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

A. 510(k) Number:
k131750

B. Purpose for Submission:
New Submission

C. Measurand:
Capillary whole blood glucose

D. Type of Test:
Quantitative, Amperometric method, glucose oxidase

E. Applicant:
Apex Biotechnology Corp.

F. Proprietary and Established Names:
AutoSure HT Blood Glucose Monitoring System

Contrex Plus 4 Glucose Control Solutions

G. Regulatory Information:

1. Regulation section:

   21 CFR 862.1345; 862.1660

2. Classification:

   Class II
   Class I (Reserved)

3. Product code:

   CGA, Glucose oxidase, glucose

   NBW, System, test, blood glucose, over the counter

   JJX, Single (specified) analyte and analyte controls (assayed and unassayed)

4. Panel:

75-Clinical Chemistry

H. Intended Use:

1. Intended use(s):

   See indications for use below.

2. Indication(s) for use:

   The AutoSure HT Blood Glucose Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood samples drawn from the fingertips, forearm, or palm. Alternative site testing should be performed only during steady-state (when glucose is not changing rapidly). Testing is done outside the body (In Vitro diagnostic use). It is indicated for lay use by people with diabetes, as an aid to monitoring levels in Diabetes Mellitus and should only be used by a single patient and it should not be shared. It is not indicated for the diagnosis or screening of diabetes or for neonatal use.

   The AutoSure HT Blood Glucose Test Strips are to be used with the AutoSure HT Blood Glucose Meter to quantitatively measure glucose in capillary whole blood taken from fingertips, palm, or forearm.

   The Contrex Plus 4 glucose control solution is used with the AutoSure HT meter and AutoSure HT test strips to verify that the meter and test strips are working together properly and that the test is performing correctly.

3. Special conditions for use statement(s):

   - For over the counter use
   - Not for neonatal use
   - Not for screening or diagnosis of diabetes
   - Not for use on critically ill patients, patients in shock, patients with severe hypotension, patients with severe dehydration, those with hyperglycemia with hyperosmolarity (with or without ketosis) and patients with hematocrit ranges outside of 10-70%
   - Meters are for single patient use only
   - Alternative site testing (AST) should only be performed during steady state glucose conditions
   - AST (forearm and palm) testing should not be used to calibrate continuous glucose monitors (CGMs)
   - AST (forearm and palm) testing should not be used for insulin dose calculations

4. Special instrument requirements:

   AutoSure HT Blood Glucose Meter

I. Device Description:

The AutoSure HT Blood Glucose Monitoring System is composed of the AutoSure HT meter, AutoSure HT test strips, and Contrex Plus 4 control solutions (Level 1, Level 2, and Level 3). It is for home use. The AutoSure HT commercial kit includes a zippered carry case, test strips, User Guide, and log book. The test strips are contained in plastic vials with attached snap caps and include a desiccant. Test strip vials are provided in a cardboard carton with a test strip package insert (instructions for use). Test strips are plasma-calibrated and the system includes a hematocrit compensation feature. The top layer of the test strip contains two channels is used detect the hematocrit value and provide feedback to the glucose-measuring algorithm, which compensates for hematocrit effects. Control solutions, lancets and lancing device are optional components for some kits and can be purchased separately. Control solutions are contained in plastic bottles with a screw-on top contained in cardboard cartons with a control solution package insert (instructions for use). Lancing devices are sold with instructions for use.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   GAL-1A Blood Glucose Monitoring System
   Contrex Plus III Glucose Control Solutions

2. Predicate 510(k) number(s):
   k113208 (GAL-1A Blood Glucose Monitoring System)
   k113098 (Contrex Plus III Glucose Control Solutions)

