VIAMED

NIBP Simulator

S4000 NIBP Calibration Procedure
VM3/COP/48.01

Date:11 Aug 2003   Revision Date:11-Jul-11   Issue: 1

Equipment required: Colin BP-408 combined BP & ECG monitor
Fluke 867B Digital multimeter, thermocouple module & probe
Digitron P2022 Digital Manometer
Picoscope Virtual Instrument
Adult Armband, Mandrel & Hand pump
Barometer / %RH temperature gauge
Rigel 233 / 255 Safety Tester

All results to be recorded on a Calibration Record Sheet.
Voltages measured relative to TG1 or TG2
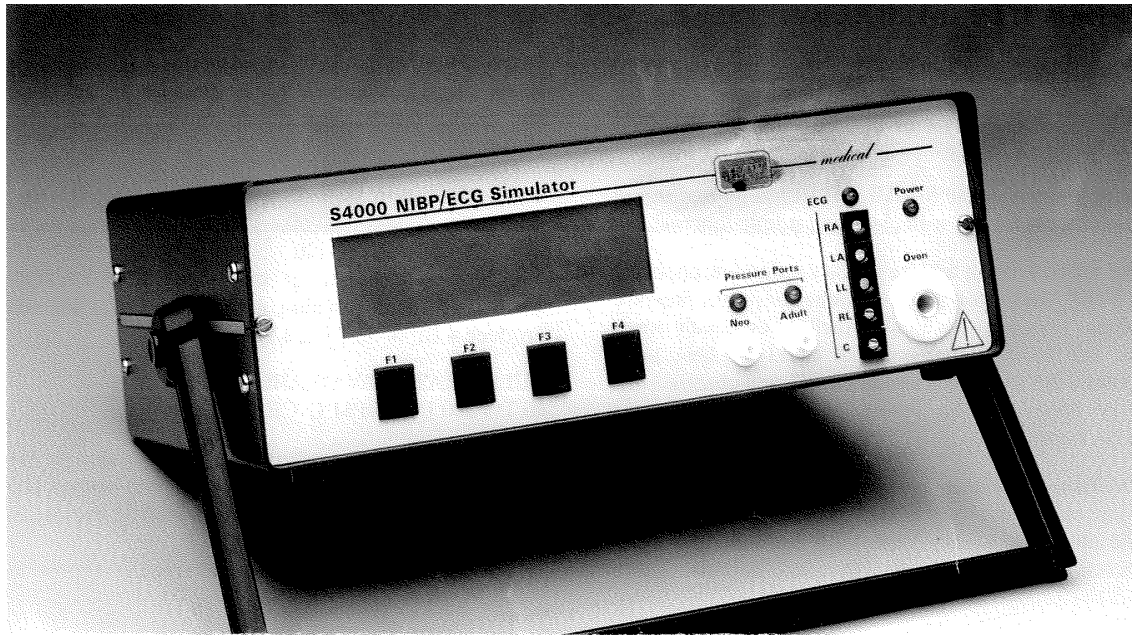
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Preliminary Checks

1. Detail the physical condition of the unit under test, and carry out a functional test against the Colin BP-408.Ensure correct simulation of BP on both adult and neo ports.
2. Record the environmental conditions of temperature, %RH and barometric pressure of the day.
3. Check that keys F1 – F4 are functional, the display angle and readability are good and that all characters are produced and displayed correctly.
4. Remove the upper case half; inspect complete assembly for good workmanship. All cables must be free from burns, and the crimps should be correctly made.
5. Ensure that the equipment has undergone and passed a full Safety Test.
6. Insert the thermocouple probe into the oven.

Full Test

1.   Calibrate power supplies and waveforms.

Using the Fluke 867B, test, then record, the power supply voltages at test points Tp1, Tp2 & Tp3 IAW specification on calibration results sheet.

2.   Pressure sensor reference voltage checks.

Ensure the pressure ports have no connection. With simulator running "Default Adult" at 120 / 80 mmHg.
Measure and record the voltage at Tp5.
If necessary, adjust R16 for + 5.000 ± 0.001V and record the adjusted voltage.
Measure and record the voltage at Tp6.
If necessary, adjust R11 for 0.000 ± 0.001V and record the adjusted voltage.

