April 6, 2020

Nova Biomedical Corporation
Rachel Gilbert
Regulatory Affairs Specialist II
200 Prospect Street
Waltham, MA 02454

Re: K200204
Trade/Device Name: Stat Profile® Prime Plus Analyzer System
Regulation Number: 21 CFR 864.7500
Regulation Name: Whole Blood Hemoglobin Assays
Regulatory Class: Class II
Product Code: GGZ, GHS, GKK, GKR, JPI
Dated: January 23, 2020
Received: January 28, 2020

Dear Rachel Gilbert:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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 Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR

803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Marianela Perez-Torres, M.T., Ph.D.
Acting Deputy Director
Division of Chemistry
and Toxicology Devices
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
k200204

Device Name
Stat Profile® Prime Plus Analyzer System

Indications for Use *(Describe)*
The Stat Profile Prime Plus Analyzer System is indicated for use by healthcare professionals in clinical laboratory settings and for point-of-care usage for quantitative determination of Hematocrit, Oxygen Saturation, Total Hemoglobin, Oxyhemoglobin, Carboxyhemoglobin, Methemoglobin, and Deoxyhemoglobin in heparinized arterial and venous whole blood.

Hct	Hematocrit (Hct) measurements of the packed red blood cell volume are used to distinguish normal from abnormal states, such as anemia and erythrocytosis.
SO_2	Oxygen Saturation (SO_2) measurements are used to assess the oxygenation of the hemoglobin and the adequacy of tissue oxygenation in the evaluation of pulmonary function. Measurements are also used to diagnose and treat cyanosis.
tHb	Total Hemoglobin (tHb) measurements are used in the evaluation of chronic and acute anemia as well as the oxygen transport capability of the hemoglobin.
O_2Hb	Oxyhemoglobin (O_2Hb) measurements are used to assess pulmonary function in combination with Deoxyhemoglobin and are also used in the diagnosis and treatment of cyanosis.
COHb	Carboxyhemoglobin (COHb) measurements are used to determine if and to what level carbon monoxide has been inhaled by the patient. High levels of carbon monoxide can lead to tissue anoxia and death.
MetHb	Methemoglobin (MetHb) measurements are used to determine congenital methe-moglobinemia or determine the ingestion of nitrates, chlorates, or any other drug or chemical that can cause methemoglobin formation. High levels of methemoglobin can lead to cyanosis and death.
HHb	Deoxyhemoglobin (HHb) measurements are used to assess pulmonary function in combination with Oxyhemoglobin.

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.

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510(k) Summary
k200204

510(K) Owner: Nova Biomedical Corporation
Registration Number: 1219029
Address: 200 Prospect St.
Waltham, MA 02454
Phone: 781-894-0800
Fax Number: 784-891-4806
Contact Person: Rachel Gilbert, Regulatory Affairs Specialist II
Date Prepared: January 23, 2020

Proprietary Name: Stat Profile® Prime Plus Analyzer System

Common or Usual Name: Blood Analyzer

Classification Name: Multiple

Regulation section	Classification	Product code	Panel
21 CFR § 864.7500 Whole blood hemoglobin assays (Oxyhemoglobin)	Class II	GGZ	Hematology (81)
21 CFR § 864.7500 Whole blood hemoglobin assays (Cyanomethemoglobin)	Class II	GKK	
21 CFR § 864.6400 Hematocrit measuring device	Class II	JPI	
21 CFR § 864.7425 Carboxyhemoglobin assay	Class II	GHS	
21 CFR § 864.5620 Automated hemoglobin system	Class II	GKR	

Predicate Device:
k180186 – Stat Profile Prime Plus Analyzer System

Device Description:
The Stat Profile Prime Plus Analyzer System is a low cost, low maintenance analyzer for hospital laboratory and point-of-care settings. It consists of the analyzer, sensor cartridges, and thermal paper for an onboard printer. Optionally, it provides for reading of barcode labels (such as operator badges and data sheets).

