General Description of the Automated Hematology Analyzer, XT-2000*i*

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The automated hematology analyzer, XT-2000i, is the fully automated hematology analyzer capable of performing the differentiation of 5 while blood cell types and screening.
This analyzer was developed to target satellite laboratories and mid range medical facilities based on our technologies for the automated hematology analyzer, XE-2100, with plans to share a scattergram and reagents with XE-2100 and to provide added values by utilizing networks.
By combining conventional and new technologies, XT-2000i realized a compact, high performance and high accuracy instrument.

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Key Words Automated Hematology Analyzer, XT-2000i, Network, Flowcytometry

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INTRODUCTION

As time has passed from the 20th to the 21st century, market environments have changed greatly.
Waves of change are also upon the field of the biological sample test. For example, national medical costs have been reduced, new facilities such as core laboratories and satellite laboratories have emerged, and the information technology is in progress due to the popularization of internet and networks. These new trends are forcing the biological sample test to be changed.
In order to respond to these changes, we have developed the automated hematology analyzer, XT-2000*i* (***Fig. 1***), which is aimed at high performance and high accuracy, based on our technologies for the automated hematology analyzer, XE-2100, released in 1999. The general description of XT-2000*i* is reported below.

Fig. 1 *XT-2000i*

DEVELOPMENT CONCEPT

As mentioned above, in order to provide the solution in response to the change of the times, XT-2000*i* was developed mainly to target satellite laboratories and mid range medical facilities on the basis of the following XE-2100 based concept:

Matching with environmental changes

1) Offering solutions such as case sharing through the use of the XE-2100 scattergram
2) Sharing the user interface with XE-2100

Measures against the reduction of medical costs

1) Reduction of reagent and management costs by commom reagent with XE-2100
2) Reduction of running costs by discrete measurement
3) Efficiency improvement by simultaneous RET measurement

Providing of added values by the use of networks

1) Utilization of the online QC and online support by the Sysmex Network Communication Systems (SNCS)
2) High expandability by using Windows 2000 as a platform

TECHNOLOGY

Measurement principles

Flowcytometry using semiconductor laser

XT-2000*i's* flowcytometry using the semiconductor laser, which technique had been established during the development of XE-2100, provides the common scattergram and reagent system. These sharing principles made XT-2000*i* high performance and high accuracy instrument. The diagram of the flowcytometry using semiconductor laser for XT-2000*i* is shown in ***Fig. 2***.
Scattergrams are generated by this method in the following combinations and analyzed:

(1) WBC/BASO:
Side scattered light – forward scattered light
(2) 4DIFF (NEUT, LYMPH, MONO and EO):
Side scattered light – Side fluorescence
(3) RET: Side fluorescence – forward scattered light
An example of the display of measurement results is shown in ***Fig. 3***.

Hydrodynamic focussing DC detection method

A hydrodynamic focussing DC detection is used for the measurement of RBC and PLT. This method is to enclose the diluted sample ejected from a nozzle with a circumfluent sheath fluid, to allow the sample to flow through the center of an aperture, and to detect the changes in the electric current flowing through the aperture.

