

System Accuracy (ISO 15197)

Test system: EasyMax MU SOMA be (A)

Reference system: YSI 2300

Sample: Whole blood (capillary)

Data file: 1225_EMMU_A_Ausw_Y_121119.xls

System accuracy results for glucose concentration < 4.2 mmol/L (75 mg/dL)

Within ± 0.28 mmol/L (Within ± 5 mg/dl)	Within ± 0.56 mmol/L (Within ± 10 mg/dl)	Within ± 0.83 mmol/L (Within ± 15 mg/dl)
26 / 38 (68 %)	34 / 38 (89 %)	38 / 38 (100 %)

System accuracy results for glucose concentration ≥ 4.2 mmol/L (75 mg/dL)

Within ± 5 %	Within ± 10 %	Within ± 15 %	Within ± 20 %
84 / 162 (52 %)	135 / 162 (83 %)	158 / 162 (98 %)	162 / 162 (100 %)

Combined system accuracy results (absolute and relative deviations)

Within ± 0.28 mmol/L & ± 10 % (Within ± 5 mg/dl & ± 10 %)	Within ± 0.56 mmol/L & ± 10 % (Within ± 10 mg/dl & ± 10 %)	Within ± 0.56 mmol/L & ± 15 % (Within ± 10 mg/dl & ± 15 %)	Within ± 0.83 mmol/L & ± 20 % (Within ± 15 mg/dl & ± 20 %)
161 / 200 (80.5 %)	169 / 200 (84.5 %)	192 / 200 (96 %)	200 / 200 (100 %)

The EasyMax MU SOMA be (A) blood glucose system complies with the system accuracy requirements of the ISO 15197 Standard. 200 of 200 (100%) results meet the requirements.

Absolute differences between EasyMax MU SOMA be (A) and YSI 2300

