INCORPORATION OF MODELS OF CGM SENSOR ERROR AND FAULTS AFFECTING CGM SENSORS IN THE UVA/PADOVA TYPE-1 DIABETIC SIMULATOR: ASSESSMENT ON CLINICAL DATA

DIPARTIMENTO DI INGEGNERIA DELL'INFORMAZIONE

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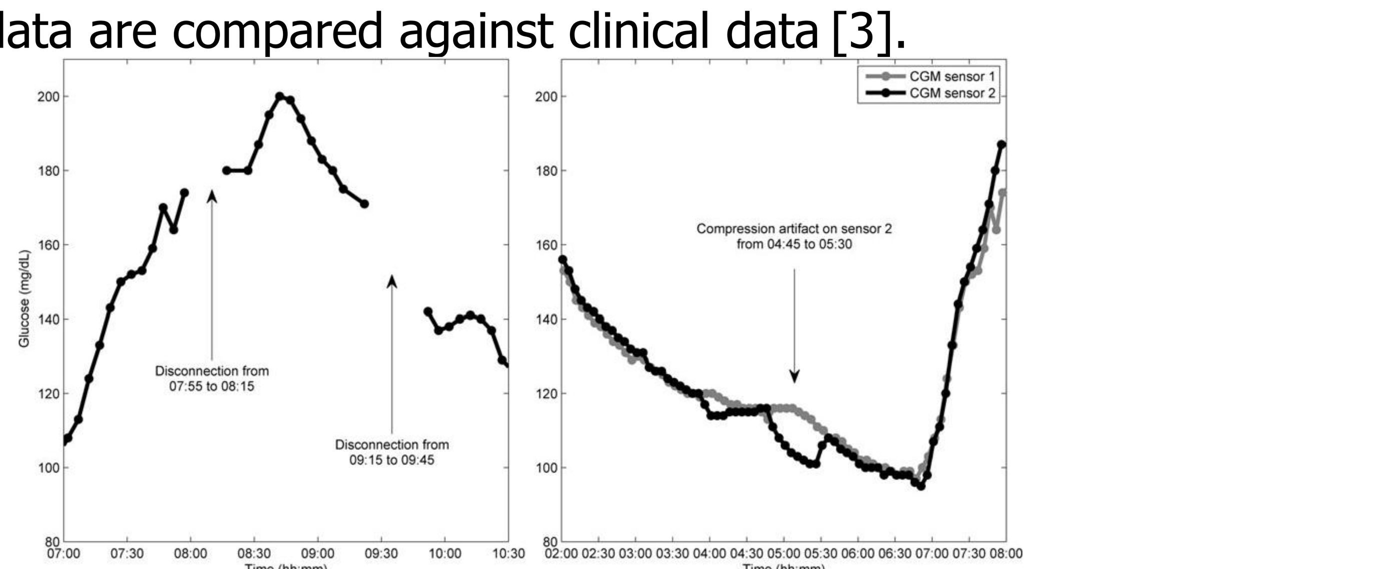
BACKGROUND AND AIM

Recently, a new model of the measurement errors in continuous glucose monitoring (CGM) sensor was identified for Dexcom® G4™ Platinum [1]. Furthermore, a model for the faults affecting CGM sensors (e.g. disconnections and compression artifacts (CA)) was proposed [2]. The inclusion of these two components in the UVA/Padova Type-1 diabetic simulator is critical for accurate in silico testing of CGM-based applications like the artificial pancreas. In this work, both models are incorporated into the most recent version of the simulator and simulated data are compared against clinical data [3].



