3

Functional verification

Functional verification overview

This section describes the procedure for a complete functional test to support recommended preventive-maintenance schedules.

The verification includes tests for a monitor configured with the printer, temperature, and SpO_2 options. Perform only the tests applicable to the actual configuration.

A checklist of the functional tests is provided on "Checklist and test results report form" on page 30. It is recommended that you print a copy of the checklist each time you perform the functional verification procedure, so that you can record and save the test results. If the monitor ever requires service, the records of test results can often facilitate troubleshooting.

Functional verification does not require opening the monitor case.

Equipment required

This equipment is required for functional verification of a fully configured monitor.

Commercially available general-purpose/medical test equipment			
Item Manufacturer part number/specification			
Power supply	Variable, 0-8 VDC, 0.75 amperes (minimum), with voltage and current indicators (for 1mA current measurement)		
Digital pressure meter	Netech Digimano 1000 or equivalent		
AC withstand voltage (hi-pot) tester	Associated Research 3605 or equivalent		
\mbox{SpO}_2 functional tester (Nellcor, for testing the monitor only)	Nellcor SRC-MAX		
\mbox{SpO}_2 functional tester (Masimo, for testing the monitor only)	Masimo Tester REF 1593		
\mbox{SpO}_2 extension cable (required for SRC-MAX)	Nellcor DEC-8		
\mbox{SpO}_2 simulator (for testing the monitor and the \mbox{SpO}_2 sensor)	Fluke (Biotek) Index2 XL/XLFE or equivalent		
Syringe, 60 mL, Slip tip, Luer	BD (Becton, Dickinson) 309654 or equivalent		
Hi-pot cable connectors	See "Hi-pot test connections" on page 29.		
Timer (to display elapsed time, in seconds)			

Welch Allyn accessories and test equipment				
Temperature test key (for testing the monitor only)	06138-000			
9600 Temperature calibration tester (for testing the monitor and the temperature probe)	01800-210, 110 V 01800-500, 220 V 01800-810, 220 V UK 01800-910, 220 V Australia			
Neonatal cuff hose, 96-inch	008-0265-XX			
Neonatal #1 cuff, disposable, box of 10	008-0620-XX			
Cuff simulator	020-0702-XX			
DC power adapter	5200-101A			
Battery substitution connector (Use the female end from the cable set)	660-0237-00			
Welch Allyn Monitor Service Utility (required for NIBP repair or replacement; not required for functional testing)	810-1784-XX			
Service Serial Cable (for use with the Welch Allyn Monitor Service Utility 810-1784-XX)	008-0842-XX			
Tycos air release valve and small bulb	WA 5088-01			
NIBP tubing connector, threaded	600-0021-XX			
tubing, 1'	600-0179-XX			
Tee, plastic	600-0043-XX			

Functional verification procedure

Reference illustration



System/power

Note Other than the optional NIBP overpressure test (page 18), the tests described here must be performed as part of a complete functional verification procedure.

Setup

- If the monitor is configured with the temperature option, connect the temperature probe and insert it into the probe well.
- If you are using the optional Welch Allyn Model 9600 Calibration Tester (01800-200), plug it in and set it to 96.4 °F (35.8 °C).
- If the monitor is configured with the SpO₂ option, connect the SpO₂ sensor.

Battery charge and beeper

- 1. With the monitor turned off, disconnect the power adapter from the monitor.
- 2. Verify that the charge LED ~ is off.
- 3. Connect the power adapter. The monitor emits a single beep tone.
- 4. Verify that the charge LED \frown is on.
- **Note** Depending on the charge level of the battery, the charge LED may be either flashing or steady.

 \sim flashing indicates that the monitor is running on AC, the battery is charging, and the battery is charged to less than 90% capacity.

✓ steady indicates that the monitor is running on AC, the battery may or may not be charging, and the battery is charged to at least 90% capacity.

Battery substitution cable setup

- 1. Disconnect the power adapter.
- 2. Remove the battery cover and remove and disconnect the battery.
- 3. Separate the connector pair (660-0237-00). Use the end that is identical to the connector on the battery as a battery substitution test cable.
- 4. Connect the open-ended red (+) and black (-) wires of this cable to the variable DC power supply.
- 5. Set the power supply to 6.0 V \pm 50 mV.
- 6. Connect the test power cable to the battery connector on the monitor.

Monitor-off current

With the monitor powered down, verify that the current draw from the power supply is less than 1 mA.

Power-on self-test

- 1. Power the monitor on.
- **Note** If the monitor displays error E38, power the monitor off and then power it on again.
- 2. Verify that the start-up tone (double beep) is audible.
- 3. Verify that all front-panel lights (background indicators, LCD pixels, and LED segments and periods) come on in the proper order: left, center, and right.

