

Anexa 33

150530 Analizator hematologic, automat (5diff)

Specificarea tehnică deplină solicitată de către autoritatea contractantă	Specificatia tehnica ofertata, model <b>H60 (EDAN INSTRUMENTS, INC., China)</b>
<p>Analizator hematologic, automat (5 diff), cu sistem de Cod 150530                      Descriere Analizator hematologic automat (5 diff) destinat analizei componente<span>ei</span> sanguine                      Parametru Specifica<span>ția</span> optică (5 diff)                      Procedura de curățire automată                      Parametri determina<span>ți</span> și calcula<span>ți</span>: WBC                      RBC                      Hgb                      Hct                      MCV                      MCH                      MCHC                      PLT                      LYM #                      MON#                      NEU#                      BAS#                      EOS#                      LYM%                      MON%                      NEU%                      BAS%                      EOS%                      RDW                      PDW                      MPV                      PCT                      Capacitate (probe/oră) ≥ 60                      Diluarea automată                      Afișaj grafic                      Imprimantă color                      Introducerea datelor manual                      Interfața PC obligatoriu                      Afișarea histograme<span>lor</span> obligatoriu                      Stocarea datelor obligatoriu                      Calibrarea automată manuală                      Grafice RBC (repartizarea eritrocitelor după volum)                      PLT (repartizarea trombocitelor după volum)                      Scatergrame WBC - 5 diff                      Afișarea pe ecran a tuturor datelor- histograme rezultate grafice</p>	<p>Analizator hematologic, automat (5 diff), cu sistem de Cod 150530                      Descriere Analizator hematologic automat (5 diff) destinat analizei componente<span>ei</span> sanguine                      Parametru Specifica<span>ția</span> optică (5 diff)                      Procedura de curățire automată                      Parametri determina<span>ți</span> și calcula<span>ți</span>: WBC                      RBC                      Hgb                      Hct                      MCV                      MCH                      MCHC                      PLT                      LYM #                      MON#                      NEU#                      BAS#                      EOS#                      LYM%                      MON%                      NEU%                      BAS%                      EOS%                      RDW-CV                      RDW-SD                      PDW                      MPV                      PCT                      Capacitate (probe/oră) 60                      Diluarea automata - DA                      Afișaj graphic -DA                      Imprimantă color - External Laser printer                      Introducerea datelor manual                      Interfața PC da                      Afișarea histograme<span>lor</span> da                      Stocarea datelor – DA, 100,000 results                      Calibrarea automata - DA manuală                      Grafice RBC (repartizarea eritrocitelor după volum)                      PLT (repartizarea trombocitelor după volum)                      Scatergrame WBC - 5 diff                      Afișarea pe ecran a tuturor datelor- histograme rezultate</p>

<p> 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 obligatoriu  Control al calității <math>\geq 3</math> nivele  Construirea tabelor și graficelor Levey-Janings  Memorie internă <math>\geq 1000</math> 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 <math>\geq 1000</math>  analize"  Consumabile Sa fie incluse <math>\geq 1000</math> eprubete 2,5 ml cu  anti-coagulant, pentru colectarea  singelui integru, compatibile cu analizorul oferit  Perioada de valabilitate a reagentilor din momentul  livrării <math>\geq 6</math> luni </p>	<p> 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 <math>\geq 3</math> 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 <math>\geq 1000</math>  analize  Consumabile vor fi incluse <math>\geq 1000</math> eprubete 2,5 ml cu  anti-coagulant, pentru colectarea singelui integru,  compatibile cu analizorul oferit  Perioada de valabilitate a reagentilor din momentul  livrării <math>\geq 6</math> luni - da </p>
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# H60 Series

5-Part Hematology Analyzer

# Specification





## **Technical Specifications:**

### **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 colorimetry method

### **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 Basophil

### **Reagent**

Routine: HD600, HL600

Maintenance: HC310

## Performance

Parameter	Linearity Range	Precision
WBC(10 <sup>9</sup> /L)	0-500	≤3.0% (3.5-7) ≤2.5% (7.01-15)
RBC(10 <sup>12</sup> /L)	0-8.5	≤1.5% (3.5-6.5)
HGB(g/L)	0-250	≤1.5% (100-180)
MCV(fL)		≤1.0% (70-120)
PLT(10 <sup>9</sup> /L)	0-4000	≤5.0%(100-500)