The Stat Profile Prime Plus Analyzer has slots to accommodate two sensor cartridges (Primary and Auxiliary). The analyzer will determine the configuration of the system by detecting which sensor cards are installed.

Primary Sensor Card Port:

There are two options for the primary sensor card:

- **Primary Sensor Card 1** shall enable and report the following listed analytes:
  - Hct, tHb, SO_2, O_2Hb, COHb, MetHb, HHb
- **Primary Sensor Card 2** shall enable and report the following listed analytes:
  - Hct, tHb, SO_2

As with the predicate, the Stat Profile Prime Plus Analyzer is a blood gas, co-oximetry, electrolyte, chemistry, and hematology analyzer with an enhanced test menu and multiple quality control options. Both traditional internal and external quality control is available, as well as an on-board Quality Management System (QMS), and an electronic monitoring approach that insures the analyzer is working properly at all times.

The Stat Profile Prime Plus Analyzer accepts samples from syringes and open tubes. The minimum sample size for analysis is 135 µL.

Sample collection, preparation and application to the analyzer are the same as for the previously cleared predicate. The end user can select which analytes are to be tested in the panel.

Stat Profile Prime Plus Analyzer System Components:

The Stat Profile Prime Plus Analyzer System is comprised of the following components.

- Stat Profile Prime Plus Analyzer System
- Primary Sensor Cartridge
- Auxiliary Sensor Cartridge
- Stat Profile Prime Plus Auto-Cartridge Quality Control Pack
- Stat Profile Prime Plus Calibrator Cartridge
- Stat Profile Prime Plus External Ampuled Control
- IFU/Labeling

Sample Types:

The Stat Profile Prime Plus Analyzer System accepts lithium heparinized arterial and venous whole blood.

Measured Parameters:

The Stat Profile Prime Plus Analyzer measures:

- Hematocrit (Hct)
- Oxygen Saturation (SO_2)
- Total Hemoglobin (tHb)
- Oxyhemoglobin (O_2Hb)
- Carboxyhemoglobin (COHb)
- Methemoglobin (MetHb)
- Deoxyhemoglobin (HHb)

Calculated Parameters:
The Prime Plus Analyzer also provides the following parameter results calculated based on results of the directly measured parameters:

- Arterial Oxygen Content (CaO_2)
- Arterial-Venous Oxygen Content Difference ($C(a\text{-}v)O_2$)
- Base Excess of Blood (BE-b)
- Fractional Oxyhemoglobin (FO_2Hb)
- Oxygen Capacity (O_2Cap)
- Oxygen Content (O_2Ct)
- P_{50}
- Qsp/Qt (Physiological Shunt)
- Standard Bicarbonate Concentration (SBC)

Intended Use:

The Stat Profile Prime Plus Analyzer System is indicated for use by healthcare professionals in clinical laboratory settings and for point-of-care usage for quantitative determination of Hematocrit, Oxygen Saturation, Total Hemoglobin, Oxyhemoglobin, Carboxyhemoglobin, Methemoglobin, and Deoxyhemoglobin in heparinized arterial and venous whole blood.

Indications for Use:

Hct	Hematocrit (Hct) measurements of the packed red blood cell volume are used to distinguish normal from abnormal states, such as anemia and erythrocytosis.
SO_2	Oxygen Saturation (SO_2) measurements are used to assess the oxygenation of the hemoglobin and the adequacy of tissue oxygenation in the evaluation of pulmonary function. Measurements are also used to diagnose and treat cyanosis.
tHb	Total Hemoglobin (tHb) measurements are used in the evaluation of chronic and acute anemia as well as the oxygen transport capability of the hemoglobin.
O_2Hb	Oxyhemoglobin (O_2Hb) measurements are used to assess pulmonary function in combination with Deoxyhemoglobin and are also used in the diagnosis and treatment of cyanosis.
COHb	Carboxyhemoglobin (COHb) measurements are used to determine if and to what level carbon monoxide has been inhaled by the patient. High levels of carbon monoxide can lead to tissue anoxia and death.
MetHb	Methemoglobin (MetHb) measurements are used to determine congenital methe-moglobinemia or determine the ingestion of nitrates, chlorates, or any other drug or chemical that can cause methemoglobin formation. High levels of methemoglobin can lead to cyanosis and death.
HHb	Deoxyhemoglobin (HHb) measurements are used to assess pulmonary function in combination with Oxyhemoglobin.

