3
Performance Verification Testing

Overview

This chapter includes the following information:

- Testing and inspection guidelines
- Recommended frequency of performance tests
- Test procedures following monitor repair or during routine maintenance
- NBP calibration procedure

If the monitor fails any test, it must be repaired before it is returned to use.

Note — *The procedures in this chapter assume knowledge of basic monitor operation. For details about using the monitor, see the Instructions for Use provided with your monitor.*

Testing and Inspection Guidelines

The following table lists the tests that Philips requires that you complete after performing monitor repairs or upgrading the software.

For information about routine maintenance procedures, see Chapter 2, "Performing Routine Maintenance."

For information about repair procedures, see Chapter 5, "Repairing the Monitor."

After	Complete These Tests
Upgrading the software	- Power–on self test - Verify that your system settings are preserved
Opening the monitor for any reason	- Power–on self test - Alarms test - Pneumatic leakage test - All safety tests
Replacing any internal parts (except NBP parts, SpO$_2$ board)	- Power–on self test - Pneumatic leakage test - All safety tests
Replacing the NBP module or parts	- Power–on self test - NBP test - Pneumatic leakage test - All safety tests

After	Complete These Tests
Replacing the Philips SpO$_2$ board **Note —** *Monitors with the Masimo SpO$_2$ board must be returned to Philips for Masimo SpO$_2$ board replacement. Contact the Philips Customer Care Center or your local Philips representative.*	• Power-on self test • SpO$_2$ • Pneumatic leakage test • All safety tests
Replacing the temperature module	• Power-on self test • Alarms test • Pneumatic leakage test • All safety tests • Temperature test
Replacing the LCD	• Power-on self test • Alarms test • Pneumatic leakage test • All safety tests • Touch Screen Calibration
Replacing the CO$_2$ module	• Power-on • CO$_2$ calibration • Pneumatic leakage • All safety tests

Recommended Frequency

Perform the test procedures at the recommended frequency outlined in the following table.

Caution **The frequency recommendations in the following table do not supersede local requirements. Always perform locally required testing in addition to the testing outlined in the table.**

Suggested Testing	Frequency
Preventive Maintenance	
NBP calibration	Once every two years.
Battery reconditioning	When the **Max Error** is 10% or greater.
Tympanic temperature calibration[1]	Once a year.
Temporal Temperature calibration[2]	Once a year.

CO_2 calibration	• First calibration at 1,200 hours of use or after one year, whichever comes sooner. • After the first calibration, once a year or after 4,000 hours, whichever comes sooner. • After any repairs or the replacement of any parts. Replace the entire CO_2 module after 20,000 hours of use.
Performance	
• Predictive temperature accuracy • NBP accuracy test • SpO_2	Once every two years, or if you suspect the measurement is incorrect.
• Nurse call relay[3]	Once every two years.
Safety **In accordance with IEC 60601-1**	
• Enclosure leakage current • Ground integrity • Patient leakage current	Once a year or after repairs where the monitor has been opened (front and back separated) or the monitor has been damaged by impact.

[1.] Requires a Covidien calibration module. For more information, see "Tympanic Temperature Test" on page 3–22.
[2.] Requires an Exergen calibration module.
[3.] When used as part of facility protocols.

Required Test Equipment

The following table lists the additional test equipment that you need to perform each of the tests in this chapter. Many of these tests also use the standard accessories that are shipped with the mo monitor..

To Perform This Test	You Need This Test Equipment
"Visual Test" on page 3–13	None
"Power–On Self Test" on page 3–13	None
"Alarms Test" on page 3–14	NBP cuff and hose
"SpO2 Test" on page 3–14	Adult SpO_2 transducer

"CO2 Calibration Test" on page 3–15	• Electronic flowmeter, M1026–60144
	• Gas calibration equipment:
	  – Cal 1 gas 15210–64010 (5% CO_2)
	  – Cal gas flow regulator M2267A
	  – Cal tube 13907A

"NBP Test" on page 3–17	• A reference manometer (including hand pump and valve) with an accuracy 0.2% • An expansion chamber (volume 250 ml ± 10%) • Appropriate tubing

To Perform This Test	You Need This Test Equipment
"Predictive Temperature Test" on page 3-21	• SureSigns temperature probe • SureSigns Temperature Calibration Key (part number 4535 640 33691)
"Safety Tests" on page 3-19	A multimeter
"Nurse Call Relay Test" on page 3-25	• A patient simulator • An ohmmeter • A phono connector

Test Recording

Authorized Philips personnel report test results back to Philips to add to the product development database. Hospital personnel, however, do not need to report results.

The following table describes what to record on the service record after you complete the tests in this chapter.

Note — *P = pass, F = fail, X = measured value as defined in tests in this chapter.*

Test	What to record
Visual	V:P or V:F
Power-On	PO:P or PO:F
NBP	NBP:P/*X1*/*X2*/*X3* or NBP:F/*X1*/*X2*/*X3*
CO_2	CO_2 cal:P or CO_2 cal:F
SpO_2	SpO_2:P or SpO_2:F
Safety	S(1): P/*X1*/*X2* or S(1):F/*X1*/*X2* S(2): P/*X1* or S(2): F/*X1* S(3): P/*X1* or S(3): F/*X1*

Accessing the System Menu

Use the **System Menu** to configure the monitor, view system information, shut down the monitor, and access the **System Admin Menu**. For more information about using the **System Menu** to configure the monitor, see the *Instructions for Use* or the *Installation and Configuration Guide* provided with your monitor.

To access the **System Menu**:

·   Select the **System** 🔧 button.

    The **System Menu** appears.

