RADIOMETER COPENHAGEN

510(k) Summary - ABL800 FLEX

OCT 8 - 2004

Submitter:	Radiometer Medical ApS
Address:	Åkandevej 21, DK-2700 Brønshøj, Denmark
Phone:	+45 3827 3827 or +45 3827 3390 (direct)
Fax:	+45 3827 2736
Contact Person:	Ms. Kirsten Rønø
Date Summary Prepared:	September 30, 2004

Device Trade Name:	ABL800 FLEX
Common name:	Blood Gas, Co-oximetry, Electrolyte and Metabolite Analyzer
Classification Name:	Blood gases and blood pH test system

Predicate Devices

RADIOMETER ABL700 Series Upgrade (K002290) and ABL700 with AutoCheck Module (K992859).

Device Description

The ABL800 FLEX is an automatic analyzer for in vitro testing of blood gases, electrolytes, metabolites and co-oximetry parameters in samples of whole blood.

The ABL800 FLEX includes the capability (FLEXMODE) of automatically measuring a reduced number of parameters when there is not enough sample to measure the desired number of parameters. The analyzer further includes a new inlet supporting test tubes and has a new software platform, which makes the user interface fully customizable.

Intended Use

The ABL800 FLEX is intended for in vitro testing of samples of whole blood for the parameters pH, pO_2, pCO_2, potassium, sodium, calcium, chloride, glucose, lactate, total bilirubin, and co-oximetry parameters (total hemoglobin, oxygen saturation, and the hemoglobin fractions FO_2Hb, *F*COHb, *F*MetHb, *F*HHb and *F*HbF). In addition the ABL800 FLEX is intended for in vitro testing of samples of expired air for the parameters pO_2 and pCO_2. The ABL800 FLEX includes an AutoCheck Module to perform automated analysis of quality control fluids.

Statement of Indication for Use

Indication for use information for the analytes measured by the ABL800 FLEX:

pH: pH is the indispensable measure of acidemia or alkalemia and is therefore an essential part of the pH/blood gas measurement. The normal function of many metabolic processes requires a pH to be within a relatively narrow range.

***p*O_2:** The arterial oxygen tension is an indicator of the oxygen uptake in the lungs.

***p*CO_2:** *p*CO_2 is a direct reflection of the adequacy of alveolar ventilation in relation to the metabolic rate.

Potassium (*c*K^+): The measurements of the concentration of potassium ions in plasma are used to monitor the electrolyte balance.

Sodium (*c*Na^+): The measurements of the concentration of sodium ions in plasma are used to monitor the electrolyte balance.

Calcium (*c*Ca^{2+}): The measurements of the concentration of calcium ions in plasma are used to monitor the electrolyte balance.

Chloride (*c*Cl^-): The measurements of the concentration of chloride ions in plasma are used to monitor the electrolyte balance.

Glucose (*c*Glu): The glucose measurements measure the concentration of glucose in plasma. The glucose measurements are used to screen for, diagnose and monitor diabetes, pre-diabetes, and hyper- and hypoglycemia.

Lactate (*c*Lac): The lactate measurements measure the concentration of lactate in plasma. Lactate measurements serve as a marker of critical imbalance between tissue oxygen demand and oxygen supply.

Bilirubin (*c*tBil): The bilirubin measurements measure the total concentration of bilirubin in plasma. *c*tBil is used to assess the risk of hyperbilirubinemia.

Total Hemoglobin (*c*tHb): *c*tHb is a measure of the potential oxygen-carrying capacity of the blood.

Oxygen Saturation (*s*O_2): *s*O2 is the percentage of oxygenated hemoglobin in relation to the amount of hemoglobin capable of carrying oxygen. *s*O2 allows evaluation of oxygenation.

Fraction of Oxyhemoglobin (*F*O_2Hb): *F*O_2Hb is a measure of the utilization of the potential oxygen transport capacity; that is the fraction of oxyhemoglobin in relation to all hemoglobins present (tHb) including dyshemoglobins.