## Sample Volume

Whole Blood (WB)	16 µL
Capillary (CAP)	16 µL
Pre-diluted (PD)	20µL

## Throughput

60 samples per hour

## Adapter and Autoloader

Adapter supported with various sample tubes

Auto scan via rotating structure

60 samples capacity

## Display

12 inch TFT Touch Screen

## Multi-language

Chinese, English, French, Russian, Spanish

## Data Storage Capacity

Up to 100,000 results including numeric and graphical information

60 QC files (100 data per file)

## Communication

LAN Port supports HL7 protocol

## Input Device

Built-in virtual keyboard, external barcode reader

## Interface

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

1 LAN port

Support LIS/HIS Connectivity

## Printout

External Laser printer / Inkjet printer, various printout formats and User-defined formats

## Operating Environment

Temperature: 15°C~32°C

Humidity: 30% ~ 85%

Air pressure: 70kPa~106kPa

## Power Requirement

100V-240V, 50Hz/60Hz

## Dimension and Weight

H60: 501±5mm (D)×320±5mm (W)×502.5±5mm (H), 29.3±0.5kg

H60S: 626.5±5mm (D)×565±5mm (W)×580±5mm (H), 42.1±0.5kg



**Edan Instruments, Inc.**

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**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

PLACE, DATE OF ISSUE:

SHENZHEN, 2021. 8. 10

SIGNATURE:

NAME **LIU YONGYING**  
MANAGEMENT REPRESENTATIVE



# 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 <sup>9</sup> /L)	0.0-500	≤3.0% (3.50-7.00) ≤2.5% (7.01-15.00)
	RBC (10 <sup>12</sup> /L)	0.0-8.5	≤1.5%
	HGB (g/L)	0-250	≤1.5%
	PLT (10 <sup>9</sup> /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

### Global Headquarters:

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ENG-IVD-H60-V1.2-20211115



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.

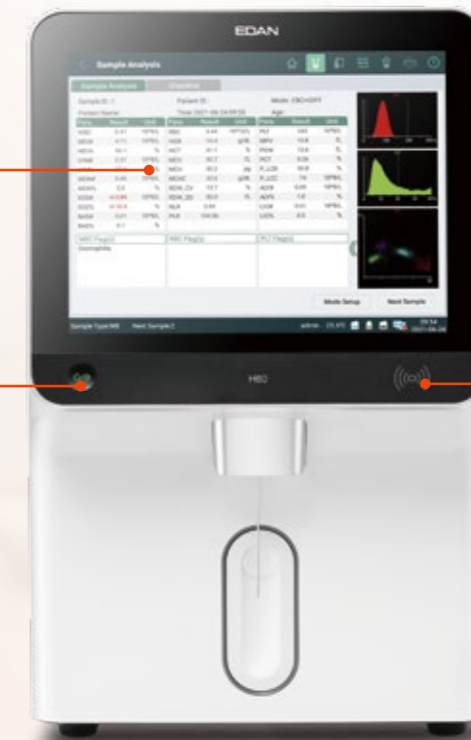
Within our Elegant Design concept, we are emphasizing five tenets to enhance your experience.

