



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD.
ZHENG ZHE
ENGINEER OF TECHNICAL REGULATION DEPARTMENT
MINDRAY BUILDING, KEJI 12TH RD SOUTH,
HI-TECH INDUSTRIAL PARK,
NANSHAN, SHENZHEN, 518057 P.R. CHINA

June 9, 2016

Re: K160370

Trade/Device Name: BS-800M/ ABS800/BA-800M ISE KIT
BS-800M Chemistry Analyzer
BA-800M Chemistry Analyzer
ABS-800 Chemistry Analyzer

Regulation Number: 21 CFR 862.1665
Regulation Name: Sodium Test System
Regulatory Class: II
Product Code: JGS, CGZ, CEM, CDQ, JJE
Dated: April 15, 2016
Received: May 2, 2016

Dear Zeng Zhe:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, “Misbranding by reference to premarket notification” (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH’s Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,


Katherine Serrano -S

For: Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K160370

Device Name

BS-800M Chemistry Analyzer, BA-800M Chemistry Analyzer, ABS800 Chemistry Analyzer, BS-800M/ABS800/BA-800M ISE Kit

Indications for Use (Describe)

The BS-800M/ABS800/BA-800M Chemistry Analyzer is designed for clinical chemistry laboratory use, making direct quantitative measurements of Na⁺(sodium), K⁺ (potassium), Cl⁻ (chloride) in serum, plasma and urine samples, and Urea Nitrogen in serum samples. Additionally, other various chemistry tests may be adaptable to the analyzer depending on the reagent used to induce a photometric reaction.

The BS-800M/ABS800/BA-800M ISE Kit is for the in vitro quantitative determination of Sodium (Na⁺), Potassium (K⁺), and Chloride (Cl⁻) concentrations in serum, plasma and urine samples on the The BS-800M/ABS800/BA-800M Chemistry Analyzer.

Sodium measurements monitor electrolyte balance and in the diagnosis and treatment of diseases involving electrolyte imbalance.

Potassium measurements monitor electrolyte balance and in the diagnosis and treatment of disease conditions characterized by, low or high blood potassium levels.

Chloride measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders.

Urea Nitrogen (BUN) measurements are used to aid in the determination of liver and kidney function and other diseases associated with protein catabolism.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92.

The assigned 510(k) number is: K160370.

Submitter:

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

Tel: +86 755 2658 2888
Fax: +86 755 2658 2680

- **Contact Person:**

Zeng Zhe
Shenzhen Mindray Bio-medical Electronics Co., LTD
Mindray Building, Keji 12th Road South, Hi-tech Industrial Park,
Nanshan, Shenzhen, 518057, P. R. China

- **Date Prepared:**

June 2, 2016

Name of the device:

- **Trade/Proprietary Name:**

BS-800M Chemistry Analyzer, BA-800M Chemistry Analyzer, ABS800 Chemistry Analyzer, BS-800M/ABS800/BA-800M ISE Kit
(BS-800M, BA-800M and ABS800 are the same analyzers except the appearance, logo and name of the models. For convenience of explanation, the BS-800M Chemistry Analyzer is represented of the three in this summary.)

- **Common Name:** Clinical Chemistry Analyzer (with optional ISE Module)

- **Classification Number/Class:**

75JJE, Class I
75CDQ, Class II

75CEM, Class II

75CGZ, Class II

75JGS, Class II

Legally Marketed Predicate Device:

K072018

BS-200 Chemistry Analyzer, SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD

K972671

BUN (LIQUID) REAGENT SET, POINTE SCIENTIFIC, INC.

Description:

The BS-800M/BA-800M/ABS800 Chemistry Analyzer is an automated clinical chemistry analyzer capable of performing various in vitro photometric assays. The BUN (LIQUID) REAGENT SET was cleared under K972671 and is the chosen assay to demonstrate performance for the photometric unit. The BS-800M Chemistry Analyzer has an optional Ion-Selective Electrode (ISE) module which measures the concentration of the electrolytes, sodium, potassium, and chloride, in samples using ion selective electrode technology.

Intended Use/ Indication for Use:

The BS-800M/ABS800/BA-800M Chemistry Analyzer is designed for clinical chemistry laboratory use, making direct quantitative measurements of Na⁺(sodium), K⁺ (potassium), Cl⁻ (chloride) in serum, plasma and urine samples, and Urea Nitrogen in serum samples. Additionally, other various chemistry tests may be adaptable to the analyzer depending on the reagent used to induce a photometric reaction.