System Menu

Recorder Speed:	25.0 mm/s	System Admin
Waveform Print:	20 seconds	Lock Touch Screen
Date Format:	mm/dd/yyyy	Brightness
Display Time:	Yes	Shutdown
Default Patient Type:	Adult	
Monitor Name:	USL0000001	
Serial Number:	USL0000001	
Hardware ID:	6 - 00 - A7	
Software Version:	A.04.52	
LAN MAC Address:	00-09-FB-13-4B-3C	
LAN IP Address:	0.0.0.0	
WLAN MAC Address:	00-17-23-A1-84-B2	
WLAN IP Address:	0.0.0.0	
Language:	English	
Configuration:	VS4 SpO2-P Temp-T NBP-P	
	Recorder Wireless CO2-S	

Main Screen

Accessing the System Admin Menu

You can use the **System Admin Menu** to configure password–protected functions of the monitor, including Demo Mode, system diagnostics, and upgrading the software. For more information about using the **System Admin Menu** to configure the monitor, see the Installation and Configuration Guide provided with your monitor.

Notes

- *The **System Admin Menu** is password–protected, and should only be accessed by qualified service personnel.*

- *The procedures in this guide use the default Administrator password, **215**. To improve the security of the monitor settings, you can change the administrator password after you install the monitor. For more information about changing the password, see the Installation and Configuration Guide provided with your monitor.*

To access the **System Admin Menu**:

Step	
1	In the **System Menu**, select the **System Admin** button.
2	In the window that appears, enter the Administrator password, **215**, or the password defined by your institution and select **OK**.

Step	
3	Select **OK**.
	The **System Admin Menu** opens.

Note — *Masimo settings appear only if the Masimo SpO$_2$ module is installed.*

System Admin Menu

Language:	English	Diagnostics
Line Frequency:	60 Hz	LAN
Default NBP Interval:	Off	Wireless
Default Save Measurements to Record:	On	Data Export
Default Blue Probe Site:	Oral	Upgrade Software
Auto Suspend:	2 minutes	Export Settings
Default Initial NBP Inflation Pressure:		Import Settings
Adult: 160 Pediatric: 140 Neonate: 100		Patient ID Settings
Align Interval to Clock:	No	QuickCapture
Auto Save Patient Record:	1 minute	QuickAlerts
Masimo Pulse Smart Tone:	Off	QuickCheck
Masimo RRa Freshness Timeout:	15 Minutes	Date/Time Settings
☐ Demo Mode		Security
☑ Large Battery Icon		Default Alarm Settings
☐ QuickNBP		Dashboard
		Return

Caution

The System Admin Menu remains unlocked for 1 minute after you close it. This allows you to open the menu again without having to re-enter the password. Do not leave the monitor unattended during the *unlock* time.

System Admin Menu Options

The following table describes the **System Admin Menu** options that are explained in this guide. All other options on the menu are explained in the Installation and Configuration Guide and the Network Configuration Guide provided with your monitor.

Option	Description
Demo Mode	Demo Mode allows the monitor to be demonstrated without actually monitoring parameters.
	For more information, see "Enabling Demo Mode" on page 3–7.

Option	Description
Diagnostics	Opens the **System Diagnostics** menu. Monitoring is suspended while this menu is open.
	Note — *This button is unavailable when the monitor is running in Demo mode.*
	For more information, see "Performing Verification Tests" on page 3-11.
Upgrade Software	Opens the **Upgrade Software** menu.
	For more information, see "Upgrading the Software" on page 3-8.

Enabling Demo Mode

Warning — **Do not connect a patient to a monitor running in Demo mode. Values represented in Demo mode do not represent measurements from a patient connected to the monitor, and may lead to incorrect diagnoses.**

Demo mode is used for demonstrating the monitor without monitoring parameters. Demo mode simulates all patient parameters and generates alarms when alarm settings are exceeded.

By default, the check box is cleared.

Caution — **Entering Demo mode clears the patient data.**

Note — *You cannot access the* **System Diagnostics** *menu when the monitor is in Demo mode.*

To put the monitor in Demo mode:

Step	
1	Open the **System Admin Menu**. See "Accessing the System Admin Menu" on page 3-5.
2	Select the **Demo Mode** check box.
3	Select the **Return** button.
4	Select **Yes**. The monitor enters Demo mode and clears all patient data and ** **DEMO** ** is displayed.

Step	
5	To exit Demo mode, press the **On/Standby** key to turn off the monitor.
	The monitor clears all simulated patient data.

Upgrading the Software

Use the following procedure to upgrade the system software with a USB flash drive. When you upgrade the software, the monitor saves all of the system settings, including the **System Admin Menu** settings, the Error log, and the patient list.

Before you place an upgraded monitor back into service, Philips recommends that your facility establishes a protocol to train users about any changes in the functionality of the monitor resulting from the software upgrade.

Registering for Software Upgrades from Philips InCenter

You can download a software upgrade from Philips InCenter, which requires an active registration and password.

Before you register, obtain the serial number of the monitor you plan to include in your registration. The serial number is located on the product identification label on the rear of case of the monitor.

To register:

Step	
1	Access the Philips InCenter website at **incenter.medical.philips.com**.
2	Click **Need Help?**.
3	Under **Software Updates**, click **Click here for SureSigns patient monitor account registration**.
	The **SureSigns InCenter Registration Form** appears.
4	Enter your personal information and answer the questions, and then click **Submit**.
	After your information is processed, an email with temporary login information is sent to the email address you entered. It may take 24 to 48 hours to receive the email.

Note — *Philips recommends using a SanDisk® or Kingston® USB flash drive for software upgrades.*

Caution **Before you upgrade the software, you can back up the system settings by exporting the current configuration settings or by recording them on the worksheets. For worksheets and more information, see the Installation and Configuration Guide provided with your monitor.**

Do not downgrade the software to an earlier version, because it may cause hardware incompatibility and loss of system settings and patient records. The current software version is displayed on the start-up screen and the System Menu. **For more information, see "Viewing System Information" on page 4-1.**

When you upgrade the software:

- **Charge the battery before upgrading the software.**
- **Never perform a software upgrade with the monitor connected to a patient.**
- **Disconnect any USB peripherals.**
- **Do not upgrade software through a USB hub.**
- **If the USB port has a clamp in place, you may need to remove the clamp to ensure that the USB flash drive can be inserted completely into the USB port.**

After the upgrade starts:

- **Do not unplug the monitor.**
- **Do not remove the USB flash drive.**
- **Do not press any keys.**

If the upgrade is inadvertently interrupted and the main board data is lost, replace the main board.   For more information, see "Removing the Main Board" on page 5–33.

