

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

A. 510(k) Number:

k093262

B. Purpose for Submission:

New device

C. Measurand:

Capillary whole blood glucose

D. Type of Test:

Quantitative, electrochemical biosensor, glucose oxidase

E. Applicant:

Andon Medical Co. Ltd.

F. Proprietary and Established Names:

AG-608 Blood Glucose Monitoring System
AG-610 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 (Assayed and Unassayed)
4. Panel:
Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

See Indications for Use below.

2. Indications(s) for use:

The AG-608 and AG-610 Blood Glucose Monitoring Systems are intended for the quantitative measurement of glucose in fresh capillary whole blood from the finger only. Testing is done outside the body (In Vitro diagnostic use). It is intended for use by healthcare professionals and people with diabetes mellitus at home as an aid in monitoring the effectiveness of a diabetes control program. Not for use on neonates. It is not intended for the diagnosis of or screening for diabetes mellitus.

3. Special conditions for use statement(s):

- For in vitro diagnostic use only
- Over the Counter and professional 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 only

4. Special instrument requirements:

The AG-608 Blood Glucose Monitoring System
The AG-610 Blood Glucose Monitoring System

I. Device Description:

The AG-608 and AG-610 Blood Glucose Monitoring Systems contain a blood glucose meter (AG-608 or AG-610, respectively) AGS-1000 blood glucose test strips (including code bottle), Level II control solution, Owner's booklet and carrying case are provided in the kit. Level III control solution, an adjustable lancing device, and sterile lancets are sold separately.

The differences between the two meters (AG-608 and AG-610) are the battery source and the dimensions of meters. They both use the same code bottle.

J. Substantial Equivalence Information:

1. Predicate device name(s):

AG-606 Blood Glucose Monitoring System

2. Predicate 510(k) number(s):

k073030

3. Comparison with predicate:

Similarities			
Item	Device	Device	Predicate (k073030)
Intended use/ Indications for use	It is intended for use by healthcare professionals and people with diabetes mellitus at home as an aid in monitoring the effectiveness of a diabetes control program.	It is intended for use by healthcare professionals and people with diabetes mellitus at home as an aid in monitoring the effectiveness of a diabetes control program.	Same
Brand Name	AG-608 Blood Glucose Monitoring System	AG-610 Blood Glucose Monitoring System	AG-606 Blood Glucose Monitoring System
Detection Method	Amperometry	Amperometry	Same
Enzyme	Glucose oxidase	Glucose oxidase	Same
Sample Type	Fresh capillary whole blood	Fresh capillary whole blood	Same
Measurement range	20-600 mg/dL	20-600 mg/dL	Same
Hematocrit Range	30-55%	30-55%	Same
Sample Site	Fingertip	Fingertip	Same
Measuring time	5 sec	5 sec	same
Memory feature	350 measurement results with date and time	350 measurement results with date and time	same

Differences			
Item	AG-608 Device	AG-610 Device	Predicate (k073118)
Sample volume	0.7 µL	0.7 µL	1.0 µL
Coding function	Code Bottle	Code Bottle	Enter code number into meter
Display the average of test results	7-, 14-, and 28-day average glucose result	7-, 14-, and 28-day average glucose result	14 and 30 day Average glucose result
Meter	85 mm x 53 mm	134 mm x 64 mm x 43	82 mm x 59 mm x 20

Differences			
Item	AG-608 Device	AG-610 Device	Predicate (k073118)
dimensions (mm)	x 13.7 mm	mm	mm
Weight (g)	2.6 oz [82 g]	2.6 oz [82 g]	75 g
Test strip	AGS-1000	AGS-1000	AGS-600
Power Source	DC 3V (CR2032)	DC 3V (2xAAA)	DC 3V (2 AAA)

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.

