5
Performance Verification Testing

Overview

This chapter includes the following information:

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

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 on using the monitor, see the *SureSigns VS2 Vital Signs Monitor Instructions for Use*.

Testing and Inspection Guidelines

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

See Chapter 3, "Performing Routine Maintenance," for information on routine maintenance.

See Chapter 7, "Repairing the Monitor," for information on repair procedures.

After …	Complete These Tests …
Installing or exchanging a monitor	• Visual inspection • Power-on
Upgrading the software	• Visual inspection • Power-on
Opening the monitor for any reason	• Power-on • Pneumatic leakage • All safety tests
Replacing any internal parts (except NBP parts, SpO$_2$ board)	• Power-on • Pneumatic leakage • All safety tests
Replacing the NBP module or parts	• Power-on • NBP test • Pneumatic leakage • All safety tests
Replacing the SpO$_2$ board	• Power-on • SpO$_2$ Test • 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, or more often if specified by local laws.
Performance	
• Temperature accuracy • NBP accuracy test • SpO_2 • Nurse call relay[1]	Once every two years, or if you suspect the measurement is incorrect.
Safety—Patient leakage current In accordance with IEC 60601-1	Once a year and after repairs where the unit has been opened (front and back separated) or 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 5-6	None
"Power-On Self Test" on page 5-7	None
"Alarms Test" on page 5-7	NBP cuff
"SpO2 Test" on page 5-8	Adult SpO_2 sensor
"NBP Test" on page 5-9	• Reference manometer (includes hand pump and valve), accuracy 0.2% of reading • Expansion chamber (volume 500 ml ± 10%) • Appropriate tubing
"Temperature Test" on page 5-13	SureSigns temperature calibration key (part number 4535 640 33691)
"Safety Test" on page 5-14	Multimeter

To Perform This Test …	You Need This Test Equipment …
"Nurse Call Relay Test" on page 5-15	• Patient simulator • Ohmmeter • Phono connector
"Barcode Scanner Test" on page 5-19	Barcode scanner

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

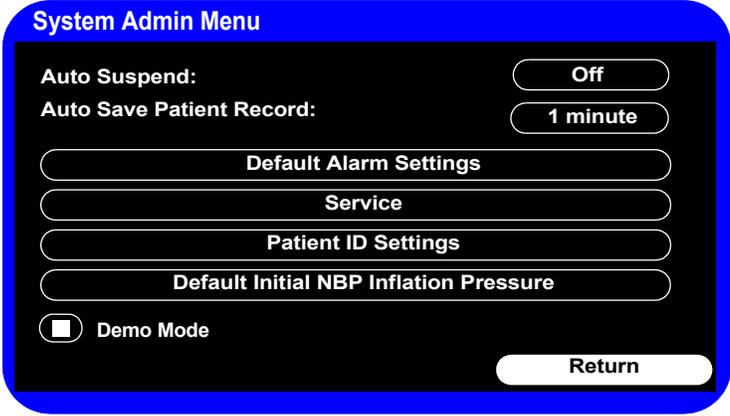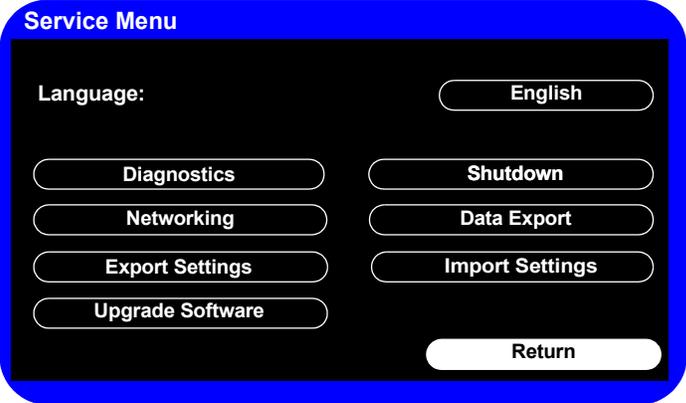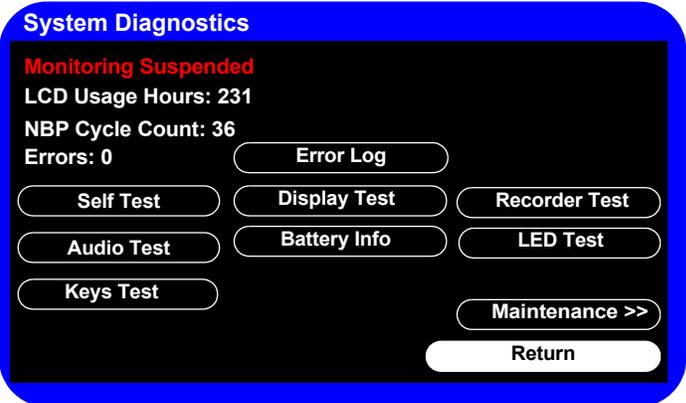| Test	What to record
Visual	V:P or V:F
Power-On	PO:P or PO:F
NBP	NBP:P/X1/X2/X3 or NBP:F/X1/X2/X3
Safety	S(3): P/X1 or S(3): F/X1

