

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

A. 510(k) Number:

k112916

B. Purpose for Submission:

New device

C. Measurand:

Venous and capillary whole blood glucose from the finger, palm and forearm

D. Type of Test:

Quantitative, electrochemical amperometric biosensor, glucose dehydrogenase, FAD

E. Applicant:

Tyson Bioresearch, Inc.

F. Proprietary and Established Names:

Tyson MD100 Blood Glucose Monitoring System

Tyson MD100 Pro Blood Glucose Monitoring System

TysonBio MD100 Control Solutions

G. Regulatory Information:

1. Regulation section:

Regulation	Name	Classification	Panel
21 CFR § 862.1345	Glucose test system	II	Chemistry (75)
21 CFR § 862.1660	Quality control material	I, reserved	Chemistry (75)

3. Product code:

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

LFR, Glucose Dehydrogenase, Glucose

JJX, Single (Specified) Analyte Controls

H. Intended Use:

1. Intended use(s):

See Indications for Use below.

2. Indication(s) for use:

TysonBio MD100 Blood Glucose Monitoring System

The **TysonBio MD100 Blood Glucose Monitoring System** is intended for the quantitative measurement of glucose in capillary whole blood samples. Capillary samples may be drawn from the fingertip, palm and forearm. The TysonBio MD100 Blood Glucose Monitoring System is intended to be used by a single person and should not be shared. The TysonBio MD100 Blood Glucose Monitoring System is intended for self-testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The TysonBio MD100 Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonatal use. Alternative site testing should be done only during steady - state times (when glucose is not changing rapidly).

The TysonBio MD100 Test Strips are for use with the TysonBio MD100 Blood Glucose Meter to quantitatively measure glucose in fresh capillary whole blood samples drawn from the fingertips, forearm or palm.

The TysonBio MD100 Control Solutions is for use on the TysonBio MD100 Blood Glucose Monitoring Systems to check that the meter and test strips are working together properly and providing accurate results.

TysonBio MD100 Pro Blood Glucose Monitoring System

The **TysonBio MD100 Pro Blood Glucose Monitoring System** is intended for the quantitative measurement of glucose in capillary and venous whole blood samples. Capillary samples may be drawn from the fingertip, palm and forearm. The TysonBio MD100 Pro Blood Glucose Monitoring System is intended for testing outside the body (in vitro diagnostic use) and is intended for multiple-patient use in professional healthcare settings as an aid to monitor the effectiveness of diabetes control program. This system should only be used with auto-disabling, single-use lancing devices. The TysonBio MD100 Pro Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonatal use. Alternative site testing should be done only during steady – state times (when glucose is not changing rapidly).

The TysonBio MD100 Pro Blood Glucose Test Strips are for use with the TysonBio MD100 Pro Blood Glucose Meter to quantitatively measure glucose in venous whole blood sample and fresh capillary whole blood samples drawn from the fingertips, forearm or palm.

The TysonBio MD100 Control Solutions is for use on the TysonBio MD100 Pro Blood Glucose Monitoring Systems to check that the meter and test strips are working together properly and providing accurate results.

3. Special conditions for use statement(s):

- TysonBio MD100 Blood Glucose Monitoring System is for over-the-counter (OTC) use, is for single patient use only and should not be shared
- TysonBio MD100 Pro Blood Glucose Monitoring System is for prescription use and over the counter (OTC), and should only be used with auto-disabling, single use lancing devices
- 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.
- AST measurements should not be used to calibrate continuous glucose monitors or for insulin dose calculations

4. Special instrument requirements:

TysonBio MD100 Blood Glucose Meter

TysonBio MD100 Pro Blood Glucose Meter

I. Device Description:

The TysonBio MD100 and TysonBio MD100 Pro Blood Glucose Monitoring Systems are for single patient and multiple patient use. The systems consist of the Tyson MD100 or Tyson MD100 Pro Blood Glucose Test Strips and the TysonBio MD100, or MD100 Pro Control Solutions. The device uses auto-coding for recognizing different test strip lots. A start up kit consists of the meter, one vial of test strips, user's manual, quick guide, a log book, lancing device and normal control solution.

The EZtake Lancing Device is for single patient use only and is provided with the Tyson MD100 home use start up kit.

The TysonBio MD100 Control Solutions are for use on the TysonBio MD100 and the TysonBio MD100 Pro Blood Glucose Monitoring Systems to check that the meter and test strips are working together properly. One control level is supplied with the start up kit. Subsequent control materials are purchase separately.