**USER | SPACE | OUTLINE | SERIAL | LIFESPAN**

12 inch touch screen

Power button

RFID recognition



## 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

12 degree angle



# 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

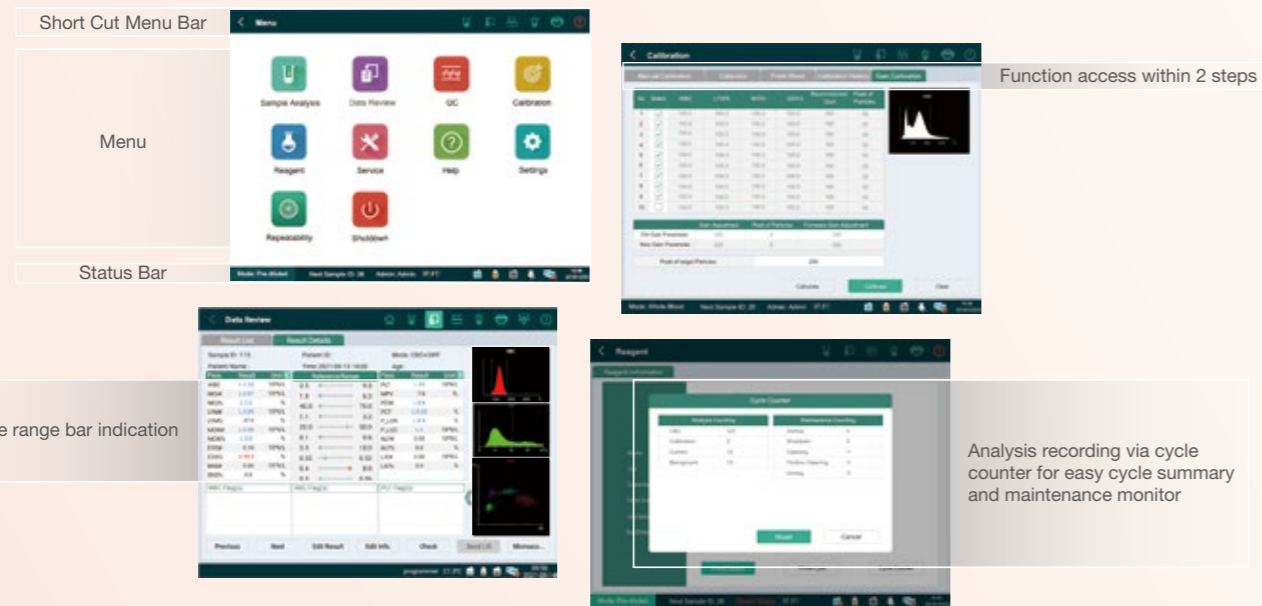


Two routine reagents  
to support test



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.

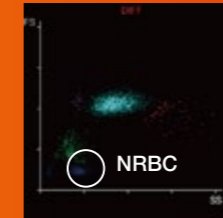
## Communicate and print like never before

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

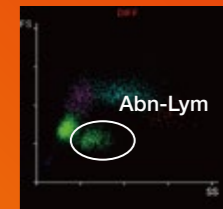
## NRBC

NRBC PRESENCE FLAGGING  
REMINDS TO CORRECT WHITE BLOOD CELL COUNTS BY SMEAR



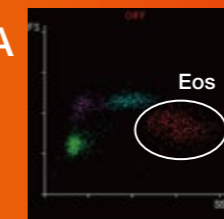
## ALY

ABNORMAL LYMPHOCYTE FLAGGING  
SUSPICIOUS OF VARIANT LYMPHOCYTES AND MALIGNANT LYMPHOCYTES



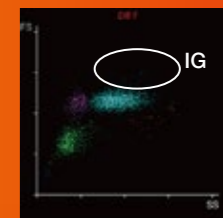
## EOSINOPHILIA

HIGH SPECIFICITY ON EOSINOPHIL  
GREAT DIFFERENTIATION ON EOSINOPHILIA SAMPLES



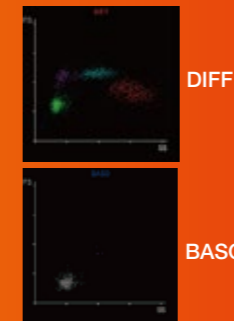
## IG

IG PRESENCE FLAGGING ASSESSMENT OF SEPSIS AND INFLAMMATION  
COMPRISED OF METAMYELOCYTES, MYELOCYTES & PROMYELOCYTES



## DIFF

10 DIFF PARAMETERS  
HIGH CLUSTERING OF 5-DIFF  
TWO 2D SCATTERGRAMS  
HIGH SENSITIVITY FLAGGING



## REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

Введите текст для поиска...						
Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul
						EDAN
DM000331384	ANALIZATOR HEMATOLOGIC		iH30 PRO		China	EDAN INSTRUMENTS, INC.
DM000331390	ANALIZATOR HEMATOLOGIC		H60		China	EDAN INSTRUMENTS, INC.