
6.0 *Test and Calibration*

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6.1 Introduction

To ensure the monitor always functions properly, qualified personnel should perform regular inspections, maintenance, and testing. This chapter provides the test procedures for the monitor and includes recommended test equipment and frequency. Qualified personnel should perform the testing and maintenance procedures as required and use appropriate test equipment.

The testing procedures provided in this chapter are intended to verify that the monitor meets the performance specifications. If the monitor or a module fails to perform as specified in any test, repair or replacement is required to correct the problem. If the problem persists, contact service.

CAUTION: All tests should be performed by qualified personnel only.

NOTE: Qualified personnel should acquaint themselves with the test tools and confirm that test tools and cables are applicable.

NOTE: When fields or buttons in a dialog have a line through them, they are not available for selection or modification.

6.1.1 Test Report

After completing the tests, service personnel should record test results in this table and retain them for hospital records.

TEST EQUIPMENT

Name	Model/PN	Next Calibration Due Date

TEST RECORD

No.	Test Item	Test Site	Test Results
1			
2			

CONCLUSION

Pass/Fail:	Tested by:	Date:
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6.1.2 Recommended Frequency

CHECK/MAINTENANCE ITEM	FREQUENCY
Visual test	When first installing or after reinstalling.
Power on test	1. When first installing or after reinstalling. 2. Following any maintenance or replacement of any main unit parts.
NIBP tests	1. If the user suspects that the measurement is incorrect. 2. Following any repairs or replacement of the NIBP module. 3. At least once every two years.
SpO ₂ test	
Temperature test	

Bar code scanner test		If the user suspects that bar code scan is incorrect.
Electrical safety tests	Enclosure leakage current test	<ol style="list-style-type: none"> 1. Following any repair or replacement of the power module. 2. At least once every two years.
	Earth leakage current test	
	Patient leakage current test	
	Patient auxiliary current test	
Recorder check		Following any repair or replacement of the recorder.

6.2 Visual Test

Inspect the equipment for obvious signs of damage. Follow these guidelines when inspecting the equipment:

- Carefully inspect the case, the display screen, and the buttons for physical 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 the labels on the equipment are clearly legible.

6.3 Power-on Test

Verify that the monitor can power up correctly by following this procedure:

- 1.** Insert the lithium battery in the battery compartment and connect the monitor to the AC mains. The AC mains LED and battery LED light.
- 2.** Press the Power On/Off button to turn on the monitor.
 - The operating status LED built into the Power On/Off button illuminates.
 - The system beeps to indicate it has passed the alarm sounds self test.
 - All the LEDs on the front panel illuminate.
 - The technical alarm lamp illuminates yellow, then red, and then turns off to indicate it has passed the alarm lamp self test.
 - The start-up screen clears, and the monitor enters the main screen, indicating start-up is complete.

6.4 NIBP Calibration

Required Tools:

- One (1) T-Connector
- Three (3) pieces of Tubing
- One (1) Metal Vessel with volume of 500 ±25 ml
- One (1) Reference manometer with accuracy of 1 mmHg

To calibrate NIBP:

1. Attach the calibration vessel and reference manometer as shown in FIGURE 6-1.

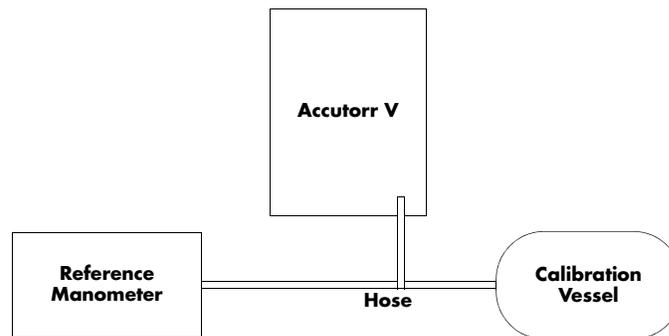


FIGURE 6-1 NIBP calibration configuration

2. If needed, press  (11) to display the Normal Screen.
3. Press  (12) to display the **SYSTEM SETUP** dialog.
4. Press  (16) or  (19) to highlight **MAINTENANCE**.
5. Once **MAINTENANCE** is highlighted, press  (18) to display the **MAINTENANCE** dialog as shown in FIGURE 6-2.