3. Comparison with predicate:

Similarities and Differences: Blood Glucose Meter		
	AutoSure HT (Current Device)	**GAL-1A (Predicate)**
Indications for Use	Same	Measurement of glucose in capillary whole blood taken from fingertips, palm, or forearm for self-testing.
Intended Users	Same	Lay Users
Testing Site	Same	Fingertips, palm, forearm
Detection Method	Same	Amperometry
Enzyme	Same	Glucose Oxidase (Aspergillus Niger)
Plasma Calibrated	Same	Yes
Sample Size	≥0.9 µl	≥0.8 µl
Measurement Range	Same	20 – 600 mg/dL
Test Time	Same	6 seconds
Units of Measure (mg/dL	Same	Factory set to mg/dL Cannot be

or mmol/L)		changed by user
Meter Dimensions	89L x 60W x 14H (mm) Shape: Oval	76Lx45Wx13H (mm) Shape: Rectangle
Meter Weight	42g (without battery)	29g (without battery)
Hematocrit	10-70%	33-55%
Altitude	Same	10,335 feet
Coding	Autocoding (8 calibration codes)	Autocoding (7 calibration codes)
Memory Feature	Same	300 test results including blood and control test
Day Average	Same	7/14/30 days averaging
Auto Shut Off	Same	Yes
Battery Type	Two CR2032 3V lithium coin cell batteries	One CR2032 3V lithium coin cell battery
Meter Storage	Same	4°C - 55°C
Meter Operating Conditions	5°C - 45°C, 20-90% Relative Humidity	10°C - 40°C, 20-85% Relative Humidity
Test Strip Stability	Same	Unopened Store at 5-30°C until expiration date Opened 5-30°C for 3 months

Similarities and Differences: Control Solutions		
	Contrex Plus 4 (Current Device)	**Contrex Plus III (Predicate)**
Indications for Use/Intended Use	Same	Serve as a quality control check to verify the meter and test strip are working together properly, and that the test is performing correctly.
Number of Levels	Same	3
Color Dye	Same	Red
Fill Volume	2.5 mL	3.0 mL
Matrix	Same	Aqueous solution containing D-glucose
Stability	Store at 4-30°C until expiration date	Store at 15-30°C until expiration date

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

1. ISO 15197; 2003, In vitro diagnostic test systems – Requirements for blood glucose monitoring systems for self-testing in managing diabetes mellitus.

2. CLSI - EP6-A: Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline

3. IEC – 60601 – 1- 2; 2001, Medical Electrical Equipment – Part 1-2: General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility-Requirements and Tests

4. IEC – 61000-3-2; 2005, Electromagnetic compatibility (EMC) – Part 3-2: Limits – Limits for harmonic current emissions (equipment input current ≤ 16A per phase)

5. IEC – 61000-3-3; 2005, Electrical equipment for measurement, control and laboratory use-EMC requirements – Part 1: General requirements

6. IEC – 61326 – 1; 2005, Electrical equipment for measurement, control and laboratory use-EMC requirements – Part 1: General requirements

7. IEC – 61326 – 2-6; 2005, Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 2-6: Particular requirements – In vitro diagnostic (IVD) medical equipment

8. IEC – 61010 – 1; 2010, Safety requirements for electrical equipment for measurement, control, and laboratory use – Part 1: General requirements

9. IEC/EN – 61010-2-101; 2009, Safety requirements for electrical equipment for measurement, control and laboratory use- Part2 – 101: Particular requirements for in vitro diagnostic (IVD) medical equipment

10. IEC – 60601-1; 1995, Medical Electrical Equipment – Part 1: General Requirements for Safety

11. CEN/EN 55011; 2007, Industrial, scientific and medical (ISM) radio-frequency Equipment, Electromagnetic disturbance characteristics. Limits and methods of measurement

L. Test Principle:

The meters and test strips use biosensor technology. The test strips contain glucose oxidase (*Aspergillis niger*) that reacts to glucose present in blood, releasing electrons. The meter applies a small electrical current to the test strip and measures changes in the current caused by the reaction of glucose in the blood sample to the enzyme in the test strip. The meter converts the measured current into a blood glucose reading that is displayed on the meter's liquid crystal display.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Repeatability: Within-Run

Within-run precision studies were performed using pooled venous whole blood samples adjusted to 5 different glucose concentrations within the following ranges: 30-50, 51-110, 111-150, 151-250 and 251-400 mg/dL. Each glucose level was analyzed in replicates of 10 across 10 meters using 3 lots of test strips over 20 days. The results are summarized below:

	Level	**1**	**2**	**3**	**4**	**5**
Lot 1	Mean (mg/dL)	51	95	145	240	351
	SD (mg/dL)	2.4	2.9	4.8	7.8	9.7
	% CV	4.8	3.0	3.3	3.3	2.8

