



GUVERNUL
REPUBLICII
MOLDOVA



SERVICIUL FISCAL DE STAT



CERTIFICAT

privind lipsa sau existența restanțelor față de bugetul public național

Nr.
№

1113048

Din
От

18.11.2024 11:13



DATE DESPRE CONTRIBUABIL / ИНФОРМАЦИЯ О НАЛОГОПЛАТЕЛЬЩИКЕ

Codul fiscal / Numărul de identificare

Фискальный код / Идентификационный номер

1010600028048

Denumirea

Наименование

Societatea cu Răspundere Limitată BIOSISTEM MLD



ATESTAREA LIPSEI SAU EXISTENȚEI RESTANȚELOR CONFORM DATELOR SISTEMULUI INFORMAȚIONAL AUTOMATIZAT / ПОДТВЕРЖДЕНИЕ ОТСУТСТВИЯ ИЛИ НАЛИЧИЯ ЗАДОЛЖНОСТЕЙ СОГЛАСНО ДАННЫМ ИНФОРМАЦИОННОЙ АВТОМАТИЗИРОВАННОЙ СИСТЕМЫ

La data emiterii prezentului certificat restanța față de bugetul public național constituie

На дату выдачи данной справки задолженность перед национальным публичным бюджетом составляет

0 MDL



VALABIL PÂNĂ LA / ДЕЙСТВИТЕЛЕН ДО

03.12.2024 11:13



Prezentul document este eliberat în temeiul Art. 29, alin. (3) din Legea cu privire la registre nr. 71/2007 și în baza datelor furnizate de Serviciul Fiscal de Stat în Portalul Guvernamental al Cetățeanului și al Unităților de Drept / Справка выдана в соответствие со ст. 29 п. (3) Закона о реестрах № 71/2007 на основании данных, предоставленных Государственной налоговой службой на Портале Правительства Гражданина и Юридических Лиц.

Generat și semnat de Portalul Guvernamental al Cetățeanului și al Unităților de Drept la 18.11.2024 11:13

Prezentul certificat este semnat electronic în conformitate cu Legea nr.124 din 19.05.2022

Сертификат подписан электронной подписью в соответствии с Законом № 124 от 19.05.2022



Certificatul este descărcat din Portalul Guvernamental al Cetățeanului și al Unităților de Drept (mcabinet.gov.md) și este semnat electronic de către posesorul acestui portal și are aceeași valoare juridică ca și documentele eliberate pe suport de hârtie de către organele cu atribuții de administrare fiscală. Verificarea autenticității semnăturii electronice poate fi realizată cu ajutorul Serviciului Guvernamental de Semnătură Electronică (msign.gov.md)

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REPUBLICA



MOLDOVA

CERTIFICAT DE ÎNREGISTRARE

Societatea cu Răspundere Limitată "BIOSISTEM MLD"
— ESTE ÎNREGISTRATĂ LA CAMERA ÎNREGISTRĂRII DE STAT —

Numărul de identificare de stat - codul fiscal
1010600028048

Data înregistrării

12.08.2010

Data eliberării

12.08.2010

Svirepova Ludmila, registrator

*Funcția, numele, prenumele persoanei
care a eliberat certificatul*

L. Svirepova
semnătura

MD 0101250





AGENȚIA SERVICII PUBLICE

Departamentul înregistrare și licențiere a unităților de drept

EXTRAS

din Registrul de stat al persoanelor juridice

Nr. 531522 data 15.09.2023

Denumirea completă: **Societatea cu Răspundere Limitată "BIOSISTEM MLD"**

Denumirea prescurtată: **"BIOSISTEM MLD" S.R.L.**

Forma juridică de organizare: **Societate cu răspundere limitată,**

Numărul de identificare de stat și codul fiscal (IDNO): **1010600028048**

Data înregistrării de stat: **12.08.2010**

Sediul: **MD-2001, str. Albișoara, 16/1, ap. 7, mun. Chișinău, Republica Moldova.**

Obiectul principal de activitate:

- 1. Activitatea farmaceutică; importul și (sau) producerea articolelor de parfumerie și cosmetică**
- 2. Fabricarea, comercializarea, asistența tehnică, repararea și verificarea articolelor de tehnică și optică medicală**
- 3. Acordarea asistenței medicale de către instituțiile medico-sanitare private**
- 4. Comerțul cu ridicata al calculatoarelor, echipamentelor periferice și software-ului**
- 5. Întreținerea și repararea mașinilor de birou și a tehnicii de calcul**
- 6. Consultații în domeniul sistemelor de calcul**

Capitalul social: **5400 lei.**

Administrator: **POIATA VITALIE, IDNP 0983103892591,**

Asociații:

1. **POIATA VITALIE, IDNP 0983103892591, cota 1803,60 lei, ce constituie 33,4%**

Beneficiar efectiv:

- 1.1. **POIATA VITALIE, IDNP 0983103892591,**

2. **NASEDCHIN ALEXANDR, IDNP 2002001070747, cota 1798,20 lei, ce constituie 33,3%**

Beneficiar efectiv:

- 2.1. **NASEDCHIN ALEXANDR, IDNP 2002001070747,**

3. **KOJEVNIKOV DMITRII, IDNP 0972305012362, cota 1798,20 lei, ce constituie 33,3%**

Beneficiar efectiv:

- 3.1. **KOJEVNIKOV DMITRII, IDNP 0972305012362**

Prezentul extras este eliberat în temeiul art.34 al Legii nr.220-XVI din 19 octombrie 2007 privind înregistrarea de stat a persoanelor juridice și a întreprinzătorilor individuali și confirmă datele din Registrul de stat la data de: **15.09.2023.**

**Registrator în domeniul
înregistrării de stat**

Digitally signed by Rusu Diana
Date: 2023.09.15 16:44:17 EEST
Reason: MoldSign Signature
Location: Moldova



Rusu Diana



EB 0461494



BC "MOLDINDCONBANK" S.A.

Filiala "Invest"

Republica Moldova, MD-2068
mun. Chișinău, bd. Moscovei, 14/1
Tel. : (373-22) 43-44-81, 43-46-24
Fax : (373-22) 43-44-22
cod: MOLDMD2X329

Data 14. IAN. 2016
Nr. 03/2 - 19/23

Республика Молдова, MD-2068
мун. Кишинэу, бул. Московской, 14/1
Тел. : (373-22) 43-44-81, 43-46-24
Факс : (373-22) 43-44-22
код: MOLDMD2X329

Filiala „Invest” BC „Moldindconbank” SA confirmă existența contului curent în moneda națională al **“BIOSISTEM MLD” S.R.L. (c/f 1010600028048)**, cu **IBAN MD95ML000000002251429243.**

Codul băncii MOLDMD2X329.

Director

Nina Turcan

Director financiar



Nina Balmuş

Ex. Diana Brinza
Tel. 43-45-96

Lista fondatorilor Biosistem-mld SRL

Nr.	Nume, Prenume	IDNP
1.	Vitalie Poiata	0983103892591
2.	Alexandr Nasedchin	2002001070747
3.	Dmitrii Kojevnikov	0972305012362

SITUAȚIILE FINANCIARE

pentru perioada 01.01.2023 - 31.12.2023

Entitatea: BIOSISTEM MLD S.R.L.

Cod CUIÎO: 40717392

Cod IDNO: 1010600028048

Sediul:

MD:

Raionul(municipiul): 106, DDF RASCANI

Cod CUATM: 0150, SEC.RISCANI

Strada: Albisoara nr.16 bl.1 of.7

Activitatea principală: G4646, Comert cu ridicata al produselor farmaceutice

Forma de proprietate: 16, Proprietate colectivă

Forma organizatorico-juridică: 530, Societăți cu răspundere limitată

Date de contact:

Telefon: +37322808719

WEB:

E-mail: zmii13@mail.ru

Numele și coordonatele al contabilului-șef: DI (dna) Tel.

Numărul mediu al salariaților în perioada de gestiune: 10 persoane.

Persoanele responsabile de semnarea situațiilor financiare* Nasedchin Alexandr

Unitatea de măsură: leu

BILANȚUL

Anexa 1

Nr. cpt.	Indicatori	Cod rd.	Sold la	
			Începutul perioadei de gestiune	Sfârșitul perioadei de gestiune
1	2	3	4	5
	A C T I V			
A.	ACTIVE IMOBILIZATE			
	I. Imobilizări necorporale			
	1. Imobilizări necorporale în curs de execuție	010		
	2. Imobilizări necorporale în exploatare, total	020		
	din care:			
	2.1. concesiuni, licențe și mărci	021		
	2.2. drepturi de autor și titluri de protecție	022		
	2.3. programe informatice	023		

2.4. alte imobilizări necorporale	024		
3. Fond comercial	030		
4. Avansuri acordate pentru imobilizări necorporale	040		
Total imobilizări necorporale (rd.010 + rd.020 + rd.030 + rd.040)	050		
II. Imobilizări corporale			
1. Imobilizări corporale în curs de execuție	060		
2. Terenuri	070		
3. Mijloace fixe, total	080	3384131	4438372
din care:	081		
3.1. clădiri			
3.2. construcții speciale	082		
3.3. mașini, utilaje și instalații tehnice	083	3363063	4423127
3.4. mijloace de transport	084		
3.5. inventar și mobilier	085	21068	15245
3.6. alte mijloace fixe	086		
4. Resurse minerale	090		
5. Active biologice imobilizate	100		
6. Investiții imobiliare	110		
7. Avansuri acordate pentru imobilizări corporale	120	5250844	2337159
Total imobilizări corporale (rd.060 + rd.070 + rd.080 + rd.090 + rd.100 + rd.110 + rd.120)	130	8634975	6775531
III. Investiții financiare pe termen lung			
1. Investiții financiare pe termen lung în părți neafiliate	140		
2. Investiții financiare pe termen lung în părți afiliate, total	150		
din care:	151		
2.1. acțiuni și cote de participație deținute în părțile afiliate			
2.2 împrumuturi acordate părților afiliate	152		
2.3 împrumuturi acordate aferente intereselor de participare	153		
2.4 alte investiții financiare	154		
Total investiții financiare pe termen lung (rd.140 + rd.150)	160		
IV. Creanțe pe termen lung și alte active imobilizate			
1. Creanțe comerciale pe termen lung	170		
2. Creanțe ale părților afiliate pe termen lung	180		
inclusiv: creanțe aferente intereselor de participare	181		
3. Alte creanțe pe termen lung	190		

