

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY AND INSTRUMENT COMBINATION TEMPLATE**

A. 510(k) Number:

k063376

B. Purpose for Submission:

New submission for configuring a Cl^- option to the EasyStat pH, PCO_2 , PO_2 , Htc, Na^+ , K^+ , Ca^{++} Analyzer (K021515). Medica's Cl^- option was originally cleared on the EasyElectroLyte Na^+ , K^+ , Cl^- Analyzer (K000926).

C. Measurand:

pH (hydrogen ion activity), PCO_2 (partial pressure of carbon dioxide), PO_2 (partial pressure of oxygen), Htc (Hematocrit), Na^+ (sodium ions), K^+ (potassium ions), Ca^{++} (ionized calcium) and Cl^- (chloride ions)

D. Type of Test:

Quantitative Ion specific electrodes, Amperometric for PO_2 and conductivity for Hct

E. Applicant:

Medica Corp.

F. Proprietary and Established Names:

EasyStat pH, PCO_2 , PO_2 , Hct, Na^+ , K^+ , $\text{Ca}^{++}/\text{Cl}^-$ Analyzer

G. Regulatory Information:

1. Regulation section:

21CFR Sec.- 862.1120-Blood gases (PCO_2 , PO_2) and blood pH test system.

21CFR Sec. 864.5600 Automated hematocrit instrument.

21CFR Sec. 862.1665 Sodium test system.

21CFR Sec. 862.1600 Potassium test system.

21CFR Sec. 862.1145 Calcium test system.

21CFR Sec. 862.1170 Chloride test system.

2. Classification:

Class II

3. Product code:

CHL - Electrode Measurement, Blood-Gases (PCO_2 , PO_2) and Blood pH

GKF - instrument, hematocrit, automated

JGS - electrode, ion specific, sodium

CEM - electrode, ion specific, potassium

JFP - electrode, ion specific, calcium

CGZ - electrode, ion-specific, chloride

4. Panel:

Chemistry (75)

H. Intended Use:

1. Intended use(s):

See indications for use below

2. Indication(s) for use:

The EasyStat pH, PCO_2 , PO_2 , Htc, Na, K, Ca/Cl analyzer is designed for clinical laboratory use, making direct measurements of pH (hydrogen ion activity), PCO_2 (partial pressure of carbon dioxide), PO_2 (partial pressure of oxygen), Htc

(Hematocrit), Na^+ (sodium ions), K^+ (potassium ions), Ca^{++} (ionized calcium) and Cl^- (chloride ions) in whole blood samples from syringes or capillary tubes.

pH measurements are used in the diagnosis and treatment of diseases involving imbalance in the acid-base equilibrium in blood.

PCO₂ measurements are used in the diagnosis and treatment of diseases involving imbalance in the partial pressure of carbon dioxide in blood.

PO₂ measurements are used in the diagnosis and treatment of diseases conditions characterized by low or high blood oxygen levels in blood.

Hematocrit (Hct) measurements are used in the diagnosis and treatment of diseases characterized by erythrocyte imbalances in whole blood.

Sodium measurements are used in the diagnosis and treatment diseases involving electrolyte imbalance.

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

Calcium (ionized) measurements are used to determine the physiologically active form of calcium in blood and establish the patient's calcium metabolism.

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

3. Special conditions for use statement(s):
For prescription use
4. Special instrument requirements:
EasyStat pH, PCO₂, PO₂, Hct, Na^+ , K^+ , $\text{Ca}^{++}/\text{Cl}^-$ Analyzer

I. Device Description:

The EasyStat (ES) pH, PCO₂, PO₂, Hct, Na, K, Ca/Cl Blood Gas Analyzer is an analyzer that has all the features of the Medica's EasyStat (ES) pH, PCO₂, PO₂, Hct, Na, K, Ca analyzer, but the Ca ISE sensor may be replaced by a Cl sensor by either a distributor or an end-user. Depending on the operation mode chosen, the EasyStat Ca/Cl will analyze a whole-blood patient sample or a QC material for pH, PCO₂, PO₂, Hct, Na^+ , K^+ , Ca^{++} or pH, PCO₂, PO₂, Hct, Na^+ , K^+ , Cl^- .

