

Respiration Performance

- Change the Patient Simulator configuration to:
 - Base impedance line 1500 Ohm.
 - Delta impedance 0.5 Ohm.
 - Respiration rate 40 rpm or 45 rpm.
- The value should be 40 rpm +/- 2 rpm or 45 rpm +/- 2 rpm.

| Test | Expected test results |
|------------------------------|---|
| ECG Performance Test | 100 bpm +/- 2 bpm or 120 bpm +/- 2 bpm |
| Respiration Performance Test | 40 rpm +/- 2 rpm or 45 rpm +/- 2 rpm |

ECG Out Performance Test (not available via SRR)

This test checks the performance of ECG synchronization between the monitor and a defibrillator. It only needs to be performed when this feature is in use as a protocol at the customer site.

Tools required:

- Defibrillator with ECG Input.
 - Patient simulator.
- Connect the patient simulator to the ECG connector of the MMS and the defibrillator to the ECG Output on the monitor with the ECG Sync cable.
 - Set the patient simulator to the following configuration:
 - HR = 100 bpm or 120 bpm (depending on your patient simulator).
 - ECG sinus rhythm.
 - Switch the defibrillator to simulation mode.
 - Check that the ECG signal is displayed.

| Test | Expected test results |
|--------------------------|-------------------------------------|
| ECG Out Performance Test | ECG signal is displayed (pass/fail) |

SpO₂ Performance Test

This test checks the performance of the SpO₂ measurement.

Procedure for Philips FAST SpO₂ Technology:

Tools required: none

- Connect an adult SpO₂ transducer to the SpO₂ connector.
- Measure the SpO₂ value on your finger (this assumes that you are healthy).
- The value should be between 95% and 100%.

| Test | Expected test results |
|-----------------------------------|-----------------------|
| SpO ₂ Performance Test | between 95% and 100% |

Procedure for Nellcor OxiMax SpO₂ Technology:

Nellcor recommends that the functionality of this parameter be verified using the SRC-MAX.

A possible performance assurance check requiring no tools would be:

- Connect an adult SpO₂ transducer to the SpO₂ connector.
- Measure the SpO₂ value on your finger (this assumes that you are healthy).

3 Testing and Maintenance

- The value should be between 95% and 100%.

| Test | Expected test results |
|-----------------------------------|-----------------------|
| SpO ₂ Performance Test | between 95% and 100% |

Procedure for Masimo SET SpO₂ Technology:

The end user may verify SpO₂ performance via commercially available SpO₂ simulators specifically designed to work with Masimo Pulse Oximeter technology. Optical simulators are recommended as they use the patient cable and sensor as part of the test setup. Additionally, a test that includes placing the sensor on a healthy subject and confirming the device reads a normal saturation and pulse rate and displays a clean pleth waveform (while the subject is still) may further increase the confidence that the device is functioning properly.

Procedure for Masimo rainbow SET Technology:

Tools required: none

- Connect an adult SpO₂ transducer to the SpO₂ connector.
- Measure the SpO₂ value on your finger (this assumes that you are healthy).
- The value should be between 95% and 100%.

| Test | Expected test results |
|-----------------------------------|-----------------------|
| SpO ₂ Performance Test | between 95% and 100% |

In addition to the SpO₂ Performance Test procedure described above, the following tests are recommended when using Masimo rainbow SET technology after a field repair or if the performance of the Masimo rainbow SET board in the MMS is in question.

NOTE

The part numbers listed below are subject to change. All parts required for the tests described in this section must be ordered directly from Masimo.

SET Tester and RRa Simulator:

- Connect a dual patient cable (Masimo part number 3503) to the board.
- Connect a Masimo SET tester (Masimo part number 3776) to M15 side of the dual cable.
- Connect one end of an RRa simulator cable (Masimo part number EQ-12070) to M6 side of the dual cable.
- Connect the other end (3.5MM) of the RRa simulator cable (Masimo part number EQ-12070) to a laptop or PC which contains TR19673A_Appendix_A.wav wave file.
- Play the wave file and set up the computer per instructions in R-EQ-12070 document.
- Verify that all enabled parameters are within specified range.

Sensor Port Test Tool:

- Connect a round connector sensor port test tool (Masimo part number 3494) to the board.
- Confirm that each LED turns on one at a time and then all LEDs turn on.

Shield Continuity:

- Connect a shield continuity test cable (Masimo part number 3854) to the board.
- Using a multimeter, measure the resistance across the red and black banana plugs. Verify that the resistance is less than 5Ω.