

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

**A. 510(k) Number:**

K113098

**B. Purpose for Submission:**

New device

**C. Measurand:**

Capillary whole blood glucose

**D. Type of Test:**

Quantitative, amperometric assay, glucose oxidase

**E. Applicant:**

Apex Biotechnology Corporation

**F. Proprietary and Established Names:**

AutoSure Voice II Plus Blood Glucose Monitoring System

**G. Regulatory Information:**

1. Regulation section:

21 CFR 862.1345, Glucose test system

21 CFR 862.1660, Quality Control Material (assayed and unassayed)

2. Classification:

Class II, Class I (Reserved)

3. Product code:

NBW, System, Test, Blood Glucose, Over The Counter

CGA, Glucose Oxidase, Glucose

JJX, Quality Control Material

4. Panel:

**H. Intended Use:**

1. Intended use(s):

See Indications for Use below.

2. Indication(s) for use:

**AutoSure Voice II Plus Blood Glucose Monitoring System**

The AutoSure Voice II Plus 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. The meter includes voice functionality to assist visually impaired users. 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 should not be shared. It is not indicated for the diagnosis or screening of diabetes or for neonatal use.

**AutoSure Plus Blood Glucose Test Strips**

The AutoSure Plus Blood Glucose Test Strips are to be used with the AutoSure Voice II Plus Blood Glucose Meter to quantitatively measure glucose in capillary whole blood taken from a fingertip, palm, or forearm. They are not indicated for the diagnosis or screening of diabetes or for neonatal use.

**Contrex Plus II Glucose Control Solutions**

The purpose of the control solution test is to validate the performance of the blood glucose monitoring system using a testing solution with a known range of glucose. A control test that falls within the acceptable range indicates the user's technique is appropriate and the test strip and meter are functioning properly.

3. Special conditions for use statement(s):

For Over the Counter use

Not intended for use on neonates

Not for the diagnosis of or screening for diabetes mellitus

Not to be used for patients who are dehydrated, hypotensive, in shock, critically ill or in a hyperosmolar state

Allows testing on the fingertip, palm, or forearm.

Alternative site testing can be used only during steady-state blood glucose conditions

Alternative site testing (AST) should not be used to calibrate continuous glucose monitors (CGMs) nor for use in insulin dose calculations.

4. Special instrument requirements:

The AutoSure Voice II Plus Blood Glucose Meter

**I. Device Description:**

The AutoSure Voice II Plus Blood Glucose Monitoring System consists of the AutoSure

Voice II Plus Blood Glucose Meter, AutoSure Plus Blood Glucose Test strips, and three levels of control solution (Low, Level 1, and Level 2). The control solutions for use with the system (Contrex Plus III Control Solutions) have been previously cleared (k102816). The AutoSure Voice II Plus Blood Glucose Monitoring System is used for testing of blood glucose by self-testers at home.

The AutoSure Voice II Plus Glucose Monitoring System is based on an electrochemical biosensor technology (electrochemical) and the principle of capillary action. Capillary action at the end of the test strip draws the blood into the action chamber and the blood glucose result is displayed in 6 seconds. The control solutions are used to test the performance of the device.

**J. Substantial Equivalence Information:**

1. Predicate device name(s):  
AutoSure Voice II Blood Glucose Monitoring System
2. Predicate 510(k) number(s):  
k102037
3. Comparison with predicate:

Item	Candidate Devices AutoSure Voice II Plus Blood Glucose Monitoring System	Predicate (k102037) AutoSure Voice II Blood Glucose Monitoring System
Indications for use	<p>The AutoSure Voice II Plus Blood Glucose Monitoring Systems are intended for the quantitative measurement of glucose in fresh capillary whole blood taken from fingertips, palm, or forearm. Testing is done outside the body (In Vitro Diagnostic use).</p> <p>It is indicated for lay use by people with diabetes as an aid to monitoring levels in Diabetes Mellitus and should only be used on a single patient.</p>	Same
Test Principle	Electrochemical biosensor with carbon electrodes that measures current produced by a chemical reaction	Same
Enzyme	Glucose oxidase	Same
Sample Type	Fresh capillary whole blood	Same

