

Anexa 52 Analizator hematologic, automat (5 diff), cu sistem tip deschis, model H60 (EDAN INSTRUMENTS, INC., China)

Parametri solicitati	Parametri oferiti, model model H60
Analizator hematologic, automat (5 diff), cu sistem de tip deschis, Cod 150530	Analizator hematologic, automat (5 diff), cu sistem de tip deschis, Cod 150530
Descriere Analizator hematologic automat (5 diff) cu sistem de reactivi de tip deschis destinat analizei componenteii sanguine	Descriere Analizator hematologic automat (5 diff) cu sistem de reactivi de tip deschis destinat analizei componenteii sanguine
Parametru Specificația	Parametru Specificația
Tip sistem deschis	Tip sistem deschis
Metode de măsurare impendansmetrică fotometrică	Metode de măsurare impendansmetrică fotometrică
optică (5 diff)	optică (5 diff)
Procedura de curățire automată	Procedura de curățire automată
Parametri determinați și calculați: WBC	Parametri determinați și calculați: WBC
RBC	RBC
Hgb	Hgb
Hct	Hct
MCV	MCV
MCH	MCH
MCHC	MCHC
PLT	PLT
LYM #	LYM #
MON#	MON#
NEU#	NEU#
BAS#	BAS#
EOS#	EOS#
LYM%	LYM%
MON%	MON%
NEU%	NEU%
BAS%	BAS%
EOS%	EOS%
RDW	RDW-CV
PDW	RDW-SD
MPV	PDW
PCT	MPV
Capacitate (probe/oră) ≥ 60	PCT
Diluarea automată	Capacitate (probe/oră) 60
Afișaj grafic	Diluarea automata - DA
Imprimantă color	Afișaj graphic -DA
Introducerea datelor manual	Imprimantă color - External Laser printer
Interfața PC da	Introducerea datelor manual
Afișarea histogramei da	Interfața PC da
Stocarea datelor da	Afișarea histogramei da
Calibrarea automata manuală	Stocarea datelor – DA, 100,000 results
Grafice RBC (repartizarea eritrocitelor după volum)	Calibrarea automata - DA
PLT (repartizarea trombocitelor după volum)	manuală
Scatergrame WBC - 5 diff	Grafice RBC (repartizarea eritrocitelor după volum)
	PLT (repartizarea trombocitelor după volum)

Afișarea pe ecran a tuturor datelor- histograme rezultate grafice rezultate din arhivă date de servis Monitorizarea datelor pacientului nume pacient ID pacient sex vîrsta Monitorizarea reactivelor numărul lotului data expirării volumul rămas Afișarea rezultatelor pe imprimantă Parametri determinați și calculați histograme pe parametrii de bază- RBC, WBC, PLT date despre pacient Indicatori de avertizare da Control al calității ≥ 3 nivele Construirea tabelor și graficelor Levey-Janings Memorie internă > 1000 pacienți Alimentarea 220 V, 50 Hz Accesorii Vas pentru deșeuri tuburi pentru reagenți tuburi pentru spălare Limba de comunicare rom/rus Reagenți Reagenți Să fie inclus toți reagenții necesari pentru efectuarea analizelor și buna funcționare a ≥ 1000 analize Consumabile Sa fie incluse ≥ 1000 eprubete 2,5 ml cu anti-coagulant, pentru colectarea singelui integru, compatibile cu analizorul oferit Perioada de valabilitate a reagentilor din momentul livrării ≥ 6 luni	Scatergrame WBC - 5 diff Afișarea pe ecran a tuturor datelor- histograme rezultate grafice rezultate din arhivă date de servis Monitorizarea datelor pacientului nume pacient ID pacient sex vîrsta Monitorizarea reactivelor numărul lotului data expirării volumul rămas Afișarea rezultatelor pe imprimantă Parametri determinați și calculați histograme pe parametrii de bază- RBC, WBC, PLT date despre pacient Indicatori de avertizare da Control al calității ≥ 3 nivele Construirea tabelor și graficelor Levey-Janings Memorie internă 100000 pacienți Alimentarea 220 V, 50 Hz Accesorii Vas pentru deșeuri - da tuburi pentru reagenți – da, se vor livra impreuna cu dispozitivul tuburi pentru spălare - da Limba de comunicare rus Reagenți Reagenți vor fi inclus toți reagenții necesari pentru efectuarea analizelor și buna funcționare a ≥ 1000 analize Consumabile vor fi incluse ≥ 1000 eprubete 2,5 ml cu anti-coagulant, pentru colectarea singelui integru, compatibile cu analizorul oferit Perioada de valabilitate a reagentilor din momentul livrării ≥ 6 luni - da
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H60 Hematology Analyzer