Initialization/idle mode current

- **Note** If your monitor is configured without the temperature option and without the SpO₂ option, skip these steps and proceed to "Baseline current draw" on page 13.
- 1. If the temperature option is present:
 - a. Verify that the temperature probe is in the probe well.
 - b. Set the temperature mode to MONITOR.
 - c. Remove the temperature probe from the probe well.
 - d. Verify that the temperature reading appears within 4 seconds.
 - e. Do not return the probe to the probe well.
- 2. If the SpO_2 option is present:
 - a. Verify that the SpO₂ sensor cable is connected to the monitor.
 - b. Verify that the current draw from the bench power supply is less than 800 mA.
- 3. Disconnect the SpO₂ sensor (if equipped).
- 4. Insert the temperature probe (if the monitor is so equipped) into the probe well.

Baseline current draw

- 1. With the monitor powered on, wait for the monitor LEDs to blank. In this state, the SpO2 % reads -, the time of day is displayed in the message window, and the rest of the displays are blank.
- 2. Note and record the exact current from the power supply. (This value will be used in the NIBP and printer tests.)

Battery voltage

- 1. Power the monitor off.
- Simultaneously press and hold and to bring up the monitor in SERVICE MODE. (When the monitor completes the power-on self-test in service mode, the main software version number appears in the message display.)
- 3. Press (a) repeatedly until BATTERY VOLTAGE appears in the message display.
- 4. Verify that the displayed battery voltage is within 0.1 volt of the DC power supply input.
- 5. Exit Service Mode by turning off the monitor and then turning it on again.

NIBP

Note The tests described in this section are to be performed only as part of a complete functional verification procedure.

Characterization test

- 1. Attach a neonate hose (part 008-0265-01) to the NIBP fitting on the monitor.
- 2. Prepare the 60-mL syringe as follows, with reference to the illustration below:
 - a. Move the syringe plunger to the 35 mL line.
 - b. Drill a small hole (for example, 9/64 inch) through the syringe and the plunger shaft, at a location between the plunger and the top of the syringe.
 - c. Insert a rod or bolt (for example, a 6-32 screw) through the hole so that the plunger cannot move, creating a constant volume in the syringe of 35 mL \pm 2 mL. Secure the rod or bolt so that it cannot fall out of the hole.



- 3. Insert the tip of the syringe into the open end of the neonate hose. Verify that the fit is tight and secure.
- 4. Set the monitor patient type to **Adult**, as follows:
 - a. Press 🖲 once.
 - b. If the monitor is not already in **Adult** mode, press once or twice until **Adult** appears in the message display.
 - c. Press 🕲.
- 5. Press 🧐.
- 6. Verify that the error code **C03** appears in the message display within a few seconds.



WARNING If the error code C03 does not appear, characterize NIBP according to the instructions presented on page 35, and then repeat the NIBP characterization test.

WARNING Do not use the monitor if it does not pass the NIBP characterization test. If the NIBP module is not properly characterized, the monitor could overinflate a neonatal cuff, which could create a hazard for neonatal patients.

WARNING If you cannot characterize the NIBP module, remove the monitor from service immediately and return it to Welch Allyn for service. (See "Returning products" on page 6.)

Leak test

This tests the NIBP system for abnormal leakage.

If the NIBP system is leaking, check for leaks in the external plumbing before opening the case to look for internal leaks.

If you determine that any NIBP module component is causing abnormal leakage, you must replace the NIBP module before returning the monitor to clinical use.



Caution Do not attempt component-level repair of the NIBP module. Any change to the NIBP module requires that the monitor be returned to the factory for NIBP module calibration.

- 1. Put the monitor in Service mode:
 - a. Power the monitor off.
 - b. Power the monitor **on** while pressing 🧐.



WARNING Do not connect the monitor to a patient while the monitor is in Service mode. Overpressure detection is disabled while the monitor is in NIBP test mode.

2. Attach a #1 neonatal cuff and hose to the monitor

Wrap the cuff securely around a solid cylindrical object of circumference between 1.6 and 1.9 inches (4.1 and 4.8 cm).

- 3. Press (a) repeatedly until **NIBP TEST** appears in the message window and **0** is displayed in the SYS and DIA windows.
- **Note** When you first enter the NIBP test mode, give the monitor about a minute to initialize NIBP before you change the target test pressure.

When switching from one target pressure to the next, give the monitor time to fully inflate and stop before you select the next target pressure.

In the NIBP test mode, press repeatedly to select the target NIBP test pressure. The target pressure is displayed on the DIA LEDs. The measured instantaneous pressure determined by the monitor is displayed on the SYS LEDs.

- 4. Press ▲ once to select 80 mmHg (10.7 kPa). The cuff inflates to approximately 115 mmHg (15.3 kPa).
- **Note** In the NIBP test mode, and especially at small test volumes, the pressure achieved can vary significantly (30-40 mmHg or 4-5.3 kPa) from the target pressure.
- 5. Wait 15 seconds, and note the current pressure.
- 6. Wait another 10 seconds and verify that the pressure has not dropped more than 8 mmHg (1.1 kPa) below the pressure noted in step 5.

If the pressure drop is greater than 8 mmHg (1.1 kPa), check the cuff, the hose, and all external connections for leaks, and then repeat from step 3.

- 7. Press 🛦 several times to select 0 mmHg (0 kPa). The valve opens to release pressure.
- 8. Disconnect the neonate cuff.

