

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

A. 510(k) Number:

k072905

B. Purpose for Submission:

Modifications to the 3test meter (Addition of more memory and change in coding from a code key to manual entry of the calibration code).

C. Measurand:

Whole blood glucose

D. Type of Test:

Quantitative Amperometric Assay (Glucose Oxidase)

E. Applicant:

NEUERO Engineering Inc.

F. Proprietary and Established Names:

3test Supreme Glucose Monitoring System

G. Regulatory Information:

1. Regulation section:
21 CFR § 862.1345, Glucose Test System
2. Classification:
Class II
3. Product code:
NBW, CGA
4. Panel:
Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):
See Indications for use below.
2. Indication(s) for use:
The 3test® Glucose Supreme Monitoring System is intended for the quantitative measurement of glucose in fresh capillary whole blood from the finger. Testing is done outside the body (in vitro diagnostic use). It is indicated for use at home (over the counter [OTC]) by person with diabetes, or in clinical setting by health care professionals, as an aid to monitor the effectiveness of diabetes control.
3. Special conditions for use statement(s):
 - The 3test Supreme system provides whole blood equivalent results
 - Not for neonatal use
 - Not for screening or diagnosis of diabetes mellitus
 - Not for patients who are dehydrated, in shock, critically ill, or in a hyperosmolar state
4. Special instrument requirements:
NEUERO Engineering Inc. 3test Supreme Glucose Monitoring System

I. Device Description:

The 3test Supreme Glucose Monitoring System includes Meter, Blood Glucose Test Strips (that contain 3 testing areas in each strip), a tool to break off these test areas when finished, a Function Key (for testing the meter electronics), a Unit Key (which is required if the units are to be changed), High Control Solution (a Low level will also be available for purchase separately), Lancing Device, and Lancets. The meter quantitatively measures glucose in fresh capillary whole blood. The meter and test strips are verified by Control Solutions. The Function Key verifies the status of the meter.

J. Substantial Equivalence Information:

1. Predicate device name(s):
NEURO Engineering Inc. 3test Glucose Monitoring System
2. Predicate 510(k) number(s):
k050224
3. Comparison with predicate:

Similarities		
Item	Subject Device	Predicate Device
Detection method	Amperometry	Amperometry
Enzyme	Glucose Oxidase (Aspergillus niger)	Glucose Oxidase (Aspergillus niger)
Test range	20 – 600 mg/dL	20 – 600 mg/dL
Test Time	5 seconds	5 seconds
Sample Volume	2 uL	2 uL
Battery life	Running 1,000 test	Running 1,000 test

Differences		
Item	Subject Device	Predicate Device
Power	1 3V Lithium Coin Cell	2 3V Lithium Coin Cells
Memory capability	200 tests	100 tests
Coding	Manual Code Entry	Code strip
Available Controls	Low and High	Low, Medium, and High

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

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

L. Test Principle:

The glucose oxidase and mediator in the strip react with the glucose in the sample to produce an electrical current which is proportional to the amount of glucose in the sample. The meter measures the current and converts it to the corresponding glucose concentration.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. *Precision/Reproducibility:*

Within-day precision was performed at 6 sites with each spiked whole blood sample tested by 10 different meters with 1 strip lot 20 times. Testing results are summarized in the table below:

	Site 1	Site 2	Site 3	Site 4	Site 5	Site 6
Level 1						
N	20	20	20	20	20	20
Mean (mg/dL)	47.7	42.4	50.3	46.5	49.9	42.3
SD (mg/dL)	3.2	2.3	3.0	2.1	2.9	2.4
%CV	6.7	5.5	5.9	4.6	5.7	5.6
Level 2						
N	20	20	20	20	20	20
Mean (mg/dL)	80.7	80.4	99.5	75.5	85.4	103.4
SD (mg/dL)	3.9	3.2	4.6	2.6	4.1	4.0
%CV	4.4	4.0	4.6	3.5	4.8	3.9
Level 3						
N	20	20	20	20	20	20
Mean (mg/dL)	130	148	143	139	129	146
SD (mg/dL)	5.8	5.6	5.0	7.5	6.1	5.3
%CV	4.4	3.8	3.5	5.4	4.8	3.6
Level 4						
N	20	20	20	20	20	20
Mean (mg/dL)	195	229	212	223	183	228
SD (mg/dL)	7.4	7.0	9.0	7.8	6.9	8.2
%CV	3.8	3.1	4.3	3.5	3.8	3.6
Level 5						
N	20	20	20	20	20	20
Mean (mg/dL)	288	351	325	340	334	309
SD (mg/dL)	9.1	9.6	10.4	11.7	10.0	11.0
%CV	3.2	2.7	3.2	3.5	3.0	3.6
Level 6						
N	20	20	20	20	20	20
Mean (mg/dL)	419	446	437	529	474	505
SD (mg/dL)	10.7	11.8	11.0	13.7	12.4	14.1
%CV	2.6	2.6	2.5	2.6	2.6	2.8

