

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

A. 510(k) Number:

k083628

B. Purpose for Submission:

New device

C. Measurand:

Whole blood glucose

D. Type of Test:

Quantitative, glucose dehydrogenase (FAD-GDH)

E. Applicant:

All Medicus, Co. Ltd.

F. Proprietary and Established Names:

GlucoDR auto Blood Glucose Monitoring System

G. Regulatory Information:

<u>Product Code</u>	<u>Classification</u>	<u>Regulation Section</u>	<u>Panel</u>
NBW – over the counter glucose test system	II	862.1345	75, Chemistry
LFR – Glucose, glucose dehydrogenase			
JJX – single (specified) analyte controls (assayed and unassayed)	I (reserved)	862.1660	

H. Intended Use:

1. Intended use(s):

See indications for use below.

2. Indication(s) for use:

The GlucoDr auto blood glucose monitoring system is intended for in vitro diagnostic use (i.e., for external use only) for quantitative measurement of glucose in venous, arterial, and capillary whole blood. Testing sites include traditional fingertip site along with palm, arm, thigh, and calf.

The GlucoDr auto blood glucose monitoring system may be used by healthcare professionals or for self testing by diabetic lay users with diabetes at home as aid in monitoring the effectiveness of diabetes control program.

The GlucoDr auto blood glucose monitoring system is not intended for the diagnosis of or screening for diabetes mellitus nor intended for use on neonates.

The GlucoDr auto control solution is for use with the The GlucoDr auto meters and strips as a quality control check to verify the accuracy of blood glucose test results.

3. Special conditions for use statement(s):

- Not for use on critically ill patients, dehydrated patients or hyperosmolar patients
- Not for neonatal use
- Not for screening or diagnosis of diabetes mellitus
- Alternative site testing is for use at times of steady state only

4. Special instrument requirements:

The GlucoDr auto Blood Glucose Monitoring System

I. Device Description:

The GlucoDr auto Blood Glucose Monitoring System consists of glucose meter, blood glucose test strips and two control materials.

J. Substantial Equivalence Information:1. Predicate device name(s):

Accu-Chek Aviva System, Roche Diagnostics Corporation

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

k043474

3. Comparison with predicate:

Similarities		
Item	Device	Predicate
Detection Method	Amperometry	Amperometry
Enzyme	Glucose dehydrogenase	Glucose dehydrogenase
Sample type	Capillary or venous blood	Capillary or venous blood
Test time	5 seconds	5 seconds
Memory Capacity	500 results with date and time	500 results with date and time
Control solution	2 range	2 range

Differences		
Item	Device	Predicate
Measurement range	20-600 mg/dL	10-600 mg/dL
Sample Volume	0.5 ul	0.6 ul
Coding of Strip	Auto Coding	Code Chip

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

CLSI EP5-A2: Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline-Second Edition (2004)

CLSI EP6-A: Evaluation of Linearity of Quantitative Measurement Procedures, A Statistical Approach: Approved Guideline (2003)

CLSI EP7-A2: Interference Testing in Clinical Chemistry; Approved Guideline (2002)

CLSI EP9-A2: Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline (2002)

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

ISO 14971: 2007, Medical devices – Application of risk management to medical devices

EN 13612: 2002, Performance evaluation of in vitro diagnostic medical devices

EN 13640: 2002, Stability testing of in vitro diagnostic medical devices
EN 61010-2-101: 2002, Safety requirements for electrical equipment for measurement, control and laboratory use. Particular requirements for in vitro diagnostic (IVD) medical equipments
FDA Guideline, Review criteria for assessment of portable blood glucose monitoring in vitro diagnostic devices using glucose oxidase, dehydrogenase or hexokinase methodology

L. Test Principle:

The GlucoDr auto Blood Glucose Monitoring System is based on measurement of electrical currents caused by the reaction of glucose with reagents on the gold electrode strip. Glucose in the blood sample reacts with FAD glucose dehydrogenase and potassium ferricyanide in the test strip, which creates electrical currents. The subsequent electrical currents are proportional to the glucose concentration in the blood and converted to the equivalent glucose concentration by the algorithm programmed in the test meter.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

The sponsor performed precision studies using venous whole blood with concentrations between 58 and 324 mg/dL (spiked samples). Testing was performed at 3 sites with 10 meters (3 meters used at site 1 and 2 and 4 meters at site 3) and three lots of test strips were tested with 10 replicates of each lot in one day. The results for all three lots are presented in the table below:

Level	Mean of glucose (mg/dL)	Within-run (SD)	%CV
1	58	1.88	3.22
2	103	1.95	1.89
3	150	2.73	1.82
4	190	3.72	1.96
5	324	5.95	1.84

In addition, repeatability of the test strip was tested with control solutions (low, medium and high). Testing was performed at 3 sites with 10 meters (3 meters used at site 1 and 2 and 4 meters at site 3) and three lots of test strips were tested with 10 replicates in one day. The results for all three lots are presented in the table below:

Glucose control solution level	Mean of glucose (mg/dL)	Total imprecision (SD)	Total % CV
Low	39.8	2.32	5.82
Medium	110	3.28	2.99
High	311	9.20	2.96

b. Linearity/assay reportable range:

The linearity of the glucose measurements was demonstrated by comparing prepared blood samples on the GlucoDr auto blood glucose monitoring system and a glucose reference method. The seventeen samples ranged in concentration from a low of approximately 10 mg/dL to a high of approximately 600 mg/dL. Three GlucoDr meters and three lots of blood glucose test strips were tested in replicates of three. Linear regression of the comparison data yielded the following relationship:

$$\text{Lot 1 - } y = 0.9973x - 1.6265, R^2 = 0.9996$$

$$\text{Lot 2 - } y = 1.0018x + 0.0570, R^2 = 0.9986$$

$$\text{Lot 3 - } y = 1.0004x + 0.9824, R^2 = 0.9987$$

The reportable range for glucose measurements is 20-600 mg/dL

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

Values for the control materials are assigned by repeat testing over time and analyzing the variation of the results. Expected values for each lot of control solutions are printed on the strip vial. The test strip and control solution stability was assessed by performing real-time and accelerated studies for the shelf life and in use stability. Stability protocols and acceptance criteria were evaluated and found to be acceptable. The claimed shelf life is 18 months and the claimed in-use stability is 90 days for control solution and 4 months in-use shelf life for the test strips when stored at room temperature.

d. Detection limit:

See linearity/reportable range studies above.

e. *Analytical specificity:*

Endogenous and exogenous substances were tested for interference on this assay at three glucose concentration (58, 163 and 261 mg/dL). Three test strip lots and 4 meters were used in the study. The sponsor defined interference as a change in glucose measurement from the control greater than 10 mg/dL for glucose concentration <75 mg/dL and greater than 10% for glucose concentration >75 mg/dL. The following substances were tested.

Exogenous Substances	Concentration Showing No Interference (mg/dL)
Acetaminophen	6
Ascorbic Acid	4
Dopamine	13
Ephedrine	30
Ibuprophen	40
L-dopa	13
Methyl dopa	13
Salicylate	50
Tetracycline	4
Tolazamide	100
Tolbutamine	100
Maltose	20

Endogenous Substances	Concentration Showing No Interference (mg/dL)
Bilirubin	4
Creatinine	30
Citric Acid	30
Hemoglobin	500
Oleic Acid	1.4
Palmitic Acid	1.0
Protein –Albumin	6.0
Triglycerides	300
Uric Acid	10

All substances tested, except for the ones listed below, show no interference at the concentrations tested. The sponsor notes in the labeling that the following substances may affect the test results above concentrations tested; Acetaminophen, Ascorbic Acid, Total bilirubin, Triglyceride and Uric acid.

Hematocrit study:

The effect of hematocrit was evaluated in a study using samples with 5 glucose concentrations (40-60, 80-120, 150-200, 250-300, and 350-450 mg/dL) and varying

hematocrit levels from 20 - 60%. Each glucose level/hematocrit combination was tested on 5 meters using 3 lots of test strips, by comparing the results of samples at each of the varying hematocrit levels to the sample of the same glucose concentration at a normal (40%) hematocrit level. Each glucose level/hematocrit combination was also compared to the corresponding YSI value. The data supports the sponsor's claimed hematocrit range of 20-60%.

Altitude study:

An altitude study was performed with four whole blood samples spiked to the following concentration 80-120, 180-200, 280-320 and 380-420 mg/dL. The samples were tested at ground level up to 8,200 feet. All samples met the sponsor's acceptability criterion of the difference between the minimum and maximum result at each concentration range is < 10%. The data submitted supports use of the device up to 8,200 feet.