	Level	**1**	**2**	**3**	**4**	**5**
Lot 2	Mean (mg/dL)	49	93	143	240	350
	SD (mg/dL)	2.7	2.9	4.9	7.3	9.8
	% CV	5.6	3.1	3.4	3.0	2.8

	Level	**1**	**2**	**3**	**4**	**5**
Lot 3	Mean (mg/dL)	50	95	143	242	350
	SD (mg/dL)	2.5	3.1	4.8	7.7	10.3
	% CV	4.9	3.3	3.3	3.2	2.9

Intermediate Precision—Between Day

Intermediate precision was evaluated using three levels of glucose control solutions with approximate concentrations of: 50, 110, and 200 mg/dL. Each glucose level was analyzed once per day on 10 meters using 3 lots of test strips over 20 days. Results for intermediate, between-day per lot precision are summarized below:

Lot 1	**Level (mg/dL)**	**1**	**2**	**3**
	Mean (mg/dL)	50	111	210
	SD (mg/dL)	2.2	3.1	5.7
	% CV	4.4	2.8	2.7

Lot 2	Level (mg/dL)	1	2	3
	Mean (mg/dL)	48	112	210
	SD (mg/dL)	3.2	2.6	5.7
	% CV	6.6	2.3	2.7

Lot 3	Level (mg/dL)	1	2	3
	Mean (mg/dL)	50	110	209
	SD (mg/dL)	1.9	3.3	4.9
	% CV	-3.8	3.0	2.4

b. Linearity/assay reportable range:

Linearity for the device was evaluated using CLSI-EP6 using venous whole blood supplemented with glucose, or allowed to undergo glycolysis, to provide samples at 8 glucose concentrations of 18, 60, 81, 124, 211, 325, 438 and 618 mg/dL. Forty tests were performed using AutoSure HT meters at each glucose concentration and a glucose test using the same blood sample was performed on the YSI 2300 Glucose Analyzer as the reference method. A total of 320 samples were tested on each test strip lot for a total of 960 tests. Regression analysis demonstrated a linear relationship between the AutoSure HT glucose meter and the YSI 2300 reference method. The linear regression results for each test strip lot are shown below:

Strip Lot	Slope	Intercept	R^2
1	0.9996	-0.1472	0.9996
2	1.0004	-0.3014	0.9993
3	1.0002	-0.2169	0.9993

The study provided supports the claimed measurement range for glucose of 20 - 600 mg/dL. If a sample is less than 20 mg/dL, the result is flagged by the meter as LO. If a sample result exceeds 600 mg/dL, the result is flagged by the meter as HI.

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

Traceability:

The AutoSure HT Blood Glucose Monitoring System is traceable to NIST SRM 917c glucose. A NIST SRM 917c traceable Glucose Standard Set (JCCRM 521-10) with glucose concentrations of 50,100, 150, 250, 500 mg/dL, is used to calibrate the reference instrument YSI 2300 Glucose Analyzer.

Expected Values:

Value assignment of glucose control solutions was performed by testing 3 lots of AutoSure HT control solutions (for all 3 levels) using 2 AutoSure HT meters daily for

10 days, with 2 tests/meter for each control solution, for a total of 360 test results. Results were verified against values taken on the YSI-2300 reference method and pre-determined acceptance criteria for glucose recovery within a specified range must have been met for each control lot/level. The acceptable control range is established as the mean value ±15 mg/dL for Level 1 control solution or ±15% for Levels 2 & 3 control solutions. Glucose control ranges are lot dependent and are listed on the test strip vial label for each lot and level.

Test Strip Stability:

Stability testing protocols and acceptance criteria for the AutoSure HT test strips were reviewed and found to be acceptable. The manufacturer claims a shelf life stability of 18 months and an open-vial stability of 6 months at the recommended storage temperatures of 4°C to 30°C. Relative humidity should be between 20-85% for open and closed vial test strip stability.