J. Substantial Equivalence Information:

1. Predicate device name(s):

Ascensia Contour Blood Glucose Monitoring System

2. Predicate 510(k) number(s):
k062058

3. Comparison with predicate:

Similarities		
Item	Device (k112916)	Predicate (k062058)
Intended use	Same	Measurement of glucose for the monitoring of diabetes
Test principle	Same	Electrochemical biosensor with glucose dehydrogenase (FAD)
Test Sample	Same	Whole blood (Capillary and venous blood)
Measuring Time	Same	5 seconds
Coding	Same	Auto coding by inserting the test strip
Hypoglycemic and hyperglycemic alarm	Same	2 user setting alarms
Average result	Same	7,14 and 30days

Differences		
Item	Device (k112916)	Predicate (k062058)
Meter size	94 mm (H) x 63 mm (W) x 25 mm (T)	77 mm (H) x 57 mm (W) x 19 mm (T)
Meter weight	60 grams without battery	47.5 grams
Sample volume	0.5uL	0.6uL
AST	Palm and forearm	Palm, forearm and heel (neonates)
Measuring Range	20-600mg/dL	10-600mg/dL
Hematocrit range	10-70%	0 ~70 %
Operating Temperature Range:	10 to 40 °C (50-104°F)	5 to 45 °C (41-113°F)
Humidity	10-90%	10-93%
Memory Feature	Stores most recent 500 test results	Stores most recent 480 test results
Battery Type:	Two AAA batteries	Two 3-volt lithium batteries (DL2032 or CR2032)
Battery Life:	Approximately 1000 tests	Approximately 1000 tests (1 yr. average use)
Marker	Meal	Meal and log book

Differences		
Item	Device (k112916)	Predicate (k062058)
Reminder alarm	4 user setting alarms	Post-Meal Test Alarm
Button	Three operating button (M, up and down) One ejection button	Three operating button (M, up and down)
Sample type	Capillary and venous whole blood	Capillary, venous and arterial whole blood, neonatal blood samples.

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

ISO 14971, Medical Devices—Application of Risk Management to Medical Devices

ISO 15197, In Vitro Diagnostic Test Systems—Requirements for Blood Glucose Monitoring Systems for Self-testing in Managing Diabetes Mellitus

L. Test Principle:

The device uses an amperometric biosensor used to quantitatively measure glucose in capillary and venous whole blood. The test strips use glucose dehydrogenase, FAD for glucose measurement.

M. Performance Characteristics (if/when applicable):

The meter and test strips for the TysonBio MD100 and TysonBioMD100 Pro Blood Glucose Test Systems are the same components. The two Systems only differ in name and intended use. (single versus multiple patient use). Therefore, 1 set of data are presented for both test systems.

1. Analytical performance:

a. Precision/Reproducibility:

Repeatability studies were performed on the TysonBio MD100 using 5 levels of spiked EDTA venous whole blood with hematocrits of approximately 42%. The samples were spiked with β -D-glucose to concentrations from approximately 42 mg/dL to 357 mg/dL. Glucose concentrations were determined by the YSI 2300 glucose analyzer. Samples were tested 10 times using 10 meters (n=100 total) with each level of blood sample using 3 lots of test strips. Results are summarized below:

	YSI	Mean	Bias %	SD	%CV
Lot 1	42.1	44.0	4.4	2.91	6.63
	76.3	76.6	0.3	3.28	4.29
	134	134.9	0.6	4.43	3.29
	238	237	-0.4	7.22	3.05
	357	353.1	-1.1	10.37	2.97
Lot 2	43.2	44.3	2.5	3.15	7.12
	74.5	74.7	0.2	3.43	4.59
	130	129.5	-0.4	4.60	3.56
	234	232.6	-0.6	7.57	3.25
	354	349.9	-1.2	9.30	2.66
Lot 3	44.2	45.2	2.3	2.91	6.43
	73.9	73.9	-2.0	3.24	4.38
	133	133.8	1.3	4.12	3.08
	235	234.6	-0.2	7.82	3.33
	355	351.6	-1.0	10.27	2.92

Day to day precision test was performed with 3 levels of glucose control solutions: (1) Level 1: 30-60mg/dL; (2) Level 2: 68-128mg/dL; (3) Level 3: 245-335mg/dL. 3 lots test strips were used by 3 operators. Samples were tested with 10 measurements obtained from 10 meters with each level of control solution over 10 days.