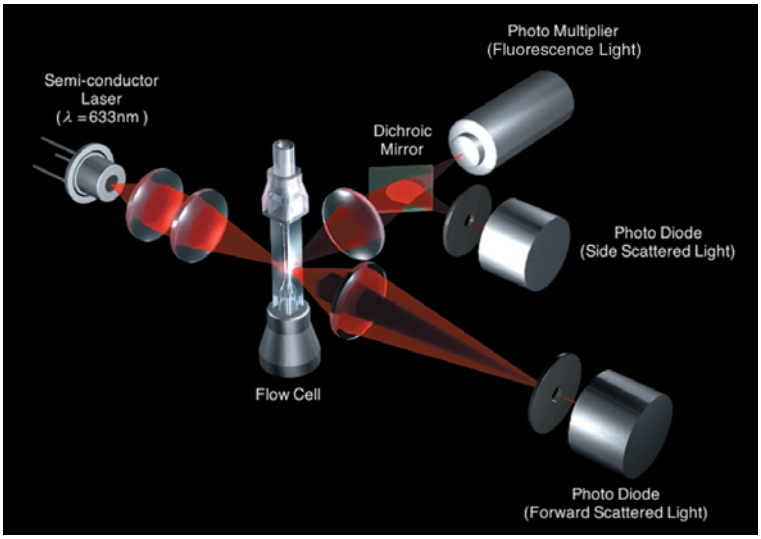

Fig. 2 *Flowcytometry using semiconductor laser*

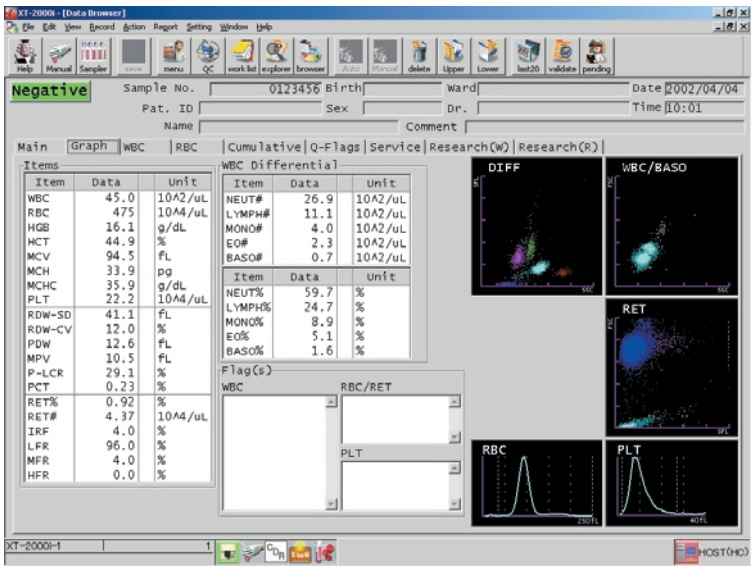

Fig. 3 *Data display screen*

For XT-2000*i*, the detector was developed to be compact and maintained easily. Maintenance procedures such as detachment and attachment of components to both sides of the aperture and washing of the aperture were simplified by changing the direction of sample flow from upward (conventional direction) to horizontal. The schematic diagram of the RBC and PLT detector unit of XT-2000*i* is shown in ***Fig. 4***.

SLS hemoglobin method

HGB is measured by colorimetry using the SLS hemoglobin method, which is employed to almost all HGB measuring analyzers of Sysmex. This method is highly accurate and safe because it is cyanide free.

Combination of conventional technologies with new technologies

Although XT-2000*i* inherits Sysmex existing technologies, it was made compact by combining conventional technologies with new technologies.

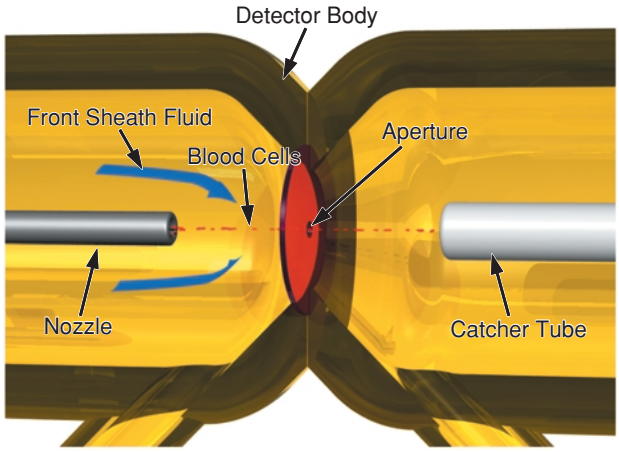

Fig. 4 *Hydrodynamic focussing DC detection in XT-2000i*

Other new technologies employed for the development of XT-2000*i* are deseribed below.

Digital technology

In conventional analyzers including XE-2100, the signal waves obtained by a detector unit were processed by analogue circuits and input to a computer.

On the other hand, in the XT-2000*i*, the digital wave processing is used for the analysis of the signal waves of flowcytometry using a semiconductor laser. In this processing, signal waves from a detector are converted to digital data in real time at very short intervals and processed on a programmed logic.

By employing this digital processing, the analogue circuit, which had occupied a large space conventionally, could be removed and it became possible to make the instrument compact. The wattage could also be reduced as well. This method may be said to be a new technologies matching the 21st century.

Integration of the user interface to information processing unit (IPU), and the use of icons

In XE-2100, all operations for the analyzer unit were performed using the liquid crystal display (LCD) and panel keyboard equipped to the analyzer unit.

In the meanwhile, XT-2000*i*, the user interface is integrated to the IPU which employs Windows 2000 as its OS. By this alternation, overlapping functions could be ommited and the instrument became compact. In addition, the maintenance menu displayed on the LCD of the analyzer unit has been changed to icons to improve a user interface with excellent operability (***Fig. 5***).