The BS-800M/ABS800/BA-800M ISE Kit is for the in vitro quantitative determination of Sodium (Na⁺), Potassium (K⁺), and Chloride (Cl⁻) concentrations in serum, plasma and urine samples on the The BS-800M/ABS800/BA-800M Chemistry Analyzer.

Sodium measurements monitor electrolyte balance and in the diagnosis and treatment of diseases involving electrolyte imbalance.

Potassium measurements monitor electrolyte balance and in the diagnosis and treatment of disease conditions characterized by, low or high blood potassium levels.

Chloride measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders.

Urea Nitrogen (BUN) measurements are used to aid in the determination of liver and kidney function and other diseases associated with protein catabolism.

Comparison of Technological Characteristics:

Substantial equivalence has been demonstrated between the BS-800M Chemistry Analyzer and BS-200 Chemistry Analyzer. Both of them utilize absorbance photometry to perform and output quantitative results for kinetic and endpoint clinical chemistries. For analytes, BS-800M Chemistry Analyzer and BS-200 Chemistry Analyzer determine the concentration of unknown samples from a standard curve generated with known analyte concentrations. The BS-800M Chemistry Analyzer and BS-200 Chemistry Analyzer both utilize Ion-Selective Electrodes technology to measure the concentration of the electrolytes, sodium, potassium, and chloride in samples.

Comparison Table of BS-800M and Predicate Device:

Comparison Section	BS-800M	BS-200 (Predicate Device)
510(K) Number	K160370	K072018
Intended use	The BS-800M/ABS800/BA-800M Chemistry Analyzer is designed for clinical chemistry laboratory use, making direct quantitative measurements of Na ⁺ (sodium), K ⁺ (potassium), Cl ⁻ (chloride) in serum, plasma and urine samples, and Urea Nitrogen in serum samples. Additionally, other various chemistry tests may be adaptable to the analyzer depending on the reagent used to induce a photometric reaction.	The BS-200 Chemistry Analyzer is designed for clinical laboratory use, making direct quantitative measurements of Na ⁺ (sodium), K ⁺ (potassium), Cl ⁻ (chloride) in serum, plasma and urine samples and Glucose in serum samples. Additionally, other various chemistry assays may be adaptable to the analyzer depending on the reagent used to induce a photometric reaction.
Parameter(photometric)	BUN	BUN
Parameter(ion selective electrode)	Na ⁺ , K ⁺ , Cl ⁻	Na ⁺ , K ⁺ , Cl ⁻

Comparison on photometric assay Chart 1: BS-800M and BS-200 analyzer

Feature	BS-800M	BS-200 (Predicate Device)	Same (S)/Different (D)
510(K)	K160370	K072018	/

1 System Function			
System Control	Automatic, computer controlled	Automatic, microprocessor controlled	S
LIS external connectivity capability	Yes	Yes	S
Calibration/QC	Automatic and Manual calibration/QC	Automatic and Manual calibration/QC	S
Barcode	Yes	Yes	S
2 Throughput (Max)			
	800 photometric tests per hour 1200 tests per hour with ISE	200 photometric tests per hour 330 tests per hour with ISE	D
3 Configuration			
	Analyzing unit, the Rack Feeder System, Operation unit, Output unit	Analytical unit, Operation unit, Output unit	D
4 Principle of Analysis			
Mode of detection	Photometric	Photometric	S
Analytical methods	Endpoint Fixed-time Kinetic	Endpoint Fixed-time Kinetic	S
Calibration methods	Linear calibration and nonlinear calibration	Linear calibration and nonlinear calibration	S
5 Optical Measurement Unit			
Measurement Modes	Absorbance	Absorbance	S
Optical Modes	Monochromatic, Bichromatic	Monochromatic, Bichromatic	S
Photometer	Multi-wavelength, diffraction grating spectrophotometer	Multi-wavelength, Light transmission mode of the filter	D
Wavelength	340nm, 380nm, 412nm, 450nm, 505nm, 546nm, 570nm, 605nm, 660nm, 700nm, 740nm and 800nm	340nm, 405nm, 450nm, 510nm, 546nm, 578nm, 630nm, 670nm	D
Linear absorbance range	0-3.4 absorbance	0-4.0 absorbance	D
Light Source	Tungsten halogen lamp	Tungsten halogen lamp	S
Detector	Photodiode	Photodiode	S

