MONITORING AND SUPERVISION OF ARTIFICIAL PANCREAS OPERATION WITH MULTIVARIABLE STATISTICAL ALGORITHMS

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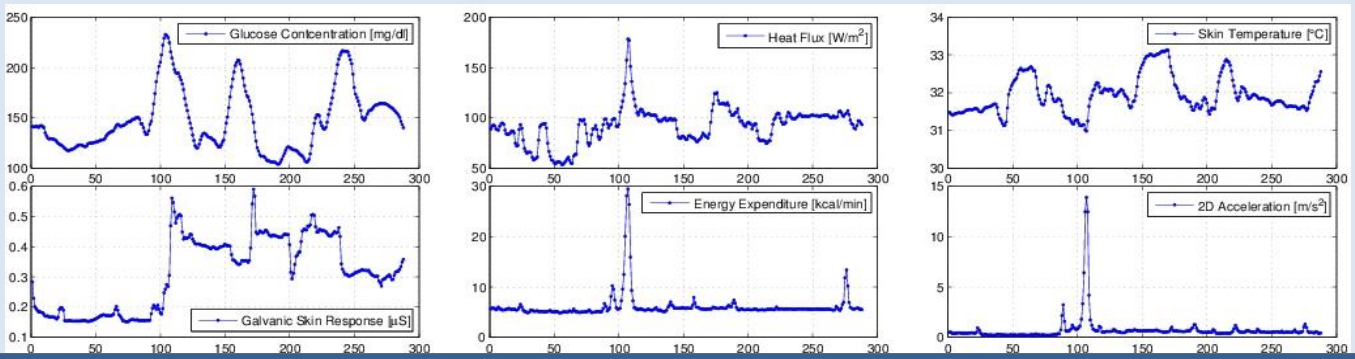
Introduction

Detection and mitigation of the effects of faults in an artificial pancreas (AP) is critical for its safe operation. Faults in glucose sensors, insulin pump and control system can yield insulin infusion rates that can cause hypoglycemia or hyperglycemia. The multivariable AP system developed at IIT enables the use of additional variables in monitoring the AP operation, detection abnormalities in its operation, and diagnosis of faults. The algorithms developed focus on real-time detection of unexpected changes in signals that may be caused by faults or disturbances. This novel system monitoring approach uses dynamic time warping for synchronization of several signal trajectories, Savitzky-Golay filter and multiway principal component analysis.

Materials and Methods

- **Statistical Process Monitoring approach based on Multiway Principal Component Analysis**
  - Synchronization of several signal trajectories using Dynamic Time Warping
  - Calculation of real-time numerical derivatives using Savitzky-Golay filter
- **Validation with Clinical Data**
  - Data for 43 days from 14 subjects in 60-hours closed-loop AP experiments with variations in meal amounts and exercise levels and times
  - Glucose measurements from a continuous glucose monitoring sensor
  - Biometric variables: heat flux (HF), skin temperature (ST), galvanic skin response (GSR), energy expenditure (EE) and 2D acceleration from a physical activity armband (BodyMedia SenseWear armband)
- **Monitoring real glucose measurements and detecting virtually created faults on CGM measurements inspired by real faulty observations**
- **Monitoring biometric variables without adding virtual faults**



Results

Real-time Multivariate Monitoring

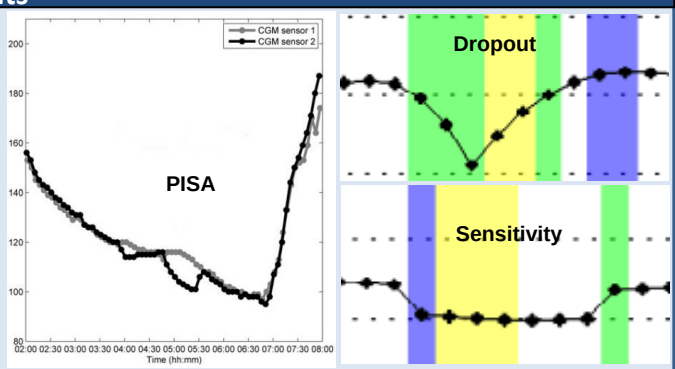
$\overset{+}{\Lambda}$: high readings $\overset{+}{\nabla}$: low readings $\overset{II}{\Lambda}$: increase in readings $\overset{II}{\nabla}$: decrease in readings