		Lot 1	Lot 2	Lot 3
Level 1 (30-60 mg/dL)	Mean	39.5	42.2	41.1
	SD	2.2	2.3	2.2
	CV%	5.5	5.3	5.4
Level 2 (68-128 mg/dL)	Mean	95.9	93.0	94.5
	SD	4.0	3.3	3.3
	CV%	4.2	3.5	3.5
Level 3 (245-335 mg/dL)	Mean	294.1	288.4	298.1
	SD	6.5	6.3	6.9
	CV%	2.2	2.2	2.3

b. Linearity/assay reportable range:

Linearity was performed using EDTA venous whole blood samples spiked with β -D-glucose to 12 concentrations ranging from 18.7 mg/dL to 612 mg/dL as determined by the YSI 2300. The samples were tested in quadruplicate on each of 4 meters using three test strip lots. Observed values were plotted against the expected values and least squares regression analysis was used to determine linearity. Summarized data for each lot is presented below.

Strip Lot	Slope	Intercept	R2	Sample range tested mg/dL
1	0.995	1.255	0.999	23-611
2	1.009	1.935	1.00	22-630
3	1.012	1.336	0.999	20-629

Based on the results of this study, the measuring range was determined to be 20-600 mg/dL.

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

Traceability: The method comparison study was performed using the candidate device and the YSI as the reference method (see section M.2.a.). The MD100 and MD100 Pro are autocoding meters.

Control Value Assignment: The three levels of glucose control solutions are analyzed on the YSI 2300 which has been calibrated with NIST traceable materials. Value assignment is based on testing the control materials on multiple meters and test strip lots. The protocols were reviewed and found to be adequate.

Stability:

MD100 Test Strips: Real time and accelerated stability studies were performed for MD100 test strips to assess the shelf-life and open-vial stability. Stability studies protocol and acceptance criteria for open and unopened vials were provided and found to be adequate to support the labeling claims of 3 months for open vial stability when stored tightly closed between 39°F and 86°F (4°C and 30°C) and 18 month shelf life for unopened vials when stored between 39°F and 86°F (4°C and 30°C).

MD100 Control Solutions: Real time stability studies were performed on open and closed vials at three control levels. Stability studies protocol and acceptance criteria for open and unopened vials were provided and found to be adequate to support the labeling claims of 3 months for open vial stability when stored tightly closed between 39°F and 86°F (4°C and 30°C) and 18 month shelf life for unopened vials when stored between 39°F and 86°F (4°C and 30°C).

d. Detection limit:

See linearity study above.

e. Analytical specificity:

Specificity studies were performed using venous whole blood samples with glucose concentrations of 70-90 mg/dL and 200-285 mg/dL. The low and high glucose

samples were spiked with potential endogenous and exogenous interferents at therapeutic or reference intervals, and at toxic levels or ten times the therapeutic concentrations. One set of samples was unaltered and used as a control. Samples were analyzed in quintuplicate. Significant interference was defined by the sponsor as $> \pm 10\%$ bias relative to the control.

Substance	Interferent range tested	Highest concentration without interference (mg/dL)
Acetone	7.5-60	60
Acetaminophen	1.25-10	10
Ascorbic acid	1.875-15	3.75
Alcohol	43.75-350	350
Bilirubin	2.5-20	20
Benzoic acid	18-144	144
Caffeine	3.75-30	30
Cholesterol	50-400	400
Creatinine	3.75-30	30
EDTA	50-400	400
Ephedrine	0.5-4	0.5
Erythromycin	2.5-20	20
Galactose	125-1000	500
Glycerol	1.15-9.21	9.21
Heparin	7.5-60	60
Ibuprofen	3.74-30	30
L-Dopa	0.375-3.0	0.375
Lecithin	62.5-500	500
Maltose	125-1000	500
KCl	0.932-7.455	7.455
Salicylate	15.6-125	125
Sodium Fluoride	125-1000	500
Tetracycline	0.5-4	4
Tolazamide	12.5-100	100
Tolbutamide	12.5-100	100
Triglyceride	125-1000	500
Urea	62.5-500	500
Uric Acid	5-20	15
Xylose	3-20	5

Mannitol	100-800	800
Xylitol	6.25-50	50
Sorbitol	1.25-10	10
Hemoglobin	0-500	500

No significant interference is observed for cholesterol up to 400 mg/dL, triglyceride up to 500 mg/dL, galactose up to 500 mg/dL, maltose up to 500 mg/dL and xylose up to 5 mg/dL.

f. *Assay cut-off:*

Not applicable.