Temperature and Humidity study:

Temperature and humidity studies were performed and showed that the meter can be used at temperatures from 10 to 40°C and humidity from 35 to 55%; and exposed to temperatures from -10 to 51°C and a relative humidity from 11 to 91%

f. Assay cut-off:

Not applicable

2. Comparison studies:

a. Method comparison with predicate device:

The consumer study was performed at three POC sites with a total of 130 lay-users. The lay-users ranged in age, education and were about equally divided between males and females. Each participant performed their own fingerstick and tested their blood using the instructions in the User's manual and package insert. A trained healthcare professional then performed another fingerstick and tested the blood on the same meter. Samples ranged from 31 to 552 mg/dL with samples below 63 mg/dL and above 423 mg/dL adjusted to acquire these extreme ranges. Blood was collected and measured on a YSI analyzer.

System accuracy results for glucose are present in the tables below:

For glucose concentrations < 75 mg/dL Lay-User

within ± 5 mg/dL	within ± 10 mg/dL	within ± 15 mg/dL
9/17 (53%)	16/17 (94%)	17/17 (100%)

For glucose concentrations ≥ 75 mg/dL Lay-User

within ± 5 %	within ± 10 %	within ± 15 %	within ± 20 %
83/113(73.5%)	107/113(95%)	113/113(100%)	113/113(100%)

For glucose concentrations < 75 mg/dL Healthcare Professional

within \pm 5 mg/dL	within \pm 10 mg/dL	within \pm 15 mg/dL
10/17 (59%)	16/17 (94%)	17/17 (100%)

For glucose concentrations \geq 75 mg/dL Healthcare Professional

within \pm 5 %	within \pm 10 %	within \pm 15 %	within \pm 20 %
85/113(75.2%)	104/113(92%)	112/113(99%)	113/113(100%)

Alternate site testing:

The consumer study was performed at one POC site with a total of 51 lay-users. The lay-users ranged in age, education and were equally divided between males and females. Each participant performed a self-test on their finger, palm, arm and thigh testing their blood using the instructions in the User's guide. A trained professional then performed testing on the finger, palm, forearm, upper arm, thigh, and calf testing the blood on the same meter.

System accuracy alternative site Professional and Lay-user results for glucose are present in the tables below:

For glucose concentrations < 75 mg/dL Lay-User

	within \pm 5 mg/dL	within \pm 10 mg/dL	within \pm 15 mg/dL
Finger	6/9 (67%)	9/9 (100%)	9/9 (100%)
Palm	5/9 (56%)	9/9 (100%)	9/9 (100%)
Upper Arm	5/9 (56%)	8/9 (89%)	9/9 (100%)
Forearm	6/9 (67%)	9/9 (100%)	9/9 (100%)
Thigh	6/9 (67%)	9/9 (100%)	9/9 (100%)
Calf	5/9 (56%)	8/9 (89%)	9/9 (100%)

For glucose concentrations \geq 75 mg/dL Lay-User

	within \pm 5 %	within \pm 10 %	within \pm 15 %	within \pm 20 %
Finger	22/42 (52%)	35/42 (83%)	42/42 (100%)	42/42 (100%)
Palm	25/42 (60%)	39/42 (93%)	41/42 (98%)	42/42 (100%)
Upper Arm	23/42 (55%)	36/42 (86%)	42/42 (100%)	42/42 (100%)
Forearm	26/42 (62%)	39/42 (93%)	42/42 (100%)	42/42 (100%)
Thigh	25/42 (60%)	36/42 (86%)	42/42 (100%)	42/42 (100%)
Calf	34/42 (81%)	38/42 (91%)	41/42 (98%)	42/42 (100%)

For glucose concentrations < 75 mg/dL Healthcare Professional

	within \pm 5 mg/dL	within \pm 10 mg/dL	within \pm 15 mg/dL
Finger	5/9 (56%)	8/9 (89%)	9/9 (100%)
Palm	5/9 (56%)	9/9 (100%)	9/9 (100%)
Upper Arm	6/9 (67%)	9/9 (100%)	9/9 (100%)

Forearm	5/9 (56%)	9/9 (100%)	9/9 (100%)
Thigh	7/9 (78%)	9/9 (100%)	9/9 (100%)
Calf	7/9 (78%)	9/9 (100%)	9/9 (100%)