Summary of the Technological Characteristics:

The Stat Profile Prime Plus Analyzer is substantially equivalent to the previously cleared for market Stat Profile Prime Plus Analyzer in intended use. It uses the same sensor technology and measurement algorithms, and the formulations of the internal and external controls and the calibration cartridge are the same for the tested parameters.

Principles of Measurement:

Oxygen Saturation:

Oxygen saturation (SO_2%) represents the percent of hemoglobin bound to oxygen, expressed as a fraction of the amount of hemoglobin capable of binding to oxygen (oxyhemoglobin plus deoxyhemoglobin). As the level of SO_2% changes within a blood sample, the color of the whole blood changes. Oxygen Saturation is determined by using a standard equation.

Hematocrit:

Hematocrit is defined as the percentage of red blood cells to the total blood volume and can be obtained by measuring electrical resistance of the blood sample. Two standard solutions are used to calibrate the hematocrit sensor and to obtain the slope. The analyzer then measures the electrical resistance of the blood sample to obtain the hematocrit value. The hematocrit value obtained is corrected for the concentration of the sodium ion.

Total Hemoglobin:

Hemoglobin is a protein found in red blood cells that carries oxygen from the lungs to the body's tissues and returns carbon dioxide from the tissues back to the lungs. Total Hemoglobin is the sum of all measured hemoglobin fractions expressed as the amount of hemoglobin in a specified volume of whole blood. Total Hemoglobin is calculated using a standard equation.

Oxyhemoglobin:

Oxyhemoglobin is the combined form of hemoglobin and oxygen. Oxygen is bound reversibly and is readily given up to the tissues because of the lower tissue oxygen tension. Conversely in the lungs, there is a higher oxygen tension and greater oxygen uptake by hemoglobin. The percentage of oxyhemoglobin is determined using a standard equation.

Carboxyhemoglobin:

Carboxyhemoglobin is the combined form of carbon monoxide and hemoglobin. The affinity of hemoglobin for carbon monoxide is approximately 210 times greater than for oxygen. Because of this high affinity, inhalation of large amounts of carbon monoxide can lead to death if left undiagnosed. The percentage of carboxyhemoglobin is determined by using a standard equation.

Methemoglobin:

Methemoglobin is the form of hemoglobin in which the iron has been oxidized from the ferrous to the ferric state. Oxygen cannot bind with methemoglobin. Therefore, increased amounts can lead to cyanosis, tissue anoxia, and death. There are congenital and acquired forms of methemoglobinemia. The percentage of methemoglobin is determined by using a standard equation.

Deoxyhemoglobin:

Deoxyhemoglobin is the form of hemoglobin that is not combined with oxygen but can easily uptake oxygen in the lungs. The percentage of deoxyhemoglobin is determined by using a standard equation.

Summary of Performance Testing:

Bench testing was previously completed and summarized in k180186 to show that the Stat Profile Prime Plus Analyzer demonstrates substantial equivalence to the predicate submission.

The bench testing included:

- Method Comparison Studies
- Precision/Reproducibility – Within Run and Run to Run Studies
- Linearity Testing
- Specificity/Interference Testing
- Detection Limit

The results of that testing confirmed that the performance of the Stat Profile Prime Plus Analyzer System is substantially equivalent to that of the Nova Stat Profile pHOx Ultra Analyzer System (predicate device).