To perform a software upgrade:

Step	
1	Connect the monitor to AC power and power up the monitor. **Note —** *Your monitor must be connected to AC power and have a fully charged battery before upgrading the software.*
2	Insert the USB flash drive with the software upgrade into the USB port on the back of the monitor. **Note —** *The software upgrade folder must be located in the top directory of the USB flash drive.*
3	Open the **System Admin Menu**. See "Accessing the System Admin Menu" on page 3–5.

Step	
4	Select the **Upgrade Software** button. The monitor searches for a valid software image on the USB flash drive, and then displays the software image information in the **Upgrade Software** window. **Upgrade Software** **Current Version:** **A.05.24** **New Version:** **A.05.25** **Upgrade** WARNING: Battery should be charged before upgrading software. Do no unplug the monitor, remove the USB flash drive, or press any keys after the upgrade process begins. Any user interaction during the upgrade may cause the upgrade to fail and adversely affect monitor performance. **Return** If the monitor cannot find a valid software image, the screen returns to the **System Admin Menu**.
5	Select the **Upgrade Software** button to start the upgrade. The **Upgrade in Progress** indicator increments while the upgrade is in progress. When the upgrade is complete, the **Checking Memory CRC** and **Upgrade Successful** messages appear. After the software upgrade, the monitor automatically shuts down and restarts.
6	Remove the USB flash drive.
7	Before placing the monitor back in service, perform the following: · Power-on self test. See "Power-On Self Test" on page 3-13. · Verify that your system settings are as expected.

Performing Verification Tests

Some of the verification tests require using the **System Diagnostics** menu or the **Maintenance** options. When you open the **System Diagnostics** menu, monitoring is suspended and measurements stop.

Notes
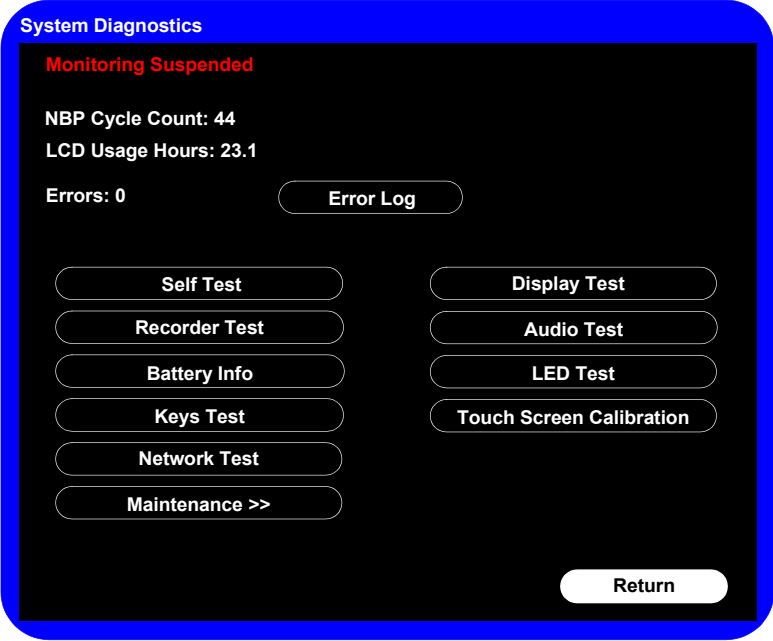
- *The Charging LED does not show battery status while the **System Diagnostics** menu is open.*

- *The **System Diagnostics** menu is not available when the monitor is in Demo mode.*

Accessing the System Diagnostics Menu

Use the **System Diagnostics Menu** to track component usage hours and perform the system diagnostic and verification tests.

Note — *You cannot access the **System Diagnostics** menu when the monitor is in Demo mode.*

To access the **System Diagnostics** menu:
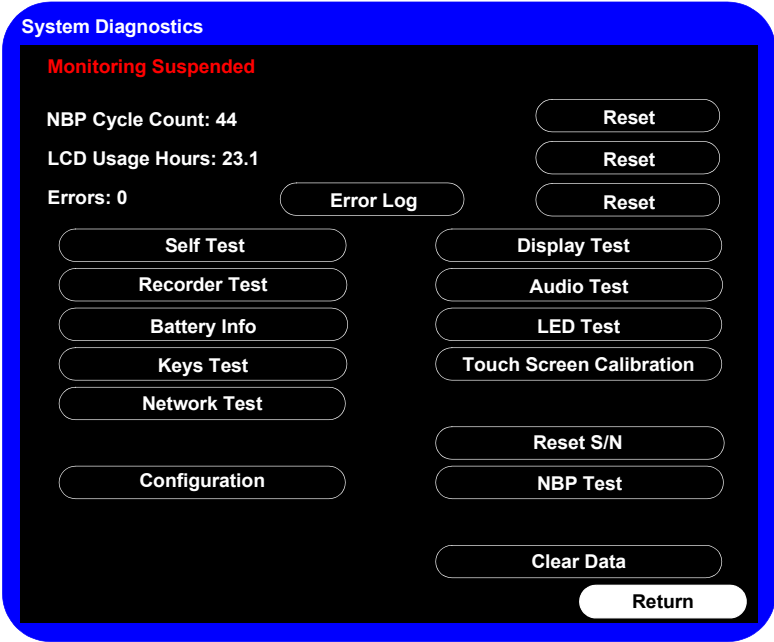
Step	
1	Open the **System Admin Menu**. See "Accessing the System Admin Menu" on page 3–5.
2	Select the **Diagnostics** button. The **System Diagnostics** menu appears. **System Diagnostics** Monitoring Suspended NBP Cycle Count: 44 LCD Usage Hours: 23.1 Errors: 0 (Error Log) (Self Test) (Display Test) (Recorder Test) (Audio Test) (Battery Info) (LED Test) (Keys Test) (Touch Screen Calibration) (Network Test) (Maintenance >>) (Return)

Step	
3	To access the options under the **Maintenance >>** button, see "Accessing Maintenance Options" on page 3–12.