Specification

Parameters

25 reportable parameters: WBC, Lym%, Mon%, Neu%, Bas%, Eos%, Lym#, Mon#, Neu#, Eos#, Bas#, RBC, HGB, HCT, MCV, MCH, MCHC, RDW-CV, RDW-SD, PLT, MPV, PDW, PCT, P-LCR, P-LCC.

6 research parameters include LIC%, LIC#, ALY%, ALY#, NLR, PLR

2 histograms for RBC and PLT

2 scattergrams for DIFF and BASO

Performance	Parameter	Linearity Range	Precision (CV %)
	WBC (10 ⁹ /L)	0.0-500	≤3.0% (3.50-7.00) ≤2.5% (7.01-15.00)
	RBC (10 ¹² /L)	0.0-8.5	≤1.5%
	HGB (g/L)	0-250	≤1.5%
	PLT (10 ⁹ /L)	0-4000	≤5.0%

Principles

Semiconductor laser flow cytometry analysis for WBC, DIFF and BASO counting

Electrical impedance method for RBC, PLT counting

Cyanide-free reagent for HGB with colorimetric method

Sample Volume

Whole blood mode	16 µL
Capillary whole blood mode	16 µL
Pre-diluted mode	20 µL

Reagent

HD600 Diluent 20L
HL600 Lyse 500mL/1L
HC310 Cleaner 50mL

Operating Environment

Temperature: 15°C~32°C;
Humidity: 30% RH~85% RH;
Air pressure: 70 kPa~106 kPa

Throughput

60 samples per hour

Interface

12 inch colorful touch screen

Control and Calibrator

ED-60D, ED-CAL PLUS

Data Storage Capacity

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

Dimension and Weight

501(D)×320(W)×502.5(H)
Weight: 29.3kg



Deliver reliable results with maximum uptime

H60

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.



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A world of potential

ELEGANT DESIGN AS USUAL

At Edan, we are a new player in the IVD field, while we are well known around the world for the excellence of our medical products. We are a successor in hematology, whereas we are not a follower. We are, as USUAL, to provide professional service and trustable performance to reshape your experience.

We are on a journey to understand your needs, solve your challenges and provide a better solution. Our fundamental goal is to make sure our products truly meet your needs without generating an extra burden. And this is about design.

A good design includes everything, which influences the entire user experience. Our answer is Elegant Design as USUAL.

Within our Elegant Design concept, we are emphasizing five tenets to enhance your experience.