	4. Cheltuieli anticipate pe termen lung	200		
	5. Alte active imobilizate	210		
	Total creanțe pe termen lung și alte active imobilizate (rd.170 + rd.180 + rd.190 + rd.200 + rd.210)	220		
	TOTAL ACTIVE IMOBILIZATE (rd.050 + rd.130 + rd.160 + rd.220)	230	8634975	6775531
B.	ACTIVE CIRCULANTE			
	I. Stocuri			
	1. Materiale și obiecte de mică valoare și scurtă durată	240	13899	24776
	2. Active biologice circulante	250		
	3. Producția în curs de execuție	260		
	4. Produse și mărfuri	270	11123640	11490033
	5. Avansuri acordate pentru stocuri	280		
	Total stocuri (rd.240 + rd.250 + rd.260 + rd.270 + rd.280)	290	11137539	11514809
	II. Creanțe curente și alte active circulante			
	1. Creanțe comerciale curente	300	4552459	2646694
	2. Creanțe ale părților afiliate curente	310		
	inclusiv: creanțe aferente intereselor de participare	311		
	3. Creanțe ale bugetului	320	27696	45618
	4. Creanțele ale personalului	330		
	5. Alte creanțe curente	340		
	6. Cheltuieli anticipate curente	350		
	7. Alte active circulante	360	2268111	2251145
	Total creanțe curente și alte active circulante (rd.300 + rd.310 + rd.320 + rd.330 + rd.340 + rd.350 + rd.360)	370	6848266	4943457
	III. Investiții financiare curente			
	1. Investiții financiare curente în părți neafiliate	380		
	2. Investiții financiare curente în părți afiliate, total	390		
	din care:			
	2.1. acțiuni și cote de participație deținute în părțile afiliate	391		
	2.2. împrumuturi acordate părților afiliate	392		
	2.3. împrumuturi acordate aferente intereselor de participare	393		
	2.4. alte investiții financiare în părți afiliate	394		
	Total investiții financiare curente (rd.380 + rd.390)	400		
	IV. Numerar și documente bănești	410	10281443	27361722
	TOTAL ACTIVE CIRCULANTE (rd.290 + rd.370 + rd.400 + rd.410)	420	28267248	43819988

	TOTAL ACTIVE (rd.230 + rd.420)	430	36902223	50595519
	P A S I V			
	CAPITAL PROPRIU			
	I. Capital social și neînregistrat			
	1. Capital social	440	5400	5400
	2. Capital nevărsat	450	()	()
	3. Capital neînregistrat	460		
	4. Capital retras	470	()	()
	5. Patrimoniul primit de la stat cu drept de proprietate	480		
	Total capital social și neînregistrat (rd.440 + rd.450 + rd.460 + rd.470 + rd.480)	490	5400	5400
	II. Prime de capital	500		
	III. Rezerve			
	1. Capital de rezervă	510		
	2. Rezerve statutare	520		
	3. Alte rezerve	530		
	Total rezerve (rd.510 + rd.520 + rd.530)	540		
	IV. Profit (pierdere)			
	1. Corecții ale rezultatelor anilor precedenți	550	X	
	2. Profit nerepartizat (pierdere neacoperită) al anilor precedenți	560	35876971	29813141
	3. Profit net (pierdere netă) al perioadei de gestiune	570	X	18618853
	4. Profit utilizat al perioadei de gestiune	580	X	()
	Total profit (pierdere) (rd.550 + rd.560 + rd.570 + rd.580)	590	35876971	48431994
	V. Rezerve din reevaluare	600		
	VI. Alte elemente de capital propriu	610		
	TOTAL CAPITAL PROPRIU (rd.490 + rd.500 + rd.540 + rd.590 + rd.600 + rd.610)	620	35882371	48437394
C.				
	DATORII PE TERMEN LUNG			
	1. Credite bancare pe termen lung	630		
	2. Împrumuturi pe termen lung	640		
	din care:			
	2.1. împrumuturi din emisiunea de obligațiuni	641		
	inclusiv: împrumuturi din emisiunea de obligațiuni convertibile	642		
	2.2. alte împrumuturi pe termen lung	643		
	3. Datorii comerciale pe termen lung	650		
D.				

	4. Datorii față de părțile afiliate pe termen lung	660		
	inclusiv: datorii aferente intereselor de participare	661		
	5. Avansuri primite pe termen lung	670		
	6. Venituri anticipate pe termen lung	680		
	7. Alte datorii pe termen lung	690		
	TOTAL DATORII PE TERMEN LUNG (rd.630 + rd.640 + rd.650 + rd.660 + rd.670 + rd.680 + rd.690)	700		
E.	DATORII CURENTE			
	1. Credite bancare pe termen scurt	710		
	2. Împrumuturi pe termen scurt, total	720		
	din care:	721		
	2.1. împrumuturi din emisiunea de obligațiuni			
	inclusiv: împrumuturi din emisiunea de obligațiuni convertibile	722		
	2.2. alte împrumuturi pe termen scurt	723		
	3. Datorii comerciale curente	730	5266	59765
	4. Datorii față de părțile afiliate curente	740		
	inclusiv: datorii aferente intereselor de participare	741		
	5. Avansuri primite curente	750	143160	273711
	6. Datorii față de personal	760	866	
	7. Datorii privind asigurările sociale și medicale	770		
	8. Datorii față de buget	780	831429	1766706
	9. Datorii față de proprietari	790		
	10. Venituri anticipate curente	800		
	11. Alte datorii curente	810	39131	57943
	TOTAL DATORII CURENTE (rd.710 + rd.720 + rd.730 + rd.740 + rd.750 + rd.760 + rd.770 + rd.780 + rd.790 + rd.800 + rd.810)	820	1019852	2158125
F.	PROVIZIOANE			
	1. Provizioane pentru beneficiile angajaților	830		
	2. Provizioane pentru garanții acordate cumpărătorilor/clientilor	840		
	3. Provizioane pentru impozite	850		
	4. Alte provizioane	860		
	TOTAL PROVIZIOANE (rd.830 + rd.840 + rd.850 + rd.860)	870		
	TOTAL PASIVE (rd.620 + rd.700 + rd.820 + rd.870)	880	36902223	50595519

SITUAȚIA DE PROFIT ȘI PIERDERE

de la 01.01.2023 până la 31.12.2023

Anexa 2

Indicatori	Cod rd.	Perioada de gestiune
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		precedenta	curenta
1	2	3	4
Venituri din vânzări, total	010	40621876	58891757
din care:			
venituri din vânzarea produselor și mărfurilor	011	39203671	57105542
venituri din prestarea serviciilor și executarea lucrărilor	012	1390733	1771148
venituri din contracte de construcție	013		
venituri din contracte de leasing	014		
venituri din contracte de microfinanțare	015		
alte venituri din vânzări	016	27472	15067
Costul vânzărilor, total	020	22086174	32917436
din care:			
valoarea contabilă a produselor și mărfurilor vândute	021	21991682	32793096
costul serviciilor prestate și lucrărilor executate terților	022	92356	124340
costuri aferente contractelor de construcție	023		
costuri aferente contractelor de leasing	024		
costuri aferente contractelor de microfinanțare	025		
alte costuri aferente vânzărilor	026	2136	
Profit brut (pierdere brută) (rd.010 - rd.020)	030	18535702	25974321
Alte venituri din activitatea operațională	040	128694	829270
Cheltuieli de distribuire	050	15271	4167
Cheltuieli administrative	060	3076978	3996115
Alte cheltuieli din activitatea operațională	070	1325483	879808
Rezultatul din activitatea operațională: profit (pierdere) (rd.030 + rd.040 - rd.050 - rd.060 - rd.070)	080	14246664	21923501
Venituri financiare, total	090	1530710	1070406
din care:			
venituri din interese de participare	091		
inclusiv: veniturile obținute de la părțile afiliate	092		
venituri din dobânzi	093	250190	337916
inclusiv: veniturile obținute de la părțile afiliate	094		
venituri din alte investiții financiare pe termen lung	095		
inclusiv: veniturile obținute de la părțile afiliate	096		
venituri aferente ajustărilor de valoare privind investițiile financiare pe termen lung și curente	097		
venituri din ieșirea investițiilor financiare	098		
venituri aferente diferențelor de curs valutar și de sumă	099	1280520	732490

Cheltuieli financiare, total	100	512939	1786338
din care:	101		
cheltuieli privind dobânzile			
inclusiv: cheltuielile aferente părților afiliate	102		
cheltuieli aferente ajustărilor de valoare privind investițiile financiare pe termen lung și curente	103		
cheltuieli aferente ieșirii investițiilor financiare	104		
cheltuieli aferente diferențelor de curs valutar și de sumă	105	512939	1786338
Rezultatul: profit (pierdere) financiar(ă) (rd.090 - rd.100)	110	1017771	-715932
Venituri cu active imobilizate și excepționale	120		
Cheltuieli cu active imobilizate și excepționale	130		
Rezultatul din operațiuni cu active imobilizate și excepționale: profit (pierdere) (rd.120 - rd.130)	140		
Rezultatul din alte activități: profit (pierdere) (rd.110 + rd.140)	150	1017771	-715932
Profit (pierdere) pînă la impozitare (rd.080 + rd.150)	160	15264435	21207569
Cheltuieli privind impozitul pe venit	170	1872862	2588716
Profit net (pierdere netă) al perioadei de gestiune (rd.160 - rd.170)	180	13391573	18618853

SITUAȚIA MODIFICĂRILOR CAPITALULUI PROPRIU

de la pînă la

Anexa 3

Nr. d/o	Indicatori	Cod rd	Sold la începutul perioadei de gestiune	Majorări	Diminuări	Sold la sfîrșitul perioadei de gestiune
1	2	3	4	5	6	7
I.	Capital social și neînregistrat					
	1. Capital social	010				
	2. Capital nevărsat	020	()	()	()	()
	3. Capital neînregistrat	030				
	4. Capital retras	040	()	()	()	()
	5. Patrimoniul primit de la stat cu drept de proprietate	050				
	Total capital social și neînregistrat (rd.010 + rd.020 + rd.030 + rd.040 + rd.050)	060				
II.	Prime de capital	070				
III.	Rezerve					
	1. Capital de rezervă	080				
	2. Rezerve statutare	090				