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-day precision studies were performed using venous whole blood samples spiked with five different glucose concentrations, three different test strip lots, 10 AG-608 meters and 10 AG-610 meters. Each level was analyzed 10 times for a total of 100 tests per each glucose level for each type of meter. Results are summarized below:

Meter	AG-608				AG-610		
Sample Level (mg/dL)	Mean (mg/dL)	SD (mg/dL)	CV (%)		Mean (mg/dL)	SD (mg/dL)	CV (%)
30-50	45	1.3	2.78		41.2	2.7	6.61
51-110	101.2	2.6	2.60		105.0	2.5	2.34
111-150	129.9	3.5	2.70		133.7	3.7	2.79
151-250	213.2	5.6	2.62		212.5	7.0	3.29
251-400	345.2	9.1	2.64		348.5	11.4	3.27

Day-to-day precision was evaluated using three glucose control solutions with concentration levels of low (45 mg/dL), normal (135 mg/dL), and high (320

mg/dL), three different reagent lots and 10 AG-608 meters and 10 AG-610 meters. These tests were performed over 10 days, for a total of 100 tests per glucose level for each meter (AG-608 and AG-610). Results are summarized below.

Meter	AG-608			AG-610		
Control Sample	Mean (mg/dL)	SD (mg/dL)	CV (%)	Mean (mg/dL)	SD (mg/dL)	CV (%)
Low (45 mg/dL)	42.8	1.6	3.85	40.7	2.8	6.87
Medium (135 mg/dL)	129.7	4.5	3.44	110.8	4.1	3.67
High (320 mg/dL)	326.3	8.5	2.61	327.2	12.5	3.83

b. Linearity/assay reportable range:

Linearity was evaluated using 11 spiked whole blood samples ranging in glucose concentrations from 18 to 605 mg/dL (18, 41, 72, 164, 221, 268, 332, 402, 503, 557, 605 mg/dL) as measured by YSI. Each level was measured 5 times and the values from the AG-608 meter were compared with those obtained from YSI-2300. The same evaluation was performed with the AG-610 meter with samples ranging from 17 to 613 mg/dL glucose (17, 56, 114, 168, 257, 346, 419, 472, 534, 581, 613 mg/dL) as measured by YSI. Results from regression analysis:

$$\text{AG-608 meter: } y = 1.0265x - 4.916; R^2 = 0.9946$$

$$\text{AG-610 meter: } y = 0.9772x + 7.2978; R^2 = 0.9985.$$

The claimed range of measurement for this device is 20 to 600 mg/dL.

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

The sponsor claims that the system accuracy of the AG-608 and AG-610 meters is calibrated to a laboratory analyzer, YSI 2300.

Two levels of control material, Level II (96 to 144 mg/dL) and Level III (250 to 420 mg/dL) are available for use with this test system.

The controls are prepared in an aqueous matrix. The reference values are determined using YSI 2300 then each control solution is tested 100 times using meter and test strip combinations and the mean value, SD and CV calculated. The control solution range is then determined for each manufactured lot and printed on the corresponding test strip vial label.

Control solution stability was assessed with accelerated studies and on-going real-time studies. Testing supports the claimed shelf life of 18 month shelf-life when stored at 4-30°C (39 to 86 °F) with relative humidity of <80% and a 90 day stability after opening when stored at 4-30°C with relative humidity of <80 %.

c. Detection limit:

The reportable range for the AG-608 and AG-610 Blood Glucose Monitoring Systems is 20 to 600 mg/dL. This range was verified by the linearity study (M.1.b).

d. Analytical specificity:

The sponsor spiked venous whole blood samples with glucose to obtain concentrations of 80, 120, and 350 mg/dL. Each of these samples was divided into a test pool and a control pool and each potential interfering substance was added to the test pool.

Each level was analyzed 5 times total with two AG-608 meters and 5 times total with two AG-610 meters with 3 lots of glucose test strips. The % difference between the interference containing sample and the control sample calculated. The sponsor defines no significant interference as $\leq 10\%$ difference. Results are presented in the table below:

Potential Interfering Substance	Concentration with no Significant Interference (mg/dL)		Potential Interfering Substance	Concentration with no Significant Interference (mg/dL)
Acetaminophen	5.0		Tolazamide	30
Ascorbic Acid	2		Tolbutamide	64
Ephedrine	3.6		Bilirubin	15
Ibuprofen	50		Creatinine	10
L-Dopa	1.35		Uric Acid	8
Methyldopa	1.5		Cholesterol	500
Dopamine	0.09		Triglycerides	3000
Salicylate	60			

The user manual and test strip insert state that the following substances at levels greater than normal or therapeutic levels may cause significant interference: acetaminophen, ascorbic acid, uric acid, dopamine and L-dopa. Do not use icterus samples or high lipemia samples.

