ARTIFACT SUPPRESSION ALGORITHM IN A SECOND-GENERATION LONG TERM IMPLANTABLE CONTINUOUS GLUCOSE MONITORING SYSTEM

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Background

The GlySens® ICGM® System is a long-term, fully-implanted, continuous glucose monitoring (CGM) system, incorporating a self-contained, self-powered sensor that is intended to function for up to one year without need for skin-attached or body-worn elements (Figure 1.). Surveys of people with diabetes indicate that such a system configuration would provide distinct advantaes for a large percentage of potential users[1]. The long life of the ICGM Sensor derives partly from the use of a novel differential oxygen-based enzyme electrode measurement technique to generate signals responsive to interstitial fluid glucose levels; correspondence of system output with plasma or capillary blood glucose has been demonstrated in pre-clinical and feasibility-level clinical studies[2-3]. Additional clinical studies of an updated second-generation system are ongoing.

Noise characteristics present in signals from conventional CGM devices (employing non-differential enzyme electrode detectors) have been previously studied. Noise and spurious excursions ("spikes") in certain cases have been attributed to pressure on the sensor patch area, particular movements of the patients, etc. and candidate denoising algorithms suitable for use with these devices have been presented[4-5].

The aim of the present study was to evaluate the effectiveness of a new real-time artifact suppression algorithm on the reduction of non-physiological excursions in sensor-generated glucose measurements. The algorithm was specifically developed and adapted for the unique requirements of the ICGM Sensor differential enzyme electrode measurement approach. Underlying glycemic profiles in diabetic patients contain significant energy only at time scales exceeding periods ~25 minutes[6]. Therefore, algorithm development was aimed at suppression of spike-type artifacts with characteristic frequencies higher than once/25 minutes.

Figure 1. The Model 100 ICGM Sensor with the system receiver. The sensor is fully implantable and requires no on-the-skin or body-worn components. The handheld receiver displays blood glucose trends and provides alerts and glucose history.

Methods

Sensor data utilized for algorithm development and testing were obtained from the FAST Trial[7] in which four adult participants were implanted with the Eclipse® Model 100 ICGM Sensor subcutaneously in the lower abdomen during a minor outpatient surgical procedure utilizing local anesthesia and (optionally) light sedation. Participants self-monitored blood glucose four times per day and simultaneously wore a Dexcom® G5® CGM. Algorithm effectiveness was assessed by examining reduction in spurious, non-physiological artifacts from the measured glycemic profiles, accompanied by avoiding introducing clinically significant lag in the processed output signal. Prior to evaluation with clinical sensor data, numerical simulations (using COMSOL), along with in vitro sensor recordings were utilized to evaluate algorithm effectiveness.

Results

There were no significant adverse events associated with the sensor implantations. Extensive simulations and in vitro evaluations indicated that the proposed real-time artifact suppression algorithm should be expected to significantly reduce the impact on the glucose signal from spurious, non-physiologic "spike-type" artifacts. In evaluation with human clinical data (Figure 2.), artifacts are seen to be significantly suppressed with minimal added lag.