Performing Verification Tests

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

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

To access the **System Diagnostics** menu:

Step	
1	Press the **System Menu** key. The **System Menu** appears.
2	Rotate the wheel until the **System Admin** button is highlighted, and then press the wheel.

3	In the window that appears, enter the Administrator password, **2-1-5**, as shown: **Please enter the password:** (2) (1) (5 ⬍) (OK) (Cancel)
4	Rotate the wheel until **OK** is highlighted, and then press the wheel. The **System Admin Menu** appears. **System Admin Menu** **Auto Suspend:** (Off) **Auto Save Patient Record:** (1 minute) (Default Alarm Settings) (Service) (Patient ID Settings) (Default Initial NBP Inflation Pressure) ☐ **Demo Mode** (Return)

5	Rotate the wheel until **Service** is highlighted, and then press the wheel.
	The **Service Menu** appears.
	Service Menu
	Language: English
	Diagnostics Shutdown
	Networking Data Export
	Export Settings Import Settings
	Upgrade Software
	Return
6	Rotate the wheel until **Diagnostics** is highlighted, and then press the wheel.
	The **System Diagnostics** window appears.
	System Diagnostics
	Monitoring Suspended
	LCD Usage Hours: 231
	NBP Cycle Count: 36
	Errors: 0 Error Log
	Self Test Display Test Recorder Test
	Audio Test Battery Info LED Test
	Keys Test
	Maintenance >>
	Return

To access the **Maintenance** options:

Step	
1	In the **System Diagnostics** window, rotate the wheel to highlight the **Maintenance >>** button and press the wheel.
2	In the window that appears, enter the password, **1**-**2**-**9**, as shown: **Please enter the password:** 　**1**　　**2**　　**9** ⬍ 　　**OK**　　**Cancel**
3	The **Maintenance** options appear. **System Diagnostics** **Monitoring Suspended** **NBP Cycle Count: 36**　　　　　　**Reset** **LCD Usage Hours: 231**　　　　　**Reset** **Errors: 0**　　　**Error Log**　　　**Reset** **Self Test**　　**Display Test**　　**Recorder Test** **Audio Test**　　**Battery Info**　　**LED Test** **Keys Test**　　**NBP Test**　　**Reset S/N** **Configuration**　　**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, or wrong connections.
3	Ensure that all markings and labeling are legible.
4	Check for any obstructions to mechanical parts. The expected test result is that the system has no obvious signs of damage or obstruction.

Power-On Self Test

To perform the power-on self test:.

Step	
1	Connect the monitor to the external power supply and plug the power supply cord into an AC power source.
2	Press the **Power** key to turn on the monitor.
3	Make sure that the monitor boots 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 battery 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 boots up and displays the main (or appropriate) screen. For detailed information on the boot and power sequences, see "Boot and Power Sequences" on page 6-4. If the LEDs do not function as expected, see "Power Problems" on page 6-6.

Alarms Test

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

To verify that the general monitor alarms are working, test them while using the NBP monitoring function.

To test the monitor alarm:

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 button on the front panel.
5	Check that the NBP Timeout or NBP Loose Cuff message appears and an alarm tone sounds.
6	If you do not get the results in Step 5, see Chapter 6, "Troubleshooting".

SpO₂ Test

This test checks the performance of the SpO_2 measurement.

