

MAY 1 1998

510(k) Summary

1. Submitter Diametrics Medical, Inc.
2658 Patton Road
Roseville, MN 55113
2. Establishment Registration Number: 2183953
3. Device Names
Proprietary Name: IRMA Blood Analysis System

Common Name: Blood Gas/Electrolyte/Hematocrit Analyzer

Classification Name: Blood gases (pCO₂, pO₂), pH, sodium, potassium, ionized calcium, blood urea nitrogen, chloride, and hematocrit test systems
4. Device Classification
The blood gases (pCO₂ and pO₂), pH, sodium, potassium, ionized calcium, chloride, blood urea nitrogen and hematocrit systems have been classified under Clinical Chemistry Test Systems 21 CFR 862.1120, 862.1665, 862.1600, 862.1145, 862.1170, 862.1770 and under Hematology and Pathology Devices, 864.6400. All are Class II devices.
5. Compliance to Classification Requirements _
No performance standards have been established for the above referenced systems. Diametrics Medical intends to comply with any standards applicable to this product developed in the future.
6. Proposed labels, labeling, and advertisements
The proposed labeling appears in Appendix B (Pouch and cartridge label), Appendix C (Package insert) and Appendix D (User manual). There are no required changes to the current device label. Diametrics Medical, Inc. does not intend to advertise the product at this time.

7. System Description and Statement of Substantial Equivalence

System Description

The current IRMA Blood Analysis System comprises a system of an electronic instrument and disposable cartridges (single-use or multi-use) intended for the measurement of blood gases (pCO₂ and pO₂), pH, potassium, sodium, ionized calcium, and hematocrit in blood.

The new system will measure the above mentioned analytes plus blood urea nitrogen (BUN) and chloride (Cl⁻) in blood on the single-use cartridge. Except for the addition of these two analytes and their associated changes, the system will remain the same as the current system. A description of the new system follows.

The IRMA analyzer can use either battery or AC power. The system's operation utilizes a microprocessor which is controlled by internal electronics and diagnostics. The microprocessor controls the touch screen, analog electronics which collect the digital signals from the sensors and the controls the printer. The printer provides a hard copy of the measured and calculated values.

Samples are introduced via syringe or capillary injections with the IRMA Capillary Collection Device. The minimum sample volumes are 200µL from a syringe injection and 125µL from a Capillary Collection Device injection. Other capillary collection devices which require aspiration are not compatible with the system.

The cartridges utilize microelectrode technology for the measurement of the following blood analytes: pH, pCO₂, pO₂, sodium, potassium, ionized calcium, blood urea nitrogen, chloride, and hematocrit.

The principles of measurement are similar to traditional electrode methodologies for blood gas and electrolyte measurements. The pH, pCO₂, Na⁺, K⁺, iCa⁺⁺, BUN, and Cl⁻ utilize ion-selective potentiometric electrodes including a reference electrode. The pO₂ electrode is an amperometric Clark electrode. The hematocrit sensor utilizes a conductivity electrode. Further description of the principles of operation for the electrodes can be found in the draft labeling of the user manual.

Calibration

The IRMA sensors are calibrated prior to each test using a calibrant prepackaged over the sensors. The calibrant is manufactured and tested with NIST traceable gases and salt standards. Calibration of the cartridge is completed when information determined at the factory for each lot of cartridges is combined with measurements taken during the calibration process. Factory derived calibration parameters are input into the analyzer by calibration code entry.

Throughout the calibration and analysis process, signals from the sensors are analyzed. If any abnormal conditions are detected, an error message is generated and the test will be terminated. If there are no abnormal conditions, then the sample results (measured and calculated) are displayed after successful calibration and analysis. In addition, the user has the option to print a hard copy of the results.

The user may also output the stored data via a RS232 serial port to IDMS (IRMA Data Management System) or to a LIS.

Cartridge operation

Upon insertion of the cartridge, the user will enter a calibration code and the software's checksums will determine whether the code is appropriate for that cartridge type. Screen prompts will guide the user through the calibration process and sample analysis

For a more detailed description of the sample sequence refer to Section 2 of the User Manual Draft Labeling which is located in Appendix D.