Accessing Maintenance Options

You must enter an additional password to access the **Maintenance** options. Only trained biomedical engineers or support personnel should access the **Maintenance** options.

To access the **Maintenance** options in the **System Diagnostics** menu:

Step	
1	Open the **System Diagnostics** menu. See "Accessing the System Diagnostics Menu" on page 3–11.
2	Select the **Maintenance >>** button.
3	In the window that appears, enter the password, **129**. The **System Diagnostics** menu displays additional options. **Note —** **Masimo SpO$_2$** *and* **CO$_2$** *settings appear only if those modules are installed.* **System Diagnostics** Monitoring Suspended NBP Cycle Count: 44 — Reset LCD Usage Hours: 23.1 — Reset Errors: 0 — Error Log — Reset Self Test / Display Test Recorder Test / Audio Test Battery Info / LED Test Keys Test / Touch Screen Calibration Network Test Reset S/N Configuration / NBP Test Clear Data Return

Visual Test

To perform the visual test:

Step	
1	Inspect the system for obvious signs of damage; for example, cracks, cuts, or breakage.
2	Check all external cables and accessories for damage; for example, cuts, kinks, wrong connections.
3	Ensure that all markings and labeling are legible. If the labels on the rear case are not legible, replace the rear case. If the serial number label is not legible, contact the Philips Customer Care Center or your local Philips representative to return the monitor for label replacement.
4	Check for any obstructions to mechanical parts. The expected test result is that the system has no obvious signs of damage or obstruction. **Note —** *Philips employees record this value as **V:P** or **V:F**.*

Power-On Self Test

To perform the power-on self test:

Step	
1	Connect the monitor to an AC power source.
2	Press the **On/Standby** key to power up the monitor.
3	Make sure that the monitor powers up successfully as described in the following sequence: · The screen displays color bars for about five seconds. · The LCD turns off for three seconds, and the charging LED lights. · The Philips screen appears for one second, and a startup tone sounds. · The main screen appears. The expected result is that the monitor starts up and displays the main screen. For detailed information about the start-up and power sequences, see "Start-up and Power Sequences" on page 4-2. If the LEDs do not function as expected, see "Power Problems" on page 4-4. If the display does not function as expected, see "Power Problems" on page 4-4 or "Display Problems" on page 4-6. If you do not hear a startup tone, or the monitor displays the **Speaker Malfunc** error message, see "Error Codes" on page 4-13. **Note —** *Philips employees record this value as **PO:P** or **PO:F**.*

Alarms Test

The following test allows you to verify that the visual and audio alarms are working.

To perform this test, you need an NBP cuff and hose.

To test the alarms:

Step	
1	With the monitor turned on, make sure that all alarms are enabled (the monitor is not in Audio Pause or Audio Off mode).
2	Make sure the NBP alarm is enabled (the crossed bell icon does not appear in the NBP numeric pane).
3	Connect the NBP hose to the NBP input connector, but do not place the cuff on your arm.
4	Press the **NBP** key on the front panel.
5	Wait for the NBP module to cycle and check that an NBP error message appears and an alarm tone sounds.
6	If you do not get the results in step 5, see "NBP Problems" on page 4–6.

SpO$_2$ Test

The following procedure tests the performance of the SpO$_2$ measurement and alarm.

To perform this test, you need an adult SpO$_2$ sensor.

To perform the SpO$_2$ test:

Step	
1	Connect an adult SpO$_2$ sensor to the SpO$_2$ connector on the monitor. Ensure that the red LED in the sensor is lit.
2	Connect the other end of the sensor to your finger.
3	Verify that the SpO$_2$ value displayed on the monitor is between 95% and 100%. If it is not, try the test again with a patient simulator.
4	If you still do not get the results in step 3, see "SpO2 Measurement Problems" on page 4–9.

Caution   **A functional tester cannot be used to assess the accuracy of a pulse oximeter monitor. However, if there is independent demonstration that a particular calibration curve is accurate for the combination of a pulse oximeter monitor and a pulse oximeter sensor, then a functional tester can measure the contribution of a monitor to the total error of a monitor/sensor system. The functional tester can then measure how accurately a particular pulse oximeter monitor is reproducing that calibration curve.**

CO$_2$ Calibration Test

This test checks the calibration of the Microstream CO$_2$ gas measurement. The CO$_2$ calibration test is required after the first 1,200 hours of use or one year, whichever comes sooner. After the first calibration, calibrate after 4,000 hours of continuous use or every year, whichever comes sooner. In addition, perform the calibration tests when the instrument is repaired or when parts are replaced.

Note — Replace the CO$_2$ module after 20,000 hours of use.

Caution	**If the initial calibration is performed before 720 hours of use, the module resets to require the next calibration after 1,200 hours instead of after 4,000 hours.**

This test uses calibration equipment that you can order. Refer to the documentation accompanying the calibration equipment for more details.

Warning	**A monitor that is not calibrated at the recommended intervals may provide inaccurate results.**
	Dispose of empty or partially empty calibration gas containers in accordance with the manufacturer's instructions and local regulations.
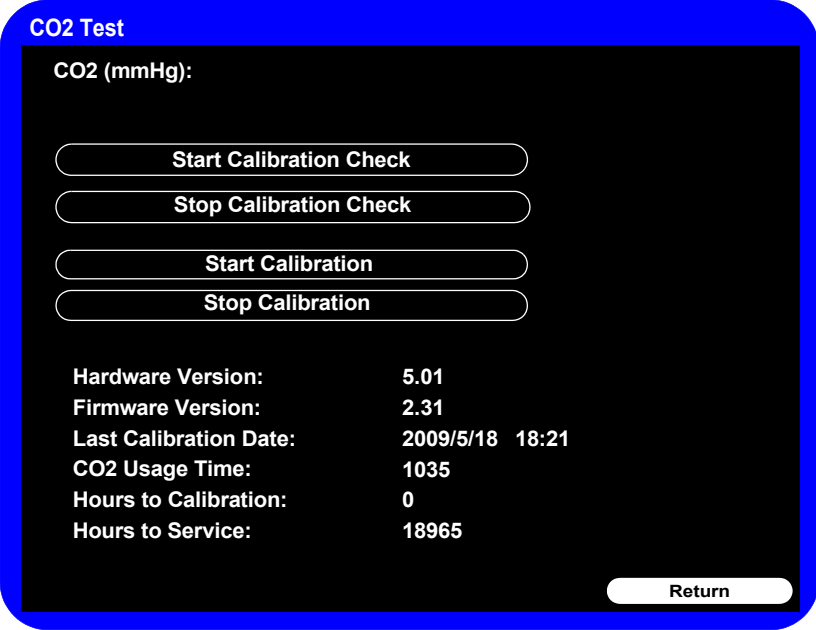
Required Test Equipment