Control Solution Stability:

Stability testing protocols and acceptance criteria for the glucose control solutions were reviewed and found to be acceptable. The manufacturer claims a shelf life stability of 24 months and an open-vial stability of 3 months at the recommended storage temperatures of 4°C to 30°C.

d. Detection limit:

The measuring range of the AutoSure HT glucose meter is 20-600 mg/dL. This range was verified by the linearity study (see section M.1.b of this decision summary).

e. Analytical specificity:

To evaluate potential interference, a number of endogenous/exogenous substances at two or more levels (normal/therapeutic and high) were added to venous whole blood samples (HCT 43±2%) containing three different glucose levels (70-90, 110-130, and 300-330 mg/dL). Ten glucose measurements obtained from samples containing each potential interfering substance were evaluated and compared against measurements with a control group using the AutoSure HT glucose monitoring system. Test and control samples were tested using 10 AutoSure HT test strips and 10 AutoSure HT glucose meters. The table below shows the levels at which no significant interference (defined by the sponsor as ≤ 10%) was detected when testing for glucose with the AutoSure HT glucose meter:

Endogenous Substance	No Interference at Listed Level (mg/dL)
Fructose	20
Hemoglobin	200
Creatinine	5.0
Uric Acid	15
Cholesterol	400
Bilirubin-unconjugated	15
Bilirubin-conjugated	25
Triglyceride	2000
Galactose	15
Exogenous Substance	**No Interference at Listed Level (mg/dL)**
Acetaminophn	10
L-DOPA	1.5
Tobutamide	64
Dopamine	0.1
Ibuprofen	50
Salicylic Acid	65
Methyl-Dopa	7.5
Tetracycline	1.5
Ephedrine	0.05
Mannitol	30
Mannose	4.0
Sorbitol	0.2
Tolazamide	70
Ascorbic Acid	5.0
Maltose	50
Lactose	25
Maltotriose	240
Maltotetraose	120
Xylitol	0.1
Xylose	25

The following limitations are included in the labeling:

• Acetaminophen levels above 10 mg/dL may give falsely low test results (therapeutic range: 1-3 mg/dL).

• L-dopa levels above 1.5 mg/dL may cause falsely high test results. People taking this drug should consult their medical professional if they are taking high doses of Ldopa.

• Methyldopa >7.5 mg/dL may cause falsely high test results.

• Ascorbic acid levels above 5 mg/dL may give falsely high test results (therapeutic range: 0.4-2 mg/dL).

• Uric acid levels above 15 mg/dL may give falsely high test results (normal range: 2.5-8 mg/dL).
• Cholesterol levels above 400 mg/dL may give falsely low test results (reference range: 114-201 mg/dL).
• Unconjugated bilirubin levels above 15 mg/dL, and conjugated bilirubin levels above 25 mg/dL, may give falsely high test results (normal ranges: unconjugated bilirubin: 0.3-1.2 mg/dL; conjugated bilirubin: 0-0.3 mg/dL).
• Triglyceride levels above 2000 mg/dL may give falsely low test results (normal range: 30-300 mg/dL).

f. Assay cut-off:

Not applicable.

2. Comparison studies:

a. Method comparison with predicate device:

System Accuracy Study:

To demonstrate system accuracy, fingertip, palm and forearm samples were obtained from 143 participants. For the fingertip samples, 8 samples were allowed to glycolize to achieve low glucose concentrations below 50 mg/dL and 2 samples were spiked to obtain values >450 mg/dL to cover the glucose range of 37-472 mg/dL. Thus, 153 fresh capillary blood fingertip samples and 143 palm and forearm samples (glucose concentration of 56-435 mg/dL) were tested by health care professionals for the study. The study was performed using 8 AutoSure HT glucose meters and 3 lots of AutoSure HT test strips. The glucose meter measurements obtained using the AutoSure blood glucose meter were compared to YSI 2300 reference method values for fingerstick, palm and forearm samples. The accuracy data is summarized in tables below.