Intended Use Comparison

The IRMA Blood Analysis System is intended for professional use in those settings where direct measurement of blood such as blood gases (pCO₂ and pO₂), pH, Na⁺, K⁺, iCa⁺⁺, Cl⁻, BUN, and Hct in whole blood are performed such as the clinical laboratory or the patient bedside.

Substantial Equivalence

This notification demonstrates that the IRMA Blood Analysis System's BUN and Cl⁻ sensors are substantially equivalent to several other commercially cleared products: Johnson and Johnson Vitros Chemistry System DT60II (BUN) and the Buchler Digital Chloridometer (Cl⁻).

The IRMA and Vitros analysis systems are similar in that both systems are intended for the measurement of blood urea nitrogen (BUN) by enzymatic methods which utilize an urease reaction. The IRMA and Buchler Digital Chloridometer systems are similar in that both systems are intended for the measurement of chloride by electrochemical methods.

The predicate systems and proposed IRMA Blood Analysis System are compared in Tables #1-2.

Table #1 Comparison of IRMA to Vitros System Features

	IRMA	Vitros
Detection Method	enzymatic electrochemical urease reaction	enzymatic colorimetric urease reaction
Analytes measured	pH, pCO ₂ , pO ₂ , Na ⁺ , K ⁺ , iCa ⁺⁺ , BUN, Cl ⁻ , Hct *BUN and Cl ⁻ not available on multi-use	BUN, ammonia, amylase, cholesterol, creatinine, glucose, HDL cholesterol, hemoglobin, lactate, magnesium, neonatal bilirubin, phosphorus, total bilirubin, total protein, triglycerides, uric acid
Measuring Range	BUN 0 - 150 mg/dL	BUN 1 - 100 mg/dL
Operating Temp.	15-30°C (59-86°F)	15.5-29.4°C (60-85°F)
Operating Humidity	0-80%	15-75%* *Upper RH value dependent of temperature.
Sample	Whole blood 0.2 - 3.0 mL, syringe 0.125 mL from capillary collection device	Serum/plasma 10 µL per test
Power	7.2 V NiCAD rechargeable battery or AC adapter	120 VAC 1 amp 240 VAC 0.5 amp
Reagents	Supplied in self-contained disposable cartridge	Supplied in self-contained disposable slide
Weight	5 lbs.	19 lbs.
Results	Display and printer on board	Display and printer on board
Calibration	Automatic with each sample	User initiated process upon installation, changing of slide lots, when QC is out, or as needed for system verification.
Sensors	disposable single-use or multi-use	disposable single-use

Table #2 Comparison of IRMA to Buchler Chloridometer System Features

	IRMA	Buchler Chloridometer
Detection Method	electrochemical	electrochemical
Analytes measured	pH, pCO ₂ , pO ₂ , Na ⁺ , K ⁺ , iCa ⁺⁺ , BUN, Cl ⁻ , Hct *BUN and Cl ⁻ not available on multi-use	Cl ⁻
Measuring Range	Cl ⁻ 30-150 mM or mEq/L	Cl ⁻ 1.0-999.9 mEq/L
Operating Temp.	15-30°C (59-86°F)	Room temperature (range not specifically defined)
Operating Humidity	0-80%	Not defined
Blood Sample	Whole blood 0.2 - 3.0 mL, syringe 0.125 mL from capillary collection device	serum/plasma 10 µL on low range 100 µL on high range
Power	7.2 V NiCAD rechargeable battery or AC adapter	115 VAC, 60 Hz 230 VAC, 50 Hz
Reagents	Supplied in self-contained disposable cartridge	Chloridometer acid reagent which is manually measured
Weight	5 lbs.	10 lbs.
Results	Display and printer on board	Display on board
Calibration	Automatic with each sample	Manual blank adjustment of reagents and check with chloride standard
Sensors	disposable single-use or multi-use	reusable silver wire

8. Performance Characteristics: Supporting data for Substantial Equivalence -

This section provides blood and aqueous data generated in-house using the IRMA Blood Analysis System's chloride and BUN sensors. The samples used in the study were spiked heparinized blood and prepared aqueous standards.