- Electronic flowmeter, M1026–60144
- Gas calibration equipment:
    - Cal 1 gas 15210–64010 (5% CO$_2$)
    - Cal gas flow regulator M2267A
    - Cal tube 13907A

CO$_2$ Gas Measurement Calibration Check

To check the calibration of the CO$_2$ gas measurement:

Step	
1	Ensure that the CO$_2$ module is not in Standby mode (when the monitor is in Display Waveform mode, **Standby** is displayed in the CO2 waveform pane). If necessary, turn on the CO$_2$ module by opening the **CO2 Menu** and setting **CO2 Hardware:** to **On**.
2	Open the **Maintenance** options in the **System Diagnostics** menu. See "Accessing Maintenance Options" on page 3-12.

3	Select the **CO2 Test** button. The **CO2 Test** menu appears.

> **CO2 Test**
>
> **CO2 (mmHg):**
>
> (**Start Calibration Check**)
> (**Stop Calibration Check**)
> (**Start Calibration**)
> (**Stop Calibration**)
>
> | | |
> |---|---|
> | **Hardware Version:** | 5.01 |
> | **Firmware Version:** | 2.31 |
> | **Last Calibration Date:** | 2009/5/18   18:21 |
> | **CO2 Usage Time:** | 1035 |
> | **Hours to Calibration:** | 0 |
> | **Hours to Service:** | 18965 |
>
> (**Return**)

4	Connect one end of the sampling line to the CO_2 inlet on the monitor and leave the other end unconnected.
5	In the **CO2 Test** menu, select **Start Calibration Check**. A message to connect the gas to the CO_2 module appears.
6	Connect the other end of the sampling line to the gas controller equipment inlet with a 5% gas concentration.
7	Open the valve on the gas controller equipment to allow 5% CO_2 gas to flow into the monitor.
8	Select **OK** in the confirmation window to begin checking the calibration. **Note —** *The calibration check can take up to one minute to complete. The monitor checks the calibration and when the calibration check completes, the* **CO2 Test** *window displays a message. For example:* **CO2 calibration check successful. CO2 rate: 5.1.**
9	If the module is not in calibration, an error message appears. Calibrate the module. See "Calibrating the CO2 Module" on page 3-16.
10	Turn off the flow of gas and select **Return** in the **CO2 Test** menu. Press the wheel to exit the test.

Calibrating the CO_2 Module

Caution   **Because the monitor uses the current date and time as the calibration date and time, ensure that the system date and time is set correctly.**

Note — The monitor always displays the CO_2 module's operating (usage) time in the **CO2 Test** menu.

To calibrate the CO_2 module:

Note — Do not perform the initial calibration before 720 hours of use. If the initial calibration is performed before 720 hours of use, the module will reset, and then require its next calibration after 1,200 hours, instead of after 4,000 hours.

Step	
1	Connect one end of the sampling line (if not already connected) to the CO_2 inlet on the monitor and leave the other end unconnected.
2	In the **CO2 Test** menu, select **Start Calibration**. A confirmation window appears telling you to connect the gas to the CO_2 module.
3	Connect the other end of the sampling line to the gas controller equipment inlet with a 5% gas concentration.
4	Open the valve on the gas controller equipment to allow 5% CO_2 gas to flow into the monitor.
5	Select **OK** in the confirmation window to begin calibrating. The monitor begins calibrating the CO_2 module and displays the calibration value when complete. **Note —** *The calibration process can take up to one minute to complete.*
6	Turn off the flow of gas and select **Return** in the **CO2 Test** menu. Press the wheel to exit the test.
7	If the calibration is successful, the **Last Calibration Date** and **Hours to Calibration** in the **CO2 Test** menu reset. To check this, re-open the **CO2 Test** menu.
8	If the module is not able to calibrate itself, an error message appears. Replace the CO_2 module. See "Removing the CO2 Module" on page 5-15.

NBP Test

These tests check the performance of the non-invasive blood pressure measurement:

- NBP accuracy
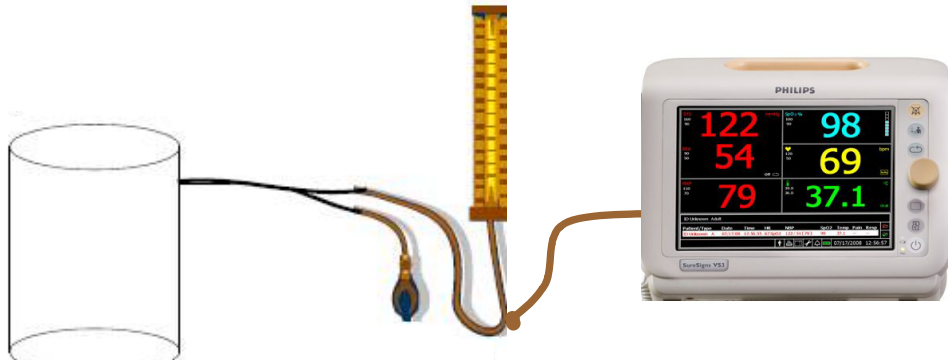- NBP calibration procedure (if required)
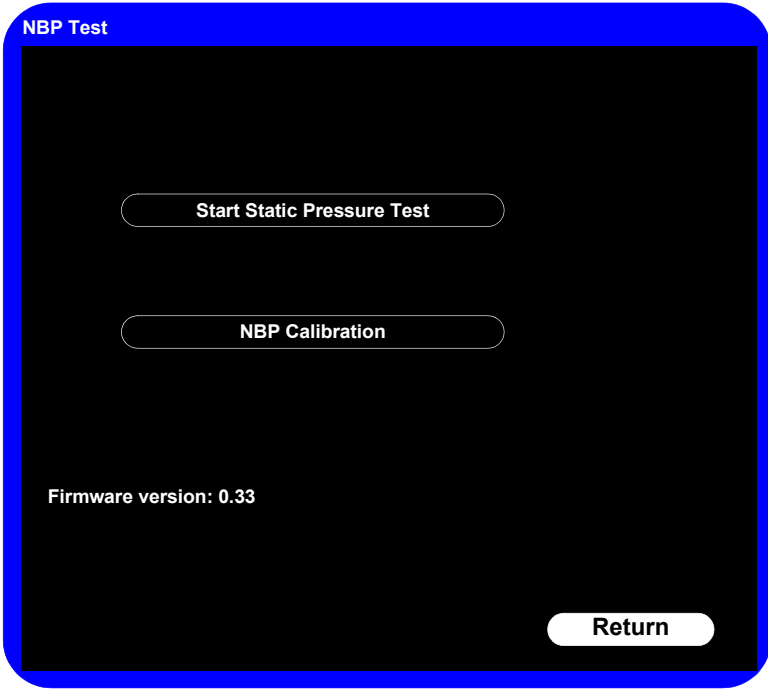- NBP pneumatic leakage