	3. Alte rezerve	100				
	Total rezerve (rd.080 + rd.090 + rd.100)	110				
IV.	Profit (pierdere)					
	1. Corecții ale rezultatelor anilor precedenți	120	X			
	2. Profit nerepartizat (pierdere neacoperită) al anilor precedenți	130				
	3. Profit net (pierdere netă) al perioadei de gestiune	140	X			
	4. Profit utilizat al perioadei de gestiune	150	X	()	()	()
	Total profit (pierdere) (rd.120 + rd.130 + rd.140 + rd.150)	160				
V.	Rezerve din reevaluare	170				
VI.	Alte elemente de capital propriu	180				
	Total capital propriu (rd.060 + rd.070 + rd.110 + rd.160 + rd.170 + rd.180)	190				

SITUAȚIA FLUXURILOR DE NUMERAR
de la până la

Anexa 4

Indicatori	Cod rd	Perioada de gestiune	
		precedentă	curentă
1	2	3	4
Fluxuri de numerar din activitatea operațională			
Încasări din vânzări	010		
Plăți pentru stocuri și servicii procurate	020		
Plăți către angajați și organe de asigurare socială și medicală	030		
Dobânzi plătite	040		
Plata impozitului pe venit	050		
Alte încasări	060		
Alte plăți	070		
Fluxul net de numerar din activitatea operațională (rd.010 - rd.020 - rd.030 - rd.040 - rd.050 + rd.060 - rd.070)	080		
Fluxuri de numerar din activitatea de investiții			
Încasări din vânzarea activelor imobilizate	090		
Plăți aferente intrărilor de active imobilizate	100		
Dobânzi încasate	110		
Dividende încasate	120		
inclusiv: dividende încasate din străinătate	121		

Alte încasări (plăți)	130		
Fluxul net de numerar din activitatea de investiții (rd.090 - rd.100 + rd.110 + rd.120 ± rd.130)	140		
Fluxuri de numerar din activitatea financiară			
Încasări sub formă de credite și împrumuturi	150		
Plăți aferente rambursării creditelor și împrumuturilor	160		
Dividende plătite	170		
inclusiv: dividende plătite nerezidenților	171		
Încasări din operațiuni de capital	180		
Alte încasări (plăți)	190		
Fluxul net de numerar din activitatea financiară (rd.150 - rd.160 - rd.170 + rd.180 ± rd.190)	200		
Fluxul net de numerar total (± rd.080 ± rd.140 ± rd.200)	210		
Diferențe de curs valutar favorabile (nefavorabile)	220		
Sold de numerar la începutul perioadei de gestiune	230		
Sold de numerar la sfârșitul perioadei de gestiune (± rd.210 ± rd.220 + rd.230)	240		

Documente atașate - Notă explicativă (fișierul pdf)

Recipisa

Respondent

Codul fiscal: 1010600028048, denumire: BIOSISTEM MLD S.R.L.

A prezentat raportul: RSF1_21

Pentru perioada fiscala: A/2023

Data prezentarii: 26.03.2024

Marca temporală a raportului înregistrat în Sistemul de Raportare Electronică și expediat pentru procesare în Sistemul Informațional al BNS : 26.03.2024 17:05:42

Recipisa 2

Respondent

Codul fiscal: 1010600028048, denumire: BIOSISTEM MLD S.R.L.

A prezentat raportul: RSF1_21

Pentru perioada fiscala: A/2023

Data prezentarii: 26.03.2024

Marca temporală a raportului înregistrat în Sistemul Informațional al BNS : 09.04.2024 09:26:11

Biroul Național de Statistică (BNS) a recepționat varianta electronică a raportului, expediat de DVs.
Urmează verificarea și validarea raportului de către specialistul BNS pe domeniu.

Declaration of Conformity



Manufacturer: Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Mindray Building, Keji 12th Road South, Hi-tech Industrial
Park, Nanshan, Shenzhen, 518057, P. R. China

EC-Representative: Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80
20537 Hamburg, Germany

Product: Auto Hematology Analyzer

Model: BC-5000

Including reagents as following:

M-52D DILUENT

M-52DIFF LYSE

M-52LH LYSE

PROBE CLEANSER

Classification: The device not in IVDD annex II and not for self
testing/performance evaluation

Conformity Assessment Route: IVDD Annex III(excluding Section 6)

We herewith declare that the above mentioned products meet the provisions of the Directive 98/79/EC on In Vitro Diagnostic Medical Devices. All supporting documentations are retained under the premises of the manufacturer.

Standards Applied:

List of (harmonized) standards for which documented evidence for compliance can be provided as attachment.

Start of CE-Marking: 2013-9-26

Place, Date of Issue: Shenzhen, 2013-9-26

Signature:

Name of Authorized Signatory: Mr.tan ChuanBin

Position Held in Company: Manager ,Technical Regulation

Declaration of Conformity



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Mindray Building, Keji 12th Road South, Hi-tech Industrial
Park, Nanshan, Shenzhen, 518057, P. R. China

EC-Representative: Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80
20537 Hamburg, Germany

Product: Auto Hematology Analyzer

Model: BC-5150

Including reagents as following:

M-52D DILUENT

M-52DIFF LYSE

M-52LH LYSE

PROBE CLEANSER

Classification: The device not in IVDD annex II and not for self
testing/performance evaluation

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Product: **Auto Hematology Analyzer**

BC-5150、BC-5000

Including reagents as following:

M-52D DILUENT

M-52DIFF LYSE

M-52LH LYSE

PROBE CLEANSER

Applied Standards:

EN ISO 18113-1:2009	In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) Part 1: Terms, definitions and general requirements
EN ISO 18113-2:2009	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use
EN ISO 18113-3:2009	In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) Part 3: In vitro diagnostic instruments for professional use
EN ISO 15223-1:2012	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements
EN 13612: 2002	Performance evaluation of in vitro diagnostic medical devices
ISO 14971:2012	Medical devices – Application of risk management to medical devices
EN 61010-1:2001	Safety requirements for electrical equipment for measurement, control, and laboratory use Part 1: General requirement
EN 61010-2-081:2002+A1: 2003	Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-081: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes
EN 61010-2-101: 2002	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment

Declaration of Conformity V 1.0

IEC 61010-2-010: 2005	Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-010: Particular requirements for laboratory equipment for the heating of materials
EN 61326-1:2006	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements
EN 61326-2-6:2006	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment
EN 62304:2008	Medical device software- Software life cycle processes
EN 62366:2008	Medical devices — Application of usability engineering to medical devices
EN 13640: 2002	Stability testing of in vitro diagnostic medical devices

Cert.Code: YFPX2022051000008

CERTIFICATE

Award to

Nasedchin Alexander

BIOSISTEM-MLD SRL, Moldova

For Successfully Completed the Course

Hematology

BC-5000 Series

Level: Service Professional

2018/06/06 - 2018/06/07

Ukraine

Cherry Yang
Manager

Training Department

Shenzhen Mindray Bio-medical Electronics Co.,Ltd.

Date: 2022.05.10

BS-600M

Chemistry Analyzer



Technical Specifications

System Function:

Throughput: 600 photometric tests per hour, up to 800 tests per hour with ISE

Measuring principles: Absorbance Photometry, Turbidimetry

On-board tests: up to 77 photometric tests + 3 ISEs+ 3 serum indices

Methodology: End-point, Fixed-time, Kinetic, ISE

Sample Handling:

SDM: 120 samples by 12 racks, sample continuous loading, STAT in priority

Sample volume: 1.5~45μL, step at 0.1μL

HbA1c sample: Whole blood for HbA1c test

Sample probe: Liquid level detection, clot detection and collision protection

Reagent Handling:

Reagent tray: 80 positions with cooling system (2~8°C)

Reagent volume: 10~200μL, step at 0.5μL

Reagent probe: Liquid level detection, bubble detection and collision protection

Built-in Bar Code Reader:

Sample and reagent bar code readers support Codabar, ITF (Interleaved Two of five), Code 128, Code 39, UPC/EAN and Code 93;

Capable to connect with LIS in the bi-directional mode

Reaction System:

Reaction volume: 70~300μL

Reaction temperature: 37°C with 0.1°C fluctuation

Reaction cuvettes: 124 reusable cuvettes with 8-step auto wash

Optical System:

Light source: Tungsten-halogen lamp

Photometer: Grating photometer

Wavelength: 16 wavelengths (340nm, 380nm, 412nm, 450nm, 480nm, 505nm, 546nm, 570nm, 605nm, 630nm, 660nm, 700nm, 740nm, 770nm, 800nm, 850nm)

Absorbance range: 0~3.5Abs(10mm conversion)

Control and Calibration:

Calibration mode: Linear(one-point, two point and multi-point), Logit-Log 4P, Logit-Log 5P, Spline, Exponential, Polynomial, Parabola

Control rules: Westgard multi-rule, Twin plot

Operation Unit:

Operation system: Touch screen(optional), Windows 10(64bit)

Interface: RS-232, Network Port, USB/ parallel port

Working Conditions:

Power Supply: 200~240V, 50/60Hz, 1700VA
or 110/115V, 60Hz, 1700VA

Temperature: 15~30°C

Humidity: 35~85%

Dimension: 1380mm(length)*860mm(width)*1200mm(high)

Weight: 350kg



www.mindray.com

P/N:ENG-BS-600M-210285X8P-20220302

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mindray
healthcare within reach

BS-600M

Chemistry Analyzer

Powerful yet Efficient



BS-600M

Powerful yet Efficient



Flexible Sample Management

- Sample batch transfer
- Continuous sample loading by racks
- STAT Priority
- Quick rerun



HbA1c Tests with Whole Blood

- NGSP certified and IFCC traceable
- Onboard hemolysis without sample preparation
- No significant interference from Hb variants
- Lower detection limit of Hb, less rerun rate



Integrated ISE Module

- 1 blood tube for electrolytes and photometric chemistry tests
- long-life of ISE electrodes
- Easy operation and maintenance



Reliable Testing System

- World-class and excellent sigma metric performance with original reagent
- Intelligent abnormal reaction detection, alarming and auto-rerun to minimizes erroneous results