A. Accuracy Data

To determine chloride and BUN accuracy of the IRMA Blood Analysis, split sample studies were conducted using whole blood samples measured by both the IRMA system and a reference method (refer to Table #3). The method of least squares was used to determine the best fit line. Testing was conducted by three laboratory personnel. The IRMA system was cleared in a previous 510k submission for use by non-laboratory personnel therefore this submission does not include data by non-laboratory personnel such as nurses. The heparinized whole blood samples were prepared by spiking with varying concentrations of electrolytes to allow testing throughout the reportable range.

The data shown below in Table #4 and the x-y plots located in Appendix A indicate substantial equivalence between Cl- and BUN sensors on the IRMA Blood Analysis System and the predicate devices.

Table #3 Reference methods

Reference method	Parameter
Buchler Digital Chloridometer	Cl-
Johnson and Johnson DT60	BUN

Table #4 Blood Accuracy: The method of least squares was used to determine the best fit line.

Analyte	n	Range evaluated	Slope	Intercept	r	Sy.x
Cl-	56	74.8 - 136.4 mM	0.9561	4.64	0.9861	3.0
BUN	56	12.5 - 74.6 mg/dL	0.9846	0.46	0.9953	1.9

r = correlation coefficient

B. Precision Data

To determine precision of the Cr and BUN sensors of the IRMA system, samples at a given level were tested repeatedly. The samples used in the study consisted of three levels of aqueous solutions similar to commercially available quality control materials. Each day of testing, each operator analyzed a minimum of 4 samples from each of the three levels. Data from this study are shown in Tables #5-6.

Table #5 Cr Aqueous Precision

Day	Operator	n	Level	Mean	SD	CV
Day 1	1	5	1	30.6	0.76	2.5
	2	5	1	30.2	0.27	0.9
	3	5	1	30.8	0.94	3.0
	Combined	15	1	30.5	0.72	2.4
Day 2	1	5	1	30.5	0.94	3.1
	2	5	1	30.2	0.63	2.1
	3	4	1	30.5	0.17	0.6
	Combined	14	1	30.4	0.65	2.1
Day 1	1	5	2	56.6	0.22	0.4
	2	5	2	57.1	0.28	0.5
	3	5	2	57.0	0.43	0.8
	Combined	15	2	56.9	0.36	0.6
Day 2	1	5	2	57.0	0.30	0.5
	2	5	2	57.1	0.15	0.3
	3	5	2	57.1	0.30	0.5
	Combined	15	2	57.1	0.24	0.4
Day 1	1	5	3	85.9	1.78	2.1
	2	5	3	87.1	0.61	0.7
	3	4	3	87.0	0.42	0.5
	Combined	14	3	86.6	1.20	1.4
Day 2	1	4	3	86.0	1.59	1.9
	2	5	3	86.2	1.45	1.7
	3	5	3	85.2	1.90	2.2
	Combined	14	3	85.8	1.60	1.9

Combined = Results from all users combined for a day of testing.

Table #6 BUN Aqueous Precision

Day	Operator	n	Level	Mean	SD	CV
Day 1	1	5	1	17.5	2.40	13.7
	2	5	1	18.0	1.72	9.6
	3	5	1	17.4	1.36	7.8
	Combined	15	1	17.6	1.76	10.0
Day 2	1	5	1	17.7	0.96	5.4
	2	5	1	16.3	1.43	8.8
	3	5	1	17.3	1.06	6.1
	Combined	15	1	17.1	1.25	7.3
Day 1	1	5	2	33.8	1.40	4.1
	2	5	2	34.8	2.98	8.6
	3	5	2	34.2	3.93	11.5
	Combined	15	2	34.3	2.77	8.1
Day 2	1	5	2	33.3	2.19	6.6
	2	5	2	33.7	1.29	3.8
	3	5	2	34.5	2.84	8.2
	Combined	15	2	33.8	2.09	6.2
Day 1	1	5	3	64.1	4.56	7.1
	2	4	3	64.8	1.81	2.8
	3	5	3	65.4	4.81	7.4
	Combined	14	3	64.7	3.82	5.9
Day 2	1	5	3	68.7	1.46	2.1
	2	5	3	67.4	3.79	5.6
	3	5	3	67.6	2.55	3.8
	Combined	15	3	67.9	2.63	3.9

Combined = Results from all users combined for a day of testing.