To perform these tests, you need:

- A reference manometer (includes hand pump and valve), accuracy 0.2% of reading
- An expansion chamber (volume 250 ml ± 10%)
- Appropriate tubing

NBP Accuracy

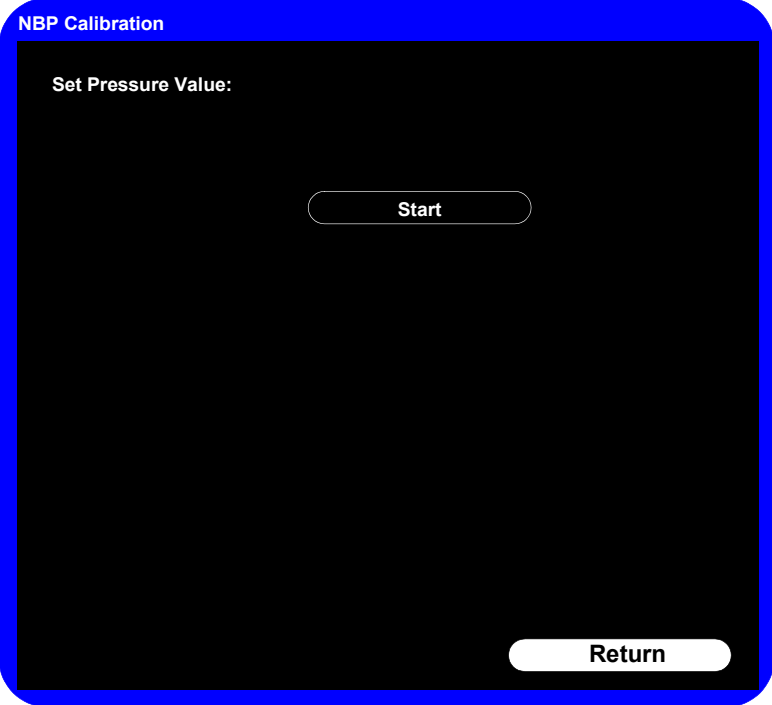**Note —** *Philips recommends that you do not test NBP accuracy with a simulator.*

To test the NBP accuracy:

Step	
1	Connect the manometer and the pump with tubing to the NBP connector on the monitor.
2	Connect the tubing to the expansion chamber (250 ml cylinder). **Expansion chamber** **Manometer** **Monitor**
3	Open the **Maintenance** options in the **System Diagnostics** menu. See "Accessing Maintenance Options" on page 3–12.

Step	
4	Select **NBP Test**. The **NBP Test** menu appears. NBP Test Start Static Pressure Test NBP Calibration Firmware version: 0.33 Return
5	Select the **Start Static Pressure Test** button to start the test.
6	Squeeze the manometer pump and apply a pressure of 280 mmHg.
7	Wait 10 seconds for the pressure to stabilize. Note the pressure displayed in the **NBP Test** menu. The value should be 280 mmHg ± 3 mmHg. **Note —** *Philips employees record this value as X1.*
8	Squeeze the manometer pump to apply a pressure of 150 mmHg to the monitor.
9	Wait 10 seconds for the pressure to stabilize. Note the pressure displayed in the **NBP Test** menu. The value should be 150 mmHg ± 3 mmHg. **Note —** *Philips employees record this value as X2.*
10	Select the **Stop Static Pressure Test** button to stop the test.
11	If the difference between the manometer and displayed values is greater than 3 mmHg, calibrate the monitor (see "NBP Calibration Procedure" on page 3–20). If the results are as expected, proceed to the "Pneumatic Leakage Test" on page 3–21.

NBP Calibration Procedure

To calibrate the NBP module:

Step	
1	In the **NBP Test** menu, Select **NBP Calibration**. **Note —** *To stop the calibration process at any time, select **Stop**.* The **NBP Calibration** menu appears. **NBP Calibration** **Set Pressure Value:** **Start** **Return** **Note —** *If you are using a manual manometer, close the valve before continuing.*
2	Select the **Start** button to begin calibration. The monitor inflates the expansion chamber and displays the message, **Starting NBP Calibration...**
3	Wait until the message, **Ready for calibration at first pressure point...**, appears.
4	Select the **Set Pressure Value** field, and then select the value to match that displayed on the manometer.
5	Select **CAL Point** to save the calibration point.
6	Wait until the message, **NBP calibration successful**, appears. If the test fails for any reason, select the **Stop** button to stop the test.
7	Select the **Return** button to exit the test.
8	To verify the calibration, check the accuracy of the NBP. See "NBP Accuracy" on page 3–18.

Step	
9	If you do not get the expected results after several tries, see Chapter 4, "Troubleshooting."