3.   Dynamic pneumatic transducer drive signal checks.

Select Bpm / ECG simulation at 120 / 80 blood pressure, and 80 Bpm heart rate.
Using the Picoscope, display the waveform at Tp8, 2 to 3 cycles, IAW specification on calibration results sheet.. Copy, paste and format the image to the calibration results sheet. Record the voltage, peak to peak.
Using the Picoscope, display the waveform at Tp9, 2 to 3 cycles, IAW specification on calibration results sheet. Copy, paste and format the image to the calibration results sheet. Record the voltage, peak to peak.

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4.   **ECG drive signal checks.**

Using the Picoscope, display the waveform at Tp7, 2 to 3 cycles, IAW specification on calibration results sheet. Copy, paste and format the image to the calibration results sheet (column 1). Record the voltage, peak to peak.
If necessary, adjust using R41 to obtain specified tolerance and copy, paste and format the new waveform image to the calibration results sheet (column 2). Record the voltage, peak to peak.

Using the Picoscope, display the waveform at Tp10, 2 to 3 cycles, IAW specification on calibration results sheet. Then copy, paste and format the image to the calibration results sheet. Record the voltage, peak to peak.

5.   **Pneumatic system integrity checks.**

Connect the pressure meter to the adult port and a blanking plug to the neo port. Select Calibration Test (Manual) from the menu options.
Pump the unit up to 300mmHg on the pressure meter and record the simulator pressure reading. If necessary, adjust R8 until 300 ± 1 mmHg is achieved on the display. Record this value.

Reduce pressure to 200 mmHg and ensure simulator display reading is 200 ± 2mmHg. Record the simulator pressure reading.

Reduce pressure to 100 mmHg and ensure simulator display reading is 100 ± 2mmHg. Record the simulator pressure reading.

Blank both the adult and the neo ports. Complete a Monitor Leakage test and record the leakage rate. Ensure the leakage rate is no greater than 10mmHg / min.

6.   **Oven temperature check.**

Connect the thermocouple module to the Fluke. Record temperature reading in °C prior to, and after, adjustment. Ensure the temperature is 37.4 ± 0.2°C using R46.

7.   **Miscellaneous**

Refit the upper casing and seal with anti-tamper labels. Connect the outputs to BP-408 and monitor the ECG waveform from 40 – 200 Bpm at 40 Bpm intervals. Complete a Soak Test – check calibration by functional test of simulator against Colin BP-408 at 120 / 80 mmHg. Ensure that readings shown on the BP-408 are 120 / 80 +/- 5mmHg.

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Rigel 255 Safety Test

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Data Entry into Rigel 255 Safety Tester:

1. System Test Results: Results correct? : **Press "Y".**

2. Enter Name or Initials: Press multifunction key 1: **"Enter".**

3. Press multifunction key 2: **"DATA".** Press multifunction key 5: **"EQUIP".**

4. Type the equipment name: **"S4000 XXXXXXXXX"** where **XXXXXXXXX** is the S4000 serial number

5. Unknown equip. no. Add to data stores (Y/N)? : **Press "Y".**

6. Equipment configuration record:

    Type the following entries, following each with keyboard Enter:

    Location: **"VIAMED"**
    Ward: **"QA"**
    Manufacturer: **No entry**
    Description: **"S4000 NIBP SIMULATOR,**
    Serial No.: **"XXXXXXXXX"** where **XXXXXXXXX** is the S4000 serial number
    Class: **"1"**
    Type: **"B"**
    Applied parts: **"0"**
    Test Interval: **"12"**
    Test mode: **"A"**
    Test name: **"XX…XX"** where **XX…XX** is the testers name or initials
    Press multifunction key 1: **"ENTER".**

7. Save data: Press **"Y".**

8. Press "◄" twice to get to **"TEST SELECTION MENU"**

9. Press multifunction key 5: **"AUTO".**

10. In AUTOMATIC TEST MODE, type in the equipment name, **"S4000 XXXXXXXXX"** where **XXXXXXXXX** is the S4000 serial number

11. Press multifunction key 1: **"ENTER".**

12. Press start on the safety tester (⟨|⟩). (To stop the safety test at any point press ⊗. The automatic test sequence will stop after it has completed its current step).

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13. After completion of the automatic test sequence, in the Additional Notes box, type **"TESTED WITH ???????????"**.

14. Press multifunction key 1: **"ENTER".** Press multifunction key 2: **"REMOTE".**

15. Ensure the calibration certificate **(QC10)** is printed and photocopy.

16. Disconnect the safety tester and store the earth return lead.