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Interim Clinical Presentation sugarBEAT®

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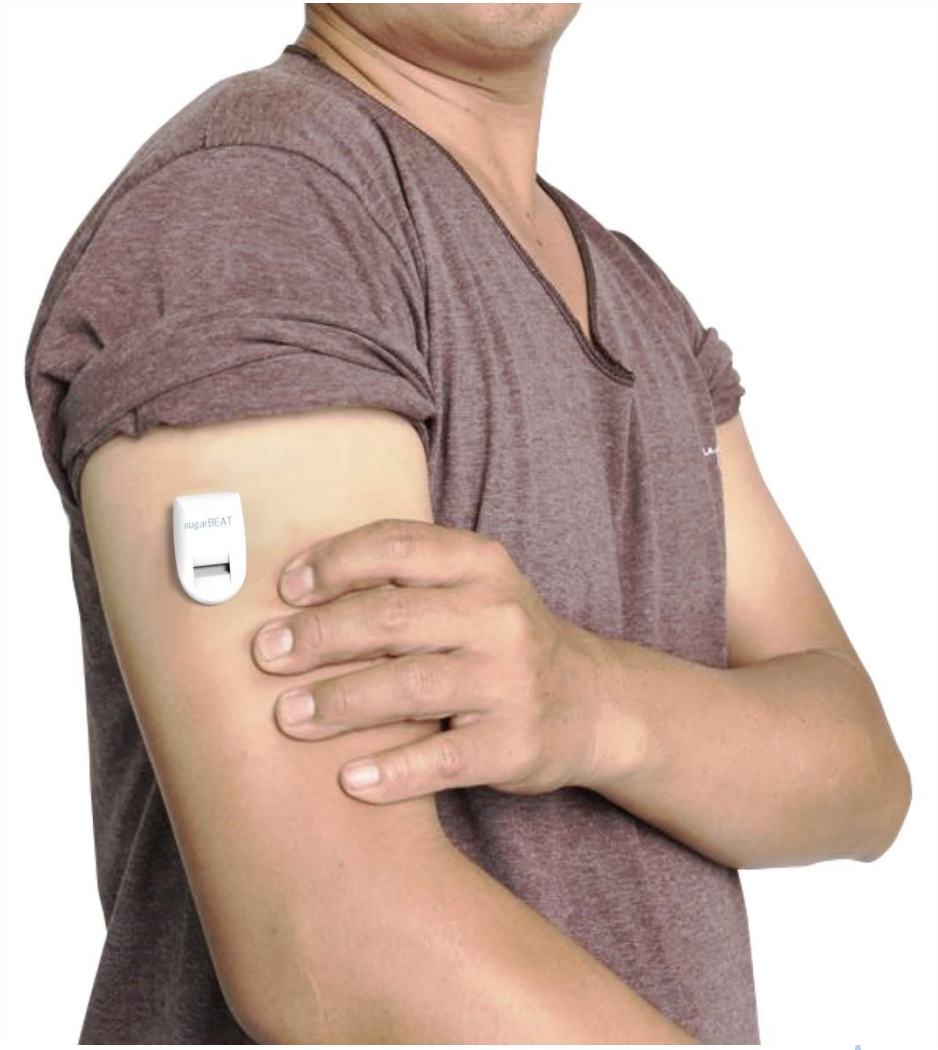
A Prospective Single Centre Evaluation of the Accuracy and safety of the sugarBEAT® Non-invasive Continuous Glucose Monitor (CGM) System: An interim Evaluation

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

sugarBEAT® Study Objective

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



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

- >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 subjects had single device during in-clinic phase
- 25 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

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Baseline Characteristics

Variable	
Age - Range	27-67 years
Age - Mean	52.8 years
Age - Median	54.5 years
Type 1 (n)	12
Type 2 (n)	13

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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	**4630**	36.89	(4.59)	50.95	(6.81)	62.61	(8.77)	79.91	(12.19)	91.47	(14.99)	8.53	(17.31)
40-60	5	0.00	NaN	0.00	NaN	0.00	NaN	40.00	27.22	80.00	31.08	20.00	33.47
61-80	98	65.31	3.66	70.41	4.19	75.51	5.00	81.63	6.53	89.80	8.98	10.20	13.58
81-180	2992	34.16	4.65	46.82	6.78	58.79	8.97	78.01	12.82	90.91	15.89	9.09	19.08
181-300	1355	42.73	4.52	60.37	6.82	71.81	8.50	85.02	10.99	93.36	13.11	6.64	15.49
301-400	180	23.89	4.29	39.44	7.39	51.67	9.78	73.33	14.22	87.78	17.58	12.22	21.21

MAD: Mean Absolute Deviation
MARD: Mean Absolute Relative Deviation

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/doi/pdf/10.1177/1932296814559746

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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	**4741**	47.42	(4.22)	62.41	(6.21)	74.10	(7.97)	88.57	(10.65)	96.03	(12.20)	3.97	(13.56)
40-60	21	9.52	8.16	28.57	10.82	38.10	12.50	76.19	18.14	90.48	20.76	9.52	22.87
61-80	112	60.71	4.38	73.21	5.69	83.04	7.05	91.96	8.64	96.43	9.81	3.57	11.10
81-180	3035	46.82	4.17	60.76	6.07	72.32	7.89	87.78	10.78	95.72	12.73	4.28	14.28
181-300	1407	48.83	4.36	65.74	6.46	77.61	8.10	90.05	10.34	96.52	11.95	3.48	13.29
301-400	166	42.17	3.76	61.45	6.44	75.30	8.47	89.76	11.13	98.19	13.20	1.81	13.71

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 40-400mg/dL range

Note 2: Total maximum number of paired points analysed = 4741, and not the sum of 1-point and 2-point calibration paired points, (as reported in error in Press release dated 12th September 2018).

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/doi/pdf/10.1177/1932296814559746

Interim Comparative MARD for **In-Clinic** phase as Primary Accuracy Metric

Dexcom G5*	no. of calibrations not known	Overall MARD (20%/20mg/dL)	9.00
		% Data	94.00
sugarBEAT	1-point calibraiton	Overall MARD (20%/20mg/dL)	8.77
		% Data	62.61
	2-point calibraiton	Overall MARD (20%/20mg/dL)	7.97
		% Data	74.00
	1-point calibraiton	Overall MARD (30%/30mg/dL)	12.19
		% Data	79.91
	2-point calibraiton	Overall MARD (30%/30mg/dL)	10.65
		% Data	88.57

* https://dexcom.gcs-web.com/static-files/0a1461dd-e75a-4759-9ddf-50b834756bdd

Interim Comparative MARD for **home-study** phase as Primary Accuracy Metric

Device	Number of subjects	Paired Data Points with BGM	Nominal MARD	Reference BGM
Senseonics Eversense*	23	829	14.80%	Nova Biomedical StatStrip Xpress
Dexcom G5*	23	829	16.30%	Nova Biomedical StatStrip Xpress
Abbott Libre Pro*	23	829	18.00%	Nova Biomedical StatStrip Xpress
sugarBEAT	36	126	16.30%	Abbott Freestyle Optimum neo

Note 1: Senseonics, Dexcom G5 and sugarBEAT = 2 point finger prick calibration

*http://www.diabetesincontrol.com/accuracy-comparison-of-the-dexcom-g5-abbott-freestyle-libre-pro-and-senseonics-eversense/

sugarBEAT® Safety Evaluation

Previous 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 study:

>250 Patient days to date with no major adverse events or skin irritation reported.

sugarBEAT® Conclusion

The interim analysis indicates the 3 day 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.