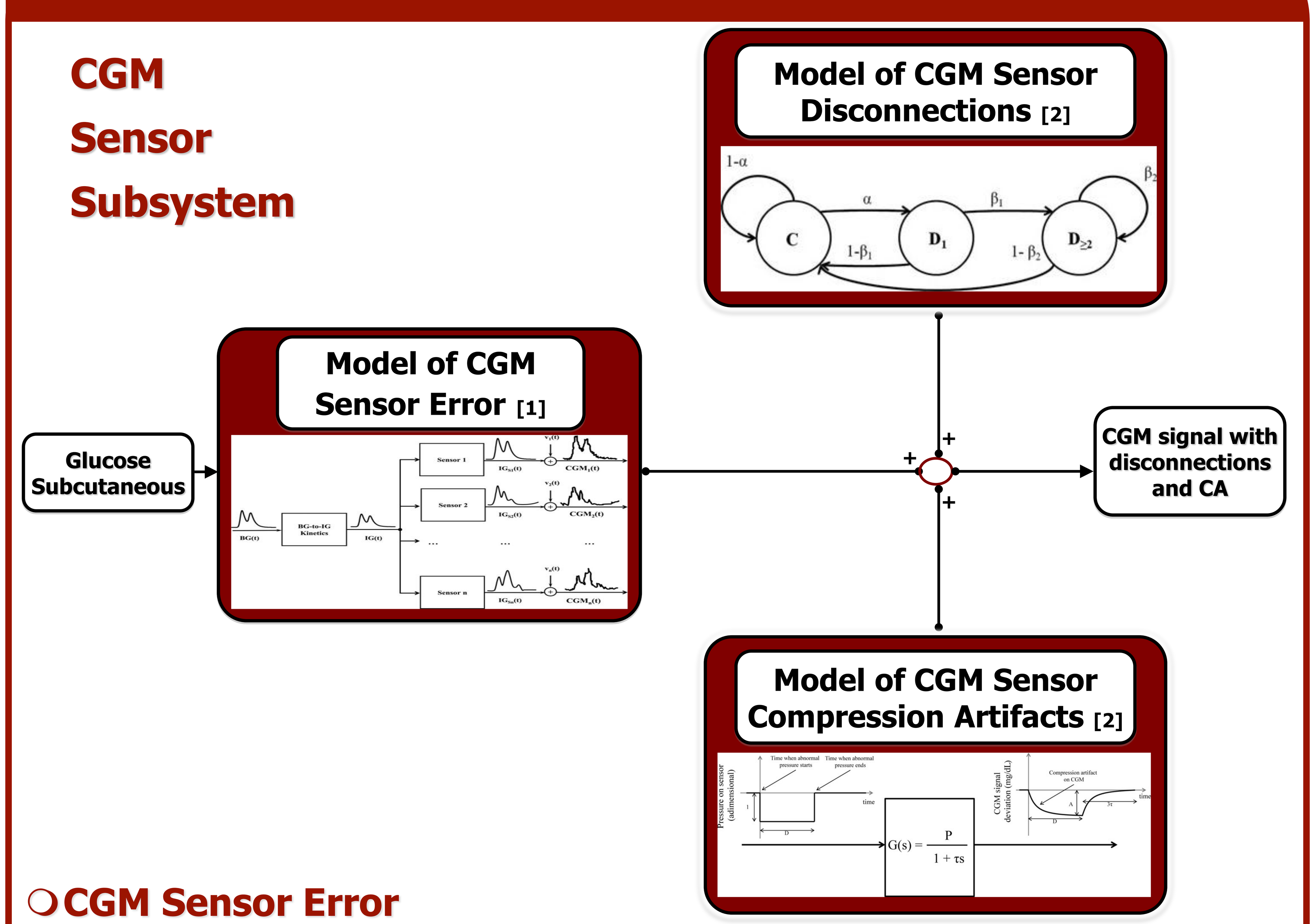
Example of disconnections (left) and compression artifact (right) on CGM real data

DATABASE AND SCENARIOS

❍ Subjects

108 traces of subjects wearing the Dexcom G4™ Platinum (DG4P) and undergoing an 1 day hospital admission are available. Blood glucose samples were collected every 15±5 min using YSI®. The accuracy of these CGM measurements was compared with the accuracy of the simulated CGM in 108 traces obtained replicating the clinical protocol from 72 in silico type 1 diabetic (T1DM) adults by using the UVA/Padova T1DM simulator [4].