D. Display range

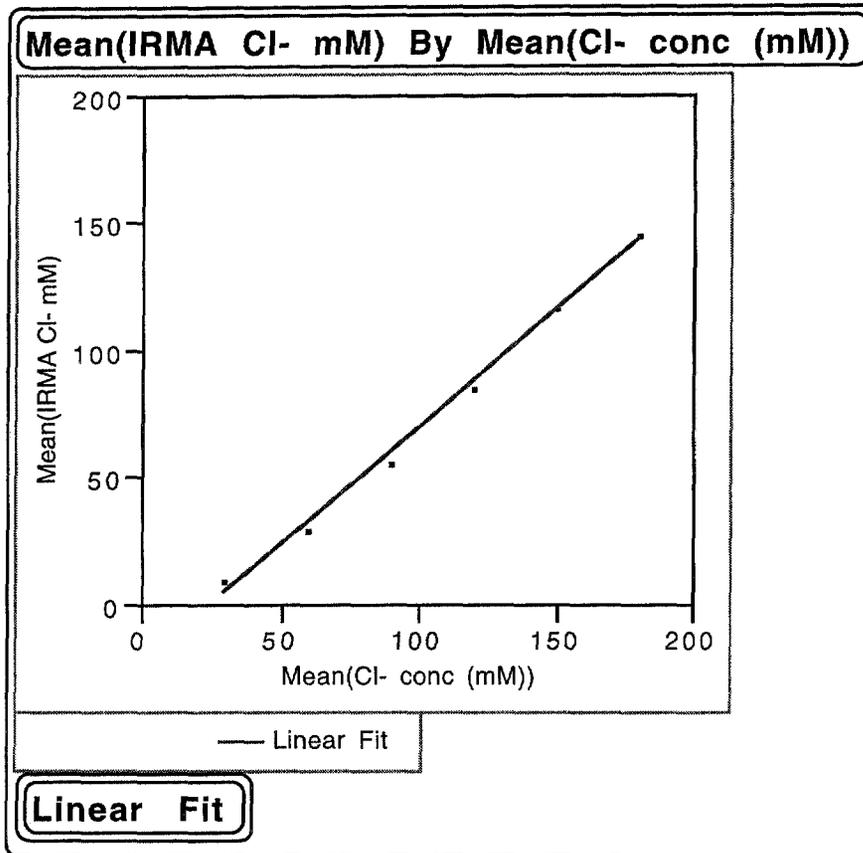
Graphs #1-2 show the tested linear range of the product. This data along with the blood accuracy data which were shown earlier justify the display ranges shown in Table #8.