Fraction of Carboxyhemoglobin (*F*COHb): *F*COHb is the fraction of carboxyhemoglobin. It is incapable of transporting oxygen.

Fraction of Methemoglobin (*F*MetHb): *F*MetHb is the fraction of methemoglobin. It is incapable of transporting oxygen.

Fraction of Deoxyhemoglobin in Total Hemoglobin (*F*HHb): *F*HHb is the fraction of deoxyhemoglobin in total hemoglobin. It can bind oxygen then forming oxyhemoglobin.

Fraction of Fetal Hemoglobin (*F*HbF): Fetal hemoglobin consists of two α-chains and two β-chains, and has a higher oxygen affinity than adult Hb.

Clinical Interpretation

Clinical interpretation for the analytes measured by the ABL800 FLEX:

pH: Common causes of low pH (acidosis) may be A) respiratory acidosis as alveolar hypoventilation or increased metabolic rate or B) metabolic acidosis as circulatory impairment, renal failure, diabetic ketoacidosis or gastro-intestinal loss of bicarbonate (diarrhea). Common causes of high pH (alkalosis) may be A) respiratory alkalosis as alveolar hyperventilation or B) metabolic alkalosis as diuretics, gastrointestinal loss of acid (vomiting) or hypokalemia (low cK^+).

pO_2: Common causes of low pO_2 is pulmonary disease, cardiac right to left shunt, low alveolar ventilation and ambient pressure.

pCO_2: Common causes of low pCO_2 (alveolar hyperventilation - hypocapnia) may be A) aggressive ventilator treatment or psychogenic hyperventilation or B) compensatory to metabolic acidosis, secondary to central nervous system affection or secondary to hypoxia. Common causes of high pCO_2 (alveolar hypoventilation - hypercapnia) may be lung disease, central nervous system depression, either primary, or secondary to sedation or analgesics or ventilator treatment, either with strategy of permissive hypercapnia or with too low alveolar ventilation.

Potassium (cK^+): Common causes of low cK^+ may be diuretics, diarrhoea, vomiting, respiratory or metabolic baseosis or hyperaldosteronism. Common causes of high cK^+ may be renal failure, metabolic acidosis or toxic acidosis (salicylate, methanol, etc.).

Sodium (cNa^+): Common causes of low values of cNa^+ may be water intoxication, renal failure, heart failure, liver failure, increased ADH secretion, diuretics or nephrotic syndrome. Common causes of high values of cNa^+ may be increased Na-load, steroids, vomiting, diarrhea, excessive sweating or osmotic diuresis.

Calcium (cCa^{2+}): Common causes of low values of cCa^{2+} may be baseosis, renal failure, acute circulatory insufficiency, lack of vitamin D or hypoparathyroidism. Common causes of high values of cCa^{2+} may be malignancies, thyreotoxicosis, pancreatitis, immobilization or hyperparathyroidism.

Chloride (*c*Cl⁻): Common causes of low *c*Cl⁻ may be primary metabolic acidosis or a secondary metabolic acidotic compensation for respiratory alkalosis. Common causes of high *c*Cl⁻ may be metabolic alkalosis either as primary disorder of as compensation for chronic respiratory acidosis.

Glucose (*c*Glu): Common causes of low *c*Glu may be insulin overdose, adrenal insufficiency and extensive liver disease. Common causes of high *c*Glu may be lack of insulin, acute stress (response to trauma, heart attack, and stroke).

Lactate (*c*Lac): In most situations, elevated blood lactate will be caused by hypoperfusion, severely impaired arterial oxygen supply, or a combination of the two. Decreasing or persistently low levels of blood lactate (*c*Lac) during critical illness signal successful treatment.

Bilirubin (*ct*Bil): Bilirubin is formed as a result of the catabolism of hemoglobin. Typically, the major part of bilirubin in plasma comes from the breakdown of red cells. Neonates have an increased breakdown of hemoglobin, limited hepatic function and low concentrations of albumin. If the concentration of bilirubin in neonates exceeds defined levels it requires specific therapy.