Both EasyStat analyzers (Ca^{++} and Cl^- versions) utilize the same three aqueous calibrants enclosed in a sealed pack (Reagent Module) along with a waste container. These solutions are used in the calibration and sample analysis modes. The analyzer establishes the mathematical slope of the sensors by means of a two point calibration, and then determines the values of an unknown sample by direct comparison with one of the calibrants. One of the predicate devices for the Medica EasyStat chloride

analyzer is its predecessor the Medica EasyStat ionized calcium analyzer (K021515). The calibrants for both analyzers have identical formulations. In addition, the packaging of the calibrants is identical.

J. Substantial Equivalence Information:

1. Predicate device name(s):
EasyStat pH, PCO₂, PO₂, Htc, Na⁺, K⁺, Ca⁺⁺ Analyzer
EasyElectroLyte Na⁺, K⁺, Cl⁻ Analyzer (for Cl⁻ only)
2. Predicate 510(k) number(s):
k021515, k000926 respectively
3. Comparison with predicate:

	New device	Predicate	Predicate
	EasyStat Ca/CL	EasyStat Ca	EasyElectroLytes Na/K/Cl
510(k)	k063376	K021515	k000926
Manufacturer	Medica Corp.	Medica Corp.	Medica Corp.
Indications for use	See indications above	Within scope	Within scope
pH	Ion Selective Electrode Technology	Ion Selective Electrode Technology	
PCO ₂	Ion Selective Electrode Technology	Ion Selective Electrode Technology	
PO ₂	Amperometric (Pt electrode)	Amperometric (Pt electrode)	
Htc	Conductivity	Conductivity	
Na ⁺	Ion Selective Electrode Technology	Ion Selective Electrode Technology	Ion Selective Electrode Technology
K ⁺	Ion Selective Electrode Technology	Ion Selective Electrode Technology	Ion Selective Electrode Technology
Ca ⁺⁺	Ion Selective Electrode Technology	Ion Selective Electrode Technology	
Cl ⁻	Ion Selective Electrode Technology		Ion Selective Electrode Technology
Calibrator	Aqueous	Aqueous	Aqueous
Measured Parameters	pH, PCO ₂ , PO ₂ , Htc, Na ⁺ , K ⁺ , Ca ⁺⁺ , Cl ⁻	pH, PCO ₂ , PO ₂ , Htc, Na ⁺ , K ⁺ , Ca ⁺⁺	Na ⁺ , K ⁺ , Cl ⁻

	New device	Predicate	Predicate
	EasyStat Ca/CL	EasyStat Ca	EasyElectroLytes Na/K/Cl
Sample Volume	120 µl Syringe / 95 µl Capillary	120 µl Syringe / 95 µl Capillary	55 µl Syringe / 50 µl Capillary
Analysis time	120 sec	120 sec	35 sec
Measured range:			
pH	6.5 -8.0 pH units	6.5 -8.0 pH units	
PCO ₂	5.0 – 150.0 mmHg	5.0 – 150.0 mmHg	
PO ₂	5 - 700 mmHg	5 - 700 mmHg	
Htc	10-70%	10-70%	
Na ⁺	80 – 200 mmol/l	80 – 200 mmol/l	
K ⁺	1.0 – 20.0 mmol/l	1.0 – 20.0 mmol/l	
Ca ⁺⁺	0.25 – 5.00 mmol/l	0.25 – 5.00 mmol/l	
Cl ⁻	50.0 – 150.0 mmol/l		50.0 – 150.0 mmol/l
Dimensions	14.25"W x 12.5"H x 7"D	14.25"W x 12.5"H x 7"D	14.25"W x 12.5"H x 7"D
Voltage requirements	1001115VAC,50-60Hz, 0.8A 220VAC, 50-60Hz, 0.4A	1001115VAC,50-60Hz, 0.8A 220VAC, 50-60Hz, 0.4A	1001115VAC,50-60Hz, 0.8A 220VAC, 50-60Hz, 0.4A

