

## CUVETTE TYPE Hb ANALYSERS



	EKF Hemo Control/Hemo Control Manager	HemoCue 201+/201 DM	EKF DiaSpect Hemoglobin T/Diaspect Tm	HemoCue Hb 301	Biotech Med Inc Hemochromaplus	EKF Ultracrit (US only)/UltraCrit Plus	Human HumaMeter HbPlus (OEM version of Medisynthana)
METHODOLOGY	Photometric azide methemoglobin	Photometric azide methemoglobin	Photometric, broad spectrum	Optical absorption photometry	Spectrophotometry	Ultrasound technology	Photometer AHD: Alkaline haematin detergent method
REAGENT TYPE	Microcuvettes - dry chemistry	Microcuvettes - dry chemistry	Microcuvettes - reagent free	Microcuvettes - reagent free	Microcuvette - reagent free	Cuvette	Microcuvettes prefilled with 3ml liquid reagent
MEASUREMENT RANGE	0-25.6 g/dL	0 - 25.6 g/dL	0.3 - 25.5 g/dL	0-25.6 g/dL	0.1-27.0 g/dL	10.3-72.0% Hct	0 - 30 g/dL
TIME TO RESULT	ca. 25-60 sec	15-60 Seconds	1-2 seconds	About 10 seconds	About 3 seconds	Within 30 seconds	< 10 seconds
MEMORY: PATIENT RECORDS	Hemo Control = 4,000 Additionally 500 QC results on DM activated devices	Hb201+ = 600 Hb201 DM = 4,000 + 500 QC results	None	None	1,000 tests	None	1,000 including date and time
SAMPLE VOLUME	8 or 10 µl depending on cuvette type	10 µl	<10 µl	10 µl	12-15 µl	40 µl	20 µl
SPECIMEN TYPE	Capillary, venous & arterial	Capillary, venous & arterial	Capillary & venous	Capillary, venous & arterial. Reproducible measurements only within 40 sec. after filling the cuvette	Capillary & venous	Capillary & venous	Capillary & venous or arterial
IMPRECISION, CV	≤2 %	±1.5 %	<1 %	<1 %	<3 %	<0.8 % CV at 41Hct	0-2.5 AU
ACCURACY	Correlation of 0.98 compared to NCCLS reference method: 0-20 g/dL ±0.3 g/dL >20 g/dL ±0.7 g/dL	Correlation of 0.99 compared to ICSH method	±0.3 g/dL for 0-20 g/dL ±0.7 g/dL for >20 g/dL (ICSH)	Correlation of 0.998 (ICSH) 2-5 g/dL: 4% difference, 5-25 g/dL 3% difference	Correlation of R2 = 0.983 vs Sysmex XE-2100	<0.4% Hct	Correlation of 0.983 to HiCN reference method ± 0.002 AU
CALIBRATION	Factory calibrated against NCCLS reference method (H15-A3, 2000)	Factory calibrated against the ICSH method	Factory calibrated (ICSH)	Factory calibrated (ICSH)		Factory calibrated	Factory calibrated
SELF-TEST	Automatic at start-up and with every return from stand-by (complete test) and before each test (short test)	Hb201+ = Automatic at start-up and every second hour Hb201 DM = Automatic at start-up and every eighth hour	Automatic self-check between measurements	Automatic at start-up and in regular intervals		Automatic when powered on	
QUALITY CONTROL	Control cuvette included for quality control Low, normal, high, liquid controls available	Control cuvette not included. 3 levels of liquid control available.	Liquid controls available (low, medium and high)	Control cuvette not included, 3 levels of liquid control		Non-biohazardous, unrefrigerated single use controls available	2-level control