6 Reaction Unit			
Reaction cuvettes	Glass, 165 non-disposable	Plastic, 80 disposable	D
Reaction volume	100~360 μ L	180~500 μ L	D
Optical path	5mm	5mm	S
Reaction temperature	37°C	37°C	S
7 Sample and Reagent System			
Sample disk	140 positions. 45 positions respectively for outer two circles of outer rings and 25 positions respectively for inter two circles of inter rings	40 sample tube positions on the outer circle	D
Reagent disk	120 positions. 50 positions for inner circle and 70 positions for outer circle.	40 reagent bottle positions on the inner circle	D
Pipettor System	Positive displacement stepper motordrive	Positive displacement stepper motor drive	S
Refrigerator temperature	2-8°C	4-15°C	D
Sample Dispense	1.5 μ L -50 μ L	3 μ L -45 μ L	D
Reagent Dispense	15 μ L-300 μ L	30 μ L-450 μ L	D
8 POWER			
Input	110/115V \sim \pm 10%, 60Hz \pm 1 Hz	100-130V \sim ,50/60 \pm 1 Hz	D
Consumption	3800VA	1000 VA	D
9 Operating environmental conditions			
Temperature	15°C to 30°C	15°C to 30°C	S
Humidity	35% to 85%, non-condensing	35% to 80%, non-condensing	S

Comparison on Electrolytes assay Chart 2: BS-800M ISE module and BS-200 ISE module

Feature	BS-800M ISE Kit	BS-200 ISE Kit (Predicate Device)	Same (S)/Different (D)
510(K)	K160370	K072018	/
1 Indication for use/Intended Use			
ISE Kit	The BS-800M/ ABS800/ BA-800M ISE Module is for the in vitro quantitative determination of Sodium	The BS-200 ISE Module is for the in vitro quantitative determination of Sodium (Na ⁺), Potassium (K ⁺), and	S

		(Na ⁺), Potassium (K ⁺), and Chloride (Cl ⁻) concentrations in serum, plasma and urine samples on the the BS-800M/ABS800/BA-800M Chemistry Analyzer.	Chloride (Cl ⁻) concentrations in serum, plasma and urine samples on the the BS-200 Chemistry Analyzer.	
	Sodium	Sodium measurements monitor electrolyte balance and in the diagnosis and treatment of diseases involving electrolyte imbalance.	Sodium measurements monitor electrolyte balance and in the diagnosis and treatment of diseases involving electrolyte imbalance.	S
	Potassium	Potassium measurements monitor electrolyte balance and in the diagnosis and treatment of disease conditions characterized by, low or high blood potassium levels.	Potassium measurements monitor electrolyte balance and in the diagnosis and treatment of disease conditions characterized by, low or high blood potassium levels.	S
	Chloride	Chloride measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders.	Chloride measurements are used in the diagnosis and treatment of electrolyte and metabolic disorders.	S
2 System Function				
	Method Principle	Ion Selective Electrode	Ion Selective Electrode	S
	Electrode	Na ⁺ electrode, K ⁺ electrode, Cl ⁻ electrode, reference electrode	Na ⁺ electrode, K ⁺ electrode, Cl ⁻ electrode, reference electrode, Space electrode	D
	Reference reagent	MR Serum Standard, MR Urine Standard, MR Buffer Solution, MR Detergent Solution, MR Na/K Check Solution	Reagent Pack, Urine Diluent, Cleaning Solution,	D
	ISE Internal Standard	None	None	S
	Sample Volume	22 µL total for all three tests	70 µL Serum, plasma mode; 140 µL Urine mode	D
	ISE Throughput Rate	600 tests/hour	300 tests/hour Serum, plasma mode;	D

