



DATAMED S.r.L. Via Giovanni XXIII, 45 20090 Rodano (Mi)	MEASUREMENT REPORT	Mod.REP.MIS Rev. 0 Date: 07/04/2003
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DESCRIPTION: BLOP4 measurements verification

PRODUCT: **BLOP4**

REPORT N°: **BLPO4Meas_Verification**

DATE: **September 2005**

COPY:

ORIGINAL:

N° of Pages: **5**

Responsible Technical Office

Responsible Quality Control

1. SCOPE

The aim of the test is to verify that the sensor probe BLOP4 meets the accuracy of Saturation and Hematocrit measurements claimed by the product requirements as summarized in the following table:

1. Saturation	
Range	40% - 100%
Accuracy	+/- 5% from 40% to 100%
Resolution	1%
2. Hematocrit	
Range	15% - 50%
Accuracy	+/- 5% from 15% to 50%
Resolution	1%
3. Blood Flow	
Range	100 ml/min – 800 ml/min
4. Temperature	
Ambient	15°C – 45°C
Blood	32°C – 37°C

2. EXPECTED RESULT- ACCEPTANCE CRITERIA

a. Saturation

The error between the BLOP4 sensor probe reading vs. reference instrument should be within $\pm 5\%$ at 37°C with a blood flow of 400 ml/min (human blood with MCV = 90 ± 10 fL).

After having inserted the cuvette in the probe 5,000 time, the measurement error of oxygen saturation has to remain within the allowed interval.

MTBF = 6 years

6 years = 3,000 cycles at 500 cycles/years

5,000 cycles is 80% confidence that MTBF will be 6 years

Note: for the test execution the cuvette under test will be accelerated aged at 60°C for 3,7 weeks.

(Simplified Protocol for Accelerated Aging based on Arrhenius' chemical kinetics theory. Practically the simplified formula used is:

$$TIME_{T\ oven} = TIME_{T\ ambient} / Q_{10}^{(T_{oven} - T_{ambient})/10}$$

where $Q_{10} = 2$ and TIME expressed in weeks

therefore the simulation of 1 year at room temperature is 3,7 weeks in oven at 60°C:

$$TIME_{T\ oven} = 52 / 2^{(60-22)/10} = 3,7\ weeks$$

b. Hematocrit

The error between the BLOP4 sensor probe reading vs. reference instrument should be within $\pm 5\%$ at 37°C with a blood flow of 400 ml/min (human blood with $\text{MCV} = 90 \pm 10 \text{ fL}$).

After having inserted the cuvette in the probe 5,000 time, the measurement error of oxygen saturation has to remain within the allowed interval.

MTBF = 6 years

6 years = 3,000 cycles at 500 cycles/years

5,000 cycles is 80% confidence that MTBF will be 6 years

Note: for the test execution the cuvette under test will be accelerated aged at 60°C for 3,7 weeks.

3. RESPONSABILITY

Person in charge for executing the test is the Technical Responsible.