Summary of Point-of-Care Testing:
A Point-of-Care (POC) study was conducted to show that the Stat Profile Prime Plus Analyzer demonstrates substantial equivalence to the predicate submission. The testing compared results obtained by trained Healthcare Professionals to results obtained by POC personnel on the same specimens using the same analyzer. The Stat Profile Prime Plus Analyzer was evaluated by point-of-care (POC) personnel in 3 POC sites including a Cardiothoracic Intensive Care Unit (CTICU), an Emergency Department (ED) and a Respiratory Therapy Lab (RT). A total of 61 Respiratory Care, 12 Nursing, and 1 Exercise Physiology POC personnel participated from the 3 POC settings over the course of the study. The personnel represent trained, qualified staff found in typical POC sites where blood gas analyzers are utilized. All testing was performed using quality control materials or discarded blood gas specimens.

Method Comparison studies on venous and arterial whole blood specimens were conducted using methods described in CLSI "Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline – Second Edition", CLSI EP9-A2. Combined method comparison data from all 3 POC settings is summarized in Table 1.

Table 1: Venous and Aterial Whole Blood Method Comparison Results – Point of Care vs Lab (ED, RT and CTICU)

								95% Confidence Interval of Bias	
analyte	**N**	**# altered samples**	**range**	**Slope**	**Intercept**	**r**	**MDL**	**Lower Limit**	**Upper Limit**
Hct	417	3	18 - 69	0.9997	0.1315	0.9929	**20**	20	20
							56	56	56
SO_2	398	1	30 - 100	1.0084	-0.9664	0.9982	**80**	80	80
							90	90	90
tHb	416	2	5.0 - 24.2	1.0042	-0.0058	0.9923	**7**	6.9	7.1
							22	22.0	22.2
O_2Hb	422	8	7.1 - 98.4	1.0072	-0.8636	0.9983	**85**	84.6	85.1
							90	89.6	90.1
COHb	425	11	0.3 - 50.5	1.0024	-0.0013	0.9986	**3**	3.0	3.0
							10	10.0	10.1
MetHb	437	23	0.3 - 56.7	1.0040	0.0006	0.9993	**5**	5.0	5.0
							10	10.0	10.1
HHb	322	7	0.4 - 39.7	1.0123	0.0882	0.9962	**6**	6.0	6.3
							15	14.8	15.4

Total Imprecision Performance:

The estimates for total impression were obtained from different POC personnel running 3 levels of Stat Profile Prime Plus Quality Control/Linearity Materials in duplicate each day for a total of 20 runs on 3 Stat Profile Prime Plus analyzers. The protocol was based upon methods described in CLSI Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline—Second Edition, CLSI EP5-A2T. The total imprecision data from one representative POC site is shown in Table 2 is representative of the expected total imprecision performance obtainable by POC personnel using the Stat Profile Prime Plus analyzer using external quality control and linearity materials.

Table 2: Total Imprecision From ED Site

Total Imprecision Data-Level 1					
	Mean	**Within Run SD**	**Within Run %CV**	**Total SD**	**Total %CV**
Hct (%)	61	0.5	0.8	0.6	0.9
SO_2 (%)	47.5	0.6	1.2	0.7	1.4
tHb (g/dL)	19.8	0.2	0.9	0.2	1.0
O_2Hb (%)	20.5	0.3	1.2	0.4	1.7
COHb(%)	29.2	0.1	0.5	0.2	0.7
MetHb(%)	27.7	0.1	0.4	0.1	0.4
HHb (%)	22.7	0.1	0.5	0.1	0.6
Total Imprecision Data-Level 2					
Hct (%)	38	0.2	0.6	0.3	0.8
SO_2 (%)	78.0	0.4	0.5	0.4	0.5
tHb (g/dL)	13.3	0.3	1.9	0.3	2.2
O_2Hb (%)	47.1	0.4	0.8	0.4	0.9
COHb(%)	21.2	0.3	1.2	0.3	1.4
MetHb(%)	18.4	0.2	1.1	0.2	1.2
HHb (%)	13.2	0.2	1.2	0.2	1.2
Total Imprecision Data-Level 3					
Hct (%)	27	0.4	1.6	0.4	1.6
SO_2 (%)	91.0	0.0	0.0	0.0	0.0
tHb (g/dL)	6.6	0.1	1.9	0.1	2.2
O_2Hb (%)	80.1	0.1	0.2	0.2	0.2
COHb(%)	6.2	0.1	1.4	0.1	1.5
MetHb(%)	5.8	0.1	2.2	0.1	2.3
HHb (%)	7.9	0.1	1.5	0.1	1.7