Table #8 IRMA Blood Analysis System Display Range

Parameter	Display Range
Cl-	30-150 mM
BUN	0-150 mg/dL

Graph #1

IRMA Cl- Linear Range



$IRMA\ Cl = 0.9262\ Cl\text{-}\ conc\ (mM) - 22.43$

n = 99 samples - with mean of each level shown

r = 0.9976

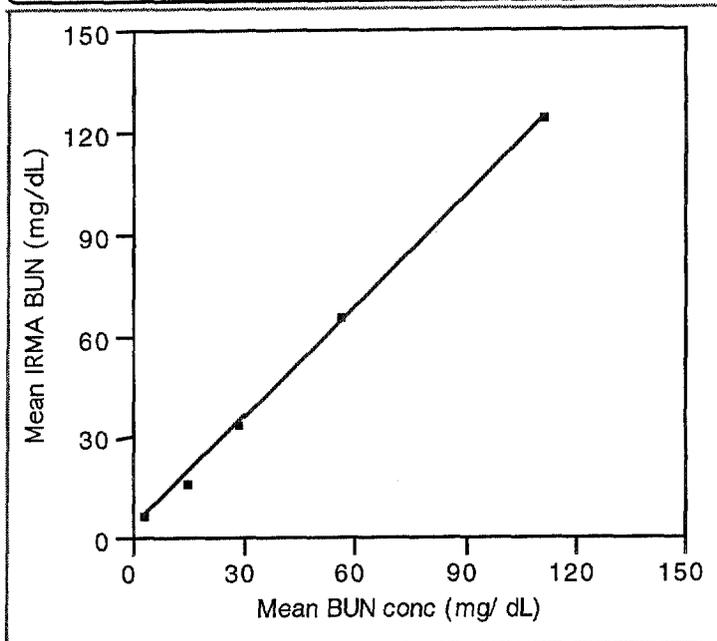
Sy.x = 4.0

Range evaluated = 10.6 - 146.8 mM

Graph #2

IRMA BUN Linear Range

Mean IRMA BUN (mg/ dL) By Mean BUN conc (mg/ dL)



— Linear Fit

Linear Fit

$$\text{IRMA BUN} = 1.0831 \text{ BUN conc (mg/ dL)} + 3.7837$$

N = 97 samples - with mean of each level shown

r = 0.9996

Sy.x = 1.5

Range evaluated = 7.3 - 124.5 mg/ dL

11. Safety and Effectiveness

The addition of the Cl- and BUN sensors to the IRMA Blood Analysis System has not been found to interfere or cause any adverse effects with the operation of the IRMA instrument or other nearby equipment. There are no additional risks to the patient or user when cartridges containing these sensors are utilized with the IRMA system.

The IRMA Blood Analysis System has already been certified to the required electrical and EMI safety specifications of medical equipment such as UL 2601-1 and UL 2601-2 (or equivalent).

11. Software Information

The IRMA Blood Analysis System's software has been developed, tested and will be validated in accordance with Diametrics' software development procedures and where applicable, the FDA's Reviewer's Guide to Computer Controlled Medical Devices (August, 1991). Based on the criteria of this document, our product is perceived to be of a low level of concern. Below is a description of the software development process.

Software requirements are developed based on approved product design requirements. All design specifications are reviewed for consistency and accuracy with respect to one another and a software hazard analysis is performed. The software hazard analysis for this product is located in Table #9. The software code is developed from the approved software requirements. Software revisions are maintained under a software version control system.

Software test plans and procedures are developed based on the software requirements specifications. Related software requirements are grouped to form the basis of test procedures. Each functional requirement (or group of requirements) is translated into a functional test and is included in a test procedure. These procedures are designed to ensure that functional requirements are met, software related system specifications fulfilled and software safety features adequately tested.

Code inspections and walk-throughs are performed by software engineers not involved in the code development in order to detect design flaws and validate software logic where functional testing is insufficient.

Written test procedures are executed and the results are reviewed to ensure that acceptance criteria have been met.

Software testing is also conducted in a less structured environment (free-form testing) by technicians and users under a variety of conditions in an attempt to "break" the software.

Considerable attention is applied to system safety throughout the verification, validation and testing of the software. A system hazard analysis which is done in the early development phase of the product is reviewed and updated as required. Safety requirements are identified in the hazard analysis and incorporated into the design specifications and tests via functional procedures. Potential error and exception conditions are also identified and tested. Stress conditions are also tested during the verification and validation phase.

All events identified as potential hazards for the IRMA Blood Analysis System have been addressed through hardware, software, or product labeling.

Changes to software requirements are documented, reviewed and approved. Each revision of the software is reviewed and evaluated for complete functionality and impact to the hazard analysis. New revisions are subjected to the same tests as the previous version. Revisions to areas that do not affect calculations may be regression tested. Each version of the software released to manufacturing will be archived with a list of the changes and validation data.