Pressure calibration verification

This tests pressure readings on the monitor against a calibrated external pressure meter.

- 1. Put the monitor in Service mode:
 - a. Power the monitor off.
 - b. Power the monitor **on** while pressing 👻.



WARNING Do not connect the monitor to a patient while the monitor is in Service mode. Overpressure detection is disabled while the monitor is in NIBP test mode.

2. Connect the monitor to an adult cuff or a cuff simulator, a pressure meter or a manometer, and a pump bulb, as shown.



3. Press (a) repeatedly until **NIBP TEST** appears in the message window and **0** is displayed in the SYS and DIA windows.

- Press ▲ once to select 80 mmHg (10.7 kPa). The cuff quickly inflates to approximately 80 mmHg (10.7 kPa), and then settles at a slightly lower pressure level. Wait a few seconds for the pressure to stabilize.
- 5. Verify that the value displayed in SYS is within 3 mmHg (0.4 kPa) of the value displayed on the digital pressure meter.
- 6. Press ▲ to select 150 mmHg (20 kPa) target pressure. The cuff quickly inflates to approximately 150 mmHg (20 kPa), and then settles at a slightly lower pressure level. Wait a few seconds for the pressure to stabilize.
- 7. Verify that the value displayed in SYS is within 3 mmHg (0.4 kPa) of the value on the digital pressure meter.
- 8. Press (to select 300 mmHg (40 kPa). The cuff quickly inflates to approximately 300 mmHg (40 kPa), and then settles at a slightly lower pressure level. Wait a few seconds for the pressure to stabilize.
- 9. Verify that the value displayed in SYS is within 6 mmHg (0.8 kPa) of the value on the digital pressure meter.

Valve and pump current, inflation, and deflation tests

Note Replace the internal battery with an external power supply. (See "Battery substitution cable setup" on page 12.)

To test pump current

- 1. Put the monitor in Service mode:
 - a. Power the monitor off.
 - b. Power the monitor **on** while pressing 🧐.



WARNING Do not connect the monitor to a patient while the monitor is in Service mode. Overpressure detection is disabled while the monitor is in NIBP test mode.

- 2. Press (a) repeatedly until **NIBP TEST** appears in the message window and **0** is displayed in the SYS and DIA windows.
- 3. Press 🛆 to select 0 mmHg (0 kPa) target pressure.
- 4. While watching the current meter, press (to select 80 mmHg (10.7 kPa) target pressure.
- 5. Note the highest current reading during inflation.
- 6. While the pump is running, verify that the reading on the current meter is not more than 750 mA above the current level noted in step 2 of the verification test ("Baseline current draw" on page 13).
- 7. Press A three times to select 0 mmHg (0 kPa) target pressure.

To test inflation

1. Press (a) repeatedly until **NIBP TEST** appears in the message window and **0** is displayed in the SYS and DIA windows.

- 2. Press A once to select 80 mmHg (10.7 kPa).
- 3. Wait for the pump to start and stop.
- 4. Press 🛆 once to select 150 mmHg (20 kPa).
- 5. Wait for the pump to start and stop.
- 6. Bleed the pressure to 0 by opening the relief valve on the bulb.
- 7. Close the relief valve on the bulb.
- 8. Have a timer ready.
- 9. Press 🔊 once to select 300 mmHg (40 kPa), and immediately observe the manometer.
- 10. As soon as the manometer reads 5 mmHg (0.67 kPa), start the timer.
- 11. When the manometer reaches 250 mmHg (33.3 kPa), stop the timer.
- 12. Verify that the elapsed time (step 11 minus step 10) is less than 8 seconds.

To test deflation

- 1. If the pressure has dropped more than 10 mmHg, use the pump bulb to raise it to 300 mmHg \pm 5 mmHg.
- 2. While the pressure is still at approximately 300 mmHg (as shown by the manometer and the SYS window), press () once to select 0 mmHg, and immediately start the timer.
- 3. After 10 seconds, verify that the manometer reads less than 15 mmHg.

If you are doing the NIBP overpressure test, skip to "Overpressure tests (optional)" on page 18.

4. Disconnect the hose from the monitor.

Overpressure tests (optional)

Note Redundant circuitry in the VSM 300 series monitor guarantees that the bloodpressure cuff cannot overinflate.

The allowable cuff pressure and the overpressure cutoff are controlled by software. A software failure (a defective PROM) would generate a checksum error, disabling monitor operation and setting it in a safe mode.

These tests demonstrate that:

- the monitor cannot exceed the maximum allowable cuff pressure for adults (280 mmHg), pediatrics (200 mmHg), and neonates (141 mmHg)
- the overpressure cutoff feature shuts down the pump and dumps pressure before the pressure reaches 330 mmHg (44 kPa)

To verify maximum allowable cuff pressure in the adult or pediatric mode

1. Assemble one of the test setups illustrated on page 16, using an adult cuff or cuff simulator.

- 2. Turn on the monitor.
- 3. Set the monitor to **ADULT** mode.
 - a. Press 🖲 twice.
 - b. Press A repeatedly until **ADULT** appears.
- 4. Set the inflation target pressure to 270 mmHg (36 kPa).
 - a. Press () repeatedly until TARGET PRESSURE appears in the display window.
 - b. Press () repeatedly as needed to set the target pressure (displayed in the SYS window) to 270 mmHg (36 kPa).
- 5. Press 💓 to start the pump.

