set IP address as follows: Select [**Main Menu**]→ [**Maintenance >>**]→ [**User Maintenance >>**]→ enter the required password→ [**IP Address Setup >>**] and set the IP address of the patient monitor in the same network segment with that of the network printer. (See the instructions for use accompanying the printer)

3 Search for printer by selecting [**Main Menu**]→ [**Print Setup >>**]→ [**Printer Setup >>**]→ [**Search Printer**]. After a while, the printer's model and IP address will appear in the box beside [**Printer**].

3.10.2 Print Function Test

1 Enter the Demo mode of the patient monitor.

2 Select [**Main Menu**]→ [**Print Setup >>**]→ [**Realtime Reports >>**]→ [**Normal Report**] and then select [**Print**]. The network printer shall print out the report correctly.

3.11 Battery Check

Tools required:

- None.

Function Test

1. If the patient monitor is installed with batteries, remove the batteries first.
2. Verify that the patient monitor works correctly when running powered form an AC source.
3. Insert two batteries per the procedures provided in the Operator's Manual.
4. Remove the AC power cord and verify that the patient monitor still works correctly.
5. For T5 only: Remove one battery and verify that the patient monitor continues to work correctly. Verify that the patient monitor can also work independently from another battery.

Performance Test

Perform the test by referring to the *Battery* chapter in the Operator's Manual and verify the operating time of the battery meets the product specification.

3.12 Factory Maintenance

3.12.1 Accessing Factory Maintenance Menu

To access the factory maintenance menu, select [**Main Menu**]→ [**Maintenance >>**] → [**Factory Maintenance**]and then enter the required password.

The [**Factory Maintenance**] menu is shown below.
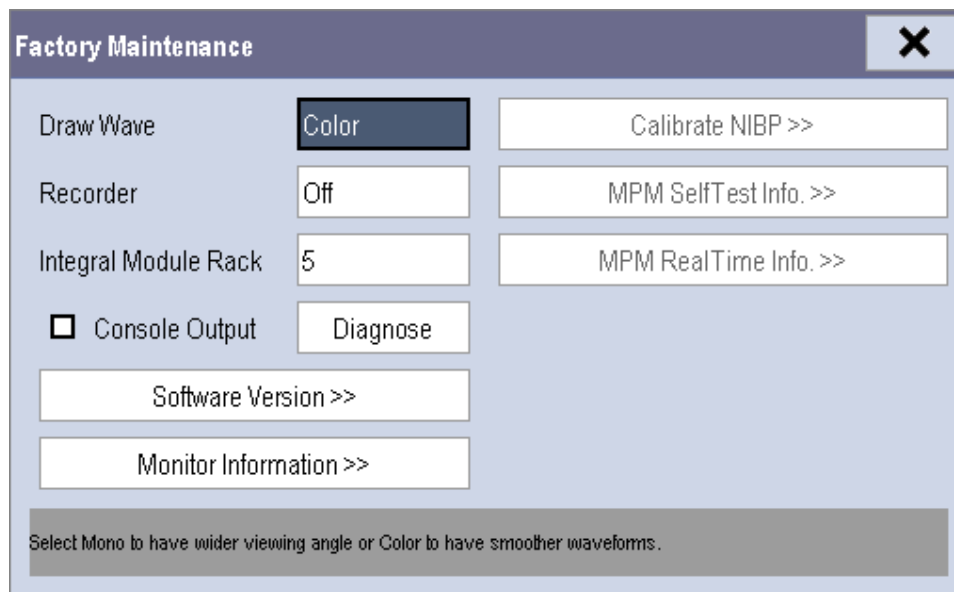
3.12.2 Drawing Waves

There are two methods to draw waves.

■ Color: selecting Color will have smoother waveforms.

■ Mono: selecting Mono will have a wider viewing angle.