<b>Item</b>	<b>Candidate Devices</b> AutoSure Voice II Plus Blood Glucose Monitoring System	<b>Predicate</b> (k102037) AutoSure Voice II Blood Glucose Monitoring System
Sample Site	Fingertip, the palm, the forearm	Same
Memory feature	300 tests	Same
Day average	7-, 14-, 30- day average glucose result	Same
Speaking function	Yes	Same
Measuring time	6 sec	Same
Measurement range	20-600 mg/dL	Same
Sample Volume	0.8 µL	1 µL
Meter dimensions (mm)	93(L)x58(W)x21(H) mm	Same
Weight (g)	79 g	Same
Test strip	AutoSure Plus Test Strip	AutoSure Test Strip
Autocoding	Yes	Same

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

- ISO15197:2003- *In vitro* diagnostic test systems – Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus.
- CLSI EP6-A: Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach

**L. Test Principle:**

The test is based on electrochemical biosensor technology and the principle of capillary action. The electrical current generated by the reaction of glucose with the reagent of the strip is measured by the meter and is displayed as the corresponding blood glucose level. The strength of the current produced by the reaction depends on the amount of glucose in the blood sample.

**M. Performance Characteristics (if/when applicable):**

1. Analytical performance:

a. *Precision/Reproducibility:*

Within-run and between-run precision studies were performed. For the within-run precision studies, 10 replicates of each of 6 spiked venous whole blood glucose levels, were analyzed using 10 meters, and 3 lots of test strips. These tests were performed every day for 20 days. Results are summarized below.

<b>Test Strip Lot 1</b>			
<b>Samples</b>	Mean	SD	% CV
Interval 1 40-60 mg/dL	50	2.7	5.4
Interval 2 51-110 mg/dL	85	3.6	4.2
Interval 3 100-140 mg/dL	122	3.2	2.7
Interval 4 180-250 mg/dL	202	6.3	3.1
Interval 5 300-380 mg/dL	326	8.6	2.6
Interval 6 400-500 mg/dL	440	5.7	1.3

<b>Test Strip Lot 2</b>			
<b>Samples</b>	Mean	SD	% CV
Interval 1 40-60 mg/dL	51	3.3	6.5
Interval 2 51-110 mg/dL	84	2.9	3.4
Interval 3 100-140 mg/dL	123	1.9	1.6
Interval 4 180-250 mg/dL	202	6.9	3.4
Interval 5 300-380 mg/dL	327	11.5	3.4
Interval 6 400-500 mg/dL	439	16.2	3.6

<b>Test Strip Lot 3</b>			
<b>Samples</b>	Mean	SD	% CV
Interval 1 40-60 mg/dL	51	2.3	4.5
Interval 2 51-110 mg/dL	86	3.1	3.6
Interval 3 100-140 mg/dL	122	3.8	3.1
Interval 4 180-250 mg/dL	203	5.7	2.8
Interval 5 300-380 mg/dL	327	8.0	2.4

Interval 6 400-500 mg/dL	442	14.8	3.3
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A between-run precision study consisting of 10 replicates per day, for 20 days using each of 6 spiked venous whole blood glucose levels and 2 levels of control solution. Each sample was tested using 10 meters and 3 lots of test strips. Blood samples were prepared fresh daily over the 20 days. Results are summarized below.

<b>Test Strip Lot 1</b>			
<b>Samples</b>	Mean	SD	% CV
Interval 1 40-60 mg/dL	50	1.2	2.4
Interval 2 51-110 mg/dL	85	0.7	1.9
Interval 3 100-140 mg/dL	122	1.3	1.0
Interval 4 180-250 mg/dL	202	2.8	1.4
Interval 5 300-380 mg/dL	326	3.9	1.2
Interval 6 400-500 mg/dL	440	3.6	0.8
Control Level 1	110	1.2	1.9
Control Level 2	208	1.6	0.8

<b>Test Strip Lot 2</b>			
<b>Samples</b>	Mean	SD	% CV
Interval 1 40-60 mg/dL	51	1.2	2.4
Interval 2 51-110 mg/dL	84	0.9	1.1
Interval 3 100-140 mg/dL	123	1.7	1.4
Interval 4 180-250 mg/dL	202	2.6	1.3
Interval 5 300-380 mg/dL	327	4.2	1.3
Interval 6 400-500 mg/dL	439	3.1	0.7
Control Level 1	110	1.3	1.9
Control Level 2	209	1.5	0.7

