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

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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
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)*
Accuracy vs Glucose Range

**In-clinic 1-point calibration**

<table>
<thead>
<tr>
<th>Glucose range (mg/dl)</th>
<th>Number of paired points</th>
<th>Within ±10% or ±10 mg/dl</th>
<th>Within ±15% or ±15 mg/dl</th>
<th>Within ±20% or ±20 mg/dl</th>
<th>Within ±30% or ±30 mg/dl</th>
<th>Within ±40% or ±40 mg/dl</th>
<th>Outside ±40% or ±40 mg/dl</th>
<th>Overall</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall</td>
<td>13639</td>
<td>49.06%</td>
<td>64.56%</td>
<td>76.38%</td>
<td>89.24%</td>
<td>95.95%</td>
<td>11.92%</td>
<td>4.05%</td>
</tr>
<tr>
<td>40-60</td>
<td>82</td>
<td>18.29%</td>
<td>24.39%</td>
<td>6.61%</td>
<td>32.93%</td>
<td>59.76%</td>
<td>16.91%</td>
<td>84.15%</td>
</tr>
<tr>
<td>61-80</td>
<td>425</td>
<td>31.06%</td>
<td>48.71%</td>
<td>7.89%</td>
<td>62.59%</td>
<td>80.71%</td>
<td>13.23%</td>
<td>90.82%</td>
</tr>
<tr>
<td>81-180</td>
<td>7236</td>
<td>50.65%</td>
<td>66.92%</td>
<td>6.36%</td>
<td>78.66%</td>
<td>89.98%</td>
<td>9.95%</td>
<td>96.08%</td>
</tr>
<tr>
<td>181-300</td>
<td>4774</td>
<td>50.46%</td>
<td>64.96%</td>
<td>6.28%</td>
<td>77.29%</td>
<td>90.87%</td>
<td>10.50%</td>
<td>97.00%</td>
</tr>
<tr>
<td>301-400</td>
<td>1122</td>
<td>41.89%</td>
<td>56.60%</td>
<td>6.54%</td>
<td>66.13%</td>
<td>82.98%</td>
<td>11.48%</td>
<td>93.40%</td>
</tr>
</tbody>
</table>

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
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 2-point Calibration**

<table>
<thead>
<tr>
<th>Glucose range (mg/dl)</th>
<th>Number of paired points</th>
<th>Within ±10% or ±10 mg/dl %</th>
<th>MARD (MAD)</th>
<th>Within ±15% or ±15 mg/dl %</th>
<th>MARD (MAD)</th>
<th>Within ±20% or ±20 mg/dl %</th>
<th>MARD (MAD)</th>
<th>Within ±30% or ±30 mg/dl %</th>
<th>MARD (MAD)</th>
<th>Within ±40% or ±40 mg/dl %</th>
<th>MARD (MAD)</th>
<th>Outside ±40% or ±40 mg/dl %</th>
<th>MARD (MAD)</th>
<th>Overall %</th>
<th>MARD (MAD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall</td>
<td>13568</td>
<td>50.97</td>
<td>4.42</td>
<td>66.81</td>
<td>6.32</td>
<td>78.77</td>
<td>7.96</td>
<td>91.77</td>
<td>10.20</td>
<td>96.76</td>
<td>11.40</td>
<td>3.24</td>
<td>12.44</td>
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<td></td>
</tr>
<tr>
<td>40-60</td>
<td>79</td>
<td>20.25</td>
<td>3.86</td>
<td>26.58</td>
<td>5.91</td>
<td>40.51</td>
<td>9.92</td>
<td>64.56</td>
<td>15.23</td>
<td>78.48</td>
<td>18.60</td>
<td>21.52</td>
<td>27.84</td>
<td></td>
<td></td>
</tr>
<tr>
<td>61-80</td>
<td>421</td>
<td>43.23</td>
<td>5.12</td>
<td>55.82</td>
<td>6.76</td>
<td>69.12</td>
<td>8.79</td>
<td>80.76</td>
<td>11.12</td>
<td>88.36</td>
<td>13.11</td>
<td>11.64</td>
<td>17.51</td>
<td></td>
<td></td>
</tr>
<tr>
<td>81-180</td>
<td>7233</td>
<td>50.46</td>
<td>4.39</td>
<td>66.57</td>
<td>6.33</td>
<td>78.99</td>
<td>8.01</td>
<td>91.73</td>
<td>10.15</td>
<td>96.78</td>
<td>11.41</td>
<td>3.22</td>
<td>12.63</td>
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<td></td>
</tr>
<tr>
<td>181-300</td>
<td>4767</td>
<td>53.70</td>
<td>4.48</td>
<td>69.94</td>
<td>6.31</td>
<td>81.43</td>
<td>7.90</td>
<td>94.13</td>
<td>10.10</td>
<td>98.05</td>
<td>11.08</td>
<td>1.95</td>
<td>11.80</td>
<td></td>
<td></td>
</tr>
<tr>
<td>301-400</td>
<td>1068</td>
<td>47.47</td>
<td>4.36</td>
<td>61.80</td>
<td>6.27</td>
<td>72.00</td>
<td>7.88</td>
<td>87.83</td>
<td>10.91</td>
<td>95.51</td>
<td>12.80</td>
<td>4.49</td>
<td>14.22</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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
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.
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.