K. Standard/Guidance Document Referenced (if applicable):

CLSI - Evaluation of Precision Performance of Clinical Chemistry Devices - EP05-A2

CLSI - Method Comparison and Bias Estimation Using Patient Samples - EP09-A2

L. Test Principle:

The EasyStat Ca/Cl in this submission utilizes the same basic technologies and software architecture as Medica's EasyElectroLytes Na, K, Cl (for chloride) and EasyStat pH, PCO₂, PO₂, Htc, Na, K, Ca line of analyzers. The EasyStat analyzer in this submission measures pH, PCO₂, PO₂, Na⁺, K⁺, and Ca⁺⁺ or Cl⁻ using ion selective electrode (ISE) technology that measures changes in voltage (a potentiometric measurement). The PO₂ electrode measures a change in current (an amperometric measurement). These changes are then compared with those occurring with on-board calibration standards to produce final results. Hct is measured using electrical conductivity, which is a technique used in other currently marketed devices. The hematocrit sensor is also calibrated with standard solutions. The analyzer then measures the impedance of the sample to obtain the Hct value. Next, the Hct value is corrected for the concentration of the sodium ions.

M. Performance Characteristics (if/when applicable):

Because the modules used were all previously cleared, the sponsor demonstrated that the new configurations did not change performance through new precision and method comparison studies. All other performance parameters remain as cleared previously in k021515 and k000926.

1. Analytical performance:a. *Precision/Reproducibility:*

The precision of the EasyStat Ca/Cl was evaluated following the guidelines of CLSI EP-5. This section provides data on the precision of the EasyStat Ca/Cl operating in the Ca^{++} and Cl^- modes for all sensors using both the syringe and capillary sampling modes.

This study incorporated the use of three EasyStat Ca/Cl analyzers operating in the Cl^- mode (Chloride sensor and software) and three EasyStat Ca/Cl analyzers operating in the Ca^{++} mode (Calcium sensor and software). Three levels of ampuled aqueous based QC material were analyzed daily (AM & PM) for twenty days according to CLSI EP-5. Since the Hematocrit (Hct) QC material is available in two levels only, there are no precision data for level 3.

The data summaries below are from one analyzer in both the Cl^- mode and the Ca^{++} mode. The other two analyzers had comparable precision in both modes.

Summary The within-run and Day-to-Day CV% and SD for Precision Testing for ES Ca/Cl (Ca^{++} Mode) Analyzers in Syringe Mode							
Level 1	pH	PCO2	PO2	Hct	Na	K	Ca
Total Average	7.144	67.5	62.70	31.94	115.93	2.54	1.52
Swr (CLSI)	0.01	0.32	1.77	0.22	0.47	0.02	0.01
CVwr (CLSI)	0.08%	0.47%	2.83%	0.70%	0.41%	0.89%	0.57%
Sdd (CLSI)	0.00	0.48	0.65	0.27	0.00	0.01	0.01
CVdd	0.00%	0.71%	1.03%	0.85%	0.00%	0.59%	0.52%
Level 2	pH	PCO2	PO2	Hct	Na	K	Ca
Total Average	7.398	42.6	103.3	51.19	136.7	4.17	1.11
Swr (CLSI)	0.00	0.29	1.15	0.18	0.33	0.01	0.00
CVwr (CLSI)	0.05%	0.68%	1.11%	0.35%	0.24%	0.21%	0.43%
Sdd (CLSI)	0.00	0.18	0.86	0.28	0.20	0.00	0.00
CVdd	0.01%	0.43%	0.83%	0.54%	0.15%	0.00%	0.28%
Level 3	pH	PCO2	PO2	Hct	Na	K	Ca
Total Average	7.615	20.62	145.29		159.40	5.89	0.64
Swr (CLSI)	0.01	0.10	1.04		0.54	0.02	0.01
CVwr (CLSI)	0.12%	0.48%	0.72%		0.34%	0.37%	0.82%
Sdd (CLSI)	0.00	0.22	0.00		0.22	0.02	0.00
CVdd	0.06%	1.06%	0.00%		0.14%	0.27%	0.00%
Summary The within-run and Day-to-Day CV% and SD for Precision Testing for ES Ca/Cl (Ca^{++} Mode) Analyzers in Capillary Mode							
Level 1	pH	PCO2	PO2	Hct	Na	K	Ca

