Grosse O, Holzhey D, Falk V, Schaarschmidt J, Krämer K, Mohr FW
Universität Leipzig Herzzentrum GmbH
Strümpellstr. 39, 04289 Leipzig

IN VITRO EVALUATION OF THE NEW IN-LINE MONITOR BMU 40

Background: Reliable information about different blood parameters is essential maintaining haemodynamics, perfusion and gas exchange during CPB. For this purpose a precise and continuous monitoring is needed. The objective of this in vitro study was to compare a novel continuous in-line blood parameter monitoring system (CIBPMS) vs. a reference laboratory analyser.Methods: The study was conducted as an in vitro prospective experimental study during a CPB simulation. The reliability of BMU 40 was tested against a conventional laboratory analyser (gold standard) in monitoring the pO_2, SO_2 and Hct under physiological and extreme conditions with regards to temperature, oxygenation and blood concentration. Four different tests were performed and five test runs per test were conducted with five sensors each. A total of 350 measurement points were compared. Correlation analyses and Bland-Altman analyses were performed.

Results: A total of 350 measurement points were compared. All monitored values of blood parameters correlated highly with laboratory values (all r values > 0.90). Test 1: Biases of pO_2(act) vary from -3.24 (±6.86) up to 6.0 (±17.89). The biases of pO_2(37°C) ranged from -3.08 (±5.53) up to 68.8 (±67.82). Test 2: The biases (SD) for Hct ranged from -0.35 (±0.79) up to 2.35 (±0.91). Test 3: The biases (SD) of Hct ranged from -0.67 (±1.49) up to -1.00 (±1.84). Test 4: The biases (SD) for SO2 vary from -0.36 (±1.60) up to 0.48 (±0.90).

Conclusions: The BMU 40 is a reliable device in measuring the pO_2, SO_2, Hct and Hb under normal physiological and extreme conditions with regards to temperature, oxygenation and blood concentration in simulation of CPB. The algorithm to calculate pO_2(37°) under hypothermic conditions need to be adjusted.*

* In the meantime and before the official market launch a new software version of the BMU 40 has been developed. The algorithm to calculate pO_2(37°) under hypothermic conditions has been improved and the miscalculation eliminated.