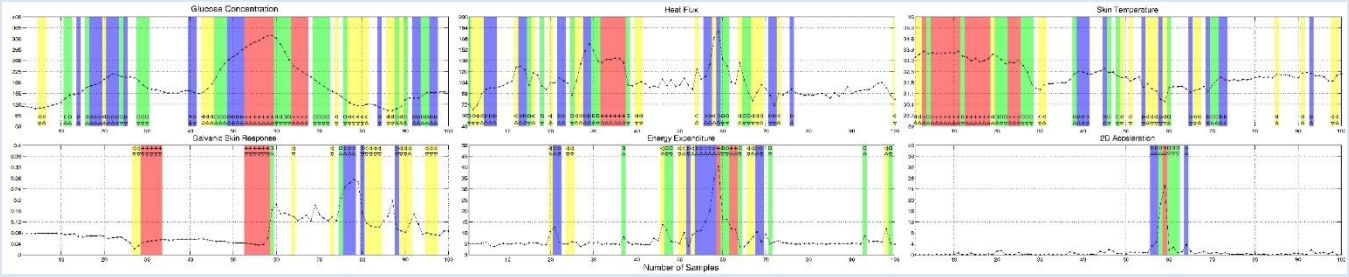
$\overset{\triangleright}{\Lambda}$: increasing concavity down in readings $\overset{\triangleright}{\nabla}$: deccreasing concavity down in readings

$\overset{\triangleleft}{\Lambda}$: increasing concavity up in readings $\overset{\triangleleft}{\nabla}$: decreasing concavity up in readings

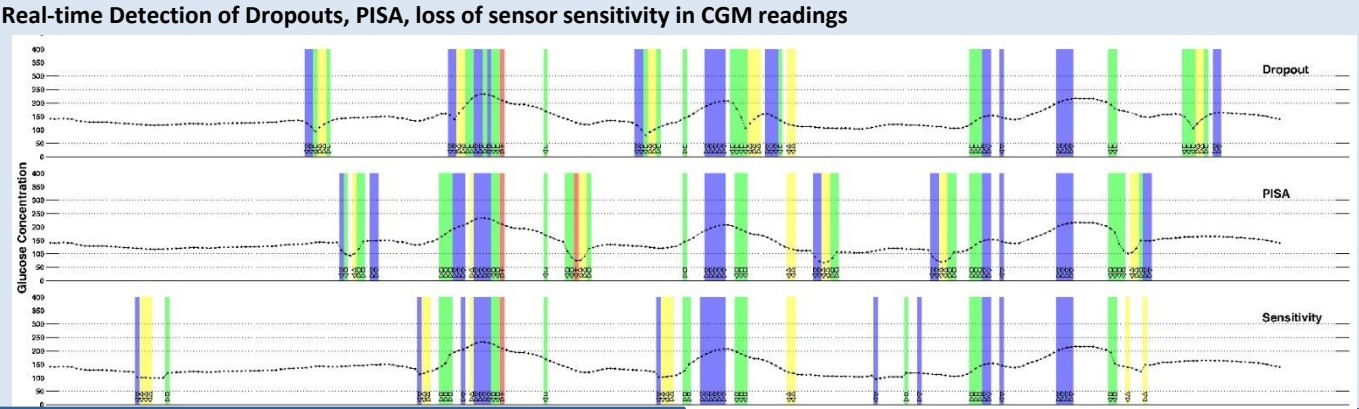
	Positive	Negative
x	High readings	Low readings
x'	Increase in readings	Decrease in readings
x''	Increasing concavity up in readings ($x' > 0$)	Increasing concavity down in readings ($x' > 0$)
	Decreasing concavity up in readings ($x' < 0$)	Decreasing concavity down in readings ($x' < 0$)

- Detecting unexpected changes in biometric variables due to exercise (higher HF and EE) or stress (higher GSR) and labeling them
- Detecting unexpected changes in glucose measurements due to sensor faults or a meal and a subsequent bolus infusion, and labeling them





Real-time Detection of Dropouts, PISA, loss of sensor sensitivity in CGM readings



Conclusion

The proposed algorithm is able to successfully detect unexpected dynamical changes or faults and label them according to predefined rules for many variables simultaneously. Using such an algorithm can inform people with T1D about any unexpected trends in their glucose levels and faults in sensor measurements. The algorithm provides valuable information to an AP system for prevention hypoglycemia or hyperglycemia that may have occurred due to sensor faults.

Acknowledgment

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