Total Average	7.150	66.58	67.19	30.97	117.26	2.63	1.51
Swr (CLSI)	0.007	0.95	1.97	0.42	0.79	0.03	0.02
CVwr (CLSI)	0.09%	1.42%	2.94%	0.01%	0.67%	1.11%	1.10%
Sdd (CLSI)	0.004	0.48	2.49	0.19	0.69	0.02	0.01
CVdd	0.05%	0.73%	3.71%	0.62%	0.59%	0.65%	0.60%
Level 2	pH	PCO2	PO2	Hct	Na	K	Ca
Total Average	7.402	43.05	107.15	50.51	136.89	4.14	1.12
Swr (CLSI)	0.005	0.23	1.34	0.42	0.69	0.02	0.01
CVwr (CLSI)	0.07%	0.53%	1.25%	0.01%	0.51%	0.55%	0.95%
Sdd (CLSI)	0.003	0.33	1.38	0.37	0.31	0.01	0.00
CVdd	0.03%	0.76%	1.29%	0.72%	0.22%	0.26%	0.21%
Level 3	pH	PCO2	PO2	Hct	Na	K	Ca
Total Average	7.617	21.61	148.89		157.95	5.73	0.68
Swr (CLSI)	0.011	0.17	1.74		0.70	0.04	0.01
CVwr (CLSI)	0.14%	0.79%	1.17%		0.44%	0.66%	2.15%
Sdd (CLSI)	0.007	0.23	0.88		0.51	0.02	0.01
CVdd	0.09%	1.06%	0.59%		0.33%	0.33%	0.98%

Summary The within-run and Day-to-Day CV% and SD for Precision Testing for ES Ca/Cl (Cl Mode) Analyzers in Syringe Mode							
Level 1	pH	PCO2	PO2	Hct	Na	K	Cl
Total Average	7.147	66.71	68.05	31.54	116.00	2.59	72.90
Swr (CLSI)	0.003	0.36	1.78	0.17	0.42	0.03	0.36
CVwr (CLSI)	0.04%	0.55%	2.62%	0.55%	0.36%	1.03%	0.49%
Sdd (CLSI)	0.003	0.16	0.27	0.15	0.00	0.01	1.09
CVdd	0.05%	0.24%	0.40%	0.48%	0.00%	0.54%	1.50%
Level 2	pH	PCO2	PO2	Hct	Na	K	Cl
Total Average	7.400	41.92	106.66	50.69	136.38	4.16	97.96
Swr (CLSI)	0.003	0.24	1.18	0.14	0.22	0.01	0.23
CVwr (CLSI)	0.04%	0.58%	1.10%	0.28%	0.16%	0.20%	0.23%
Sdd (CLSI)	0.000	0.06	0.88	0.10	0.00	0.00	0.78
CVdd	0.00%	0.14%	0.82%	0.19%	0.00%	0.07%	0.80%
Level 3	pH	PCO2	PO2		Na	K	Cl
Total Average	7.637	20.37	144.03		159.87	5.96	127.12
Swr (CLSI)	0.003	0.08	1.17		0.25	0.01	0.27
CVwr (CLSI)	0.04%	0.38%	0.81%		0.15%	0.19%	0.21%
Sdd (CLSI)	0.000	0.08	0.00		0.31	0.01	0.51
CVdd	0.00%	0.39%	0.00%		0.20%	0.13%	0.40%
Summary The within-run and Day-to-Day CV% and SD for Precision Testing for ES Ca/Cl (Cl Mode) Analyzers in Capillary Mode							
Level 1	pH	PCO2	PO2	Hct	Na	K	Cl
Total Average	7.159	65.57	73.25	30.79	117.42	2.67	76.62
Swr (CLSI)	0.01	0.79	2.01	0.80	1.23	0.05	1.01
CVwr (CLSI)	0.12%	1.21%	2.75%	2.61%	1.05%	1.97%	1.32%
Sdd (CLSI)	0.00	0.15	1.01	0.43	0.62	0.01	1.37
CVdd	0.04%	0.23%	1.38%	1.38%	0.53%	0.48%	1.78%
Level 2	pH	PCO2	PO2	Hct	Na	K	Cl

