In Vitro Comparison of the New In-Line Monitor BMU 40 versus a Conventional Laboratory Analyzer

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Abstract: Reliable information about different blood parameters is essential in maintaining hemodynamics, perfusion, and gas exchange during cardiopulmonary bypass (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 versus a reference laboratory analyzer. The study was conducted as an in vitro prospective experimental study during a CPB simulation. The reliability of BMU 40 was tested in monitoring the pO₂, oxygen saturation (SO₂), and hematocrit (Hct) under physiological and extreme conditions with regards to temperature, oxygenation, and blood concentration. Four different tests were performed and conducted with five sensors each. Correlation analyses and Bland-Altman analyses were performed. A total of 350 measurement points were compared. All monitored values of blood parameters correlated highly with laboratory values (all r values >.90). Test 1: Biases of pO₂ (act) varied from −3.24 mmHg (±6.86 mmHg) up to 6.0 mmHg (±17.89 mmHg). The biases of pO₂ (37°C) ranged from −3.52 mmHg (±6.01 mmHg) up to 68.8 mmHg (±67.82 mmHg). Test 2: The biases standard deviations (SD) for Hct ranged from −0.35% (±.79%) up to 2.35% (±.91%). The biases (SD) for SO₂ varied from −45% (±.86%) up to .85% (±.10%). Test 3: The biases (SD) for Hct ranged from −1.00% (±1.84%) up to −.67% (±1.49%). Test 4: The biases (SD) for SO₂ varied from −.36% (±1.60%) up to .48% (±.90%). The BMU 40 is a reliable device in measuring the partial oxygen pressure (pO₂), SO₂, and Hct under normal physiological and extreme conditions with regards to temperature, oxygenation, and blood concentration in simulation of CPB. The algorithm to calculate pO₂ (37°C) under hypothermic conditions needs to be adjusted. (Before the official market launch a new software version of the BMU 40 has been developed. The algorithm to calculate pO₂ (37°C) under hypothermic conditions has been improved and the miscalculation eliminated.) Keywords: continuous in-line blood parameter monitoring system, sensor reliability, blood parameter, laboratory analyzer, cardiopulmonary bypass.

Access to accurate, continuous information is a necessity for optimum patient management during cardiopulmonary bypass (CPB). Complications such as brain damage because of hypoperfusion or hypoxemia remain problems to be prevented and solved (1). To monitor blood parameters during CPB, laboratory blood gas analyzers and continuous in-line blood parameter monitoring systems (CIBPMSs) have been developed. Many authors have repeatedly proven the benefits of CIBPMSs and concluded that they are effective tools in the management of intraoperative blood parameters during CPB (2–13). Previous studies have concluded that continuous blood parameter monitoring, based on optical fluorescence and/or optical reflectance technology, may not be accurate enough to replace conventional laboratory analyzers (2,10,14,15). Laboratory analyzers, such as the ABL 700 (Radiometer Medical AS, Brønshøj, Denmark), using an electrochemical technology to provide intermittent samples are the “gold standard” for accuracy in blood parameter monitoring during CPB (2–6,10,15).

However, continuous in-line blood parameter monitoring is getting more and more state-of-the-art in perfusion because of the on-line availability of important blood parameters. Cardiac surgical procedures using CPB can cause dramatic shifts in temperature, flow, oxygenation, and hemoconcentration (1–5,10–12,16,17). Continuous

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measurements of these parameters enable the perfusionist to quickly adapt in critical situations during extracorporeal circulation (ECC). A strict control of critical physiological parameters ensures patient outcome and safety (1–5,8,10,16,18–20).

CIBPMSs use different measurement technologies (optical-fluorescence/electrochemical/optical-reflectance/optical-luminescence) with inherent advantages and disadvantages yielding different accuracy, precision, and stability. In previous studies, the reliability of the optical technology used by other monitor devices has been documented (2–10,12,13,17,20–22).

Our investigation was conducted to show that the new developed BMU 40 blood monitor unit (MAQUET Cardiopulmonary AG, Hirrlingen, Germany) is a reliable CIBPMS during a wide range of unstable, rapidly changing conditions with regards to temperature, hematocrit, and oxygenation.