USER | SPACE | OUTLINE | SERIAL | LIFESPAN



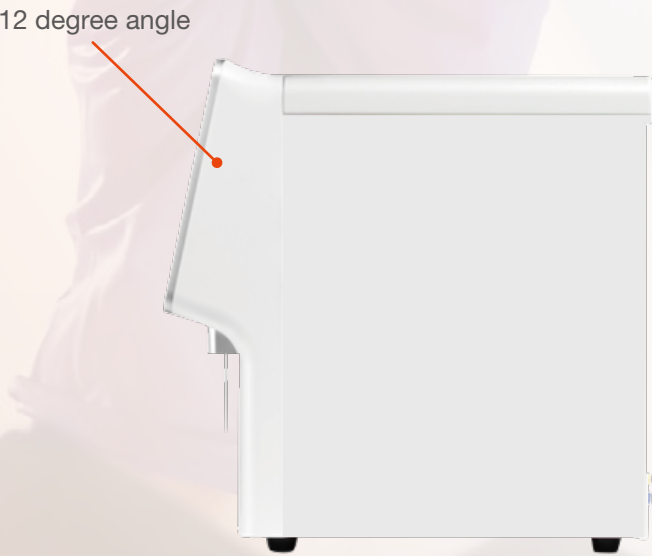
USER
Design with user-oriented

SPACE
Design to suit your surroundings

OUTLINE
Design to simplify your operation

SERIAL
Different model tailored to your needs

LIFESPAN
Design for long product life



H60 SERIES: BRIGHTEN YOUR HEMATOLOGY LIGHTEN YOUR WORK

People who work in the laboratory deserve great respect and attention. It's a challenging job with a high workload and fast response. Every day, with patients and physicians counting on you, you have no space for error and hardly have time to breathe, so you have to be focused at all times. Having the right instrument is the ultimate solution.

We invent the requirements and explore the pain points to develop a new concept in hematology. The hematology approach has been in the market for decades, but many challenges haven't been tackled. Adapted to the fundamental but significant appeal points, the Edan H60 series can well suit your needs.

The Edan H60 series are positioned in low to moderate volume laboratories, committed to lightening your work with an enjoyable experience. Equipped with an integrated, intuitive operation system, it brings a reliable system with clinical values and effective cost control. The Edan H60 series is tailored to you.