Total Average	7.403	42.40	110.78	49.96	136.54	4.12	101.24
Swr (CLSI)	0.01	0.35	1.34	0.34	0.97	0.04	0.83
CVwr (CLSI)	0.09%	0.83%	1.21%	0.68%	0.71%	0.92%	0.82%
Sdd (CLSI)	0.00	1.53	0.90	0.33	0.52	0.01	1.00
CVdd	0.02%	3.62%	0.81%	0.66%	0.38%	0.28%	0.99%
Level 3	pH	PCO2	PO2		Na	K	Cl
Total Average	7.609	21.45	148.54		157.48	5.66	127.78
Swr (CLSI)	0.01	0.17	1.40		0.69	0.07	0.55
CVwr (CLSI)	0.10%	0.81%	0.94%		0.44%	1.18%	0.43%
Sdd (CLSI)	0.00	3.18	0.96		0.30	0.03	0.33
CVdd	0.03%	14.82%	0.65%		0.19%	0.47%	0.26%

b. Linearity/assay reportable range:

	Reportable Range
pH	6.5 -8.0 pH units
PCO2	5.0 – 150.0 mmHg
P02	5 700 mmHg
Htc	10-70%
Na ⁺	80 – 200 mmol/l
K ⁺	1.0 – 20.0 mmol/l
Ca ⁺⁺	0.25 – 5.00 mmol/l
Cl ⁻	50.0 – 150.0 mmol/l

Reportable Range was determined in predicate devices k021515 and k000926 for these instrument modules.

c. Traceability, Stability, Expected values (controls, calibrators, or methods):

There were no changes to the existing calibrator cleared under k021515. The Reagent Module value assignment method for pH, PCO2, PO2, Na, K, and Ca remains the same. The chloride (Cl⁻) value assignment for the EasyStat Calcium/ Chloride calibrants has been established via titration with a primary Silver Nitrate (AgNO3) solution. This standard volumetric method used a potentiometric end-point detection and it was applied to the Master Secondary Primary (MSP) calibrant A and calibrant C. Stability is based on accelerated shelf life study, and supported by a real time study.

Controls were cleared under k021515, k955630 and k880447.

d. Detection limit:

see k021515 and k000926

e. Analytical specificity:

see k021515 and k000926

f. *Assay cut-off:*
Not Applicable

2. Comparison studies:

a. *Method comparison with predicate device:*

A study was done to compare the performance of the pH, PCO₂, PO₂, Htc, Na, K, and Ca⁺⁺ sensors on the EasyStat Ca/Cl analyzer operating in the Ca⁺⁺ mode, against the same sensors on the predicate EasyStat analyzer cleared by k021515. This study was repeated to compare the performance of the pH, PCO₂, PO₂, Htc, Na, K and Cl⁻ sensors on the EasyStat Ca/Cl analyzer operating in the chloride (Cl) mode, against the same sensors on the predicate EasyStat and EasyElectroLyte -Cl analyzers cleared by K021515 and K000926 respectively. Two predicate devices were employed using the “Syringe” option.