4. MATERIALS and METHODS

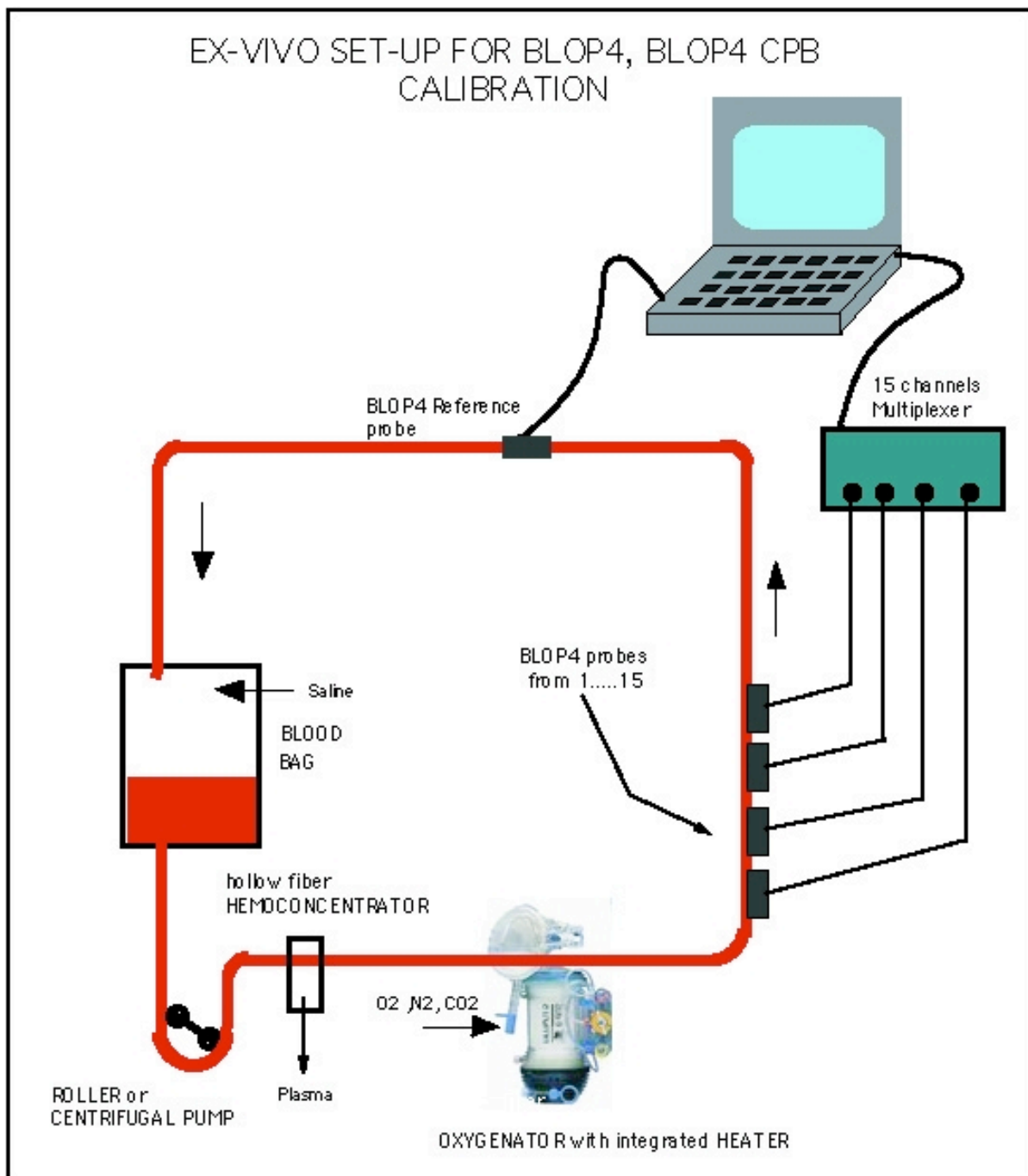
Equipment	BLPO4 probes
Serial Numbers	51, 52A50012, 52A50013, 52A50015, 52A50015, 52A50017, 52A50017, 22025, 22023, 22024
SW version	BLOP4T4 0
Personal computer	COMPAQ Pentium III
SW version	acquisition "BLPO4 15CH"

Instruments		Calibration expiry date	Ref. N°
Reference for Sat%	Co-Oxymeter RADIOMETER A/B model OSM3	12/2005	OSM389R111N03
Reference Flowmeter	TRANSONIC HT110 by- pass flowmeter	05/2006	A304499A
Biopump	MEDTRONIC BIO-PMP model BPX-80	N/A	2153962
Peristaltic Pump	BELLCO model BL-705	12/2005	13878B77
Thermostatic bath	ELETTROFOR model GT- 80/P	N/A	GT80200306
Reference for Ht%	Centrifuge for micro hematocrit ALC model Centrifugette 4203	04/2006	30304260

