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Retrospective data analysis for the evaluation of factory (zero finger-stick) calibration potential for 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: A retrospective application of algorithms to evaluate factory calibration potential

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sugarBEAT® Study Objective

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

Study Design

- Prospective single arm, single centre study
- Retrospective evaluation of 3 non-consecutive in-clinic visits by 75 patients.
- Venous blood samples used as reference for in-clinic portion of study using Architect c8000

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
- 12 subjects wore devices bilaterally during in-clinic phase
- 13 subjects had single device during in-clinic phase

All subjects blinded to real-time glucose display

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Baseline Characteristics

Variable	
Age - Range	19 to 70 years
Age - Mean	54.1 years
Age - Median	56 years
Type 1 (n)	39
Type 2 (n)	36

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Accuracy vs Glucose Range
In-clinic portion of study using retrospectively applied factory calibration constant

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	9863	22.69	[5.02]	33.07	[7.31]	42.19	[9.44]	58.66	[13.61]	73.01	[17.83]	26.99	[28.21]
40-60	0	Na	Na	Na	Na	Na	Na	Na	Na	Na	Na	Na	Na
61-80	137	24.09	5.18	28.47	6.43	35.04	8.37	48.18	13.10	63.50	18.55	36.50	36.14
81-180	5311	22.75	4.93	33.08	7.17	42.70	9.37	59.31	13.40	75.18	18.13	24.82	27.26
181-300	3785	22.69	5.21	33.58	7.54	42.30	9.59	58.34	13.79	70.38	17.36	29.62	29.18
301-400	630	21.90	4.54	30.95	6.88	38.73	9.03	57.46	14.05	72.54	18.30	27.46	29.22

MAD: Mean Absolute Deviation
MARD: Mean Absolute Relative Deviation

Note: 9,863 paired data points represents 66% of the total available paired data points. 34% of the data points were not included as they did not show potential for factory calibration.

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 – based on 1 and 2 finger prick calibrations

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® Conclusion

The retrospective analysis of data by applying factory calibration constants, indicates there is potential for either factory calibration or potentially reduced frequency of finger stick calibrations. The proportion of patients to whom this would apply, and their skin characteristics and/or patient type is yet to be established.