3
Performance Verification Testing

This chapter includes the following information:

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

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 information about using the monitor, see the *Instructions for Use* for your monitor.

Testing and Inspection Guidelines

The following table lists the tests that Philips requires you to complete after performing monitor installations, repairs, or software upgrades.

For information about routine maintenance, 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
Opening the monitor for any reason	• Power-on self test • Alarms Test • Pneumatic leakage test • All safety tests
Replacing any internal parts (except NBP module, SpO_2 board, Temperature module)	• Power-on self test • Pneumatic leakage test • All safety tests
Replacing the NBP module	• Power-on self test • NBP test • Pneumatic leakage test • All safety tests
Replacing the SpO_2 module	• Power-on self test • SpO_2 Test • Pneumatic leakage test • All safety tests

After	Complete these tests
Replacing the temperature module	• Power-on self test • Alarms Test • Temperature Test • Pneumatic leakage test • All safety tests
Replacing the wireless module	• Power-on self test • Alarms Test • Pneumatic leakage test • 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	Once every six months.
Performance	
• Temperature accuracy • NBP accuracy test • SpO_2	Once every two years, or if you suspect the measurement is incorrect.
• Nurse call relay[1]	Before first use, and then once every two years.
Safety In accordance with IEC 60601-1	
• Enclosure leakage current • Ground integrity • Patient leakage currents	Once a year and after repairs where the monitor has been opened (front and back separated) or if the monitor has been damaged by impact.

1. 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 monitor.

To Perform This Test	You Need This Test Equipment
"Visual Test" on page 3-11	None
"Power-On Self Test" on page 3-11	None
"Alarms Test" on page 3-12	Temperature probe and well
"SpO_2 Test" on page 3-13	Adult SpO_2 sensor
"NBP Tests" on page 3-13	• Reference manometer (includes hand pump and valve), with an accuracy 0.2% • Expansion chamber (volume 250 ml ± 10%) • Appropriate tubing
"Temperature Test" on page 3-16	• Temperature well and probe • SureSigns temperature calibration key (part number 4535 640 33691)
"Safety Tests" on page 3-17	Multimeter
"Nurse Call Relay Test" on page 3-20	• Patient simulator • Ohmmeter • 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
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

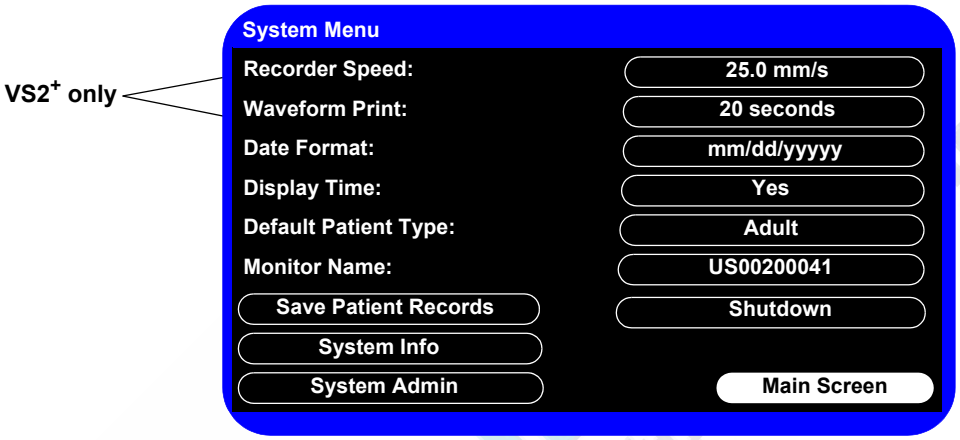
Accessing the System Menu

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* for your monitor or the *SureSigns VS2+ and VSi Installation and Configuration Guide*.

To access the **System Menu**:

- Select the **System** button.

  The **System Menu** appears.