Hematocrit study:

The effect of different hematocrit levels was evaluated using whole blood samples with hematocrit levels 30, 35, 40, 45, 50 and 55% spiked with glucose to achieve 7 concentrations ranging from 21 to 597 mg/dL. Each sample was then tested 4 times using the AG-608 Blood Glucose meter and 3 times using the AG-610 meter. The

values compared with the glucose values from YSI-2300 analyzer. The % biases were acceptable within the claimed range of 30 to 55%. The results from regression analysis are summarized in the table below:

Meter	Hematocrit %	Slope and Intercept	R ²
AG-608	30	$y = 1.0076x - 5.8491$	0.998
	35	$y = 0.9681x + 8.4681$	0.997
	40	$y = 0.9910x - 3.4569$	0.997
	45	$y = 0.9766x + 2.9518$	0.998
	50	$y = 0.9536x + 3.7195$	0.998
	55	$y = 0.9433x - 1.8869$	0.998
AG-610	30	$y = 0.9735x - 0.8382$	0.996
	35	$y = 1.0033x - 2.4038$	0.997
	40	$y = 0.976x + 1.1097$	0.998
	45	$y = 0.9804x + 0.2287$	0.998
	50	$y = 0.9808x - 2.1713$	0.998
	55	$y = 0.9081x + 5.2522$	0.998

Altitude study:

Capillary whole blood samples from 20 volunteers with glucose concentrations ranging from 66 to 403 mg/dL for the AG-608 meter and 62 to 422 mg/dL for the AG-610 meter were tested at 11,975 feet (3650 meters). Results were compared to YSI values and resulted in a % bias < 10% for all samples tested. The results support the claims in the labeling that altitudes up to 11,975 feet have no significant effect on blood glucose measurements from the AG-608 and AG-610 meters.

Temperature and humidity studies:

The sponsor performed temperature and humidity studies using the AG-608 and the AG-610 meter with low (40 mg/dL), normal (120 mg/dL) and high (350 mg/dL) glucose level control solutions. Results demonstrated that both systems (meters and test strips) can be used in conditions of 50 to 104°F (10 to 40°C) with relative humidity < 80% and stored under conditions of 39 to 86°F and relative humidity of <80%. The test strip labeling states to store the test strips in a cool dry place between 39 to 86°F.

- e. *Assay cut-off:*
Not Applicable.

2. Comparison studies:

- a. *Method comparison with predicate device:*

System Accuracy:

The sponsor performed accuracy studies to demonstrate that the AG-608 and AG-610 meters are equivalent to the reference method, YSI 2300. Capillary samples from

100 volunteers with concentrations ranging from 21.6 to 504 mg/dL were evaluated using 2 AG-608 meters and samples ranging from 23.4 to 526 mg/dL were evaluated using 2 AG-610 meters at two different hospitals. To obtain blood glucose concentrations <50 and > 500 mg/dL, samples were allowed to glycolize or were spiked to achieve the desired glucose concentration. The results relative to YSI are summarized in the tables below:

For glucose concentrations <75 mg/dL

Meter	within $\pm$ 5 mg/dL	within $\pm$ 10 mg/dL	within $\pm$ 15 mg/dL
AG-608	24/40 (60%)	32/40 (80%)	38/40 (95%)
AG-610	16/38 (42%)	31/38 (81%)	37/38 (97%)

For glucose concentrations $\geq$ 75 mg/dL

Meter	within $\pm$ 5 %	within $\pm$ 10 %	within $\pm$ 15 %	within $\pm$ 20 %
AG-608	71/160 (44%)	119/160 (74%)	141/160 (88%)	157/160 (98%)
AG-610	38/162 (23%)	109/162 (67%)	154/162 (95%)	161/162 (99%)

Regression Analysis vs. YSI

Comparison	N	Slope and y-intercept	R ²
AG-608 vs. YSI	100	y=1.0621x-4.3344	0.978
AG-610 vs. YSI	100	y=1.006x+2.210	0.978

