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

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

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

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Date: 2024.01.29 09:41:41 EET
Reason: MoldSign Signature
Location: Moldova

EDAN
A world of potential

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CE

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

Empowering CBC test with maximum capabilities

H30 Pro

Hematology Analyzer

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H30 Pro

Empowering CBC test with maximum capabilities

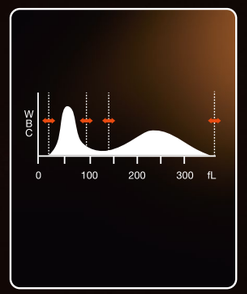
H30 Pro is a robust 3-part hematology analyzer integrating a range of advanced features intended for a cost-minded and quality-focused clinical laboratory. The enhanced specification expands clinical capabilities; The brand new operating system simplifies the working process; The quality hardware components 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

Intuitive operating system

Offering NLR, PLR

Small sample volume



Adaptive threshold

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

- The memory contains up to100,000 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

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CERTIFICATE
OF TRAINING

Sergiu Sorocovici,

From "GBG-MLD" SRL, has successfully completed H30 pro, H60 series training courses including operation and maintenance, and is qualified to offer technical support for above mentioned products.

深圳市理邦精密仪器股份有限公司
EDAN INSTRUMENTS, INC.

_____ International Customer Service Manager

Date Nov 1st, 2023

EDAN INSTRUMENTS, INC.

DECLARATION OF CONFORMITY TO COUNCIL DIRECTIVE 98/79/EC

MANUFACTURER:	Edan Instruments, Inc. #15 Jinhui Road, Jinsha Community, Kengzi Sub-District, 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**

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SIGNATURE: Liu Yongying

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MANAGEMENT REPRESENTATIVE