			198 tests/hour Urine mode	
	Test Environment	Clinical Lab	Clinical Lab	S
3	Calibration			
	Calibrator	MR Serum Standard for Serum, Plasma mode; MR Urine standard for Urine mode;	ISE reagent pack for all three sample types	D
	Standardization	Na: NIST standard material SRM919 K: NIST standard material SRM 918 Cl: NIST standard material SRM 919	Na: NIST standard material SRM956 K: NIST standard material SRM 956 Cl: NIST standard material SRM 956	D
	Calibrator Stability	5°C~35°C, 12 months of shelf-life, 8 weeks of in-use stability	4°C~25°C, 24 months of shelf-life	D
	Calibrator Matrix	Buffered Aqueous matrix	Buffered Aqueous matrix	S
	Calibrator Form	liquid	liquid	S
	Number of Calibrator levels	Two for serum/Plasma and Two for Urine	Two for serum/plasma/urine	S
	Calibration Frequency	Daily	8 hours	D
4	Performance Characters			
	Analytical Measuring (mmol/L)	Serum/Plasma Na: 100-200 K: 1-8 Cl: 50-150 Urine Na: 10-400 K: 5-200 Cl: 15-400	Serum/Plasma Na: 113-194 K: 1.1-8.6 Cl: 53-154 Urine Na: 27-372 K: 13-184 Cl: 42-422	D
	Reference Interval	Serum(Adults): Sodium: 136-145 mmol/L Potassium: 3.5-5.1 mmol/L Chloride: 98-107 mmol/L Plasma(Adults): Sodium: 136-145 mmol/L Potassium: 3.4-4.5 mmol/L Chloride: 98-107 mmol/L Urine, 24 hour (Adults):	Serum(Adults): Sodium: 136-145 mmol/L Potassium: 3.5-5.1 mmol/L Chloride: 98-107 mmol/L Plasma(Adults): Sodium: 136-145 mmol/L Potassium: 3.4-4.5 mmol/L Chloride: 98-107 mmol/L Urine, 24 hour (Adults):	S

		Sodium: 40-220 mmol/24h Potassium:25-125 mol/24h Chloride:110-250 mol/24h	Sodium: 40-220 mmol/24h Potassium:25-125 mol/24h Chloride:110-250 mol/24h	
NSI Interferences concentration		Bilirubin Na/K/Cl for three sample types: 40 mg/dL Hemoglobin Na/Cl for three sample types: 500 mg/dL Urine K: 500 mg/dL Lipemia Na/K/Cl for three sample types: 1000 mg/dL Ascorbic acid Na/K/Cl for three sample types: 30 mg/dL	Bilirubin Na/K/Cl for three sample types: 20 mg/dL Hemoglobin Na/K/Cl for three sample types: 500 mg/dL Lipemia Na/K/Cl for three sample types: 1000 mg/dL	D

Performance Characteristics:

Performance testing of the BS-800M Chemistry Analyzer consisted of running the FDA previously cleared assay and the ISE module on the BS-800M to evaluate precision, linearity, and method comparison, Limits of Detection and Limits of Quantitation, interference, ISE plasma sample type studies.

A correlation analysis between the BS-800M Chemistry Analyzer and BS-200 Chemistry Analyzer yielded the following results:

Analyte	Unit	Sample Range	N	Slope	Intercept	Correlation Coefficient
BUN	mg/dL	5.4-149.5	122	0.98	0.81	0.9997
Serum Na ⁺	mmol/L	100.2-196.4	124	1.03	-5.95	0.9966
Serum K ⁺	mmol/L	1.40-7.70	121	1.04	-0.09	0.9994
Serum Cl ⁻	mmol/L	50.4-149.4	124	1.00	0.15	0.9993
Urine Na ⁺	mmol/L	12.1-395.4	120	0.99	-2.52	0.9997
Urine K ⁺	mmol/L	5.1-194.7	120	0.98	-1.00	0.9997
Urine Cl ⁻	mmol/L	15.2-381.3	120	0.97	2.06	0.9988

And the bias at the medical decision points of method comparison yielded the following

results:

Analyte	Unit	Medical decision points	Bias at the medical decision points (Difference/Difference%)		
			Point 1	Point 2	Point 3
BUN	mg/dL	6,26,50	0.696/11.6%	0.317/1.2%	-0.138/-0.3%
Serum Na ⁺	mmol/L	115,135,150	-2.713/-2.4%	-2.149/-1.6%	-1.727/-1.2%
Serum K ⁺	mmol/L	3.0,5.8,7.5	0.032/1.1%	0.144/2.5%	0.212/2.8%
Serum Cl ⁻	mmol/L	90,112	0.245/0.3%	0.267/0.2%	/
Urine Na ⁺	mmol/L	40,112	-2.759/-6.9%	-3.837/-1.7%	/
Urine K ⁺	mmol/L	25,125	-1.418/-5.7%	-3.085/-2.5%	/
Urine Cl ⁻	mmol/L	110,250	-1.112/-1.0%	-5.147/-2.1%	/

