

Anexa 16 Analizator hematologic automat 3diff, tip deschis, 40 probe

Specificatia tehnica solicitata	Specificatia tehnica ofertata PCE-350 , Erma, Japonia
Analizator hematologic, automat (3diff), tip deschis, 40 probe, Cod 150510 Descriere Analizator hematologic automat (3 diff) destinat analizei componentei sanguine cu sistem deschis de reactivi Parametrul Specificația Tip sistem deschis 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 PDW-SD PDW-CV MPV PCT Capacitate (probe/oră) ≥ 40 Diluarea automată Afișaj graphic Imprimantă încorporată Sistem ID pacient da Introducerea datelor manual Interfața PC da Afișarea histogramelor da Stocarea datelor da 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 parametrii de bază- RBC, WBC, PLT, date despre pacient Indicatori de avertizare da Control al calității în 3 nivele cu construirea graficelor LeveyJanings 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	Analizator hematologic, automat (3diff), tip deschis, 40 probe, Cod 150510 Descriere Analizator hematologic automat (3 diff) destinat analizei componentei sanguine cu sistem deschis de reactivi Parametrul Specificația Tip sistem deschis 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 PDW MPV PCT Capacitate (probe/oră) -60 Diluarea automată Afișaj graphic Imprimantă încorporată Sistem ID pacient da Introducerea datelor manual Interfața PC da Afișarea histogramelor da Stocarea datelor da Calibrarea- manuala 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 parametrii de bază- RBC, WBC, PLT, date despre pacient Indicatori de avertizare da Control al calității în 3 nivele cu construirea graficelor LeveyJanings Limba de comunicare engleza Memorie internă - 1000 pacienți Accesorii : Vas pentru deșeuri, tuburi pentru reagenți, tuburi pentru spălare Alimentare 220 V, 50 Hz Reagenți Reagenți "Vor fi inclusi toți reagenții necesari pentru

Reagenți "Să fie inclus toți reagenții necesari pentru efectuarea analizelor și buna funcționare a ≥ 500 probe" Accesorii, consumabile Să fie incluse toate acesoriile, consumabile necesare pentru efectuarea analizelor și buna funcționare pentru ≥ 500 probe Perioada de valabilitate a reagentilor din momentul livrării ≥ 6 luni	efectuarea analizelor și buna funcționare a ≥ 500 probe"- da Accesorii, consumabile Vor fi incluse toate acesoriile, consumabile necesare pentru efectuarea analizelor și buna funcționare pentru ≥ 500 probe -da Perioada de valabilitate a reagentilor din momentul livrării ≥ 6 luni-da
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ERMA

Full Automatic Blood Cell Counter

PCE-350

Small size, light weight and easy to use



ERMA INC.
TOKYO JAPAN

ERMA Full Automatic Blood Cell Counter PCE-350

Easy, quick and convenient Small size body and light weight

- With up-to-date colour touch screen, simple and easy to use. Data is shown clearly on large display with back light.
- With 20 μ L whole blood sample, you can obtain 18 items of hemogram and 3 kinds of the histogram.

Non cyanide method is adopted
for hemoglobin measurement.



Functions

1

Simple and Quick

To start measurement, the only you have to do is to put the sampling nozzle into a sample container and press the start switch. It needs only 60 seconds to display the result including the histogram.

2

Auto Nozzle Cleaning

The analyzer automatically cleans the remaining blood on the sampling nozzle, so it is safe and there is no risk of touching the blood as well as the error caused by wiping manually.

3

Touch Screen User Interface

For initial setup, setting of measurement condition and cleaning of the liquid circuit etc, you can do them with easy touch screen input.

4

Self-diagnosis

Self-diagnosis function makes the device reliable; it always check for cloggings, the liquid circuit condition, the measured data etc.

5

Cost-reducing

Streamlining the design of device structure including the liquid circuit enable to reduce the cost of the device itself as well as the operating cost.

6

Others

- Auto-priming at power ON and auto-cleaning at power OFF.
- Clogging removal of the detection hole is performed in each measurement.
- Memory capacity: 1,000 samples including histograms. You can set 5 digit sample number and the name of patients.