2. Comparison studies:

a. *Method comparison with predicate device:*

109 Fresh capillary fingerstick samples were collected and analyzed by healthcare professionals using multiple MD100 meters and 3 lots of test strips. 19 additional samples were either glycolyzed to obtain values < 50 mg/dL of glucose or spiked to obtain values > 400 mg/dL of glucose. HCPs also collected samples from the palm and forearm. All results were compared to the YSI. Glucose concentrations of the samples ranged from 21.4 mg/dL to 535 mg/dL, (n=384). Hematocrits ranged from 10%-70%. Sample distribution is below:

YSI range (mg/dL)	Sample number	Distribution (%)
<50	7	5.47
51-80	19	14.84
81-120	24	18.75
121-200	35	27.34
201-300	21	16.41
301-400	15	11.72
>400	7	5.47

Linear regressions for fingerstick studies were calculated for each lot of test strips and the combined comparison of all lots to the YSI 2300 using ISO15197 tables are below:

	Lot 1	Lot 2	Lot 3
N	128	128	128
Slope	1.01	1.03	1.02
Intercept	0.05	-3.08	-0.67
r ²	0.9812	0.9791	0.9824

Distribution for glucose concentration < 75mg/dL compared to YSI

within ±5mg/dL	within ±10mg/dL	within ±15mg/dL
14/54 (25.9%)	42/54 (77.8%)	52/54 (96.3%)

Distribution for glucose concentration ≥ 75mg/dL compared to YSI

within ±5 %	within ±10 %	within ±15 %	within ±20 %
172/330 (52.1%)	266/330 (80.6%)	308/330 (93.3%)	325/330 (98.5%)

Alternative Site Testing (AST):

Linear regressions for AST studies were calculated comparing the MD100 to the YSI 2300 using ISO15197 tables are below:

HCP vs. YSI		
Site	Palm	Forearm
Slope	0.94	0.96
Intercept	7.7	-0.17
r²	0.9736	0.9647

Distribution for glucose concentration < 75mg/dL compared to YSI

	within ±5mg/dL	within ±10mg/dL	within ±15mg/dL
Palm	(50%)	(100%)	(100%)
Forearm	(50%)	(100%)	(100%)

Distribution for glucose concentration ≥ 75mg/dL compared to YSI

	within ±5 %	within ±10 %	within ±15 %	within ±20 %
Palm	(44.7%)	(71.1%)	(97.4%)	(100%)
Forearm	(26.8%)	(47.4%)	(92.1%)	(100%)

Venous blood studies were performed with 143 whole blood samples collected in K₂ EDTA with glucose concentrations ranging from 23.4 mg/dL to 578 mg/dL. Contrived samples were added to cover low and high glucose ranges. Hematocrits ranged from 10-70%. Samples were analyzed on 3 lots of MD100 test systems and the YSI. Sample distribution, linear regression and agreement with the YSI are presented below:

YSI range (mg/dL)	Sample number	Distribution (%)
*<50	6	4.2
51-80	21	14.7
81-120	29	20.3
121-200	41	28.7
201-300	23	16.1
301-400	16	11.2
>400*	7	4.9

HCP vs YSI	
N	143
Slope	0.935
Intercept	2.660
r ²	0.9794

Distribution for glucose concentration <75mg/dL compared to YSI

Venous blood	within ±5mg/dL	within ±10mg/dL	within ±15mg/dL
HCP	16/24 (66.7%)	21/24 (87.5%)	23/24 (95.8%)

Distribution for glucose concentration ≥75mg/dL compared to YSI

Venous blood	within ±5 %	within ±10 %	within ±15 %	within ±20 %
HCP	55/119(46.2%)	83/119 (69.7%)	105/119 (88.2%)	116/119 (97.5%)

b. Matrix comparison:

Matrix comparison studies were performed on 39 natural and 5 altered venous whole blood samples collected in K₂EDTA, lithium heparin, and sodium heparin vacutainer tubes. The measuring range evaluated was 26.4 mg/dL to 585 mg/dL. Samples were analyzed in singlicate on two MD100 meters, one lot of test strips from 10 vials, and the YSI 2300 STAT Plus. Least squares regression and bias was calculated between the MD100 and YSI. Sample distribution, linear regression and accuracy are summarized below.

