

Anexa 59 Analizator hematologic, automat (5 diff) Cod 150530, model H60 (EDAN INSTRUMENTS, INC., China)

Parametri solicitati	Parametri ofertati, model model H60
Analizator hematologic, automat (5 diff) Cod 150530	Analizator hematologic, automat (5 diff) Cod 150530
Descriere Analizator hematologic automat (5 diff) cu sistem de reactivi de tip deschis destinat analizei componentei sanguine	Descriere Analizator hematologic automat (5 diff) cu sistem de reactivi de tip deschis destinat analizei componentei sanguine
Parametru Specificația	Parametru Specificația
Metode de măsurare impendansmetrică fotometrică optică (5 diff)	Metode de măsurare impendansmetrică fotometrică optică (5 diff)
Procedura de curățire automată	Procedura de curățire automată
Parametri determinați și calculați:	Parametri determinați și calculați:
WBC	WBC, Lym%, Mon%, Neu%, Bas%, Eos%, Lym#, Mon#, Neu#, Eos#, Bas#, RBC, HGB
RBC	HCT, MCV, MCH, MCHC, RDW-CV, RDW-SD, PLT, MPV, PDW, PCT, P-LCR, P-LCC.
Hgb	8 research parameters include LIC%, LIC#, ALY%, ALY#, NRBC%, NRBC#, NLR, PLR
Hct	3 histograms for WBC, RBC si PLT
MCV	2 scattergrams for DIFF si BASO.
MCH	Capacitate (probe/oră) 60teste ora.
MCHC	Diluarea automată
PLT	Afișaj graphic
LYM #	Imprimantă color
MON#	Introducerea datelor manual
NEU#	Interfața PC da
BAS#	Afișarea histogramelor da
EOS#	Stocarea datelor da
LYM%	Calibrarea automata; manuală
MON%	Grafice
NEU%	RBC (repartizarea eritrocitelor după volum)
BAS%	PLT (repartizarea trombocitelor după volum)
EOS%	Scatergrame WBC - 5 diff
RDW	Afișarea pe ecran a tuturor datelor- histograme
PDW	Rezultate grafice
MPV	rezultate din arhivă
PCT	date de servis
Capacitate (probe/oră) ≥ 60	Monitorizarea datelor pacientului nume pacient
Diluarea automată	ID pacient, sex, vârsta
Afișaj graphic	Monitorizarea reactivelor numărul lotului
Imprimantă color	data expirării
Introducerea datelor manual	volumul rămas
Interfața PC da	Afișarea rezultatelor pe imprimantă Parametri determinați și calculați
Afișarea histogramelor da	histograme pe parametrii de bază- RBC, WBC, PLT
Stocarea datelor da	
Calibrarea automata; manuală	
Grafice	
RBC (repartizarea eritrocitelor după volum)	

<p>PLT (repartizarea trombocitelor după volum) 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 > 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 anticoagulant, pentru colectarea singelui integru, compatibile cu analizorul oferit Perioada de valabilitate a reagentilor din momentul livrării ≥ 6 luni</p>	<p>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 anticoagulant, pentru colectarea singelui integru, compatibile cu analizorul oferit Perioada de valabilitate a reagentilor din momentul livrării ≥ 6 luni</p>
---	---



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 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 ⁹ /L)	0-500	≤3.0% (3.5-7) ≤2.5% (7.01-15)
RBC(10 ¹² /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 ⁹ /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.

No.15 Jinhui Rd., Jinsha Community, Kengzi Subdistrict, Pingshan District, Shenzhen
518122 P.R. China | +86.755.26898326 | www.edan.com.cn | info@edan.com.cn

H60 Hematology Analyzer

Specification

Parameters **NEW**

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.

8 research parameters include LIC%, LIC#, ALY%, ALY#, **NRBC%**, **NRBC#**, NLR,PLR

3 histograms for **WBC**, 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% (3.5-6.5)
	HGB (g/L)	0-250	≤1.5% (100-180)
	PLT (10 ⁹ /L)	0-4000	≤5.0% (100-500)
	MCV (fL)		≤1.0% (70-120)

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:

Edan Instruments, Inc. | 15 Jinhui Road, Pingshan District, Shenzhen, 518122 P.R. China | +86.755.26898326 | www.edan.com | info@edan.com

U.S. and Canada inquiries:

EDAN Diagnostics, Inc. | 9918 Via Pasar, San Diego, CA 92126
+1.858.750.3066 | www.edandiagnostics.com | edan-info@edandiagnostics.com

© Edan Instruments, Inc. All rights reserved. Features and specifications are subject to change without prior notice. No reproduction, copy or transmission may be made without written permission. Not all products or features are available in all countries, contact Edan for local availability.