The pressure reaches approximately 270 mmHg (36 kPa), the pump shuts off, and the pressure begins stepping down.

- 6. Carefully squeeze the pump bulb to raise the pressure to 280 mmHg (37.3 kPa).
 - The dump valve opens and quickly drops the pressure to approximately 0.
 - The monitor displays **C10** to indicate that an overpressure event has occurred.
- 7. Set the monitor to **PEDIATRIC** mode.
- 8. Set the inflation target pressure to 170 mmHg (22.7 kPa).
- 9. Raise the pressure to 200 mmHg (26.7 kPa).
 - a. Press 🥙 and wait for the pressure to reach 170 mmHg (22.7 kPa). The pump shuts off and the pressure reading starts stepping down.
 - b. Carefully squeeze the pump bulb to raise the pressure to 200 mmHg (26.7 kPa).
 - The dump valve opens and quickly drops the pressure to approximately 0.
 - The monitor displays **C10** to indicate that an overpressure event has occurred.
- 10. Replace the adult cuff with a #1 neonate cuff, and wrap the neonate cuff securely around a solid cylindrical object with circumference between 1.6 and 1.9 inches (4.1 and 4.8 cm).
- 11. Set the monitor to **NEONATE** mode.
- 12. Set the inflation target pressure to 132 mmHg (17.6 kPa).
- 13. Raise the pressure to 141 mmHg.
 - a. Press 🐑 and wait for the pressure to reach 132 mmHg (17.6 kPa). The pump shuts off and the pressure reading starts stepping down.
 - b. Carefully squeeze the pump bulb to raise the pressure to 141 mmHg (18.8 kPa).
 - The dump valve opens and quickly drops the pressure to approximately 0.
 - The monitor displays **C10** to indicate that an overpressure event has occurred.

To verify overpressure cutoff for NIBP versions 4.20.00 and later

This test demonstrates that the overpressure cutoff feature prevents pressure from rising fast enough to exceed the cutoff pressure (295 to 330 mmHg, or 39.3 to 44.0 kPa) before the pump stops and the dump valve and the bleed valve open.

When the overpressure cutoff triggers, the pump stops, the dump and bleed valves open, and the monitor displays **E40**. Any subsequent button press shuts off the monitor.

Note Due to NIBP implementation differences, this test does not verify overpressure cutoff in earlier NIBP versions.

In those versions, due to a longer software delay in activating the cutoff function, the normal overpressure cuff pressure is exceeded before the overpressure cutoff safety triggers. If the normal overpressure-detection algorithm were to fail, the overpressure cutoff safety function would trigger immediately.

- 1. Restart the monitor.
- 2. Set the monitor to **ADULT** mode.
- 3. Set the inflation target pressure to 270 mmHg (36.0 kPa).
- 4. Increase the inflation rate, causing the overpressure cutoff to stop the pump and open the bleed and dump valves.
 - a. Start the pump.
 - b. When the pressure (SYS window) reaches approximately 230 mmHg (32.4 kPa), very rapidly squeeze the pump bulb while observing the digital pressure meter.

Assuming that you squeeze the bulb rapidly enough to reach the trigger threshold and activate the overpressure cutoff:

- The pressure does not exceed 280 mmHg.
- The dump valve and bleed valve open, dropping the pressure to approximately 0.
- E40 appears in the Sys window.
- Pressing any button causes the monitor to shut down.
- 5. Disconnect the test setup from the monitor.

If you executed this test as part of the functional verification procedure, proceed to...

- "Printer" on page 21.
- If the monitor has no printer, "SpO₂" on page 23.
- If the monitor has no SpO2 option, "Temperature" on page 25.
- If the monitor has no temperature option, "Nurse call" on page 26.

Printer

- **Note** This test is to be performed only as part of a complete functional verification procedure.
- 1. Put the monitor into Service Mode.
- 2. Verify that the printer has paper.
- 3. Press ④. Verify that a settings report prints, and that it contains no printed anomalies and no missing or faded sections.
- **Note** With a new roll of paper, the first line might be faded. This does not indicate a problem.
- **Note** The settings report (as shown in the example below) contains a calibration record, user record, hardware status record, and software versions record.
 - The calibration record includes manufacturing configuration data: monitor serial number, set parameters, and language.
 - The user record includes user-configurable settings: alarm limits, patient type, parameter modes/units, auto interval, tone volume, and others.
 - The hardware status record shows the hardware revision number, the battery voltage level, the total number of NIBP monitoring cycles completed on the monitor, and the total number of hours of operation of the monitor.
 - The software versions record indicates the software version numbers of the main board, SpO₂ and Temperature options (if present), and NIBP.
- 4. After 2 seconds of printing, verify that the current draw is no more than 2.5A above the baseline current recorded in step 2 of the verification test "Baseline current draw" on page 13.
- 5. Exit the Service Mode.

