HemoCue® Glucose 201+ System Specifications

Intended use: Quantitative determination of glucose in whole blood using a specially designed analyzer, the HemoCue® Glucose 201 DM Analyzer specially designed microcuvettes, the HemoCue Glucose 201 Microcuvettes. The quantitative determination of the instant blood glucose concentration in circulation supplements the clinical evidence in the diagnosis and treatment of the diabetic patient as well as in the monitoring of neonatal blood glucose levels. To establish HemoCue Glucose reference values and an intervention level, neonatal blood samples should be evaluated against a suitable laboratory method, taking into consideration the difference between whole blood and plasma reference values. The HemoCue Glucose 201 DM Analyzer with blood plasma conversion multiplies the measured whole blood glucose value by a factor of 1.11 and displays a plasma equivalent glucose result. The HemoCue Glucose 201 Microcuvettes are for In Vitro Diagnostic use only. The HemoCue Glucose 201 DM Analyzer is only to be used with HemoCue Glucose 201 Microcuvettes. For professional use only.

| Category | HemoCue® Glucose 201+ System specifications |
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| Principle | Modified glucose dehydrogenase in which the total amount of glucose is |
| | measured at the end point photometrically |
| Calibration | Factory calibrated and traceable to the ID GC-MS method, needs no further |
| | calibration and no coding |
| Sample Material | Capillary, venous or arterial whole blood including neonatal blood |
| Displayed Range | Whole blood values: 0-22.2 mmol/L (0-400 mg/dL) |
| | Plasma equivalent values: 0-24.6 mmol/L (0-444 mg/dL) |
| Results | 40-240 seconds |
| Sample Volume | Approximately 5 μL whole blood |
| Shelf Life | Vials and each individually wrapped microcuvette: 9 months from manufacturing |
| Package Size | Individually wrapped: 4 x 25 microcuvettes |
| | Vial: 4 x 25 microcuvettes |
| Dimension | Analyzer: 160 x 85 x 43 mm (6.3 x 3.35 x 1.69 inches) |
| Weight | Analyzer: 350 g (0.77 pounds) including batteries |
| Storage Temperature | Analyzer: 0-50 °C (32-122 °F) Microcuvette: below 8 °C (46 °F), incl. freezer. |
| | Up to 3 days in room temperature. |
| Operating Temperature | 18-30 °C (64-86 °F) |
| Operating Humidity | Up to 90 % relative humidity, non-condensing |
| Hematocrit Range | 20%-70% |
| Altitude | Not affected by altitude |
| Power | AC adapter or 4 AA batteries |
| Quality Control | Built-in self test; system can be verified using liquid control |
| Data Management | HemoCue® Basic Connect software, store and view and transfer result and patient data |