Feature

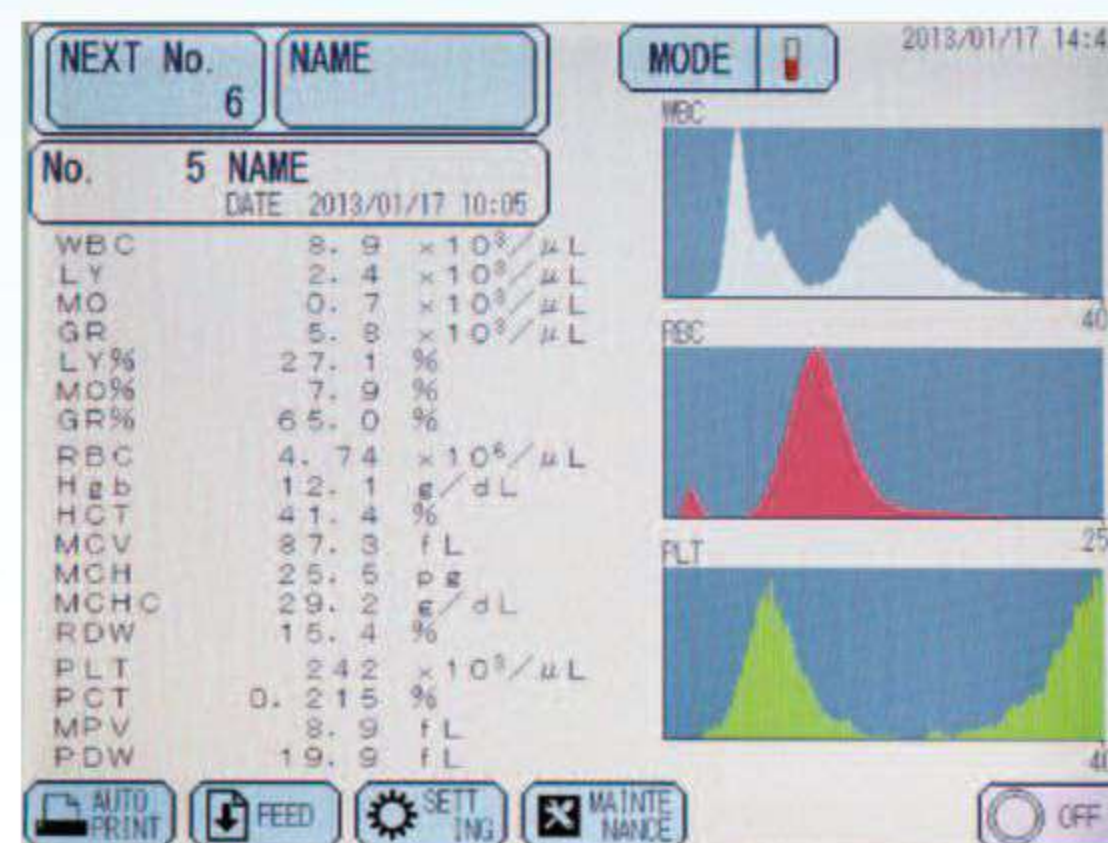
Quick and easy to measure WBC 3-part differentiation

WBC 3-part differentiation into LYM, MID and GRA provide easy access to detailed information that cannot be found from quantitative measurement of WBC, which enable to enhance the efficiency for screening of urgent inflammation and infection.

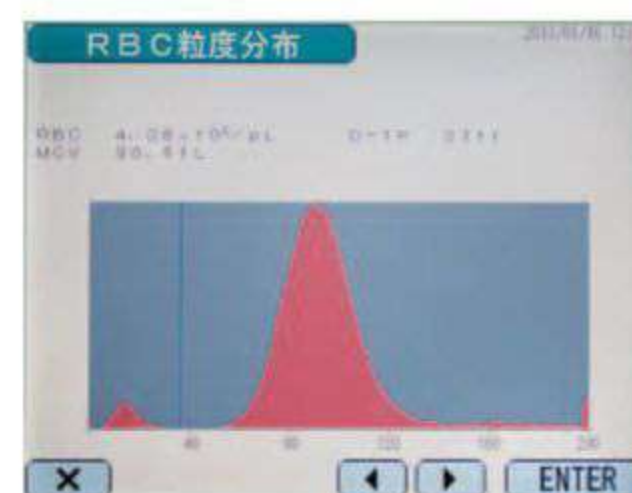
Parameters

WBC : White Blood Cell Count (Cell Count/ μ L e.g.: 81.3 = 81,300 pcs)
 LYM : Lymphocyte count and percent
 MID : Monocyte count and percent
 GRA : Granulocyte count and percent
 RBC : Red Blood Cell Count (Cell Count/ μ L e.g.: 4.57 = 4,570,000 pcs)
 Hgb : Hemoglobin Concentration (gram/100mL)
 HCT : Hematocrit (%)
 MCV : Mean Corpuscular Volume (fL)(the average volume of a red blood corpuscle)
 HCH : Mean Corpuscular Hemoglobin (pg)(the average mass of Hgb per RBC)
 HCHC : Mean Corpuscular Hemoglobin Concentration (g/dL)
 RDW : Red Blood Cell Distribution Width
 PLT : Platelet Count (Cell Count/ μ L e.g.: 337 = 337,000 pcs)
 PCT : Platelet Crit (the ratio of PLT in the sample blood)
 MPV : Mean Platelet Volume (average size of platelets found in blood)
 PDW : Platelet Distribution Width

