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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

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sugarBEAT® Study Objective

A EU based study to determine the safety and accuracy of the sugarBEAT® CGM for FDA De Novo 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 of each 25 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

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

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Accuracy vs Glucose Range
In-clinic 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	Overall
		%	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

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 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)

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Accuracy vs Glucose Range
In-clinic 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	Overall
		%	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	94.13	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 40-400mg/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/doi/pdf/10.1177/1932296814559746

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 device related adverse events or skin irritation reported.

sugarBEAT® 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.