3.12.3 Recorder
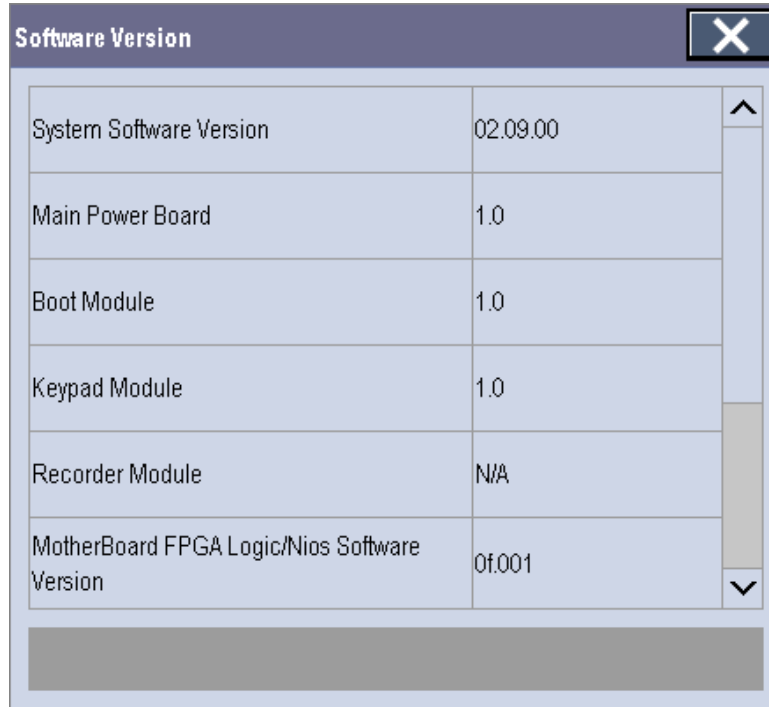
To enable/disable the recorder, select [**Recorder**] and toggle between [**On**] and [**Off**].

⚠CAUTION

● **The recorder is disabled if [Recorder] is switched off in the [Factory Maintenance] menu.**

3.12.4 Software Version

Selecting [**Software Version**] will show software version information. The [**Software Version**] menu is as follows:

Software Version	
System Software Version	02.09.00
Main Power Board	1.0
Boot Module	1.0
Keypad Module	1.0
Recorder Module	N/A
MotherBoard FPGA Logic/Nios Software Version	0f.001

3.12.5 Monitor Information

Selecting [**Monitor Information**] will show the status of the patient monitor. Monitor information is displayed as follows:

Monitor Information	
Total Runtime	0Days22Hours5Minutes
CPU PCB/BOM Version	1.0
CPU ID	1.0
MotherBoard PCB/BOM	/
IMR Nios Module PCB/BOM Version	N/A

Fan On

Turn on/off the monitor's fan.

3.12.6 Calibrate NIBP

For details, refer to section *3.2.2 NIBP Tests and Calibration.*

Maintenance and Test Report

(See the above sections for detailed test procedures and contents)

Customer name	
Customer address	
Servicing person	
Servicing company	
Equipment under test (EUT)	
Model of EUT	
SN of EUT	
Hardware version	
Software version	

Test equipment	Model/No.	Effective date of calibration

Test items	Test records	Test results(Yes/No)
Visual inspection		
The case, display screen, buttons, knob, SMR, modules, power cord, wall-mount bracket and accessories have no obvious signs of damage.		Yes No
The external connecting cables are not frayed and the connector pins are not loose and bent.		Yes No
The external connectors are not loose or their pins are not bent.		Yes No
The safety labels and data plate are clearly legible.		Yes No
Power-on test		
The power-on test is passed. The power indicator and alarm system work correctly and the monitor start up properly.		Yes No
Performance test		
ECG performance test and calibration		