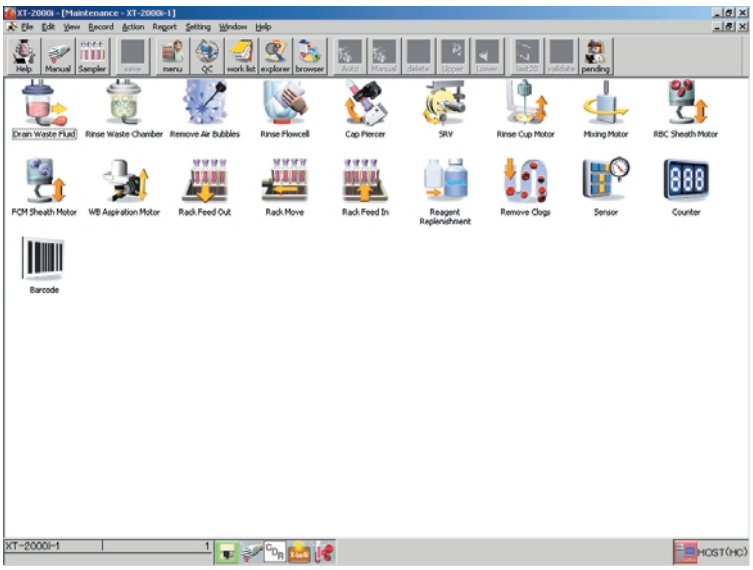

Fig. 5 *Maintenance menu screen*

Table 1 *Reproducibility*

		WBC ($\times10^9$/L)	RBC ($\times10^{12}$/L)	HGB (g/L)	HCT (%)	MCV (fL)	MCH (pg)	MCHC (g/L)	PLT ($\times10^9$/L)	NEUT% (%)	LYMPH% (%)	MONO% (%)	EO% (%)	BASO% (%)	RET% (%)
	MEAN	7.36	4.56	138	43.6	95.7	30.2	316	239	52.3	36.5	5.9	4.6	0.8	0.90
1	SD	0.135	0.0291	0.7	0.28	0.20	0.24	2.4	2.8	0.72	0.56	0.55	0.27	0.15	0.08
	CV (%)	1.83	0.64	0.49	0.64	0.20	0.80	0.75	1.19	1.37	1.54	9.32	5.84	20.12	9.08
	MEAN	4.49	4.45	132	40.9	91.9	29.6	323	219	63.4	25.5	6.9	3.6	0.6	0.98
2	SD	0.079	0.0164	0.4	0.15	0.12	0.20	2.1	3.2	1.04	1.05	0.50	0.31	0.21	0.07
	CV (%)	1.76	0.37	0.32	0.37	0.13	0.66	0.65	1.45	1.64	4.12	7.21	8.49	36.17	7.08
	MEAN	5.07	4.71	145	43.5	92.3	30.7	333	240	53.9	30.8	12.7	2.1	0.5	1.00
3	SD	0.101	0.0204	0.5	0.21	0.16	0.21	2.4	3.4	0.57	1.03	0.68	0.22	0.14	0.07
	CV (%)	1.99	0.43	0.36	0.47	0.18	0.69	0.71	1.40	1.06	3.34	5.38	10.38	29.13	7.09
	MEAN	4.15	4.30	137	42.3	98.4	31.8	323	235	48.4	36.4	9.0	4.8	1.4	0.45
4	SD	0.098	0.0281	0.9	0.25	0.21	0.36	3.4	4.5	1.62	1.31	0.82	0.25	0.16	0.04
	CV (%)	2.36	0.65	0.67	0.60	0.21	1.13	1.07	1.90	3.34	3.61	9.12	5.29	10.96	9.57
	MEAN	5.42	5.56	163	48.3	87.0	29.3	337	185	54.2	36.5	6.2	1.9	1.2	1.34
5	SD	0.113	0.0235	1.2	0.27	0.28	0.25	3.1	5.9	0.72	0.58	0.52	0.23	0.21	0.10
	CV (%)	2.08	0.42	0.77	0.56	0.32	0.87	0.93	3.17	1.32	1.59	8.43	11.95	18.26	7.65

Evaluation results at a final developing stage

As an example of the evaluation results of XT-2000*i* at a final developing stage, the simultaneous reproducibility obtained by 10 times consecutive measurements of blood samples from a healthy men is shown in ***Table 1***.
Good reproducibility was obtained for all items examined.