Welch Allyn (R) Vital Signs Monitor -- Unit Settings --13:04:21 15-Oct-2003 Calibration Record Serial #: XXXXX.XXXX Serial # signature: NULL Calibration time/date 12:00:00 01-Jan-2000 Calibration signature NULL Language: (0) English Configuration Sp02 = 1 Temp = 1 Printer = 1 Ambient bias (K) X.XX Sp02 valid ver.: X.X.X Temp valid ver.: X.X NIBP valid ver.: XX.XX.XX XXXXX User Record -----Alarm Settings High Sys (0.01 mmHg): 220 Low Sys (0.01 mmHg): 75 High Dia (0.01 mmHg): 110 Low Dia (0.01 mmHg): 35

 High MAP (0.01 mmHg):
 120

 Low MAP (0.01 mmHg):
 50

 High PR (bpm):
 120

 Low PR (bpm):
 50

 High O2 (%):
 0

High O2 (흥): 0 Low 02 (%):85Patient type (A, P, N):ABP Units (mmHg, kPa):mmHgTarget press (0.01 mmHg)160Auto interval:15 MAP (On, Off): Off MAP (On, Off):OffTemperature units (C, F):FTemperature mode (P, M):PPulse tone volume:3Clinical pause (msec)0Print button mode (B, S)B Print button mode (B, S) H/W Status _ _ _ _ _ _ _ _ _ _ _ _ Hardware revision: XXXX Х Battery voltage (mv) Total Cycles Total Runtime XXXXXX XXXX (hrs) S/W Versions _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ Unit: X.XX.XX XXXXX SpO2: X.X.X.X Temp: X.X NIBP: XX.XX.XX XXXXX ----------

SpO_2

Note The tests described in this section are to be performed only as part of a complete functional verification procedure.

Perform one of the following three SpO_2 tests.

Testing the monitor only (Nellcor SpO₂)

Use this procedure to test only the monitor SpO₂ function.

- 1. Power the monitor off.
- 2. Connect the Nellcor SRC-MAX SpO₂ functional tester to the SpO₂ input connector through a Nellcor DEC-8 extension cable.
- 3. Power the monitor on.
- **Note** In the following tests, if the SRC-MAX defaults are outside the monitor alarm limits, readjust the limits or silence the alarms.
- 4. Verify the following on the SRC-MAX:
 - All of the LEDs flash: left panel, center panel, right panel.
 - SRC-MAX initializes to a default condition where the four test parameter LEDs are lit closest to their selector buttons
 - The default pulse rate is 60 bpm and the default SpO₂ is 75%
- 5. Give the monitor up to 30 seconds to stabilize, and verify a displayed pulse rate of 60 ± 3 bpm and a displayed SpO₂ of 75 ± 3%.
- 6. Set the SRC-MAX pulse rate to 200 bpm.
- 7. Give the monitor up to 30 seconds to stabilize, and verify a displayed pulse rate of 200 ± 3 bpm.
- 8. Switch the SRC-MAX SpO₂ saturation percentage to 90.
- 9. Give the monitor up to 30 seconds to stabilize, and verify a displayed SpO₂ saturation level of 90 \pm 3%.
- 10. Disconnect the SRC-MAX.

Testing the monitor only (Masimo SpO₂)

Use this procedure to test only the monitor \mbox{SpO}_2 function.

- 1. Power the monitor off.
- 2. Connect the Masimo Tester REF 1593.
- 3. Power the monitor on.
- 4. Give the monitor up to 30 seconds to stabilize, and then verify a displayed pulse rate (from SpO2) of 61 bpm \pm 1 bpm and a displayed saturation of 81% \pm 3%.

Testing the sensor with the monitor

Use this procedure to test the monitor $\ensuremath{\mathsf{SpO}_2}$ function while verifying a sensor.

1. Set the BioTek Index2 SpO₂ simulator as follows:

SpO ₂ manufacturer type	Nellcor (MP-506A or Nell-3A)
	Masimo (MS-11)
% SpO ₂	94
Rate	60 (Motion Artifact not selected)

- 2. Connect an SpO_2 sensor to the simulator optical finger and to the monitor.
- 3. Wait for the monitor display to stabilize.
- 4. Verify an SpO₂ saturation level of 94 \pm 4.
- 5. Verify that the monitor displays a pulse rate of 60 ± 4 .

Temperature

Note The tests described in this section are to be performed only as part of a complete functional verification procedure.

Perform one of the following temperature tests.

Testing the monitor only

Use this procedure to test only the temperature function.

- 1. With monitor power on and with the temperature probe in the well, disconnect the probe cable from the temperature input connector on the rear of the unit.
- 2. Connect the Welch Allyn Sure Temp Plus temperature test key (06138-000) to the temperature input connector.
- 3. Remove the probe from the well.
- 4. Verify that the displayed temperature is 97.3 \pm 0.2 °F (36.3 \pm 0.1 °C).