Linear Regression Analyses:

Sample Site	Strip Lot	Slope	Intercept	R2	N
Fingertip	1	1.0516	-2.9566	0.986	50
Fingertip	2	1.0245	-1.9982	0.9911	50
Fingertip	3	0.9997	1.9328	0.9952	53
Fingertip	Combined	1.0209	-0.3785	0.9907	153
Palm	1	1.0263	-5.7895	0.9815	47
Palm	2	0.9959	-1.2094	0.9927	46
Palm	3	0.9953	0.4953	0.9941	50
Palm	Combined	1.0052	-1.9461	0.9901	143

Forearm	1	0.9923	0.4039	0.9809	47
Forearm	2	1.0106	-4.9167	0.9896	46
Forearm	3	0.9953	0.4953	0.9941	50
Forearm	Combined	1.0026	-2.5327	0.9893	143

Fingertip:

System Accuracy Results for Glucose concentration <75mg/dL			
Strip Lot	Within ± 5mg/dL	Within ± 10 mg/dL	Within ±15 mg/dL
1	7/8 (88%)	8/8 (100%)	8/8 (100%)
2	7/9 (78%)	9/9 (100%)	9/9 (100%)
3	4/9 (44%)	7/9 (78%)	9/9 (100%)
Combined	17/26 (65%)	24/26 (92%)	26/26 (100%)

System Accuracy Results for Glucose concentration ≧75mg/dL				
Strip Lot	Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
1	21/42 (50%)	34/42 (81%)	42/42 (100%)	42/42 (100%)
2	26/41 (63%)	38/41 (93%)	41/41 (100%)	41/41 (100%)
3	34/44 (77%)	43/44 (98%)	44/44 (100%)	44/44 (100%)
Combined	81/127 (64%)	115/127 (91%)	127/127 (100%)	127/127 (100%)

Palm:

System Accuracy Results for Glucose concentration <75mg/dL			
Strip Lot	Within ± 5mg/dL	Within ± 10 mg/dL	Within ±15 mg/dL
1	4/5 (80%)	5/5 (100%)	5/5 (100%)
2	5/6 (83%)	6/6 (100%)	6/6 (100%)
3	3/7 (43%)	6/7 (86%)	7/7 (100%)
Combined	12/18 (67%)	17/18 (94%)	18/18 (100%)

System Accuracy Results for Glucose concentration ≧75mg/dL				
Strip Lot	Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
1	20/42 (48%)	34/42 (81%)	42/42 (100%)	42/42 (100%)
2	29/40 (73%)	38/40 (95%)	40/40 (100%)	40/40 (100%)
3	31/43 (72%)	39/43 (91%)	43/43 (100%)	43/43 (100%)
Combined	80/125 (64%)	111/125 (89%)	125/125 (100%)	125/125 (100%)

Forearm:

System Accuracy Results for Glucose concentration <75mg/dL			
Strip Lot	Within ± 5mg/dL	Within ± 10 mg/dL	Within ±15 mg/dL
1	3/5 (60%)	5/5 (100%)	5/5 (100%)
2	4/6 (67%)	6/6 (100%)	6/6 (100%)
3	4/7 (57%)	7/7 (100%)	7/7 (100%)
Combined	11/18 (61%)	18/18 (100%)	18/18 (100%)

System Accuracy Results for Glucose concentration ≧75mg/dL				
Strip Lot	Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
1	26/42 (62%)	36/42 (86%)	40/42 (95%)	42/42 (100%)
2	25/40 (63%)	34/40 (85%)	40/40 (100%)	40/40 (100%)
3	26/43 (60%)	39/43 (91%)	43/43 (100%)	43/43 (100%)
Combined	77/125 (62%)	109/125 (87%)	123/125 (98%)	125/125 (100%)

b. Matrix comparison:

Not applicable.

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):

User Performance Evaluation:
A total of 143 fresh blood samples from fingertip, palm and forearm were collected by 143 lay users. Fingertip and alternative site samples were tested by lay users and results were compared to fingerstick glucose measurements obtained by healthcare professionals on the YSI 2300 Analyzer as a reference test. The results are summarized in the tables below:

User Performance Linear Regression Analyses

Sample Site	Strip Lot	Slope	Intercept	R2	N
Fingertip	1	1.0443	-4.8582	0.9836	47
Fingertip	2	1.0242	-4.6619	0.9879	46
Fingertip	3	0.9872	1.7905	0.9943	50
Fingertip	Combined	1.0139	-1.8974	0.9888	143
Palm	1	1.0361	-5.4183	0.9802	47
Palm	2	1.021	-4.3534	0.9825	46
Palm	3	0.9911	1.7829	0.9932	50
Palm	Combined	1.0125	-2.1266	0.9865	143
Forearm	1	0.9889	0.405	0.9763	47
Forearm	2	1.0077	-3.2175	0.9835	46
Forearm	3	0.9878	-0.8044	0.9936	50
Forearm	Combined	0.9929	-1.0439	0.9863	143

Fingertip:

System Accuracy Results for Glucose concentration <75mg/dL			
Strip Lot	Within ± 5mg/dL	Within ± 10 mg/dL	Within ±15 mg/dL
1	5/5 (100%)	5/5 (100%)	5/5 (100%)
2	5/6 (83%)	6/6 (100%)	6/6 (100%)
3	3/7 (43%)	6/7 (86%)	7/7 (100%)
Combined	13/18 (72%)	17/18 (94%)	18/18 (100%)

System Accuracy Results for Glucose concentration ≧75mg/dL				
Strip Lot	Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
1	24/42 (57%)	37/42 (88%)	42/42 (100%)	42/42 (100%)
2	23/40 (58%)	35/40 (88%)	39/40 (98%)	40/40 (100%)
3	32/43 (74%)	42/43 (98%)	43/43 (100%)	43/43 (100%)
Combined	79/125 (63%)	114/125 (91%)	124/125 (99%)	125/125 (100%)

Palm:

System Accuracy Results for Glucose concentration <75mg/dL			
Strip Lot	Within ± 5mg/dL	Within ± 10 mg/dL	Within ±15 mg/dL
1	5/5 (100%)	5/5 (100%)	5/5 (100%)
2	5/6 (83%)	6/6 (100%)	6/6 (100%)
3	4/7 (57%)	6/7 (86%)	7/7 (100%)
Combined	14/18 (78%)	17/18 (94%)	18/18 (100%)

System Accuracy Results for Glucose concentration ≧75mg/dL				
Strip Lot	Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
1	20/42 (48%)	35/42 (83%)	40/42 (95%)	42/42 (100%)
2	25/40 (63%)	36/40 (90%)	38/40 (95%)	40/40 (100%)
3	28/43 (65%)	40/43 (93%)	43/43 (100%)	43/43 (100%)
Combined	73/125 (58%)	111/125 (89%)	121/125 (97%)	125/125 (100%)

Forearm:

System Accuracy Results for Glucose concentration <75mg/dL			
Strip Lot	Within ± 5mg/dL	Within ± 10 mg/dL	Within ±15 mg/dL
1	5/5 (100%)	5/5 (100%)	5/5 (100%)
2	4/6 (67%)	6/6 (100%)	6/6 (100%)
3	3/7 (43%)	7/7 (100%)	7/7 (100%)
Combined	12/18 (67%)	18/18 (100%)	18/18 (100%)

System Accuracy Results for Glucose concentration ≧75mg/dL				
Strip Lot	Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
1	21/42 (50%)	36/42 (86%)	39/42 (93%)	42/42 (100%)
2	18/40 (45%)	34/40 (85%)	40/40 (100%)	40/40 (100%)
3	30/43 (70%)	39/43 (91%)	43/43 (100%)	43/43 (100%)
Combined	69/125 (55%)	109/125 (87%)	122/125 (98%)	125/125 (100%)

4. Clinical cut-off**:**

   Not applicable

5. Expected values/Reference range:
   Expected values for adults without diabetes are as follows:

Before Meals	< 100 mg/dL before meals
After Meals	> 140 mg/dL after meals

   Reference:
   American Diabetes Association, Clinical Practice Recommendations (2013) Diabetes Care, Vol 36, Supplement 1, p S1–S100.

N. Instrument Name:
AutoSure HT Blood Glucose Monitoring System.

O. System Descriptions:

1. Modes of Operation:
   Each test strip is single use and requires a sample volume of 0.9 μL.

   Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device?

   Yes _____ or No ___X___.

   The sponsor has included a USB port to upload results to a computer (which is not available at this time).

   Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission?

   Yes _____ or No ___X___.