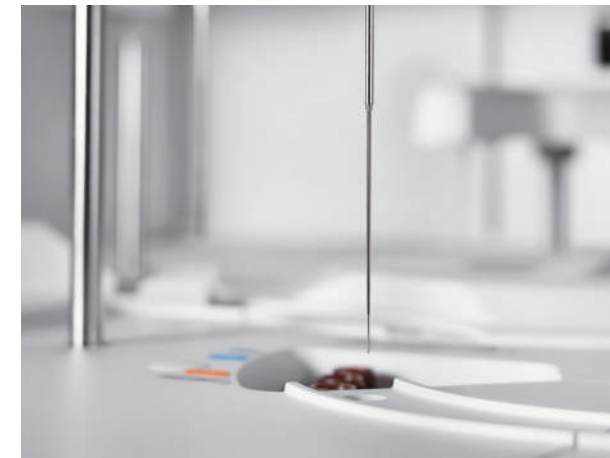
Small Footprint :

1.2m²

Photometric 600T/H
up to 800T/H with ISE



HbA1c Tests with Whole Blood



Onboard hemolysis with whole blood
to improve working efficiency

No manual pretreatment to reduce
biohazardous risks and human errors

120 T/H for HbA1c test to shorten
turn-around-time

Flexible Sample Management

Continuous Sample Loading

Sample continuous loading by racks
Up to 120 sample positions
long walk-away time



Quick Start for Sample Rerun

Auto start for sample test
Automatic priority for STAT and rerun

STAT Priority

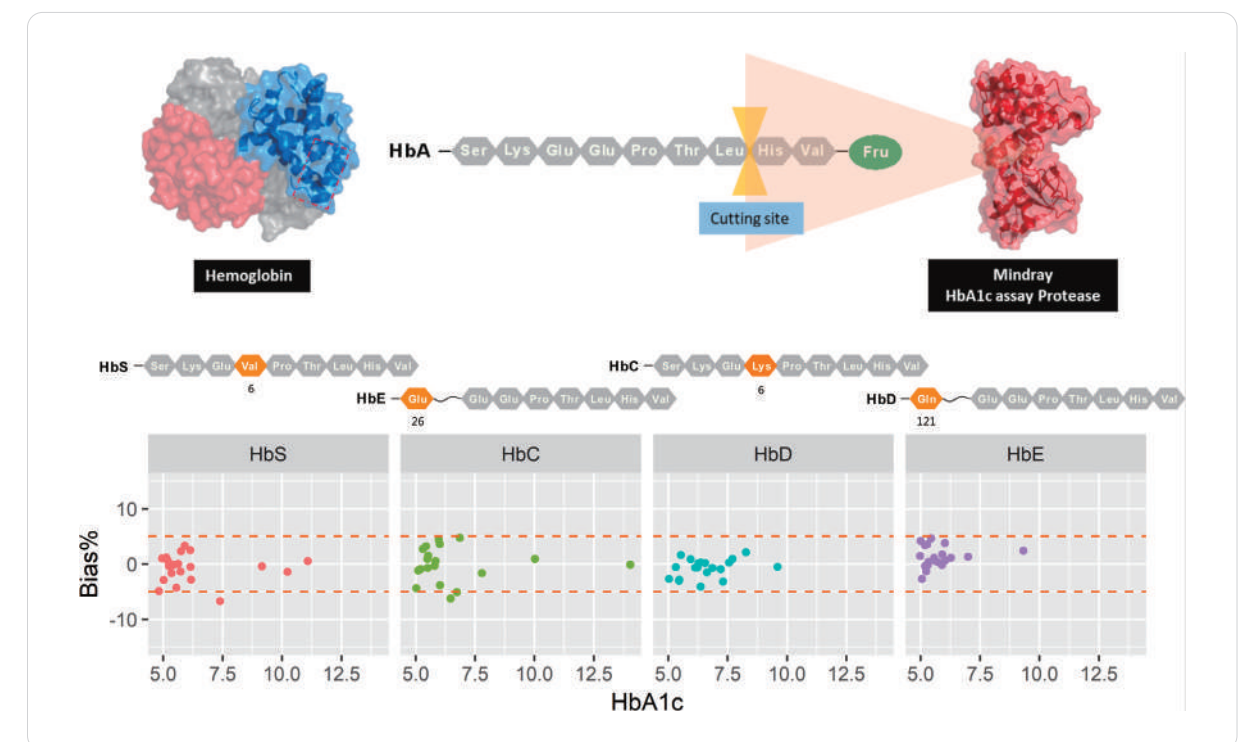
Dedicated STAT position, 1 minute aspiration
Quick report ISE+CO2 results in 7 minutes

Smart Dilution

Patented smart dilution function
Faster report

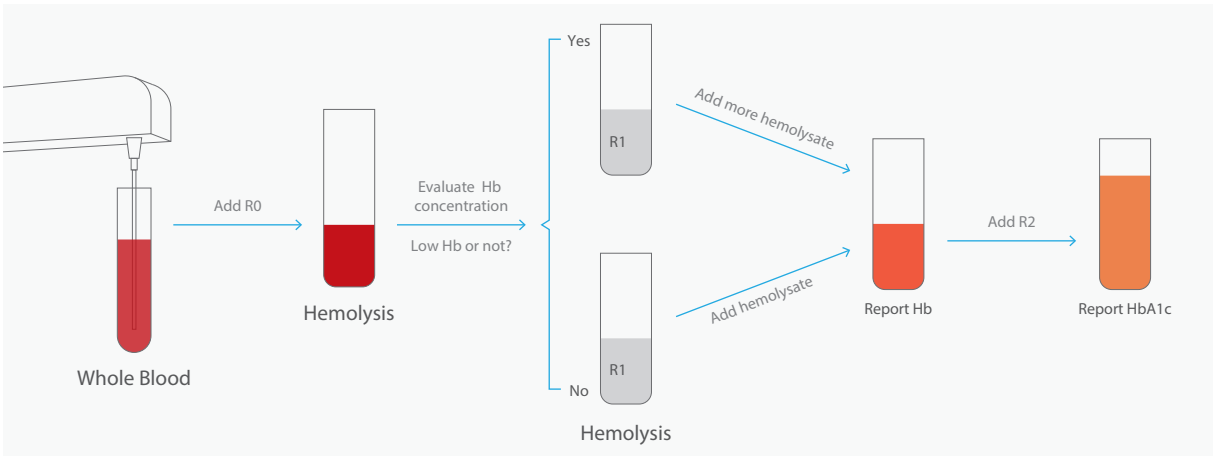
Mindray HbA1c reagent with enzymatic method can specifically detect glycated N-terminal amino acids from the hemoglobin beta-chains, which can effectively avoid interference from Hb variants (HbS, HbC, HbE and HbD) and other Hb derivatives (labile HbA1c, carbamylated Hb, and acetylated Hb).

Mindray enzymatic HbA1c gives reliable and cost efficient result with the first measurement and reduce further confirmations.



Lower Hb Detection Limit for HbA1c Test

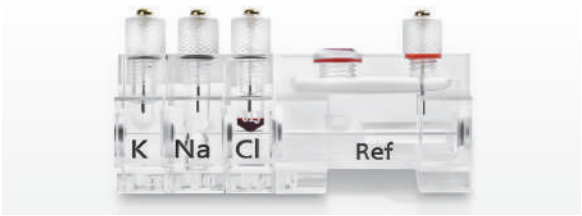
Evaluate the Hb concentration in the process of hemolysis and start sample increasement tests in advance for low Hb concentration samples. This function can lower the detection limit and expand linearity range Hb to reduce the rerun rate and reagent waste for anemia samples.



Integrated ISE Module

Built-in ISE Module

- Report Na^+ , K^+ , Cl^-
- 1 blood tube for electrolytes and photometric chemistry tests



Efficient and Easy operation

- Up to 300 tests per hour
- Up to 9 months of Na/K/Ref electrodes service time
- Automatic calibration
- Low consumption
- Easy operation and maintenance

Reliable Testing System

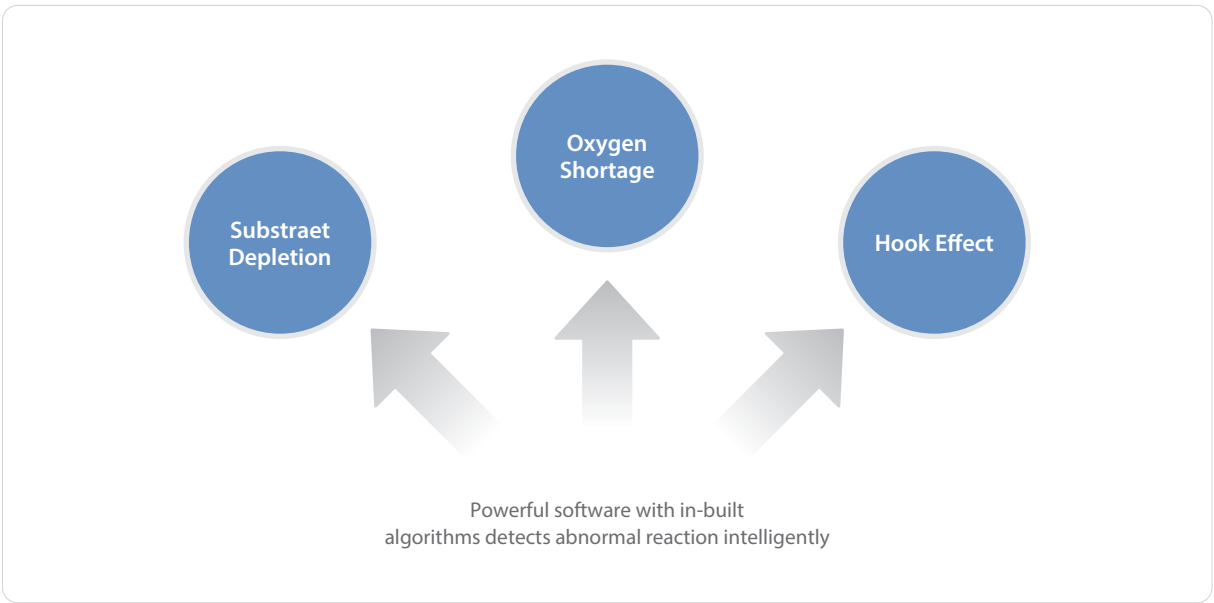


High Level Sigma Metric Performance

Original reagents and validated application protocol lower the inaccuracy and imprecision which contributes to achieving world-class and excellent sigma metric performance. Higher sigma level system can help laboratories offer high level of quality at reduced cost and enhance clinician confidence and satisfaction.