The method comparison summary data below are from one representative analyzer configuration for each analyte and mode of measurement.

Cl Linearity/Method Comparison for EasyStat Ca/Cl Syringe Values Vs. EasyElectrolyte-Cl syringe Values (N=102) range 68.45 - 133.1 mM/L

$$y = 0.9771x + 2.6944$$

$$R^2 = 0.9817$$

Cl Linearity/Method Comparison for EasyStat Ca/Cl Capillary Values Vs. EasyElectrolyte Cl- Values (N=102) range 93.4 - 140.5 mM/L

$$y = 0.9726x + 4.5443$$

$$R^2 = 0.9726$$

Ca Linearity/Method Comparison for EasyStat Ca/Cl Syringe Values Vs. EasyStat Ca⁺⁺ syringe Values (N=100) range 0.765 - 1.64 mM/L

$$y = 0.9797x + 0.0309$$

$$R^2 = 0.9882$$

Ca Linearity/Method Comparison for EasyStat Cl Capillary Values Vs. EasyStat Ca⁺⁺ Capillary Values (N=100) range 0.76 - 1.635 mM/L

$$y = 0.9487x + 0.0632$$

$$R^2 = 0.9783$$

pH Linearity/Method Comparison for EasyStat Ca/Cl Syringe Values Vs. EasyStat Ca⁺⁺ Syringe Values (N=106) range 6.567 - 7.779 units

Cl mode

$$y = 0.9669x + 0.2428$$

$$R^2 = 0.9954$$

Ca mode

$$y = 0.9525x + 0.344$$

$$R^2 = 0.996$$

pH Linearity/Method Comparison for EasyStat Ca/Cl Capillary Values Vs.
EasyStat Ca⁺⁺ Capillary Values (N=106) range 6.571 - 7.731 units

Cl mode	Ca mode
$y = 0.9714x + 0.2113$	$y = 0.9541x + 0.3361$
R2 = 0.9919	R2 = 0.9966

PCO2 Linearity/Method Comparison for EasyStat Ca/Cl Syringe Values Vs.
EasyStat Ca⁺⁺ Syringe Values (N=102) range 8.2 - 143.8 mmHg

Cl mode	Ca mode
$y = 0.9632x + 0.7453$	$Y = 0.9634x + 1.836$
R2 = 0.996	R2 = 0.9946

PCO2 Linearity /Method Comparison for EasyStat Ca/Cl Capillary Values Vs.
EasyStat Ca⁺⁺ Capillary Values (N=102) range 10.3 - 141 mmHg

Cl mode	Ca mode
$y = 0.9494x + 1.5595$	$y = 0.956x + 2.431$
R2 = 0.9968	R2 = 0.9963

PO2 Linearity/Method Comparison for EasyStat Ca/Cl Syringe Values Vs.
EasyStat Ca⁺⁺ Syringe Values (N=102) range 19 – 462 mmHg

Cl mode	Ca mode
$y = 0.9693x + 2.6519$	$y = 1.0032x + 0.4322$
R2 = 0.9976	R2 = 0.9972

PO2 Linearity /Method Comparison for EasyStat Ca/Cl Capillary Values Vs.
EasyStat Ca⁺⁺ Capillary Values (N=102) range 17 - 423 mmHg

Cl mode	Ca mode
$y = 0.9805x + 2.4841$	$y = 1.0093x + 0.8746$
R2 = 0.9988	R2 = 0.9994

Na Linearity/Method Comparison for EasyStat Ca/Cl Syringe Values Vs.
EasyStat Ca⁺⁺ Syringe Values (N=102) range 89.2 - 163.2 mM/L

Cl mode	Ca mode
$y = 0.9895x + 2.3029$	$y = 0.9903x + 1.8699$
R2 = 0.992	R2 = 0.9937