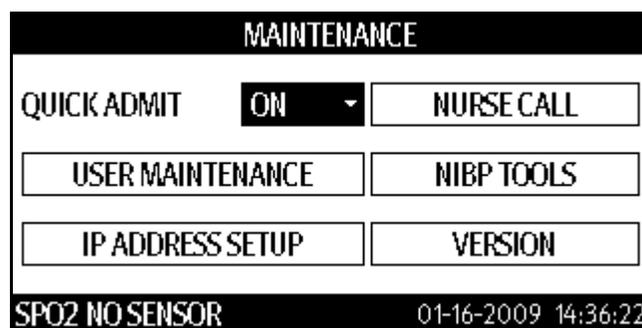


FIGURE 6-2 MAINTENANCE dialog

6. Press  (16) or  (19) to highlight **NIBP TOOLS**.
7. Once **NIBP TOOLS** is highlighted, press  (18) to display the **NIBP TOOLS** dialog.
8. Press  (16) or  (19) to highlight **CALIBRATION**, as shown in FIGURE 6-3.

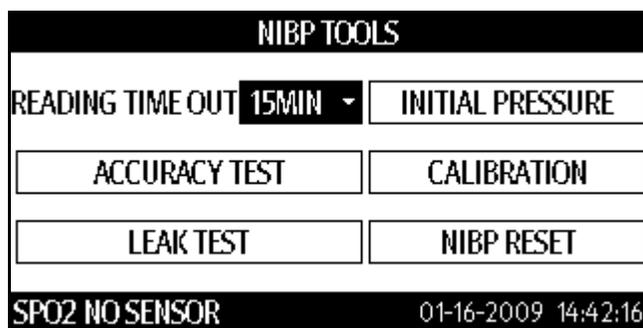


FIGURE 6-3 NIBP TOOLS dialog

9. Once **CALIBRATION** is highlighted, press  (18) to display the Enter Password dialog, as shown in FIGURE 6-4.

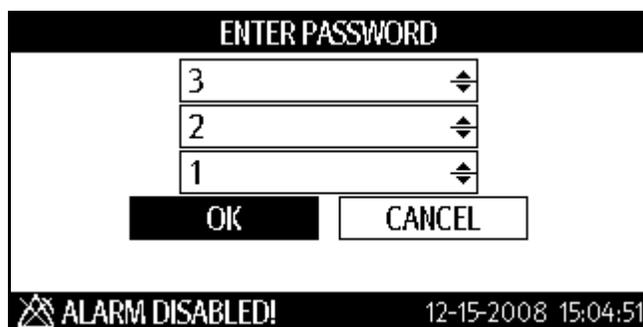


FIGURE 6-4 ENTER PASSWORD dialog

10. In the Enter Password dialog, press  (18). See FIGURE 6-4.
11. Press  (16) or  (19) to set the first password digit to 3.
12. Press  (18).
13. Press  (16) or  (19) to highlight the second password digit.
14. Press  (18).
15. Press  (16) or  (19) to set the second password digit to 2.
16. Press  (18).
17. Press  (16) or  (19) to highlight the third password digit.
18. Press  (18).
19. Press  (16) or  (19) to set the third password digit to 1.
20. Press  (18).
21. Press  (16) or  (19) to highlight **OK**.
22. Press  (18).

NOTE: When the NIBP CALIBRATION dialog is first displayed, **INFLATE** is highlighted, as shown in FIGURE 6-5.

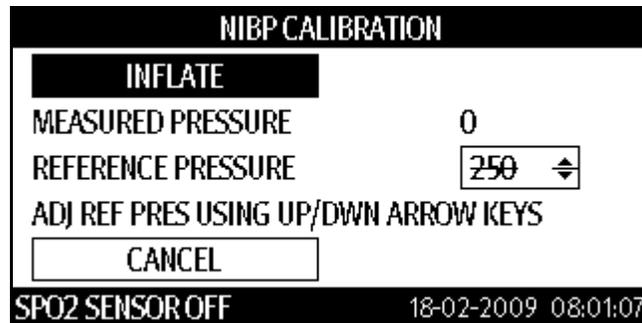


FIGURE 6-5 NIBP CALIBRATION dialog with **INFLATE** highlighted

23. Press  (18) to start pressurizing the calibration vessel.

NOTE: Use  (16) or  (19) to highlight **CANCEL**, then press  (18) to cancel the calibration.

NOTE: After the calibration vessel is pressurized, the reference pressure field is highlighted, as shown in FIGURE 6-6.