Total Hemoglobin (*ct*Hb): High values of *ct*Hb typically indicate a high blood viscosity, which increases the afterload to the heart and thereby can cause forward failure. In extreme cases, the microcirculation can be impaired. Common causes of high values of *ct*Hb (polycytemia) may be A) polycytemia vera or B) dehydration, chronic lung disease, chronic heart disease, living at high altitude or trained athletes. Low concentrations of total hemoglobin or effective hemoglobin imply a risk of tissue hypoxia because of the lowered arterial oxygen content (*ct*O2). Common causes of low values *ct*Hb (anemia) may be A) impaired red cell production or B) hemolysis, bleeding, dilution (overhydration) or multiple blood samples (neonates).

Oxygen Saturation (sO_2): High (normal) sO_2 may be a measure of sufficient utilization of actual oxygen transport capacity. Common causes of low sO_2 may be impaired oxygen uptake.

Fraction of Oxyhemoglobin (FO_2Hb): High (normal) *F*O2Hb may be an indication of sufficient utilization of oxygen transport capacity. Common causes of low FO_2Hb may be impaired oxygen uptake or presence of dyshemoglobins.

Fraction of Carboxyhemoglobin (*F*COHb): *F*COHb levels are normally below 2 %, but heavy smokers may have up to 9-10 %. Newborns may present up to 10-12 % of *F*COHb because of an increased hemoglobin turnover combined with a less developed respiratory system. In the acute exposition, headache, nausea, dizziness and chest pain occur with 10-30 %. Severe headache, general weakness, vomiting, dyspnea and tachycardia occur at 30-50 %. Above 50 %, seizures, coma and death occur.

Fraction of Methemoglobin (*F*MetHb): *F*MetHb levels above 10-15 % can result in pseudocyanosis. Methemoglobinemia may cause headache and dyspnea at levels above 30 % and may be fatal, especially in levels above 70 %.

Fraction of Deoxyhemoglobin in Total Hemoglobin (*F*HHb): *F*HHb is an expression of the amount of hemoglobin not bound to oxygen, but capable of being bound to oxygen if the oxygen supply is increased.

Fraction of Fetal Hemoglobin (*F*HbF): *F*HbF indicates the amount of fetal hemoglobin. *F*HbF is seldom used clinically.

Test

The precision (i.e. repeatability or within-run imprecision) and reproducibility (i.e. total imprecision) results for the parameters as well as the linearity/assay reportable ranges were established from a single large-sized non-clinical test. The test was performed as a large comparative in-house study using 11 ABL800 FLEX analyzers and 5 ABL735 analyzers (for reference).

The test comprised all measuring modes of all the configurations of the ABL800 FLEX analyzer on all parameters. The study was performed on samples of whole blood having syringe volumes of 20 ml and 50 ml and capillary volumes of 224 µl, 104 µl, 94 µl, 83 µl, 57 µl, 50 µl and 35µl. 16 different mixtures of heparinized whole blood samples were used in the test.

In the test, a total of approx. 4,700 measurements was performed on the ABL800 FLEX with corresponding ABL735 reference values.

The result of the non-clinical test showed that when looking at repeatability, reproducibility, bias, test range etc. the ABL800 FLEX performed substantially equivalent to the predicate devices.

Summary of Technological Characteristics

The measuring technology of the ABL800 FLEX includes electrochemical and optical technology. The sensors for measuring blood gases and pH, sodium, potassium, calcium, chloride, glucose and lactate are electrochemical sensors. The electrochemical sensors are based on potentiometric and amperometric methods.

The optical system of the ABL800 FLEX for measuring co-oximetry parameters and bilirubin includes a 128-wavelength spectrophotometer. The system is based on absorbance measurements.

The ABL800 FLEX may be interfaced with the RADIANCE STAT analyzer management system software as well as with the hospital LIS/HIS systems through network interfaces.