To investigate the reliability of the BMU 40, an in vitro evaluation of the BMU 40 monitor device in comparison with the reference laboratory analyzer ABL 700 during CPB simulations was performed. The following question was posed: How reliable is the BMU 40 in predicting simultaneous laboratory values for pO₂, SO₂, and Hct during unstable, rapidly changing blood parameter conditions?

MATERIALS AND METHODS

Study Design

The study was conducted as an in vitro prospective experimental study with the continuous in-line blood parameter monitoring system BMU 40 against the reference laboratory blood gas analyzer ABL 700. The reliability of BMU 40 was tested in measuring the pO₂ (act) (ph-stat), pO₂ (37°C) (alpha-stat), SO₂, and Hct under normal physiological and extreme conditions with regards to temperature, oxygenation, and blood concentration in four different tests with five sensors each during CPB simulation. A total of 20 sensors of BMU 40 were tested and a total of 350 blood samples were compared with the reference blood gas analyzer.

The BMU 40 Blood Monitoring Unit and Sensors

The BMU 40 blood monitoring unit is a CIBPMS to monitor pO₂ (act), pO₂ (37°C), SO₂, Hct, hemoglobin (Hb), arterial temperature (T a ), venous temperature (T v ), and oxygen consumption (VO₂) during CPB or similar procedures with an ECC. The device has two probes, one for measuring arterial blood variables and one for measuring venous blood variables.

The arterial probe (Figures 1 and 2) with optical waveguide and infrared sensor measures the arterial pO₂ based on an optical luminescence technique. Temperature is measured non-invasively with a thermopile infrared sensor. A pO₂-sensitive dye sensor, hermetically embedded in the arterial sensor (Figure 1), has contact with the blood on the inner side of the sensor and optical contact with the BMU 40 on the outer side via the optical waveguide. The monitor system can display the pO₂ either at actual temperature or calculate the measured value at 37°C. The arterial sensor was constructed in different sizes (3/8″, 1/4″, and 3/16″) according to the type of perfusion.

The venous sensor cell (Figure 3) is an optical reflectance cell for measuring SO₂, Hct, Hb, and venous temperature in the venous return tubing line of an ECC. The venous probe (Figures 3 and 4) has three light emitting diodes which irradiate the blood through the venous sensor cell at different wavelengths, an optical spectrometric sensor to measure Hb and Hct concentration and a second optical sensor to measure SO₂ contactless in the same way. The venous temperature is measured non-invasively by a thermopile infrared sensor. The venous sensor cell is also available in three different sizes (1/2″, 3/8″, and 1/4″) according to the type of perfusion.

Every arterial and venous BMU 40 sensor has a barcode label on which a 2D barcode is printed to clearly identify the sensor. The barcode contains manufacturing data and also the calibration data of the sensor that is used to calibrate the BMU 40. A barcode scanner is incorporated into the front side of the monitor housing beside the touch screen of the BMU 40 accordingly. All displayed blood parameter values and temperature values can be adjusted by demand to values of reference devices during CPB. The BMU 40 displays all blood values in a numerical or in a combined graphical and numerical display. The numerical values displayed are updated every three seconds. The response times of 90% value change are for SO₂, Hct, and
Hb less than 6 seconds, for \( pO_2 \) and \( T_a \) less than 60 seconds, and for \( T_v \) and calculated \( VO_2 \) less than 70 seconds.

