Nemaura Medical

Better Diagnostics for Life

NASDAQ: NMRD

Clinical presentation of sugarBEAT®

A Prospective Single Centre Evaluation of the Accuracy and safety of the sugarBEAT® Non-invasive Continuous Glucose Monitor (CGM) System

18th December 2018

Author
Dr T Rahman, MBBS, PhD
Clinical research Manager,
Nemaura Medical Inc.,

Study Objective

A EU based study to determine the safety and accuracy of the sugarBEAT® CGM for FDA De Novo submission

NEMAURA MEDICAL

Study Design

Prospective single arm, single centre study

Accuracy and safety assessed over 7 consecutive wear days, consisting of 3 non-consecutive in-clinic visits, and 4 home wear days.

Venous blood samples used as reference for in-clinic portion of study using Architect C8000

Abbott Freestyle Optimum Neo BGM used as reference for Home Study Portion

Study Methods

NEMAURA MEDICAL

>25 subjects enrolled for screening at each of 3 stages

25 subjects selected after screening in each stage, with approximately equal split between Type 1 and Type 2

No subjects lost due to drop out

All 25 subjects completed 2 days home study and 3 days in-clinic study

12 subjects wore devices bilaterally during in-clinic phase

13 of each 25 subjects had single device during in-clinic phase

All subjects wore single device during home stage

All subjects blinded to real-time glucose display

All devices used single BGM calibrations per day in real-time

Accuracy vs Glucose Range
In-clinic 1-point calibration

The proportion of agreement is **76.098%** (with 95% confidence interval from 0.75382 to 0.76814). Table 1. shows the proportion of agreement broken down for different glucose and accuracy ranges and MARD / MAD. MARD +/-20% or +/-20mg/dL(76% of paired data) = 8.02%. The overall MARD (100% of data) is **13.39%**.

Table 1.2 sugarBEAT® system agreement proportion with reference glucose measurement in different glucose ranges. MARD or MAD values are given for each segment. (refined two-point algorithm, all stages)

Accuracy vs Glucose Range
In-clinic portion of study 1-point calibration

Glucose range (mg/dl)	Number of paired points	Within ±10% or ±10 mg/dl		Within ±15% or ±15 mg/dl		Within ±20% or ±20 mg/dl		Within ±30% or ±30 mg/dl		Within ±40% or ±40 mg/dl		Outside±40% or ±40 mg/dl	
		%	(MARD) MAD	%	(MARD) MAD	%	(MARD) MAD	%	(MARD) MAD	%	(MARD) MAD	%	(MARD) MAD
Overall	**13639**	49.06	4.51	64.56	6.34	76.38	8.02	89.24	10.30	95.95	11.92	4.05	13.39
40-60	82	18.29	4.84	24.39	6.61	32.93	9.29	59.76	16.91	84.15	22.04	15.85	26.92
61-80	425	31.06	5.21	48.71	7.89	62.59	10.04	80.71	13.23	90.82	15.61	9.18	19.28
81-180	7236	50.65	4.47	66.92	6.36	78.66	7.98	89.98	9.95	96.08	11.46	3.92	13.05
181-300	4774	50.46	4.57	64.96	6.28	77.29	8.05	90.87	10.50	97.00	12.01	3.00	13.15
301-400	1122	41.89	4.49	56.60	6.54	66.13	8.11	82.98	11.48	93.40	14.05	6.60	16.27

MAD: Mean Absolute Deviation - MARD: Mean Absolute Relative Deviation

Note 1: Number of paired points is different/higher compared 1-point calibration in light of better accuracy leading to more data points falling within the 40 40-400mg/ dL range

The performance evaluation included the proportion of the CGM system values that are within ±10 to >40% of relative difference of reference value at glucose levels >80 mg/ dL and ±absolute difference at glucose level ≤80 mg /dl, ref: http journals.sagepub.com com/doidoi/pdf /10.1177/1932296814559746

Accuracy vs Glucose Range
In-clinic 2-point calibration

The proportion of agreement is **78.33%** (with 95% confidence interval from 0.77646 to 0.79032). Table 1. shows the proportion of agreement broken down for different glucose and accuracy ranges and MARD / MAD. MARD +/-20% or +/-20mg/dL(78.7% of paired data) = 7.96%. The overall MARD (100% of data) is **12.44%**.

Table 1.2 sugarBEAT® system agreement proportion with reference glucose measurement in different glucose ranges. MARD or MAD values are given for each segment. (refined two-point algorithm, all stages)

Accuracy vs Glucose Range
In-clinic portion of study 2-point calibration

Glucose range (mg/dl)	Number of paired points	Within ±10% or ±10 mg/dl		Within ±15% or ±15 mg/dl		Within ±20% or ±20 mg/dl		Within ±30% or ±30 mg/dl		Within ±40% or ±40 mg/dl		Outside±40% or ±40 mg/dl	
		%	(MARD) MAD	%	(MARD) MAD	%	(MARD) MAD	%	(MARD) MAD	%	(MARD) MAD	%	(MARD) MAD
Overall	**13568**	50.97	4.42	66.81	6.32	78.77	7.96	91.77	10.20	96.76	11.40	3.24	12.44
40-60	79	20.25	3.86	26.58	5.91	40.51	9.92	64.56	15.23	78.48	18.60	21.52	27.84
61-80	421	43.23	5.12	55.82	6.76	69.12	8.79	80.76	11.12	88.36	13.11	11.64	17.51
81-180	7233	50.46	4.39	66.57	6.33	78.99	8.01	91.73	10.15	96.78	11.41	3.22	12.63
181-300	4767	53.70	4.48	69.94	6.31	81.43	7.90	94.14	10.10	98.05	11.08	1.95	11.80
301-400	1068	47.47	4.36	61.80	6.27	72.00	7.88	87.83	10.91	95.51	12.80	4.49	14.22

MAD: Mean Absolute Deviation - MARD: Mean Absolute Relative Deviation

Note 1: Number of paired points is different/higher compared 1-point calibration in light of better accuracy leading to more data points falling within the 40 40-400mg/ dL range

The performance evaluation included the proportion of the CGM system values that are within ±10 to >40% of relative difference of reference value at glucose levels >80 mg/ dL and ±absolute difference at glucose level ≤80 mg /dl, ref: http journals.sagepub.com com/doidoi/pdf /10.1177/1932296814559746

Safety Evaluation

Past Studies

100 Patient days wear time – No major adverse events or skin irritation reported

525 Patient days wear time No major adverse events or skin irritation reported

Current Studies

250 Patient days to date with no device related adverse events or skin irritation reported.

Conclusion

The analysis indicates the in clinic portion of the study shows accuracy levels, as measured using overall nominal MARD, as comparable to previously reported data and within the targets for the intended indications.

NEMAURA MEDICAL