Testing the probe with the monitor

Use this procedure to test the temperature function while verifying the temperature probe.

- 1. If the Welch Allyn 9600 Calibration Tester (01800-200) is not already warmed up, warm it up as follows:
 - a. Set the 9600 Calibration Tester temperature switch to 96.4 °F (35.8 °C).
 - b. Plug the power adapter into the 9600 Calibration Tester; wait (up to 15 minutes) until the tester 'ready' indicator light is on continuously.
- 2. Set the monitor temperature mode to Monitored.
- 3. Insert the temperature probe (without probe cover) into the small thermometer hole on the dry-heat well of the 9600 tester.
- 4. Wait two minutes and verify that the reading displayed on the monitor is 96.4 \pm 4 °F (35.8 \pm 2 °C).
- 5. Switch the 9600 Calibration Tester to 106.0 °F (41.1 °C) and wait about five minutes for the 'ready' indicator to light.
- 6. Verify that the reading displayed on the monitor is 106.0 ± 0.4 °F (41.1 ± 0.2 °C).
- 7. Remove the probe from the tester and replace it in the probe well.
- 8. Disconnect the 9600 Calibration Tester.

Nurse call

Note The tests described in this section are to be performed only as part of a complete functional verification procedure.

Relay verification

With reference to the drawing and table below, use an ohmmeter to check the contact resistance at the output pins of the Nurse Call connector, while the monitor is in the alarm state and while the monitor is out of the alarm state.

When the Nurse Call verification is done, disconnect the Nurse Call cable and turn off the monitor.



Pins	Resistance (Alarm OFF)	Resistance (Alarm ON)
1-2	> 1 MΩ	<1 Ω
2-3	<1 Ω	> 1 MΩ

Putting the monitor into the alarm state

To create an alarm condition for testing the Nurse Call relay, follow these steps.

- 1. Press 🙂 repeatedly until **INTERVAL ST** appears in the message display.
- 2. Wait for the pump to charge twice (about 10 seconds), and verify that error code **C04** appears in the SYS display.
- 3. Verify that the Nurse Call circuit is shorted. (Refer to the table shown above.)
- 4. Press 🕲.
- 5. Verify that the Nurse Call circuit is open. (Refer to the table shown above.)
- 6. To exit the alarm state, press (*) repeatedly until **INTERVAL 15** appears in the message display, and then press (*).

Battery

- **Note** This test is to be performed only as part of a complete functional verification procedure.
- 1. With the monitor power off, disconnect the battery substitution-cable connector.
- 2. Install and connect the battery.
- 3. Connect the AC power adapter to the monitor.
- 4. Verify that the AC mains indicator 🔷 is illuminated on the monitor front panel.

The indicator could be flashing or steady, depending on the state of the battery. flashing indicates that the battery is charging; steady indicates that the battery is charged to at least 90% capacity.

- 5. Charge the battery for a minimum of 12 hours (until **v** stops flashing).
- 6. Disconnect the AC power adapter.
- 7. Turn the monitor on and set it up as follows:

NIBP Auto Interval	OFF
Printer, if present	OFF (not printing)
SpO ₂ sensor (if SpO ₂ option is present)	Disconnected
Temperature probe (if temperature option is present)	Either connected or disconnected

8. Note the time and let the monitor run until **low battery** (C flashing) is indicated.

(Run time for a new, fully charged battery is at least 12 hours.)

- 9. Charge the battery for a minimum of 12 hours (until **~** stops flashing).
- 10. Disconnect the ac power adapter.
- 11. Start the monitor in Service Mode.
- 12. Press () repeatedly until "Battery: X.XXV appears in the message window.
- 13. Verify that the voltage is \geq 6.10 V.

Patient isolation test

Note This test is to be performed only as part of a complete functional verification procedure.

Patient isolation test - overview

To verify proper patient isolation, it is important to run this test following any procedure in which the monitor is opened.



WARNING Failure to run the dielectric test when indicated could cause serious injury to patients, and could lead to damage to the monitor.

The patient isolation test requires an AC Withstand Voltage (hi-pot) Tester, such as the AR 3605 or equivalent. If this equipment is not available, Welch Allyn can perform the patient isolation test for you quickly, for a nominal fee.



WARNING The patient isolation test involves exposure to extremely high voltages, and is therefore extremely hazardous.

WARNING Always follow the tester manufacturer's operation instructions exactly. Failure to perform this test properly can result in serious injury or death.

WARNING This test must be performed by qualified service personnel only.

WARNING Run this test only on an insulated table top, and away from other people and equipment.

Note To create test cables for the patient isolation test, see "Hi-pot test connections" on page 29.

Patient isolation test - procedure

- 1. Set up the test parameters on the AC Withstand Voltage Tester as follows:
- **Note** Refer to the tester manufacturer's operation manual for complete details on setup and use.