**Cardiopulmonary Bypass Simulation**

The CPB simulation (Figure 5) was set up using a roller pump, a Jostra Quadrox membrane oxygenator (MAQUET Cardiopulmonary AG, Hirrlingen, Germany) with integrated heat exchanger and a Jostra VHK reservoir (MAQUET Cardiopulmonary AG, Hirrlingen, Germany). The sensors were placed in the line behind the oxygenator and before the reservoir. A heart lung machine S 3 (Sorin Group Germany GmbH, Munich, Germany) was used. The circuit set up (Figure 5) was primed with an electrolyte solution and with recently expired units of packed red blood cells. The human blood solution was maintained tonometered to a nominal pH-value of 7.4 and \( pCO_2 \) of 40 mmHg. Sodium bicarbonate was added for acid/base balance as necessary. Solution temperature was monitored with a thermistor incorporated in the venous reservoir. Pump blood flow of 5 L/min was maintained and not altered during each test. To get a continuous perfusion pressure of 250 mmHg in the sensor line a cross clamp regulator was integrated before the reservoir. A hemocentrator DHF .2 (Sorin Group Italy S.r.l, Mirandola, Italy) was integrated to get different levels of Hct. To get different values of \( pO_2 \) and \( SO_2 \) during measurements, a gas flow mix consisting of oxygen, nitrogen, and carbon dioxide was used. Conventional methods of determining occlusion were performed.

**Blood Parameter Monitoring**

Prior to testing, each sensor of the BMU 40 was scanned to calibrate and the changeable blood parameters were adjusted according to the blood probe results of the reference laboratory analyzer. Only the sensor sizes for adult perfusion (arterial 3/8 inch, venous 1/2 inch) were tested. All values of \( pO_2 \) were measured at actual blood temperatures and calculated to 37°C by algorithms incorporated into the BMU 40. To compensate inherent delays for the CIBPMS in response to changes in blood parameter conditions, response times of the measured blood parameters were assessed.

**Laboratory Blood Parameter Analysis**

One laboratory analyzer was located in the experimental operation room beside the heart lung machine. All blood gas values were measured at 37°C blood temperature and calculated to actual temperatures by algorithms incorporated into the ABL 700. Before the beginning of the study all routine maintenance work on the laboratory analyzer was performed, including changing sensor electrode membranes according to the manufacturer’s directions. During the period of study implementation all calibrations and quality control checks were made automatically and successfully according to the manufacturer’s directions.

**In Vitro Tests**

Five complete test runs per test were conducted with one arterial sensor or venous sensor cell each.

**Test 1: Sensor reliability of \( pO_2 \) (act) and \( pO_2 \) (37°C) (changing \( pO_2 \) at different temperature levels):** The sensor reliability of \( pO_2 \) was tested at five different levels of partial oxygen pressure (30, 100, 150, 250, and 400 mmHg) at four different levels of temperature (16, 25, 37, and 40°C). Before each test run the arterial sensor was scanned for calibration. The \( pO_2 \) (act) of BMU 40 was adjusted to the
values of the reference blood gas analyzer at 200 mmHg at each temperature level. After adjustment the measurement was started at a pO₂ (act) of 30 up to 400 mmHg, as measured by the reference analyzer.

**Test 2: Sensor reliability of Hct and SO₂ (changing of temperatures at different Hct levels):** The sensor reliability of Hct and SO₂ of venous sensor cells was tested at four levels of temperature (15, 25, 37, and 40°C) and four levels of Hct (15, 30, 40, and 45%). The value of SO₂ was fixed at 95%. Only once before each test run the calibrated blood parameter values of the BMU 40 were adjusted to the measured values of ABL 700 at 37°C for Hct at 30% and for SO₂, 95%. On each level of Hct the temperature was changed in four steps from 40 down to 25°C.

**Test 3: Sensor reliability of Hct (changing of Hct at different temperature levels):** To test the sensor reliability of Hct the venous sensor cell was scanned to calibrate only once before each test run. For every level of temperature (15, 25, 37, 40°C) the blood parameters of the BMU 40 were adjusted to the values of its reference analyzer for Hct at 30%. The measurement of Hct was started at an Hct value of 15% and continued up to 50%. The measured values of CIBPMSs were recorded at six levels of Hct (15, 20, 30, 40, 45, and 50%) and controlled with the reference laboratory analyzer.