Intelligent Abnormal Reaction Detection

Powerful software with in-built algorithms that can monitor the reaction for abnormality, provide flags, and trigger auto-reruns to specimens with abnormal situations in test, such as substrate depletion, oxygen shortage, and hook effects, etc. This intelligent approach with detection, alarming and auto-rerun functions minimizes false results and the risk of a wrong diagnosis, and make reported test result accurate and reliable.



CERTIFICATE

Award to

Nasedchin Alexander

BIOSISTEM-MLD SRL, Moldova

For Successfully Completed the Course

Bio-chemistry

BS-800/BS-800M/BS-820/BS-820M/BS-830

Level: Service Professional

2021/06/01 - 2021/06/03

China

Cherry Yang
Manager

阳、杨

Training Department

Shenzhen Mindray Bio-medical Electronics Co.,Ltd.

Date: 2022.09.07

CERTIFICATE

This is to certify that

Poiata Vitalie

Biosistem-mld SRL , Moldova

For Successfully Completed the course

Coagulation

C-3100

Technical Training

2018/07/28-2018/07/29

Q.H.Li
Manager



Training Department

Shenzhen Mindray Bio-medical Electronics Co.,Ltd.

Date:2018.07.29

CERTIFICATE

This is to certify that

Nasedchin Alexandr

Biosistem-mld SRL , Moldova

For Successfully Completed the course

Coagulation

C-3100

Technical Training

2018/07/28-2018/07/29

Q.H.Li
Manager



Training Department

Shenzhen Mindray Bio-medical Electronics Co.,Ltd.

Date:2018.07.29



BC-5150

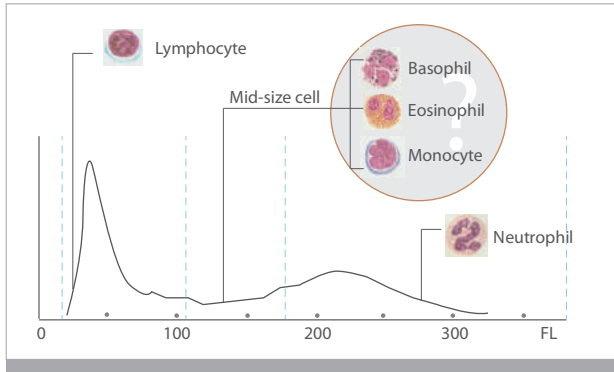
Auto Hematology Analyzer

A "CUTE" 5-part



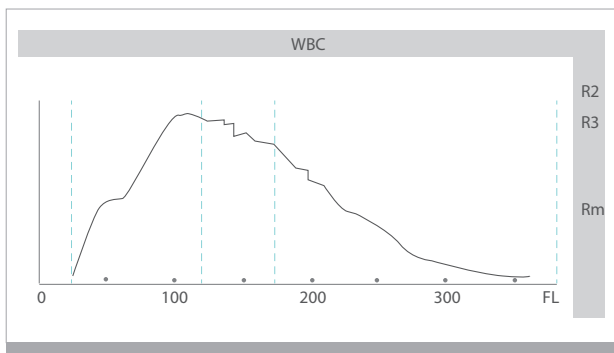
Why do we need 5-part hematology analyzers?

WBC differential: 3-part



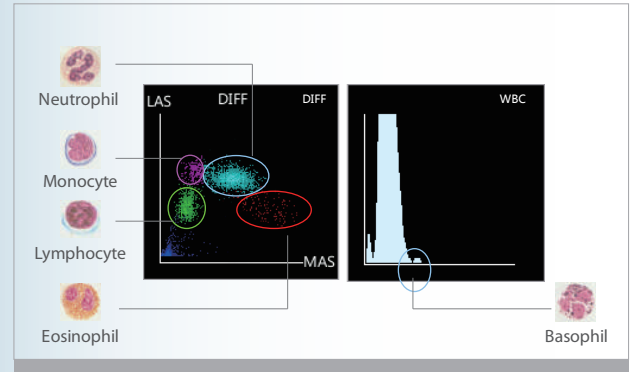
3-part hematology analyzers can not differentiate Basophil, Eosinophil and Monocyte. Additionally, Lymphocyte and Neutrophil results are easily affected by abnormal cells.

Flag information: 3-part



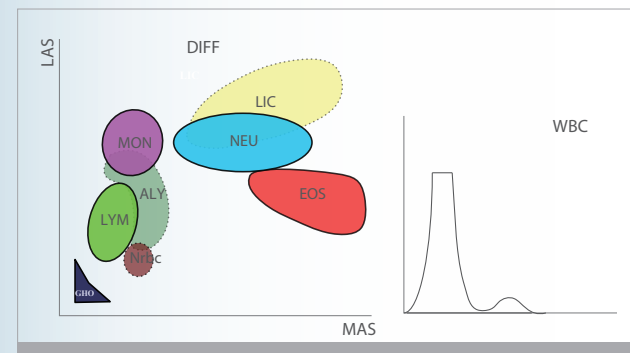
WBC histogram only indicates regional abnormal graph, it can't bring specific flags for different clinical cases.

WBC differential: 5-part



5-part hematology analyzers can provide Lymphocyte, Monocyte, Neutrophil, Eosinophil and Basophil results for every sample. Additionally, the 5-part results are less affected by abnormal cells.

Flag information: 5-part



5-part hematology analyzers provide more detailed and specific flag information. Users are able to clearly understand the clinical significance of flags and make a decision.



Dr Marisela Ramos, lab manager

Users are able to access our tailored innovation and intelligent diagnosis support to safeguard their diagnoses decisions with maximum confidence.

She said: "we upgraded to a 5-part hematology analyzer 3 months ago, and it's been working very well. Our lab has lots of abnormal samples, such as Eosinophilia and Monocytosis samples. We could only get the information that the mid-size cells percentage was higher than normal level, but couldn't distinguish which kind of cells increased exactly. Now, the 5-part hematology analyzer provides flags directly, which reduces smears need to be reviewed, and significantly improves our work efficiency."

BC-5150

Auto Hematology Analyzer

Based on Mindray's continuous innovation in hematology field, BC-5150 is especially tailored to assist diagnostic labs who need full CBC + 5-part results, with relatively low daily sample volume, restricted lab space and tight budget.

As the lightest and most compact 5-part hematology analyzer so far from Mindray, BC-5150 is a highly user-friendly and innovative analyzer that offers cost efficient CBC and 5-part white cell differential results. It is targeted to fulfill and exceed the demands of our global customers by providing more accurate, more efficient and more innovative solutions for labs.

WBC 5-part differentiation, 25 reportable parameters and 24 research parameters, 3 histograms and 4 scattergrams

Whole blood mode, Capillary whole blood mode and Prediluted mode

Tri-angle Laser scatter + Chemical dye + Flow cytometry technology

Dedicated optical counting channel for Basophil measurement

Powerful capability of flagging abnormal cells

10.4 inch large TFT touch screen with user-friendly software

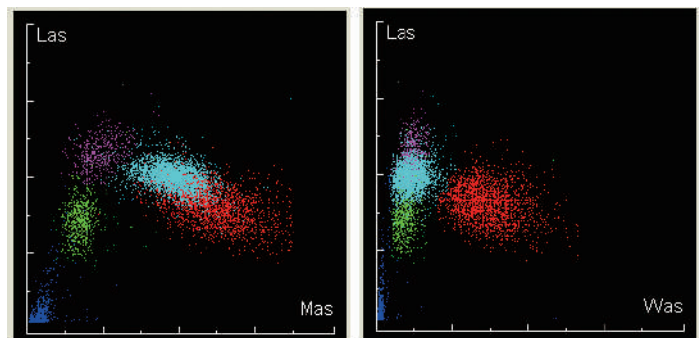
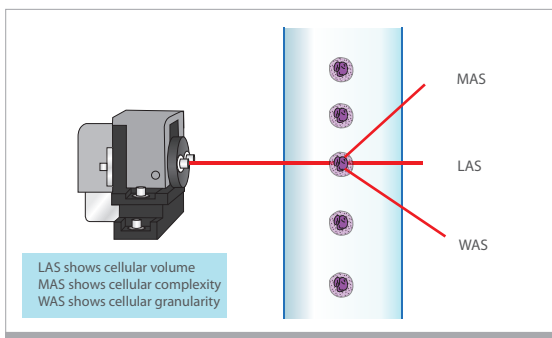
Large storage capacity: up to 250,000 samples

Throughput: 60 samples per hour

Sample volume is only 15 μ L which is ideal for pediatrics



Tri-angle laser scatter + focused flow + chemical dye, creating the possibility for a better 5-part WBC differentiation even on samples with high Eosinophil.



BC-5150, the 5-part hematology analyzer offers a great solution for clinical labs, especially for those who have limited space. Its compact foot-print is a result of innovative technology improvements, including miniaturized semi-conductor laser source, highly integrated electronic boards and optimized liquid handling system.



Compact

Two kinds of lyse reagents are located inside of BC-5150, which helps the small labs to save space.



Utility

The 10.4 inch TFT touch screen with a wide viewing angle, brings convenience to clinicians. Users can complete all instrument operations on the screen, practically eliminating the need for an external PC.



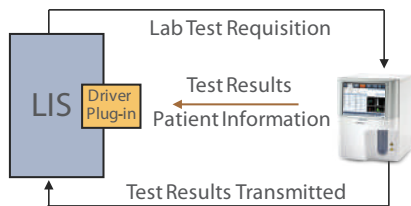
BC-5150 inherits its convenient and proven powerful software design from BC-6800 and BC-3600 platforms, the friendly interface is ideal for small sized labs.



Running capillary blood through the sample probe directly is more convenient for the users in children's hospitals, etc. For Prediluted mode, BC-5150 has higher dilution ratio than other 5-part hematology analyzers, thus it brings a better mixing effect.