Parameter	Specification	Parameter	Specification
Voltage	1500 Vac	Ramp Down	0
Maximum Limit	2.50 mA	Arc Sense	0
Minimum Limit	0.038 mA	Frequency	local line (50 Hz or 60 Hz)
Ramp Up	5.0 S	Continuity	Off
Dwell	5.0 S	Connect	Off
Delay	0		

- **Note** To create test cables for this procedure, see "Hi-pot test connections" on page 29.
- 2. Connect the hi-pot DC input test cable between the HV output jack on the tester and the DC input connector of the monitor.
- 3. Connect the hi-pot Nurse Call test cable between the nurse call connector and the return output jack on the hi-pot tester.
- 4. Press the test button to run the AC withstand voltage test.
- 5. Verify that the monitor passed the test. (If the input current never exceeds 2.50 mA, the shielding is sufficient.)
- 6. Remove the Nurse Call test cable.
- 7. Connect the hi-pot RS232 test cable between the RS232 connector and the return output jack on the hi-pot tester.

- 8. Press the test button to run the AC withstand voltage test.
- 9. Verify that the monitor passed the test. (If the input current never exceeds 2.50 mA, the shielding is sufficient.)
- 10. Remove the hi-pot RS232 test cable from the RS232 connector and the hi-pot tester.
- 11. Connect the SpO₂ test cable between the SpO₂ connector and the return output jack on the hi-pot tester.
- 12. Push the test button to run the AC withstand voltage test. Verify that the monitor passed the test. (If the input current never exceeds 2.50 mA, the isolation is sufficient.)

Hi-pot test connections

Cable	Monitor connection		Hi-pot tester connection	
	Connector/cable	Connect to	Wiring	Connect to
DC Input	Switchcraft 760 0.100" ID 0.218" OD	DC Input Connector	Both wires connected together and terminated appropriately for your hi-pot tester	Return
SpO ₂ (Nellcor)	Nellcor D-connector (DEC-8 or other OXI-MAX equivalent)	SpO ₂ Input Connector	All wires connected together and terminated appropriately for your hi-pot tester	High Voltage
SpO ₂ (Masimo)	Masimo 14-pin mini D-connector	SpO ₂ Input Connector	All wires connected together and terminated appropriately for your hi-pot tester	High Voltage
RS232	RJ45/standard patch cable	Communication Connector	All wires connected together and terminated appropriately for your hi-pot tester	High Voltage
Nurse Call	Welch Allyn Nurse Call cable 008-0634-XX (Uses Lemo connector PAB.M0.4GLAC397.)	Nurse Call Connector	All wires connected together and terminated appropriately for your hi-pot tester	High Voltage

Checklist and test results report form

Use a copy of this form to track your progress through the validation tests.