Within-Run Whole Blood Precision:

Whole blood with-run precision of the Stat Profile Prime Plus Analyzer System in the hands of point-of-care operators was assessed by a minimum of two (2) point-of-care operators at each of the three (3) POC sites for a total of nine (9) operators across the 3 testing locations. Each precision run consisted of ten (10) replicate measurements using both fresh, native and altered whole blood samples. A total of five (5) different native samples and two (2) altered samples were evaluated at each site. Each whole blood specimen was maintained in a syringe. The POC operator performed all sample analysis steps including sample analysis, removal of resultant air bubble(s) from the syringe, recapping of the syringe and mixing prior to the next sample analysis. The whole blood within-run precision data from one representative POC

site is shown in Table 3 and is representative of the expected within-run precision obtainable by POC personnel using the Stat Profile Prime Plus analyzer using whole blood samples.

Table 3: Within Run Precision with Whole Blood Samples (n=10) – ED

	Mean	SD	%CV	95% CI
Sample 1				
Hct (%)	48.4	1.43	2.95	46 - 51
SO_2 (%)	80.0	0.00	0.00	80 - 80
tHb (g/dL)	15.0	0.31	2.06	14.4 - 15.6
O_2Hb (%)	78.6	0.30	0.38	78.0 - 79.2
COHb(%)	1.28	0.25	19.42	0.8 - 1.8
MetHb(%)	0.54	0.08	15.62	0.4 - 0.7
HHb (%)	19.6	0.18	0.91	19.3 - 20.0
Sample 2				
Hct (%)	20.8	0.42	2.03	20 - 22
SO_2 (%)	89.4	0.70	0.78	88 - 91
tHb (g/dL)	7.2	0.22	3.03	6.7 - 7.6
O_2Hb (%)	85.0	0.65	0.77	83.7 - 86.3
COHb(%)	4.11	0.17	4.05	3.8 - 4.4
MetHb(%)	0.81	0.22	27.58	0.4 - 1.3
HHb (%)	10.1	0.60	5.97	8.9 - 11.3
Sample 3				
Hct (%)	49.6	0.70	1.41	48 - 51
SO_2 (%)	95.9	0.32	0.33	95 - 97
tHb (g/dL)	16.2	0.05	0.33	16.0 - 16.3
O_2Hb (%)	93.9	0.48	0.51	92.9 - 94.8
COHb(%)	1.60	0.19	11.79	1.2 - 2.0
MetHb(%)	0.58	0.09	15.84	0.4 - 0.8
HHb (%)	4.0	0.36	9.19	3.2 - 4.7
Sample 4				
Hct (%)	49.8	0.63	1.27	49 - 51
SO_2 (%)	99.4	0.52	0.52	98 - 100
tHb (g/dL)	16.1	0.05	0.32	16.0 - 16.2
O_2Hb (%)	97.7	0.13	0.13	97.4 - 97.9
COHb(%)	1.08	0.17	15.62	0.7 - 1.4
MetHb(%)	0.71	0.07	10.39	0.6 - 0.9
HHb (%)	0.5	0.11	19.99	0.3 - 0.7
Sample 5				
Hct (%)	26.7	0.48	1.81	26 - 28
SO_2 (%)	92.5	0.53	0.57	91 - 94
tHb (g/dL)	8.2	0.05	0.59	8.1 - 8.3
O_2Hb (%)	90.4	0.45	0.50	89.5 - 91.3
COHb(%)	1.53	0.27	17.44	1.0 - 2.1
MetHb(%)	0.88	0.15	16.77	0.6 - 1.2
HHb (%)	7.2	0.37	5.08	6.5 - 7.9

