

Anexa 4 la Formularul Specificații tehnice

Analizator hematologic, automat (3 diff), 40 probe

Specificatia tehnica deplina solicitata	Specificatia tehnica deplina ofertata, model H30 Pro (EDAN INSTRUMENTS, INC., China)
<p>Analizator hematologic, automat (3 diff), tip deschis, 40 probe Cod 150510 Descriere Analizator hematologic automat (3 diff) destinat analizei componentei sanguine Parametrul Specificația Metode de analiză 3 diff Procedura de curățire automată Parametri determinați și calculați: WBC, RBC, HGB HCT MCV, MCH, MCHC PLT LYM MID GRA LYM% MID% GRA% RDW-SD RDW-CV MPV PCT</p> <p>Capacitate (probe/oră) ≥ 40 Diluarea automată Afișaj graphic Imprimantă încorporată, obligatoriu Sistem ID pacient obligatoriu Introducerea datelor manual Interfața PC obligatoriu Afișarea histogramelor obligatoriu Stocarea datelor obligatoriu Calibrarea automată Histograme: WBC- repartizarea leucocitelor după volum RBC- repartizarea eritrocitelor după volum PLT- repartizarea trombocitelor după volum Afișarea pe ecran a tuturor datelor histograme Rezultate Grafice rezultate din arhivă date de service Afișarea rezultatelor pe imprimantă Parametri determinați și calculați- histograme pe parametri de bază- RBC, WBC, PLT, date despre pacient Indicatori de avertizare obligatoriu Control al calității în 3 nivele cu construirea graficelor Levey-Janings Limba de comunicare rom/rus Memorie internă ≥ 1000 pacienți Accesorii: Vas pentru deșeuri tuburi pentru reagenți tuburi pentru spălare Alimentare 220 V, 50 Hz Reagenți:</p>	<p>Analizator hematologic, automat (3 diff), 60 probe; Cod 150510 Descriere Analizator hematologic automat (3 diff) destinat analizei componentei sanguine – pag.2 Brochure-H30 Pro Parametrul Specificația Metode de analiză 3 diff - pag.2 Brochure-H30 Pro Procedura de curățire automată Parametri determinați și calculați: WBC RBC HGB HCT MCV MCH MCHC PLT LYM MID GRA LYM% MID% GRA% RDW-SD RDW-CV MPV PCT *NLR, *PLR - pag.1 Brochure-H30 Pro Capacitate (probe/oră) – 60 teste/ora; pag.1 Brochure-H30 Pro Diluarea automata - pag.2 Brochure-H30 Pro Afișaj graphic - pag.2 Brochure-H30 Pro Imprimantă încorporată obligatoriu - pag.2 Brochure-H30 Pro Sistem ID pacient da - pag.2 Brochure-H30 Pro Introducerea datelor manual - da Interfața PC da - pag.2 Brochure-H30 Pro Afișarea histogramelor da - pag.2 Brochure-H30 Pro Stocarea datelor da - pag.2 Brochure-H30 Pro Calibrarea- automata - pag.2 Brochure-H30 Pro Histograme: da- pag.1 Brochure-H30 Pro WBC- repartizarea leucocitelor după volum RBC- repartizarea eritrocitelor după volum PLT- repartizarea trombocitelor după volum Afișarea pe ecran a tuturor datelor histograme Rezultate grafice rezultate din arhivă date de service Afișarea rezultatelor pe imprimantă Parametri determinați și calculați- histograme pe parametri de bază- RBC, WBC, PLT, date despre pacient Indicatori de avertizare da Control al calității în 3 nivele cu construirea graficelor Levey-Janings Limba de comunicare rom/rus Memorie internă 100 000 pacienți - pag.2 Brochure-H30 Pro Accesorii Vas pentru deșeuri – da, 20l tuburi pentru reagenți - da tuburi pentru spălare - da Alimentare 220 V, 50 Hz</p>

Reagenți "Să fie inclus toți reagenții necesari pentru efectuarea analizelor și buna funcționare a ≥ 500 probe"
Accesorii, consumabile Să fie incluse toate accesoriile, consumabile necesare pentru efectuarea analizelor și buna funcționare pentru ≥ 500 probe
Perioada de valabilitate a reagenților din momentul livrării ≥ 6 luni

Reagenți
Reagenți: vor fi incluși toți reagenții necesari pentru efectuarea analizelor și buna funcționare a ≥ 500 analize
Accesorii, consumabile: vor fi incluse toate accesoriile, consumabile necesare pentru efectuarea analizelor și buna funcționare pentru ≥ 500 probe
Perioada de valabilitate a reagenților din momentul livrării ≥ 6 luni.