YSI range (mg/dL)	Sample number	Distribution (%)
<60*	3	6.8
60-80	6	13.6
80-120	9	20.5
120-200	13	29.8
200-300	6	13.6
300-400	4	9.1
400-430	1	2.3
>430	2	4.5

	K ₂ EDTA	Lithium heparin	Sodium heparin
Slope	0.97	0.98	0.98
Intercept	4	2.1	1.4
r ²	0.9909	0.9942	0.9932

Distribution for glucose concentration < 75mg/dL compared to YSI

Venous blood	within ±5mg/dL	within ±10mg/dL	within ±15mg/dL
K ₂ EDTA	66.7% (4/6)	83.3% (5/6)	100% (6/6)
Lithium heparin	50.0% (3/6)	100% (6/6)	100% (6/6)
Sodium heparin	66.6% (4/6)	100% (100)	100% (6/6)

Distribution for glucose concentration ≥75mg/dL compared to YSI

Venous blood	within ±5 %	within ±10 %	within ±15 %	within ±20 %
K ₂ EDTA	50.0% (19/38)	81.6% (31/38)	97.4% (37/38)	100% (38/38)
Lithium heparin	68.4% (26/38)	97.4% (37/38)	100% (38/38)	100% (38/38)
Sodium heparin	60.5% (23/38)	92.1 (35/38)	97.4 (37/38)	100% (38/38)

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 glucose testing was conducted by lay users at three sites using 3 lots of test strips. English speaking lay users performed self-testing for fingersticks, palm and forearm following instructions in the labeling. The samples ranged from 55.2-451 mg/dL with hematocrits of 27%-58%, n=120 fingerstick samples and n=109 samples for each alternative site. Participants were required to

be in a steady state of glucose metabolism prior to performing the alternative site testing. Sample distribution and results are summarized below.

YSI range (mg/dL)	Sample number	Distribution (%)
55-80	17	13.3
80-120	28	21.9
120-200	40	31.3
200-300	20	15.6
300-400	12	9.4
400-500	4	3.1

Regressions for Fingertick and Alternative Sites

Site	Lay User vs YSI		
	Fingertip	Palm	Forearm
Slope	1.00	1.00	0.97
Intercept	-0.83	-1.2	0.4
r²	0.9783	0.9501	0.9742

Fingertick results:

Distribution for glucose concentration < 75mg/dL compared to YSI

	within ±5mg/dL	within ±10mg/dL	within ±15mg/dL
Fingertick	6/11 (55%)	10/11 (91%)	11/11 (100%)

Distribution for glucose concentration ≥ 75mg/dL compared to YSI

	within ±5 %	within ±10 %	within ±15 %	within ±20 %
Fingertick	49/110 (45%)	87/110 (79%)	104/110 (95%)	107/110 (97%)

Alternative Site Testing Results:

Distribution for glucose concentration < 75mg/dL compared to YSI

	within ±5mg/dL	within ±10mg/dL	within ±15mg/dL
Palm	6/11 (54.5%)	11/11 (100%)	11/11 (100%)
Forearm	7/11 (63.6%)	10/11 (90.9%)	11/11 (100%)

Distribution for glucose concentration ≥ 75mg/dL compared to YSI

	within ±5 %	within ±10 %	within ±15 %	within ±20 %
Palm	46/109 (42.25%)	84/109 (77.1%)	101/109 (92.7%)	107/109 (98.2%)
Forearm	43/109 (39.4%)	75/109 (68.8%)	94/109 (86.2%)	107/109(98.2%)

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:

Fasting glucose range for a non-diabetic adult is below 110 mg/dL. Values should be less than 140 mg/dL one to two hours after meals.¹

¹American Diabetes Association: Standards of Medical Care in Diabetes-2011, Diabetes Care, 2011:34 (supplement 1), S11-S61.

N. Instrument Name:

TysonBio MD 100 and TysonBio MD 100 Pro

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 X or No _____

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

Yes _____ or No X

2. Software:

The software used with the TysonBio MD100 meter was previously cleared in k081726.

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, or forearm, or venous whole blood. Samples are applied directly to the test strip.

5. Calibration:

No calibration is performed by the user. The calibration code is included on each test strip and is read when the test strip is inserted into the meter.

6. Quality Control:

There are 3 levels of glucose control solutions available separately. Level 2 is provided with the start up kit. Recommendations for the frequency of quality control testing are provided in the labeling. An acceptable range for each control level is printed on the test strip vial label. The user is cautioned not to use the meter if the control result falls outside these ranges.