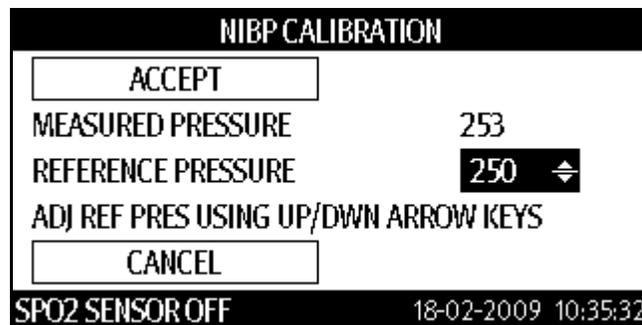


FIGURE 6-6 NIBP CALIBRATION dialog with the reference pressure field highlighted

24. Press the  (16) or  (19) to adjust the reference pressure value in 1 mm increments until it matches the **MEASURED PRESSURE** value.

25. Press  (18) to set the reference pressure value. After the reference pressure value is set, **ACCEPT** is highlighted, as shown in FIGURE 6-6.

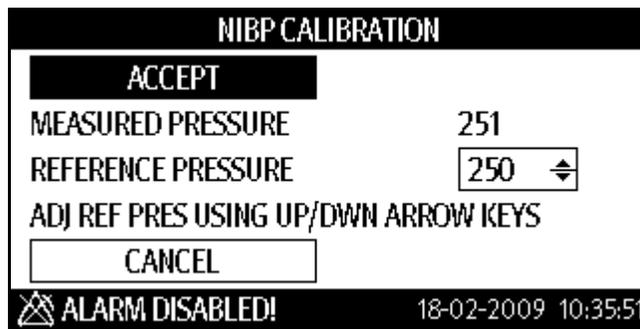


FIGURE 6-7 NIBP CALIBRATION dialog with **ACCEPT** highlighted

26. Press the  (16) or  (19) to select **ACCEPT**.

27. Press  (18) to accept the calibration.

NOTE: Use  (16) or  (19) to highlight **CANCEL**, then press  (18) to cancel the calibration.

The Accutorr V uses the new calibration factor until another calibration sequence is performed.

6.5 NIBP Accuracy Test

Required Tools:

- Two (2) T-Connectors
- Five (5) pieces of tubing
- One (1) Metal Vessel with volume of 500 ± 25 ml
- One (1) Reference manometer with accuracy of 1 mmHg
- One (1) Ball Pump

To calibrate NIBP:

1. Attach the calibration vessel, ball pump, and reference manometer as shown in FIGURE 6-8.

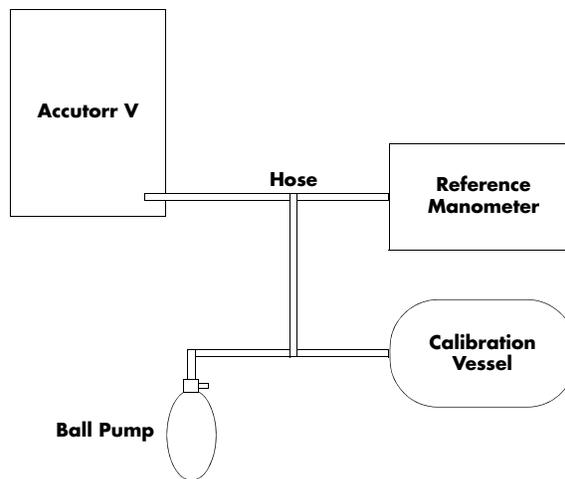


FIGURE 6-8 NIBP accuracy test configuration

2. If needed, press  to display the Normal Screen.
3. Press  to display the **SYSTEM SETUP** dialog.
4. Press  or  to highlight **MAINTENANCE**.
5. Once **MAINTENANCE** is highlighted, press  to display the **MAINTENANCE** dialog.
6. Press  or  to highlight **NIBP TOOLS**.
7. Once **NIBP TOOLS** is highlighted, press  to display the **NIBP TOOLS** dialog as shown in FIGURE 6-3.
8. Press  or  to highlight **ACCURACY TEST**.
9. Once **ACCURACY TEST** is highlighted, press  to start the **ACCURACY TEST** as shown in FIGURE 6-9.

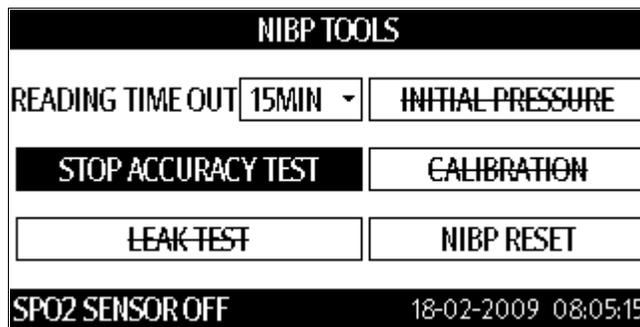


FIGURE 6-9 NIBP TOOLS dialog running the accuracy test

NOTE: The **ACCURACY TEST** button changes to **STOP ACCURACY TEST**. Use  or  to highlight **STOP ACCURACY TEST**, then press  to cancel the accuracy test.