	<b>Test Strip Lot 3</b>		
<b>Samples</b>	Mean	SD	% CV
Interval 1 40-60 mg/dL	51	1.5	2.9
Interval 2 51-110 mg/dL	86	3.1	3.6
Interval 3 100-140 mg/dL	122	1.9	1.6
Interval 4 180-250 mg/dL	203	3.6	1.8
Interval 5 300-380 mg/dL	327	5.3	1.6
Interval 6 400-500 mg/dL	442	4.1	0.9
Control Level 1	111	1.3	1.9
Control Level 2	208	1.3	0.6

*b. Linearity/assay reportable range:*

Linearity was evaluated using 3 lots of test strips, 10 meters, and 8 venous whole blood samples with glucose levels ranging from 13-651 mg/dL, obtained by spiking pooled venous blood with a glucose solution. Each glucose level was analyzed 40 times over 3 test strip lots. Linear regression analysis for each test strip lot compared to the YSI resulted in:

$$y = 1.018x - 0.3134; R^2 = 0.9983 \text{ for Test Strip Lot 1}$$

$$y = 1.031x - 3.5555; R^2 = 0.9986 \text{ for Test Strip Lot 2}$$

$$y = 1.021x - 2.1524; R^2 = 0.9979 \text{ for Test Strip Lot 3}$$

The claimed range of measurement for this device is 20 to 600 mg/dL. Data from bench studies and software verification studies were provided to demonstrate that 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):*

Three levels of control material, Contrex Plus Control Solution Low (40-70mg/dL), Contrex Plus Control Solution Level 1 (87-131 mg/dL) and Contrex Plus Control Solution Level 2 (186-280 mg/dL), are available for use with this test system. These control solutions have been previously cleared (k102816). See k102816 for control solutions traceability, shelf life, storage, and stability information. The Contrex Plus control solutions were qualified for use with the AutoSure Voice II Plus system. The

control solutions are not provided with the meter.

The AutoSure Plus test strips are identical to the test strips cleared under k102816, and differ only in trade name. Stability testing protocols and acceptance criteria for the test strips were reviewed in k102816 and were found to be acceptable. The manufacturer claims a shelf life stability of 17 months and an open-vial stability of 3 months at the recommended storage temperatures of 5°C to 30°C for the AutoSure Plus test strips.

*d. Detection limit:*

The reportable range is 20 to 600 mg/dL based on linearity/reportable range studies above (section M.1.b.).

*e. Analytical specificity:*

The sponsor tested substances for interference using 1 lot of test strips (10 test strips per interferent level), 10 meters, and 3 levels of glucose (achieved by adjusting human venous blood glucose levels to the ranges of 70-90, 110-130, and 300-330 mg/dL). Samples were then spiked with the following interfering substances. Each sample was analyzed 10 times. The labeling states that elevated concentration of L-DOPA (> 1.5 mg/dL), ibuprofen (> 40 mg/dL), tolazamide (> 60 mg/dL), ascorbic acid (> 5.0 mg/dL), fructose (> 15 mg/dL), uric acid (> 15 mg/dL), cholesterol (> 400 mg/dL), bilirubin conjugated (> 25 mg/dL), bilirubin unconjugated (> 15 mg/dL), triglyceride (> 2000 mg/dL), and methyl-dopa (> 7.5 mg/dL) may affect test results. The following table lists the concentrations of each substance at which no significant interference ( $\leq 10\%$ ) was detected:

<b>Interfering Substance</b>	<b>Therapeutic/ Physiological Levels (mg/dL)</b>	<b>Test Levels (mg/dL)</b>
Acetaminophen	1 – 3	10 and 20
Tolbutamide	5.4 – 10.8	10 and 64
Dopamine	0.03	0.05 and 0.1
Salicylic acid	10 – 30	40 and 65
Methyl-Dopa	1 – 7.5	7.5 and 15.0
Tetracycline	0.2 – 0.5	0.5 and 1.5
Ephedrine	0.014	0.02 and 0.05
Mannitol	10	15 and 30
Mannose	1.2	2.0 and 4.0
Sorbitol	0.05	0.1 and 0.2
Maltose	--	20 and 50
EDTA	--	1x and 5x
Lactose	--	10 and 25
Heparin	--	1x and 5x
Maltotriose	--	120 and 240
Maltotetraose	--	60 and 120

Xylitol	0.02	0.05 and 0.1
Xylose	--	10 and 25
Hemoglobin	100 - 200	100 and 200
Creatinine	0.6 – 1.3	2.0 and 5.0
Galactose	< 5	10 and 15

f. *Assay cut-off:*  
Not applicable.