The ABL800 FLEX is similar in technological characteristics, device performance and intended use as the predicate devices and is therefore substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 8 - 2004

Ms. Lene Meineche Marnaes
Regulatory Affairs
Radiometer Medical ApS
Åkandevej 21
Brønshøj
Denmark DK-2700

Re: k041874
Trade/Device Name: ABL800 Flex
Regulation Number: 21 CFR 862.1120
Regulation Name: Blood gases (pCO2, pO2) and blood pH test system
Regulatory Class: Class II
Product Code: CHL, JGS, CEM, JFP, CGZ, CGA, CIG, GHS, KQI, KHP, MQM
Dated: July 9, 2004
Received: July 12, 2004

Dear Ms. Marnaes:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Jean M. Cooper MS DVM.

Jean M. Cooper, MS, D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K041874

Device Name: ABL800 FLEX

Intended Use:

The ABL800 FLEX is intended for in vitro testing of samples of whole blood for the parameters pH, pO_2, pCO_2, potassium, sodium, calcium, chloride, glucose, lactate, total bilirubin, and co-oximetry parameters (total hemoglobin, oxygen saturation, and the hemoglobin fractions FO_2Hb, *F*COHb, *F*MetHb, *F*HHb and *F*HbF). In addition the ABL800 FLEX is intended for in vitro testing of samples of expired air for the parameters pO_2 and pCO_2. The ABL800 FLEX includes an AutoCheck Module to perform automated analysis of quality control fluids.

Indications For Use:
Indication for use information for the analytes measured by the ABL800 FLEX:

pH: pH is the indispensable measure of acidemia or alkalemia and is therefore an essential part of the pH/blood gas measurement. The normal function of many metabolic processes requires a pH to be within a relatively narrow range.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K041874

pO_2: The arterial oxygen tension is an indicator of the oxygen uptake in the lungs.

pCO_2: pCO_2 is a direct reflection of the adequacy of alveolar ventilation in relation to the metabolic rate.

Potassium (cK^+): The measurements of the concentration of potassium ions in plasma are used to monitor the electrolyte balance.

Sodium (cNa^+): The measurements of the concentration of sodium ions in plasma are used to monitor the electrolyte balance.

Calcium (cCa^{2+}): The measurements of the concentration of calcium ions in plasma are used to monitor the electrolyte balance.

Chloride (cCl^-): The measurements of the concentration of chloride ions in plasma are used to monitor the electrolyte balance.

Glucose (cGlu): The glucose measurements measure the concentration of glucose in plasma. The glucose measurements are used to screen for, diagnose and monitor diabetes, pre-diabetes, and hyper- and hypoglycemia.

Lactate (cLac): The lactate measurements measure the concentration of lactate in plasma. Lactate measurements serve as a marker of critical imbalance between tissue oxygen demand and oxygen supply.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K041874

Bilirubin (ctBil): The bilirubin measurements measure the total concentration of bilirubin in plasma. *c*tBil is used to assess the risk of hyperbilirubinemia.

Total Hemoglobin (ctHb): ctHb is a measure of the potential oxygen-carrying capacity of the blood.

Oxygen Saturation (sO_2): *s*O2 is the percentage of oxygenated hemoglobin in relation to the amount of hemoglobin capable of carrying oxygen. *s*O2 allows evaluation of oxygenation.

Fraction of Oxyhemoglobin (FO_2Hb): FO_2Hb is a measure of the utilization of the potential oxygen transport capacity; that is the fraction of oxyhemoglobin in relation to all hemoglobins present (tHb) including dyshemoglobins.

Fraction of Carboxyhemoglobin (*F*COHb): *F*COHb is the fraction of carboxyhemoglobin. It is incapable of transporting oxygen.

Fraction of Methemoglobin (*F*MetHb): *F*MetHb is the fraction of methemoglobin. It is incapable of transporting oxygen.

Fraction of Deoxyhemoglobin in Total Hemoglobin (*F*HHb): *F*HHb is the fraction of deoxyhemoglobin in total hemoglobin. It can bind oxygen then forming oxyhemoglobin.

Fraction of Fetal Hemoglobin (*F*HbF): Fetal hemoglobin consists of two α-chains and two β-chains, and has a higher oxygen affinity than adult Hb.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K041879