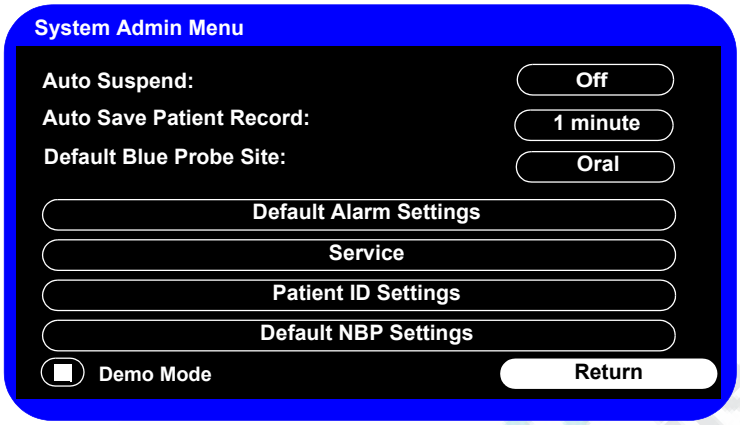


Accessing the System Admin Menu

Use the **System Admin Menu** to configure password-protected functions, including Demo mode, system diagnostics, and upgrading the software. For more information about using the **System Admin Menu** to configure the monitor, see the *SureSigns VS2+ and VSi Installation and Configuration Guide*.

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, **2-1-5**, as shown: 

Step	
3	Select the **OK** button. The **System Admin Menu** appears.  **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 described in this guide. All other options on the menu are described in the *SureSigns VS2+ and VSi Installation and Configuration Guide*.

Option	Description
Demo Mode	Demo mode allows you to demonstrate the monitor without actually monitoring parameters. For more information, see "Enabling Demo Mode" on page 3-6.
Service	Allows access to the following functions: • **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 3-9. • **Upgrade Software** — Opens the **Upgrade Software** menu. For more information, see "Upgrading the Software" on page 3-7.
Return	Returns the monitor to the **System Menu**.

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 to demonstrate the monitor without monitoring parameters. Demo mode simulates all patient parameters and generates alarms when alarm settings are exceeded.

By default, the **Demo Mode** check box is cleared.

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

To put the monitor in Demo mode:

Step	
1	Open the **System Admin Menu**. See “Accessing the System Admin Menu” on page 3-4.
2	Select the **Demo Mode** check box.
3	Select the **Return** button.
4	In the window that appears, select the **Yes** button. The monitor enters Demo mode and clears all patient data. A DEMO banner appears on the screen. 
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

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 provided in the *SureSigns VS2+ and VSi Installation and Configuration Guide*. For more information, see the *SureSigns VS2+ and VSi Installation and Configuration Guide*.**

Never downgrade the software to an earlier version. Doing so 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 Information window.

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 the 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 flash drive fits properly.**
- **If you upgrade from software version B.01.34 with Portuguese, Norwegian, Danish, Finnish, Russian, or Swedish configured, the language defaults to English and all system settings and patient data will be deleted from the monitor during the upgrade. To prevent loss of your patient data, ensure it has been exported to the EHR, print it, or save it to a USB drive for storage. Exported patient data, however, cannot be imported back into the monitor. For detailed information about saving patient data, see the *Instructions for Use* for your monitor.**

After the upgrade starts:

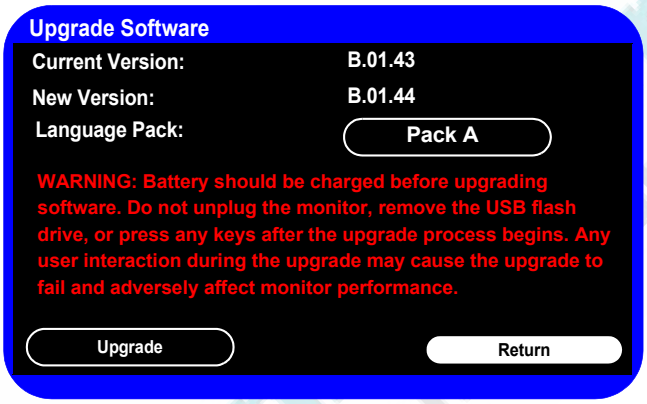
- **Do not unplug the monitor.**
- **Do not remove the USB flash drive.**
- **Do not press any keys.**

If the upgrade is inadvertently interrupted and the main board data is lost, replace the main board. For more information, see “Replacing the Main Board” on page 5-22.