To perform this test, you need:

- Adult SpO_2 transducer: M1191A, M1191AL, M1191B, M1191BL, or M1196A

To perform the SpO_2 Test:

Step	
1	Connect an adult SpO_2 transducer that you know to be working correctly to the SpO_2 connector on the monitor. Ensure that the red LED in the transducer is lit.
2	Connect the other end of the transducer to your finger (this assumes that you are healthy).
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 expected results, see "SpO2 Measurement Problems" on page 6-11

SpO_2 sensor accuracy was obtained by performing controlled hypoxie studies on healthy, non-smoking adult volunteers (according to EN ISO 9919). The SpO_2 readings have been compared to CO-oximeter measurements on arterial blood samples. To represent the general population, data from at least 10 subjects (male and female) with a wide range of skin color was taken to validate SpO_2 accuracy. Because pulse oximeter equipment measurements are statistically distributed, only approximately two-thirds of pulse oximeter equipment measurements can be expected to fall within the ± Arms value measured by a CO-oximeter.

The update rate for the SpO_2 value and pulse rate is typically 1 second. Data averaging and other signal processing on the displayed and transmitted data values of SpO_2 and pulse rate is controllable by the user-selectable SpO_2 Response Mode: Slow (20 seconds), Normal (10 seconds), and Fast (5 seconds). Depending on the magnitude of difference between the alarm limit and the displayed value, the alarm signal generation delay may be from 1 second to the value of the response time (5, 10, or 20 seconds).

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 Test

These tests check the performance of the non-invasive blood pressure measurement. Perform each of these NBP checks and procedures when checking the NBP unit:
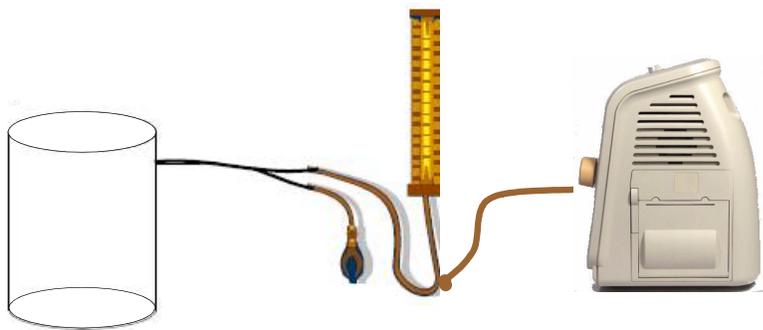
- NBP accuracy
- NBP calibration procedure (if required)
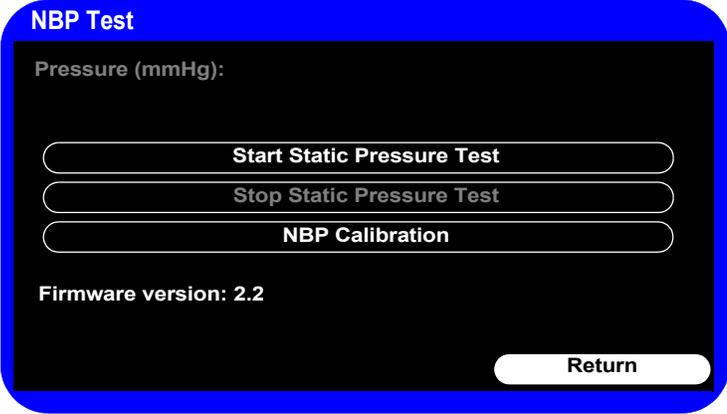- NBP pneumatic leakage
- NBP overpressure valve

To perform this test, you need:

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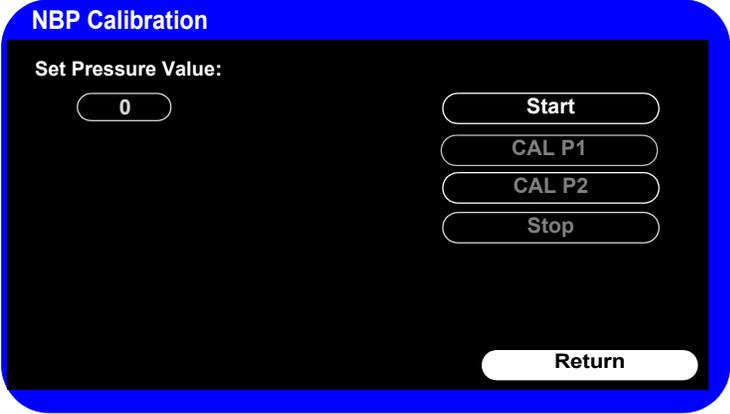- Appropriate tubing

NBP Accuracy

To test the NBP accuracy:

Step	
1	Connect the manometer and the pump with tubing to the NBP connector on the SureSigns VS2 monitor.
2	Connect the tubing to the expansion chamber (500 ml cylinder). **Expansion chamber** **Manometer** **SureSigns VS2 monitor**
3	Connect the manometer and the pump with tubing to the NBP connector on the SureSigns VS2 monitor.
4	Open the **Maintenance** options (see "Performing Verification Tests" on page 5-3 for information on accessing the **Maintenance** options).