Disposable/Supplies		Ref. N°
Oxygenator	DIDECO Lilliput model D 902	N/A
Hemoconcentrator	BELLCO model BLS 803	N/A
Saline solution	EUROSPITAL Sodio Clururo 0,9%	N/A
Blood	Hospital (blood bank)	ABO matched, controlled for MCV in the range $90 \pm 10 \text{ fL}$, controlled Standard Base Excess (SBE) $\pm 7,5 \text{ mmol/l}$

5. TEST DESCRIPTION

- a. Insert cuvette in the BLOP4 probe previously aged and prepare the test circuit.
- b. Connect the reference flowmeter.
- c. Connect the inlet and outlet port of the heat exchanger integrated in the LILLIPUT Oxygenator to the tubing of the thermostatic bath.
- d. Set the thermostatic bath properly in order to obtain circulating blood of $34^{\circ}\text{C} \pm 3^{\circ}\text{C}$.
- e. Start up the Biopump in "open loop", at 1 l/min. read on the reference flowmeter.(some test have been performed using the BELLCO BL-707 peristaltic pump setted at 350 ± 50 ml/min)
- f. By using O₂, CO₂ and N₂ reach the saturation level desired by ventilating the LILLIPUT oxygenator inlet.
- g. When steady saturation level condition is reached:
- h. Note the BLPO4 Oxygen saturation and Hematocrit read on PC.
- i. Take a blood sample for haemogas analysis.
- j. The comparison is performed with human blood:
 - at different Hematocrit values within the range of 15-50 %
 - at different Oxygen saturation conditions in the range of 40-100%

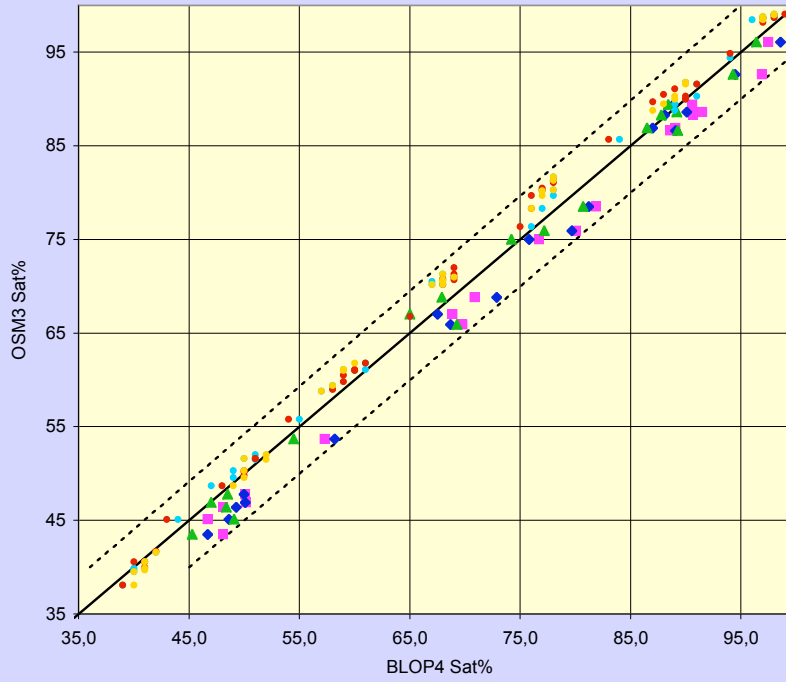


6. TEST RESULTS

The tests are performed inserting and removing the cuvette for 5,000 times in a 2 BLOP4 probes used both for 2,500 cycles each ($2,500 + 2,500 = 5,000$ cycles).

Results of the test may be found in the Excel files "BLOP4 Sat verification.xls" and "BLOP4 Hct verification.xls" and graphically shown in the following figures.