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

To upgrade the software:

Step	
1	Connect the monitor to an AC power source and press the **On/Standby** key. **Note —** *Your monitor must be connected to AC power and have a fully charged battery before you upgrade 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 (for example, F:\).*

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 (for example, F:\).*
3	Access the **System Admin Menu**. For detailed information, see "Accessing the System Admin Menu" on page 3-4.
4	Select the **Service** button. The **Service Menu** appears.
5	Select the **Upgrade Software** button. The monitor searches for a valid software image on the USB flash drive and displays the updated image information in the **Upgrade Software** menu.  **Note —** *If the USB flash drive is not detected, ensure that the drive is completely inserted into the USB connector.*
6	Select the appropriate **Language Pack** to install. The following message appears:  **Note —** *If you upgrade the software using the same language pack that is currently installed, the current language is the default If you upgrade to a different language pack, the default language is English. If needed, reset the language using the* **System Admin Menu**. *For details on resetting the language, see the* ***SureSigns VS2+ and VSi Installation and Configuration Guide.***

7	Select the **Upgrade** button to start the upgrade. The **Upgrade in Progress** indicator increments during the upgrade process. When the upgrade is complete, the **Checking Memory CRC** and **Upgrade Successful** messages appear. When the software upgrade is complete, the monitor automatically shuts down and restarts.
8	Remove the USB flash drive.

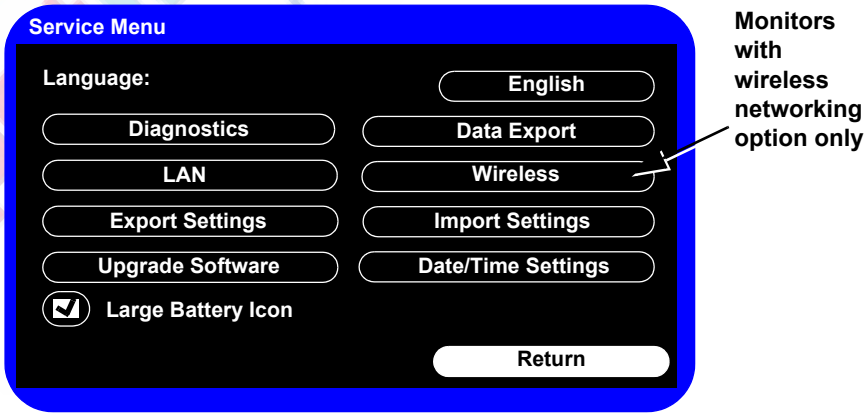
Performing Verification Tests

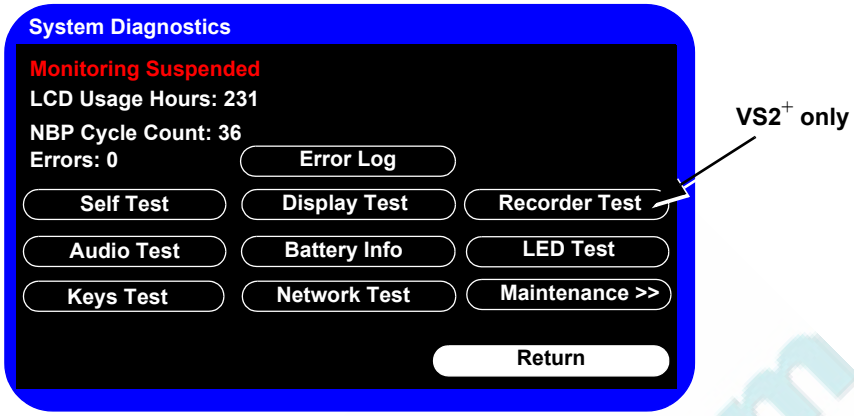
Some of the verification tests require using the **System Diagnostics** menu or the **Maintenance** options. When you open the **System Diagnostics** menu, monitoring is suspended.

Accessing the System Diagnostics Menu

Note — The **System Diagnostics** menu is not available in Demo mode.

