Fault Tolerant Glucose Sensor Readout and Recalibration

Zeljko Zilic and Katarzyna Radecka
McGill University
3480 University
Montreal, QC, Canada
{zeljko.zilic, katarzyna.radecka}@mcgill.ca

ABSTRACT

Reliable sensor operation is a must for health care cyber-biological systems, such as closed-loop glucose control. In this paper, we outline the scheme for fault tolerant measurements, re-calibration and the replacement of permanently failed sensors.

Categories and Subject Descriptors

B.4.5 [**Reliability Testing and Fault-Tolerance**]: Redundant Design

General Terms

Algorithms, Measurement, Reliability, Verification.

Keywords

Sensors, fault-tolerance, glucose control, calibration.

1. INTRODUCTION AND BACKGROUND

Tightly integrated cyber-biological systems coupled to a human body to control vital parameters can significantly improve the health and quality of life. The safety of such systems relies on the ability to guarantee the reliable and fault-tolerant operation. In particular, the current push for closed-loop insulin control (CLIC) systems for managing glucose levels is predicated on the guarantees that the continuously injected insulin will not bring the patient into the possibly dangerous state of hypoglycemia at any time. Hence, the fault-tolerant operation of sensors in an autonomous CLIC is a must, as an existing single continuous glucose monitor (CGM) can fail undetectably and endanger lives.

Ensuring fault tolerance by placing multiple sensors is a multi-faceted problem. In the case of glucose sensors, sensors alone need to be periodically calibrated in order to perform representative readings. Then, while operational, they need to compensate for lost sensitivity, and be located when failing or rejected by a body. In this paper, we consider the fault-tolerant (FT) measurement scheme for multiple sensors, and treat, in a uniform manner, the issues of accuracy reduction, fault-tolerant operation, re-calibration and the detection of permanent failures.

Fault-tolerance of sensors has been recently studied for long-term, large-scale wireless sensor networks (WSNs) [1]. The basic assumptions there differ somewhat from the intended healthcare applications such as CLIC, where sensors are read out every few minutes, and replaced more often, such that the failures and mis-calibrations happen for at most a single sensor between two consecutive verification sessions. These studies result in fault tolerance schemes based on graph coloring considering the time series over longer period of time, and rely on the information about the interval of the values observed [2]. There is also the control-theoretic work [4] (e.g., parity spaces, Kalman filters) that requires knowledge of the whole closed-loop system.

In our case, all the sensors in the system are calibrated periodically. The data from the set of sensors is sampled at ~5min. intervals. Failures or de-calibrations hence happen for individual glucose sensors within relatively short intervals [3]. We devise a memoryless on-line scheme that averages multiple sensor results close to having the information over long time horizon.

2. SENSORS AND FAILURE MODES

Several causes of failures have been reported for glucose sensors. First, the body can reject them during the early phase or after longer use. Second, their sensitivity might degrade, or the fluid flow to the sensors could be stopped. It was also observed that for some data points, the readings might be occasionally significantly off, i.e., they *drop-out* [5]. Finally, sensors can completely fail.

Any sensor employed for control such as CLIC must at least satisfy the current standards of accuracy. While there are other metrics for analytical and clinical performance of glucose sensors, the current ISO standard 15197 specifies that the 95% of readings must fall within 0.83 mmol/l in the low glucose regime (4.2 mmol/l) and within 20% error otherwise. Since the CLIC requires better accuracy at higher glucose levels, we adopt the low regime spec everywhere in our analysis. The sensor readings are impacted not only by the sensors alone, but also by parameters like the blood to interstitial fluid coupling. They are customarily assumed [6] to be normally distributed.

3. FAULT TOLERANT MEASUREMENTS

For k sensors with standard deviation σ, to tolerate one error in a readout, we apply the linear-time fault-tolerant measurement scheme that eliminates the sensor reading that is furthest from the average of all others. The fault tolerant measurement is then the average of sensor readings excluding the faulty one. As glucose sensor drop-outs can happen to any sensors at random instances, we consider a memoryless *on-line* scheme, where the values are known only for a given measurement, as opposed to the *off-line* scheme, where the whole time horizon of measurements is known.

```
SingleFT_Measurement ($k$, $\sigma$) {
1. $mtab = [sensor(i), \{i, 1, k\}]$ // sensor readout array
2. $ctab = [1/(k-1) \sum_{j \neq i}^{k} mtab(j), \{i, 1, k\}]$ //avg. of others
3. $faulty = Position(d(ctab, mtab) = \max)$ //furthest one
4. return $ctab[faulty]$ // avg. excluding faulty sensor}
```

While we do not focus on implantable sensors, for emerging implantable glucose sensor assays that could eventually be implanted, multiple faults could be considered as well. The generalization for the detection of f faults requires that f readings that are furthest from others are excluded from the total average.