				Pass	Fail
				N/A)	
Test	Result			V	~
Battery charging					
Power-on self-test					
Beeper					
Monitor-off current	(mA):				
Init/idle current	(mA):				
Baseline current	(mA):				
Battery voltage	Monitor (V):	DMM	(V):		
NIBP characterization test					
NIBP verification					
Pressure leakage	Before (mmHg):	After	(mmHg):		
Pressure accuracy	80 mmHg	SYS:	Manometer:		
	150 mmHg	SYS:	Manometer:		
	300 mmHg	SYS:	Manometer:		
Valve/pump current	Valve/Pump (mA)			
	- Baseline (mA)				
	Difference (mA)				
Inflation	Elapsed time (se	c):			
Deflation	Manometer read	ing (mmHg):			
Max allowable cuff pressure					
Adult	mmHg	kPa			
Pediatric	mmHg	kPa			
Neonate	mmHg	kPa			
Overpressure cut-off	(Pass-Fail)				
Printer current	Peak (mA):				
SpO ₂	Saturation (%):		Pulse (bpm):		
Temperature	° Fahrenheit:		° Celsius:		
Nurse call relay	pins 1-2	Alarm (Ω)	No Alarm (Ω)		
	pins 2-3	Alarm (Ω)	No Alarm (Ω)		
Battery charge time					
Battery discharge time					
Battery voltage	volts				
	TestBattery chargingPower-on self-testBeeperMonitor-off currentInit/idle currentBaseline currentBastery voltageNIBP characterization testNIBP verificationPressure leakagePressure accuracyValve/pump currentInflationDeflationMax allowable cuff pressureAdultPediatricNeonateOverpressure cut-offPrinter currentSpO2TemperatureNurse call relayBattery charge timeBattery voltage	TestResultBattery chargingPower-on self-testBeeperMonitor-off currentInit/idle current(mA):Init/idle current(mA):Baseline current(mA):Battery voltageMonitor (V):NIBP characterization testNIBP verificationPressure leakageBefore (mmHg):Pressure accuracy80 mmHg150 mmHg300 mmHgValve/pump currentValve/Pump (mA - Baseline (mA))Difference (mA)Difference (mA)InflationElapsed time (setDeflationManometer readMax allowable cuff pressureAdultAdultmmHgPediatricmmHgOverpressure cut-off(Pass-Fail)Printer currentPeak (mA):SpO2Saturation (%):Temperature° Fahrenheit:Nurse call relaypins 1-2pins 2-3Battery charge timeBattery voltagevolts	TestResultBattery charging $\end{pmatrix}$ Power-on self-test $\end{pmatrix}$ Beeper $\end{pmatrix}$ Monitor-off current(mA):Init/idle current(mA):Baseline current(mA):Battery voltageMonitor (V):DMMNIBP characterization testNIBP verificationPressure leakageBefore (mmHg):AfterPressure accuracy80 mmHgSYS:300 mmHgSYS:Valve/pump currentValve/Pump (mA) - Baseline (mA) Difference (mA)InflationElapsed time (sec):DeflationManometer reading (mmHg):Max allowable cuff pressure $\end{pmatrix}$ AdultmmHgkPaPediatricmmHgkPaOverpressure cut-off(Pas-Fail)Printer currentPeak (mA):SpO2Saturation (%):Temperature° Fahrenheit:Nurse call relaypins 1-2pins 1-2Alarm (Ω)Battery charge timeBattery discharge timeBattery voltagevolts	Test Result Battery charging Power-on self-test Beeper Monitor-off current Monitor-off current (mA): Init/idle current (mA): Bastline current (mA): Battery voltage Monitor (V): DMM (V): NIBP characterization test NIBP verification Pressure leakage Before (mmHg): After (mmHg): Pressure accuracy 80 mmHg SYS: Manometer: 300 mmHg SYS: Manometer: 300 mmHg SYS: Valve/pump current Valve/Pump (mA) -Baseline (mA) Difference (mA) Difference (mA) Inflation Elapsed time (sec): Deflation Manometer reading (mmHg): Max allowable cuff pressure Adult mmHg kPa Neonate mmHg kPa Neonate mmHg kPa SpO2 Saturation (%): Pulse (bpm): Preneture ° Fahrenheit: ° Celsius: No Alarm (Ω) No Alarm (Ω) Battery charge time Battery oitage volts	TestResultBattery chargingPower-on self-testBeeperMonitor-off current(mA):Init/idle current(mA):Bastery voltageMonitor (V):DMB (V):DMM (V):NIBP characterization testNIBP verificationPressure leakageBefore (mmHg):After (mmHg):After (mmHg):Pressure accuracy80 mmHgSYS:Manometer:300 mmHgSYS:Manometer:300 mmHgSYS:Manometer:150 mmHgSYS:Manometer:300 mmHgSYS:Manometer:4lve/pump currentValve/Pump (mA) - Baseline (mA) Difference (mA)InflationElapsed time (sec):DeflationManometer reading (mmHg):Max allowable cuff pressureAdultmmHgMax allowable cuff pressureAdultmmHgkPaPediatricmHgkPaNeonatemmHgkPaSpD2Saturation (%):Pulse (bpm):Temperature° Fahrenheit:Nurse call relaypins 1-2pins 1-2Alarm (\Omega)No Alarm (Ω)Battery charge timeBattery charge timeBattery charge timeBattery voltageVolts

Aonitor serial #:	
ested by:	
est date:	

					Pass (or N/A)	Fail
~	Test	Result				~
~	Battery charging	charge symbo	charge symbol lit			
~	Power-on self-test	normal			~	
~	Beeper	audible			~	
~	Monitor-off current	(mA): 0.00			~	
~	Init/idle current	(mA): 0.467 mA			~	
~	Baseline current	(mA): 0.199 mA			~	
~	Battery voltage	Monitor (V): 5.9	4 V DMM (V	/): 5.95 V	~	
~	NIBP characterization test	C03			~	
~	NIBP verification				~	
~	Pressure leakage	Before (mmHg):	100 After (m	mHg): 99	~	
~	Pressure accuracy	80 mmHg	SYS: 73	Manometer: 72	~	
		150 mmHg	SYS: 142	Manometer:140		
		300 mmHg	SYS: 290	Manometer: 286		
~	Valve/pump current	Valve/Pump (m/	À)	0.560	~	
		Baseline (mA) 0.199				
		Difference (mA)		0.361		
~	Inflation	Elapsed time (se	ec): 6		~	
~	Deflation	Manometer rea	ding (mmHg): 0 (3 s	ec)	~	
~	Max allowable cuff pressure				~	
~	Adult (280 [37.3])	280 mmHg	kPa		~	
~	Pediatric (200 [26.7])	200 mmHg	kPa		~	
~	Neonate (141 [18.8])	141 mmHg	kPa		~	
~	Overpressure cut-off	(Pass-Fail)			~	
~	Printer current	Peak (mA): 0.94	0 mA		~	
~	SpO ₂	Saturation (%):	90	Pulse (bpm): 200	~	
~	Temperature	° Fahrenheit: 10	5.9	° Celsius:	~	
~	Nurse call relay	pins 1-2	Alarm (Ω) > 1M	No Alarm (Ω) < 1	~	
		pins 2-3	Alarm (Ω) < 1	No Alarm (Ω) > 1M		
~	Battery charge time	12.5 h			~	
~	Battery discharge time	19 h			~	
~	Battery voltage	6.40 volts			v	

Here is an example of verification results for a typical monitor.

Monitor Serial #: JA036582	
Tested by: RJ	
Test date: 8/30/2007	
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