A single level of glucose in a whole blood sample was used to establish precision of the assay between meters and strip lots at 3 sites. Each sample was analyzed on 4

meters with each meter tested 10 times. Testing results are summarized in the table below:

Site 1							
	Inter-meter				Inter-reagent strip lot		
Meter/Strip	Meter 1 vs. Strip Lot A	Meter 2 vs. Strip Lot A	Meter 3 vs. Strip Lot A	Meter 4 vs. Strip Lot A	Strip Lot A vs. Meter 1	Strip Lot B vs. Meter 1	Strip Lot vs. Meter 1
Mean (mg/dL)	142	143	141	138	138	138	138
SD (mg/dL)	6.2	5.1	6.0	6.1	5.2	5.2	5.5
%CV	4.4	3.6	4.2	4.4	3.8	3.8	4.0

Site 2							
	Inter-meter				Inter-reagent strip lot		
Meter/Strip	Meter 1 vs. Strip Lot A	Meter 2 vs. Strip Lot A	Meter 3 vs. Strip Lot A	Meter 4 vs. Strip Lot A	Strip Lot A vs. Meter 1	Strip Lot B vs. Meter 1	Strip Lot vs. Meter 1
Mean (mg/dL)	141	138	140	142	139	136	136
SD (mg/dL)	5.2	5.3	4.8	5.1	5.7	5.7	5.1
%CV	3.7	3.9	3.4	3.6	4.1	4.2	3.8

Site 3							
	Inter-meter				Inter-reagent strip lot		
Meter/Strip	Meter 1 vs. Strip Lot A	Meter 2 vs. Strip Lot A	Meter 3 vs. Strip Lot A	Meter 4 vs. Strip Lot A	Strip Lot A vs. Meter 1	Strip Lot B vs. Meter 1	Strip Lot vs. Meter 1
Mean (mg/dL)	141	134	137	138	138	138	140
SD (mg/dL)	4.9	5.1	4.1	5.0	6.2	4.5	5.0
%CV	3.5	3.8	3.0	3.6	4.5	3.3	3.5

b. Linearity/assay reportable range:

The linearity of the device was demonstrated by comparing 20 prepared whole blood samples on the 3test Supreme and a glucose reference method; each level was tested on 8 different meters with one lot of test strips. The 20 samples covered the claimed clinical range of the meter (20 - 600 mg/dL). Analysis of the results showed a linear relationship between the meter and the reference method: $y = 1.0169x - 1.7713$, $R^2 = 0.9976$.

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

The control materials supplied for this device were cleared under k050224.

d. Detection limit:

20 mg/dL: see linearity studies above. For values below 20 mg/dL the meter reads ‘LO’ and for values above 600 mg/dL the meter reads ‘HI’.

e. *Analytical specificity:*

The sponsor tested the following exogenous and endogenous substances, and anticoagulants for interference using three levels of glucose (80, 160, and 260 mg/dL). The sponsor's acceptance criteria is a mean glucose difference of $\pm 15\%$ between the test sample and control sample (with no interfering substance). For exogenous and endogenous substances each interfering substance had 4 different levels of interferant spiked into the three levels of spiked glucose samples. For anticoagulants, two interferant concentrations were used. Results are summarized below:

Interferant	Therapeutic Conc. (mg/dL)	Concentrations tested (mg/dL)	No Interference
<i>Exogenous</i>			
Acetaminophen	1-2	0, 2, 6, 15, 20	None up to 20
Ascorbic Acid	0.8-1.2	0, 1.2, 1.5, 2, 3	None up to 1.5
Dopamine	-	0, 4.2, 15, 30, 40	None up to 40
Ibuprofen	0.5-4.2	0, 4.2, 15, 30, 40	None up to 40
Methyl Dopa	0.1-0.5	0, 0.5, 1, 1.5, 2.5	None up to 2.5
Salicylate	15-30	0, 15, 30, 40, 50	None up to 50
Tetracycline	0.4	0, 0.4, 1.4, 3.1, 4	None up to 4
Tolbutamide	5.3-10	0, 10, 35, 70, 100	None up to 100
Tolazamide	-	0, 20, 40, 75, 100	None up to 100
<i>Endogenous</i>			
Bilirubin	1.2	0, 1.2, 7, 12, 20	None up to 20
Cholesterol	300	0, 300, 370, 430, 500	None up to 500
Creatinine	1.5	0, 1.5, 14, 24, 30	None up to 30
Triglycerides	190	0, 190, 1300, 2000, 3000	None up to 3000
Uric Acid	7	0, 9, 12, 16, 20	None up to 16
L-ascorbic acid	2	0, 2.3, 2.7, 3	None up to 3
<i>Anticoagulants</i>			
	<i>Typical Amount Used</i>		
Heparin	4000 units/dL	0, 4000, 8000 units/dL	None up to 8000
EDTA (K ⁺)	150	0, 150, 300	None up to 300
Citrate (Na ⁺)	500	0, 500, 1000	None up to 1000
Oxalate	400	0, 400, 800	None up to 800
Fluoride	500	0, 500, 1000	No interference at 0

