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Non-invasive, ECG Based Low-level Glucose Detection

An algorithm that continuously detects low glucose levels using an ECG device

Header image provided by the university

IP Status

Patent application submitted

Seeking

Licensing

About **University of Warwick**

We are committed to ensuring that our research makes a distinctive, competitive impact on the world. We believe in a collaborative approach to research and education in addressing global challenges and opportunities.

Background

Tracking sugar in the blood is crucial for both healthy individuals and diabetic patients. Currently, Continuous Glucose Monitors (GCM) are available by the NHS for hypoglycaemia. They measure glucose in interstitial fluid using an invasive sensor, which sends alarms and data to a display device. In many cases, they requires calibration twice a day with invasive finger-prick blood glucose level tests.

Tech Overview

Researchers at the University of Warwick use artificial intelligence to detect hypoglycaemic events from raw ECG signals acquired using off-the-shelf non-invasive wearable or ambient sensors. Two pilot studies with healthy volunteers found the average sensitivity and specificity approximately 82% for hypoglycaemia detection.

Figure 1 shows a green line for normal glucose levels and a red line for low glucose levels. The horizontal line is the 4 mmol/L glucose threshold. The grey area surrounding the continuous line reflects the error bar.

Algorithm Overview for Hypoglycaemic Detection

The Warwick algorithm is based on deep-learning and automatically detects hypo events in real-time using non-filtered data from a single ECG sensor (1-lead). The algorithm is trained using individual patients' own CGM and ECG measurements for 1 week. After which, the algorithm operates as described below, but without any further glucose measurements being required.

In the diagram in Figure 2, the ECG is segmented into individual heartbeats (Heartbeat Extraction), automatically identifying each fiducial point (R-peak) and taking a fixed number of samples around it (400ms either side). A convolutional neural network (CNN) transforms each heartbeat into a set of relevant features. These features feed into a recurrent neural network (RNN) where a loop of 300 consecutive beats, which gives a nominal 5 min, are analysed to determine if the patient is in hypo. The RNN returns two possible outputs (normal and low glucose levels) with a probability distribution. The model gives a hypo alert if the majority of beats in two consecutive RNN loops are classified as hypo.

The features mentioned above, can be relevant to the clinicians to understand how heartbeats change in individual subjects during a hypo event, which may better inform therapy.

Further Clinical Relevance

Figure 3 is an exemplar of how the output of our model demonstrates ECG changes during hypo for each subject. The solid lines represent the mean of all the heartbeats for two subjects enrolled in our pilot study: green during normal glucose levels and red during hypo. The red and green shadows represent the standard deviation of the heartbeats around the mean. A comparison of the two highlights that these two subjects have different ECG

waveform changes during hypo events. In particular, Subject 1 presents a visibly longer QT interval during hypo, while the subject 2 does not.

The vertical bars represent the relative importance of each ECG wave in determining if a heartbeat is classified as hypo or normal. From these bars, a trained clinician sees that for Subject 1, the T-wave displacement influences classification, reflecting that when the subject is in hypo, the repolarisation of the ventricles is slower. In Subject 2, the most important components of the ECG are the P-wave and the rising of the T-wave, suggesting that when this subject is in hypo, the depolarisation of the atria and the threshold for ventricular activation are particularly affected. This could influence subsequent clinical interventions.

This result is possible because our AI model is trained with each subject's own data. Intersubjective differences are so significant, that training the system using cohort data would not give the same results. Likewise, personalised therapy based on our system could be more effective than current approaches.

Further Details

- International Clinical Engineering and Health Technology Management Congress (ICEHTMC), Italy 21 Oct 2019. Porumb, M., Stranges, S., Pescapè, A. et al. Precision Medicine and Artificial Intelligence: A Pilot Study on Deep Learning for Hypoglycemic Events Detection based on ECG. Sci Rep 10, 170, 2020

Stage of Development

Trial Results and Performance

The Warwick algorithm has been trained and tested with two pilots recruiting a total of 33 healthy volunteers, monitored continuously over 24 hours using a CE-marked wearable ECG device and with a CGM control.