4 USB ports are located on the instrument's left side. They permit BC-5150 users to transmit data conveniently and connect with printers, keyboard, mouse, barcode scanner, etc.

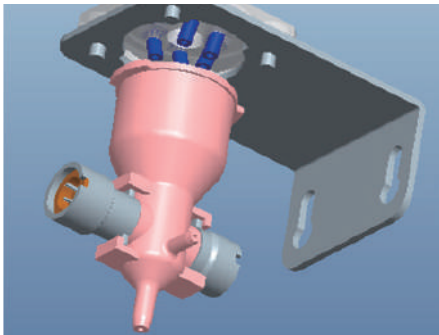


BC-5150 supports bi-directional LIS with test results and patient information. HL7 protocol is supported as well.



Technology

Compared with traditional helium neon laser or argon laser, semi-conductor laser has smaller size, lower cost and longer life cycle.



Improved DC impedance technology is used to count and size the RBC and PLT. The smaller counting aperture (50 μm in diameter) provides better performance on samples with low PLT.



Efficient

Only three routine reagents are required. These have 2 years shelf life and also less consumed by BC-5150. Original QC and calibrator are also provided to ensure the hematology analyzer's traceability and testing quality.

Technical Specifications

Principles

Impedance method for RBC and PLT counting

Cyanide free reagent for hemoglobin test

Flow Cytometry (FCM) + Tri-angle laser scatter + Chemical dye method for WBC 5-part differential analysis and WBC counting

Parameters

25 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.

24 research parameters including LIC%, LIC#, ALY%, ALY#, PLT Clump#, PLT Clump%, Lip#, Lip%, NRBC#, NRBC%, Blast#, Blast%, PDW-SD, NLR, PLR, Neu-X, Neu-Y, Neu-Z, Lym-X, Lym-Y, Lym-Z, Mon-X, Mon-Y, Mon-Z

3 histograms for WBC, RBC and PLT

4 scattergrams for WBC differential

Reagent

M-52D Diluent, M-52DIFF Lyse, M-52LH Lyse, Probe Cleanser

Performance

Parameter	Linearity Range	Precision	Carryover
WBC	0-500×10 ⁹ /L	≤2% (4-15×10 ⁹ /L)	≤0.5%
RBC	0-8×10 ¹² /L	≤1.5% (3.5-6.0×10 ¹² /L)	≤0.5%
HGB	0-250g/L	≤1.5% (110-180g/L)	≤0.6%
PLT	0-5000×10 ⁹ /L	≤6.0% (100-149×10 ⁹ /L) ≤4.0% (150-500×10 ⁹ /L)	≤1.0%

Sample Volume

Prediluted mode	20 µL
Whole blood mode	15 µL
Capillary whole blood mode	15 µL

Throughput

60 samples per hour

Display

10.4 inch TFT Touch Screen

Multi-language

Chinese, English, Spanish, Portuguese, Russian, French, Bahasa Indonesia

Data Storage Capacity

Up to 250,000 results including numeric and graphical information

Communication

LAN port supports HL7 protocol

Interface

USB, LAN

Support bi-directional LIS

Printout

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

Operating Environment

Temperature: 10°C~30°C

Humidity: 20%~85%

Air pressure: 70 kPa~106 kPa

Power requirement

100V-240V

50Hz/60Hz

Dimension and Weight

Depth(400 mm) x width(320 mm) x height(410 mm)

Weight :24kg

Chemistry Reagents

Hepatic Panel
Alanine Aminotransferase (ALT)
Aspartate Aminotransferase (AST)
Alkaline Phosphatase (ALP)
γ-Glutamyl Transferase (γ-GT)
Direct Bilirubin (D-Bil) DSA Method
Direct Bilirubin (D-Bil) VOX Method
Total Bilirubin (T-Bil) DSA Method
Total Bilirubin (T-Bil) VOX Method
Total Protein (TP)
Albumin (ALB)
Total Bile Acids (TBA)
Prealbumin (PA)
Cholinesterase (CHE)
α-L-fucosidase (AFU)

Renal Panel
Urea (UREA)
Creatinine (CREA) Modified Jaffé Method
Creatinine (CREA) Sarcosine Oxidase Method
Uric Acid (UA)
Carbon Dioxide (CO2)
Microalbumin (MALB)
β2-Microglobulin (β2-MG)
Cystatin C (CysC)
Retinol Binding Protein (RBP)
Total Protein In Urine & CSF (TPUC)

Cardiac Panel
Creatine Kinase (CK)
Creatine Kinase-MB (CK-MB)
Lactate Dehydrogenase (LDH)
α-Hydroxybutyrate Dehydrogenase (α-HBDH)
Full Range C-reaction Protein(FR-CRP)
Myoglobin (MYO)
D-Dimer (D-Dimer)

Diabetes Panel
Glucose (Glu) GOD-POD Method
Glucose (Glu) HK Method
Hemoglobin A1c (HbA1c)
Fructosamine (FUN)
β-Hydroxybutyrate (β-HB)

Inorganic & Anemia
Iron (Fe)
Ferritin (FER)
Transferrin (TRF)
Calcium (Ca)
Magnesium (Mg)
Phosphate Inorganic (P)
Unsaturated Iron Binding Capacity (UIBC)
Glucose-6-phosphate Dehydrogenase (G6PD)

Lipid Panel
Total Cholesterol (TC)
Triglycerides (TG)
HDL-Cholesterol (HDL-C)
LDL-Cholesterol (LDL-C)
Apolipoprotein A1 (ApoA1)
Apolipoprotein B (ApoB)
Lipoprotein(a) (Lp(a))

Immune Panel
Immunoglobulin A (IgA)
Immunoglobulin G (IgG)
Immunoglobulin M (IgM)
Immunoglobulin E (IgE)
Complement C3 (C3)
Complement C4 (C4)

Rheumatism Panel
C-reactive Protein (CRP)
Rheumatoid Factor (RF)
Antibodies Against Streptolysin O (ASO)

Pancreatitis Panel
α-Amylase (α-AMY)
Lipase (LIP)

Lung Panel
Adenosine Deaminase (ADA)
Angiotensin Converting Enzyme (ACE)

BS-800M
Clinical Chemistry Solution

Technical Specifications

System Function:		
Throughput:	800 photometric tests per hour for standalone unit and single analytical unit of modular system, up to 1200 tests per hour with ISE	
	From 800 to 2400 tests per hour for modular system with different configurations	
On-board tests:	68 photometric tests + 3 ISEs + 3 serum indices	
Sample Handling:		
Sample tray:	140 positions, including 25 cooled positions for calibrators and controls	
SDM:	300 samples by 30 racks	
Sample volume:	1.5~35 μL, step at 0.1μL	
Sample probe:	Liquid level detection, clot detection and collision protection	
Reagent Handling:		
Reagent tray:	120 positions in coaxial disk for R1, R2, R3 and R4	
Reagent volume:	15~300 μL, step at 0.5 μL	
Reagent probe:	Liquid level detection, bubble detection and collision protection	
Built-in Bar Code Reader (optional):	Sample and reagent bar code readers support Codabar, ITF (Interleaved Two of Five), Code128, Code39, UPC/EAN and Code93; Capable to connect with LIS in the bi-directional mode	
Reaction System:		
Reaction volume:	100~360 μL	
Reaction temperature:	37°C with 0.1°C fluctuation	
Reaction cuvettes:	165 glass cuvettes with 8-step auto wash	
Optical System:		
Light source:	Tungsten-halogen lamp	
Photometer:	Grating photometer	
Wavelength:	340nm, 380nm, 412nm, 450nm, 505nm, 546nm, 570nm, 605nm, 660nm, 700nm, 740nm, 800nm	
Absorbance range:	0~3.4Abs (10mm conversion)	
ISE Module (Optional):		
Principle:	Indirect K ⁺ , Na ⁺ and Cl ⁻ , with 22 μL sample aspiration	
Control and Calibration:		
Calibration mode:	Linear (one-point, two-point and multi-point), Logit-Log 4P, Logit-Log 5P, Spline, Exponential, Polynomial, Parabola	
Control rules:	Westgard multi-rule, Twin plot	
Operation Unit:		
Operation system:	Windows® XP Professional/Home SP2 or above, Windows® 7, Windows® 8, Windows® 10	
Scalability:	Upgradable to SAL 6000 modular system, a seamless integration of clinical chemistry module and chemiluminescence immunoassay module	

www.mindray.com

P/N: ENG-BS800M-210285x10-20171016
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mindray
healthcare within reach

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BS-800M
Clinical Chemistry Solution



BS-800 Modular System

Clinical Chemistry Solution

Total Solution for Clinical Chemistry

BS-800 Modular System combines innovation and high performance into an integrated solution. With a scalable platform, an ever more complete line of clinical chemistry reagents, as well as calibrators and controls, our new solution is tailor-made to customers' needs. Our innovative technologies also ensure the solution is accurate, convenient and cost-efficient.

Modular System

BS-800

Throughput: 800T/H, 1200T/H with ISE

Sample capacity: 140

Reagent capacity: 68



BS-800M

Throughput: 800T/H, 1200T/H with ISE

Sample capacity: 440

Reagent capacity: 68



Throughput: 1600T/H, 2400T/H with ISE

Sample capacity: 580

Reagent capacity: 136



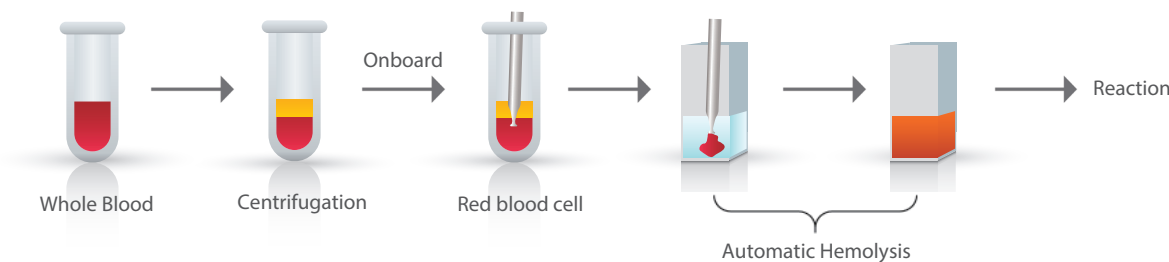
Upgradable to SAL 6000

One integrated workstation for both clinical chemistry and chemiluminescence immunoassay



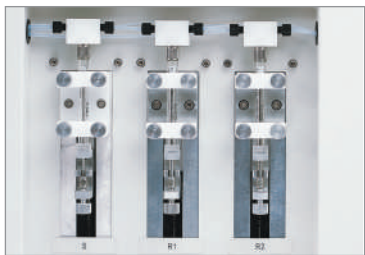
HbA1c Smart-sampling Technology

BS-800 modular system utilizes HbA1c smart-sampling technology, which allows onboard hemolysis for whole blood samples, thus achieving shorter turnaround time (TAT) and eliminating any biohazardous risks or any errors by manual operation.



