

## CARD, STRIP, NON INVASIVE & CENTRIFUGE Hb ANALYSERS



	Strip test/Card test analysers					Non-invasive methods			Centrifuge
	EKF STAT-Site M	Acon Mission Plus Hb	ApexBio HemoSmart	Urit Medical Urit12	Ceragem CeraCheck HbPlus	Masimo Pronto-7	OrSense NBM 200	Haemospect MBR	EKF HemataSTAT II
METHODOLOGY	Reflectance photometry, azide methemoglobin	Reflectance photometry	Biosensor based amperometric test strips	Optical reflectance	Electrochemistry	Pulse CO-Oximeter	Pulse Oximetry	Reflection spectrometry	Centrifuge
REAGENT TYPE	Test cards	Test strips	Test strips	Test strips	Test strips	None	None	None	None
MEASUREMENT RANGE	6-21 g/dL	5-25.6 g/dL	4-20 g/dL	4-24 g/dL	Hb: 5-26 g/dL, H-crit: 15-78 % (calculated)	0-25 g/dL			16% - 60% hematocrit
TIME TO RESULT	1-5 seconds	<15 seconds	30 seconds	About 10 seconds	5 seconds	<1 minute	<90 seconds	1 - 10 seconds	90 seconds
MEMORY: PATIENT RECORDS	'Last result' feature allows to recall the last hemoglobin result	1000 results with date, time, ID	10 tests	250 tests	1000 tests	8,000	100 preceding measurements		None
SAMPLE VOLUME	ca. 12 µl	10 µl	3 µl	15-20 µl	1 µl	N/A	N/A	N/A	Fill tube 1/2 to 3/4 full
SPECIMEN TYPE	Whole blood	Capillary and venous whole blood	Capillary and venous whole blood	Capillary or venous whole blood	Capillary or venous whole blood	N/A	N/A	N/A	Capillary or venous
IMPRECISION, CV	2.9-4.2 %	≤3 %		<5 %	<4 %				
ACCURACY	Correlation of 0.96 with NCCLS reference method	Hb 5-10 g/dL, ±0.4 g/dL; Hb 10-25.6 g/dL, ±4%		>96 %	Correlation of R2 = 0.93 vs Sysmex Analyser	±2 g/dL for 6-18 g/dL (95% of results), vs lab reference	Correlation 0.82 with Beckman Coulter Analyzer. SD error 0.86 g/dL.	Within +/-10 % of laboratory value (one reference)	Correlation of 0.99 compared to NCCLS reference method. +/-0.5 HCT
CALIBRATION	Automatic (1 CODE Key per box of cards)	Automatic	Needs coding (code card incl. with every new box of test strips)	Factory calibrated to ICSH method, needs coding of strips	Code-Key		Automatic calibration at start-up		Factory calibrated
SELF-TEST			Monitor checker included with delivery to check electronics	Automatic self checking, auto judging			Automatic at start-up and continuous background calibration check self tests		Each spin cycle checks RPM and alerts user if out of range
QUALITY CONTROL	2 levels of liquid control available	Control strips and Control devices	Control solution available (1 level)	HQ-A Hemoglobin control solution	Control solution for day-to-day precision				3 levels of unrefrigerated liquid controls available

# EKF HEMO CONTROL

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PC INTERFACE	No	USB	No	No	USB	USB, Bluetooth		USB port	No
POWER	Battery operated (one 3V Li CR 2023 Type)	4 AAA or AC adaptor (Mini USB, 5V DC, 50mA)	One 3V Lithium coin cell CR2032	DC 6v, 2xCR2032 batteries	CR2032 coin battery	Rechargeable lithium polymer battery 2 hours in use (max. 140 tests) or AC	Standard AA batteries or AC	Battery-operated 5 hours in use (external battery charger) or AC	
PRINTER	No		No	No	External	External			No
BARCODE READER	No	No	No	No	No	No	No	No	No
CONSUMABLE STORAGE	At room temperature ≤28°C use within 90 days after opening of package (resealed for storage)	2-30 °C, <85 %RH	In a dry, cool place. Keep box closed to protect strips from moisture		1-32 °C	No consumable	No consumable	N/A	15-30C, 2-year shelf life
OPERATING CONDITIONS	16-35 °C, 20-80 %RH	10-40 °C, <90 %RH	18-38°C, <85 %RH		4-40 °C (<85 % RH)	5-40 °C 5-95 %RH		10-40 °C 30-85 %RH	10-40 °C
DEVICE CHARACTERISTICS	LCD display, 3 buttons	LCD screen, 3 buttons	LCD screen, 1 push button	LCD screen, 3 buttons	LCD screen, 2 buttons	Touchscreen	Portable desktop monitor, backlit LCD display, adjustable viewing angle	Integrated soft button mini keyboard	Step by step instructions on display. Multi-lingual menu
SIZE AND WEIGHT (DxWxH)	100 x 55 x 17 mm, 57 g	137 x 79 x 26 mm	100 x 58 x 21 mm, 64 g	120 x 50 x 19 mm	58 x 101.5 x 12.5 mm, 40 g.	13 x 7.2 x 2.4 cm 296.4 g		20.8 x 11.5 x 4.0 cm 544 g	279 x 177 x 127 mm, 907g
RESULT SHOWN	Hemoglobin	Hemoglobin	Hemoglobin and Hematocrit (calculated)	Hemoglobin	Hemoglobin and Hematocrit	Hemoglobin, SpO2, pulse rate, perfusion index	Hemoglobin and pulse rate	Hemoglobin	Hematocrit
APPROVALS	CE, CLIA	CE	CE	CE	CE	CE	CE	CE	CE, FDA 510k, CLIA Waived
OTHER	Light-weight, small hand-held device	Test strip inserts for secure handling of strip and sample application	Blood needs to be applied to the side of the test strip (=reaction zone)	Blood droplet to be applied on to the top of the test strip	Test strip with wing to hold	Finger clip, needs sensor size selection. Affected by nail polish, low local blood circulation, body movement and limited to body weight (infants > 18 month)	Reusable ring-shaped sensor probe that fits on the subject's finger	Digiclip with button sensor (finger clip)	Reagents stable for 3 months once container is opened. Compensates for turbidity.