- Pilot trial 1: 14 days in a non-clinical setting, recruiting 8 healthy volunteers (mean age 25), of which 4 experienced hypo events during monitoring.
- Pilot trial 2: 36 hours in hospital setting, recruiting 25 healthy adults (min age 60 years), of which 8 experienced hypo events during the monitoring.

Overall, the model achieved sensitivity (hypo detection) 87.5% (± 10.3%), specificity (normal detection) 81.7% (±7.0%) with accuracy 82.4% (±7.0%).

Benefits

- real time detection of hypoglycaemic
- events using Artificial Intelligence
- non-invasive - no needles required

- continuous monitoring
- comparable accuracy to CGM
- personalised detection - training against patient's own glucose recordings using a CGM for up to 4 days

Applications

The algorithm is able to address these needs in patients in their everyday life:

- nocturnal hypoglycaemia
- hypoglycaemia
- patient self-monitoring
- daily activities monitoring
- potentially detects hyperglycaemic events
- potentially predictive capability
- potentially prevents diabetic coma

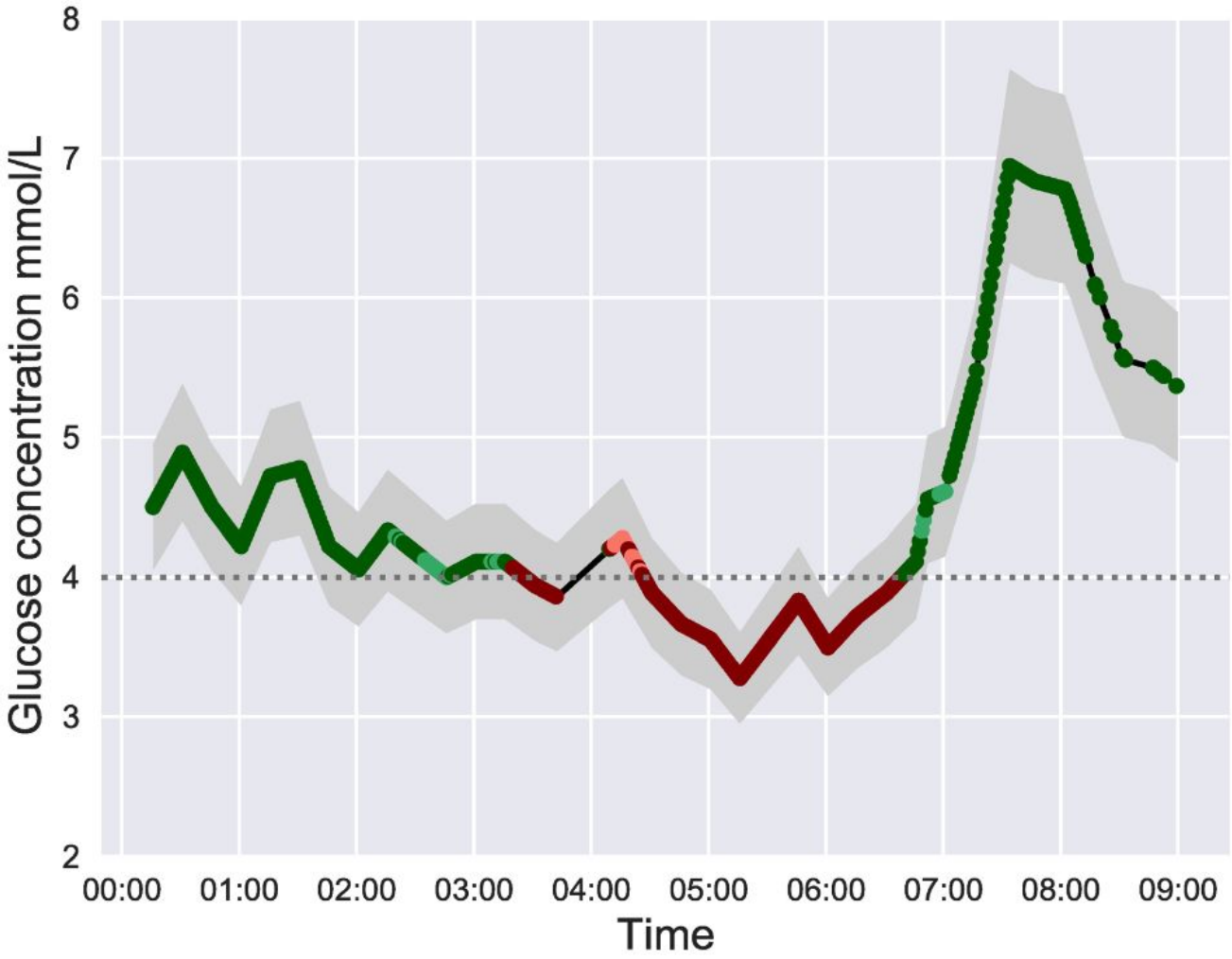
Patents

- Patent application number GB1912487.4; 30 August 2019

Appendix 1

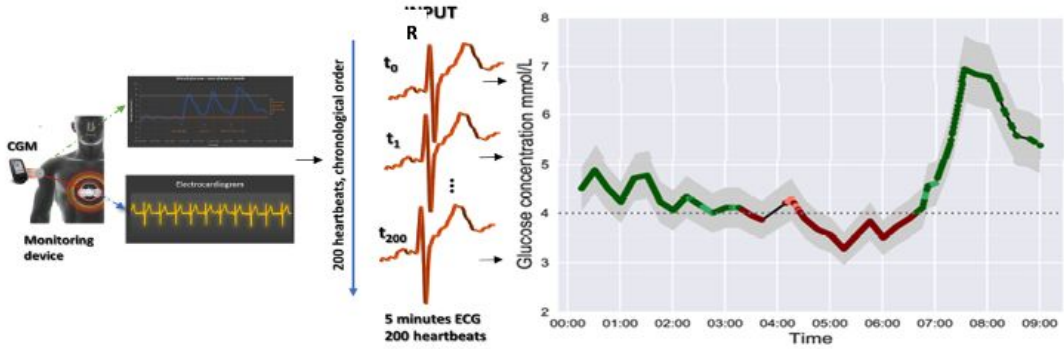
Figure 1

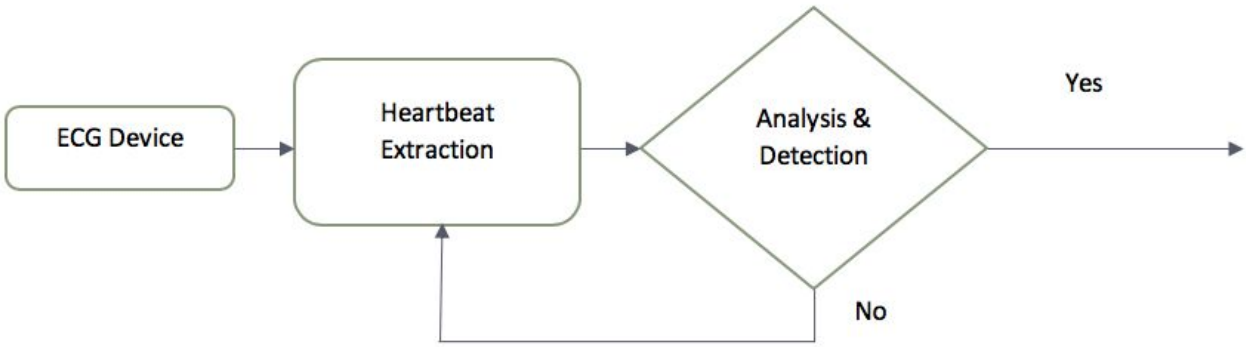
A green line for normal glucose levels and a red line for low glucose levels. The horizontal line is the 4 mmol/L glucose threshold. The grey area surrounding the continuous line reflects the error bar.



Appendix 2

Figure 2





Appendix 3

Figure 3