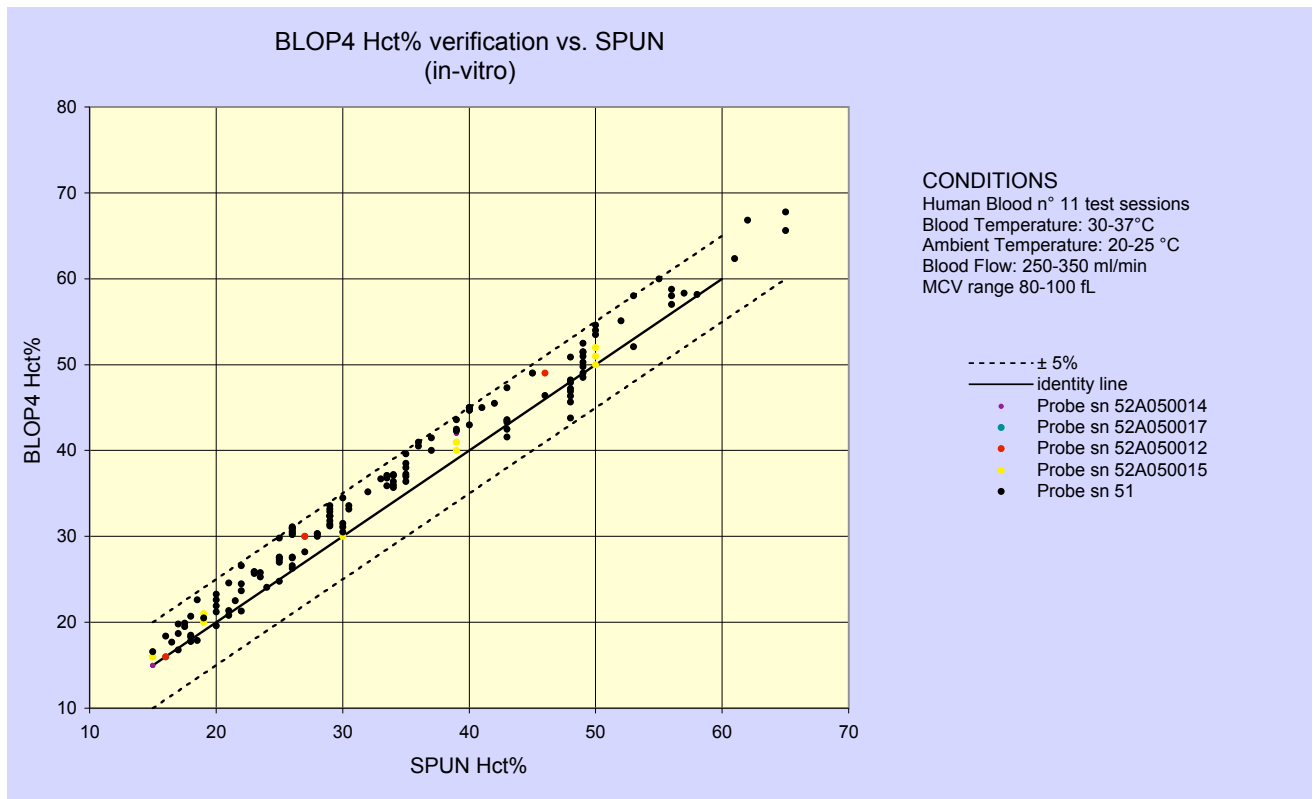
BLOP4 Sat% verification vs.OSM3



CONDITIONS

Bovine Blood and Human Blood
 Blood Temperature: 31-34°C
 Ambient Temperature: 22 °C
 Blood Flow: 300-1000 ml/min

- Probe #22023
- ◆ Probe #22025
- ▲ Probe #22024
- Probe sn 52A050012
- Probe sn 52A050017
- Probe sn 52A050016



The measured values of Oxygen Saturation and Hematocrit have to remain within the allowed interval (see Expected Result).

Note:

The error is indented as the difference between BLOP4 probe value and the absolute value measured by reference instrument.

7. **RESULTS and CONCLUSION**

The acceptance criteria were met.

The reliability of the sensor probe BLOP4 coupled with the Cuvette in the measuring set-up equipment was proven:

- for the Saturation reading accuracy,
- for HCT reading accuracy