ENG-IVD-H60-V1.4-20230424



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

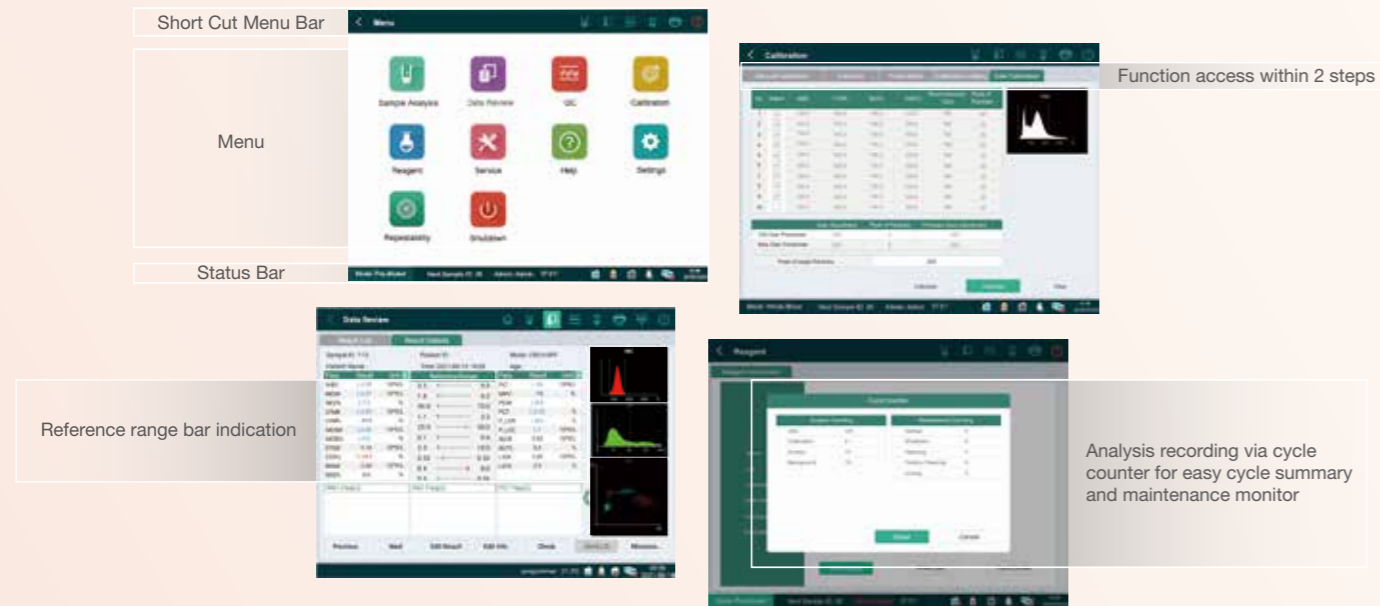


Two routine reagents to support test



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.

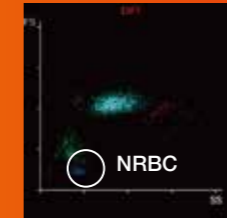
Communicate and print like never before

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
REMINDED TO CORRECT WHITE BLOOD CELL COUNTS BY SMEAR



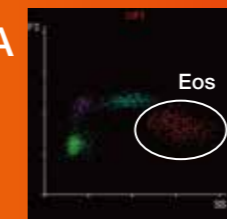
ALY

ABNORMAL LYMPHOCYTE FLAGGING
SUSPICIOUS OF VARIANT LYMPHOCYTES AND MALIGNANT LYMPHOCYTES



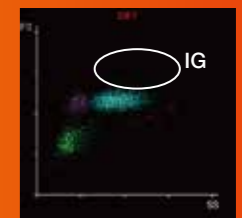
EOSINOPHILIA

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



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

Global Headquarters:

Edan Instruments, Inc. | 15 Jinhui Road, Pingshan District, Shenzhen, 518122 P.R. China | +86.755.26898326 | www.edan.com | info@edan.com

U.S. and Canada inquiries:

EDAN Diagnostics, Inc. | 9918 Via Pasar, San Diego, CA 92126
+1.858.750.3066 | www.edandiagnostics.com | edan-info@edandiagnostics.com

© Edan Instruments, Inc. All rights reserved. Features and specifications are subject to change without prior notice. No reproduction, copy or transmission may be made without written permission. Not all products or features are available in all countries, contact Edan for local availability.