FREE YOU WITH MAXIMUM UPTIME

DETAILS THAT LIGHTEN YOUR WORK



Reagent management
via RFID card
secure your reagent
business



12-inch
colorful touch screen

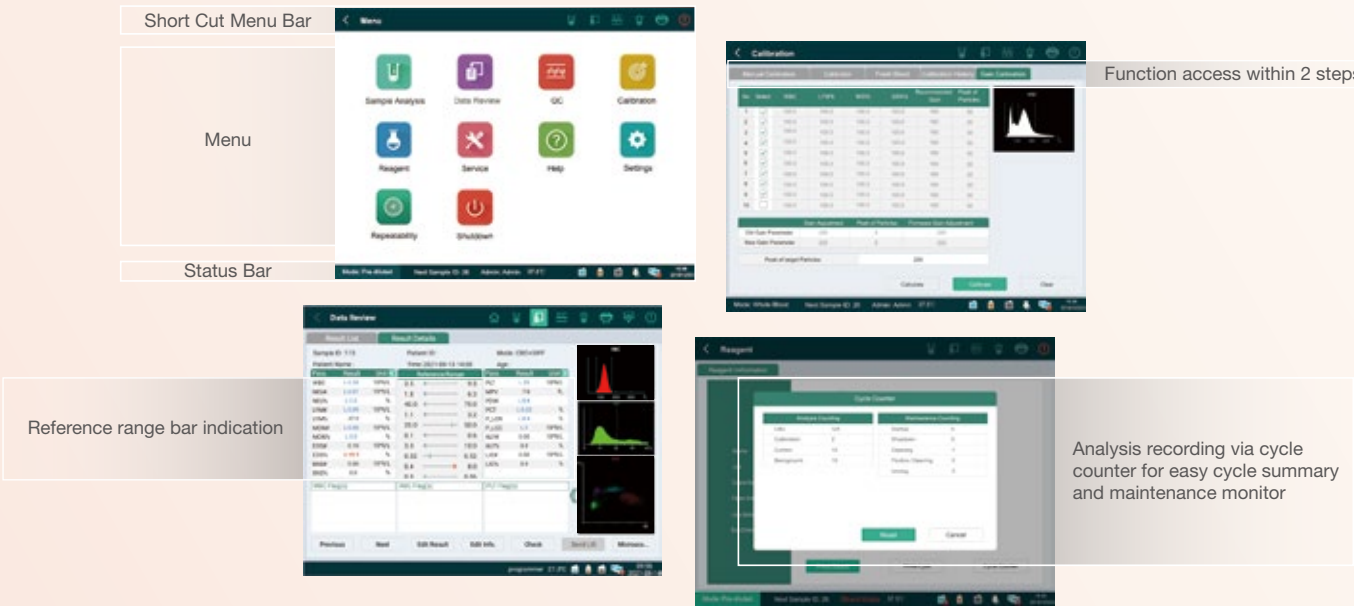


Two routine reagents
to support test



16 microliter of
sample aspiration

INTUITIVE SYSTEM THAT SIMPLIFIES YOUR HANDLING



The system that stands out

The H60S features a whole set of user-oriented functions that are hard to find elsewhere. Its android-based system has a similar experience as a smartphone – pleasure-to-operate and easy-to-use. You can get to any functionality within two steps. The 12-inch colorful touch screen makes working with H60S and viewing its results exceptionally straightforward.

Outstanding graphic interface

The user interface is undoubtedly the most visible and best-appreciated feature of the H60 series. Different set-up views, each optimized for various user situations, facilitate routine use. The most common include a sample view showing classic graphs and all parameters within one page. The other sample view features the most practical reference bar display that indicates the results' status. The comprehensive information on the short-cut menu bar and status bar give you fast access to any primary function.

Communicate and print like never before

An integrated workstation with the HIS and LIS connections further streamlines analysis and reporting. Standardized HL7 protocol and storage capacity extends up to 100,000 easily accessible sample files. The print function has the most flexible options that allow you to print individual sample results and control tests, L-J graphs, or QC lists with any parameters selection.

SENSITIVE FLAGGINGS THAT ASSIST YOUR INSIGHTS

NRBC

NRBC PRESENCE FLAGGING

REMAND TO CORRECT WHITE BLOOD CELL COUNTS BY SMEAR

A scatter plot showing NRBC presence flagging. The plot has a green circle labeled 'NRBC'.

ALY

ABNORMAL LYMPHOCYTE FLAGGING

SUSPICIOUS OF VARIANT LYMPHOCYTES AND MALIGNANT LYMPHOCYTES

A scatter plot showing Abn-Lym flagging. The plot has a green circle labeled 'Abn-Lym'.

EOSINOPHILIA

HIGH SPECIFICITY ON EOSINOPHIL

GREAT DIFFERENATION ON EOSINOPHILIA SAMPLES

A scatter plot showing Eos flagging. The plot has a green circle labeled 'Eos'.

IG

IG PRECENSE FLAGGING

ASSEMENT OF SEPSIS AND INFLAMMATION

COMPRISED OF METAMYELOCYTES, MYELOCYTES & PROMYELOCYTES

A scatter plot showing IG flagging. The plot has a green circle labeled 'IG'.

DIFF

10 DIFF PARAMETERS

HIGH CLUSTERING OF 5-DIFF

TWO 2D SCATTERGRAMS

HIGH SENSITIVITY FLAGGING

A scatter plot showing DIFF flagging. The plot has a green circle labeled 'DIFF'.

A scatter plot showing BASO flagging. The plot has a green circle labeled 'BASO'.



**EDAN**

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/ H60, H60S, H66, H66S, H68, H68S,
H69, H69S
Reagents for Hematology Analyzer/ HD600 Diluent, HL600
Lyse, HC600 Cleaner, ED-60D Control H, ED-
60D Control N, ED-60D Control L 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



START OF CE-MARKING:

2021. 8. 10

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SIGNATURE:

NAME **LIU YONGYING**
MANAGEMENT REPRESENTATIVE