**Test 4: Sensor reliability of SO₂ (changing of SO₂ at 25 and 37°C):** The sensor reliability of SO₂ measurement was tested at 25 and 37°C at five steps of SO₂ (45, 50, 60, 80, and 95%). The venous sensor cell was scanned to calibrate only once before each test run and the measured values of the BMU 40 were adjusted to the values of the laboratory analyzer once at 37°C and SO₂ at 95%. The measurement was started at 37°C and a value of SO₂ at 45%. The same measurement procedure was directly performed afterwards at 25°C without any new adjustment.

### Statistical Analysis
Analyses were performed using Microsoft Excel 2003 (Microsoft Corp., Redmond, WA) and SPSS 13 (SPSS Inc., Chicago, IL) software. The performance of CIBPMSs during unstable blood parameter conditions was evaluated first by performing a correlation analysis of CIBPMSs versus reference laboratory blood parameter values to describe the linear relationship of the measurement methods to the line of equality. The strength of the association between two variables was calculated by the Pearson correlation coefficient (r). In addition, the mean differences between CIBPMS and laboratory values, the standard deviations of the differences, and the limits of agreements were calculated. According to the methods described by Bland and Altman, the mean difference between the two measurement methods was considered to be the bias and the standard deviation of scores around that difference, the precision of the monitoring method (23). The limits of agreement indicate the range that covers the differences plus or minus twice the standard deviations for both devices.

### RESULTS

**Test 1: Sensor reliability of pO₂ (act) and pO₂ (37°C) (changing pO₂ at different temperature levels):** To assess comparisons of pO₂ monitoring during changing conditions of oxygenation and temperature overall, 100 concurrent, paired-sample measurements were obtained with use of five arterial sensors of the BMU 40. Correlation analyses revealed good correlation coefficients (r) for measured pO₂ (act) and calculated pO₂ (37°C) at all temperature levels between .9049 and .9996 (Table 1). At each temperature level, bias of measured pO₂ (act) was small (−3.24 up to 6.00 mmHg) and precision (±5.53 up to ±17.89 mmHg) was good (Figure 6), whereas the mean difference of calculated pO₂ (37°C) at 16°C was high (68.8 ± 67.82 mmHg).

Table 1. Sensor reliability of pO₂ (act) and pO₂ (37°C) (changing pO₂ at different temperature levels)—Relationship between the ABL 700 and the BMU 40.

<table>
<thead>
<tr>
<th>Variable</th>
<th>n</th>
<th>BMU 40 Mean ± SD</th>
<th>Bias ± Precision</th>
<th>Limits of Agreement (±2 SD)</th>
<th>r</th>
</tr>
</thead>
<tbody>
<tr>
<td>pO₂ (act) at 16°C</td>
<td>25</td>
<td>191.8 ± 142.6</td>
<td>6.00 ± 17.89</td>
<td>-29.79 41.79</td>
<td>.9967</td>
</tr>
<tr>
<td>pO₂ (act) at 25°C</td>
<td>25</td>
<td>188.4 ± 137.1</td>
<td>2.04 ± 8.45</td>
<td>-14.86 18.94</td>
<td>.9996</td>
</tr>
<tr>
<td>pO₂ (act) at 37°C</td>
<td>25</td>
<td>183.2 ± 132.9</td>
<td>-3.08 ± 5.53</td>
<td>-14.14 7.98</td>
<td>.9996</td>
</tr>
<tr>
<td>pO₂ (act) at 40°C</td>
<td>25</td>
<td>182.6 ± 134.4</td>
<td>-3.24 ± 6.86</td>
<td>-16.96 10.48</td>
<td>.9995</td>
</tr>
<tr>
<td>pO₂ (act) overall</td>
<td>100</td>
<td>186.5 ± 136.8</td>
<td>.43 ± 11.50</td>
<td>-22.56 23.42</td>
<td>.9980</td>
</tr>
<tr>
<td>pO₂ (37°C) at 16°C</td>
<td>25</td>
<td>282.3 ± 146.9</td>
<td>68.80 ± 67.82</td>
<td>-66.84 204.44</td>
<td>.9049</td>
</tr>
<tr>
<td>pO₂ (37°C) at 25°C</td>
<td>25</td>
<td>239.7 ± 144.4</td>
<td>22.52 ± 20.5</td>
<td>-18.48 63.52</td>
<td>.9899</td>
</tr>
<tr>
<td>pO₂ (37°C) at 37°C</td>
<td>25</td>
<td>186.3 ± 132.9</td>
<td>-3.08 ± 5.53</td>
<td>-14.14 7.98</td>
<td>.9996</td>
</tr>
<tr>
<td>pO₂ (37°C) at 40°C</td>
<td>25</td>
<td>173.2 ± 130.2</td>
<td>-3.52 ± 6.01</td>
<td>-15.53 8.49</td>
<td>.9994</td>
</tr>
<tr>
<td>pO₂ (37°C) overall</td>
<td>100</td>
<td>241.6 ± 156.9</td>
<td>21.18 ± 46.25</td>
<td>-71.31 113.67</td>
<td>.9558</td>
</tr>
</tbody>
</table>