METHODS



❍ CGM Sensor Error

- A model of blood-to-interstitial glucose diffusion process
- A linear time-varying model to account for calibration and sensor drift-in-time
- An autoregressive model to describe the additive measurement noise

❍ CGM Sensor Disconnections: Markov Model

- **C** is the regularly working state
- **D_1** describes the disconnections lasting one sample only (i.e., 10-min gap in the data)
- **$D_{\geq 2}$** describes longer disconnections.
- Arches indicate the transition between 2 states, and $1-\alpha, \alpha, \beta_1, \beta_2, 1-\beta_1, 1-\beta_2$ represent the transition probability.

❍ CGM Sensor Compression Artifacts

- **A** is the maximum amplitude A reachable by the CGM signal deviation
- **P** is the amplitude (in mg/dL) of the event
- **T** is the time constant of the system.

❍ Assessment Criteria

MARD, MAD and CEG-Zone-A were used for assessment. Frequency and duration of real and simulated disconnections were compared.

RESULTS

❍ CGM Sensor Error

Parameter	Real Data	Simulated Data
Sensors Traces (n)	108	108
Number of paired samples	13631	14329
%20/20 mg/dL (PAGE (%))	81,6	77,3
MAD (mg/dL)	21,0 (20,8)	21,2 (18,5)
MARD (%)	13,3 (12,9)	13,4 (11,5)
CEG-Zone-A (%)	80,2	77,2

Table 1. Comparison of overall performance metrics between the results reported on [3] and simulated data.

Parameter	Real Data		Simulated Data		
Sensors Traces (n)	108		108		
Number of paired samples	13631		14329		
	Median	IQR	Median	IQR	*p*
Overall					
MAD (mg/dL)	19,8	10,2	19,0	9,5	0,94
MARD (%)	12,5	6,9	12,7	6,4	0,63
CEG-Zone-A (%)	81,2	22,2	80,0	20,4	0,12
Hypoglycemic					
MAD (mg/dL)	10,9	7,5	10,0	21,9	0,23
MARD (%)	18,1	14,0	16,7	36,2	0,30
CEG-Zone-A (%)	88,6	34,4	85,7	57,5	0,21
Normoglycemic					
MAD (mg/dL)*	15,3	9,3	17,9	8,6	0,01
MARD (%)	13,1	8,3	13,6	7,1	0,56
CEG-Zone-A (%)	78,2	25,0	77,2	20,9	0,80
Hyperglycemic					
MAD (mg/dL)	23,8	16,2	20,8	15,5	0,23
MARD (%)	10,1	6,8	9,5	6,1	0,76
CEG-Zone-A (%)	89,7	23,6	90,9	26,9	0,98
Severe Hyperglycemic					
MAD (mg/dL)	28,6	18,3	25,2	14,8	0,36
MARD (%)	8,3	5,6	7,9	4,7	0,62
CEG-Zone-A (%)	100,0	10,0	100,0	10,0	0,39