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.

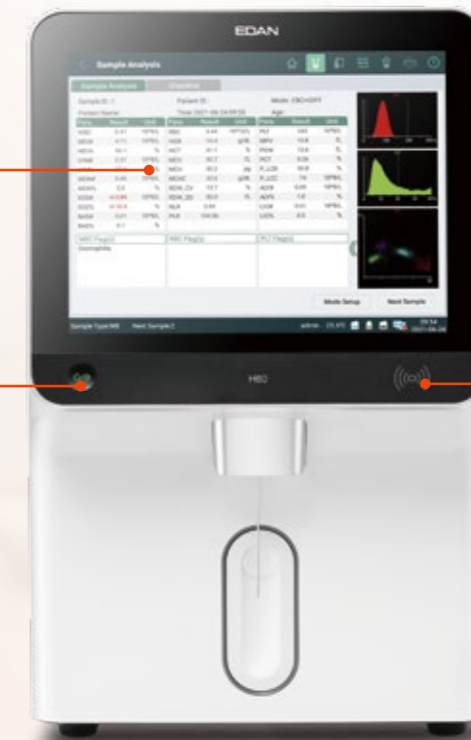
Within our Elegant Design concept, we are emphasizing five tenets to enhance your experience.

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

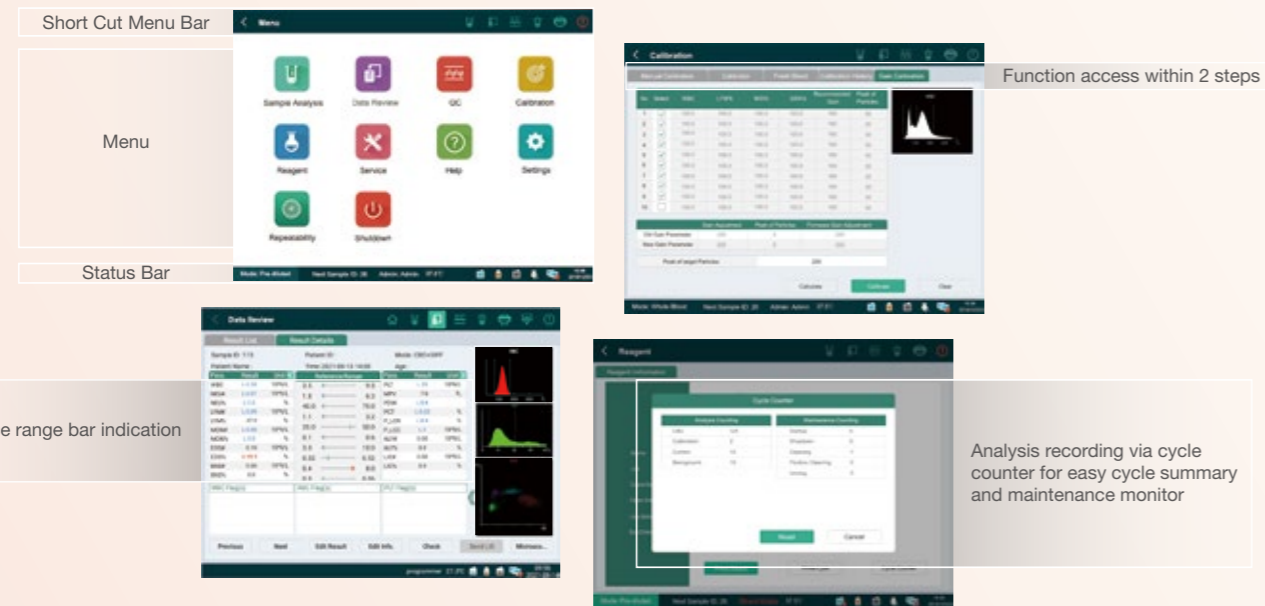


Two routine reagents to support test



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.