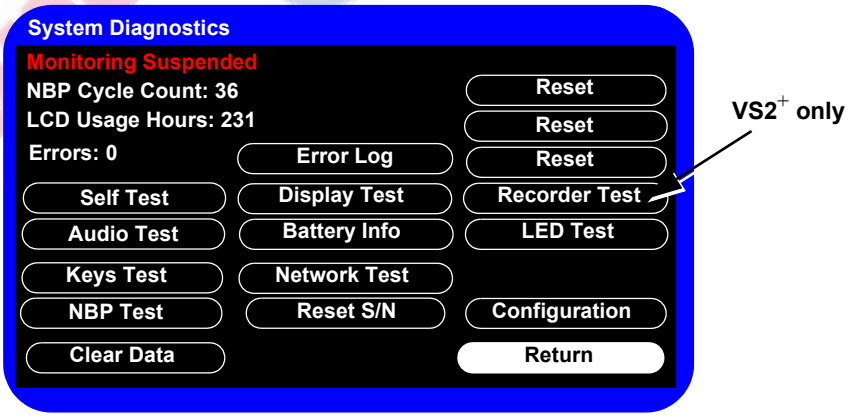
To access the **System Diagnostics** menu:

Step	
1	Access the **System Admin Menu**. For detailed information, see "Accessing the System Admin Menu" on page 3-4.
2	Select the **Service** button. The **Service Menu** appears.  **Note —** *For information about network settings, see the* ***SureSigns VS2+ and VSi Network Configuration Guide****.*

3	Select the **Diagnostics** button. The **System Diagnostics** menu appears. 

Accessing the Maintenance Options

To access the **Maintenance** options:

Step	
1	In the **System Diagnostics** menu, select the **Maintenance >>** button.
2	In the window that appears, enter the password, **1**-**2**-**9**, as shown: 
3	Select the **OK** button. The **Maintenance** options appear.  **Note —** *For information about the* **Network Test***, see the* ***SureSigns VS2+ and VSi Network Configuration Guide***.

Visual Test

To perform the visual test:

Step	
1	Inspect the system for obvious signs of damage such as cracks, cuts, or breakage.
2	Check all external cables and accessories for damage such as cuts, kinks, or 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 on the monitor.

3	Make sure that the monitor restarts 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. **Note —** It can take up to 40 seconds for the Charging LED to light. • The Philips screen appears for one second, and a startup tone sounds. • The main screen appears. The expected result is that the monitor restarts and displays the main (or appropriate) screen. For detailed information about the start-up and power sequences, see "Start-up and Power Sequences" on page 4-3. If the LEDs do not function as expected, see "Power Problems" on page 4-6. If the display does not function as expected, see "Power Problems" on page 4-6 or "Display Problems" on page 4-7. If you do not hear a startup tone, or the monitor displays the **Speaker Malfunc** error message, see "Error Codes" on page 4-12. **Note —** *Philips employees record this value as **PO:P** or **PO:F**.*

Alarms Test

This test allows you to verify that the monitor alarms are working.

To test the monitor 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	Block the NBP connector opening with your finger and press the **NBP** key.
3	Check that the **NBP Overpressure** message appears and an alarm tone sounds.
4	If you do not get the results in Step 3, see "Alarm Problems" on page 4-7.

SpO_2 Test

This test checks the performance of the SpO_2 measurement.

To perform this test, you need an Adult SpO_2 sensor. For information about compatible SpO_2 sensors, see the *Instructions for Use* for your monitor.

To perform the SpO_2 Test:

Step	
1	Connect a properly functioning 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 "SpO_2 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.**

NBP Tests

The NBP tests check the performance of the non-invasive blood pressure measurement. Perform each of the following procedures when checking the NBP module:

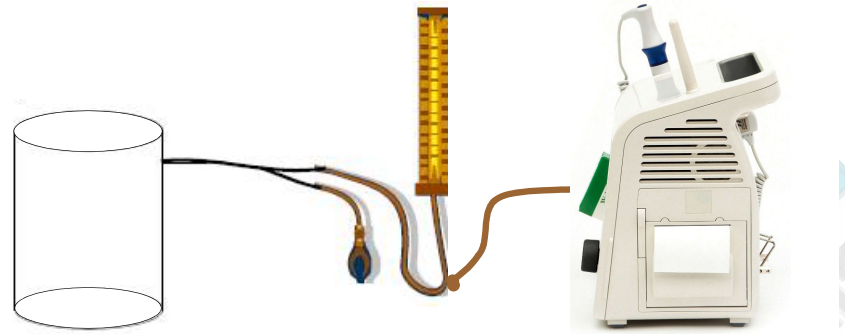
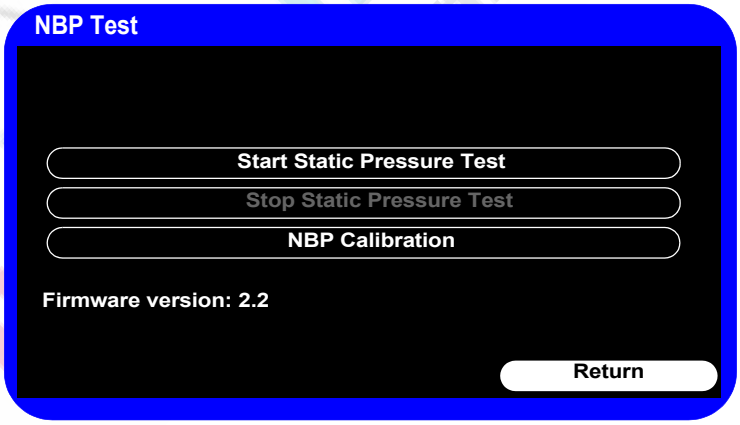
- NBP accuracy
- NBP calibration procedure (if required)
- NBP pneumatic leakage test

To perform this test, you need the following:

- Reference manometer (includes hand pump and valve), accuracy 0.2% of reading
- Expansion chamber (volume 500 ml ± 10%)
- Tubing

NBP Accuracy

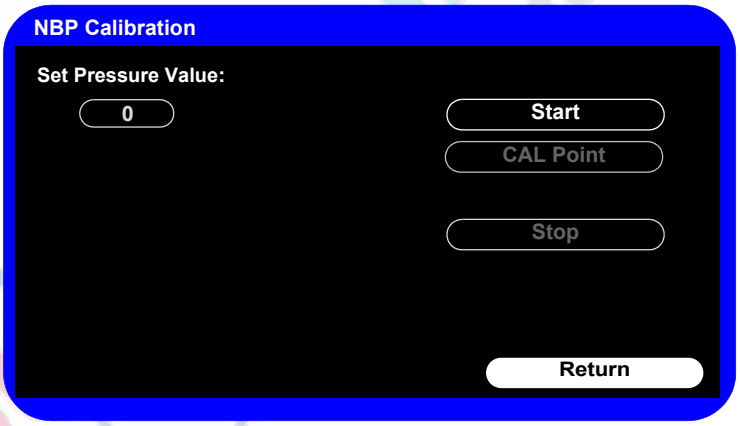
To test the NBP accuracy:

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** **SureSigns VS2+/VSi monitor**
3	Open the **Maintenance** options in the **System Diagnostics** menu. See “Accessing the Maintenance Options” on page 3-10.
4	Select **NBP Test**. The **NBP Test** menu appears. 
5	Select the **Start Static Pressure Test** button.
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 expected result is 280 mmHg ± 3 mmHg. **Note —** *Philips employees record this value as **X1**.*
8	Squeeze the manometer pump to apply a pressure of 150 mmHg.

9	Wait 10 seconds for the pressure to stabilize. Note the pressure displayed in the **NBP Test** menu. The expected result is 150 mmHg ± 3 mmHg. **Note —** *Philips employees record this value as **X2**.*
10	Select the **Stop Static Pressure Test** button.
11	If the difference between the manometer reading and displayed values is greater than 3 mmHg, calibrate the monitor (see "NBP Calibration Procedure" on page 3-15). If the results are as expected, continue with the "Pneumatic Leakage Test" on page 3-16.

NBP Calibration Procedure

To calibrate the NBP module:

Step	
1	In the **NBP Test** menu, select **NBP Calibration**. **Note —** *To stop the calibration at any time, select the **Stop** button.* The **NBP Calibration** menu appears.  **Note —** *If you are using a manual manometer, close the valve before continuing.*
2	Select the **Start** button to begin the calibration. The monitor inflates the expansion chamber and displays the following message: **Starting NBP calibration...**.
3	Wait until the following message appears: **Ready for calibration pressure point...**
4	Select the **Set Pressure Value** field.
5	Scroll through the list until the value matches the value displayed on the manometer and select it to confirm the change.
6	Select **CAL Point** to save the calibration point.
7	Wait until the following message appears: **NBP calibration successful**. If the test fails, select the **Stop** button to stop the test.
8	Select the **Return** button to exit the test.