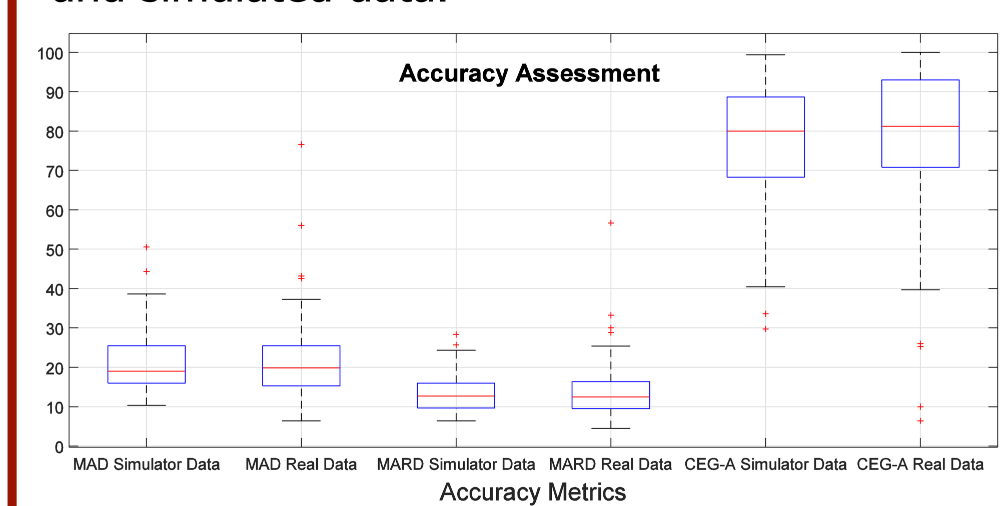


Figure 1 and Table 2. Metrics of all matched pairs for each individual sensor was evaluated. Using a standard statistical test method, the nonparametric two-sample test, the differences between the real data distributions and the simulator data were found to not be statistically significant. Only the differences on the MAD for the normoglycemic range was found to be statistically significant. Overall statistics are showed on the table and box plots.