Values for pO₂ are in mmHg. n indicates the number of test points. All r values (correlation coefficients) are significant (p < .0001).
mmHg) and large limits of agreement (from a lower limit of −66.84 to an upper limit of 204.44 mmHg) were shown (Table 1). Figure 7 shows the imprecision of pO₂ (37°C) at 16°C graphically. The calculated pO₂ (37°C) was markedly imprecise at 16°C within physiological range of pO₂ (act) from 100–150 mmHg. The calculated values below and above this range correlated acceptably. The calculated pO₂ (37°C) at 25°C was substantially overestimated by the CIBPMS (bias = 22.52 ± 20.5 mmHg) (Table 1 and Figure 7). Within the temperature range of 37 and 40°C bias of calculated pO₂ (37°C) was small and precision was good (Table 1 and Figure 7).

Test 2: Sensor reliability of Hct and SO₂ (changing of temperatures at different Hct levels): Overall, 80 concurrent, paired-sample measurements were obtained with
use of five venous sensor cells of BMU 40 during stepwise changed temperatures on different Hct levels. Correlation analyses revealed excellent correlation coefficients for Hct values between .9972 and .9998 (Table 2). The Hct values at 15 and 25°C were overestimated by the CIBPMS (Table 2 and Figure 8). The imprecision of Hct was markedly at 15°C (bias = 2.35 ± 91%). At 37 and 40°C, monitored Hct values most closely predicted laboratory values. On each measured temperature, bias of SO₂ was small (−.45 up to .85%) and precision (±.36 up to ±1.18%) was good (Table 2). Overall bias and precision of SO₂ (2 ± 1.02%) were depicted in Figure 9.

Test 3: Sensor reliability of Hct (changing of Hct at different temperature levels): A total of 120 concurrent, paired-sample measurements were obtained with use of five venous sensor cells of CIBPMSs during stepwise changed values of Hct at four temperature levels between 15 and 40°C. Again, monitored values of Hct correlated highly with laboratory values (all r values >.99) (Table 3). On each level of temperature bias of Hct was small (−0.67 up to −1.00%) and precision was good (±1.39 up to ±1.84%) (Table 3). Only at the high ranges of Hct at 45 and 50%, the values of Hct were still underestimated on each level of temperature (Figure 10). It follows from this that the lower limits of agreement ± 2 SD vary from −3.51 up to −4.69% (Table 3). Overall bias and precision of Hct at all temperatures show acceptable values (−.8 ± 1.54%).

Test 4: Sensor reliability of SO₂ (changing of SO₂ at 25 and 37°C): To assess comparisons of SO₂ monitoring in Table 2. Sensor reliability of Hct and SO₂ (changing of temperatures on different Hct levels)—Relationship between the ABL 700 and the BMU 40.