H30 Pro Hematology Analyzer

Specification

Parameters

reportable parameters: WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT, LYM, MID, GRA, LYM%
MID%, GRA%, RDW-SD, RDW-CV, PDW-SD, PDW-CV, MPV, PCT

2 RUO parameters: *NLR, *PLR

3 histograms for WBC, RBC and PLT

Performance	Parameter	Linearity Range	Precision (CV %)
	WBC (10 ⁹ /L)	0.0-300	≤2.5% (3.50-15.00)
	RBC (10 ¹² /L)	0.0-8.5	≤1.5% (3.5-6.5)
	HGB (g/L)	0-250	≤1.5% (100-180)
	PLT (10 ⁹ /L)	0-4000	≤5.0% (125-500)
	MCV(fL)	70-120	≤1.0% (70.0-120.0)
	HCT(%)		≤2.0% (30-50)

Principles

Direct impedance method for WBC, RBC and PLT counting
Cyanide free Lyse reagent for hemoglobin test

Sample Volume

Whole blood mode	10 µL
Capillary whole blood mode	10 µL
Pre-diluted mode	20 µL

Reagent

HD310 Diluent 10L/20L
HL310 Lyse 200mL/500mL/1L
HC310 Cleaner 50mL

Operating Environment

Temperature: 15°C~35°C;
Humidity: 20% RH~85% RH;
Air pressure: 70 kPa~106 kPa

Display

10.4 inch TFT color touch screen

Throughput

60 samples per hour

Control and Calibrator

ED-30D, ED-CAL PLUS

Data Storage Capacity

100,000 results including results and histograms
60 QC files (100 data per file)

Dimension and Weight

415mm(L) x 275mm(W) x 406mm(H);
Weight: 18kg

Interface

5 USB ports (for external printer, software upgrade,
barcode scanner, keyboard, mouse), 1 LAN port



Empowering CBC test with maximum capabilities

H30 Pro

Hematology Analyzer



About Edan

Edan is a healthcare company dedicated to improving the human condition around the world by delivering value-driven, innovative and high-quality medical products and services. For over 20 years, Edan has been pioneering a comprehensive line of medical solutions that address a broad range of healthcare practices including:

- Diagnostic ECG
- Patient Monitoring
- OB/GYN
- Ultrasound Imaging
- Point-of-Care Testing
- *In-Vitro* Diagnostics
- Veterinary

Healthcare professionals around the world depend on Edan's breakthrough medical technologies and outstanding customer support.



A world of potential

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Not all products or features are available in all countries, contact Edan for local availability.



ENG-IVD-H30 Pro-V1.0-20220303



A world of potential

H30 Pro

Empowering CBC test with maximum capabilities

H30 Pro is a robust 3-part hematology analyzer integrating a range of advanced features intended for a cost-minded and quality-focused clinical laboratory. The enhanced specification expands clinical capabilities; The brand new operating system simplifies the working process; The quality hardware components ensure reliable performance, and the improved fluidic system reduces reagent consumption. To pursuit higher satisfaction, H30 Pro empowers CBC test with maximum capabilities by

- Giving absolute neutrophil count
- Offering up to 23 parameters including PLR and NLR
- Extending linearity range for WBC and PLT
- Differentiating WBC, RBC, and PLT with adaptive threshold
- Requiring small sample volume for pediatric samples and difficult draw
- Simplifying the working process with an intuitive operation system
- Lowering cost with two routine reagents



Expanded clinical capabilities

- Wider linearity range and better precision meet diversified clinical cases
- 23-parameters test result, including NLR and PLR, helps with the prognosis of infectious and cardiovascular diseases
- Adaptive threshold differentiates WBC, RBC, and PLT with better accuracy
- Original hematology calibrator and controls guarantee the performance



Simplified working process

- 10.4-inch color touch screen with an innovative operating system is simple-to-use and easy-to-navigate
- A handheld barcode scanner allows easy entry of patient ID
- RFID transducer secures the distributors' reagent business
- A built-in thermal printer allows for a fast printout of test reports



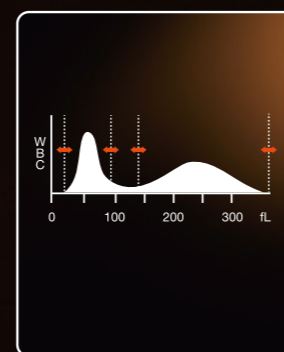
Intuitive operating system



Offering NLR, PLR



Small sample volume



Adaptive threshold



- The memory contains up to 100,000 results, including histograms
- Up to 60 QC files with 100 QC data for each can be stored
- Support external printer, barcode scanner, mouse, and keyboard for flexible connection options
- Bidirectional LIS connectivity via HL7