Na Linearity /Method Comparison for EasyStat Ca/Cl Capillary Values Vs.
EasyStat Ca⁺⁺ Capillary Values (N=102) range 91.4 - 163.3 mM/L

Cl mode	Ca mode
$y = 0.9699x + 4.5856$	$y = 1.003x - 0.4345$
R2 = 0.9869	R2 = 0.9918

K Linearity/Method Comparison for EasyStat Ca/Cl Syringe Values Vs.
EasyStat Ca⁺⁺ Syringe Values (N=102) range 2.84 - 8.06 mM/L

Cl mode	Ca mode
$y = 0.9451x + 0.2288$	$y = 0.9837x + 0.0773$
R2 = 0.9977	R2 = 0.9981

K Linearity/Method Comparison for EasyStat Ca/Cl Capillary Values Vs.
EasyStat Ca⁺⁺ Capillary Values (N=102) range 2.90 - 7.84 mM/L

Cl mode	Ca mode
$y = 0.9471x + 0.2283$	$y = 0.9642x + 0.1592$
R2 = 0.9851	R2 = 0.996

Hct Linearity/Method Comparison for EasyStat Ca/Cl Syringe Values Vs.
EasyStat Ca⁺⁺ Syringe Values (N=102) range 21.5 - 66.7 %

Cl mode	Ca mode
$y = 0.9955x + 0.6535$	$y = 1.0168x - 0.5392$
R ² = 0.9795	R ² = 0.9877

Hct Linearity/Method Comparison for EasyStat Ca/Cl Capillary Values Vs.
EasyStat Ca⁺⁺ Capillary Values (N=102) range 21.0 - 68.1 %

Cl mode	Ca mode
$y = 0.9861x + 1.4148$	$y = 1.0355x - 1.2208$
R ² = 0.9649	R ² = 0.9857

- b. Matrix comparison:*
Whole blood sample - see syringe verses capillary method comparisons above
3. Clinical studies:
 - a. Clinical Sensitivity:*
Not Applicable
 - b. Clinical specificity:*
Not Applicable
 - c. Other clinical supportive data (when a. and b. are not applicable):*
Not Applicable
4. Clinical cut-off:
Not Applicable
5. Expected values/Reference range:

	Arterial	Mixed Venous	Venous
pH	7.350-7.450	7.340-7.360	7.340-7.360
PCO ₂	35.0-45.0 mmHg	44.0-46.0 mmHg	44.0-46.0 mmHg
PO ₂	83-108 mmHg	38-42 mmHg	38-42 mmHg
Hct	35-50%	35-50%	35-50%
Na ⁺	136.0-146.0 mmol/l	136.0-146.0 mmol/l	136.0-146.0 mmol/l
K ⁺	3.5-5.1 mmol/l	3.5-5.1 mmol/l	3.5-5.1 mmol/l
Ca ⁺⁺	1.05-1.2 mmol/l	1.05-1.2 mmol/l	1.05-1.2 mmol/l
Cl ⁻	98.0-106.0 mmol/l	98.0-106.0 mmol/l	98.0-106.0 mmol/l

Cited from literature

Tietz: Fundamentals of Clinical Chemistry, 4th edition, (1996)

Fink: Clinical Practice in Respiratory Care

N. Instrument Name:

EasyStat pH, PCO₂, PO₂, Hct, NA⁺, K⁺, CA⁺⁺/CL⁻ Analyzer

O. System Descriptions:

1. Modes of Operation:

Single sample

2. Software:

The analyzer can be interfaced to an external windows based computer via an RS-232 port.

Connection for an optional Barcode Reader

FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:

Yes X or No

The applicant provided software documentation that is typical for this device type.

3. Specimen Identification:

Manual sample identification

4. Specimen Sampling and Handling:

Manual - syringe or capillary mode

5. Calibration:

Automatic Two-point calibration

6. Quality Control:

Quality control results are stored

P. Other Supportive Instrument Performance Characteristics Data Not Covered In The "Performance Characteristics" Section above:

Q. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

R. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.