Table #9 Software Hazard Analysis

Potential Hazard:	Action to Minimize Hazard	Add'l Information	Likelihood	Severity
Inaccurate Algorithms	Test & Validation plans Development Phase	QC check	Improbable	Marginal
Calibration	Test & Validation plans Development Phase	QC check	Improbable	Marginal
Sample Calculations	Test & Validation plans Development Phase	QC check	Improbable	Marginal
System operation	Test & Validation plans Development Phase	QC check	Improbable	Marginal
Incorrect IR reading	Test & Validation plans Development Phase	QC check	Improbable	Marginal
Temperature & Barometric checks	Test & Validation plans Development Phase	QC check	Improbable	Marginal

Table #10 Categories

Likelihood	Severity
Frequent	Negligible
Probable	Marginal
Occasional	Critical
Remote	Catastrophic
Improbable	
Incredible	

Software Certification

I certify that, in my capacity as Director of Quality Assurance and Regulatory Affairs of Diametrics Medical, Inc., prior to market release of the product, the software development process will be completed. The final documentation will include official signoff of the software requirements specifications, test plans and test completion criteria, and their results which demonstrate the system specifications and functional requirements were met along with release of the software revision.

We have shown substantial equivalence between the IRMA Blood Analysis System utilizing the multi-use cartridge and the predicate devices even though the software development process has not yet been completed.

Name of Company Official Correspondent: Steve Boeh

Signature: 

Title: Director of QA/RA

Company Name: Diametrics Medical Inc.

Date of Signature: 4/3/98
Month/Day/Year

13. Attachments

The proposed labeling appears in Appendix B (Pouch and Cartridge Labels), Appendix C (Cartridge Package Insert) and Appendix D (User Manual). There are no required changes to the IRMA Blood Analysis System's device label. The draft user manual which is shown contains the information which is pertinent to the addition of the new Cl⁻ and BUN sensors. Any screen changes associated with these new sensors will also be made to the pictures in the user manual. This information will either be incorporated into the current IRMA SL Series 2000 User Manual or it will become an addendum to it. Diametrics Medical, Inc. does not intend to advertise the product at this time.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAY 1 1998

Steve Boeh
Director, Quality Assurance and Regulatory Affairs
Diametrics Medical, Inc.
2658 Patton Road
Saint Paul, ~~Minneapolis~~ 55113

Minnesota

Re: K981270
IRMA® Blood Analysis System
Regulatory Class: II
Product Code: CGZ, CDS, GKG, JFP, JGS, CHL, CEM
Dated: April 2, 1998
Received: April 7, 1998

Dear Mr. Boeh:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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.

If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your pre-market notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

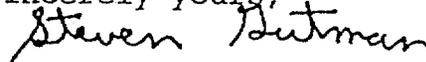
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use and Intended Use Statement

510(k) Number: K 981270
Device Name: IRMA Blood Analysis System with additional menu: blood urea nitrogen and chloride

Indications for Use

Statement of Intended Use

The IRMA Blood Analysis System is intended for professional use in those settings where direct measurement of blood such as blood gases (pCO₂ and pO₂), pH, Na⁺, K⁺, iCa⁺⁺, BUN, Cl⁻, and Hct, in whole blood are performed such as the clinical laboratory or the patient bedside.

The pH, pCO₂, pO₂ measurements, and their associated calculated values are used to assess acid-base status and state of oxygenation. Common causes of acid-base disturbances include: cardiopulmonary disease, metabolic abnormalities, drugs and poisons, and fluid imbalance.

The electrolyte measurements (Na⁺, K⁺, Cl⁻) are used to assess hydrational status, aid in the diagnosis of respiratory and metabolic acid-balance, and prevention of cardiac arrhythmia. Common disease states which utilize these measurements for diagnosis are acid-base disturbances, dehydration, diarrhea, ketoacidosis, alcoholism and other toxicities.

The measurement of ionized calcium is used to assess disease states such as thyroid abnormalities, renal failure or transplant, and to monitor dialysis patients.

The measurement of blood urea nitrogen is used to monitor renal disease, dialysis patients, and hyperalimentation.

The measurement of hematocrit is used to assess anemia, blood loss such as in an accident or during surgical procedures, and polycythemia.

With the addition of BUN and Cl⁻, the IRMA Blood Analysis System will measure: blood gases (pCO₂ and pO₂), pH, sodium, potassium, ionized calcium, blood urea nitrogen, chloride, and hematocrit. The sensor arrays of the cartridge will also be packaged in various combinations.

(Please DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

OR Over-The-Counter Use
(Optional Format 1-2-96)

Division Sign-Off
Division of Clinical Laboratory Devices
510(k) Number K 981270