<table>
<thead>
<tr>
<th>Variable</th>
<th>n</th>
<th>BMU 40 Mean ± SD</th>
<th>Bias ± Precision</th>
<th>Limits of Agreement (±2 SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hct at 15°C</td>
<td>20</td>
<td>34.85 ± 11.72</td>
<td>2.35 ± .91</td>
<td>.53 4.17 .9972</td>
</tr>
<tr>
<td>Hct at 25°C</td>
<td>20</td>
<td>33.65 ± 11.49</td>
<td>1.15 ± .65</td>
<td>−.16 2.46 .9984</td>
</tr>
<tr>
<td>Hct at 37°C</td>
<td>20</td>
<td>32.55 ± 11.45</td>
<td>.05 ± .22</td>
<td>−.39 0.49 .9998</td>
</tr>
<tr>
<td>Hct at 40°C</td>
<td>20</td>
<td>32.15 ± 11.28</td>
<td>−.35 ± .79</td>
<td>−1.93 1.23 .9977</td>
</tr>
<tr>
<td>Hct overall</td>
<td>80</td>
<td>33.30 ± 11.53</td>
<td>.8 ± 1.26</td>
<td>−1.72 3.32 .9940</td>
</tr>
<tr>
<td>SO₂ at 15°C</td>
<td>20</td>
<td>95.85 ± 1.01</td>
<td>.85 ± 1.01</td>
<td>−1.81 2.88 –</td>
</tr>
<tr>
<td>SO₂ at 25°C</td>
<td>20</td>
<td>95.25 ± 1.18</td>
<td>.25 ± 1.18</td>
<td>−2.11 2.61 –</td>
</tr>
<tr>
<td>SO₂ at 37°C</td>
<td>20</td>
<td>95.15 ± .36</td>
<td>.15 ± .36</td>
<td>−.56 .86 –</td>
</tr>
<tr>
<td>SO₂ at 40°C</td>
<td>20</td>
<td>94.60 ± .86</td>
<td>−.45 ± .86</td>
<td>−2.18 1.28 –</td>
</tr>
<tr>
<td>SO₂ overall</td>
<td>80</td>
<td>95.20 ± 1.02</td>
<td>.2 ± 1.02</td>
<td>−1.83 2.23 –</td>
</tr>
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</table>

Values for Hct and SO₂ are in %. n indicates the number of test points. All r values (correlation coefficients) are significant (p < .0001).

Figure 8. Bland-Altman plots—Hct at 15, 25, 37, and 40°C; BMU 40 versus ABL 700; The thin dotted lines are the 95% CI for the mean difference between the two methods and the fat dotted lines are the limits of agreement ± 2 SD n = 20 each.

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during stepwise changing conditions of oxygenation at 25 and 37°C, overall 50 concurrent, paired-sample measurements (with 25 blood samples each per temperature level) were obtained with the use of five venous sensor cells of CIBPMSs. Correlation analyses revealed excellent correlation coefficients ($r$) for SO$_2$ values at 25°C ($r = .9989$) and at 37°C ($r = .9966$) (Table 4). Bias and precision for SO$_2$ at 25°C were $+.48 \pm .90\%$. For SO$_2$ at 37°C, bias and precision were $-.36 \pm 1.60\%$. Small limits of agreement $\pm 2$ SD were shown (Table 4). Overall bias of SO$_2$ ($-.6\%$) at both temperatures was very small and precision ($\pm 1.53\%$) was excellent. Overall small limits of agreement $\pm 2$ SD (from $-3.12$ up to 3.00%) showed a high agreement between both measuring methods (Table 4 and Figure 11).

### DISCUSSION

#### Benefits and Limitations of CIBPMSs

The potential benefits of using CIBPMSs during ECC are well described (1–14,17,20). An earlier detection of changes of blood parameters allow the perfusionists to quickly adapt and intervene during rapid changes in temperature, flow, oxygenation, and hemoconcentration associated with the use of CPB during cardiac operations (1–5,8,10,16,18–20). Furthermore, the use of CIBPMSs