2. Software:

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

   Yes ____X ____ or No _____

3. Specimen Identification:

   There is no sample identification function with this device. Samples are applied directly to the test strip as they are collected.

4. Specimen Sampling and Handling:

   This device is intended to be used with capillary whole blood from the fingertip, palm and forearm which can be applied directly to the test strip.

5. Calibration:

   This system has an autocoding feature; coding of the meter by the user is not necessary. The meter is plasma calibrated.

6. Quality Control:

   Three levels of controls are available for use with this meter. The control solutions must be purchased separately using the contact information provided in the user guide. When a test strip is inserted into the meter, each control level can be measured by following the instructions for "Control Solution Testing" provided in the meter user guide. An acceptable range for each control level is printed on each test strip vial label. The user is instructed to contact Customer Service if the control results fall outside of these ranges.

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

Hematocrit Study: The effect of different hematocrit levels on the performance of the AutoSure HT Blood Glucose meter was evaluated using venous whole blood samples with hematocrit levels of 10, 20, 30, 35, 43, 50, 55, 60 and 70%, at glucose concentrations of 40, 60, 130, 300 and 500 mg/dL using 10 meters and 3 test strip lots. For each blood sample, individual glucose readings taken on the AutoSure HT meter were compared to YSI reference values to calculate the bias. The results demonstrate acceptable bias for hematocrit levels between 10-70%.

1. Altitude study: To assess the effect of altitude, venous whole blood samples were adjusted to 5 glucose concentrations: 50, 120, 222, 330 and 448 mg/dL (30-55% hematocrit; 23°± -2°C) and tested at sea level and 10,335 feet above sea level using 10 meters and 1 test strip lot. Three levels of control solutions were also tested for the study. Results were compared to YSI reference values. The results demonstrate acceptable bias to YSI to support the claims in the labeling that altitudes up to 10,335 feet have no significant effect on blood glucose measurements from the AutoSure HT glucose meter.
2. Temperature and Humidity Study**:** The effect of temperature and relative humidity (RH) on the AutoSure HT meter was evaluated using venous blood samples at 60, 120, 200 and 400 mg/dL. Twenty replicates were tested at each combination of temperature and relative humidity using 10 AutoSure HT meters and 3 lots of test strips. Glucose concentrations at the following temperature and humidity conditions were evaluated and compared with results obtained with the YSI reference method:

   Temperature: 4, 10, 14, 20, 24, 30, 40, 45 (±2°C) at 45-55% RH
   Relative Humidity: 20% ± 5% at 4°C and 45°C; 50% ± 5% at 24°C; 90% ± 5% at 4°C and 45°C

   The study results support the operating temperature range of 41 - 113°F (5 - 45°C) and 20– 90% RH.

3. Sample Volume Study**:** The sponsor performed a study to verify the test strip minimum

sample volume requirement (0.9 µL) and the test strip fill error requirement established for the AutoSure HT. Venous whole blood samples at 3 levels (50-70 mg/dL, 100-140 mg/dL and 310-350 dL) were tested at 8 sample volumes (0.7-1.4 µL tested in 1 µL increments) using 10 meters and 1 test strip lot. Values obtained were compared to YSI reference values. The Sponsor concludes that sample volumes ≥ 9 µL produced accurate results 100% of the time, thus this is the minimum sample volume that should be used with the meter. Adequate software validation was performed for this feature.

4. Readability Evaluation**:** Flesch-Kincaid readability assessment was conducted and the results demonstrated that the User Manual, test strip package insert, and control solution package inserts were written at the 8th grade level.
5. Electromagnetic Compatibility**:** The Sponsor provided documentation certifying that electromagnetic testing (EMC) had been performed. Testing was found to be adequate for the AutoSure HT meter.
6. Infection Control Studies**:** The device is intended for single-patient use. Clorox Healthcare Bleach Germicidal wipes (EPA registration # 67619-12-5813) were validated through disinfection efficacy studies by an outside commercial testing laboratory demonstrating complete inactivation of hepatitis B virus (HBV) using materials comprising the meter. Robustness studies were also performed by the sponsor demonstrating that there was no change in performance or in the external materials of the meter after 1,825 cleaning and disinfection cycles designed to simulate 5 years of single-patient device use. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.

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.