For glucose concentrations ≥ 75 mg/dL Healthcare Professional

	within ± 5 %	within ± 10 %	within ± 15 %	within ± 20 %
Finger	26/42 (62%)	39/42 (93%)	42/42 (100%)	42/42 (100%)
Palm	33/42 (79%)	39/42 (93%)	42/42 (100%)	42/42 (100%)
Upper Arm	37/42 (88%)	42/42 (100%)	42/42 (100%)	42/42 (100%)
Forearm	34/42 (81%)	41/42 (98%)	42/42 (100%)	42/42 (100%)
Thigh	31/42 (74%)	40/42 (95%)	42/42 (100%)	42/42 (100%)
Calf	34/42 (81%)	41/42 (98%)	42/42 (100%)	42/42 (100%)

b. Matrix comparison:

EDTA venous blood samples from 70 patients were assayed on the GlucoDr auto Blood Glucose Monitoring System and the YSI using two strip lots. Sample ranged from 58.3-431 mg/dL. The linear regression for each lot is:

$$\text{Lot 1} - y = 0.9926x + 6.3264, r^2 = 0.9969$$

$$\text{Lot 2} - y = 1.0022x + 7.0767, r^2 = 0.9969$$

$$\text{Lot 1} + \text{Lot 2} = y = 0.9974x - 6.7016, r^2 = 0.9965$$

System accuracy results for glucose are present in the tables below for the combined data from each lot:

For glucose concentrations < 75 mg/dL

within ± 5 mg/dL	within ± 10 mg/dL	within ± 15 mg/dL
10/16 (62.5%)	16/16 (100%)	16/16 (100%)

For glucose concentrations ≥ 75 mg/dL

within ± 5 %	within ± 10 %	within ± 15 %	within ± 20 %
50/124(40%)	103/124(83%)	122/124(98%)	124/124(100%)

Lithium heparin arterial blood samples from 70 patients were assayed on the GlucoDr auto Blood Glucose Monitoring System and the YSI using two strip lots. Sample ranged from 56-398 mg/dL. The linear regression for each lot is:

$$\text{Lot 1} - y = 0.9700x - 0.1545, r^2 = 0.9952$$

$$\text{Lot 2} - y = 0.9792x - 0.1199, r^2 = 0.9953$$

$$\text{Lot 1} + \text{Lot 2} = y = 0.9746x - 0.1372, r^2 = 0.9952$$

System accuracy results for glucose are present in the tables below for the combined data from each lot:

For glucose concentrations < 75 mg/dL

within \pm 5 mg/dL	within \pm 10 mg/dL	within \pm 15 mg/dL
10/18 (55.6%)	18/18 (100%)	18/18 (100%)

For glucose concentrations \geq 75 mg/dL

within \pm 5 %	within \pm 10 %	within \pm 15 %	within \pm 20 %
116/122(95%)	121/122(99%)	122/122(100%)	122/122(100%)

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:

The sponsor included the following Expected Values for people without diabetes in their strip labeling:

<u>Status</u>	<u>Range</u>
Fasting and Before meals	70-100 (mg/dL) (3.9-6.1 mmol/L)
2 hours after meals	Less than 140 mg/dl (7.8 mmol/L)

Source: ADA Clinical Practice Recommendations 2003

N. Instrument Name:

The GlucoDr auto Blood Glucose Monitoring System

O. System Descriptions:

1. Modes of Operation:

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

2. Software:

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

Yes ☒ 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, forearm or thigh and venous and arterial whole blood. For capillary whole blood, since the sample is applied directly to the test strip, there are no special handling or storage issues. For venous whole blood, samples must be tested within 15 minutes of draw and the sample cannot be stored.

5. Calibration:

Each vial of test strips has a code number which is used to calibrate the meter. The code number must be verified by turning on the meter using the power button. The code number cannot be changed with a test strip inserted into the port. The user confirms that the code number on the test strip bottle matches the code number in the instrument. No further calibrations are required of the user.

6. Quality Control:

The sponsor sells two levels of control solution with this device. To mark the test result as a control, after the test result is displayed the user is instructed to press the +/- buttons to select the attention event icon. After the attention event icon appears on the display press the power button to save. This distinguishes control results from actual blood glucose tests in the memory. An acceptable range for each control level is printed on the test strip vial label. If control results fall outside these ranges, the user is referred to a list of troubleshooting steps and the customer care line.

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

Not applicable

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 substantial equivalence decision.