Effective cost control

- Two routine reagents for sample analysis, up to 120 days on-board stability plus low reagent consumption, provide cost-effective results
- Reliable diagnostics keep costs to a minimum
- Minimal maintenance ensures maximal uptime



H30 Pro

3-Part Hematology Analyzer

Specification





Technical Specifications:

Principles

Direct impedance method for WBC, RBC and PLT counting
Cyanide free Lyse reagent for hemoglobin test

Parameters

reportable parameters: WBC, LYM%, GRA%, RBC, HGB, HCT, MCV, MCH, MCHC, RDW-CV, RDW-SD, PLT, LYM, MPV, PCT, PLCC, PLCR, MID%, MID, GRA, PDW-SD, PDW-CV

2 RUO parameters: *NLR, *PLR

3 histograms for WBC, RBC and PLT

Note: RUO means for research use only.

Reagent

HD310 Diluent 10L/20L

HL310 Lyse 200mL/500mL/1L

HC310 Cleaner 50mL

Sample Volume

Whole blood mode	10 μ L
Capillary Whole blood mode	10 μ L
Pre-diluted mode	20 μ L

Performance

Parameter	Linearity Range	Precision (CV %)
WBC ($10^9/L$)	0.0-300	$\leq 2.5\%$ (3.50-15.00)
RBC ($10^{12}/L$)	0.0-8.5	$\leq 1.5\%$ (3.50-6.50)
HGB (g/L)	0-250	$\leq 1.5\%$ (100-180)
PLT ($10^9/L$)	0-4000	$\leq 5.0\%$ (125-500)
MCV(fL)	70-120	$\leq 1.0\%$ (70.0-120.0)
HCT(%)	30-50	$\leq 2.0\%$ (30-50)

Throughput

60 samples per hour

Display

10.4 inch TFT color Touch Screen

Data Storage Capacity

100,000 results including results and histograms

60 QC files (100 data per file)

Communication

LAN Port supports HL7 protocol

Printout

Built-in thermal printer

External printer supported

Power Requirement

100V-240V, 50Hz/60Hz

Operating Environment

Temperature: 15°C~35°C;

Humidity: 20% RH~85% RH;

Air pressure: 70 kPa~106 kPa

Dimension and Weight

415mm x 275mm x 406mm (length x width x height) ;

Weight: 18kg



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EDAN

EDAN INSTRUMENTS, INC.

DECLARATION OF CONFORMITY TO COUNCIL DIRECTIVE 98/79/EC

MANUFACTURER: Edan Instruments, Inc.
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Pingshan District, 518122 Shenzhen, P.R.China

EUROPEAN REPRESENTATIVE: Shanghai International Holding Corp. GmbH
Eiffestrasse 80, 20537 Hamburg Germany

PRODUCT/ MODEL: Hematology Analyzer/ H30 Pro, H31 Pro, iH30 Pro
Reagents for Hematology Analyzer/ HD310 Diluent,
HL310Lyse, HC310 Cleaner,
ED-30D Hematology Controls,
ED-CAL PLUS Hematology Calibrator.

The accessories are used together with the product

EDMA[Name/Code]: CC Hardware + accessories + consumables + software/23.01.10.01.00
CBC-Reagents(Cleaning-/Diluting-/Lysing-/Sheat-fluids)/13.01.01.01.00
Blood Multilevel Controls/ 13.01.50.03.00
Whole Blood Calibrators/ 13.01.50.07.00

CLASSIFICATION: General/other device, devices other than those covered by Annex II and devices for performance evaluation, non-self-testing, according to article 9 of IVDD.

CONFORMITY ASSESSMENT ROUTE: Annex III

WE, EDAN INSTRUMENTS, INC., HEREWITH DECLARE THAT THE ABOVE MENTIONED PRODUCT(S) MEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF COUNCIL DIRECTIVE 98/79/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 27 OCTOBER 1998 ON IN VITRO DIAGNOSTIC MEDICAL DEVICES
ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER.

STANDARDS APPLIED: EN ISO 14971: 2012, IEC 61010-1:2017, IEC 61010-2-101:2018, EN 61326-1:2013, EN 61326-2-6:2013, EN 62304:2006 +A1: 2015, EN 62366-1:2015, EN 1041: 2008+A1:2013, EN ISO 15223-1:2016, EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN ISO 18113-3:2011, EN 13612:2002, EN 13641:2002, EN ISO 17511:2003 ,EN ISO 23640: 2015

CE MARK



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PLACE, DATE OF ISSUE: SHENZHEN, 2020.12.18

SIGNATURE:

NAME LIU YONGYING
MANAGEMENT REPRESENTATIVE

REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

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DM000331382	ANALIZATOR HEMATOLOGIC		H30 PRO		China	EDAN INSTRUMENTS, INC.