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

1. EMC testing was evaluated and certified by Aerospace Industrial Development Corporation and a certificate of compliance was issued to Tyson Bioresearch, Inc on Aug. 20, 2010.
2. Drop tests and vibration tests were conducted and results analyzed pre and post testing with the firm’s electronic check strip. The sponsor provided the test report to confirm that vibration tests were conducted on 20 meters at maximum vibration intensity (60 Hz) for 45 minutes. The drop test was conducted at approximately 24 and 35 inches and 30 meters were dropped in 6 different orientations. Results of the MD100 Blood Glucose Meter showed that the changes with the electronic check strip before and after challenge were reviewed and deemed acceptable.
3. Sample volume testing was performed with venous whole blood spiked with glucose to yield concentrations of 43.7, 71.4, 146, 254, 374, and 468 mg/dL as determined by the YSI 2300. 10 measurements were obtained from 10 meters and 3 test strip lots using 0.4, 0.5, 0.6 and 0.7 micL of sample for each glucose concentration. The mean was calculated for each glucose concentration. The data supports the sponsor’s recommended sample volume of 0.5 mL.
4. Altitude studies were performed using 5 venous whole blood and adjusting the glucose concentration by spiking or glycosylation. Glucose concentrations ranged from 44-360 mg/dL. Samples were tested 10 times on 5 glucose meters and the YSI at 164 ft, 7545 ft, and 9875 ft. The percent bias was calculated against the YSI and the results were found to support the sponsor claims that the MD100/MD100 Pro meter can be used at altitudes up to 7545 ft.

5. **Operating Stability:** The MD100 glucose meter and test strips were stored together at various combined temperature and humidity conditions to simulate real time operating conditions. Temperature conditions ranged from 10°C - 40°C (50°F-104°F) and 10%-90% relative humidity (RH). Three whole blood samples with glucose concentrations ranging from 70-300 mg/dL were tested with the stored meters and strips. Results were compared to the YSI and met the pre-determined acceptance criteria of ± 10 mg/dL for samples < 75 mg/dL and less than 10% bias for samples ≥ 75 mg/dL. The data supports the claimed operating temperature and humidity ranges of 10°C - 40°C (50°F-104°F) and 10%-90%, respectively.
6. A study was conducted to evaluate the potential interference from hematocrit. Seven different hematocrit levels ranging from 10-70% (10%, 20%, 30%, 42%, 50%, 60%, 70%) were evaluated and at 4 glucose concentrations (~ 50 mg/dL, ~ 100 mg/dL, ~ 288 mg/dL and ~500 mg/dL). Each sample was tested on 5 meters in singlicate. The differences of the glucose meter results at each hematocrit/glucose combination were calculated against YSI-2300 Glucose Analyzer results at 42% hematocrit.
7. **Usability Study:** For the user performance study summarized in section M.3.c above, the participants were asked to complete a questionnaire to evaluate the ease of use of the device and the clarity of the English language labeling. Overall the users indicated that they could successfully perform the test and that the user manual was written clearly.
8. A separate usability study was performed for downloading glucose meter results to a personal computer. The study participants were males and females of various ages and educational backgrounds. Users found the software easy to use.
9. **Readability Assessment:** The sponsor performed a readability assessment of the labeling for the MD100 and MD100 Pro Blood Glucose Monitoring Systems. The labeling is written below a 7th grade level according to the Flesch Kincaid assessment tool.
10. **Customer Service number:** 1-800-948-3894 available 24 hrs, 7 days a week. An address and website are also provided.
11. **Disinfection:** The device is intended for single (MD100) and multiple (MD100 Pro) patient use. Cavicide Surface Disinfectant with EPA registration # 46781-6 was validated demonstrating complete inactivation of live hepatitis B virus for use with the materials comprising the meter and lancing device. The sponsor demonstrated that there was no change in performance or in the external materials of the meter after 36,500 cleaning and disinfection cycles designed to simulate cleaning and disinfection 20 times a day, over 5 years of device use. The sponsor also demonstrated that there was no change in performance or in the external materials of the lancing device for single-patient use after 7,300 cleaning and disinfection cycles designed to simulate cleaning and disinfection 4 times a day, over 5 years of device use. The lancing device is only for use with the single-patient use system. Labeling has been reviewed for adequate instructions in 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.