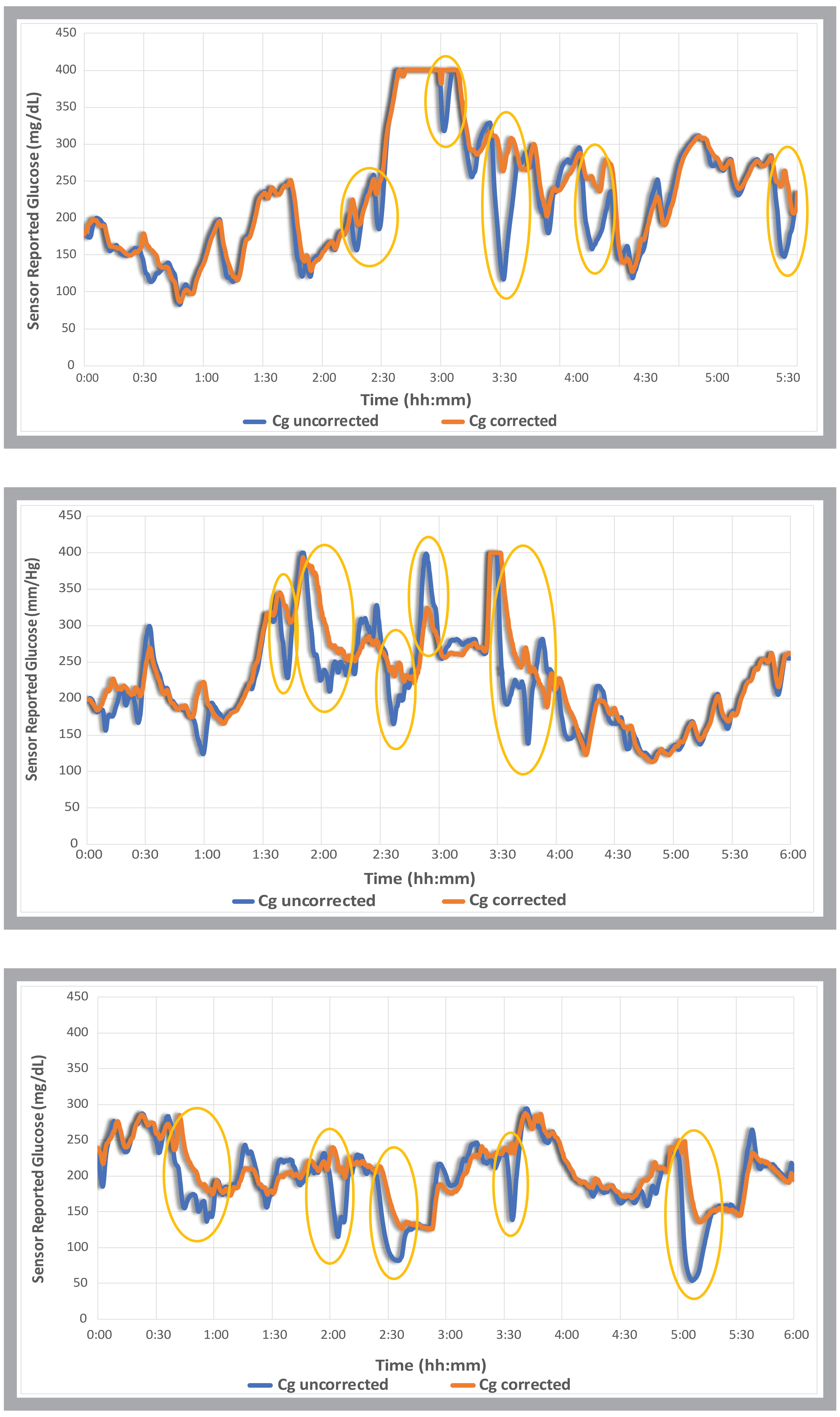

Figure 2. Application of artifact suppression algorithm to clinical results. Unprocessed glucose recordings reported by long-term subcutaneously implanted Model 100 Sensors (blue tracings) include a significant number of "spike" transients, not representative of physiologic glucose excursions. Suppression of such artifacts using previously available real-time-applicable filtering techniques typically introduces unacceptable lag, limiting the clinical utility of such approaches. The output of a new real-time-applied (i.e. not requiring any future data) artifact suppression algorithm (orange), developed for use with differential sensor techniques, demonstrates significant artifact suppression with minimal lag introduction.

Conclusions

Real-time artifact suppression algorithms implemented in the second-generation GlySens ICGM System demonstrate an advance in sensor signal performance that may enhance overall accuracy. Additional studies are underway to further evaluate the performance and accuracy of the system in adult populations.

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CAUTION - Investigational device. Limited by Federal (United States) law to investigational use.