<table>
<thead>
<tr>
<th>Variable</th>
<th>$n$</th>
<th>BMU 40 Mean ± SD</th>
<th>Bias ± Precision</th>
<th>Limits of Agreement (±2 SD)</th>
<th>$r$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hct at 15°C</td>
<td>30</td>
<td>32.67 ± 11.86</td>
<td>-.67 ± 1.49</td>
<td>-3.65 2.31</td>
<td>.9956</td>
</tr>
<tr>
<td>Hct at 25°C</td>
<td>30</td>
<td>32.67 ± 11.89</td>
<td>-.73 ± 1.39</td>
<td>-3.51 2.04</td>
<td>.9978</td>
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<tr>
<td>Hct at 37°C</td>
<td>30</td>
<td>32.43 ± 11.55</td>
<td>-.97 ± 1.72</td>
<td>-4.41 2.48</td>
<td>.9966</td>
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<tr>
<td>Hct at 40°C</td>
<td>30</td>
<td>32.37 ± 11.29</td>
<td>-1.00 ± 1.84</td>
<td>-4.69 2.69</td>
<td>.9969</td>
</tr>
<tr>
<td>Hct overall</td>
<td>120</td>
<td>32.53 ± 11.65</td>
<td>-1.00 ± 1.54</td>
<td>-3.88 2.28</td>
<td>.9965</td>
</tr>
</tbody>
</table>

Values for Hct are in %. $n$ indicates the number of test points. All $r$ values (correlation coefficients) are significant ($p < .0001$).

Figure 9. Bland-Altman plot—SO$_2$ overall (all temperatures); BMU 40 versus ABL 700; The thin dotted lines are the 95% CI for the mean difference between the two methods and the fat dotted lines are the limits of agreement $\pm 2$ SD $n = 80$.

Figure 10. Bland-Altman plots—Hct at 15, 25, 37, and 40°C; BMU 40 versus ABL 700; The thin dotted lines are the 95% CI for the mean difference between the two methods and the fat dotted lines are the limits of agreement $\pm 2$ SD $n = 30$ each.
enables the anesthetist to quickly adjust therapeutic agents to optimize perfusion, cardiac function, and anesthesia. Regarding the quality assurance perfusionists are under a legal obligation to record all relevant blood parameters in short intervals. In a combined use of data management systems (DMS), incorporated in the heart lung machine and compatible CIBPMS such as BMU 40, a continuous record of the available important blood parameters in the protocol of DMS is warranted.

One limiting aspect regarding CIBPMSs such as BMU 40 is the lack of measuring of blood parameters such as pH-value, electrolyte ions, pCO₂, bicarbonate, lactate, and glucose. Despite the high reliability of the CIBPMSs, a laboratory analyzer is always indicated as long as the number of available parameters is still limited. However, a reliable CIBPMS during CPB can allow increasing the intervals of laboratory analysis.

Considerations and Motive for this In Vitro Experiment

This in vitro study was performed during the last period of development of this new CIBPMS and before the official market launch. After the end of the study all monitored data were submitted to the Department of Research and Development of MAQUET Cardiopulmonary AG to confirm data on blood parameter measurements and calculations. Therefore, a number of tests were performed to determine monitoring differences to a reference laboratory analyzer. The simulation of unstable clinical measurement conditions with the rapid onset of temperatures, Hct levels, and oxygenation changes during ECC was applied to provoke differences between the blood parameter values from the CIBPMSs and the laboratory analyzer.

Performance and Reliability of CIBPMSs

Overall correlation analyses revealed excellent correlations (all overall r values > .95) for all summarized values for each variable of measured blood parameters and are reflected by a high linear relationship. Because correlation analyses alone are not sufficient to assess agreements between two measurement methods, the performance was analyzed by calculating the bias, precision, and limits of agreement (23). Variable differences ± 10% between values of CIBPMS and values of reference laboratory analyzer are considered clinically acceptable and are in accordance with the literature (2,7).

The results of this investigation support the hypothesis, that the BMU 40 blood monitor unit is a reliable device for continuous in-line measurement of blood parameters with one exception. Especially in the hypothermic range from 16–25°C, the calculated pO₂ (37°C) was overestimated (bias = 68.8 mmHg at 16°C) and cannot be accepted. Large limits of agreement show a marked difference between both devices (Table 1). Because pO₂ (act) at 16°C was acceptable measured by CIBPMSs (bias = 6.0 mmHg) and pO₂ (37°C) is a calculated value of measured pO₂ (act), it should not be difficult to correct the problem on a software level. At 37 and 40°C biases of calculated pO₂ (37°C) were small and precisions were good (Table 1 and Figure 7). At each level of temperature, differences of measured pO₂ (act) were small and acceptable (Table 1 and Figure 6).