Mindray HbA1c assays of enzymatic method, with application of specified protease and Fructosyl Peptide Oxidase (FPOX), has a good correlation with HPLC method. The enzymatic method is proven to have high precision, specificity and better performance to avoid interference from hemoglobin variants, and it is traceable to IFCC/NGSP reference methods.

Accurate



- **High pipetting precision**
15~300 μ L reagent with step at 0.5 μ L, 1.5~35 μ L sample with a step at 0.1 μ L.



- **Coolant circulation reagent refrigeration**
Ensure a stable refrigeration temperature at 2~8°C in the reagent disk.



- **Direct solid-heating system**
Fast heating of reaction disk while the temperature is kept at 37°C with 0.1°C fluctuation.



- **Effective mixing unit**
Independent reagent and sample mixing units; three-head mixing bars speed up process performance. The two-step washing significantly reduces potential contamination.



- **Intelligent clot detection**
Can detect and differentiate between a clot, partial clot, and bubbles ensure precise sample aspiration.

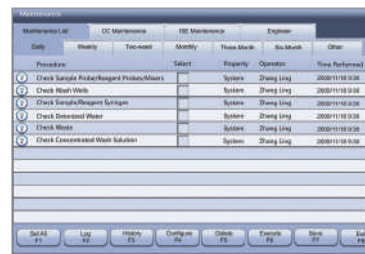
Preventive



- **Collision protection**
Vertical, horizontal sample and reagent probes collision protection.



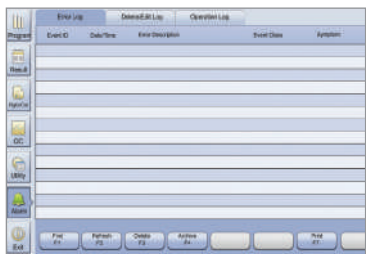
- **Waterproof design**
In the event of liquid splash, the liquid is redirected away from all electronic components with the specially designed cover.



- **Maintenance guide**
Easy to follow maintenance procedures, with embedded troubleshooting guides. Users may resolve issues quicker.



- **Covered system**
The pipetting system is covered to ensure safety. The sample disk is flexible to be partially covered only allowing convenient access during sample loading.



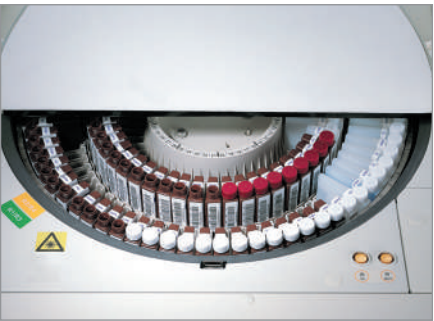
- **Warning log**
Extensive log lists alerts operator and service personnel to maintain the system.



Innovative

Coaxial reagent disk

Unique coaxial reagent disks design making reagent replacement time saving and convenient. The semi-opened cover ensures operator safety during operation.



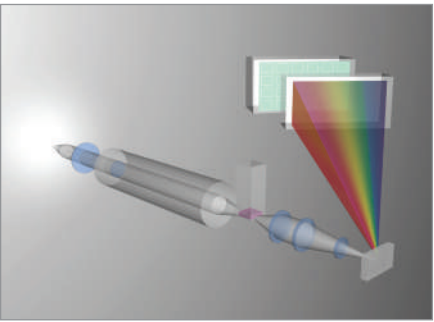
Reagent bubble detection

System provides sufficient reagent aspiration through liquid level and reagent bubble detection technology.



Dot light source

The dual focus of forward lighting is possible via the dual-diaphragm and dual-lens technology which creates a high intensity focused light. Thus, lowering the minimum reaction volume and enhancing the measuring accuracy.



Water quality monitor

The system employs resistance principle. It provides premium DI Water quality for assay analysis and reduces potential contamination.



Cost-efficient

Large capacity

Total sample capacity is 440 (140 positions on the sample tray and 300 positions on the Sample Delivery Module). The Sample Delivery Module automatically delivers samples to the analytical unit. The large sample capacity coupled with 165 washable permanent cuvettes allows the operator hours of walk-away time.



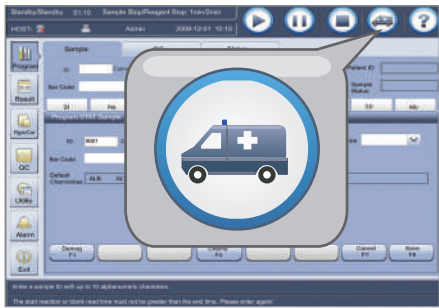
Low reagent consumption

100 µL minimum reaction volume reduces reagent cost. Uniquely designed reagent bottles maximize reagent usage and reduce residual volume.



One key STAT

Dedicated One-Key STAT test button, STAT sample position, and STAT sample rack provide prompt response to the highest priority samples.



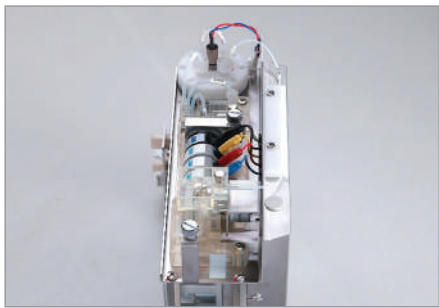
Continuous reagent loading and unloading

Two separate buttons independently control each reagent carousel; it ensures safe and continuous reagent replacement during testing.



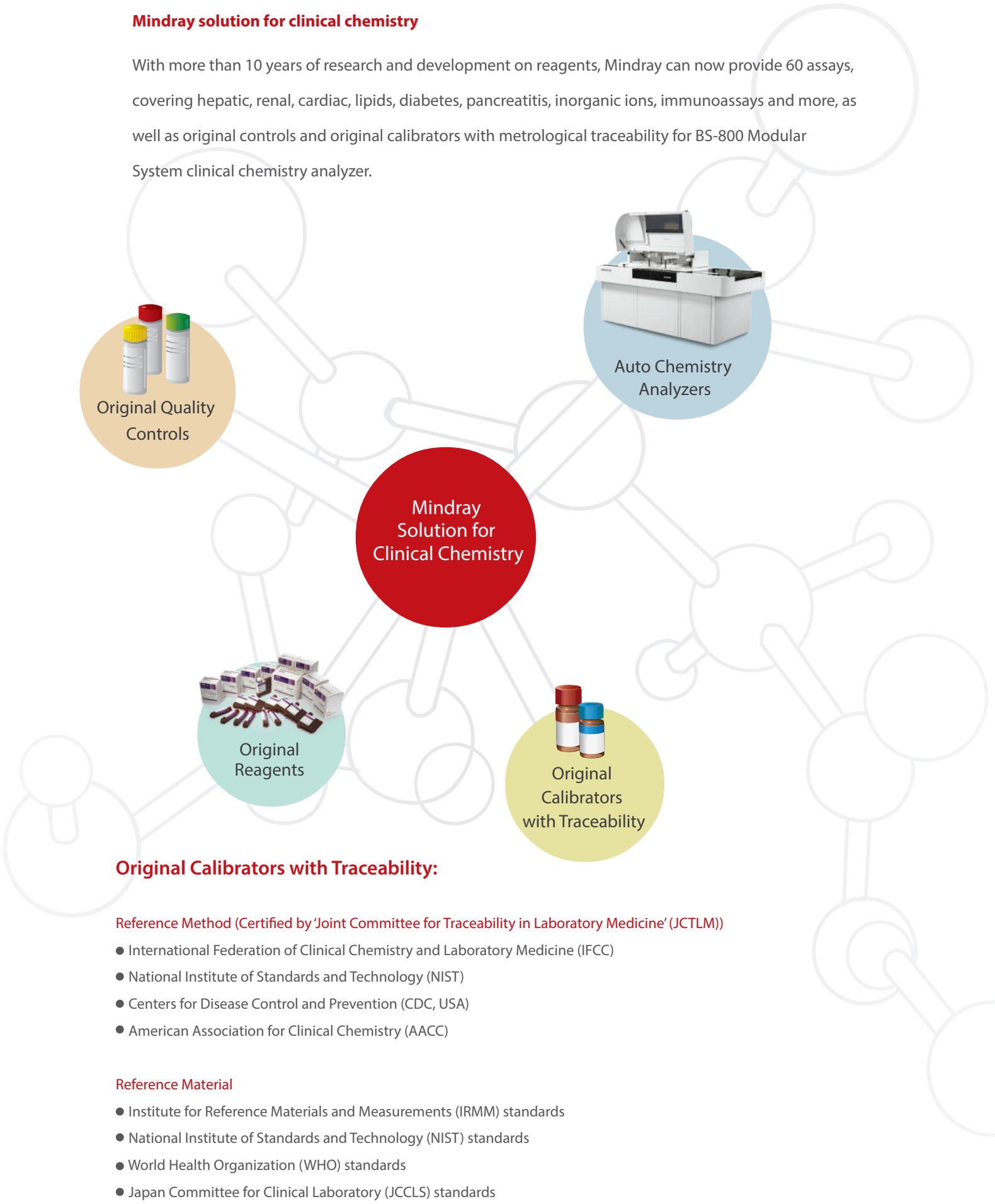
Indirect ISE

Low sample volume, high ISE analysis throughput, and cost-effective electrodes.



Mindray solution for clinical chemistry

With more than 10 years of research and development on reagents, Mindray can now provide 60 assays, covering hepatic, renal, cardiac, lipids, diabetes, pancreatitis, inorganic ions, immunoassays and more, as well as original controls and original calibrators with metrological traceability for BS-800 Modular System clinical chemistry analyzer.