The total precision test of BS-800M yielded the following results:

Analyte	Unit	Sample	n	Mean	Repeatability		Within-Device Precision	
					SD	CV%	SD	CV%
BUN	mg/dL	Control pool 1	80	11.0	0.28	2.5%	0.33	3.0%
		Control pool 2	80	46.4	0.57	1.2%	0.94	2.0%
Serum Na ⁺	mmol/L	Control pool 1	80	136.1	0.35	0.3%	0.83	0.6%
		Control pool 2	80	166.1	0.46	0.3%	1.12	0.7%
Serum K ⁺	mmol/L	Control pool 1	80	3.72	0.006	0.2%	0.021	0.6%
		Control pool 2	80	6.10	0.013	0.2%	0.033	0.5%
Serum Cl ⁻	mmol/L	Control pool 1	80	89.4	0.21	0.2%	0.38	0.4%
		Control	80	107.5	0.23	0.2%	0.44	0.4%

		pool 2						
Urine Na ⁺	mmol/L	Control pool 1	80	87.1	0.22	0.3%	0.44	0.5%
		Control pool 2	80	148.6	0.36	0.2%	0.74	0.5%
Urine K ⁺	mmol/L	Control pool 1	80	35.1	0.08	0.2%	0.21	0.6%
		Control pool 2	80	68.8	0.16	0.2%	0.41	0.6%
Urine Cl ⁻	mmol/L	Control pool 1	80	90.4	0.20	0.2%	0.40	0.4%
		Control pool 2	80	133.9	0.17	0.1%	0.48	0.4%

The linearity test of BS-800M yielded the following results:

Analyte	Unit	Slope	Intercept	Correlation Coefficient	Linear Range Tested	Claimed Linear Range
BUN	mg/dL	0.9999	0.0053	0.9996	4.5-162.6	5-150
Serum Na ⁺	mmol/L	0.9996	0.0783	1.0000	41.9-224.4	100-200
Serum K ⁺	mmol/L	0.9997	-0.0003	0.9999	0.61-9.34	1-8
Serum Cl ⁻	mmol/L	0.9998	0.0389	0.9999	11.0-162.4	50-150
Urine Na ⁺	mmol/L	1.0000	0.0139	0.9999	7.5-469.5	10-400
Urine K ⁺	mmol/L	1.0001	0.0175	0.9999	3.1-254.4	5-200
Urine Cl ⁻	mmol/L	1.0000	0.0370	0.9999	10.9-439.4	15-400

The detection limit studies test of BS-800M yielded the following results:

Analyte	Unit	LoB	LoD	LoQ
BUN	mg/dL	0.4	0.9	4.2
Serum Na ⁺	mmol/L	1.9	3.5	39.5
Serum K ⁺	mmol/L	0.04	0.05	0.54

Serum Cl ⁻	mmol/L	0.5	0.6	9.5
Urine Na ⁺	mmol/L	0.9	1.4	6.9
Urine K ⁺	mmol/L	0.1	0.2	2.4
Urine Cl ⁻	mmol/L	0.2	0.3	9.8

The Interference test of BS-800M yielded the following results:

Effects of bilirubin, hemoglobin, lipemia, ascorbic acid are tested, yielded the following results:

Results of the bilirubin interference testing

Analyte	Analyte concentration (mmol/L)	Bilirubin level(mg/dL)	Bias(mmol/L)	Comments
BUN	8.5	40	+0.0	NSI
	39.5		-0.1	
Serum Na ⁺	134.0	40	-0.4	NSI
	154.8		+0.4	
Serum K ⁺	3.23	40	-0.01	NSI
	5.94		+0.00	
Serum Cl ⁻	89.7	40	-0.1	NSI
	114.7		-0.2	
Urine Na ⁺	45.9	40	+0.6	NSI
	224.1		-1.3	
Urine K ⁺	26.9	40	+0.0	NSI
	127.3		-0.4	
Urine Cl ⁻	113.9	40	+0.1	NSI
	253.5		-1.5	