10. Use the ball pump to pressurize the vessel to each of the three different ranges shown in following table.

RANGE	ACCURACY
Low approximately 50 mmHg	±3 mmHg
Medium approximately 150 mmHg	±3 mmHg
High approximately 250 mmHg	±3 mmHg

The pressure value in the **MAP LED** display should match the value shown on the reference manometer within the accuracy for each test range as shown in the table.

11. Use  or  to highlight **STOP ACCURACY TEST**, then press  to end the accuracy test.

If the accuracy test failed, send the Accutorr V to service for repair.

6.5.1 NIBP Leakage Test

Required Tools:

- One (1) piece of tubing
- One (1) Cylinder
- One (1) Metal Vessel with volume of 500 ±25 ml

To perform the NIBP leakage test:

- 1.** Set Patient size to adult by pressing  until Adult is selected. The patient size changes with each key press.

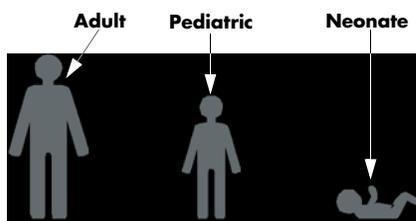


FIGURE 6-10 Patient size graphics and indicators

The Patient size indicator illuminates to indicate the selected size as shown in FIGURE 6-10. The factory default setting for the Patient size is Adult.

2. Connect the metal vessel with the NIBP connector on the Accutorr V monitor.

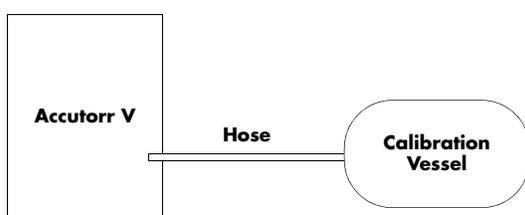


FIGURE 6-11 Leakage test configuration

3. If needed, press  to display the Normal Screen.
4. Press  to display the **SYSTEM SETUP** dialog.
5. Press  or  to highlight **MAINTENANCE**.
6. Once **MAINTENANCE** is highlighted, press  to display the **MAINTENANCE** dialog.
7. Press  or  to highlight **NIBP TOOLS**.
8. Once **NIBP TOOLS** is highlighted, press  to display the **NIBP TOOLS** dialog as shown in FIGURE 6-3.
9. Press  or  to highlight **LEAK TEST**.
10. Once **LEAK TEST** is highlighted, press  to start the leak test. The Accutorr V automatically deflates in approximately 60s, and the NIBP leakage test is complete.



FIGURE 6-12 NIBP TOOLS dialog running the leak test

NOTE: The **LEAK TEST** button changes to **STOP LEAK TEST**. Use  or  to highlight **STOP LEAK TEST**, then press  to cancel the leak test.

11. If the system leaks, the message **PNEUMATIC LEAK** will be displayed in the technical alarm area/prompt area. In this case, check for a loose connection and perform the test again.

NOTE: If the system does not leak, the **Accutorr V** does not display a message.

6.6 SpO₂ Test

NOTE: A functional tester cannot be used to assess the accuracy of a pulse oximeter probe or a pulse oximeter monitor.

Required Tool: SpO₂ simulator.

- For the monitor equipped with DPM SpO₂ module, BIO-TEK Index-2 SpO₂ simulator is recommended.
- For the monitor equipped with Nellcor SpO₂ module, an SRC-MAX SpO₂ simulator is recommended.
- For the monitor equipped with Masimo SpO₂ module, a BIO-TEK Index-2 SpO₂ simulator is recommended.

6.6.1 SpO₂ Test Under Normal Conditions

1. Connect the SpO₂ simulator to the SpO₂ sensor.
2. Select the model and the manufacturer of the SpO₂ module under test, and then configure the SpO₂ simulator as follows: SpO₂ 96%; PR 80 bpm.
3. The displayed SpO₂ and PR values should be within the ranges listed below.

6.6.2 SpO₂ Test in Motion Mode

1. Connect the SpO₂ simulator to the SpO₂ sensor.
2. Select the model and the manufacturer of the SpO₂ module under test; take measurement in the motion mode preset by the SpO₂ simulator.
3. The displayed SpO₂ and PR values should be within the ranges listed below.