Technical specifications

Principles

Mechanical method; Optical method (575nm)

Test items (For specific reagents)

PT, APTT, Fib, TT, Fib, TT, D-dimer, FDP etc.

Throughput

Up to 200 test/h for PT,
60 test/h for D-dimer

Sample position

61 positions with LED indicator

Reagent position

11 reagent position
10 with LED indicator, as well as cooling function. 2 with stirring function.

Automatic cuvette loading

1000 cuvettes auto loading

Sampling system

Separate reagent and sample probe with liquid-level detection function;
Reagent probe equipped with heating function.

Operating environment

Temperature: 10°C~30°C
Relative humidity: ≤70%

Storage and transportation environment

Temperature: -20°C~55°C
Relative humidity: ≤85%

Power supply

AC 100-240V, 50/60Hz

Calibration

Fib auto dilution, 2-6 point calibration

Dimension

L×W×H: 583mm×691mm×589mm

Weight

62kg

C3100

Auto Coagulation Analyzer

Dual magnetic circuit beads method —A promise of reliable result



H-500

Urine Analyzer



DIRUI H-500 Semi-automatic urine analyzer's outstanding performance proves itself to be a reliable friend for medium laboratories.

Product features:

- ◎ Large touch screen is convenient for users' operation
- ◎ Built-in thermal printer can print results automatically
- ◎ Waste box can collect waste strips automatically
- ◎ 4 wavelength cold light source ensure the result accuracy
- ◎ High throughput is 514 samples/hour
- ◎ 14 test items are optional
- ◎ Large capacity of data memory is convenient for review

Order Information:

Product Number	Description	Pack Size
1520104001	DIRUI H-500 Urine Analyzer	1 instrument

Product Number	Description	Volume	Pack Size
2310201003	DIRUI H8	100 strips/ bottle	1 bottle
2310201002	DIRUI H10	100 strips/ bottle	1 bottle
2310201001	DIRUI H11	100 strips/ bottle	1 bottle
2310201021	DIRUI H11-MA	100 strips/ bottle	1 bottle
2310201037	DIRUI H13-Cr	100 strips/ bottle	1 bottle
2310201089	DIRUI H14-Ca	100 strips/ bottle	1 bottle

January 13, 2022

MANUFACTURERS DECLARATION

To whom it may concern,

We, **Shenzhen Mindray Bio-Medical Electronics Co., Ltd.**, ("Mindray"), do hereby declare that engineers from **SRL Biosistem mld** with business office at Albisoara 16/1 ap.7, Chisinau, Republic of Moldova are authorized to provide service, technical maintenance and support for the below mentioned devices sold by them on the market of Republic of Moldova.

- Hematology analyzer **BC-6800plus**
- Hematology analyzer **BC-6200**
- Hematology analyzer **BC-6000**
- Hematology analyzers of **BC-700 Series**
- Biochemistry analyzers **BS-800M**
- Biochemistry analyzers **BS-2000M**
- Biochemistry analyzers **BS-620M**
- Automatic Coagulation analyzer **C-3100**
- Automatic Coagulation analyzer **C-3510**
- Automatic Urine analyzer **UA-5800**
- Automatic Urine analyzer **EU-8000**

Sincerely yours,



Duan Liang

General Manager of Sales and Marketing Division, CIS
Shenzhen Mindray Bio-Medical Electronics Co., Ltd.

BC-5150 Mindray, China



**CBC + 5-DIFF; 25 Setări de de bază + 12 setări de cercetare + 3 histograme
+ 3 diagrame; productivitate: 60 probe pe oră; un ecran mare tactil color și
operare ușoară**

Performanță îmbunătățită și tehnologii fiabile

Configurații:	Prelevare deschisa si inchisa
Metoda de calcul	Impedanță
Metoda de determinare a hemoglobinei	Fara Cianura
Volumul eșantionului (înainte de diluare)	20 ul
Volumul eșantionului (sânge integral)	15 l
Opțiuni:	WBC, Lym%, Mon%, Neu%, Bas%, Eos%, Lym#, Mo n#, Neu#, Eos#, Bas#, RBC, HGB, HCT, MCV, MCH,MCHC, RDW-CV, RDW-SD, PLT, MPV, PDW, PCT, P-LCR, P-LCC. 12 setări de cercetare LIC%, LIC#, ALY%, ALY#,PLTClump#,PLT Clump%,Lip#, Lip% ,NRBC#, NRBC %,Blast#,Blast%
Parametrul Liniaritatea	Coeficientul de variație (CV%)
WBC (0-500 x 10⁹ / L)	2.0 (4.0-15.0)
RBC (10¹² / L) 0-8.00	1.5 (3.50-6.00)
HGB (g / L) 0-250	1.5 (110-180)
PLT (10⁹ / L) 0-5000	4 (100-500)
Pontaminarea încrucișată	WBC, RBC, HGB <0,5%, PLT <1,0%
Histogramele pentru 3	WBC, RBC, PLT
Diagrame 3	WBC -Neu, Bas, Eos
productivitate	60 probe pe oră
Conexiuni	4 porturi USB (pentru imprimantă externă, actualizări de program, scanner de coduri de bare, tastatura și mouse-ul), LAN (1), RS232 (1)
Imprimanta	Lățimea de hârtie termica 57mm, diverse formate de imprimare, posibilitatea unei imprimante externe
Memoria rezultatelor	250.000 cu histograme
Procedura de cheaguri	deschidere automată de ardere
Spălare de prelevare	spălarea automată a suprafețelor interioare și exterioare
Consumul redus de reactivi sunt 3 specii	Razbavited-1, 2-Lieser hemoglobinei, 3-Lieser diferențierea leucocitelor
Dimensiuni	400x320x410 24 kg

Declaration of Conformity



Manufacturer: Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Mindray Building, Keji 12th Road South, Hi-tech Industrial
Park, Nanshan, Shenzhen, 518057, P. R. China

EC-Representative: Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80
20537 Hamburg, Germany

Product: Auto Hematology Analyzer

Model: BC-5150

Including reagents as following:

M-52D DILUENT

M-52DIFF LYSE

M-52LH LYSE

PROBE CLEANSER

Classification: The device not in IVDD annex II and not for self
testing/performance evaluation

Conformity Assessment Route: IVDD Annex III(excluding Section 6)

We herewith declare that the above mentioned products meet the
provisions of the Directive 98/79/EC on In Vitro Diagnostic Medical
Devices. All supporting documentations are retained under the premises
of the manufacturer.

Standards Applied:

List of (harmonized) standards for which documented evidence for compliance can be
provided as attachment.

Start of CE-Marking: 2013-9-26

Place, Date of Issue: Shenzhen, 2013-9-26

Signature:

Name of Authorized Signatory: Mr.tan ChuanBin

Position Held in Company: Manager ,Technical Regulation

Applied Standards List

Product: Auto Hematology Analyzer

BC-5150、BC-5000

Including reagents as following:

M-52D DILUENT

M-52DIFF LYSE

M-52LH LYSE

PROBE CLEANSER

Applied Standards:

EN ISO 18113-1:2009	In vitro diagnostic medical devices —Information supplied by the manufacturer(labelling) Part 1: Terms, definitions and general requirements
EN ISO 18113-2:2009	In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use
EN ISO 18113-3:2009	In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) Part 3: In vitro diagnostic instruments for professional use
EN ISO 15223-1:2012	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied —Part 1: General requirements
EN 13612: 2002	Performance evaluation of in vitro diagnostic medical devices
ISO 14971:2012	Medical devices – Application of risk management to medical devices
EN 61010-1:2001	Safety requirements for electrical equipment for measurement, control, and laboratory use Part 1: General requirement
EN 61010-2-081:2002+A1: 2003+A1: 2003	Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-081: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes
EN 61010-2-101: 2002	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment

Declaration of Conformity V 1.0

IEC 61010-2-010: 2005	Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-010: Particular requirements for laboratory equipment for the heating of materials
EN 61326-1:2006	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements
EN 61326-2-6:2006	Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment
EN 62304:2008	Medical device software- Software life cycle processes
EN 62366:2008	Medical devices — Application of usability engineering to medical devices
EN 13640: 2002	Stability testing of in vitro diagnostic medical devices

Cert.Code: YFPX2022061000004

CERTIFICATE

Award to

Nasedchin Alexander

BIOSISTEM-MLD SRL, Moldova

For Successfully Completed the Course

Hematology

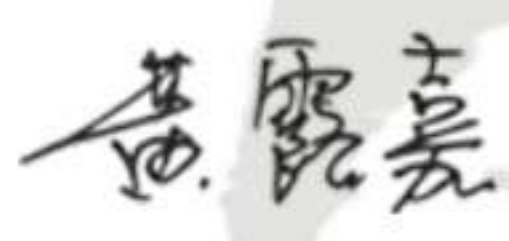
Low-High 5-DIFF Series: BC-700 Series

Level: Service Professional

2022-06-10

China

Nina Huang
Manager



Training Department

Shenzhen Mindray Bio-medical Electronics Co.,Ltd.

2022.06.10

Date:



DIRUI INDUSTRIAL CO., LTD.

95, Yunhe Street, New & High Tech. Development Zone,
Changchun, Jilin 130012, P.R. China

Tel : +86 (431) 85100409

Fax: +86 (431) 85172581

E-mail: dirui@dirui.com.cn

Http://www.dirui.com.cn

Service Training Certificate

To: Biosistem-mld SRL

Date: 30-07-2015

This is to certify that we, **DIRUI INDUSTRIAL CO., LTD** - China having registered offices at the below given address as a reputable manufacturer of Urine Reagent Strips, Urine Analyzers, Hematology analyzer and Chemistry Analyzer under ISO and CE condition to the international quality standards.

DIRUI INDUSTRIAL CO., LTD

95, Yunhe Street, New & High Tech Development Zone

Changchun 130012, China

Tel:0086-431-85100409

Fax:0086-431-85173354

Herein, we confirm that,

Mr. Vitalie Poiata the representative of Biosistem-mld SRL has attended the course of technical training devoted to Urine analyzers H-100, H-500, H-800.

For an on behalf of Dirui Industrial Co., LTD

Dima Ji
International Marketing & Sales Director
DIRUI INDUSTRTIAL CO.,LTD