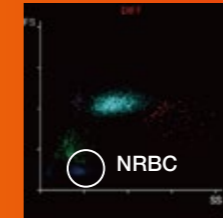
Communicate and print like never before

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

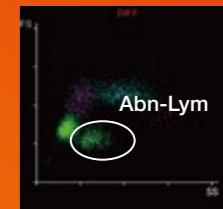
NRBC

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



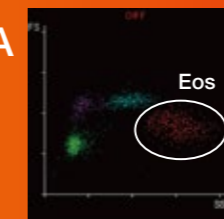
ALY

ABNORMAL LYMPHOCYTE FLAGGING
SUSPICIOUS OF VARIANT LYMPHOCYTES AND MALIGNANT LYMPHOCYTES



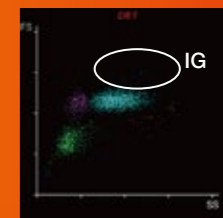
EOSINOPHILIA

HIGH SPECIFICITY ON EOSINOPHIL
GREAT DIFFERENTIATION ON EOSINOPHILIA SAMPLES



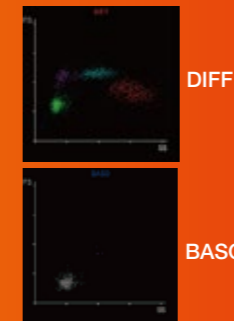
IG

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





Management Service

CERTIFICATE

The Certification Body
of TÜV SÜD Management Service GmbH

certifies that

Edan Instruments, Inc.

#15 Jinhui Road, Jinsha Community, Kengzi Sub-District, Pingshan District
Shenzhen, P.R. China
Post Code: 518122

Unified social credit code: 914403001923672010

has established and applies
a Quality Management System for

Design and Development, Production and Service, Distribution of non-implantable medical devices, In vitro diagnostic medical devices and reagents, software for medical industry, veterinary products, and their related electronic products, accessories, consumables.

An audit was performed, Order No. **748351674**.

Proof has been furnished that the requirements
according to

ISO 9001:2015

are fulfilled.

The certificate is valid from **2022-08-16** until **2024-09-12**.

The certified organization shall undergo and pass
the regular surveillance audit to maintain the validity of this certificate.

Certificate Registration No.: **12 100 61404 TMS**.

Information about this certificate can be inquired at the official website
of Certification and Accreditation Administration of the People's Republic of China (www.cnca.gov.cn).

Head of Certification Body
Munich, 2022-08-18



CERTIFICAT

CERTIFICADO

СЕРТИФИКАТ

認證證書

CERTIFICATE

ZERTIFIKAT



Certificate

No. Q5 091264 0016 Rev. 04

Holder of Certificate: **Edan Instruments, Inc.**
#15 Jinhui Road, Jinsha Community, Kengzi Sub-District
Pingshan District
518122 Shenzhen
PEOPLE'S REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate:

Design and Development, Production and Distribution of Transcranial Doppler System, Fetal Monitor, Fetal & Maternal Monitor, Patient Monitor, Central Monitoring System, Ultrasonic Pocket Doppler, Electrocardiograph, Pulse Oximeter, Digital Ultrasonic Diagnostic Imaging System, STRESS ECG, PC ECG, Vital Signs Monitor, Finger Oximeter, Ultrasonic TableTop Doppler, Data Management Software, Trolley (for medical use), ECG Electrode, Holter System, Treadmill (for medical use), Diagnostic Ultrasound System, Ultrasonic Imaging Management System, Blood Gas and Chemistry Analysis System (including Blood Gas and Chemistry Analyzer, Calibrant Fluid Pack, Test Cartridge, Controls, External electronic simulator, capillary adaptor, Ampoule adaptor), Hematology analyzer; Reagents for Hematology Analyzer (including diluent, lyse, cleaner, bleach, hematology control, hematology calibrator), Video Colposcope, Ultrasonic Transducer, TOCO Transducer, SPO2 Sensor, Temperature Probe, ECG Cable, Telemetry Transmitter, NIBP Cuff, Specific Protein Immunoassay System (including Protein Assay kit, Assay buffer, Sample dilution buffer, Washing buffer, Protein Analyzer), Biofeedback and Stimulation System, EMG/ Stimulation sensor, Ambulatory Blood Pressure Monitor, NIBP Tube, Connection Cable, Water Trap, Needle Guide Bracket, ECG analysis software, Fetal Telemetry System, Holter ECG and ABP System, Blood Sampler, Molecular Diagnostic System (including Molecular Diagnostic Analyzer, Test Kit, Sample Collection Tube), Colloidal Gold Immunosassay Analyzer, Blood Pressure Monitor

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see:

www.tuvsud.com/ps-cert?q=cert:Q5 091264 0016 Rev. 04

Report No.: BJ22089104
Valid from: 2023-06-26
Valid until: 2025-11-30



Date, 2023-06-26

Christoph Dicks
Head of Certification/Notified Body



Product Service

Certificate

No. Q5 091264 0016 Rev. 04

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies): **Edan Instruments, Inc.**
#15 Jinhui Road, Jinsha Community, Kengzi Sub-District,
Pingshan District, 518122 Shenzhen, PEOPLE'S REPUBLIC OF
CHINA

See Scope of Certificate