5	Turn the wheel to highlight **NBP Test**, and then press the wheel.
	The **NBP Test** window appears.
	NBP Test **Pressure (mmHg):** **Start Static Pressure Test** **Stop Static Pressure Test** **NBP Calibration** **Firmware version: 2.2** **Return**
6	Rotate the wheel to highlight the **Start Static Pressure Test** button and press the wheel to start the test.
7	Squeeze the manometer pump and apply a pressure of 50 mmHg.
8	Note the pressure displayed in the **NBP Test** window and record this result as **X1** (see "Test Recording" on page 5-3). It should be 50 mmHg ± 3 mmHg.
9	Squeeze the manometer pump to apply a pressure of 250 mmHg to the monitor.
10	Note the pressure displayed in the **NBP Test** window and record this result as **X2**. The pressure in the **NBP Test** window should be 250 mmHg ± 3 mmHg.
11	Press the **Stop Static Pressure Test** button to stop the test.
12	If you do not get the expected results, calibrate the monitor (see "NBP Calibration Procedure" on page 5-11).
	If the results are as expected, continue with the "Pneumatic Leakage Test" on page 5-12.

NBP Calibration Procedure

To calibrate the NBP module:

Step	
1	In the **NBP Test** window, rotate the wheel to select **NBP Calibration**, and then press the wheel. The **NBP Calibration** window appears. **NBP Calibration** Set Pressure Value: 0 Start CAL P1 CAL P2 Stop Return
2	Rotate the wheel to highlight the **Start** button, and then press the wheel to begin calibration. **Note —** *To stop the calibration process at any time, rotate the wheel to select* **Stop***, and then press the wheel to stop calibration.*
3	Squeeze the manometer pump to apply a pressure of 250 mmHg to the monitor.
4	In the **NBP Calibration** window, rotate the wheel to the **Set Pressure Value:** menu and press the wheel. Rotate it to 250, and then press the wheel to save the value.
5	Rotate the wheel to **CAL P1**, and then press the wheel to save this as the first calibration point.
6	Release the pressure in the manometer to 50 mmHg.
7	In the **NBP Pressure** window, rotate the wheel to the **Set Pressure Value** menu, and then press the wheel and rotate it to 50, and press the wheel to save the setting.
8	Rotate the wheel to select **CAL P2,** and press the wheel to save this as the second calibration point.
9	Rotate the wheel to highlight the **Stop** button and press the wheel to stop the test. The message, **NBP calibration successful**, appears.
10	Rotate the wheel to the **Return** button and press the wheel to exit the test.
11	To verify calibration, repeat the **NBP Accuracy Test** in "NBP Accuracy" on page 5-9.
12	If you do not get the expected results after several attempts, see "NBP Problems" on page 6-9.

Pneumatic Leakage Test

To check the pneumatic system and valve:

Step	
1	In the **System Diagnostics** menu, select **NBP Test**.
2	Rotate the wheel to highlight the **Start Static Pressure Test** button and press the wheel to start the test.
3	Squeeze the manometer pump to apply a pressure of 250 mmHg to the monitor and record the value displayed as **P1**.
4	Let the manometer pressure stabilize for 15 seconds.
5	Watch the pressure value in the **NBP Test** window for 60 seconds, and record this value as **P2**.
6	Calculate and document the leakage test value **X3** (where **X3** = **P1** - **P2**). The leakage test value should be less than or equal to 6 mmHg.
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 "NBP Problems" on page 6-9.

NBP Overpressure Valve Test

To check the overpressure operation of the NBP valves:

Step	
1	When performing the static pressure test (see "NBP Accuracy" on page 5-9), squeeze the manometer pump to apply a pressure of 290 mmHg to the monitor.
2	Verify that the valves open, releasing pressure on the manometer. The monitor displays an NBP Overpressure message.
3	If you do not get the expected results, see "NBP Problems" on page 6-9.

Temperature Test

This test uses a fixed temperature value to check the performance of the temperature measurement on the SureSigns VS2 monitor.