9	To verify calibration, check the accuracy of the NBP. See “NBP Accuracy” on page 3-14.
10	If you do not get the expected results after several attempts, see “NBP Problems” on page 4-8.

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 expected leakage test value is ≤ 6 mmHg. **Note —** *Philips employees record this value as **X3** (where **X3** = **P1** - **P2**).*
6	Select the **Stop Static Pressure Test** button 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. See “Removing the NBP Module” on page 5-15.
8	If you cannot eliminate the leak, see “NBP Problems” on page 4-8.

Temperature Test

This test uses a fixed temperature value to check the performance of the temperature measurement.

To perform this test, you need the following:

- SureSigns temperature probe
- SureSigns temperature calibration key (part # 4535 640 33691)

To test the performance of the predictive temperature measurement:

Step	
1	Connect the temperature probe to the monitor.
2	Open the **Temperature** menu and place the monitor in **Monitored** mode.

3	Remove the temperature probe and the probe well and disconnect the temperature probe connector from the monitor. **Note —** *A temperature probe error may be generated 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 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 ± 0.1°C (97.3 ± 0.2°F).
9	If the value is not within tolerance, see “Temperature Measurement Problems” on page 4-9.

Safety Tests

Use the following safety test procedures to verify safe service of the monitor. The setups used for these tests and the acceptable ranges of values 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 a service event. If you are using the Metron Safety tester, perform the tests in accordance with your local regulations, for example, in Europe, use IEC 60601-1/IEC 60601-1-1 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 (EN 60601-1). The SureSigns VS2$^+$ and VSi vital signs monitors have been classified as Class I equipment.

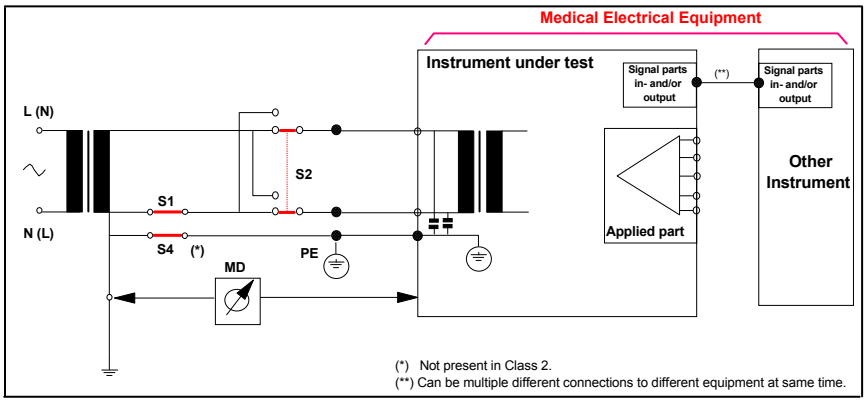
To perform these tests, you need a multimeter.

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)



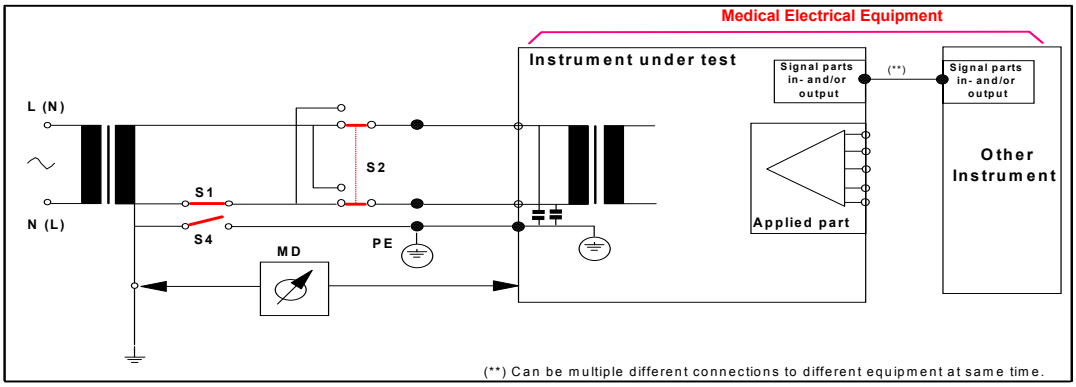
Expected Test Results

Normal condition maximum leakage current x1 ≤ 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