Pneumatic Leakage Test

To check the pneumatic system and valve:

Step	
1	In the **NBP Test** menu, select the **Start Static Pressure Test** button.
2	Squeeze the manometer pump to apply a pressure of 280 mmHg.
3	Wait 10 seconds for the pressure to stabilize. Note the pressure value in the **NBP Test** menu. **Note —** *Philips employees record this value as P1.*
4	Wait 60 seconds for the pressure to stabilize. Note the pressure value in the **NBP Test** menu. **Note —** *Philips employees record this value as P2.*
5	Calculate and document the leakage test value. The leakage test value should be less than or equal to 6 mmHg. **Note —** *Philips employees record this value as X3 (where X3 = P1 – P2).*
6	Select the **Stop Static Pressure Test** to stop the process.
7	If the leakage test value exceeds 6 mmHg, check the test setup cuff and tubing, and then test again. If the test still fails, check the pneumatic tubing inside the monitor.
8	If you cannot eliminate the leak, see Chapter 4, "Troubleshooting."

Predictive Temperature Test

The following procedure uses a fixed temperature value to check the performance of the predictive temperature module.

To perform this test, you need:

- A SureSigns temperature probe
- A SureSigns Temperature Calibration Key (part # 4535 640 33691)

To test the performance of the temperature measurement:

Step	
1	Connect the temperature probe to the monitor.
2	Open the **Temperature Menu** and select **Monitored** mode.

Step	
3	Remove the temperature probe and the probe well and disconnect the temperature probe connector from the monitor. **Note —** *A temperature probe error may occur and an alarm may sound.*
4	Connect the SureSigns temperature calibration key to the temperature module.
5	Replace the temperature probe and the probe well. **Note —** *If a temperature probe error was generated, the alarm stops.*
6	Remove the temperature probe from the probe well.
7	Wait for the monitor to display the static temperature value.
8	Check that the displayed temperature reads 36.3°C ± 0.1°C (97.3°F ± 0.2°F).
9	If the value is not within tolerance, see "Temperature Measurement Problems" on page 4-8.

Tympanic Temperature Test

To verify the performance of the tympanic temperature module, you must do one of the following:

· Send the monitor to Philips for calibration. Contact the Philips Customer Care Center or your local Philips representative

· Purchase a Covidien calibration device, part number 303079. See the Covidien web site for ordering information (www.covidien.com).

Note — *The battery compartment in the tympanic temperature probe is not functional.*

Temporal Temperature Test

To verify the performance of the temporal temperature module, you must do one of the following:

· Send the monitor to Philips for testing. Contact the Philips Customer Care Center or your local Philips representative.

· Purchase an Exergen calibration verification kit. See the Exergen web site for ordering information (www.exergen.com).

Safety Tests

Use the following safety test procedures to verify safe service of the monitor. The setups and the acceptable ranges of values used for these tests are derived from local and international standards, but may not be equivalent. These tests are not a substitute for local safety testing where it is required for an installation or a service event. If you use the Metron Safety tester, perform the tests in accordance with your local regulations. For example, in Europe, use IEC 60601–1 and in the United States, use UL 60601–1. The Metron Report should print results with the names listed below, together with other data.

Note — *Safety tests meet the standards of, and are performed in accordance with IEC 60601-1, Clause 19 (EN60601-1). The SureSigns vital signs monitors have been classified as Class I equipment.*
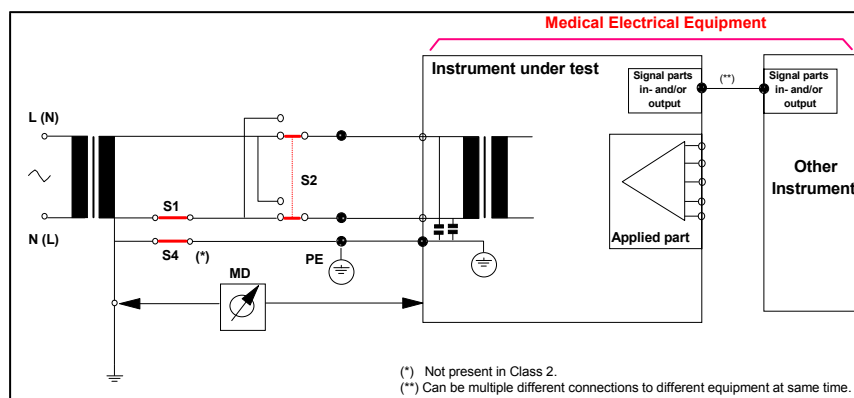
To perform these tests, you need a multimeter.

The monitor safety tests include:

- Enclosure leakage
- Ground integrity
- Patient leakage current with mains voltage

Enclosure Leakage

S(1) Part 1: Enclosure Leakage Current – NC (normal condition)

Expected Test Results

Normal condition maximum leakage current x1 $\leq$ 100µA.

This measures leakage current of exposed metal parts of Instrument under Test (IUT) and between parts of the system within the patient environment; normal and reversed polarity using S2.

Safety test according IEC 60601-1 / UL 60601-1.