❍ CGM Sensor Disconnections

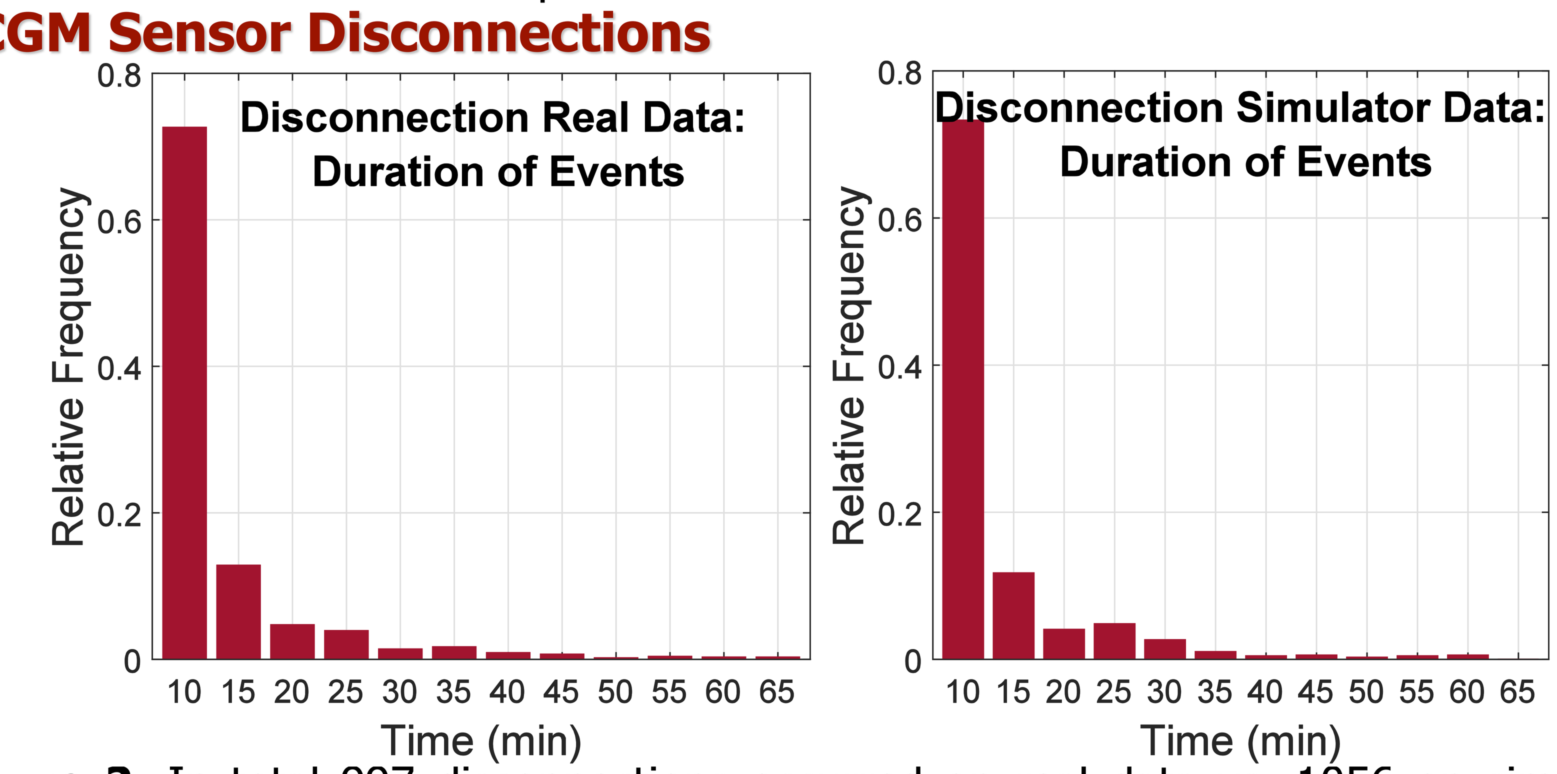


Figure 2. In total 997 disconnections occurred on real data vs. 1056 on simulated ones. Figure shows the normalized histogram of the duration of the disconnections (each bar has height given by the number of occurrences divided by the total number of events). 72.6% (left) vs. 73.3% (right) of them consist of only one sample missing (10-min gap). 90.2% (left) vs. 89.1% (right) of them lasted <=20 min.

❍ CGM Sensor Compression Artifacts

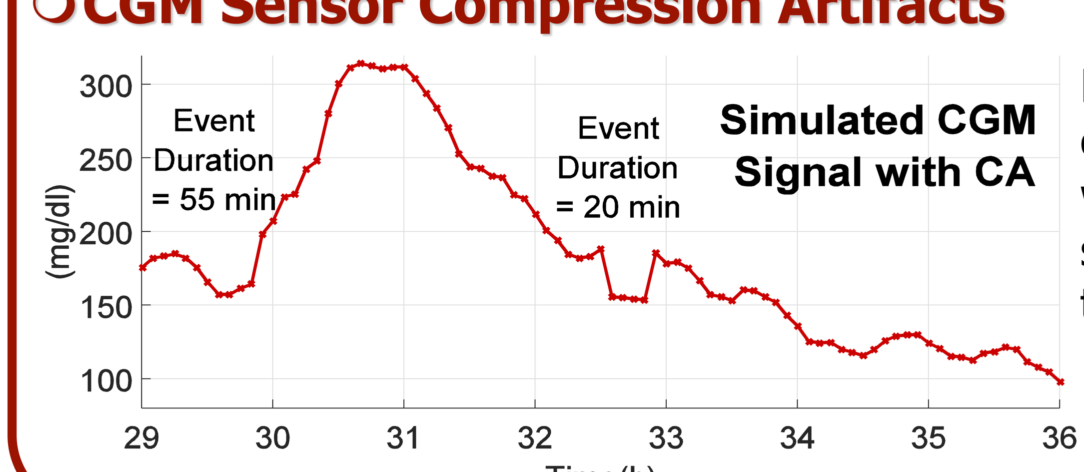


Figure 3. Example of two compression artifacts obtained with the UVA/PADOVA simulator equipped with the two models.

CONCLUSIONS AND FUTURE WORK

- Results suggest that the UVA/PADOVA simulator equipped with the two models are able to reproduce the clinical trial observations.
- Next steps will include to complete the statistical analysis of real and simulated compression artifacts, in order to compare frequency, duration and amplitude. Furthermore, to test the UVA/PADOVA simulator equipped with the two models with other real datasets.

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