To perform this test, you need:

- 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	Place the monitor in **Monitored** mode using the **Temperature** menu.
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 $36.3 \pm 0.1^{o}C$ ($97.3 \pm 0.2^{o}F$).
9	If the value is not within tolerance, see "Temperature Measurement Problems" on page 6-10.

Safety Test

Use the following safety test to verify safe installation or service of the monitor. The setup and acceptable ranges of values are derived from local and international standards, but may not be equivalent. The test is 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 test in accordance with your local regulations. For example, in Europe, use IEC 60601-1 and in the US, use UL 60601-1. The Metron Report should print results with the names listed below, together with other data. To perform this test, you need a multimeter.

Note — Safety tests meet the standards of, and are performed in accordance with IEC 60601-1. The SureSigns VS2 monitor is classified as Class II equipment.

Patient Leakage Current with Mains Voltage

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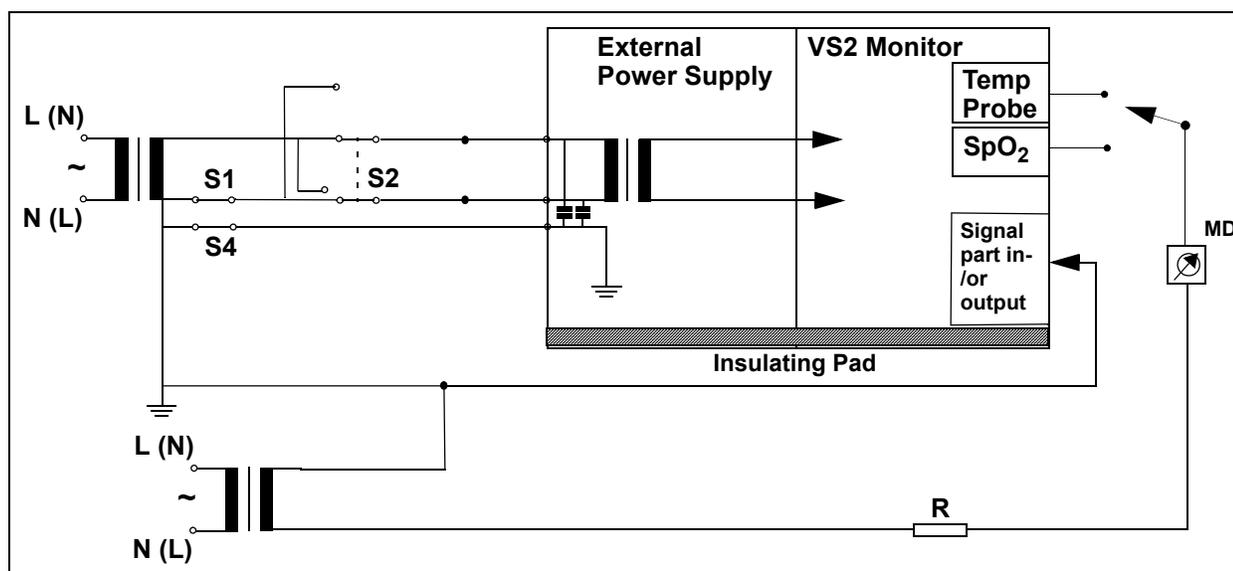
Expected Test Results

Maximum leakage current, x = 50 µA @ 250V (IEC 60601-1 and UL 60601-1).

Measures patient leakage current from applied part to earth. Each polarity combination possible is tested using S2.

Nurse Call Relay Test

The nurse call relay test checks the nurse call alarm output relay. The nurse call alarm output in the SureSigns VS2 monitor uses a phone jack connector tip or ring and is capable of both normally closed *and* normally open relay operation. Only perform this test if your site uses the nurse call.

To perform this test, you need:

- Patient simulator
- Ohmmeter
- 3.5 mm 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 simulator to verify relay operation as follows:

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

Barcode Scanner Test

The barcode scanner test checks the scanner's ability to accurately read data and input that information into the monitor.

To perform the barcode scanner test:

Step	
1	Print the following sample barcodes. Code 39 B C 3 2 1 Code 128 C o d e 1 2 8 PDF417 Advanced D
2	Scan the first barcode.
3	The **New Patient Menu** opens. The information written below the sample barcode should appear in the Patient ID fields. If the barcode information does not appear, see Chapter 6, "Troubleshooting."
4	Press the **Main Screen** key on the front panel to close the menu.
5	Repeat Step 2 through Step 4 for the remaining barcodes.