S(1) Part 2: Enclosure Leakage Current – Single Fault (open earth)
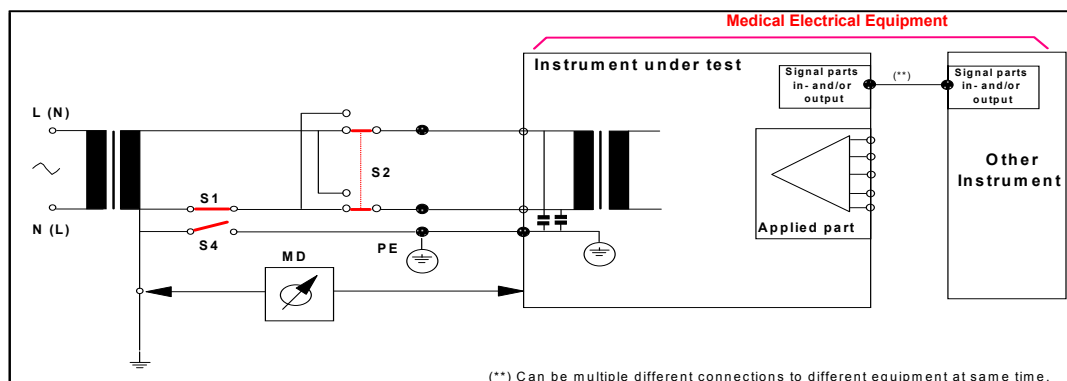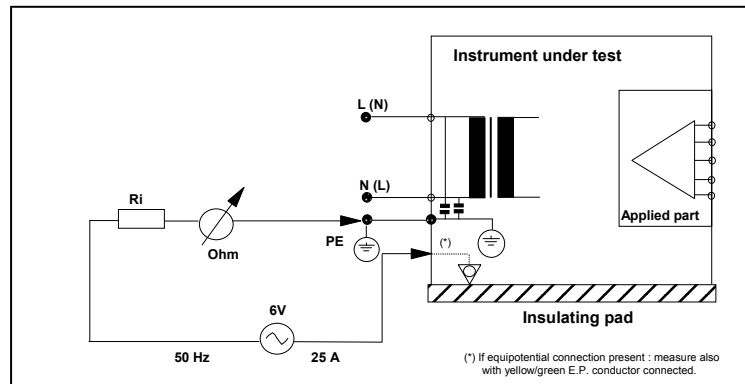

Expected Test Results

Single Fault maximum leakage current x2 ≤ 500μA (IEC 60601–1).

≤ 300μA (UL 60601–1)

This measures leakage current of exposed metal parts of Instrument under Test (IUT) with Protective Earth (PE) open circuit (S4 = open) and between parts of the system within the patient environment; normal and reversed polarity using S2.

Ground Integrity

S(2) Protective Earth Continuity

Expected Test Results

With mains cable, maximum impedance x ≤ 100 mOhms (IEC 60601–1 and UL 60601–1).

This measures impedance of Protective Earth (PE) terminal to all exposed metal parts of Instrument under Test (IUT), which are for safety reasons connected to the Protective Earth (PE). Test current 25 Amp applied for 5 to 10 seconds.

Patient Leakage Current With Mains Voltage

S(3) Patient Leakage current – Single Fault Condition (S.F.C.) mains on applied part
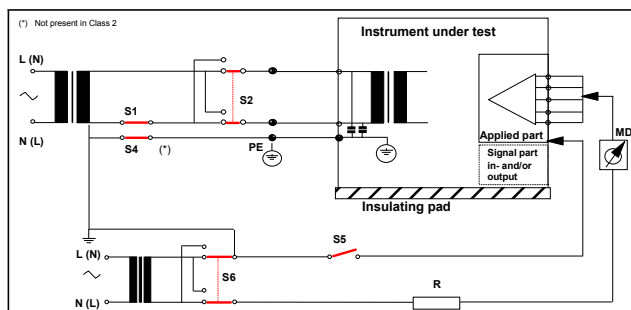
Expected Test Results

Maximum leakage current, x ≤ 50μA @ 250V (IEC60601–1 and UL 60601–1).

Measures patient leakage current from applied part to earth caused by external main voltage on applied part with switch S5 open and closed. Each polarity combination possible is tested using S2 and S6. This test is applicable for every measurement input.

Nurse Call Relay Test

If your facility uses the nurse call function on the monitor, perform the following procedure to test the nurse call alarm output relay.

The nurse call alarm output is a phone jack connector that is capable of both normally closed and normally open relay operation.

The nurse call connector jack has three contacts that connect with those on a phono connector as shown in the following illustration.
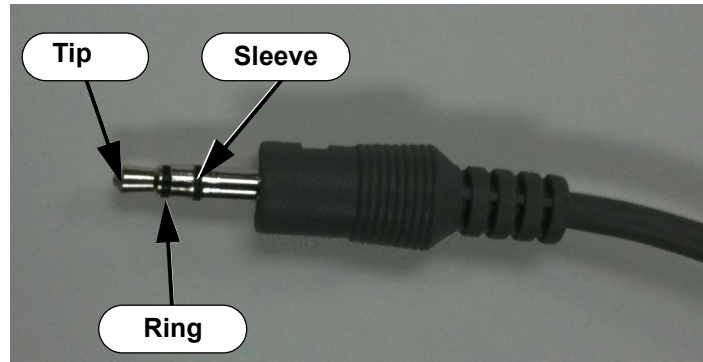
- Tip — Relay normally open, closed for alarm
- Ring — Relay normally closed, open for alarm
- Sleeve — Common

To perform this test, you need:

- A patient simulator
- An ohmmeter
- A phono connector

To perform the nurse call relay test:

Step	
1	Plug the phono connector into the Nurse Call connector on the back of the monitor.
2	Use the ohmmeter and patient simulator to verify relay operation as follows: Table below
3	If the nurse call function does not work as expected, see Chapter 4, "Troubleshooting."

Condition	Phone Jack Connector Tip (Relay Normally Open)	Phone Jack Connector Ring (Relay Normally Closed)
Alarm	Closed	Open
No alarm	Open	Closed

Calibrating the Touch Screen

When you replace the LCD, you must calibrate the touch screen after reassembly.

To calibrate the touch screen:

Step	
1	Open the **System Diagnostics** menu. See "Accessing the System Diagnostics Menu" on page 3–11.
2	Select the **Touch Screen Calibration** button. **Notes**: • *You cannot enter the calibration mode with the navigation wheel, you must select the* **Touch Screen Calibration** *button.* • *You cannot exit the test until it is completed.*
3	Select the **Touch Screen Calibration** button again. The calibration screen appears.
4	Touch and hold the center of the target cross hair ⊥ that appears until the target moves to another position. **Caution** **Use your finger to perform the test. Do not use a sharp object that could scratch the screen.**
5	For remaining target cross hairs, repeat step 4 until the calibration is complete and the following message appears: **New calibration settings have been measured.** **Press the navigation wheel to accept the new settings.**
6	Press the wheel to save the calibration settings.
7	Touch the screen anywhere to end the test.