MANUFACTURER	SPO ₂ SENSOR	SPO ₂	PR (BPM)
DPM Compatible Sensors	512E, 512G, 512F, 512H, 518B, 520A, 520P, 520I	96%±2%	80±3
	520N	96%±3%	
Masimo Compatible Sensors	LNCS-NeoPtL, LNCS Neo-L, LNOP DCI, LNOP DCIP, LNOP TCI, LNOP YI-Multisite, LNOP DCSC, LNOP Adt, LNOP Pdt, LNOP II InfL, LNOP II Neo- Neonatal L, LNOP NeoPt Preterm Neonatal Y, LNOP II NeoPt Preterm Neonatal Y	96%±3% (without motion) 96%±3% (with motion)	80±3 bpm (without motion) 80±5 bpm (with motion)
	LNCS InfL, LNCS-Pdtx, LNCS-Adtx, LNCS DC- I, LNCS DC-I Pt, TC-I	96%±2% (without motion) 96%±3% (with motion)	
Nellcor Compatible Sensors	MAX-A, MAX-P, MAX-I, DS-100A, OXI-A/N (Adult), OXI-P/I, MAX-N	96%±2% 96%±3%	80±3 bpm
	OXI-A/N (Neonate)	96%±4%	

NOTE: The SpO₂ simulator can only be used to verify that the pulse oximeter operates properly. It cannot be used to verify the accuracy of the pulse oximeter or the SpO₂ sensor. To verify the accuracy, clinical tests are required.

Contact Technical Support if the SpO₂ test fails.

6.6.3 Summary of Test Methods

6.6.3.1 DPM SpO₂

Measurement validation: The DPM SpO₂ module accuracy has been validated in human studies against arterial blood sample reference measured with a CO-oximeter. Pulse oximeter measurements are statistically distributed, and about two-thirds of the measurements can be expected to fall within the specified accuracy compared to CO-oximeter measurements.

6.6.3.2 Nellcor SpO₂

The Nellcor SpO₂ module was tested for accuracy using a simulator.

6.6.3.3 Masimo SpO₂

The Masimo SpO₂ module was tested by Masimo to verify accuracy.

6.7 Testing the Optional Temperature Module

Required Tool: Thermostatic oil tank, HART 7102 recommended

1. Set the temperature of the oil tank to 37° C and conduct the test after the temperature stabilizes.
2. Press  to display the **SYSTEM SETUP** dialog as shown in FIGURE 6-13.

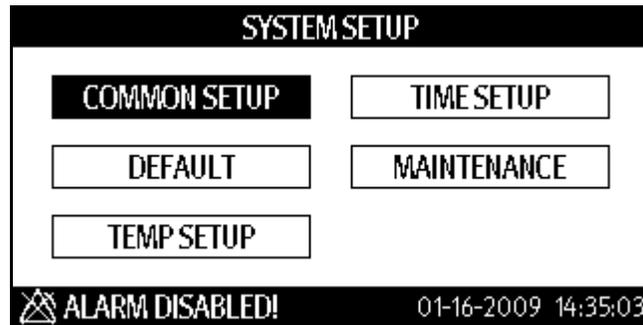


FIGURE 6-13 SYSTEM SETUP dialog

3. Press  or  to highlight **TEMP SETUP**.
4. Once **TEMP SETUP** is highlighted, press  to display the **TEMP SETUP** dialog as shown in FIGURE 6-14.

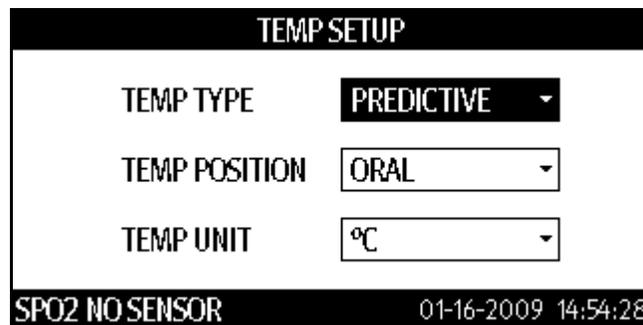


FIGURE 6-14 Example TEMP SETUP dialog

5. Press  or  to highlight the **TEMP TYPE** pull-down list.
6. Once the pull-down list is highlighted, press  to view the selections.
7. Press  or  to change the selection to **MONITOR**.
8. Once MONITOR is highlighted, press  to set it.
9. Press  or  to highlight the **TEMP UNIT** pull-down list.
10. Once the pull-down list is highlighted, press  to view the selections.