User Performance Study:

To demonstrate the accuracy of the AG-608 and AG-610 blood glucose monitoring systems the sponsor performed a study for each of the meters with 100 lay user participants and one technician at two different hospitals. The participants, who were able to read the User's Manual in English were instructed to read the manual, obtain their own finger stick sample and perform testing using the meter (AG-608 or AG-610). The technician then performed the testing on an additional fingerstick sample from the user. The samples ranged from 51.6 to 356 mg/dL for the AG-608 and 53.4 to 347 mg/dL for the AG-610. A sample was then taken from each participant by the technician and measured by YSI-2300. The results are summarized in the tables below:

Lay-user vs. YSI:

For glucose concentrations <75 mg/dL

Meter	within $\pm$ 5 mg/dL	within $\pm$ 10 mg/dL	within $\pm$ 15 mg/dL
AG-608	1/4 (25%)	4/4 (100%)	4/4 (100%)
AG-610	2/6 (33%)	5/6 (83%)	6/6 (100%)

For glucose concentrations ≥ 75 mg/dL

Meter	within ± 5 %	within ± 10 %	within ± 15 %	within ± 20 %
AG-608	40/96 (42%)	75/96 (78%)	92/96 (96%)	96/96 (100%)
AG-610	43/94 (46%)	65/94 (69%)	92/94 (98%)	94/94 (100%)

Technician vs. YSI:**For glucose concentrations <75 mg/dL**

Meter	within ± 5 mg/dL	within ± 10 mg/dL	within ± 15 mg/dL
AG-608	3/4 (75%)	4/4 (100%)	4/4 (100%)
AG-610	3/6 (50%)	6/6 (100%)	6/6 (100%)

For glucose concentrations ≥ 75 mg/dL

Meter	within ± 5 %	within ± 10 %	within ± 15 %	within ± 20 %
AG-608	38/96 (40%)	82/96 (85%)	93/96 (97%)	96/96 (100%)
AG-610	49/94 (52%)	70/94 (74%)	92/94 (98%)	94/94 (100%)

Linear Regression Analysis:

Comparison	N	Slope and y-intercept	R ²
Lay user AG-608 vs. YSI	100	$y=1.0216x-7.288$	0.9724
Technician AG-608 vs. YSI	100	$y=1.043x-5.1523$	0.9818
Lay user AG-610 vs. YSI	100	$y=1.0567x+5547$	0.9814
Technician AG-610 vs. YSI	100	$y=1.0556x-6.917$	0.9759

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):

The sponsor provided a readability study and obtained SMOG Grade Level Scores of 8 for the User's Manual, test strip insert and control solution insert.

4. Clinical cut-off:

Not Applicable.

5. Expected values/Reference range:

Time of day	People without diabetes
Fasting and before meals	<110 mg/dL
2 hours after meals	< 180 mg/dL

The sponsor references: Josline Diabetes Center. Goals for Blood Glucose Control.[Electronic version]. Retrieved July 5th, 2010:
http://www.joslin.org/info/goals_for_blood_glucose_control.html

The labeling includes the following statement: Please work with your doctor to determine a target range that works best for you.

N. Instrument Name:

AG-608 Blood Glucose Monitoring System
 AG-610 Blood Glucose Monitoring System

O. System Description: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 fingertip. Since the whole blood sample is applied directly to the test strip there are no special handling or storage issues.

5. Calibration:

The meter uses a code bottle. To code the meter the code bottle, which is the test strip vial, is plugged into the back of the meter. Once the "OK" appears on the screen, the meter is coded. The same code bottle is used for both the AG-608 and AG-610 meters. The user is instructed to compare the code number that appears on the display with that printed on the test strip vial to confirm that the meter has been coded properly.

6. Quality Control:

The sponsor provides one level of glucose control solution, Level II, with this kit. An additional Level III is available for purchase separately, as stated in the labeling. To perform a control test the user is instructed to press the S button in step 5. Once the "CTL" appears on the screen the control results will be prevented from being stored in the memory. 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 customer support for problems and more information.

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

None

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.