2. Comparison studies:

a. *Method comparison with predicate device:*

**Reference Method Comparison:**

The sponsor performed a system accuracy evaluation comparing the AutoSure Voice II Plus to YSI. Healthcare professionals tested 145 capillary finger samples in 6 concentration categories (50-80, 81-120, 121-200, 201-300, 301-400, and >400 mg/dL) per strip, using 8 meters and 3 lots of test strips using the AutoSure Voice II Plus meter and the YSI (the reference method). Seven additional glycolyzed samples were also tested to obtain concentrations < 50 mg/dL. Results are summarized below.

**For glucose concentrations <75 mg/dL**

within ± 5 mg/dL	within ± 10 mg/dL	within ± 15 mg/dL
13/28 (46%)	25/28 (89%)	28/28 (100.0%)

**For glucose concentrations ≥ 75 mg/dL**

within ± 5 %	Within ± 10 %	within ± 15 %	within ± 20 %
77/124 (62%)	111/124 (90%)	123/124 (99%)	124/124 (100.0%)

**Linear Regression Analysis:**

Comparison	N	Slope and y-intercept	R <sup>2</sup>
AutoSure Voice II Plus vs. YSI	152	Y = 0.9878x + 1.3379	0.9899

b. *Matrix comparison:*

Not applicable. Capillary whole blood is the only indicated matrix.

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):*

**Fingerstick and Alternative Site Testing Comparison Studies:**

The sponsor performed a lay-user study where accuracy of the device was tested using 145 fingerstick samples obtained by the lay-user and 145 samples per each alternative site (the palm and the forearm) obtained by the lay-user. Participants, who were able to read the User’s Manual in English, were instructed to read the manual and perform testing on the finger and then the alternative sites. A technician collected capillary blood for measurements on YSI. Results were obtained for each of the alternative sites. Samples in the study contained glucose concentrations that ranged from 62 to 492 mg/dL. Results are summarized below.

**For glucose concentrations <75 mg/dL**

Sites	within ± 5 mg/dL	within ± 10 mg/dL	within ± 15 mg/dL
Finger	10/21 (48%)	18/21 (86%)	20/21 (95%)
Palm	14/21 (67%)	19/21 (90%)	21/21 (100.0%)
Forearm	11/21 (52%)	20/21 (95%)	21/21 (100.0%)

**For glucose concentrations ≥75 mg/dL**

Site	Within ± 5 %	within ± 10 %	within ± 15 %	within ± 20 %
Finger	60/124 (48%)	106/124 (85%)	121/124 (98%)	124/124 (100.0%)
Palm	61/124 (49%)	103/124 (83%)	120/124 (97%)	124/124 (100.0%)
Forearm	63/124 (51%)	103/124 (83%)	118/124 (95%)	124/124 (100.0%)

**Linear Regression Analysis:**

Comparison	N	Slope and y-intercept	R <sup>2</sup>
Finger vs. YSI	145	Y = 0.9930x + 2.1102	0.9822
Palm vs. YSI	145	Y = 0.9944x + 0.3915	0.9802
Forearm vs. YSI	145	Y = 0.9910x - 0.6339	0.9830

4. Clinical cut-off:

Not applicable.

5. Expected values/Reference range:

Time of day	Range, Non-diabetes
Before meals	Less than 100 mg/dL
After meals	Less than 140 mg/dL

The sponsor references: American Diabetes Association. Standards of Medical Care in Diabetes , Diabetes Care. 2010;33:S11-S61.

**N. Instrument Name:**

The AutoSure Voice II Plus Blood Glucose Meter

**O. System Descriptions:**

1. Modes of Operation:

Each test strip is single use and must be replaced with a new strip for additional readings.

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

Yes \_\_\_\_\_ or No  X .

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 \_\_\_\_\_

The applicant has provided documentation that indicates the device was designed and developed under good software life-cycle processes.

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 finger, palm, and forearm. Since the whole blood sample is applied directly to the test strip there are no special handling or storage issues.

5. Calibration:

The meter is a non-coding meter, therefore no coding is required by the user.