NOTE: For this test, the monitor and test tank temperature units are in Celsius.

11. Press  or  to change the selection to °C.
12. Once °C is highlighted, press  to set it.
13. Once the choices are set, press  to exit the **TEMP SETUP** dialog.
14. Remove the Temperature probe from the probe sheath, insert a probe cover, and place the probe into the oil tank.
15. Wait till the Temp value displayed on the monitor stabilizes. Verify that the displayed value is 37 ± 0.1 °C.

Contact Technical Support if the temperature test fails.

6.8 Nurse Call Performance Test

Required Tool: Multimeter

1. Connect the nurse call cable to the analog output connector.
2. If needed, press  to display the Normal Screen.
3. Press  to display the **SYSTEM SETUP** dialog.
4. Press  or  to highlight **MAINTENANCE**.
5. Once **MAINTENANCE** is highlighted, press  to display the **MAINTENANCE** dialog shown in FIGURE 6-2.
6. Press  or  to highlight **NURSE CALL**.
7. Once **NURSE CALL** is highlighted, press  to display the **NURSE CALL SETUP** dialog shown in FIGURE 6-15.

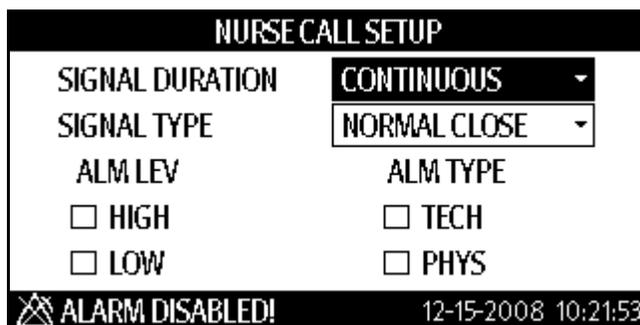


FIGURE 6-15 NURSE CALL SETUP dialog

8. Press  or  to highlight the **SIGNAL DURATION** pull-down list.
9. Once the **SIGNAL DURATION** pull-down list is highlighted, press  to select it.
10. Press  or  to highlight the **PULSE**.
11. Once the **PULSE** is highlighted, press  to select it.
12. Press  or  to highlight the **SIGNAL TYPE** pull-down list.
13. Once the **SIGNAL TYPE** pull-down list is highlighted, press  to select it.
14. Press  or  to highlight the **NORMAL OPEN**.
15. Once the **NORMAL OPEN** is highlighted, press  to select it.
16. Press  or  to highlight either **HIGH** or **LOW** for **ALM LEV**.
17. Once an **ALM LEV** is highlighted, press  to select it.
18. Press  or  to highlight either **TECH** or **PHYS** for **ALM TYPE**.
19. Once an **ALM TYPE** is highlighted, press  to select it.
20. Trigger an alarm and measure the contact output with the multimeter. The output should be square waves with an interval of 1s.

21. Press  or  to highlight the **SIGNAL DURATION** pull-down list.
22. Once the **SIGNAL DURATION** pull-down list is highlighted, press  to select it.
23. Press  or  to highlight the **CONTINUOUS**.
24. Once the **CONTINUOUS** is highlighted, press  to select it.
25. In the **NURSE CALL SETUP** dialog, set **SIGNAL TYPE** to **NORMAL OPEN**. Trigger an alarm and measure the contact output with the multimeter. The output should be continuous high level.

Contact Technical Support if the nurse call test fails.

6.9 Bar Code Scanner Test

Required Tool: None

1. Connect the barcode reader to the RS-232 connector on the back of the Accutorr V.
2. Press  to display the **SYSTEM SETUP** dialog FIGURE 6-13.
3. Press  or  to select **MAINTENANCE**.
4. Once **MAINTENANCE** is highlighted, press  to display the **MAINTENANCE** dialog as shown in FIGURE 6-16.

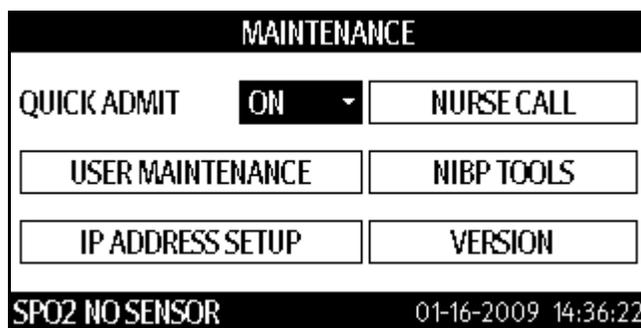


FIGURE 6-16 MAINTENANCE dialog

5. Press  or  to select **USER MAINTENANCE**.
6. Once **USER MAINTENANCE** is highlighted, press  to display the Enter Password dialog, as shown in FIGURE 6-17.