SPECIFICATIONS

Name

Name : Automated hematology analyzer
Model : XT-2000*i*

Application

The XT-2000*i* provided 30 parameters for human anticoagulated blood samples.
The anticoagulants to be used are EDTA-2K, EDTA-3K and EDTA-2Na.

Instrument composition

1) Analyzer unit
2) Auto Sampler for 50 samples
3) Pneumatic unit
4) IPU

Parameters and principles

Parameters and principles are shown in ***Table 2***.

Required sample volume

1) Manual mode :Approximately 85µL
2) Sampler mode :Approximately 150µL
3) Capillary mode :Approximately 40µL

Throughput

1) CBC :Approximately 80 samples/hr
2) CBC+DIFF :Approximately 80 samples/hr
3) CBC+DIFF+RET :Approximately 80 samples/hr
4) CBC+RET :Approximately 80 samples/hr

IPU

Data storage: 10,000 samples (including scattergrams)
Test order information storage: 1,000 orders

Reagents

The reagents and their uses are shown in ***Table 3***.

Table 2 *Measurement items and principles*

Measurement items		Principles
White blood cell count	(WBC)	Flowcytometry using semiconductor laser
Red blood cell count	(RBC)	Hydrodynamic focussing DC detection method
Hemoglobin	(HGB)	SLS-hemoglobin method
Hematocrit	(HCT)	Red blood cell pulse height detection method
Mean corpuscular volume	(MCV)	Calculation with RBC and HCT
Mean corpuscular hemoglobin	(MCH)	Calculation with RBC and HGB
Mean corpuscular hemoglobin concentration	(MCHC)	Calculation with HCT and HGB concentration
Platelet count	(PLT)	Hydrodynamic focussing DC detection method and flowcytometry using semiconductor laser
RBC distribution width-standard deviation	(RDW-SD)	Analysis from the red blood cell particle size distribution
RBC distribution width-coefficient of variation	(RDW-CV)	
Platelet distribution width**	(PDW)	Analysis from the platelet particle size distribution
Mean platelet volume	(MPV)	
Platelet large cell ratio**	(P-LCR)	
Plateletcrit**	(PCT)	Platelet pulse height detection
Neutrophil percent	(NEUT%)	Flowcytometry using semiconductor laser
Lymphocyte percent	(LYMPH%)	
Monocyte percent	(MONO%)	
Eosinophil percent	(EO%)	
Basophil percent	(BASO%)	
Neutrophil count	(NEUT#)	
Lymphocyte count	(LYMPH#)	
Monocyte count	(MONO#)	
Eosinophil count	(EO#)	
Basophil count	(BASO#)	
Reticulocyte percent	(RET%)	
Reticulocyte count	(RET#)	
Reticulocyte low fluorescence intensity ratio**	(LFR)	
Reticulocyte middle fluorescence intensity ratio**	(MFR)	
Reticulocyte high fluorescence intensity ratio**	(HFR)	
Immature reticulocyte fraction	(IRF)	
Immature granulocyte ratio*	(IG%)	
Immature granulocyte count*	(IG#)	
Other%*	(OTHER%)	
Other#*	(OTHER#)	

*Research items
**Not Reportable in USA

Table 3 *Reagents*

Reagents	Uses
CELL PACK	dilution, sheath solution, cleaning
STROMATOLYSER FB	WBC and BASO measurements
STROMATOLYSER 4DL	NEUT, LYMPH, MONO
STROMATOLYSER 4DS	and EO measurements
SULFOLYSER	HGB measurement
RETSEARCH (Ⅱ)	RET and PLT measurements

CONCLUSIONS

The general description of the newly developed automated hematology analyzer, XT-2000*i*, was reported with employed new technologies and evaluation results.
XT-2000*i* is considered to be the instrument capable of providing the analyses results with highly accuracy and many functions to the various clinical laboratories, while reducing the medical cost by inheriting technologies cultivated in the development of XE-2100. XT-2000*i* is a compact and highly expandable analyzer which is capable of providing new services through the computer network,which will be popularized further, by utilizing the new technologies such as digital signal processing while inheriting existing technologies.
It is our great pleasure if XT-2000*i* will be used practically and the users would realize that the instrument matches the 21st century and feedback ideas and opinions for our offering new solutions in the future.

Reference

1) Inoue H: Overview of automated hematology analyzer XE-2100. Sysmex J Int, 9: 58-64, 1999.