6. Quality Control:

The sponsor manufactures three levels of glucose control solution, Low, Level 1, and Level 2 to be used with the AutoSure Voice II Plus Blood Glucose Monitoring System. These control solutions must be purchased separately and are not provided with the

device kits. Instructions for how to purchase the control solution are provided in the user manuals. To perform a control test the user is instructed to press the down button while the blood drop symbol is flashing. The “ctl” symbol will then appear on the display. An acceptable range for each control level is printed on the test strip vial label. If the control values fall outside these ranges, the user is referred to the user manual and customer support for problems and more information

**P. Other Supportive Instrument Performance Characteristics Data Not Covered In The “Performance Characteristics” Section above:**

1. The device is intended for single-patient use. Disinfection studies were performed on the AutoSure Voice II Plus meter and lancet device by outside commercial laboratory testing services to determine the disinfection efficacy of the meter and lancing device to the recommended cleaning and disinfection protocol, and its effectiveness in preventing the spread of bloodborne pathogens, particularly hepatitis B virus (HBV). Dispatch Hospital Cleaner Disinfectant Towels with Bleach disposable wipes (EPA Reg. No: 56392-8) were validated, demonstrating complete inactivation of live virus for use with the meter and lancing device. The sponsor also conducted robustness studies and demonstrated that there was no change in performance or in the external materials of the meter and lancing device after 1,825 cleaning and disinfection cycles to simulate 5 years of use by lay-users. Each robustness cycle tested consisted of one pre-clean wipe and one disinfecting wipe.
2. The effect of different hematocrit levels was evaluated with 3 lots of test strips using 10 test strips at each of 5 concentration ranges of glucose (30-50, 51-70, 111-150, 250-350, 500-600 mg/dL). The glucose samples were prepared from venous blood samples at 6 hematocrit levels at approximately 30, 33, 35, 43, 50 and 55%. Each of the results were compared to the value obtained from the same plasma glucose concentration obtained by YSI. The data vs. YSI was reviewed and was found to be acceptable to support the claimed hct range of 30-55%.
3. The effect of altitude was evaluated at five whole blood samples with glucose concentrations ranging from 48 to 470 mg/dL, testing at sea level and 3150 meters (10,334 feet above sea level). Each glucose concentration was measured 20 times at each altitude. The bias was calculated relative to YSI at sea level and at 3150 meters. The results demonstrate that the system meets the acceptance criteria for testing at altitudes up to 3,150 meters (10,334 feet above sea level).
4. The sponsor performed temperature and humidity studies at the combined extremes of 10°C/RH: 18%, 40°C/RH: 20%, 10°C/RH: 88%, and 40°C/RH: 89%, with venous blood samples (50-400 mg/dL) that demonstrated that the AutoSure Voice II Plus meter can be used at temperatures of 50 to 104°F (10 to 40°C) and 20% to 90% relative humidity.
5. Insufficient sample studies were performed at volumes of 0.2 to 1.5µL on ten meters and 3 test strip lots. Three glucose concentrations were tested ranging from approximately 50-350 mg/dL, as determined by the YSI. Appropriate sample volume was determined

if the meter testing could start properly and if the meter results matched the YSI results. A blood volume  $\geq 0.8 \mu\text{L}$  met the criteria.

6. The sponsor provided a readability study and obtained Flesch-Kincaid Grade Level Scores of 8.0, 7.6, and 7.8 for the AutoSure Plus test strip insert, the AutoSure Voice II Plus User's Manual, and Contrex Plus III package insert, respectively.
7. The sponsor stated that they conformed to the following guidelines and provided the appropriate documentation to demonstrate compliance:
  - IEC/EN 60601-1-2: Medical electrical equipment, Part 2. Electromagnetic compatibility, 2007.
  - EN 61000-3-2: Medical electrical equipment Part 2. Electromagnetic compatibility, 2006.
  - EN 61000-3-3: Medical electrical equipment Part 3. Electromagnetic compatibility, 2008.
  - The AutoSure Voice II Plus meter is identical to the cleared meter of k102037 and differs only in trade name. EMC testing was evaluated and certified by QuietTek of Taiwan (R.O.C.) and a letter of attestation was issued to Apex Biotechnology Corp. See k102037.
8. The AutoSure Voice II Plus meter is identical to the cleared meter of k102037 and differs only in trade name. The voice functionality feature of the meter of k102037 was tested and appropriate software verification and validation information for this feature was provided. See k102037. Voice functionality testing results is applicable to this current submission for the AutoSure Voice II Plus meter.
9. A study with visually impaired users was previously conducted to support the claim for use with visually impaired users for the meter of k102037 (See k073137). The AutoSure Voice II Plus meter is identical to the cleared meter of k102037 and differs only in trade name. Testing results from visually impaired users is applicable to this current submission for the AutoSure Voice II Plus meter to support a claim for use with visually impaired users.

**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.