Functional verification tests

The functional verification tests help to confirm the proper operation of the monitor and its options. These tests support the requirements of routine preventive maintenance. It is not necessary to disassemble the monitor to perform these tests.

The tests may also be useful as a diagnostic tool to help isolate a malfunction.

Each time you open the case and prior to returning the monitor to service, use the service tool, Gold edition, to complete the full suite of tests to ensure that all systems are operating within the design specifications.

Functional verification and calibration

Required equipment

Material no. Description 01802-110 Tester, calibration, 9600 plus		Qty	
		3	
DOC-10	Cable, SP02 extension, Nellcor	1	
SRC-MAX	Nellcor portable oximetry tester MP506	1	
06138-000	CAL-KEY, assembly, M690/692	1	
4500-30	Blood pressure hose, 5 ft.	1	
5082-183	BP Y-tube, no fittings 1/8 in tube	1	
103507	Masimo rainbow tester (Masimo part #2368)	1	
4500-925	USB 2.0/5-pin type A to mini-B cable, gold, 6 feet	1	
407691	Service test box		
541-USB001	OAE, USB 6' cable	1	
407022	Assy, MMF Nurse call cable - Service	1	
713549	USB 2.0 Dual A to Single Mini B Cable	1	

Material no.	Description	Qty
200-2000IN	Pressure meter, NETECH	1
407672	BP Test volume repair fixture 113670	1
Off-the shelf item	NetGear router a/b/g or equivalent	1
660-0138-00	Cable, patch 5' RJ45, T568B	1
6000-30	Single tube blood pressure hose, 5 ft.	1

About the Welch Allyn Service Tool

Use the service tool, Gold edition, to complete the full suite of functional tests.

For information about the service tool, see the following:

- For instructions on installing and using the service tool, see the "Welch Allyn Service Tool Installation guide" (part number 103820).
- For instructions on performing the functional verification, see the service tool's help files on the Welch Allyn Service Tool CD (part number 103521).

Tests performed by the service tool

The service tool tests the host device and installed options as listed in the following table.

Test	Description	NIBP	Temperature	SpO2	Host
POST	Performs the power-on self test (POST) ¹		\checkmark	\checkmark	\checkmark
Firmware version	Checks the firmware version 🗸 🗸		1	\checkmark	
Firmware upgrade	le Loads the latest firmware into the module 🧹 🗸		1	\checkmark	
Leak	Verifies leaks using 100 cc volume	1			
AD noise	Checks noise on the pressure channel	\checkmark			
Calibration	Calibrates pressure transducers	\checkmark			
Accuracy (NIBP)	Checks the accuracy of transducers across pressure range	~			
Dump	Checks dump valves	1			
Inflation	Verifies the pneumatic pump	\checkmark			
Valve control	Verifies control of the system valve	\checkmark			
Inflation linearity	Verifies operation of linear inflation control hardware	1			

Test	Description	NIBP	Temperature	SpO2	Host
Probe detect	Verifies the operation of the probe detect switch		\checkmark		
Accuracy (Temp)	Verifies the accuracy of the thermometer across range		\checkmark		
Functional check	Verifies module operation with cal-key ²		\checkmark		
Current draw	Measures the module's current draw		\checkmark	√ 3	
Printer	Prints the sample patient record and test pattern				1
LCD display	Generate a test pattern	;			1
Back light interface	Operator verifies LED outputs				1
Touchscreen interface	Verifies touch-screen calibration				1
LED	Turns the light bar LEDs on and off				1
Fan interface	Turn the fan on and off				1
Beeper	Sounds the buzzer				1
Nurse call relay	Verifies the nurse call relay				\checkmark
Battery operation	Verifies the internal battery				\checkmark
Speaker	Sounds the speaker				\checkmark
USB host port communication	Verifies the USB ports				1
Ethernet communication	Verifies the Ethernet port				\checkmark

¹ POST testing checks the following:

- **NIBP**: ROM, RAM, A/D channels, calibration, and user configuration.
- **Temperature**: ROM, RAM, calibration, and heater.
- **Sp02**: ROM and RAM, and connection to the Sp02 board.
- **Printer**: ROM and RAM, and connection to the printer.

² SureTemp Plus only.

³ Normal mode.

Functionally testing the Braun ThermoScan PRO 4000 thermometer

This explains how to perform a functional verification on the Braun ThermoScan PRO 4000 thermometer using the 9600 Plus Calibration Tester.

Note

Use this procedure in place of the verification and calibration test for the Braun PRO 4000 dock in the Welch Allyn Service Tool version 1.0.2.0.



Caution Before the test, place thermometers and tester in the same room for approximately 30 minutes so that they adjust to the ambient temperature.

For more information, see the Welch Allyn 9600 Plus Calibration Tester Directions for use.

Set up the 9600 Plus Calibration Tester

Place the tester on a level surface away from sunlight, drafts, and other sources of heat or cold.

The tester takes approximately 20 minutes to heat to the lowest set point.

To expedite testing, Welch Allyn recommends the following practices:

- To eliminate waiting for the tester to heat to the next set point, use three testers, each set to
 one of three different set points.
- When using only one tester to test several thermometers at all three temperatures, test all thermometers at one set point before proceeding to the next set point.
- To eliminate waiting for the tester to cool down, start at the lowest set point. Because the tester does not have an internal fan, it requires more time to cool down than to heat up.