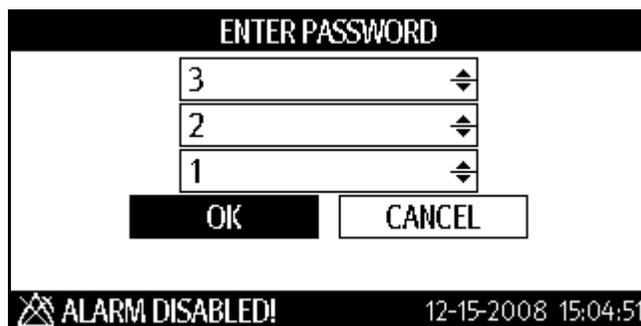


FIGURE 6-17 ENTER PASSWORD dialog

7. In the Enter Password dialog, press .
8. Enter the password 321 to display the **USER MAINTENANCE** dialog as shown in FIGURE 6-18. See Section 6.4, steps 10 – 22 for the password procedure.

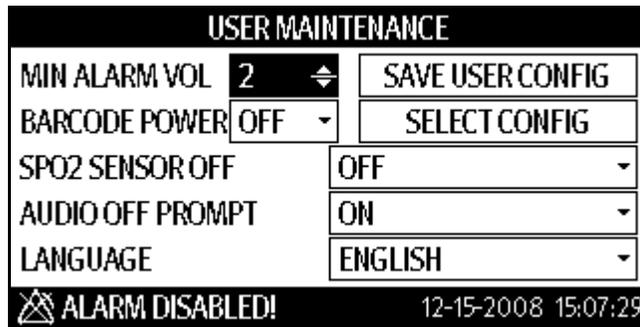


FIGURE 6-18 Example **USER MAINTENANCE** dialog

9. Press  or  to highlight the **BARCODE POWER** selection field.
10. Once the selection field is highlighted, press  select it.
11. Press  or  to select **ON**.
12. Once the selection is highlighted, press  select it.

NOTE: **When the RS-232 connector is used for DIAP, barcode power must be set to OFF.**

13. Aim the bar code scanner at the target bar code. Adjust the field of view to capture the bar code.
14. Hold the trigger until the bar code scanner beeps, indicating the bar code is successfully decoded. The indication lamp turns green and scanned characters are displayed on the monitor.

Contact Technical Support if the bar code scanner does not work as described.

6.10 Electrical Safety Tests

WARNING: Electrical safety tests are a proven means of verifying the electrical safety of the monitor. They are intended for determining potential electrical hazards. Failure to identify these hazards in a timely manner may cause personnel injury.

WARNING: Commercially available test equipment such as a safety analyzer can be used for electrical safety tests. Verify that the test equipment can be safely and reliably used with the monitor before use. The service personnel should acquaint themselves with the use of the test equipment.

WARNING: Electrical safety tests should meet the requirements of the latest editions of EN 60601-1 and UL 60601.

WARNING: These electrical safety tests do not supersede local requirements.

WARNING: All devices using the AC mains and connected to medical equipment within patient environments must meet the requirements of the IEC 60601-1-1 medical electrical systems standard and should be put under electrical safety tests at the frequency recommended for the monitor.

Electrical safety tests are intended to check the potential electrical hazards to the patient, operator, or service personnel. Electrical safety tests should be performed under normal ambient conditions of temperature, humidity, and atmospheric pressure.

The electrical safety test plan described here uses the 601 safety analyzer. Different safety analyzers may be used. Choose an applicable safety analyzer and test plan.

6.10.1 Enclosure Leakage Current Test

1. Connect the 601 safety analyzer to an AC power supply.
2. Connect SUM terminal of the applied part connection apparatus to RA input terminal of 601 safety analyzer, another terminal to the applied part of EUT.
3. Connect the EUT to the 601 analyzer's auxiliary output connector by using a power cord.
4. Attach on end of the red lead to the red input terminal of the analyzer, and the other end to tinsel over the enclosure of the EUT.
5. Power on the 601 safety analyzer and then press the "5-Enclosure leakage" button on the analyzer's panel to enter the enclosure leakage test screen.
 - Under normal condition, the enclosure leakage current should be no greater than 100 μ A.
 - Under single fault condition, the leakage current should be no greater than 300 μ A.