	Mean	SD	%CV	95% CI
Sample 6 (Altered)				
Hct (%)	38.1	0.57	1.49	37 - 39
SO_2 (%)	99.4	0.52	0.52	98 - 100
tHb (g/dL)	11.0	0.12	1.06	10.7 - 11.2
O_2Hb (%)	94.4	0.17	0.18	94.1 - 94.7
COHb(%)	4.74	0.15	3.18	4.4 - 5.0
MetHb(%)	0.38	0.08	20.76	0.2 - 0.5
HHb (%)	0.48	0.08	16.43	0.3 - 0.6
Sample 7 (Altered)				
Hct (%)	44.0	0.47	1.07	43 - 45
SO_2 (%)	98.9	0.32	0.32	98 - 100
tHb (g/dL)	14.7	0.08	0.54	14.6 - 14.9
O_2Hb (%)	60.5	1.01	1.67	58.4 - 62.5
COHb(%)	17.4	0.21	1.18	17.0 - 17.8
MetHb(%)	21.5	1.06	4.92	19.4 - 23.7
HHb (%)	0.61	0.18	29.38	0.3 - 1.0

Conclusion:

The results of the POC clinical performance verification testing confirmed that the Stat Profile Prime Plus Analyzer is substantially equivalent to the predicate Stat Profile Prime Plus Analyzer System (k180186).

Table 4: Comparison of Predicate and Proposed Devices

Characteristic	Predicate:	Proposed:
Indication For Use	The Stat Profile Prime Plus Analyzer System is indicated for use by healthcare professionals in clinical laboratory settings for quantitative determination of Hematocrit, Oxygen Saturation, Total Hemoglobin, Oxyhemoglobin, Carboxyhemoglobin, Methemoglobin, and Deoxyhemoglobin in heparinized arterial and venous whole blood.	The Stat Profile Prime Plus Analyzer System is indicated for use by healthcare professionals in clinical laboratory settings and for point-of care usage for quantitative determination of Hematocrit, Oxygen Saturation, Total Hemoglobin, Oxyhemoglobin, Carboxyhemoglobin, Methemoglobin, and Deoxyhemoglobin in heparinized arterial and venous whole blood.
Acceptable Samples		
Sample Types	Lithium heparin whole blood from syringes and open tubes	Same
Sample Volumes	135µL	Same
Measurement Range		
Hct	12-70%	Same
SO_2	30-100%	Same
tHb	5.0-25.0 g/dL	Same
O_2Hb	1.8-100%	Same
COHb	0.3-60%	Same
MetHb	0.3-60%	Same
HHb	0.4-40%	Same
Principles of Measurement		
Hct	Impedance sensor	Same
SO_2	Spectrophotometric	Same
tHb	Spectrophotometric	Same
O_2Hb	Spectrophotometric	Same
COHb	Spectrophotometric	Same
MetHb	Spectrophotometric	Same
HHb	Spectrophotometric	Same
Touch Screen	10.1” WXGA 1280 x 800 color touch screen	Same
Menu	Fully configurable test menu based on available sensors	Same
Bar Code Scanner	Internal Integrated 1D/2D	Same
Printer	2" Roll, Thermal Transfer	Same
Pump	Peristaltic Pump w/ Pressure Plate, TPE Tubing (Pharmed BPT)	Same
Analog Board	Precision low level analog front end w/ amperometric and potentiometric amplifiers, air detector circuitry and temperature control circuitry	Same