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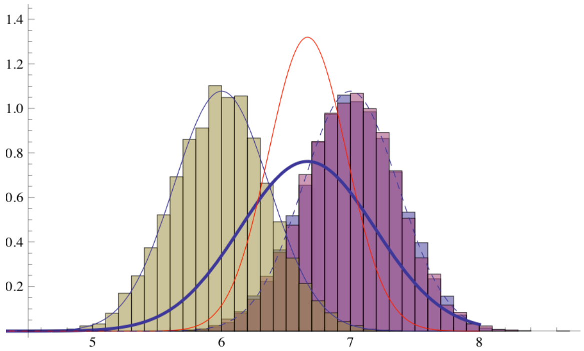

Fig. 1. Readings for k=3, *f*=1: FT, Avg, Single, Misdiagnosed

By ordering readout subsets in a Boolean lattice [7], the *f* fault detection amounts to examining O(k^f) points in f^{th} lattice layer, hence it takes O(k^f) time.

3.1 Properties of Fault-tolerant Readouts

Because of the averaging, we know by *central limit theorem* that the standard deviation of the FT measurements narrows to $\sigma_{FT} = \sigma/\sqrt{k-1}$, so the accuracy increases and the mean converges towards the fault-free readout. In comparison, if there is a single faulty reading with a mean offset Δ, the plain averaging produces the expected value offset of Δ/k, even though the variance narrows slightly for a factor $\sqrt{k/(k-1)}$.

Fig. 1 compares the simulations for ISO-compliant sensors, with *k*=3 and *f*=1. Standard deviation is obtained from specs as $\sigma \approx 0.42$. Sensors should report 6 mmol/l and the faulty one reports 8 mmol/l. The blue line represents one randomly chosen sensor, the red line is an average of 3 sensors, the FT readout is in the left histogram, and instances in which the faulty sensor was misselected are given by two overlapping histograms on right. The FT reading is at the correct average and narrower distribution.

3.2 Comparison to Off-line FT and Avg. Case

To evaluate our solution, we compare it to the straightforward averaging and the off-line scheme where sensor outputs are known for all time instances, including the future. While unrealistic, the off-line scheme provides for a useful evaluation of the FT scheme against the perfect knowledge of faults.

First, due to the probability distribution of sensors, the on-line scheme might not always identify the faulty sensor based on the single measurement point, while the off-line one always does. While the percentage of wrong calls in the on-line scheme can be relatively high (there is an analytical expression to estimate the probability of those events, omitted here), the important property is that the expected error magnitude is nevertheless kept small.

Table 1. Finding Faulty Sensor and Expected Readout Error

k, Δ	Misdiag. [%]	**FT Error**	Avging Err	L1 Distance /online	L1 Distance /offline
3, 2	11	**0.12**	0.89	0.68	0.45
4, 2	8	**0.05**	1.10	0.51	0.45
5, 2	7	**0.03**	0.69	0.40	0.34
3, 1	41	**0.23**	0.66	0.39	0.23
4, 1	42	**0.17**	0.92	0.29	0.16
5, 1	44	**0.13**	0.38	0.24	0.09

Table 1 summarizes the single-fault event comparison for various numbers of total sensors *k* and displacements Δ, for 10^5 runs of ISO-compliant sensors with normal distribution, where exactly one sensor is faulty. The on-line scheme average error (third column) is within ISO spec even including the spread, and is substantially smaller than the simple averaging (column 4), while the omitted off-line scheme error is 0. The last two columns compare on- and off-line schemes via the average *absolute* distance (i.e., L_1 norm) to the correct value.

3.3 Re-calibration and Sensor Replacement

The same scheme is useful for a sequence of steps to detect the sensors that need a re-calibration or a replacement. First, the repeated sensor readings that points to the consistent *sign/value* corrections demonstrate that the sensor can possibly be recalibrated, i.e., that a sensor can still act as a classifier, rather then being discarded. The recalibration is simply performed by re-scaling to adjust the reading of the failing sensor to the average of the others. Otherwise, inconsistent calibration directions, or repeated re-calibrations show the need for replacing a sensor.

Selecting the minimal numbers of sensors depends on the required accuracy, including during re-calibration. Clearly, at least 3 sensors are needed for FT. Since the re-calibration might take an hour for glucose sensors, for the remaining sensors to provide sufficient accuracy for CLIC and also for re-calibration, configurations with higher number of sensors are also of interest.

4. CONCLUSIONS AND FUTURE WORK

An on-line fault tolerance scheme has been presented for glucose sensors. It takes linear time for single-fault tolerant measurements. While the identification of a faulty sensor for on-line scheme can fail noticeably, the obtained error in measurements is small. The scheme is closer compared to the off-line version, with a complete knowledge of future sensor errors and inaccuracies, than to the plain averaging scheme. Further analytical evaluation (e.g. competitive ratio), the examination of sensor placement and the recalibration will follow for concrete sensors and a CLIC system.

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