Results of the hemoglobin interference testing

Analyte	Analyte concentration (mmol/L)	Hemoglobin level(mg/dL)	Bias(mmol/L)	Comments
BUN	8.6	500	+0.4	NSI
	40.0		-0.1	
Serum Na ⁺	129.4	500	+0.9	NSI
	153.1		+0.9	
Serum K ⁺	3.15	125	+0.30	NSI
		≥250	+0.61	SI
	5.81	125	+0.33	NSI
		≥250	+0.68	SI

Serum Cl ⁻	88.8	500	+2.0	NSI
	113.5		+2.6	
Urine Na ⁺	45.1	500	+1.5	NSI
	223.4		+2.2	
Urine K ⁺	29.3	500	+1.5	NSI
	135.0		+0.1	
Urine Cl ⁻	113.1	500	+2.5	NSI
	261.3		+1.8	

Results of the lipemia interference testing

Analyte	Analyte concentration (mmol/L)	Lipemia level(mg/dL)	Bias(mmol/L)	Comments
BUN	8.3	1000	-1.2	NSI
	38.2		-1.1	
Serum Na ⁺	125.3	1000	-0.5	NSI
	147.6		+0.4	
Serum K ⁺	3.08	1000	+0.05	NSI
	5.64		+0.07	
Serum Cl ⁻	85.5	1000	+0.0	NSI
	111.5		-0.1	
UrineNa ⁺	40.9	1000	-0.1	NSI
	215.8		-0.8	
Urine K ⁺	28.1	1000	+0.1	NSI
	127.8		-0.6	
UrineCl ⁻	110.8	1000	-0.2	NSI
	232.9		-0.8	

Results of the ascorbic acid interference testing

Analyte	Analyte concentration (mmol/L)	Ascorbic Acid level(mg/dL)	Bias(mmol/L)	Comments
BUN	9.0	30	-0.3	NSI
	41.1		-0.4	
Serum Na ⁺	132.9	30	-0.3	NSI
	153.4		+1.0	
Serum K ⁺	3.19	30	+0.00	NSI
	5.89		+0.01	
Serum Cl ⁻	89.1	30	-0.2	NSI
	114.0		-0.4	

Urine Na ⁺	43.3 223.3	30	+0.4 +0.8	NSI
Urine K ⁺	29.7 125.0	30	+0.1 -0.1	NSI
Urine Cl ⁻	116.2 251.4	30	+0.0 +0.3	NSI

There is no significant interference (NSI) observed when the concentrations of interference materials (including drugs) is below the ones in the following table

Interferents	Level tested(mg/dL)
Lipemia	1000
Bilirubin	40
Ascorbic Acid	30
Imipramine	0.15
Procainamide	15
Nortriptyline	0.26
Hydroxytyramine	50.7
Ibuprofen	512
Valproic acid	75
Chlorpromazine	6
Salicylic acid	72
Acetylsalicylic acid	1205
Erythromycin	7.6
Ethosuximide	30.6
Acetaminophen	242
Benzalkonium Chloride	10.4
Ampicillin	6

There was significant interference for hemoglobin and Potassium Thiocyanate.

- Avoid Hemolyzed samples for potassium. Hemolyzed samples may give incorrect elevated potassium. Intracellular potassium concentration is 30-50 fold greater than that of extracellular serum or plasma.
- Potassium thiocyanate increases potassium by 0.55 mmol/L at the concentration of 3.30 mmol/L and by 0.58 mmol/L at the concentration of 5.39 mmol/L.
- Potassium thiocyanate increases chloride by 12.3 mmol/L at the concentration of 90.9 mmol/L and by 12.6 mmol/L at the concentration of 114.6 mmol/L.

The BS-800M's sample type studies between serum and plasma of Na⁺, K⁺, Cl⁻ test yielded the following results, which proved the sample type plasma can also apply to ISE test:

Analyte	Unit	N	Sample Range	Slope	Intercept	Correlation Coefficient
Na ⁺	mmol/L	51	105.2-195.9	1.000	-0.33	0.9989
K ⁺	mmol/L	51	1.45-7.87	0.966	-0.13	0.9930
Cl ⁻	mmol/L	51	54.2-148.1	0.996	0.62	0.9997

Conclusion:

The data demonstrates that the BS-800M Chemistry Analyzer is substantially equivalent to BS-200 Chemistry Analyzer.