One factor distinguished the measurement methods of CIBPMSs and the conventional laboratory analyzer. Laboratory pO₂ values were measured at 37°C and corrected by an algorithm to the actual temperature. On the other hand, pO₂ values of the CIBPMS were measured at actual temperatures and corrected by an algorithm to 37°C if required. Limitations of algorithm accuracy impaired the comparison of date for the CIBPMSs and laboratory analyzer (2).

Differences between CIBPMSs and laboratory values for Hct in both relevant test series were small and clinically acceptable with overall biases of .8 (Table 2) and

### Table 4. Sensor reliability of SO₂ (changing of SO₂ at 25 and 37°C)—Relationship between the ABL 700 and the BMU 40.

<table>
<thead>
<tr>
<th>Variable</th>
<th>n</th>
<th>BMU 40 Mean ± SD</th>
<th>Bias ± Precision</th>
<th>Limits of Agreement (±2 SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>SO₂ at 25°C</td>
<td>25</td>
<td>66.48 ± 19.00</td>
<td>.48 ± .90</td>
<td>−1.32</td>
</tr>
<tr>
<td>SO₂ at 37°C</td>
<td>25</td>
<td>65.64 ± 19.15</td>
<td>−.36 ± 1.60</td>
<td>−3.55</td>
</tr>
<tr>
<td>SO₂ overall</td>
<td>50</td>
<td>66.06 ± 19.08</td>
<td>.6 ± 1.53</td>
<td>−3.12</td>
</tr>
</tbody>
</table>

Values for SO₂ are in %. All r values (correlation coefficients) are significant (p < .0001).
clude that the BMU 40 is an effective and reliable device in CONCLUSION

limits of the CIBPMS. A wide range of typical and atypical ranges of measurement included a well-defined experimental protocol including a

gations were clinical evaluations and compared typical lyzers during CPB (15,19). However, all these investi-

gations were clinical evaluations and compared typical physiological measurement ranges of these different ana-

lytical monitoring devices. In contrary this in vitro study included a well-defined experimental protocol including a

wide range of typical and atypical ranges of measurement limits of the CIBPMS.

Comparisons with Other Blood Parameter Monitoring Systems

Previous studies by Mark et al., Southworth et al., and Trowbridge et al. evaluated a similar CIBPMS, the CDI 500 (Terumo Cardiovascular Systems Corp., Tokyo, Japan), an optical fluorescence and reflected-based in-line system to continuously monitor critical blood parameters (2,7,8). Walton et al. and Prichard et al. have shown a good correlation between point of care analyzers, such as the ABL 70 and the ABL 77 (Radiometer Medical A/S, Brønshøj, Denmark), and conventionally reference laboratory analy-

izers during CPB (15,19). However, all these investiga-

tions were clinical evaluations and compared typical physiological measurement ranges of these different ana-

lytical monitoring devices. In contrary this in vitro study included a well-defined experimental protocol including a

wide range of typical and atypical ranges of measurement limits of the CIBPMS.

CONCLUSION

Based on our experimental data, it is justified to con-

clude that the BMU 40 is an effective and reliable device in measuring the pO₂, SO₂, and Hct under normal physiological and extreme conditions with regards to temperature, oxygenation, and blood concentrations in a simulated CPB circuit. The algorithms to calculate pO₂ (37°) in the lower hypothermic range need to be improved. (Before the official market launch a new software version of the BMU 40 has been developed. The algorithm to calculate pO₂ (37°) under hypothermic conditions has been improved and the miscalculation eliminated.) After this improvement, the implementation of further in-vivo studies’ use of this user-

friendly and reliable CIBPMS in addition to a laboratory analyzer can be recommended. Further clinical evaluations of the BMU 40 are necessary.

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