The sponsor evaluated the effect of hematocrit levels 30 – 55% on whole blood samples spiked to six hematocrit levels for three levels of glucose (75 mg/dL, 155 mg/dL, and 254 mg/dL). The values generated were compared with the glucose values from a reference method. Based on the sponsor's acceptability criterion of $<\pm 15\%$ deviation for glucose concentrations versus YSI. The data supports the sponsor's claimed range of hematocrit levels between 30-55%.

An altitude study was performed with 3 levels of spiked whole blood samples at 74 mg/dL, 156 mg/dL, and 268 mg/dL at 556, 2118, 3951, 6620, and 9766 feet. All the samples met the sponsor's acceptability criterion of a bias of $\pm 15\%$ versus the reference method. The data submitted supports use of the device up to the claimed altitude of 9,700 feet.

f. *Assay cut-off:*
Not applicable

2. Comparison studies:

a. *Method comparison with predicate device:*

A consumer study was performed with 150 lay-users and a technician to see if glucose readings from the fingertip were comparable to a laboratory glucose reference method. Each participant performed their own fingerstick and tested their blood using the instructions in the User's Guide. A technician then took a fingerstick reading. Samples ranged from 70 – 343 mg/dL. Based on ISO 15197 "In vitro diagnostic test systems — Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus" the accuracy of the device is presented below:

Patient

<75 mg/dL

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
4/5 (80%)	5/5 (100%)	5/5 (100%)

≥ 75 mg/dL

Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$	Within $\pm 20\%$
78/145 (54%)	137/145 (94%)	142/145 (98%)	144/145 (99%)

Technician

<75 mg/dL

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
3/5 (60%)	5/5 (100%)	5/5 (100%)

≥ 75 mg/dL

Within $\pm 5\%$	Within $\pm 10\%$	Within $\pm 15\%$	Within $\pm 20\%$
84/145 (58%)	140/145 (97%)	143/145 (99%)	144/145 (99%)

Linear regression analysis of the data yielded the results below:

	Patient vs. YSI	Technician vs. YSI
n	150	150
Regression	$y = 0.950x + 4.836$	$y = 0.969x + 2.736$
r value	0.976	0.98

A point of care study was performed using 6 sights testing 50 patients at each site. Samples ranged from 57 – 371 mg/dL. Based on ISO 15197 “In vitro diagnostic test systems — Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus” the accuracy of the device is presented below:

<75 mg/dL

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
12/21 (57%)	20/21 (95%)	21/21 (100%)

≥75 mg/dL

Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
185/279 (66%)	266/279 (95%)	279/279 (100%)	279/279 (100%)

Linear regression analysis of the data yielded the results below:

n	300
Regression	$y = 1.029x - 0.813$
r value	0.989

b. *Matrix comparison:*

This system is cleared for use with capillary whole blood samples from the finger only.

3. Clinical studies:

a. *Clinical Sensitivity:*

See method comparison section above.

b. *Clinical specificity:*

Not applicable.

c. *Other clinical supportive data (when a. and b. are not applicable):*

The sponsor provided a readability study that indicated that the user manual, strip labeling, and control solution labeling are at or below an 8th grade reading level.

4. Clinical cut-off:

Not applicable.

5. Expected values/Reference range:

The normal fasting adult glucose range for a non-diabetics listed by the sponsor is 70 – 110 mg/dL¹ and 2 hours after meals <140 mg/dL².

1. Stedmans Medical Dictionary, 27th Edition, 1999, p. 755

2. American Diabetes Association Clinical Practice Recommendations 2004, Diabetes Care, Vol. 27, Supplement 1, P. S9

N. Instrument Name:

3test Supreme Glucose Monitoring System

O. System Descriptions:

1. Modes of Operation:

Each test strip contains 3 sections which can be used for 3 different tests. Once a section is used it is broken off with the provided tool. Once the three sections have been used, the strip must be replaced with a new strip for further 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 finger only. Since the whole blood sample is applied directly to the test strip there are no special handling or storage issues.

5. Calibration:

A calibration code is provided with each batch of test strips and is entered into the meter to calibrate the meter for that batch. No further calibrations are required of the user.

6. Quality Control:

The sponsor is providing one of two levels of glucose control solution with this device. The high level will come with the system and the low level will be available for purchase. When the C button is pressed after a strip is inserted into the meter, the control mode is activated. This prevents control results from being stored in the internal memory. An acceptable range for each control level is printed on the test strip vial label. The user is referred to the troubleshooting section of the User's Manual if control results fall outside these ranges.

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 a substantial equivalence decision.