

**Accuracy assessment of the WaveForm Cascade CGM system versus FreeStyle Libre over 14 days**  
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**Background and aims:** WaveForm is finalizing the development of the Cascade CGM system. The Cascade CGM device features trocar-free insertion and will be launched with 14 day transdermal sensor that is based on a variant of an amperometric GOx-based technology. Completing the algorithm and validating the clinical performance of the device is the final development stage. We are reporting the preliminary analysis of 14-day clinical study that was used to evaluate the accuracy of the Abbott FreeStyle Libre and the Cascade CGM.

**Materials and methods:** The clinical study that was used to evaluate the two CGM systems included 10 subjects with type 1 and 2 diabetes. There were five in-clinic days (1, 4, 7, 10 and 14) that were used to assess the performance of the CGM's accuracies. Each subject wore two Cascade CGM devices in the abdominal area and one Abbott FreeStyle Libre sensor on the back of the upper arm over 14 days. YSI glucose measurements were performed on plasma from venous blood sampled every 15 minutes during the 12 hour in-clinic days. The overall MARD and MAD calculation for the Cascade CGM and Abbott devices based on a comparison to paired YSI values at the same time points. The Cascade CGM values were obtained by prospectively applying an advanced algorithm to data generated during the study.

**Results:** Head-to-head MARD comparison between the WaveForm and Abbott FreeStyle Libre sensor over 14 days showed that MARD for the Cascade CGM was 11.6 vs 14.0% for the FreeStyle Libre. Consensus error grid analysis for Cascade device showed that 99.7% of data points were in zone A and B, with the remaining 0.3% in zone C.

**Conclusion:** Overall performance of the Cascade CGM device over 14 days meets the clinical expectations for a potentially non-adjunctive commercial CGM. Direct comparison with the FreeStyle Libre shows that the WaveForm device met and in a number of parameters surpassed the performance of the FreeStyle Libre. The Cascade CGM will be launched as 14-day wear CGM system.

*Clinical Trial Registration Number: TD-17-012 (UP14CGM)*

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