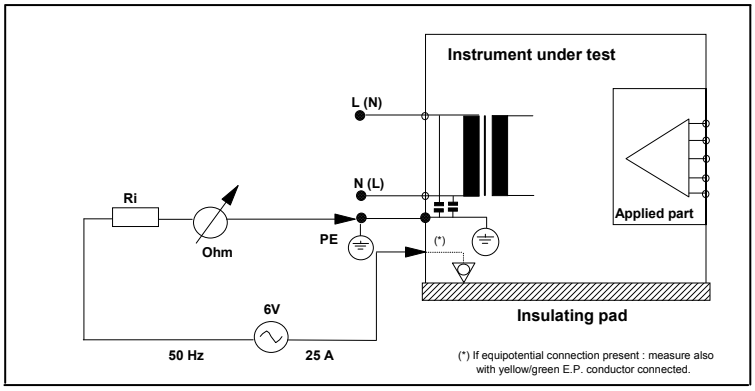
Single Fault maximum leakage current x2 ≤ 500µA (IEC 60601-1).

≤ 300µA (UL 60601-1)

This test measures the 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



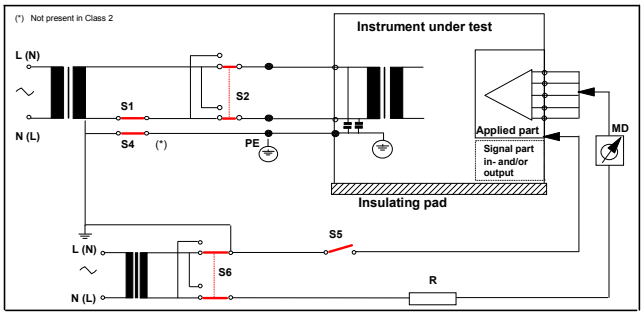
Expected Test Results

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

This test measures the impedance of the 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 ≤ 50 µA @ 250V (IEC60601-1 and UL 60601-1).

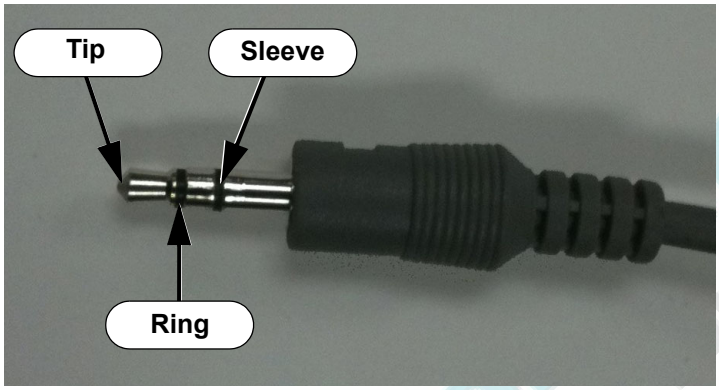
This test measures the patient leakage current from the applied part to earth caused by external main voltage on the applied part with switch S5 open and closed. Each polarity combination possible is tested using S2 and S6. This test is applicable for every measurement input.

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 3.5 mm phono connector

To perform the nurse call relay test:

<table>
<tr><th>Step</th><th></th></tr>
<tr><td>1</td><td>Plug the phono connector into the Nurse Call connector on the back of the monitor.</td></tr>
<tr><td>2</td><td>Use the ohmmeter and simulator to verify relay operation as follows:
<table>
<tr><th>Condition</th><th>Phone Jack Connector Tip (Relay Normally Open)</th><th>Phone Jack Connector Ring (Relay Normally Closed)</th></tr>
<tr><td>Alarm</td><td>Closed</td><td>Open</td></tr>
<tr><td>No alarm</td><td>Open</td><td>Closed</td></tr>
</table></td></tr>
<tr><td>3</td><td>If you do not get the expected results, see Chapter 4, “Troubleshooting.”</td></tr>
</table>