# EKF HEMO CONTROL

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	EKF Hemo Control/Hemo Control Manager	HemoCue 201+/201 DM	EKF DiaSpect Hemoglobin T/Diaspect Tm	HemoCue Hb 301	Biotech Med Inc Hemochroma plus	EKF Ultracrit (US only)/Ultracrit Plus	Human HumaMeter HbPlus (OEM version of Medisynthana)
INTERFACE	Hemo Control = Serial port Hemo Control Manager = Serial port or Bluetooth. USB or LAN connections via cable. No docking station needed. Bidirectional interface using LIS2-A2 communication standard	Hb201+ = Serial port, USB port Hb201 DM = Via docking station (USB or LAN), using POCTI-A standard	DiaSpect T = USB for charging and data transfer DiaSpect Tm = USB for charging and data transfer. Plus integrated Bluetooth	Serial port	Optional Bluetooth interface	USB port	USB port
POWER	Integrated rechargeable battery 100 hours in use or AC, power box available for use of AA standard batteries (1.5V)	Hb201+ = 4 type AA or R6 batteries 1.5V or AC Hb201 DM = Rechargeable lithium ion battery or AC	DiaSpect T = Built in rechargeable battery or AC. 40 hours in use. DiaSpect Tm = Built in rechargeable battery or AC allows for 40 days or 10,000 tests.	4 type AA batteries	Battery (4x AA) or optional USB charger	Mains power or 4 x AA batteries	100-240V AC or rechargeable batteries
PRINTER	external, optional via Bluetooth with Hemo Control Manager	Hb201+ = External Hb201DM = None	External	External	External	No	No
BARCODE READER	Hand-held scanner (on Hemo Control only with DM upgrade "Add pack")	Hb201+ = None Hb201 DM = Integrated	No	No	No	No	No
CONSUMABLE STORAGE	15-30 °C stable for 3 months after opening when stored with the cap securely closed	15-30 °C stable for 3 months after opening when stored with the cap securely closed	0-50 °C (-30-70 °C during transport) 2.5 years stability. Same expiry date for opened and unopened bag	10-40 °C Stable for 3 months after opening (short term <6 weeks at -18-50°C before opening)	0 - 30°C. 15 month shelf life	Reagents and control have 3 year shelf life	
OPERATING CONDITIONS	15-40 °C, 10-85 %RH	15-30 °C, <90 %RH	DiaSpect T = 15 - 35°C DiaSpect Tm = 10 - 35°C	15-40 °C 5-90 %RH	10 - 40°C		
DEVICE CHARACTERISTICS	User selectable language Backlit touch screen Maintenance free	Hb201+ = Symbols only on screen, operates with buttons Hb201 DM = English and German on touch screen Maintenance free	DiaSpect T = Maintenance free. Selectable language and colour screen DiaSpect Tm = Symbol based menu. Maintenance free, 'Always on' technology	Symbols only on screen, operates with buttons, maintenance free	LCD screen, 3 buttons	User friendly features minimize training time. Large display	Miniature photometer, simple LCD display. Handling requires pipetting.
SIZE AND WEIGHT (DxWxH)	160 x 160 x 68 mm 700 g	Hb201+ = 85 x 160 x 43mm 350 g Hb201 DM = Device: 93 x 170 x 50 mm, 350 g. Docking station: 206 x 135 x 61 mm, 566 g	DiaSpect T = 140 x 210 x 70 mm. 500 g DiaSpect Tm = 90 x 150 x 40 mm. 185 g	160 x 140 x 70 mm 500 g	106 x 151 x 38 mm 217 g	191 x 129 x 89 mm 545 g	163 x 100 x 60 mm 250 g
RESULT SHOWN	Hemoglobin and hematocrit	Hemoglobin	DiaSpect T = Hemoglobin & hematocrit DiaSpect Tm = Hemoglobin	Hemoglobin	Hemoglobin	UltraCrit = Hematocrit UltraCrit Plus = Hemoglobin and hematocrit	
APPROVALS	Hemo Control = CE Hemo Control Manager = CE HemoPoint H2/H2 DM: CE, CLIA waived	CE, CLIA Waived	DiaSpect T = CE, CLIA waived for blood banks. DiaSpect Tm = CE	CE, FDA 510k	CE, FDA 510k, CLIA Waived	CE	
OTHER	Soft touching closing system minimises contamination. Compensates for turbidity by measuring at two wavelengths. Data management (DM) functions for patient, operator, material ID's and comments Hemo Control = upgradeable for DM functionality Hemo C. Manager = pre-installed DM functionality Hemo Connect (light) software generates standard .txt (csv) export file.	Hb201+ = Compensates for turbidity by measuring at two wavelengths. Data export to Basic Connect PC software. Hb201 DM = DMS software for device configuration and data transfer incl. patient, operator, material ID's and comments. Up to five docking stations can be connected to each other.	DiaSpect T = Motorized cuvette holder. PC connectivity. Select unit of measurement DiaSpect Tm = No moving parts. PC and Bluetooth connectivity	No settings or configuration options	Blood can be applied to the tip of the cuvette from a finger prick or on top of the cuvette using a pipette	Reduced user subjectivity	Other clinical parameters can be measured with the haemoquick® photometer at 574 nm by using self-developed methods and adaptations