Perform the functional verification test

Test each thermometer at the low, medium, and high set points on the tester. After placing the thermometer in calibration mode, repeat the procedure from step 4 for each thermometer and temperature to be tested.

- 1. Clean the probe window with a cotton swab slightly moistened with isopropyl alcohol, remove excess alcohol with a clean cotton swab, and let air dry for 5 minutes. Do not use any chemical other than alcohol to clean the probe window.
- 2. Place the thermometer in calibration mode:
 - a. Make sure that the thermometer displays the OFF symbol.
 - b. Turn on the thermometer by pushing and releasing the I/O mem button.

Symbols and functions appear as the thermometer performs an automatic self check.

- c. Wait for two dashes and ° C or ° F to appear on the display.
- d. Push and hold the I/O mem button.

After approximately 3 seconds, a short beep sounds, and the OFF symbol flashes on the display. Then a long beep sounds.

e. Release the button immediately.

The display flashes and shows the CAL symbol.

The thermometer is now in calibration check mode.

- 3. Apply a new probe cover. Place the probe firmly into the Ear Device Port.
- 4. Wait approximately 3 seconds, and then press the thermometer Start button.

The ExacTemp light flashes.

- 5. Leave the thermometer in the tester until a beep sounds.
- 6. Remove the thermometer from the tester and read the temperature in the thermometer's display. If the temperatures are within $\pm 0.2^{\circ}$ C ($\pm 0.4^{\circ}$ F) of the tester's set point, the thermometer is within calibration.
- 7. Record the results in the service record, as shown in "Service record example."
- 8. Press the start button once to clear the previous reading.
- 9. Wait 1 minute, and then take another reading with the same thermometer. Repeated measurements in short sequence might cause higher readings.
 - **Note** If using only one tester, test all available thermometers for calibration verification at the current set point, before raising the set point.
- 10. Repeat the procedure from step 4 as necessary until all thermometers are tested at each temperature.
- 11. Exit CAL mode using one of the following methods:
 - Press and hold the I/O mem button until the OFF symbol flashes.
 - Wait for 4 minutes. The thermometer automatically exits CAL mode.

Change the tester's set point

To scroll from one set point to the next, press and hold the Temperature Selection button until a beep sounds.

The newly selected set point appears in the upper left corner of the LCD display. The device's current temperature appears, flashes, and continues flashing until the cavity reaches equilibrium at the new set point.

Service record example

Date	:	Time		
Device name	: Braun Pro 4000	Serial number:		
Temperature tested	Specificatio	n ±0.2° C (±0.4° F)	Actual reading	Pass/fail
96.8° F /36.0° C	96.4° F97.2° F	35.8° C36.2° C		
101.3° F/38.5° C	100.9° F101.7° F	38.3° C38.7° C		
105.8° F /41.0° C	105.4° F106.2° F	40.8° C41.2° C		

Electrical safety testing

Welch Allyn recommends performing ground continuity, leakage current, and dielectric strength tests¹ when replacing the power supply or primary wiring according to EN/IEC 60601-1 - Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance or EN/IEC 62353 - Medical Electrical Equipment - Recurrent Test and Test After Repair of Medical Electrical Equipment.

Due to the variability of test equipment in the field, Welch Allyn does not include specific instructions to perform electrical safety tests. When performing electrical safety tests, refer to your test equipment manuals for detailed instruction. The following table provides connections and test limits to assist you in performing these tests.

Test	Limits
Ground continuity	Ground continuity from EP stud* (equipotential terminal) to the Gnd pin of the IEC power connector shall be no greater than 0.1 ohms.
Leakage current	Leakage current shall be less than 300 μA from EP stud* to mains (Line and Neutral pins of the IEC power connector).
Dielectric strength	Dielectric strength shall be 1.8 kVAC EP stud* to IEC mains (Line and Neutral pins of the IEC power connector).

* To locate the equipotential terminal, see "Controls, indicators, and connectors."

Ground stud connector

VSM 6000 Series devices are equipped with a ground stud (equipotential terminal) for electrical safety testing, and to connect a potential equalization conductor. To ensure use of the proper connector for safety testing, the ground stud is recessed into the monitor's housing. Do not use "alligator" style clamps and connectors. The mating electrical connector requires self assembly by crimping it to appropriate connecting leads.

The mating connector (Type POAG-KBT6DIN, order number 15.0010) consists of the right-angled socket and insulator, as shown in the next figure. You can purchase the mating connector and the crimping pliers from the manufacturer, Multi-Contact (<u>http://www.multi-contact.com</u>).

¹ Perform this test only if there is a reason to doubt the integrity of the electrical insulation (e.g. multiple trips of a residual-current device or liquid ingress of a saline solution). If you determine this test should be performed, return the device to Welch Allyn for service.



ltem	Description	Туре	Order no.
1	The mating electrical connector, a right-angled socket made of nickel-plated brass with Multilam™ made of gold-plated, hard-drawn copper alloy.	POAG-WB6DIN	01.0404
2	Insulator	T-POAG6	15.5004-24
	Crimping pliers with mandrel crimp for 4 mm ² and 6mm ² flexible conductors.	POAG-PZ-N	14.5009