6.10.2 Earth Leakage Current Test

1. Connect the 601 safety analyzer to an AC power supply.
2. Connect the SUM terminal of the applied part connection apparatus to RA input terminal of 601 safety analyzer, another terminal to the applied part of EUT.

3. Connect the EUT to the 601 analyzer's auxiliary output connector by using a power cord.
4. Power on the 601 safety analyzer and then press the "4-Earth leakage" button on the analyzer's panel to enter the earth leakage test screen.
 - Under normal condition, the earth leakage current should be no greater than 300 μ A.
 - Under single fault condition, the leakage current should be no greater than 1000 μ A.

6.10.3 Patient Leakage Current Test

1. Connect the 601 safety analyzer to an AC source.
2. Connect the SUM terminal of the applied part connection apparatus to RA input terminal of 601 safety analyzer, another terminal to the applied part of EUT.
3. Connect the EUT to the 601 analyzer's auxiliary output connector by using a power cord.
4. Power on the 601 safety analyzer and then press the "6-Patient leakage" on the 601 analyzer's panel.
5. Repeatedly press the "APPLIED PART" button to measure AC and DC leakage alternatively. DC leakage reading is followed by "DC".
 - Under normal status, the patient leakage current should be no greater than 100 μ A AC, 10 μ A DC.
 - Under single fault condition, the leakage current should be no greater than 500 μ A AC, 50 μ A DC.

6.10.4 Patient Auxiliary Leakage Current Test

1. Connect the 601 safety analyzer to an AC source.
2. Connect the equipment under test (EUT) to the analyzer's auxiliary output connector by using a power cord.
3. Connect the sensors of the applied part to the applied part connection apparatus, whose RA-P terminal is connected to 601 safety analyzer's RA terminal and SUM terminal to 601 safety analyzer's LA terminal. RA terminal is switched on.
4. Power on the 601 safety analyzer and then press the "8-Patient Auxiliary Current Test" button on the analyzer's panel to enter the patient auxiliary current test screen.
5. Repeatedly press the "APPLIED PART" button to measure AC and DC leakage alternatively. DC leakage reading is followed by "DC".
 - Under normal status, the patient leakage current should be no greater than 100 μ A AC, 10 μ A DC.
 - Under single fault condition, the leakage current should be no greater than 500 μ A AC, 50 μ A DC.

Contact Technical Support if the electrical safety test fails.

6.11 Recorder Check

- 1.** Print SpO₂ Pleth waveforms. The recorder should print correctly and printout should be clear.
- 2.** Open the recorder door and verify the monitor gives the proper message. Close recorder door before proceeding to the next step.
- 3.** Set the recorder to print trend data. Check that the recorder prints accordingly.

Contact Technical Support if the recorder test fails.

6.12 Software upgrade

CAUTION: Disconnect the monitor from the patient and make sure that important data is saved before upgrading the monitor.

CAUTION: Do not shut down or power off the equipment when upgrading the bootstrap program. Otherwise, it may cause the equipment to break down.

CAUTION: Program upgrades should be performed by qualified service personnel only.

NOTE: After upgrading the boot program, re-upgrade the system program and other programs to ensure compatibility.

NOTE: Make sure the version of the upgrade package is the correct one. To obtain the latest upgrade package, contact Service.

The following is a list of upgrade programs:

- Bootstrap program
 - System program
 - Bar code recognition configuration
 - Multilingual library
 - General configurations (including passwords, company logo)
 - System functional configuration
 - FPGA program
 - Parameter module programs: SpO₂ module (DPM), NIBP module and optional Temperature module.
1. In the **MAINTENANCE** dialog (see FIGURE 6-19), check the installed software version and compare it with the currently released version to determine if an upgrade is needed.

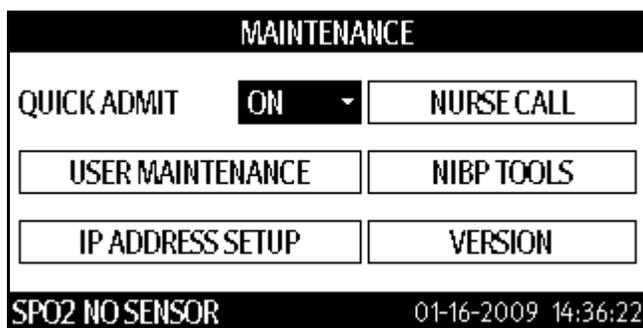


FIGURE 6-19 MAINTENANCE dialog

2. Download the upgrade software through a network to a portable PC or desktop PC. Connect the PC to the monitor using a cable plugged into the network connectors.
3. Run the upgrade software.