Display Sample



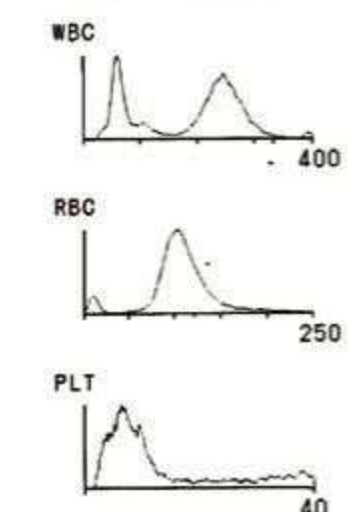
Result Screen



Particle Volume Distribution

Printing Sample

No. 1
 2013/ 3/11 11:16
 WBC 8.0 x10⁹/uL
 LY 2.5 x10⁹/uL
 MO 0.4 x10⁹/uL
 GR 5.1 x10⁹/uL
 LY% 31.2 %
 MO% 4.8 %
 GR% 64.0 %
 RBC 4.60 x10⁶/uL
 Hgb 13.4 g/dL
 HCT 43.9 %
 MCV 95.4 fL
 MCH 29.1 pg
 MCHC 30.5 g/dL
 RDW 14.4 %
 PLT 307 x10³/uL
 PCT 0.264 %
 MPV 8.6 fL
 PDW 10.6 fL



Full Automatic Blood Cell Counter

PCE-350

SPECIFICATION

Parameters

WBC	White Blood Cell Count
LYM	Lymphocyte count and %
MID	Monocyte count and %
GRA	Granulocyte count and %
RBC	Red Blood Cell Count
HGB	Hemoglobin Concentration
HCT	Hematocrit
MCV	Mean Corpuscular Volume
MCH	Mean Corpuscular Hemoglobin
MCHC	Mean Corpuscular Hemoglobin Concentration
RDW	Red Blood Cell Distribution Width
PLT	Platelet Count
PCT	Platelet Crit
MPV	Mean Platelet Volume
PWD	Platelet Distribution Width

Sample Volume

10 μ L, 20 μ L

Throughput

60 samples / hour

Reproductivity

WBC	Within CV 3.0%
RBC	Within CV 2.0%
HGB	Within CV 1.5%
HCT	Within CV 2.0%
MCV	Within CV 1.5%
MCH	Within CV 2.0%
MCHC	Within CV 2.0%
PLT	Within CV 5.0%
MPV	Within CV 5.0%

Measuring Method

Hematology Electrical resistance detection

HGB Colorimetric method

Printer

Built-in thermal printer

External Output

RS232C/USB

Display

Touch Panel Colour LCD with back light

Power Supply

AC100V/220V $\pm$ 10%

Dimensions

220 (W) $\times$ 450 (D) 374 (H) mm

Weight

Approx. 13 kg

ACCESSORIES

User Manual..... 1 copy
Power cord..... 1 pc
Shut-off valve for diluent... 1 pc
Waste Bottle 1 pc

Diluent Bottle..... 1 pc
Detergent Bottle 1 pc
Printing paper..... 1 pc
Diluent Solution..... 1 box

Detergent..... 1 btl.
Lysing Reagent 1 btl.
Fuse 2 pcs
Detergent for Clogging..... 1 btl

CONSUMABLES



Lysing Solution "Hemolyzer 500N" (500 mL)



Diluent Solution "Diluid III (N)" (20 L)



Detergent "M-6" (5 L)



Printing Paper (5 rolls/box)
Dimention: 58 mm x 25m /roll

業許可番号：11BZ006058



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代理店

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25033(M)

The management system of

ERMA INC.

Head Office 2-31-6 Yushima, Bunkyo-ku, Tokyo, 113-0034 Japan

has been assessed and certified as meeting the requirements of

ISO 13485:2016
EN ISO 13485:2016

For the following activities

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 16 November 2018 until 16 November 2021 and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 16 November 2021

Issue 9. Certified since 16 November 2006

This is a multi-site certification.

Additional site details are listed on the subsequent page.

Authorised by

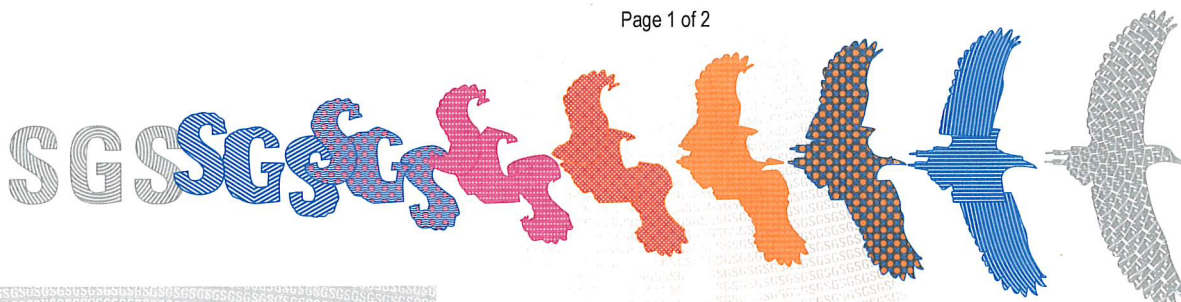



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ERMA INC.

ISO 13485:2016
EN ISO 13485:2016



Issue 9

Detailed scope

- 1. Manufacture and service of blood cell counters, spectrophotometric analyzers for IVD use and bilirubin analyzers**
- 2. Distribution of in-vitro diagnostic products for hemoglobin measurement**

Additional facilities

**Yoshikawa Branch 3-4-8 Kiuri, Yoshikawa-shi, Saitama-ken,
342-0045 Japan**



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