ECG waves are displayed correctly without noise and the HR value is within 80±1 bpm.		Yes No
ECG Lead Off alarm behaves correctly.		Yes No
Paced signals are detected and pace pulse marks are displayed when [**Paced**] is set to [**Yes**]		Yes No
The difference between the amplitude of the ECG calibration square wave and that of the wave scale is not greater than 5%.		Yes No
Resp test		
The Resp wave is not distorted and the Resp value is within 40±2 rpm.		Yes No
SpO$_2$ test		
Measure SpO$_2$ on a healthy person's finger and a Pleth wave and PR value are displayed. The displayed SpO$_2$ value is within 95% and 100%		Yes No
NIBP test and calibration		
The difference is within ±3 mm when 0, 50 or 200 mmHg is set for NIBP accuracy test.		Yes No
There is no leakage with NIBP, or the manual leakage test result does not exceed 6mmHg/min.		Yes No
Temp test		
The value displayed for each Temp channel of the monitor is within 37±0.1ºC.		Yes No
IBP test		
The static pressure value displayed for each IBP channel is within 200±2 mmHg.		Yes No
The ART and LV waves for each IBP channel are displayed correctly.		Yes No
C.O. test		
The TB value displayed on the monitor is within 37±0.2ºC.		Yes No
The displayed C.O. value is within 5±0.25L/min.		Yes No
Mainstream CO$_2$ test		
The mainstream CO2 is zeroed successfully and the waveform baseline recovers to zero.		Yes No
CO2 Apnea alarm behaves correctly.		Yes No
The displayed CO2 value is within $6.0\pm0.3\%$.		Yes No
Sidestream CO$_2$ test and calibration		

Block the gas inlet of the module or watertrap. The sidestream CO_2 flowrate is slower than 10ml/min and an alarm of CO_2 Filterline Err is given. It indicates that there is no leakage.		Yes	No
The displayed CO_2 value is within $6\pm0.05\%$.		Yes	No
Miscrostream CO_2 test and calibration			
Block the gas inlet of the module or watertrap. An alarm of CO_2 Filterline Err is given. It indicates that there is no leakage.		Yes	No
The displayed CO_2 value is within $6.0\pm0.3\%$		Yes	No
AG test and calibration			
When AG flowrate is slower than 10ml/min, an alarm of AG Airway Occluded is given. It indicates that there is no leakage.		Yes	No
The fan inside the AG module works properly.		Yes	No
The measurement accuracy of CO_2, N_2O, O_2 and AA (AA represents an anaesthetic agent) meets the product specifications in the Operator's Manual.		Yes	No
ICG test			
The measured results are as follows: HR=60±2 bpm, VI=61±4/1000s, TFC=32±2/kOhms.		Yes	No
The measured results are as follows: HR=70±2 bpm, VI=48±4 /1000s, TFC=32±2 / kOhms.		Yes	No
BIS test (you can select either method to perform the test)			
Method 1: The BIS value measured on healthy, wide-awake adult is within 80-100.		Yes	No
Method 2: Connect to the BIS simulator to perform a cyclic impedance check. The EEG wave and BIS numeric are displayed on the monitor.		Yes	No
RM test			
The displayed TV is within 500±50ml and RR is within 20±1rpm.		Yes	No
CCO/SvO$_2$ test			
The CCO/SvO$_2$ numerics displayed on the patient monitor and Vigilance monitor are consistent.		Yes	No
The waves (at the ECG signal output port) displayed on the oscillograph are consistent with the ECG calibration waves displayed on the monitor screen.		Yes	No
The amplitude of electrical level at the signal output port of MAP, CVP and SpO$_2$ are 5±0.25V, 5±0.25V and 10±0.5V		Yes	No

respectively.		
Nurse call relay performance test		
The relay contacts are close when an alarm occurs.		Yes No
Analog output performance test		
The waves displayed on the oscillograph are identical with those displayed on the monitor.		Yes No
Electrical safety tests		
Refer to *A Electrical Safety Inspection*. All the electrical safety tests should be passed.		Yes No
Touchscreen calibration		
The touchscreen is calibrated successfully.		Yes No
Recorder check		
The recorder can print ECG waves correctly and the printout is clear.		Yes No
Set the recorder to some problems such as out of paper, paper jam, etc. the monitor gives corresponding prompt messages. After the problem is removed, the recorder is able to work correctly.		Yes No
Automatic alarm recording for each parameter functions correctly when parameter alarms occur.		Yes No
Network print test		
The network printer can print out ECG reports correctly.		Yes No
Battery check		
The monitor can operates correctly from battery power when an AC power failure accidentally occurs.		Yes No
T5 patient monitor can operate independently on a single battery.		Yes No
The operating time of the battery meets the product specification.		Yes No

Test conclusion:

Tested by:_____   **Test Date:**_____